GILEAD SCIENCES THIRD QUARTER 2025
EARNINGS PREPARED REMARKS

Jacquie Ross, CFA, *SVP, Treasury and Investor Relations*

Thank you, Rebekah.

Just after market close today, we issued a press release with earnings results for the third quarter of 2025. 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, Dietmar Berger, 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.

Let me remind you that we will be making forward-looking statements. Please refer to slide 2 regarding the risks and uncertainties relating to forward-looking statements that could cause actual results to differ materially.

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

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

Thank you, Jacquie, and good afternoon, everyone. We appreciate you joining today as we take you through another very strong set of quarterly results.

Our third quarter earnings underscore the growing momentum you're seeing from Gilead today, which is driven by our strong portfolio and the impressive execution of our teams. As you'll hear during the call, our progress is visible in both our quarterly results and in our strong clinical pipeline.

Highlights of our third quarter include commercial outperformance across our HIV therapies and Livdelzi. This resulted in 6% year-over-year growth for Biktarvy, 20% year-over-year growth for Descovy, and 35% sequential growth for Livdelzi. Disciplined operating expense management contributed to 22% year-over-year growth in non-GAAP EPS. Even excluding a twenty-five cent benefit from a nonrecurring accounting item, non-GAAP EPS grew 10%, compared to 4% base business growth year-over-year, highlighting the leverage in our business model.

As a reflection of our strong performance year-to-date, we are increasing our full year HIV revenue growth expectations to approximately 5%. This is despite the $900 million headwind for our HIV business in 2025 associated with the Medicare Part D Redesign.

Our newest addition to the HIV portfolio, Yeztugo for HIV prevention, delivered third quarter sales of $39 million, or $54 million including the first few weeks of launch in June. Of course, our initial priority has been securing payer coverage, and I'm very pleased to share that we have already achieved our 75% coverage goal, nearly three months ahead of our target. This sets a strong foundation for continued growth in 2026.

Our confidence in our HIV business comes from both our existing on-market product leadership and our innovative pipeline. We look forward to sharing progress on one of our next-generation HIV treatments before the end of the year, with an update on the ARTISTRY-1 and ARTISTRY-2 studies. These Phase 3 programs are evaluating an investigational single-tablet regimen of bictegravir and lenacapavir, and we continue to target a product launch in early 2027.

As I mentioned, Livdelzi was a standout of the quarter, contributing to 12% year-over-year growth in our Liver portfolio. Livdelzi exceeded $100 million in quarterly sales for the first time and is already the number one treatment for second-line PBC in the U.S.

We're also pleased to share that we have filed for FDA approval of bulevirtide for the treatment of chronic Hepatitis Delta Virus. This therapy has been available in Europe since 2020 under the brand name of Hepcludex, and we expect to bring it to patients in the U.S. in 2026.

Turning to oncology, we continue to make significant clinical progress, most recently with the presentation of our ASCENT-03 detailed data at ESMO and simultaneous publication in the *New England Journal of Medicine.* Given the particularly aggressive nature of this disease, we are moving as quickly as we can to bring Trodelvy to first line metastatic triple negative breast cancer patients. We have submitted sBLAs with the FDA and are targeting a potential commercial launch in 2026 that could extend Trodelvy's leadership in breast cancer. We also continue to target commercial launch for anito-cel for multiple myeloma in 2026 and look forward to sharing an update from the pivotal iMMagine-1 study before the end of this year.

In summary, we are very pleased with our performance in the third quarter, building on a very strong 2025 overall and, just as importantly, we have significant potential ahead. The quality, breadth and diversity we've built into the portfolio over the past years is now presenting us with multiple opportunities to drive benefits for patients. With several just-launched or soon-to-be-launched products across HIV, oncology and liver disease, and clinical readouts on the horizon with further commercial potential, this continues to be an exciting phase of growth. The fact that we now have no major LOEs until 2036 reinforces our strong position.

My thanks as always to the Gilead team for their incredible work this quarter, and their continued dedication to doing more for the communities we serve.

With that, I'll hand it over to Johanna.

Johanna Mercier, *Chief Commercial Officer*

Thanks Dan, and good afternoon, everyone. I'm pleased to share our third quarter results, representing another strong quarter of commercial execution, with exciting momentum in our most recently launched products, Yeztugo and Livdelzi, in addition to continued, robust Biktarvy and Descovy growth.

Starting on slide 7, third quarter product sales excluding Veklury were $7.1 billion, up 4% year-over-year and up 2% sequentially, driven by strength across our HIV portfolio, offset in part by lower Oncology revenue. Including Veklury sales of $277 million, third quarter total product sales were $7.3 billion, up 4% sequentially and down 2% year-over-year, primarily reflecting lower Veklury sales associated with fewer COVID-19 related hospitalizations.

Moving to slide 8, HIV sales of $5.3 billion represented 4% growth versus prior year and prior quarter, primarily driven by higher demand and favorable inventory dynamics, partially offset by lower average realized price. Year-to-date, our HIV business has grown more than 5%, which is particularly impressive as we manage through a $900 million headwind for the full-year related to the Medicare Part D Redesign. Consistent with our performance year-to-date, we are increasing our guidance for full year HIV revenue growth to approximately 5%, up from 3% last quarter.

On slide 9, Biktarvy sales of $3.7 billion were up 6% year-over-year and 4% sequentially, due to higher demand reflecting continued market growth of 2 to 3%, and strong commercial execution. Biktarvy's year-over-year market share in the US has grown every quarter since launch, and achieved a record high of approximately 52% in the third quarter. Given Biktarvy's clear differentiation and market leadership, we are pleased that the expected loss of exclusivity in the U.S. for Biktarvy has been extended into 2036.

Moving to Descovy, third quarter sales were a record $701 million, increasing 20% year-over-year primarily due to higher demand for Descovy for PrEP. Sequentially, sales were up 7%, driven by higher demand and average realized price due to channel mix, partially offset by inventory dynamics. As a reminder, roughly three-quarters of Descovy sales are for HIV Prevention. This highlights the incredible momentum in the prevention market driven by the growing awareness and increasing unrestricted access, as well as excellent commercial execution. Descovy for PrEP achieved a new record market share of more than 45% in the US in the third quarter. This reflects the strength of our PrEP team, and the impact they are having in ensuring HIV PrEP reaches more of the people who could benefit from it. Overall, the PrEP market grew approximately 14% year-over-year.

Moving to slide 10, and one quarter in, we are really excited with the initial, positive reception to our Yeztugo launch across consumers, clinicians, and payers. Yeztugo is increasingly recognized in clinical guidelines, including most recently the U.S. CDC. This strong endorsement of Yeztugo offers healthcare providers, public health leaders, and communities clear guidance on an innovation that could help shift the trajectory of the HIV epidemic.

As we have discussed previously, expanding payer coverage is a critical indicator in our initial launch, and we are working with every payer to accelerate access. I am thrilled that we have already achieved 75% access in the U.S. – almost three months ahead of our target. This includes coverage by United Healthcare and Express Scripts, as well as 20 of the top 25 State Medicaid plans. In most cases, payers do not require prior authorizations or co-pays.

Keep in mind that much of our progress to the 75% access goal has been made in the last several weeks. We continue to work on an account-by-account basis to help clinicians navigate the new logistics and reimbursement process, and the benefits of this access will pull through in 2026. Looking forward, we are moving quickly to expand access beyond 75%, and continue to target 90% by the end of the first half of 2026.

Altogether Yeztugo is off to a strong start, delivering $39 million in sales in the third quarter. From launch in the middle of June to the end of the third quarter, Yeztugo revenue was $54 million, including $15 million of new launch-related stocking at the end of the second quarter. As we expected, most early prescribers are existing HIV PrEP clinicians who are leveraging white-bagging to simplify the logistic and reimbursement arrangements.

In August, the European Commission approved lenacapavir for PrEP, under the name Yeytuo. We look forward to further regulatory decisions across other geographies. Additionally, as part of our broader commitment to access, Gilead has agreed with the Global Fund and the U.S. State Department, through PEPFAR, to supply enough doses of lenacapavir for PrEP to reach up to 2 million people over three years in certain low- and lower-middle-income countries.

Moving to Liver Disease on slide 11, sales of $819 million were up 12% year-over-year and 3% sequentially, driven almost entirely by Livdelzi for primary biliary cholangitis. Livdelzi grew 35% sequentially driven by strong commercial execution – including some new launches outside the U.S. – and withdrawal of a competitor's product in the U.S. We are particularly pleased to see strong levels of persistence among users and believe Livdelzi shows clear differentiation and value to those with PBC. Livdelzi is now the market leader in second-line PBC in the U.S., and quarterly revenue topped $100 million for the first time.

Moving to slide 12, Trodelvy sales of $357 million were up 7% year-over-year, primarily due to higher demand, and down 2% sequentially with higher demand offset by unfavorable inventory dynamics and lower ex-U.S. average realized price. Trodelvy's continued strength in the U.S. and international markets across metastatic breast cancer more than offset – on a year-over-year basis – the expected impact from the bladder cancer withdrawal in the U.S. With Trodelvy's potential launch in first-line metastatic TNBC following the potentially practice-changing ASCENT-03 and ASCENT-04 readouts this year, we look forward to expanding the options available for patients in this earlier line setting. There are almost twice as many patients in the first-line metastatic setting compared to second-line, and patients typically have a longer duration of therapy.

For Cell Therapy on slide 13, and on behalf of Cindy and the Kite team, third quarter sales of $432 million were down 11% both year-over-year and sequentially with continued competitive headwinds from in-and out-of-class therapies. We anticipate these headwinds to continue in the near future.

We remain committed to increasing the adoption and utilization of cell therapies given their curative potential for many patients. Year-to-date, we have added more than 40 authorized treatment centers, and now have more than 570 globally. As shared in prior quarters, our efforts to lower the hurdles to community adoption are progressing, but it is clear that we have more to do before all eligible patients have the opportunity to benefit from these cell therapies. In addition to the team's work to expand the reach of cell therapies, Kite is also progressing its next-generation pipeline to offer similar efficacy with better safety, which would result in enhanced outpatient usage potential.

Additionally, we are very excited by the development of anito-cel, which continues to show potential best-in-class safety and efficacy as a BCMA CAR T therapy for late-line relapsed, refractory multiple myeloma. We look forward to providing an update from the iMMagine-1 study later this year.

Wrapping up our third quarter, I'd like to thank the commercial teams who are executing relentlessly across both our in-line portfolio as well as our newer opportunities like Yeztugo and Livdelzi. Looking to 2026, we are preparing for a number of additional potential launches across our therapeutic areas of focus, and are excited by the opportunity to extend our reach and impact on the patients and communities we serve.

And so with that, I'll hand the call over to Dietmar.

Dietmar Berger, MD, PhD, *Chief Medical Officer*

Thank you, Johanna, and good afternoon everyone.

In the third quarter, the team progressed 56 clinical programs across our three therapeutic focus areas with 4 additions since last quarter, as we advance our research with the most meaningful potential scientific and patient impact into the clinic.

Building on Johanna's comments on our Yeztugo launch, we continue to lead HIV innovation with ten clinical programs across treatment and prevention. Lenacapavir and its prodrugs are foundational in our treatment and prevention programs, and in July we initiated the registrational Phase 3 PURPOSE-365 trial evaluating lenacapavir as HIV prevention with once-yearly injections. This is a single arm PK and safety study, which along with the unprecedented efficacy seen in the Phase 3 PURPOSE-1 and 2 studies, is expected to support a regulatory filing, with potential for approval in 2028.

Moving to treatment, we have seven ongoing clinical programs evaluating daily, weekly, monthly, quarterly and twice-yearly regimens, based on lenacapavir or one of its prodrugs.

- Beginning with our next generation daily oral regimen, BIC/LEN, we continue to expect an update from our Phase 3 ARTISTRY studies later this year. ARTISTRY-1 and ARTISTRY-2 are evaluating the potential of Gilead's investigational complete regimen that combines bictegravir, the key integrase inhibitor in Biktarvy, and lenacapavir, our breakthrough capsid inhibitor. The regimen is a potential option for virologically suppressed people with HIV, including many people currently on complex regimens.

- Further, we have a suite of long-acting oral and injectable agents in development for a range of dosing frequencies, from once-weekly oral to twice-yearly injectables. Our strategy has been to set up our pipeline for multiple shots on goal and then choose the best option for each dosing frequency. Notably, for our development of a twice-yearly treatment regimen combining a novel integrase inhibitor with lenacapavir, we took two INSTI agents to Phase 1: GS-1219 and GS-3242. Aligned with the guidance we shared at our HIV analyst event last year, we have now chosen to prioritize the development of GS-3242 over GS-1219, and we expect to share more details on GS-3242 at a Virology conference in 2026.

On slide 16, I'm pleased to highlight that we have completed the BLA filing for bulevirtide in chronic hepatitis delta virus, or HDV. We are excited by the potential to bring bulevirtide to HDV patients in the

U.S, with a potential regulatory decision in 2026. As a reminder, HDV affects approximately 2% of patients with HBV, or about 40,000 people in the U.S. Patients with chronic untreated HDV infection can experience accelerated development of cirrhosis, or severe scarring of the liver, and have higher risk of liver cancer and potentially end-stage liver disease and failure.

Beyond bulevirtide, we are also evaluating next-generation approaches to HDV treatment. Specifically, we have advanced GS-4321, a pre-S1 neutralizing antibody, into Phase 1 clinical development. We believe GS-4321 has significant potential given its pre-clinical safety profile and long half-life, with potentially quarterly subcutaneous dosing.

Moving to Trodelvy on slide 17, earlier this month, at the ESMO meeting, we presented detailed, potentially practice-changing Phase 3 ASCENT-03 data in first-line metastatic triple-negative breast cancer patients who are not candidates for PD-(L)1 inhibitors. Specifically, Trodelvy demonstrated a 9.7 month median progression-free survival compared to 6.9 months for standard-of-care chemotherapy. This reflects a statistically significant and clinically meaningful 38% reduction in disease progression or death versus standard-of-care chemotherapy. As we expected when we initiated the study, the median overall survival data are not yet mature. These results were simultaneously published in the *New England Journal of Medicine*.

Additionally, the detailed results from ASCENT-04, were shared at the ASCO meeting in May. These data, combined with ASCENT-03 highlight the potential for Trodelvy to be a backbone treatment across first-line metastatic TNBC.

Based on these positive Phase 3 updates from ASCENT-03 and -04, we have submitted two supplemental biologics license applications for Trodelvy in first-line metastatic TNBC, and expect regulatory decisions in 2026. This is incredibly important for patients as metastatic TNBC is the most aggressive subtype of breast cancer, with limited treatment options and poor prognosis. Historically, progress in first-line therapy has been minimal, and nearly half of patients do not progress beyond first-line treatment, meaning they may never access Trodelvy if it remains a later-line option.

Similarly, we are currently exploring Trodelvy for first-line post-endocrine Hormone Receptor Positive/HER2- metastatic breast cancer patients in the Phase 3 ASCENT-07 trial. We now expect to provide an update from this trial before the end of the year.

On slide 18, we are highlighting overall survival results shared at ESMO earlier this month from Arm A1 of the Phase 2 EDGE-Gastric study evaluating domvanalimab, our Fc-silent anti-TIGIT, plus zimberelimab and chemotherapy in patients with locally advanced unresectable or metastatic upper gastrointestinal cancers. In the 41 patients who received the novel regimen in this analysis, the median overall survival was 26.7 months. These findings were simultaneously published in *Nature Medicine.*

These data are in a small number of patients. Survival results for this patient population still need to be confirmed in our ongoing Phase 3 STAR-221 trial evaluating domvanalimab plus zimberelimab and chemotherapy in patients with metastatic upper gastrointestinal cancers. We continue to expect an update from the event-driven STAR-221 trial in 2026.

We also continue to develop domvanalimab plus zimberelimab and chemotherapy in first-line metastatic non-small cell lung cancer in the Phase 3 STAR-121 trial.

Moving to Cell Therapy on slide 19, and on behalf of Cindy and the Kite team, you can see that we have strengthened our *in vivo* capabilities.

The *in vivo* cell therapies are potentially off-the-shelf products that could shorten the time it takes to treat patients, and are also expected to have more simplified and cost-effective manufacturing processes. Given these potential advantages over autologous CAR T, we believe *in vivo* could unlock broad access to cell therapies. With that in mind, we have welcomed the Interius team into the Kite family, adding a novel in vivo platform and a strong IP portfolio. We have also entered into a new research and licensing collaboration with Pregene Biopharma. It's early days for *in vivo*, but we're excited to accelerate our exploration of the opportunities these technologies could bring to patients.

As we step up our investment in *in vivo* therapies, we remain committed to our current Yescarta and Tecartus portfolios. For example, FDA recently granted priority review for Yescarta in primary CNS lymphoma, with a PDUFA date in February 2026. Primary CNS lymphoma is a rare, yet aggressive subtype of Non-Hodgkins Lymphoma that affects the central nervous system. Additionally, CD19-CAR T products including Yescarta have recently received a Category 2A recommendation from the NCCN for Richter's Transformation. We are pleased with these review and guideline decisions, which will provide HCPs with additional opportunities to prescribe Yescarta.

For our next-generation CAR Ts, we look forward to sharing Phase 1 data from KITE-753 and KITE-363 in lymphoma at an upcoming medical congress later this year, as well as pivotal Phase 2 initiation of KITE-753 for third line Large B-cell Lymphoma in the first quarter of 2026. In autoimmune diseases, KITE-363 is enrolling patients for its Phase 1 trial in rheumatology, and a Phase 1 study in neuroinflammatory conditions is expected to start in the first quarter of 2026. We look forward to providing updates from these earlier-stage programs.

Together with our partner Arcellx, we plan to share additional follow-up data from the pivotal iMMagine-1 trial of anito-cel at an upcoming medical meeting. We continue to believe anito-cel has the potential to offer a best-in-class efficacy and safety profile for patients with relapsed and/or refractory multiple myeloma. The target commercial launch in fourth line plus relapsed and/or refractory multiple myeloma remains in 2026.

On slide 20, I will quickly highlight the key milestones updates. First, we have received European Commission marketing authorization of Yeytuo and remain on-track to provide updates for our Phase 3 ARTISTRY-1 and ARTISTRY-2 trials for BIC/LEN and for our pivotal Phase 2 iMMagine-1 trial for anito-cel in the fourth quarter. Finally, we now also expect ASCENT-07 data in the fourth quarter.

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

Andrew Dickinson, *Chief Financial Officer*

Thank you, Dietmar, and good afternoon, everyone.

Starting on slide 22, our third quarter results show continued strong execution across the company. Our base business was up 4% year-over-year to $7.1 billion, driven by growth in Biktarvy, Descovy, and Livdelzi. Veklury sales were down 60% year-over-year to $277 million, which continued to reflect fewer COVID-related hospitalizations. Including Veklury sales, total product sales were $7.3 billion.

Moving to slide 23, you can see we benefited from a $400 million contribution in "Royalty, Contract & Other Revenues" in the third quarter. This relates to an IP asset sale from 2018. Given we are now able to reasonably estimate future royalty and milestone payments, we are required to recognize this revenue in the third quarter. This is a nonrecurring accounting item and does not reflect cash received during the quarter.

As a reminder, this contribution was not part of our product sales and therefore did NOT impact our product gross margin in the third quarter, but it does otherwise flow through to the bottom line, contributing approximately $0.25 after tax.

Moving to our non-GAAP results on slide 24:

- Third quarter product gross margin was 86%, in line with 87% in the third quarter of 2024.
- R&D expenses of $1.3 billion were down 3% compared to the third quarter of 2024. Year-to-date 2025 R&D expenses were $4.1 billion, in line with 2024, suggesting we are on track for our full-year goal.
- Acquired IPR&D expenses were $170 million in the third quarter, including a $120 million upfront payment to Pregene for a research and licensing collaboration in the *in vivo* cell therapy space.
- SG&A expenses of $1.4 billion were down 4% compared to the third quarter of 2024, modestly lower than we expected due to the timing of spending.
- Third quarter operating margin was 50%, reflecting the continued focus on operating expense discipline and leverage.
- The non-GAAP effective tax rate was 18% this quarter, slightly below our expectations due to a $79 million tax settlement.
- And finally, non-GAAP diluted EPS was $2.47 for the quarter. Excluding the $400 million nonrecurring other revenue, non-GAAP diluted EPS would have been $2.22 for the third quarter.

Moving to our full-year guidance on slide 25, we are raising the low end of our product sales range by $100 million to reflect our strong performance year-to-date. As a reminder, the $400 million included in our Royalty, Contracts and Other Revenue in the third quarter, does NOT impact our full year guidance, as we do not guide to Total Revenue.

We now expect Total Product sales, excluding Veklury, to be between $27.4 billion and $27.7 billion, primarily reflecting higher HIV growth. Driven by the outperformance of both Biktarvy and Descovy year-to-date, we now anticipate our HIV franchise will grow approximately 5% year-over-year versus our prior guidance of 3%.

Consistent with last quarter, I'll note that our assumptions for the impact of the Medicare Part D redesign remain unchanged from the beginning of the year, and we continue to expect approximately $900 million of impact to our HIV business in 2025. Our 2025 assumptions for Yeztugo also remain unchanged and we remain very encouraged by the launch so far, particularly the accelerated timeline for payer coverage.

In other parts of our business, strength in HIV is expected to be partially offset by weaker Cell Therapy estimates, where we now forecast approximately a 10% decline for full-year 2025 versus full-year 2024.

For Veklury, we continue to expect full-year revenue of approximately $1 billion. As a result, total product sales are anticipated to be in the range of $28.4 to $28.7 billion. As noted earlier, this reflects a $100 million increase at the low end of the range from our previous guidance.

Finally, we continue to expect the impact of known tariffs to be manageable in 2025.

Moving to the rest of the P&L, there is no change to our prior non-GAAP guidance for product gross margin, R&D and SG&A expenses. We continue to expect:

- Product gross margin of approximately 86%;
- R&D expenses to be roughly flat on a dollar basis from 2024;
- And, SG&A expenses to decline by a mid-to high-single digit percentage compared to 2024.
- Similar to last year, we expect a step up in both R&D and SG&A expenses in the fourth quarter reflecting normal end-of-year trends.

We have updated our IPR&D expectations for the full year to reflect our actuals through the third quarter and our known fourth quarter commitments – including $300 million relating to the Interius acquisition. We now expect full year acquired IPR&D to be $900 million.

Rounding out the P&L:

- We expect operating income to be between $13.1 billion and $13.4 billion; reflecting an increase of $100 million at the low end of the prior guidance range;
- We continue to expect our effective tax rate to be approximately 19%; and
- Finally, we expect non-GAAP EPS in the range of $8.05 and $8.25, raising non-GAAP EPS by $0.10 at the low end of the range. GAAP EPS is expected in the range of $6.65 to $6.85.

On slide 26, our capital priorities remain unchanged, and we returned $1.4 billion to shareholders in the third quarter, which included $435 million of share repurchases. These repurchases are intended to offset equity dilution at a minimum, but can also be used opportunistically, as you have seen in the first three quarters of 2025.

Overall, we are pleased with the strong performance this quarter, highlighted by our clinical and commercial execution and supported by our disciplined operating model. We continue to be well-positioned for near-term and long-term growth, and we remain focused on delivering on our strategic commitments.

With that, I'll invite Rebekah to begin the Q&A.