GILEAD SCIENCES THIRD QUARTER 2023
EARNINGS PREPARED REMARKS

Jacquie Ross, CFA, *VP, Investor Relations*

Thank you, Operator, and good afternoon, everyone. Just after market close today, we issued a press release with earnings results for the third quarter of 2023. The press release, slides, and supplementary data are available on the investors section of our website at gilead.com.

The speakers on today's call will be our Chairman and Chief Executive Officer, Daniel O'Day, our Chief Commercial Officer, Johanna Mercier, our Chief Medical Officer, Merdad Parsey, and our Chief Financial Officer, Andrew Dickinson. After that, we'll open the call to Q&A, where the team will be joined by Cindy Perettie, the Executive Vice President of Kite.

Before we get started, let me remind you that we will be making forward-looking statements, including those related to Gilead's business, financial condition and results of operations; plans and expectations with respect to products, product candidates, corporate strategy, business and operations, financial projections and the use of capital; and 2023 financial guidance, all of which involve certain assumptions, risks and uncertainties that are beyond our control and could cause actual results to differ materially from these statements.

A description of these risks can be found in the earnings press release and our latest SEC disclosure documents. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

Non-GAAP financial measures will be used to help you understand the company's underlying business performance. The GAAP to non-GAAP reconciliations are provided in the earnings press release, in our supplementary data sheet, as well as on the Gilead website.

With that, I'll turn the call over to Dan.

Daniel O'Day, *Chairman and Chief Executive Office*

Thank you, Jacquie, and good afternoon, everyone.

I'm pleased to share that Gilead teams have delivered another strong quarter that rounds out two years of continuous growth for our base business. Our track record of commercial execution continued in the third quarter with our base business up 5% compared to the third quarter of 2022, and up 10% year-over-year for the first 9 months of 2023.

In the third quarter, our growth was driven by our leading therapies across Virology and Oncology. Biktarvy had another very strong quarter, up 12% from the same quarter in 2022, and contributing to 9% growth overall in HIV in the first nine months of 2023. Oncology is also driving growth, and was up 33% in the third quarter compared to last year. Revenue is now annualizing at more than $3 billion, with growing adoption of Trodelvy, the only approved TROP2-directed ADC, and our industry-leading cell therapies.

This was also another very good quarter for clinical execution as we continued to advance our 60 clinical programs across Virology, Oncology, and Inflammation.

Some of the highlights for the quarter included:

- The European Commission approval of Trodelvy for pre-treated hormone receptor positive, HER2-negative metastatic breast cancer, allowing us to extend Trodelvy's reach to many more patients globally.
- The first data for Trodelvy in combination with pembro for first-line metastatic non-small cell lung cancer presented at World Lung. Our Phase 2 EVOKE-02 trial showed a strong objective response rate in the PD-L1 high cohort, which supports proof-of-concept for our ongoing Phase 3 EVOKE-03 trial.

- Important new data at ESMO from Trodelvy's Phase 2 TROPiCS-03 basket trial in our small cell lung cancer and head and neck squamous cell carcinoma cohorts. All of these milestones reinforce our conviction in Trodelvy as our cornerstone oncology asset with pan-tumor potential.

- Staying with Oncology, today we presented positive data from our Phase 2 EDGE-Gastric trial in partnership with Arcus, which further establishes proof-of-concept for the ongoing Phase 3 STAR-221 trial in first-line metastatic upper GI cancers.

- Additionally, we're encouraged by the continued strong data emerging from the ongoing Phase 1 study of CART-ddBCMA in multiple myeloma. Together with our partner Arcellx, we look forward to providing even more data during next month's ASH conference.

The clinical momentum continues in Virology. In HIV Treatment, we reviewed promising data from the Phase 1 study of GS-1720, our once-weekly long-acting oral integrase inhibitor to be combined with lenacapavir, and Phase 2 ARTISTRY-1 trial evaluating a once-daily oral lenacapavir and bictegravir combination. We expect to share the data with you at a medical conference in early 2024.

In HIV prevention, we completed enrollment ahead of schedule in our Phase 3 PURPOSE-1 trial investigating a once every-6-month lenacapavir subcutaneous injection and announced plans to initiate the Phase 2 PURPOSE-5 trial in 2024 to support access in Europe.

In COVID-19, we completed enrollment in our Phase 3 OAKTREE trial evaluating obeldesivir in standard-risk non-hospitalized COVID-19 patients. We look forward to providing an update early next year. Veklury remains an important therapeutic option for hospitalized patients with COVID-19. We recently received approvals from both the FDA and the European Commission to extend use of Veklury in patients with mild to severe hepatic impairment.

Looking at our pipeline overall, our aggregate progress in 2023 is such that we have already completed most of the milestone events as shown on slide 6. Our clinical pipeline now includes 27 programs in Phase 2 and 19 in Phase 3. We are looking forward to a busy period of updates from many of these studies in 2024, including those evaluating lenacapavir, Trodelvy, and obeldesivir.

In summary, it has been another strong quarter of commercial and clinical execution resulting in important progress for Gilead and the people and communities we aim to serve.

With that, I'll hand the call over to Johanna to cover commercial results. Johanna?

Johanna Mercier, *Chief Commercial Officer*

Thanks Dan, and good afternoon, everyone.

I'm pleased to share the details of another strong quarter for Gilead, and would like to thank the teams that have delivered 10% growth in our base business in the first nine months of 2023.

Our third quarter results represent the eighth consecutive quarter of year-over-year growth in our base business, illustrating strong commercial execution and revenue growth as our Virology and Oncology products impact more patient lives.

In the third quarter of 2023, total product sales, excluding Veklury were up 5% to $6.4 billion as shown on slide 8, with notable growth in our Oncology and HIV businesses, partially offset by lower HCV sales. Total product sales including Veklury were $7 billion, with the solid base business performance contributing $305 million of growth, offset – as we expected – by lower Veklury sales compared to the same quarter last year.

Moving to HIV on slide 9, the treatment market continued to grow in-line with our expectations of 2% to 3% annually.

And as we've discussed previously, the favorable pricing dynamics in recent quarters have begun to normalize with HIV sales growth more closely mirroring market and demand growth. This was evident in the third quarter where HIV sales were up 4% year-over-year to $4.7 billion, driven by higher treatment and prevention demand, and higher channel inventory, partially offset by lower average realized price due to a shift in channel mix. Sequentially, sales were up 1%.
Looking to the full-year, we continue to expect HIV product sales to grow slightly more than the 5% reported in 2022.

Turning to slide 10, third quarter Biktarvy sales were $3.1 billion, up 12% year-over-year, driven by higher demand, as well as higher channel inventory. Sequentially, sales were up 4%.
Once again, Biktarvy gained market share, up over 2% year-over-year in the U.S. to over 47% share in the third quarter. Thanks to its robust clinical profile, Biktarvy remains the #1 prescribed regimen for new starts and #1 in treatment switches across most major markets, including the U.S.

Descovy sales in the third quarter were $511 million, up 2% year-over-year, with strong year-over-year growth in demand for Descovy for PrEP, offset by less favorable pricing dynamics to ensure broad access ahead of the potential launch of lenacapavir as early as late 2025. The U.S. PrEP market grew about 15% year-over-year, and Descovy for PrEP continues to maintain more than 40% market share due to its strong clinical profile – and despite the availability of other regimens, including generics.

Moving to the Liver Disease portfolio on slide 11, sales were down 10% year-over-year to $706 million, primarily due to the resolution of a rebate claim in HCV recognized in the third quarter of 2022, as well as other pricing dynamics.

From a demand perspective, HCV new starts increased compared to the third quarter of 2022 in both the U.S. and Europe, driven by our continued efforts to link HCV patients to care. Given the curative nature of our treatments, we expect HCV new starts to trend down over time, but are pleased that we are maintaining 50-60% market share in the U.S. and Europe, and that our Liver portfolio more broadly has stabilized from a revenue perspective.

Onto slide 12, Veklury sales continue to be highly variable and declined 31% year-over-year in the third quarter to $636 million. On a quarter-over-quarter basis, sales were up 149%, driven by an uptick in hospitalizations during the third quarter. And over the last few weeks, we have seen a slowdown in COVID-related hospitalizations.

Veklury's strong clinical profile continues to be recognized, most recently by the FDA and the European Commission for use in patients with mild to severe hepatic impairment. While the COVID environment remains ever-changing, Veklury's performance in the third quarter further reinforces its established role as a key part of the standard of care for patients hospitalized with COVID-19.

Moving to slide 13, our Oncology business achieved another strong quarter with sales up 33% year-over-year to $769 million – representing an annual run-rate that now exceeds $3 billion. With clear momentum and a solid infrastructure in place – in addition to our compelling clinical pipeline – we look forward to providing more patients with potentially new and effective options.

Looking at Trodelvy on slide 14, sales were up 58% year-over-year and 9% sequentially to $283 million. As a reminder, Trodelvy is the only approved TROP2-directed antibody drug conjugate, and – to date – we have delivered this therapy to more than 20,000 patients, reinforcing the clinically meaningful benefit Trodelvy can provide across multiple tumor types.

Trodelvy remains the leading regimen in second-line metastatic triple-negative breast cancer, across both the U.S. and Europe. In pre-treated HR+/HER2- metastatic breast cancer, Trodelvy is showing particular strength in the IHC0 setting and as a later-line treatment in the HER2-low setting, consistent with expectations. Altogether, these dynamics reflect the notable work the team has done to raise awareness in both indications as well as the strength of Trodelvy's clinical profile.

Turning to slide 15, on behalf of Cindy and the Kite team, Cell Therapy sales in the third quarter were $486 million, up 22% year-over-year and 4% quarter-over-quarter, reflecting strong demand with particular strength outside the U.S. in the third quarter.

Yescarta sales grew 23% year-over-year to $391 million, primarily driven by strong growth ex-U.S. in second- and third-line relapsed or refractory large B-cell lymphoma. Tecartus sales were $96 million, up 18% year-over-year, reflecting increased demand in both the U.S. and Europe for relapsed or refractory mantle cell lymphoma, as well as adult acute lymphoblastic leukemia.

Given the strong clinical data, it is surprising that only about 10% of eligible second-line large B-cell lymphoma patients in the U.S. are treated with a cell therapy, and it is clear that there is still a significant opportunity to drive adoption.

As cell therapies are offered and delivered to more and more patients, we are confident that Kite remains well-positioned to benefit from this expansion with its differentiated overall survival data for Yescarta and industry-leading manufacturing capabilities. We understand the importance of delivering these potentially curative medicines as quickly as possible to patients with severe and challenging diseases. To that end, we continue to identify opportunities to bring our therapies to patients faster and are actively working on initiatives to shorten even further our industry-leading 16-day median turnaround time in the U.S.

Wrapping up the third quarter, I'd like to recognize the strong execution of the commercial teams and our cross-functional partners across Gilead and Kite. Thanks to their efforts, our therapies are positively impacting more and more people, driven by growing market share and expanding reach as we bring our therapies to new geographies around the world.

And with that, I'll hand the call over to Merdad for an update on our pipeline.

Merdad Parsey, MD, PhD, *Chief Medical Officer*

Thank you, Johanna. The clinical highlight of our third quarter was the release of our promising, Phase 2 data for Trodelvy in combination with pembrolizumab in first-line metastatic non-small cell lung cancer, highlighting Trodelvy's potential to bring a much-needed treatment alternative for patients. More broadly, we continued to progress our increasingly diverse pipeline of 60 ongoing clinical programs, spanning Virology, Oncology, and Inflammation.

Starting with our Virology programs on slide 17, we have 10 clinical programs with our long-acting capsid inhibitor, lenacapavir, including two Phase 3 studies underway in PrEP.

I'm pleased to share that we have completed enrollment earlier than anticipated for our Phase 3 PURPOSE-1 trial evaluating lenacapavir for prevention in adolescent girls and young women. Our Phase 3 PURPOSE-2 trial in cis-men and trans-women and -men, and non-binary people continues to enroll well, and we could have an opportunity to share data from one or both PURPOSE trials in late 2024, ahead of schedule. We are targeting our first approval for lenacapavir in prevention in late 2025, potentially making lenacapavir the first 6-monthly dosing regimen available for PrEP.

Turning to treatment, we continue to make strong progress on evaluating nine candidate partners for lenacapavir. Of the remaining candidates, six are already in Phase 1 or 2. We expect to share updates on at least four of these in 2024, including data from our Phase 1 trial of GS-1720, our once-weekly long-acting oral integrase inhibitor to be combined with lenacapavir, and from our Phase 2 ARTISTRY-1 trial evaluating a once-daily, oral combination of lenacapavir and bictegravir for virologically suppressed, treatment-experienced people living with HIV.

We plan to share results from both trials at a conference in early 2024, and we look forward to advancing these programs into the next phase of development.

We're also pleased to share that enrollment for our Phase 2 program evaluating our lenacapavir plus bNAbs combination dosed every six months is progressing very well and is another program we expect to update you on next year.

Putting this all together, our data continue to support our confidence that lenacapavir has the potential to transform HIV treatment and prevention globally.

Turning to Oncology on slide 18, to date, Trodelvy has been delivered to more than 20,000 patients across three approved indications since our launch three years ago. Trodelvy remains the first-and-only marketed TROP2-directed antibody drug conjugate to achieve meaningful overall survival benefit in two of its indications. With that said, we are seeing both growing real-world evidence and clinical trial data supporting not only the approach we are taking for Trodelvy's clinical development across tumor types, but also Trodelvy's unique ADC construct.

In particular, Trodelvy is the only ADC to have a high 7-to-8 drug-to-antibody ratio that is able to deliver a highly potent SN-38 payload directly into the tumor microenvironment through its hydrolyzable linker. As a result, in our studies to date, Trodelvy has shown a potentially differentiated safety profile with regards to ILD and stomatitis. We look forward to sharing more emerging Trodelvy data in 2024 as we continue to expand Trodelvy across tumor types and lines of therapy.

Our comprehensive clinical development program for Trodelvy consists of more than 30 active or planned clinical trials across eight tumor types.

In 2023, we've shared several datasets demonstrating clear signals of activity for Trodelvy across several indications. For example:

- At the ASCO meeting this past June, we presented data for Trodelvy that demonstrated encouraging preliminary ORR and PFS in relapsed or refractory endometrial cancer patients in the Phase 2 TROPiCS-03 basket trial.

- More recently at the ESMO meeting, we presented additional, early data from TROPiCS-03 showing promising ORR in both relapsed or refractory head and neck squamous cell carcinoma and previously treated extensive stage small cell lung cancer.

- We reported strong data from EVOKE-02 at World Lung in September , shown on slide 19, establishing clear proof-of-concept for Trodelvy plus pembro in first-line, metastatic non-small cell lung cancer.

- In the PD-L1 high cohort, Trodelvy plus pembro demonstrated ORR of 69% including unconfirmed responses. This compares favorably to the historical pembro monotherapy benchmark with response rates of 45% and 39% in KEYNOTE-024 and KEYNOTE-042, respectively. As a reminder, we are currently enrolling patients with 1L PD-L1 high metastatic non-small cell lung cancer in our registrational Phase 3 EVOKE-03 study.

- Preliminary data from the PD-L1 TPS <50% cohort has also been encouraging, demonstrating an ORR of 44%, similar to previous trials that evaluated pembro plus chemotherapy.

These results inform our plans to expand into broader first-line non-small cell lung cancer patient populations across all PD-L1 expression levels. We are looking forward to sharing further analysis from EVOKE-02 that will highlight the efficacy of Trodelvy and pembro across both squamous and non-squamous histologies in first-line, metastatic non-small cell lung cancer patients.

Moving to our TIGIT program on slide 20, an initial update of one arm of the Phase 2 EDGE-Gastric study was presented in an ASCO plenary session earlier today. The study found that the addition of dom and zim to a FOLFOX chemo regimen showed encouraging 77% 6-month PFS and 59% ORR , including unconfirmed responses, in first-line metastatic upper GI cancer. In patients with PD-L1 high tumors, the ORR was an impressive 80% and the 6-month PFS was 93%. We're pleased to see that dom and zim added to the standard-of-care was generally well tolerated, with an adverse event profile similar to anti-PD-1 plus FOLFOX.

These results increase our confidence in the ongoing registrational Phase 3 STAR-221 trial in the similar first-line gastric, gastroesophageal junction, and esophageal adenocarcinoma population and our broader anti-TIGIT program. Although anti-TIGIT will not work in every tumor type, we are excited to see dom has shown encouraging efficacy and tolerability in the tumor types we have advanced to Phase 3 studies, including 1L non-small cell lung cancer and upper GI cancer.

Turning to Cell Therapy on slide 21, we are continuing to work to expand the benefits of cell therapy to even more patients, with 8 ongoing trials in earlier lines, new indications, or new settings. We also have an extensive early-stage pipeline, where we are exploring allogeneic CAR Ts, including healthy donor and iPSC-derived cell therapies, as well as natural killer and invariant natural killer T cell therapies. Beyond therapies, we continue to invest in manufacturing innovation to maintain our position as the world's leading cell therapy manufacturer and drive more rapid treatment for patients.

We will continue to explore emerging disease areas in cell therapy where we have the potential to apply our expertise to the treatment of difficult diseases. This includes multiple myeloma, where we are pleased that the Phase 2 iMMagine-1 trial of CART-ddBCMA has resumed enrollment, and we share in Arcellx's confidence in the therapeutic profile of CART-ddBCMA to be able to deliver benefit to patients.

To that end, the data unveiled in last week's abstract release for the upcoming American Society of Hematology meeting further reinforce CART-ddBCMA's robust efficacy and safety profile where, at 22 months follow-up in the ongoing Phase 1 trial, two-thirds of patients continue to respond, and median survival has not yet been reached. We look forward to additional data and even longer median follow-up next month.

In the meantime, we are further strengthening the body of clinical evidence highlighting the long-term durability and survival benefits of both Yescarta and Tecartus at the ASH meeting in December.

Finally, and before I hand over to Andy, the team's progress on key 2023 clinical milestones is shown on slide 22.

As is expected with a diverse and large clinical portfolio, not all our programs will benefit patients the way we hope they will, and the ENHANCE and ENHANCE-2 programs evaluating magrolimab have both been discontinued based on futility analyses. The ENHANCE-3 study remains under partial clinical hold in front line unfit AML, and we continue to evaluate the progress of this and other Phase 2 solid tumor trials for magrolimab.

With regards to some of the remaining milestones for 2023:

- As referenced previously, we look forward to sharing data from ARTISTRY-1 at a medical conference in 2024. For our HIV prevention studies, we continue to expect to have our first patient in for the PURPOSE-3 and PURPOSE-4 clinical trials by the end of this year.

- Additionally, we remain on-track to initiate our Phase 2 PALEKONA trial, evaluating our potentially first-in-class TPL2 inhibitor for ulcerative colitis later this year. Our TPL2 inhibitor represents one of our many oral agents for inflammation.

Looking beyond 2023, we will share our target 2024 milestones in due course, but it is already clear that it will be a rich year of data updates for Gilead, including potential updates or regulatory filings for obeldesivir, lenacapavir, Trodelvy, and CART-ddBCMA.

With that, I'll hand the call over to Andy. Andy?

Andrew Dickinson, *Chief Financial Officer*

Thank you Merdad, and good afternoon, everyone.

We had another solid quarter, as shown on slide 24, with total product sales, excluding Veklury, up 5% year-over-year driven by growth across Oncology and HIV, partially offset by lower HCV sales.

Total product sales were $7.0 billion, flat year-over-year with lower Veklury sales offsetting more than $300 million growth in our base business.

Our non-GAAP results are shown on slide 25:

- Product gross margin was 86%, down 85 basis points from last year.

- R&D was $1.5 billion, up 24% year-over-year reflecting ongoing clinical trial activities.

- Third quarter R&D expenses also reflected some sizeable wind-down costs related to the discontinuation of two Phase 3 magrolimab ENHANCE studies, and faster-than-anticipated enrollment in our Phase 3 PURPOSE-1 and OAKTREE studies, both of which have recently completed enrollment and could accelerate timelines for data readouts in due course.

- Acquired IPR&D was $91 million, reflecting the Tentarix collaboration announced in August, in addition to other payments associated with ongoing partnerships.

- SG&A was $1.3 billion, up 7% year-over-year, primarily driven by increased commercial investments, namely in Oncology.

- Moving to tax, our effective tax rate in the third quarter was 7.0%, primarily reflecting a decrease in tax reserves as a result of reaching an agreement with a tax authority on certain tax positions. Excluding this settlement, our non-GAAP effective tax rate would have been approximately 16%.

Our non-GAAP diluted earnings per share was $2.29 compared to $1.90 for the same period last year. This was primarily driven by growth in our base business, lower tax, and lower acquired IPR&D expenses compared to the third quarter of 2022, partially offset by lower Veklury sales and higher R&D and commercial investments.

Moving to slide 26, year-to-date base business revenue has grown 10% year-over-year, highlighting strong performance across Virology and Oncology. From an OpEx perspective, the investment we have made this year in R&D is notable. With a robust and diverse clinical pipeline, and with our commercial sales and marketing organization scaled to meet growing demand for our on-market oncology portfolio, we continue to expect a moderation of expense growth in 2024 and beyond.

Moving to slide 27, we are updating many of our guidance ranges to reflect our year-to-date performance and our expectations for the rest of the year.

- Total product sales is now expected to be in the range of $26.7 to $26.9 billion, up from $26.3 to $26.7 billion previously.

- We are increasing total product sales, excluding Veklury at the midpoint. We now expect the range to be between $24.8 to $25 billion, up from $24.6 to $25 billion, previously. This range represents growth of 7% to 8% for our base business year-over-year – and an increase of $650 million at the midpoint from the initial guidance we issued in February.

- On Veklury, based on our results year-to-date, we now expect full year Veklury sales of approximately $1.9 billion. As always, this remains highly variable and correlated with COVID-related hospitalizations.

Moving to the rest of the P&L:

- We continue to expect non-GAAP gross margin to be approximately 86%.

- On R&D, reflecting the accelerated enrollments and magrolimab discontinuation expenses, our full-year non-GAAP R&D expense is now expected to grow approximately 15% in 2023 compared to 2022. Excluding these items, our full-year R&D expense is consistent with our prior guidance in the low double-digits.

- Reflecting the Tentarix collaboration closed in the third quarter as well as previously committed acquired IPR&D amounts and known milestone payments from existing collaborations, we now expect non-GAAP acquired IPR&D of approximately $1 billion in 2023. Similar to prior quarters, we will update expected acquired IPR&D expenses if they are incurred during the fourth quarter.

- We continue to expect non-GAAP SG&A expenses to increase by a high single digit percentage compared to 2022. As a reminder, this includes the one-time legal settlement accrual of $525 million in the second quarter. Excluding this, we continue to expect non-GAAP SG&A expense for 2023 to be down a low single-digit percentage compared to 2022.

Non-GAAP operating income is expected to be $10.5 to $10.8 billion, as compared to $10.4 to $10.9 billion previously, driven by higher R&D expenses offset by higher product sales.

Given certain one-time tax benefits in 2023, we now expect our non-GAAP effective tax rate to approximately 16% for the full year.

Altogether, we now expect our non-GAAP diluted EPS to be between $6.65 and $6.85 per share, as compared to $6.45 and $6.80 per share previously. As shown on slide 28, the chart highlights the continued strength of our business, with higher total product sales guidance flowing into the bottom-line, which, together with the lower expected tax rate, more than offsets the higher R&D expenses in the third quarter.

On a GAAP basis, our diluted EPS is expected to be in the range of $4.55 and $4.75 per share.
Moving to slide 29, our capital allocation priorities remain focused and unchanged. In the third quarter, we returned $1.3 billion to shareholders through our dividend and repurchase of shares, totaling $3.7 billion year-to-date. In the third quarter, we repaid 2 and a quarter billion dollars of Senior Notes, and issued $2 billion in new Senior Notes, maturing in 2033 and 2053.

Overall, the third quarter was another solid quarter of commercial and clinical execution in an extremely strong 2023 for Gilead so far. Our planning for 2024 is well underway, and we have taken steps in the third quarter to continue to evolve our business model and expense structure to set us up for strong execution next year.

2023 has been a year of considerable investment, notably in R&D, and we are excited to finally be at the point where many of our key programs will start reading out data. With that in mind, we are preparing for a catalyst-rich 2024, and look forward to sharing more early next year.

With that, I'll invite the Operator to open the Q&A.