GSK plc

GSK plc - Q4 2023 Earnings Call

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Event Participants

Executives 6
Nick Stone, Emma Walmsley, Luke Miels, Deborah Waterhouse, Julie Brown, Tony Wood

Analysts 11
Peter Welford, James Gordon, Jo Walton, Simon Baker, Timothy Anderson, Richard Parkes, Andrew Baum, Graham Parry, Mark Purcell, Kerry Holford, Steve Scala

Nick Stone Executive

Hello, everyone. It's Nick Stone, Head of Investor Relations. Welcome to today's call and webcast. 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 will comment on our performance using constant exchange rates, or CR unless stated otherwise. As a reminder, following the Consumer Healthcare demerger in 2022, we're presenting performance and growth at the continuing operations for GSK.

Please turn to Slide 3. Today's call will last approximately 1 hour with the presentation taking around 30 minutes and the remaining time for your questions. We request that you ask 1 to 2 questions so that everyone has a chance to participate.

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

Emma Walmsley Executive

Hello, and a warm welcome to everybody joining this call. Today, we are updating you on our performance for 2023, giving guidance for 2024, and providing you with new upgraded longer-term outlooks. Please turn to the next slide.

In 2021, we set out a series of commitments to shareholders, including for a step change in performance following the significant transformation in GSK's structure, strategy, capital allocation and culture. Since then, we've delivered 10 quarters of consecutive sales growth ex COVID and our priority to invest in new vaccines and specialty medicines to reshape GSK's portfolio is now strongly evident with around 2/3 of sales now generated from these 2 product areas. At the same time, we continue to strengthen our pipeline. The majority of the late-stage assets that we highlighted in 2021 have moved forward positively. And we've

added multiple new opportunities to this portfolio, including through targeted business development, where we've secured more than 16 acquisitions and alliances for innovative assets and new technologies.

We have achieved all of this whilst maintaining a continued sharp focus on operating margins, cash flow and capital allocation, mindful of the need to both invest for the future and to deliver attractive returns to shareholders. Next slide, please.

Our performance for 2023 demonstrates all of this. Sales and profits ex COVID solutions grew double-digit levels for the year. Sales were up 14% to over GBP 30 billion, a clear highlight being the exceptional launch of Arexvy. Adjusted operating profit was up 16% and adjusted EPS were up 22%. All 3 of our product areas demonstrated good growth with sales from new products since 2017, contributing more than GBP 11 billion in 2023.

This level of performance helped deliver 2 upgrades to guidance in '23 and led to the increased dividend we've announced today of 58p per share. We also sustained good progress with our trust in the ESG goals, not least reflected in our sector leadership of the S&P's Global Corporate Sustainability Assessment. Highlights for the year included moving to Phase III for our low-carbon Ventolin inhaler program, hitting our leadership diversity ambitions 2 years ahead of schedule, and extending rollout of our malaria vaccine to 12 new countries in Africa. Altogether, 2023 provided us with good momentum, which we're now carrying into this year. Next slide, please.

In 2024, we expect another year of meaningful growth. Sales growth of 5% to 7%, adjusted operating profit growth of 7% to 10% and adjusted EPS growth of 6% to 9%. For the period 2021 to 2026, we now expect sales to grow more than 7% on a CAGR basis and adjusted operating profit to increase more than 11% CAGR.

For 2026 to '31, with the progress we've made in our portfolio, we now believe that we can deliver more than GBP 38 billion of sales by 2031. This is an increase of GBP 5 billion versus the estimate we gave in 2021 and continues to exclude any contributions from early-stage pipeline assets and further anticipated business development. We've also not included any potential future sales contribution from Blenrep here either. So this new outlook represents a marked sales acceleration. As in effect, we now expect to reach our original 2031 goal of more than GBP 33 billion by 2026, so 5 years earlier.

Beyond sales, we expect a continued strong focus on margin improvements during this period while retaining flexibility to invest in growth. Recognizing that we'll likely face loss of exclusivity for dolutegravir from '28 to 2030. We're also able to say today that we expect operating margins to be broadly stable through that 3-year period.

Julie and I will cover these outlooks in more detail shortly. But first, we're going to review our 2023 performance and 2024 guidance, starting with comments from Luke.

Luke Miels Executive

Thanks, Emma, please turn to the next slide. 2023 was a great year for operating performance with strong growth across all our product areas and regions, up 14% for the full year. Please turn to Slide 10.

In Vaccines, sales were up 24% for the year, with the outstanding launch performance of Arexvy, contributing more than GBP 1.2 billion together with the strong performances from Shingrix and our meningitis portfolio.

I'll come to Arexvy in a minute, but first, a few points on the rest of the portfolio and specifically prospects for growth. We continue to expect strong growth for Shingrix this year and to deliver more than GBP 4 billion in peak year sales. In the U.S., our immunization rate is 35% in those people 50 years and older, which means close to 80 million people who are eligible are unvaccinated with more than 4 million people joining this cohort each year. We expect 2024 growth to be driven outside the U.S. where the vaccine is now approved in 39 countries, most of which have less than 4% penetration, and we're really excited about our new partnership with Zhifei in China.

Our meningitis portfolio supports a major public health need and continues to be an important contributor to growth. Bexsero and Menveo sales were up 14% and 12% in 2023. We're also excited to be submitting our MenABCWY vaccine for approval in the U.S. this year. Combined, this franchise is expected to deliver around GBP 2 billion in nonrisk-adjusted peak year sales.

Beyond the marketed portfolio, we expect to see further progress in 2024 for our mRNA vaccine with Phase II data and flu, the development of our pneumococcal MAPS vaccine candidates and our potential HSV therapeutic vaccine. Next slide, please.

As Emma said, the Arexvy launch has been exceptional, and we expect good growth this year, mainly driven by further penetration in the U.S. but also early adoption from the international rollout of the vaccine. We are currently approved in 39 countries. And in the U.S., our choice to emphasize our 94.6% efficacy in the comorbid population continues to resonate well. Script data shows strong brand preference and market data tells us that 2 out of 3 HCPs prefer Arexvy, and we continue to have a strong position with all major pharmacies as we start 2024.

Looking into this year, we have a major opportunity subject to approval and ACIP recommendation with a potential label for at-risk individuals in the 50- to 59-year-old cohort. This is around 15 million people. And on other dynamics for this year, we know we're facing a more competitive environment. And of course, we won't benefit from launch stocking. We'll also start to see how seasonality affects use patents for Arexvy.

But we are ready for all of this and are ambitious for 2024. We remain very confident this vaccine can achieve more than GBP 3 billion in peak year sales over time.

Overall, looking across the Vaccines portfolio, we expect sales to increase high single-digit to low double-digit percent in 2024, and we're also upgrading our vaccines outlook from '21 to '26 from high single digits to low double digits. Next slide, please.

Moving to Specialty Medicines. Here, overall sales were up 15% for the year, driven by strong performance from key products in HIV, which Deborah will cover shortly, respiratory, immunology and oncology. In Respiratory, our market-leading IL-5, Nucala, saw strong growth across all geographies and receive severe asthma approval in China. And as we said at our recent Respiratory, Meet the Management event, we expect pivotal COPD data for Nucala in

the second half of this year. Before then, and excitingly for this class of respiratory medicines, we expect first pivotal trial results for depemokimab, our new 6-monthly IL-5, a key new growth opportunity for our respiratory business.

Benlysta was also a major contributor for '23, with sales up 19% in oncology. We are very pleased with the strong uptake for Ojjaara, and we're also seeing increasing usage of Jemperli and Zejula in patients with endometrial and ovarian cancers driven by generation of compelling data and launch of new patient valued formulations.

A quick word on Blenrep, sales decreased for the year as expected, but following positive headline results from a planned interim efficacy analysis of the DREAMM-7 trial, we are now waiting for further overall survival data from this study, and we continue to expect DREAMM-8 results later this year. Overall, we can expect another year of strong performance from our Specialty Medicines in 2024, with growth of low double-digit percent and continue to expect double-digit growth between 2021 and 2026. Please turn to Slide 13.

Finally, our General Medicine portfolio. Sales grew 5% in 2023 and led by Trelegy, which is now contributing over GBP 2 million per year and is the world's top-selling brand in asthma and COPD. We are now using our respiratory expertise across both vaccines and medicines with the benefit of Trelegy and Arexvy co-promotion being recognized by HCPs who want to discuss both respiratory, prevention and treatment. Overall, we expect general medicines to decrease mid-single digit percentage in 2024, and this guidance takes into account the AMCAP removal in the U.S., which we previously highlighted as impacting the business by up to USD 700 million. We provided for around 20% of this in 2023 and continue to expect a broadly flat outlook between 2021 and 2026.

I'll now hand over to Deborah to cover HIV.

Deborah Waterhouse Executive

Thank you, Luke. HIV sales grew 13% to GBP 6.4 billion in 2023, driven by a notable acceleration in our Oral 2 Drug and long-acting injectable regimens. Sales from these 2 areas represent 55% of our portfolio compared to an exit of 46% in 2022. For the year, Dovato sales grew 33% to GBP 1.8 billion. Cabenuva grew more than 100% with sales over GBP 700 million, and Apretude contributed sales of GBP 149 million.

The growth of these products reflect strong patient demand and our deep commitment to innovation. For long-acting regimens, specifically, more than 80% of U.S. health care prescribers now tell us they are convinced that these regimens will become a key part of HIV care. Based on this demand and our growth and momentum, we're projecting a growth rate of high single to low double digits in 2024.

We're excited by the potential of our early-stage pipeline to deliver more innovative longer-acting injectable regimens. And as I said at last year's investor event, 2024 will be an important year for us as we select regimens for 4 monthly treatment and self-administered treatment as well as starting the registrational studies for our 4 monthly prep. We will be presenting data on our early pipeline and our current portfolio at CROI in March.

To conclude, 2023 was another positive year of performance and portfolio development. As

such, we're looking forward to 2024 and are confident that we are well on track to deliver our 2021 to 2026 sales ambition of 6% to 8%.

With that, I shall hand to Julie.

Julie Brown Executive

Thank you, Deborah, and good morning, everyone. Next slide, please.

Starting with the income statement, with growth rates stated at CER. Sales increased 14%, excluding COVID solutions and were up 5% overall, reflecting continued strong business performance. Adjusted operating profit grew 16%, excluding COVID and 12% overall. The margin increased to 29%, driven largely by favorable product mix and operational efficiencies as well as increased royalties. COGS and SG&A grew broadly in line with sales, excluding COVID.

R&D costs increased due to the investment in late-stage programs in vaccines, respiratory, immunology and infectious diseases with the step-up in Q4 due to reorganization costs and the acceleration of late-stage projects. Adjusted earnings per share grew 22%, excluding COVID solutions and 16% overall. And this benefited also from lower net finance expense down 15% following debt restructuring. The effective tax rate was 15.5%, in line with our guidance.

Turning to the reported results. Total operating profit increased 10% to GBP 6.7 billion, driven by overall performance and favorable CCL movements. The reconciliation of total to adjusted results is included in the appendix.

On currency, there was an adverse 200 basis point impact on sales and 400 basis points on adjusted operating profit versus the prior year, primarily due to the strengthening of sterling against emerging market currencies. Next slide, please.

Moving on to the adjusted operating margin dynamics for the year. On this slide, we have shared, including and excluding COVID to provide an underlying review of margin dynamics. Excluding COVID solutions, the margin improved 60 basis points CER to 29.1% due to improved product mix, productivity improvements and increased royalty income. Including COVID, there was a 180 basis point improvement, primarily reflecting reduced sales of lower margins Xevudy. Regarding SG&A, growth was focused on investment in vaccines, including disease awareness and the launch of Arexvy, together with Shingrix, long-acting HIV, Jemperli and Ojjaara.

Royalty income also contributed to margin improvement. Next slide, please.

Free cash flow increased to GBP 3.4 billion. And this, despite annualizing the receipt of GBP 0.9 billion from Gilead in 2022. This increase was primarily driven by higher operating profit, together with favorable timing of Xevudy cash flows and a lower U.K. pension contribution. This was partly offset by higher trade receivables from sales of Arexvy in the last quarter.

Q4 CGFO performance was particularly strong, delivering GBP 3.7 billion versus GBP 2.1 billion last year. And this increase was primarily driven by higher collections following the strong launch of Arexvy in Q3. We expect cash generated from operations to remain strong,

and we're fully committed to delivering more than GBP 10 billion by 2026. Next slide, please.

Slide 19 shares our net debt position and how we've deployed capital in the business in line with the capital allocation framework. We look to deploy funds to enhance growth and deliver attractive shareholder returns. We started the year with net debt of GBP 17 billion and strong free cash generation in addition to the monetization of our stake in Haleon supported GBP 3.8 billion of investment in targeted business development and capital expenditure and GBP 2.2 billion in returns to shareholders via the dividend. Overall, this led to a further reduction in net debt to GBP 15 billion by the end of 2023 and a net debt to adjusted EBITDA ratio of 1.5x.

Post the year-end, we conducted a further sale of 300 million Haleon shares, yielding proceeds of GBP 978 million and leaving our equity holding at just over 4%. Further, we reached a successful agreement to acquire Aiolos Bio, subject to customary regulatory clearances and to further strengthen our respiratory portfolio.

I'll now turn to our expectations for the coming year. Next slide, please.

In 2024, we expect another year of meaningful growth for GSK. We expect sales to increase between 5% and 7%, adjusted operating profit to increase between 7% and 10% and adjusted earnings per share to increase between 6% and 9%. Important to note that the cessation of Gardasil royalties negatively impacts profit growth by 6 percentage points within our 2024 guidance. As a reminder, our guidance is provided at CER and excludes the impact of COVID-19 solutions.

Some points to note for modeling purposes. Firstly, our sales composition. As Luke and Deborah have said, for vaccines, we expect high single-digit to low double-digit percent growth. For Specialty Medicines, we expect a low double-digit percent growth. For HIV, sales to grow high single-digit to low double-digit percent.

And within General Medicines, we expect sales will decrease by a mid-single-digit percent largely as a result of the [AMP cap] removal in the U.S. We also do not anticipate any further revenue from COVID solutions, and this will reduce sales growth by 1% and operating profit growth by 2% in 2024.

Secondly, turning to operating margin dynamics. We have been in an investment cycle, supporting our newly launched vaccines and medicines, and we now expect to move to a period of delivering increasing returns on our investment. In this new cycle, we expect a step down in SG&A growth to a low single-digit percentage, improving productivity and providing margin leverage whilst remaining competitive. We will continue to invest for growth as established in our capital allocation framework, and we will continue to build a strong R&D pipeline for the longer term. And finally, we expect an increased tax rate of 17% to 2024.

And I'll now hand back to Emma.

Emma Walmsley Executive

Thanks, Julie. So in this final section, we'd like to provide you with a bit more detail on the key elements that we see as underpinning our performance in '26 to 2031. We know this period is a key area of focus for investors with growth and profitability being two clear dynamics for us

to manage. Next slide, please.

First, growth and its most important driver portfolio development. We start from a very healthy position with a core set of marketed vaccines and specialty medicines driving significant growth. With the progress we're making, particularly in vaccines and HIV, these marketed assets now support an outlook of more than 7% sales growth on a 5-year CAGR basis in 2026. These growth drivers will be supplemented by a planned set of near-term new product launches, each with peak year sales potential of GBP 2 billion or more. Here, we have new potential vaccines for meningitis, influenza, pneumococcal disease and HSV and new potential medicines for long-acting HIV treatment and prevention, a functional cure for hepatitis B, bepirovirsen, a new portfolio of anti-infective treatments, including gepotidacin, new medicines for respiratory diseases with high burden and unmet need, depemokimab and camlipixant.

And in oncology, further indications for Jemperli and potentially CD226 targeting a variety of cancer types. Altogether, we are currently planning for at least 12 major product launches in the period 2025 to 2031. With these planned launches and our current marketed growth drivers, we expect to deliver more than GBP 38 billion in risk-adjusted sales for GSK by 2031. And beyond this, so not included in that GBP 38 billion, we continue to develop a promising early-stage pipeline, and we will continue to pursue targeted business development. Next slide, please.

Of course, we recognize that there is development risk and that refreshing and progressing our pipeline is a continual process. By definition, not everything will come through. Continued strong execution is needed, and we're committed to it. We forecast our sales on an RA, risk-adjusted and NRA, nonrisk-adjusted basis. As you can see here, there is significant potential for upside with successful development outcomes.

Our highest adjustments are in specialty oncology, reflecting the development risk and the upside returns the assets we have in this space offer. Overall, our portfolio offers scale growth opportunity and has an attractive risk profile, more than 90% of those future sales come from products already approved or from planned launches of GBP 2 billion or more, most of which we plan to launch in the next 4 years. Next slide, please.

You'll be increasingly familiar with many of these assets following our meet the management events last year. We will, of course, continue to provide updates as we expect significant amounts of pipeline value to unlock this year in '25 and in 2026, as this growing late-stage portfolio matures. As shown here, you can see we have multibillion pound scale opportunities in all of our core product areas. These peak year sales estimates are given on a non-risk-adjusted basis, and all of them are at least GBP 2 billion with many significantly higher.

So let's now turn to the second dynamic for us to manage in '26 to '31, a continued focus on profitability and disciplined capital allocation. So over to Julie to comment on this.

Julie Brown Executive

Thanks, Emma. And first, I will cover operating margins. Since 2021, we've delivered an increase in margin of 290 basis points and we remain focused on delivering further margin improvements in the next 3 years to achieve an operating margin in excess of 31% by the end

of 2026. This represents more than a 530 basis point improvement over the 5 years. Our margin is benefiting from the strategic shift we've made to invest in Vaccines and Specialty Medicines together with the significant productivity improvements across supply chain, commercial operations and global functions.

This margin progression is after absorbing various headwinds, including several already highlighted, such as Gardasil royalties and the impact from [AMP cap]. These are all factored into our outlook.

Moving to the period 2026 to '31. Whilst we do not plan to guide on operating margin beyond 2026, we do understand that investors are concerned about the period when dolutegravir loses exclusivity. We would, therefore, like to set out our expectations for this 3-year period, starting in 2028 with the majority impact in 2029, '30.

Offsetting this are a number of positive factors. Firstly, and very importantly, the development of new long-acting and ultra long-acting HIV treatment and prevention therapies, such that by the time the loss of exclusivity starts, we would expect around 40% of our HIV business to be in long-acting therapies.

Second, the mix benefit to the operating margin from growth in Vaccines and Specialty Care products, which we anticipate to be around 3/4 of revenues by 2026.

Thirdly, accelerating productivity gains, notably in supply chain and in SG&A, with increased use of AI and analytics to underpin and further support GSK's profitability in this period.

Taking all of this together, our expectation is for operating margins to be broadly stable through the 3 years where dolutegravir loses exclusivity. Known headwinds, including the impact of the IRA on certain products are also incorporated into this expectation.

And finally, we will continue to have a strong focus on margin improvement and ensure our P&L is both competitive and invested for growth. We remain ambitious and we'll seek further upside through progression of the early-stage pipeline, targeted business development and a continued drive for efficiency. Next slide, please.

Turning to capital allocation. Our first priority remains to invest in the business with capital allocated towards development of the pipeline, both organic and targeted business development. We also remain committed to delivering attractive returns to shareholders and pursuing a progressive dividend policy. We are, therefore, pleased to announce an uplift in the fourth quarter dividend to bring the total for 2023 to 58p allowing shareholders to benefit from the upgraded performance last year and our increased confidence in the future. In addition, we are announcing today that we expect to pay a dividend of 60p for the year 2024, in line with our progressive policy and to be paid in equal quarterly installments.

Next slide, please.

It is important that we share our progress with you and that you're able to track our major milestones and value unlocks, Emma referred to earlier. Last year, we set out an IR road map for investors covering the next 18 months, inclusive of 4 major areas: execution, pipeline, capital allocation and investor engagement. Our progress on this has been very positive and

is available in our appendix. Today, we are providing you with a new and updated road map for 2024 and extending this into 2025. Outlining the milestones and potential inflection points, we expect to deliver in the next 24 months.

The Phase III and regulatory decisions are highlighted and aligned to the planned major launches, Emma referenced and include expected progress from MenABCWY vaccines, depemokimab, Nucala, COPD and camlipixant in respiratory, gepotidacin in infectious disease, together with Blenrep, and Jemperli in oncology. We hope you'll find this useful, and we also look forward to providing you with updates at several scientific conferences this year. And we were also planning to hold 2 additional Meet The Management events, covering oncology in the summer and selected early-stage pipeline assets towards the end of the year.

I will now hand back to Emma to conclude.

Emma Walmsley Executive

Thanks, Julie. So to summarize, GSK is delivering on its commitments and performing to a new standard. The excellent performance that we delivered in 2023 provides us with clear momentum, and we expect to deliver another year of meaningful growth in 2024 as we continue to focus on prevention and changing the course of disease for millions of people. Our progress means we're also upgrading our outlooks for 2026 and 2031. All of this bodes well.

But equally, we also know there is much to be done. We remain very focused on delivering this potential and more at continued pace for patients, for shareholders and for our people, combining science, technology and talent to get ahead of disease together.

With that, I will now open up the call for the Q&A with the team.

Nick Stone Executive

Thanks, Emma. We're going to take our first question from Peter Welford.

Peter Welford Analyst

You said 1 or 2. So I'll stick to 2, if I may. Firstly, on Arexvy, I wonder if Luke can just talk a little bit about the contracting discussions that you've got in place for 2024, given comments from Pfizer about trying to become more competitive this year? And if you could give us any insights into the sort of levels of stocks that you have at the moment and whether that is now at sort of sustainable level that you think going forward, given the apparent lack of seasonality, at least relative to flu that we're seeing?

And then the second, just a quick one, just on oncology. Looks though you've got 2 -- over GBP 2 billion peak year sales potential in oncology that you're including in the 2031 now. Just we're curious when could we get some visibility, I guess, to increase the confidence in the oncology part of that GBP 38 billion. And to be clear, that presumably doesn't include a return of Blenrep.

Emma Walmsley Executive

Right. Thanks, Peter. We'll come to Luke. First on Arexvy, we're obviously delighted with doing the [indiscernible] to blockbuster in 4 months that the company has ever done in '23 and ambitious for the path forward. And then I'm going to ask Tony to comment on oncology.

Just to confirm, though, Blenrep isn't included in any of the outlook, although we do have some more data to come. And as a reminder, in one of the slides that I presented, this is the more heavily risk-adjusted portfolio in our outlook to 2031 and particularly with the 226 portfolio, not starting right towards the end of that period. But Tony can give you more visibility on when we'll know what for Jemperli. But Luke, first to you.

Luke Miels Executive

Yes, sure. Thanks. Thanks, Emma. Thanks, Peter. Look, stocking levels are about 20% of what we've sold in.

And if you remember, we had that initial loading with the launch, as you'd expect, you need to fill the shelves. But yes, now we're at steady state. I think I agree with you in terms of shifting away from -- I think we're increasingly confident this is not going to be a seasonal vaccine, and we're working very hard to do that. I think the [certainties] in data that we'll get in the middle of the year will also help to cement that.

In terms of contract, as you can imagine, I'm going to be a little bit coy there because as we've said on the past call, people get up early to listen to these calls. So -- but I would say we're very pleased with the launch so far in the 2023 performance. But our mindset is this is the first round of a multi-round fight. And in 2024, of course, we've got a third boxer jumping into the ring to make things interesting. So we're very focused on it.

We're very confident, and I think we've shown that we can compete with the best. And our aim is to have another good year in 2024.

Emma Walmsley Executive

Thanks, Luke. Tony, for oncology?

Tony Wood Executive

Yes. So just to reiterate, first of all, Blenrep is not in the projections. For Jemperli, as you've called out, there are 2 areas. And the way to think about this is the continued development of [value] from Jemperli in areas where the underpinning genetics of the cancer support its activity, for example, building on the results that we have with RUBY and looking at other areas, which dMMR or MSI-High status are likely to generate transformative results. In addition, we've taken a careful look back on what we might call opportunities for which the PD-1 class is showing some effect, but adjustments in the approach would deliver potential differentiated -- long-term differentiated efficacy for Jemperli, that would be in the third line head and neck.

And then broadly speaking, which -- and you'll hear more about this towards the end of the year is the data that we have in the CD226 access begin to mature and we hold Meet the Management session is going to be associated with exploring our combinations with TIGIT in particular, and that's a question of how those data play out in [lungs] and other opportunities

like head and neck.

Emma Walmsley Executive

Thanks, Tony. Next question, please.

Nick Stone Executive

Okay. So we're going to take our next question from Jo Walton at UBS.

Emma Walmsley Executive

Jo?

Nick Stone Executive

I'll come back to you, Jo. Bear with me. We'll take our next question from James Gordon at JPMorgan.

James Gordon Analyst

James Gordon, JPMorgan. First question was just about Arexvy and about the revaccination data that I think we're going to get in the first half. So I remember 1 year, there wasn't a revaccination benefit, even though the protection had fallen quite a long way. So my question is confidence that we are going to see a strong benefit and how strong a benefit do you need to see? What would be a clinically meaningful benefit that would justify vaccinating people at 2 years?

And is it right that the '26 assumption is that there is a strong benefit from revaccinating people? So that's the first question, please.

Second question was just on the longer-term margin. So I saw the comment about broadly stable operating margin and as dolutegravir goes away, and I understand it's partly about productivity gains. But can you just remind us -- what is the headwind, how much are you losing? So I think when you did break out [indiscernible] before in dolutegravir when it was really just dolutegravir, it was a margin north of 70%. And presumably, the margin will be even higher as that business has grown and you've got more operating leverage.

So is that right that you'll be losing a business that's more than 70% EBIT margin when it goes away? And is part of it that you think there's going to be a new pipeline that's going to come in at a similarly high margin? Or am I overestimating the profitability you lose?

Emma Walmsley Executive

Thanks, James. So we'll come to Julie to give you a response on the building blocks to the margin. But first, Tony, to comment on revaccination. And just to be clear, the '26 outlooks, we haven't given the specific '26 outlook but RSV, given the peak year sales for RSV and overall vaccines growth, upgraded outlook to '26 as well. But this is obviously a key asset and very excited with the efficacy of more data to come.

So Tony?

Tony Wood Executive

Yes, sure. Look -- so James, just, of course, a reminder that the existing 2-year data is what is supporting the deseasonalization of the product. I'll talk about the plan to get to the decision point for determining the seasonality of the product. We're on track with regards to the third season data. That is -- will be presented at ACIP, it's worthwhile reminding everybody that the season is called by CDC and the determination of attack rates.

So on track for that as far as we stand at the moment, and that will include boost comparison. If you ask me to make the best guess based on what we see from immunogenicity data in the 006 study and other smaller studies than I think we're heading for a 2-season vaccine again though that and the data supporting it will be on the basis of the ACIP decision and our conversations with ACIP. So I'll just give you a plan on this.

Emma Walmsley Executive

Yes. And I think the other thing to say on deseasonalization. As Luke presented, obviously, RSV vaccination is holding up better than flu and pneumococcal, but it still came down between October and December. And we don't -- we've got work to do, and we will soon discover more over the coming quarter on how those efforts play forward.

Julie, the margin [indiscernible].

Julie Brown Executive

Thanks, Emma, and thank you for the question. In terms of the -- obviously, we are conscious that people are concerned about the loss of margin from dolutegravir, it's not at the level of the HIV business of the 70% that you mentioned. We've continued to invest heavily in this franchise and build in particular, the long-acting portfolio. And the reason for the confidence that we can hold it stable during that period. First of all, I'd draw attention to the 12 launches that Emma called out in her review.

We've got some of them near term. I mean the majority of these will be launching within the next 4 years. So the inflections are coming quite quickly, but we've got meningitis, ABCWY, we've got the mRNA influenza. We've also very importantly, got HIV. We're confident of the 4 months, and we've got work going on, on that already.

So the long-acting portfolio, very importantly, at the time the dolutegravir patent expiry starts we expect to have 40% of the business already in long-acting. So that's an important mechanism. In addition to that, as you know, we've got camlipixant launching, depemokimab, important readout coming out in the first half of this year, together with the anti-infective portfolio and others that Emma mentioned. So 12 major product launches just coming out now the majority in the next 4 years.

The other factors are the productivity gains. We're very confident you see we've stepped down SG&A growth into 2024. Luke and I have worked very closely together. We are very confident that we can leverage the great base that we've built. And very importantly, some of those assets that are launching, particularly in respiratory, we've got very capable field forces in the areas where we're launching these assets.

So the leverage capability is there. And you've seen us leverage the margin. We're committing to more than 500 basis points already by 2026. You'll see is we're never going to be satisfied. We are going to grow the top line.

The GBP 38 billion, we're saying above the GBP 38 billion, that's a risk-adjusted number, very importantly. Secondly, we continue to do business development. We've got the balance sheet to do it. It's part and parcel of building the R&D pipeline further. And also finally, that more than GBP 38 billion does not include those early-stage projects that Emma alluded to in her conversation.

So we're very confident of withstanding the DTG patent expiry.

Emma Walmsley Executive

I mean in the end, the outlook that we're updating today, we have added GBP 5 billion top line versus where we were in the summer of '21, and we know there's still more to do. So we're confident on making further progress with a lot of ambition. Next question, please.

Nick Stone Executive

So I'm going to come back to you, Jo. So hopefully, you can speak now.

Jo Walton Analyst

Could I ask about U.S.? Patients are already beginning to see lower co-pays as we go into 2024. Is there any benefit that you have in terms of less charitable giving to support people on Medicare who might need your assistance or any view that you have for some of your more expensive medications that there would be an increase in volume coming through?

And my second question would be to look a bit more about Shingrix in China. If we look at how Merck has dealt with their relationship with Zhifei and Gardasil, which has obviously been extremely successful, Merck is promoting as well as Zhifei is promoting. So given your relatively small base in China, can you tell us what you are doing to ensure that there is a strong uptake of Shingrix in China, so that over time, it will be more than the minimum amount of sales Zhifei is taking from you?

Emma Walmsley Executive

Thanks, Jo. Both of those questions will come to Luke. We're after a record quarter on Shingrix, again, we really do see Zhifei as a very important building block for the ongoing growth of this great vaccine. So Luke, to you on that? Any other thoughts?

Luke Miels Executive

Thanks, Jo. I'll cover to the China question first. So -- we -- the way the deal is structured, we still maintain the license in China, and we preserve 600 head count. We are promoting the product in addition to Zhifei's structure, which is several orders of magnitude larger. We also partner with them in terms of profile, positioning and life cycle work with Shingrix.

So we're very engaged. And I think the partnership has started very well. there's high levels of trust. And you mentioned the Merck structure, which has been in place, I think, 11 years,

nearly 12 years now, and that's been very successful. So our aim is to replicate or even exceed that.

One thing to keep in mind with revenue recognition in China next year, it's driven by shipments. So there will be a bolus, which is between 60% and 80%, depending on how much we shift which will be recognized in quarter 2. So that's just one watch out. But yes, we're very excited about the long-term potential for Shingrix in China and the partnership and also the capacity to expand that to include RSV.

In terms of co-pay assistance, indigent programs, et cetera, we do have extensive programs across the business in HIV, of course, oncology and other areas. We're not seeing an increase in those, Jo, but we do have extensive progress that people can take advantage of. And of course, the co-pay has now been removed from Shingrix and RSV, which is a big advantage for seniors citizens.

Nick Stone Executive

So our next question is going to come from Simon Baker.

Simon Baker Analyst

Two if I may, please. Firstly, on Arexvy. Arexvy ex U.S., you've said in the past that you expect a Shingrix-like broadly flat global pricing for Arexvy. Given that that's now beginning to roll out, I just wonder if you could confirm if that's still the case and give us any updates on how things are going outside in terms of those negotiations?

And then secondly, and forgive my pronunciation, I probably get this wrong. On the Aiolos acquisition, it's slightly earlier than we've seen from your acquisitions in the past where you've prepared -- been prepared to pay more for later-stage products. So I just wonder if you could give us an idea of whether this marks a shift in your business development approach or whether there was something particular about that [T-slip], which -- to go earlier than perhaps we've done in the past?

Emma Walmsley Executive

Thanks very much. Well, let's come to Luke for some globalization of Arexvy though the U.S. will still be, by far, the biggest part of the business. But obviously, that's going to be a key contributor for the future. And then Tony to comment on the Aiolos deal, and our consistent approach strategically to BD, which starts with getting a very good return on the investment of that because of the sizable assets and their differentiation, which is definitely what we're excited about here.

But first to you, Luke.

Luke Miels Executive

Thanks, Simon. Yes, I mean, as I said, we're approved in 39 countries. If you look below that, and it's very similar to what we've seen with Shingrix. It just takes time to assemble the arguments for the infrastructure in those countries to review the data. We know that some governments are waiting for that third season, which we'll have shortly.

But if you look within that, of those 89 countries, we've got 9 that have issued recommendations and 4 that have voluntary reimbursement. So for example, I was in Germany yesterday, if you look at the 60-plus population, we've already got reimbursement through the 6 funds on about 24% of that population.

So it's early days. But in terms of pricing, our aim in the private market is to preserve that pricing level. Of course, always, we open if we can secure a contract because the structural nature of those contracts is such that we don't have to do the DTC, et cetera, that we need to do in the U.S., there's smaller sales forces because the system itself will pull through those scripts, the U.K. being a typical example. So early days, it's been exciting.

And I mentioned China before. there, we're working actively to get Arexvy to China as quickly as possible.

Emma Walmsley Executive

Thanks, Luke. Tony, comment on Aiolos and BD [indiscernible].

Tony Wood Executive

Yes, Simon. So first of all, the way to think about Aiolos deal. Let me just reemphasize something to begin with. This is in the low [T2] population. So it gives us access to an additional 40% of the severe asthma population for which Nucala and depemokimab aren't addressed.

Now similarly to Nucala and depemokimab. The reason we were confident to go early with the Aiolos asset is we have a very clear understanding of the PK/PD proposition there. So you can learn an awful lot with regards to projected dosing and efficacy through Phase Ib data, which is the case of Aiolos, and we look upon that as being a best-in-class opportunity, which will appear in the market, potentially first-in-class with a Q6M profile and well matched in depemokimab. Those features, I would say, emphasize a continuing focus that we'll have on BD with deals [indiscernible] that scale to match our overall therapeutic area focus on in an appropriate strategic way of the factors that Emma just mentioned. For earlier deals, then what you should be expecting there is a focus more on the underpinning technologies that are transforming R&D for us.

Emma Walmsley Executive

Thank you. And obviously, extremely clear as our top priority in the capital allocation framework and as Julie laid out in her slides around allocation of capital. That's a consistent approach we're taking and was all part of the demerger strategy to create that balance sheet capacity for us to put a BD as the way we do R&D at GSK now as it is across the industry. Next question please.

Nick Stone Executive

Okay? So we've got about 7 people with their hands raise with about 10 minutes left. So if I can ask people to keep the questions short and equally, we'll try and keep answers concise. But our next question is going to come from Tim Anderson at Wolfe Research.

Timothy Anderson Analyst

If I could go back to Shingrix in China and just drawing the analogy to Merck's Gardasil or even your server. The question I have is the disease awareness among the general population about shingles versus cervical cancer vaccine because with Gardasil, there's been a high consumer awareness that's really kind of created this classic poll demand at the consumer level, but I don't have a feel for is what is it like with shingles among consumers in China. Is the awareness -- disease awareness high? Or do you have to build that?

Luke Miels Executive

Yes. Thanks, Tim. It's relatively low. But I was in China at the stage when Gardasil did launch and awareness around HPV vaccination, it was also very low. What we found through our market research is that people are receptive to it.

The main challenge we had was just navigating the 30,000 points of vaccination in China because all vaccines need to be administered in those centers. So I think we can build that awareness. And whether we can get to the level of Gardasil did. I think before COVID, it was actually the #1 selling product in China, so a remarkable achievement. The key thing I took away from that is, one, you've got a company that partners well with multinational over many years with extensions to that relationship.

And two, they can build a market in partnership very successfully. So yes, I'm very optimistic about the long-term outlook there with China.

Emma Walmsley Executive

Thanks, Luke. Next question, please.

Nick Stone Executive

We take our next question from Richard Parkes of BNP Paribas.

Richard Parkes Analyst

I can stick to one. I just wondered if you could just discuss the challenges to specifically growing RSV in the U.S. market next year? It looks like about 10% of the eligible population has been vaccinated with an RSV vaccine now. And obviously, clearly, that leaves a lot of room for growth given the 35% penetration you've achieved with Shingrix, but it's taking you 6 years to get to that level.

And clearly, the RSV market competition is going to intensify over the next 12 months. So given that the very strong start you've had, I'm just wondering how challenging it will be to grow RSV specifically in the U.S. market and to what extent we should expect growth to be more driven by ex U.S.?

Luke Miels Executive

Sure, Richard. Great question. So I think the pie is going to grow. You've got 3 companies in there. The level of awareness is remarkable already.

I think it's 86% awareness for individuals in the U.S. around RSV, the willingness to prescribe and recommend on part of doctors and pharmacists is very, very positive. And your numbers are right. I mean, if you look at Shingrix, we're 4%, 11%, 17%, 23% in those first years. So hitting 11% immediately is encouraging, but we just don't know what the other 2 competitors, how they're going to behave going into the year, so that's an unknown.

But again, if we look at the long term, if you look at 65-plus individuals to a 65% and above about 72%, 73% and typically every year, get a flu vaccine. So that's the potential here, and that's why we're very confident about our long-term GBP 3 billion peak revenue outlook. But it will -- let's see how we go in 2024. It's probably all I should say at this point.

Tony Wood Executive

Worthwhile adding the cost of the 50-plus label [indiscernible] the 15 million at risk eligible individuals.

Nick Stone Executive

Okay. Next question is from Andrew Baum, Citi.

Emma Walmsley Executive

Andrew, we can't hear you.

Andrew Baum Analyst

There we go. Sorry about that. I apologize. So 2 questions for Deborah on HIV. First, given how important the switch is to long-acting for both the margin and the revenues, could you talk to what are the current barriers to adoption?

Is it any evidence for step editing given you've got 50% falling under PBMs. Is it clinical inertia? Is it access? I'm curious to understand that in terms of the risks and opportunities there?

And then second, I note that there's been a pause placed on your litigation with Exavir for their cabo pro drug. Given the patent expiration on cabo and I'm thinking particularly about Apretude, is there any interest in licensing this compound in order to secure the future of a once-yearly long-acting prep formulation?

Deborah Waterhouse Executive

Thanks, Andrew. So in terms of barriers to switch in the long-acting market, actually, they're pretty typical to the barriers that you see across many long-acting injectables that are in the Medicare Part B, and part is about clinic capacity. So for us, that is a barrier, but we're seeing the belief in physicians increase that long-acting is going to be favorably a bigger part of the way that they treat their HIV patient population. So we are seeing them expanding capacity to bit as a slow journey.

The second thing is the ability to get physicians' offices ready and able to manage their way through the benefit verification, the element of specialty pharmacy versus buy-and-build. Again, we are seeing more and more uptake and more and more process flows within the

clinician offices that are making this faster and slicker but still is a learning journey as we are building a brand-new market for HIV physicians. So I would say complexity around payer and pharmacy buy-and-build and the capacity to inject in the clinics, the 2 biggest barriers, and we're seeing significant progress on all of those areas, which is why we're seeing the continued significant growth amongst long-acting injectables in both preps and in treatment mainly because there is enormous patient demand, and that just keeps on growing as awareness grows.

In terms of Exivir, I'm not going to comment on any of the litigation, but we have our own in-house long-acting injectable that we were formulating cabotegravir to get to every 4 and hopefully, we'll be able to get throughput where we can get to every 6 months, either with VH184 or other options. And we've also got in-house options that can take us to every 12 months but we keep an eye on the whole landscape from a BD perspective of HIV. And if there is something to do a deal on, we will actually do that.

Emma Walmsley Executive

Next question please.

Nick Stone Executive

Okay. Our next question is from Graham Parry at Bank of America.

Graham Parry Analyst

It's -- going back to Arexvy in the third season data, can you just confirm that there's no vaccine efficacy measurement to compare one and done vaccination with and every other year vaccination in either the RSV 006 or 004 trials? And if it is just immunogenicity data that you're going to be using there, how do you go to ACIP and convince them that a boost in immunogenicity in the third season would correlate with vaccine efficacy when we didn't see that in the first season in data?

And then second question, just any sense of what percentage of the high-risk or comorbid population, so let's say, over 80s or the comorbid population has been vaccinating with the Arexvy now? Or has it been across a fairly broad age range?

Emma Walmsley Executive

So very briefly, Luke, any comment on the penetration [indiscernible].

Luke Miels Executive

Yes, it's about 13% in the older individuals, so 65-plus. It's about 4% in the 60 to 64. That's the only data we have at this point, Graham, but we will get more in Q2.

Tony Wood Executive

And on the third season, the comparison will be exactly the same as the one we took in second season, Graham. So that is vaccine efficacy based on a 3-year duration versus a 3-year [indiscernible]. Sorry, 2-year.

Nick Stone Executive

Yes. Okay. So I'm going to try and push us a little bit over a [mindful] of the call starting, but we can take the next question from Mark Purcell at Morgan Stanley.

Mark Purcell Analyst

Just a quick one, sticking on HIV. Ahead of the CROI data, historically, Phase II data has translated very nicely into Phase III profile. So when it comes to assessing your combination options and the 4-month formulations, how confidently should we be extrapolating Phase II data into Phase III and effectively the derisking of the portfolio strategy?

Deborah Waterhouse Executive

So just to answer that very quickly. So we're incredibly confident in our ability to replace a significant proportion of the revenue that will be lost through the dolutegravir patents expiry. This is a big year for us. So we'll be presenting data at CROI, we'll be starting the Phase III study for every 4-month prep. We'll be regimen selecting every 4 month for treatment and we'll also be regimens selecting for [indiscernible].

So I would say we're extremely confident in the progression of our HIV pipeline. And very confident in the statement that we've been making for some time that we will be able to potentially replace a significant proportion of the revenue that you'll lose when dolutegravir goes.

Nick Stone Executive

We've got 2 more questions. I'm going to take the next question from Kerry Holford of Berenberg.

Kerry Holford Analyst

Thanks, Nick. Just one final pipeline question, well, recently launched product question, Ojjaara, I know it's early days but how is the U.S. launch progressing relative to expectations? And in which line of therapy are patients predominantly using this drug?

Emma Walmsley Executive

Very well, Luke?

Luke Miels Executive

I'll go quickly. So 750 patients since launch, 43% of them are in academic centers, 57% are in community centers. Market research is very, very encouraging. Unaided awareness is well above benchmarks, aided awareness is 99%. I'm not sure about that 1%.

We've got around 15% patient share in patients with anemia and about 25% share in the second line. If you look at the intent to prescribe 1/4 of doctors have already prescribed it, and over 64% who have not prescribed intent to prescribe over the next few months. So very encouraging, very exciting launch.

Emma Walmsley Executive

Great. And so last question, Nick.

Nick Stone Executive

Last question. So Steve Scala, TD Cowen.

Steve Scala Analyst

On Cabenuva, emerging resistance in 1% to 2% of people is viewed by clinicians as a real risk seems to occur in the obese population, but could tarnish prospects overall. So I'm just wondering what is GSK's position on this? And secondly, pneumococcal vaccine, do you plan an efficacy study? And if not, is that because you think that is not important?

Emma Walmsley Executive

Well, we do think the pneumococcal vaccine is very important, but -- so Tony can comment on that. But Deborah, I'm not sure we characterize it quite as Steve has though.

Deborah Waterhouse Executive

So you've got less than 1% failure on Cabenuva. There are some risk factors that all physicians are aware of, obesity is one of them. Being resistant to rilpivirine is the other. And then there is a sort of [pet] relatively rare subtype, so we are clearly characterizing where people should not use the drug. It's a very limited population.

And the real-world evidence is actually showing less than 1%, in fact, significantly less than 1% failure because physicians have taken on board the multivariate analysis that guides where to use it. And when they use it in that population, you see very low levels of failure and very, very high satisfaction with the drug and continuity on the drug over time. So that's why we're seeing significant growth with Cabenuva that we are.

Emma Walmsley Executive

Thanks. Tony?

Tony Wood Executive

Just quickly then on pneumococcal. Obviously, we're focused on using immunogenicity data and in particular, restarting the infant [24mg/ml] this year alongside the data that we have in adult and starting in adults 30+. In terms of our strategies with regards to vaccine efficacy and broader competitive content of that, I'll keep that to future discussions.

Emma Walmsley Executive

Great. So thank you very much, everyone, for the call. I'm very pleased to have been able to share with the team today, how GSK is delivering on its commitments, strengthening our outlook for growth, we are making great progress. We know there's always more to do, and we're looking forward to keeping you updated. Thanks to everybody for joining the call.