## Q323 Financial Results

November 7, 2023

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## Contents



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## Q323 Key Takeaways

## Gilead Q323 Key Takeaways

## Financial Results

- Q323 Total Product Sales excl. Veklury $+5 \%$ Yo to $\$ 6.36 \mathrm{~B}$
- Total HIV +4\% Yo due to higher demand \& inventory, offset by price; Biktarvy +12\% Yo to \$3.09B
- Oncology +33\% Yo to \$769M driven by ongoing demand across Trodelvy and Cell Therapy
- YTD Total Product Sales excl. Veklury $+10 \%$ YoY; Oncology $+42 \%$ and Virology $+7 \%$
- Phase 1 GS-1720 \& Phase 2 ARTISTRY-1 BIC/LEN data promising; presentation at a 2024 conference
- Phase 3 PURPOSE-1 trial of lenacapavir for HIV prevention completed enrollment
- Phase 3 OAKTREE trial of obeldesivir in standard-risk COVID-19 patients completed enrollment
- FDA \& EC approval to extend use of Veklury to treat COVID-19 in patients with hepatic impairment


## Oncology Updates

- Trodelvy received EC approval for pre-treated HR+/HER2- mBC
- EVOKE-02 supports PoC for Trodelvy plus pembrolizumab in 1L PD-L1 High mNSCLC at WCLC 2023
- Encouraging Trodelvy data from TROPiCS-03 SCLC and HNSCC cohorts presented at ESMO 2023
- EDGE-Gastric data reinforces potential of dom + zim + chemo for 1 L upper GI cancers at ASCO Plenary


## 2023 Focus: Select Key Catalysts Across Portfolio



2H23


 MNSCLC - metastatic non-small cell lung cancer, OPT - outpatient, PrEP - preexposure prophylaxis, sBLA - supplemental biologic license application, TE - treatment experienced, TNBC - triple-negative breast cancer, VS - virally suppressed.

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## Commercial Results \& Market Dynamics

## Solid Q323 Base Business Performance



[^0]
## HIV: Solid Growth Across PrEP \& Treatment

Product Sales (\$M)


## Q323 Growth of 4\% YoY \& 1\% QoQ

- YoY primarily driven by higher demand and channel inventory, partially offset by lower average realized price due to channel mix
- QoQ due to higher channel inventory and demand, partially offset by channel mix


## Market Dynamics

- U.S. \& Europe Tx markets continue to grow 2-3\% annually
- U.S. PrEP market up $15 \%$ YoY


## Leading Market Shares Across Treatment \& PrEP



Q323 sales: $\$ 3.1 \mathrm{~B} ;+12 \% \mathrm{YoY},+4 \%$ QoQ
>47\%
U.S. Treatment

Market Share
$>2 \%$
U.S. Market Share Gain YoY

YoY due to higher demand as well as higher channel inventory

QoQ due to higher channel inventory and higher demand, partially offset by pricing dynamics related to shifts in channel mix

Q323 sales: $\$ 511 \mathrm{M} ;+2 \%$ YoY, -1\% QoQ

U.S. PrEP

Market Share
+15\%
U.S. PrEP Market Growth YoY

YoY due to higher demand and channel inventory, partially offset by pricing dynamics

QoQ due to pricing dynamics, partially offset by higher channel inventory.

## Liver Disease: Steady Growth in HCV New Starts

Product Sales (\$M)


QEPCLUSA
sofosbuvir/velpatasvir
$400 \mathrm{mg} / 100 \mathrm{mg}$ tablets
HARVONI
ledipasvir/sofosbuvir
$90 \mathrm{mg} / 400 \mathrm{mg}$ tablets

## Q323 sales -10\% YoY; -1\% LoQ

- YoY primarily due to a favorable resolution of a rebate claim in Europe in Q322 as well as other pricing dynamics, partially offset by higher HCV patient starts
- QoQ primarily due to lower demand, partially offset by favorable pricing dynamics


## Veklury: Established Role in COVID-19 Treatment

Product Sales (\$M)

Veklury ${ }^{\circ}$
remdesivir wesue
>50\%
U.S. hospitalized patients treated for COVID ${ }^{1}$

- Received U.S. FDA and EC approval to extend indication for treatment of COVID-19 patients with hepatic impairment


## Accelerating Oncology Business


\$769M
Sales in Q323
+33\%
Q323 YoY Growth

- Annual run-rate exceeds \$3B
- Oncology portfolio on-track to meet goal of contributing ~1/3 Gilead product revenue by 2030


## Trodelvy: Continued Strength in Breast Cancer

Product Sales (\$M)



- YoY and QoQ primarily driven by increased uptake in pre-treated HR+/HER2- mBC
- Strong awareness across mTNBC and pre-treated HR+/HER2- mBC


## Cell Therapy: Expanding Demand Globally


(axicabtagene ciloleucel) ${ }^{\text {sumpunimen}}$

## Q323 sales +23\% YoY; +3\% QoQ

- YoY growth driven by strong underlying demand in R/R large B-cell lymphoma outside of the U.S.


## TECARTUS

(brexucabtagene autoleucel) $)_{\text {town }}^{\substack{\text { supsinion }}}$

Q323 sales +18\% YoY; +8\% QoQ

- YoY growth driven by increased demand for R/R mantle cell lymphoma and adult acute lymphoblastic leukemia

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## Pipeline Updates

## Industry Leading HIV Clinical Development Portfolio



Pre-IND
Phase 1
Phase 2
Phase 3

## Lenacapavir

| Pre-IND | Phase 1 | Phase 2 |
| :---: | :---: | :---: |
| Lenacapavir + GS-1219 (INSTI) | Lenacapavir + GS-6212 (INSTI) | Lenacapavir + Islatravir (NRTI) |
| * q6m injection | * Q3m injection | - WEEKLY ORAL |
| Treatment | Treatment | Treatment |
| Lenacapavir + GS-3242 (INSTI) | $\begin{gathered} \text { GS-4182 } \\ \text { (Len pro-drug) } \end{gathered}$ | Lenacapavir + TAB/ZAB (bNAbs) |
| * q6M injection | - WEEKLY ORAL | * Q6m Injection |
| Treatment | Treatment | Treatment |
| Lenacapavir + GS-1614 (NRTI) | Lenacapavir + <br> GS-1720 (INSTI) <br> O WEEKLY ORAL | Bictegravir + <br> Lenacapavir <br> 1 |
| * Q3M InJection | Treatment | Treatment |
| Treatment | Data in 1H24 | 24 W data in 1H24 |


| Pre-IND | Phase 1 | Phase 2 |
| :---: | :---: | :---: |
| Lenacapavir + GS-1219 (INSTI) | Lenacapavir + GS-6212 (INSTI) | Lenacapavir + Islatravir (NRTI) |
| * q6m injection | * Q3m injection | - Weekly oral |
| Treatment | Treatment | Treatment |
| Lenacapavir + GS-3242 (INSTI) | $\begin{gathered} \text { GS-4182 } \\ \text { (Len pro-drug) } \end{gathered}$ | Lenacapavir + TAB/ZAB (bNAbs) |
| * q6M injection | (- WEEKLY ORAL | * q6m injection |
| Treatment | Treatment | Treatment |
| Lenacapavir + GS-1614 (NRTI) | Lenacapavir + GS-1720 (INSTI) - WEEKLY ORAL | ( $\begin{aligned} & \text { Bictegravir + } \\ & \text { Lenacapavir }{ }^{1} \\ & \text { - DAILY ORAL }\end{aligned}$ |
| * Q3m injection | Treatment | Treatment |
| Treatment | Data in 1H24 | 24 W data in 1H24 |


| Lenacapavir + <br> Islatravir (NRTI) | Lenacapavir $^{2}$ |
| :---: | :---: |
| - WEEKLY ORAL | Q6M INJECTION |
| Treatment | Prevention |



10
Clinical programs with lenacapavir

Phase 3 studies in prevention

## Candidate partners

 for lenacapavir
## Trodelvy is First and Only Approved TROP2 ADC

## >30 Active or Planned Clinical Trials by YE2023

## Solid Foundation in Multiple Tumor Types

## Pan-Tumor Opportunities

$>20 \mathrm{~K}$ fated $\sim 50$ camp as

- Clinically meaningful mOS benefit in ASCENT and TROPiCS-02 studies
- NCCN Category 1 recommended for both 2L mTNBC and pretreated HR+/HER2- mBC
- Well-characterized safety profile with no causal relationship seen to date with ILD/pneumonitis

Encouraging Early Results Across:

```
Head and Neck
    Cancer
    TROPiCS-03
```

```
Non-Small Cell
    Lung Cancer
        EVOKE-02
```

```
Small Cell
Lung Cancer
    TROPiCS-03
```


## Endometrial Cancer TROPiCS-03

## Promising Responses Seen in 1L mNSCLC

## Established Proof-of-Concept in 1L PD-L1 High mNSCLC

- Phase 2 EVOKE-02 demonstrated antitumor activity of Trodelvy plus pembrolizumab across PD-L1 subgroups
- Strong 69\% ORR compared to historical anti-PD-1 monotherapy, in PD-L1 TPS $\geq 50 \%$
- Preliminary 44\% ORR in PD-L1 TPS<50\% patients, similar to historical anti-PD-1 + chemo
- Safety profile observed consistent with the known safety profile of each agent


Cohort A (PD-L1 TPS $\geq 50 \%$ )

## EDGE-Gastric Provides PoC for Phase 3 STAR-221

Dom + zim + FOLFOX shows encouraging ORR \& 6-month PFS in 1L metastatic upper Gl cancers

|  | Overall <br> $n=41$ | PD-L1 High <br> $(T A P \geq 5 \%)$ <br> $n=15$ | PD-L1 Low <br> $(T A P<5 \%)$ <br> $n=24$ |
| :---: | :---: | :---: | :---: |
| ORR $^{1}$ | $59 \%$ | $80 \%$ | $46 \%$ |
| Complete response $^{1}$ | $7 \%$ | $7 \%$ | $4 \%$ |
| Partial response |  |  |  |
| 6-Month PFS Rate | $51 \%$ | $73 \%$ | $42 \%$ |
|  | $77 \%$ | $93 \%$ | $68 \%$ |



Phase 3 STAR-221 trial comparing dom + zim + chemotherapy versus nivolumab + chemotherapy is currently enrolling in 1L metastatic upper Gl cancers

## Cell Therapy: Driving Future Growth

Clinicaltrials
4. Line

New indications


## Next-Generation Programs

- Autologous and allogeneic
- Across HD, iPSC, iNKT and NK constructs
- Manufacturing innovations

Supported by business development


Other programs include 3L+ DLBCL

## 2023 Focus: Select Key Catalysts Across Portfolio



2H23


 mNSCLC - metastatic non-small cell lung cancer, OPT - outpatient, PrEP - pre-exposure prophylaxis, sBLA - supplemental biologics license application, TE - treatment experienced, TNBC - triple-negative breast cancer, VS - virally suppressed.

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## Financial Results

## Solid Base Business Growth

Product Sales (\$M)


# Product Sales excluding Veklury +5\% YoY 

- Strong growth across HIV, Trodelvy and Cell Therapy


## Total Product Sales flat YoY

- Strong performance across base business, offset by a decrease in Veklury sales due to lower hospitalizations


## Q323 Non-GAAP Data

|  | Q322 | Q323 | YoY <br> Change |
| :---: | :---: | :---: | :---: |
| In millions, except percentages and per share amounts |  | 923 | 985 |
| COGS | $87 \%$ | $86 \%$ | -85 bps |
| Product Gross Margin | 1,173 | 1,453 | $24 \%$ |
| R\&D | 448 | 91 | $-80 \%$ |
| Acquired IPR\&D | 1,212 | 1,298 | $7 \%$ |
| SG\&A | $\mathbf{\$ 3 , 7 5 6}$ | $\mathbf{\$ 3 , 8 2 6}$ | $\mathbf{2 \%}$ |
| Non-GAAP Costs and Expenses | $\mathbf{\$ 3 , 2 8 6}$ | $\mathbf{\$ 3 , 2 2 4}$ | $\mathbf{- 2 \%}$ |
| Non-GAAP Operating Income | $47 \%$ | $46 \%$ | -92 bps |
| Operating Margin | $22 \%$ | $7 \%$ | -1540 bps |
| Effective Tax Rate | $\mathbf{\$ 2 , 3 9 1}$ | $\mathbf{\$ 2 , 8 7 9}$ | $\mathbf{2 0 \%}$ |
| Non-GAAP Net Income | $\$ 1.90$ | $\$ 2.29$ | $21 \%$ |
| Non-GAAP Diluted EPS | $\mathbf{1 , 2 6 1}$ | $\mathbf{1 , 2 5 7}$ |  |
| Shares used in per share calculation-diluted |  |  |  |

## Product Sales excl. Veklury up 5\% YoY

- Growth in Oncology and HIV, offset by lower HCV sales


## Higher Operating Expenses

- Higher R\&D primarily driven by ongoing clinical activities, magrolimab wind-down costs, and faster-than-anticipated enrollment in PURPOSE-1 and OAKTREE trials
- Acquired IPR\&D primarily reflects Tentarix collaboration and other collaboration-related payments
- Higher SG\&A primarily driven by increased commercial investments, namely in Oncology


## Lower Effective Tax Rate

- Lower tax expense due to decreased tax reserves as a result of reaching an agreement with a tax authority on certain tax positions


## Strong Non-GAAP Results Year-to-Date

| In millions, except percentages and per share amounts | $\mathbf{2 0 2 2}$ YTD | $\mathbf{2 0 2 3}$ YTD | YoY <br> Change |
| :--- | :---: | :---: | :---: |
| COGS | 2,634 | 2,717 | $3 \%$ |
| Product Gross Margin | $87 \%$ | $86 \%$ | -27 bps |
| R\&D | 3,425 | 4,268 | $25 \%$ |
| Acquired IPR\&D | 786 | 808 | $3 \%$ |
| SG\&A | 3,566 | 4,464 | $25 \%$ |
| Non-GAAP Costs and Expenses | $\mathbf{\$ 1 0 , 4 1 1}$ | $\mathbf{\$ 1 2 , 2 5 7}$ | $\mathbf{1 8 \%}$ |
| Non-GAAP Operating Income | $\mathbf{\$ 9 , 4 8 0}$ | $\mathbf{\$ 7 , 7 4 5}$ | $-\mathbf{- 1 8 \%}$ |
| Operating Margin | $48 \%$ | $39 \%$ | -894 bps |
| Effective Tax Rate | $\mathbf{2 0 \%}$ | $15 \%$ | -555 bps |
| Non-GAAP Net Income | $\mathbf{\$ 7 , 0 5 2}$ | $\mathbf{\$ 6 , 2 9 3}$ | $\mathbf{- 1 1 \%}$ |
| Non-GAAP Diluted EPS | $\$ 5.59$ | $\$ 5.00$ | $-11 \%$ |
| Shares used in per share calculation-diluted | $\mathbf{1 , 2 6 1}$ | $\mathbf{1 , 2 5 9}$ |  |

Product Sales excl. Veklury up 10\% YoY

- Growth in HIV, Cell Therapy and Trodelvy
- HIV up 9\% YoY and Oncology up 42\% YoY


## FX a Minor Headwind

- Net of hedges, FX negatively impacted Total Product Sales by ~\$191M YoY, or ~1\%


## Higher R\&D and SG\&A YoY

- R\&D primarily reflects ramp-up of clinical activities, including new study starts
- SG\&A primarily reflects legal settlement accrual in Q223 and increased commercial activities


## 2023 Guidance Update

|  | 2 Feb 2023 | 27 Apr 2023 | 3 Aug 2023 | 7 Nov 2023 |
| :---: | :---: | :---: | :---: | :---: |
| Total Product Sales | \$26.0B - \$26.5B | No change | \$26.3B-\$26.7B | \$26.7B - \$26.9B |
| Product Sales exVeklury | \$24.0B - \$24.5B | No change | \$24.6B-\$25.0B | \$24.8B - \$25.0B |
| Veklury Sales | ~\$2.0B | No change | - \$1.7B | -\$1.9B |
| Non-GAAP |  |  |  |  |
| Product Gross Margin | 86\% | No change | No change | No change |
| R\&D Expense | High singledigit \% growth | Low doubledigit \% growth | No change | ~15\% |
| Acquired IPR\&D | \$0.7B | No change | \$0.9B | \$1.0B |
| SG\&A Expense | Low single-digit \% decline | No change | High singledigit \% growth | No change |
| Operating Income | \$11.0B - \$11.6B | No change | \$10.4B - \$10.9B | \$10.5B - \$10.8B |
| Effective Tax Rate | ~20\% | No change | ~17\% | ~16\% |
| Diluted EPS | \$6.60-\$7.00 | No change | \$6.45-\$6.80 | \$6.65-\$6.85 |
| GAAP Diluted EPS | \$5.30-\$5.70 | \$4.75-\$5.15 | \$4.50-\$4.85 | \$4.55-\$4.75 |

## Base Business \& Total Product Sales Guidance Raised

- Base business growth of $7 \%$ to $8 \%$ YoY, from 6.5\% to 8\% previously
- Veklury guidance increased by ~\$200M, reflecting Q323 hospitalizations


## Non-GAAP R\&D Guidance Revised

- Increased to $\sim 15 \%$ YoY due to magrolimab-related wind-down costs and accelerated study enrollments for PURPOSE-1 and OAKTREE
- Excluding these, guidance unchanged from low double-digit \% growth YoY


## Non-GAAP Effective Tax Rate Lowered

- Reflects certain one-time tax benefits in 2023


## FY23 Non-GAAP EPS Guidance Bridge



## Capital Priorities Unchanged: Returned ~\$1.3B in Q3

## \$953M

Dividends Paid in Q323

## \$300M

Shares Repurchased in Q323 ${ }^{1}$
$\sim 4 \mathrm{M}$ shares at average $\$ 77.08$Continue to invest in our business and R\&D pipeline while managing expenses
$\Theta$ Continue ordinary course partnerships and business development transactions
$\Theta$ Grow our dividend
$\Theta$ Repurchase shares to offset dilution and opportunistically reduce share count

## Q\&A



Daniel O'Day
Chairman and Chief Executive Officer


Andrew Dickinson
Chief Financial Officer


Johanna Mercier Chief Commercial Officer


Merdad Parsey, MD, PhD
Chief Medical Officer


Cindy Perettie
Executive Vice President, Kite
(®) GILEAD
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## Appendix

## Robust Pipeline with Upcoming Catalysts

60 Clinical stage programs ${ }^{1}$
(8) Potential clinical stage opt-in assets


## Oncology Cell Therapy Pipeline



## Oncology Pipeline 1/2

Breakthrough Therapy Designation





## Oncology Pipeline 2/2



## Viral Diseases Pipeline



## Inflammatory Diseases Pipeline

|  | Clinical Program | Indication | Phase 1 | Phase 2 | Phase 3 | Filed | Updates since Q2＇23 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Edecesertib（COSMIC） | Lupus |  |  |  |  |  |
|  | Tilpisertib fosmecarbil | Inflammatory Bowel Disease |  |  |  |  |  |
|  | a4B7 inhibitor（GS－1427） | Inflammatory Bowel Disease |  |  |  |  |  |
|  | BTLA agonist（GS－0272） | Inflammatory Diseases |  |  |  |  |  |
| 京䁬 | Cilofexor／firsocostat／semaglutide combination ${ }^{1}$ | NASH |  |  |  |  |  |
| 京．$=$ | Galapagos | Inflammatory Diseases | 1 clinical st | programs |  |  |  |

## GAAP to Non-GAAP Reconciliation of Outstanding Adjusted Debt and Adjusted EBITDA

| in billions where applicable | Sep 30, 2022 | Dec 31, 2022 | Mar 31, 2023 | Jun 30, 2023 | Sep 30, 2023 |
| :---: | :---: | :---: | :---: | :---: | :---: |
| Total Debt, net | \$25.22 | \$25.23 | \$25.24 | \$25.25 | \$24.98 |
| Debt Discounts, Premiums and Issuance Costs | 0.17 | 0.16 | 0.16 | 0.15 | \$0.17 |
| Liability related to sale of future royalties ${ }^{1}$ | (1.14) | (1.14) | (1.15) | (1.15) | (\$1.15) |
| Total Adjusted Debt ${ }^{1,2}$ | \$24.25 | \$24.25 | \$24.25 | \$24.25 | \$24.00 |

Last Twelve Months Ended

|  | Sep 30, 2022 | Dec 31, 2022 | Mar 31, 2023 | Jun 30, 2023 | Sep 30, 2023 |
| :---: | :---: | :---: | :---: | :---: | :---: |
| Net Income attributable to Gilead | \$3.33 | \$4.59 | \$5.58 | \$5.48 | \$5.88 |
| Add: Interest Expense ${ }^{3}$ \& Other Income (expense), net | 1.46 | 1.52 | 1.58 | 1.12 | 1.02 |
| Add: Tax | 1.23 | 1.25 | 1.73 | 1.91 | 1.41 |
| Add: Depreciation | 0.32 | 0.32 | 0.34 | 0.34 | 0.35 |
| Add: Amortization ${ }^{4}$ | 2.16 | 2.08 | 2.05 | 2.08 | 2.19 |
| Add: Acquired in-process research and development expenses ${ }^{5}$ | 0.71 | 0.84 | 1.30 | 1.21 | 0.88 |
| Add: In-process research and development impairment | 2.70 | 2.70 | 0.00 | 0.00 | 0.00 |
| Add: Litigation matters ${ }^{6}$ | 1.25 | 0.00 | 0.00 | 0.53 | 0.53 |
| Adjusted EBITDA ${ }^{7,8}$ | \$13.17 | \$13.30 | \$12.58 | \$12.67 | \$12.24 |
| Adjusted Debt to Adjusted EBITDA ratio ${ }^{\text {7, } 8}$ | ~1.84x | ~1.82x | ~1.93x | ~1.91x | ~1.96x |

[^1]
[^0]:    (in \$M except as otherwise noted)

[^1]:    
    
    
    
    performance measures used by our investors and analysts to assess the overall operating performance in the context of financiai leveragae.

