

Gilead Sciences

CRL on Filgo is Disappointing, We Predict Even More Pivot and Focus to Cancer

August 18, 2020

Key Takeaway

CRL for filgotinib is a setback given it was a key growth driver and \$2B+ peak consensus. On the other side, we don't think expectations were super high for GILD against leader ABBV anyway and we've been saying there was some risk around 200mg high dose all along in reports/videos. We predict GILD will await more safety data in H1-21 but ultimately GILD could make tough decisions on FILG and will continue to increase focus on oncology (5 deals this year).

Filgo now in question....GILD received a CRL for filgotinib in rheumatoid arthritis and FDA has requested the full datasets from the ongoing MANTA and MANTA-RAY male toxicity studies. The FDA had access to blinded interim data, but it has requested the full data in H1-21 (so we est and re-filing would be mid-21 and PDUFA YE:21 or early 2022). GILD emphasized FDA had questions on risk/benefit for 200mg including the male tox signal at 200mg and other higher AEs vs lower 100mg dose - despite the fact overall JAK safety class issues are in fact lower for filgotinib than competitors...in our prior notes and videos we highlighted 200mg as a risk factor given MANTA 200mg data had not finished yet and the FDA is extremely conservative on the JAK class given lots of other RA drugs are available....we lowered our 2021-22 estimates and removed USA sales for now.

So big picture - setback today but stock still cheap at 10-11x and it's still a turn-around...

We're disappointed in the CRL for the USA given GILD could use as many growth drivers as possible. As a reminder, filgotinib still has a positive CHMP in EU (including for the high dose) and full approval is imminent. That said, we do believe there is a reasonable debate amongst investors as to how much investment GILD should make into filgo anyway - and if they backed off of filgo investments....would this actually be a potential positive to GILD margins and ROI to invest in other areas....As a reminder, it could be at least a 1 year delay and the JAK is already 4th to market.....that said, GILD will likely stick w/ this for now and they have a big 10-year deal with GLPG for auto-immune pipeline programs (Street may question this a bit too now) that is separate from this filgo deal. With the stock likely to trade in the mid \$60s on the news and trading around a low 10x P/E, the stock reflects a lot of the mixed sentiment on GILD already as an ongoing turn-around story since 2019 new CEO Dan O'Day came on.

Fundamentals fine, continuing to bolster oncology....

While the stock has traded between \$65-85 during 2020 and is back at the lower end, O'Day has been doing positive things to support better fundamentals today than 2018-2019 (yet P/E is the same at 10x): (1) executed on HIV and advanced capsid and long-acting HIV drugs coming soon, (2) has generally been hitting numbers, (3) acquired FTSV for \$5B and did 4 other Phase I/early-stage oncology partnerships and deals this year (RCUS, Pionyr, Tizona, Tango...) and (4) executed on RemD bringing in \$2-3B+ this year and pot'l sales next year. We retain our BUY but lower our PT to \$78 from \$97 to reflect a low probability of USA success on filgo and lower multiple pending greater visibility on 2021-2023.

Target | Estimate Change

USA | Biotechnology

RATING	BUY
PRICE	\$69.06 [^]
MARKET CAP	\$87.2B
PRICE TARGET (PT)	\$78.00 (FROM \$97.00)
UPSIDE SCENARIO PT	\$110.00
DOWNSIDE SCENARIO PT	\$55.00

[^]Prior trading day's closing price unless otherwise noted.

FY Dec

USD	2018A	2019A	2020E	2021E
EPS	6.68	6.64	6.91	↓ 6.13
Prev.				6.17
FY P/E	10.3x	10.4x	10.0x	11.3x

EPS calculation accounts for stock-comp (starting in Q1:20)

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GILEAD SCIENCES (GILD)

Estimates				
	2018A	2019A	2020E	2021E
Rev. (MM)	22,127.0	22,449.0	↓ 24,234.0	↓ 22,619.0
Previous			24,252.0	22,776.0
Consensus EPS	-	-	↑ 6.98	↑ 7.02
Previous			6.56	6.64
EPS				
Q1	1.48	1.76	1.68A	1.54
Previous				
Q2	1.91	1.82	1.11A	↓ 1.53
Previous				1.54
Q3	1.84	1.75	2.17	↓ 1.53
Previous				1.54
Q4	1.44	1.30	1.95	↓ 1.54
Previous				1.55
FY Dec	6.68	6.64	6.91	↓ 6.13
Previous				6.17

Valuation				
	2018A	2019A	2020E	2021E
P/Rev	3.9x	3.9x	3.6x	3.9x
FY P/E	10.3x	10.4x	10.0x	11.3x

EPS calculation accounts for stock-comp (starting in Q1:20)

Market Data		Financial Summary	
52-Week Range:	\$85.97 - \$60.89	Long-Term Debt (MM)	\$24,097.0
Total Entprs. Value	\$90.1B	Cash & ST Invest. (MM)	\$21,190.0
Avg. Daily Value MM (USD)	565.56		
Float (%)	99.0%		

The Long View

Scenarios

Base Case

- Our \$78 PT is based on our view that GILD remains a cheap and low-expectation story that is getting better and can achieve even a 13x multiple on 2021 earnings which is still the lower end of biotech peers.
- Our DCF analysis suggests a durable HIV business (capsid, etc) along with a manageable/more predictable HCV business and includes a probability-based analysis of the pipeline including filgotinib and others
- Importantly, GILD does more M&A, including string-of-pearls type bolt-ons and continues to build its mid/late-stage pipeline to improve 2021-23 visibility

Upside Scenario

- Our \$110 upside scenario price is based on applying a 15-16x multiple to a 2021-2022 non-GAAP EPS estimate
- We assume a durable HIV business that remains flattish instead of declining post 2020 and in fact can grow over the next 5+ years as the business continues to take share and there are no major threats from competitors
- We could see multiple expansion from continued M&A and BD and/or positive data readouts from pipeline programs in inflammation and oncology and from the GLPG "pipeline" including OA, IPF, and other targets

Downside Scenario

- Our \$55 downside scenario is based on applying a 9x multiple to our 2021 non-GAAP EPS estimate
- Viread will face generics in the EU that could take more share than expected
- GSK could take increasing market share in HIV based on dolutegravir-based two-drug regimens
- HCV franchise is likely to face pricing pressures from ABBV, MRK, and JNJ with new effective HCV regimens
- The Yescarta launch could disappoint in 2020-21 and allogeneic data could come out that suggests traditional autologous is murky and the KITE deal is not panning out

Investment Thesis / Where We Differ

- We believe GILD will continue to do more M&A (potentially in the gene therapy/ gene-editing space)
- We believe GILD's HIV franchise could be durable against potential GSK competition and generics
- We believe the HCV business has increased visibility and will become more manageable (volume stabilization)

Catalysts

- **H2:20:** Data from pivotal Phase III study in 2nd line DLBCL (ZUMA-7)
- **H2:20:** Phase II OA data from GLPG-1972 and with partner GLPG
- **2020-21:** Remdesivir developments (strong launch, positive clinical studies)
- **H1:21:** MANTA/ MANTA-RAY readout, and decision on next steps for Filgotinib

Exhibit 1 - GILD Income Statement

Fiscal Year (Ending in December)	FY18	1Q19	2Q19	3Q19	4Q19	FY19	1Q20	2Q20	3Q20E	4Q20E	FY20E	1Q21E	2Q21E	3Q21E	4Q21E	FY21E	FY22E	FY23E
(\$ figures in MM, except per share)		Mar-19	Jun-19	Sep-19	Dec-19		Mar-20	Jun-20	Sep-20	Dec-20		Mar-21	Jun-21	Sep-21	Dec-21			
Non-GAAP Income Statement																		
HCV Sales	\$3,688	\$790	\$842	\$674	\$630	\$2,936	\$729	\$448	\$472	\$489	\$2,138	\$481	\$472	\$463	\$454	\$1,870	\$1,777	\$1,688
Harvoni	\$1,224	\$225	\$193	\$124	\$101	\$643	\$112	\$67	\$60	\$57	\$296	\$54	\$52	\$50	\$48	\$204	\$194	\$184
Sovaldi	\$102	\$11	\$81	(\$29)	\$8	\$71	\$5	\$7	\$2	\$2	\$16	\$2	\$2	\$2	\$2	\$8	\$8	\$8
Epcusa (SOF / VEL)	\$1,966	\$491	\$493	\$516	\$465	\$1,965	\$564	\$335	\$365	\$385	\$1,649	\$380	\$375	\$370	\$365	\$1,490	\$1,416	\$1,345
Vosevi (SOF/VEL/VOX)	\$396	\$63	\$75	\$63	\$56	\$257	\$48	\$39	\$45	\$45	\$177	\$45	\$43	\$41	\$39	\$168	\$160	\$152
HIV Sales	\$14,704	\$3,618	\$4,041	\$4,202	\$4,577	\$16,438	\$4,134	\$4,000	\$4,214	\$4,169	\$16,517	\$4,206	\$4,216	\$4,224	\$4,237	\$16,883	\$16,354	\$16,298
Atripla (Emtriva/Viread/Sustiva)	\$1,206	\$171	\$152	\$149	\$128	\$600	\$95	\$103	\$92	\$81	\$371	\$65	\$54	\$43	\$32	\$194	\$61	\$45
Truvada (Emtriva/Viread)	\$2,997	\$606	\$718	\$721	\$768	\$2,813	\$406	\$387	\$356	\$215	\$1,364	\$215	\$189	\$163	\$137	\$704	\$352	\$176
Complera (Rilpivirine/Emtriva/Viread)	\$653	\$115	\$123	\$93	\$75	\$406	\$76	\$72	\$58	\$45	\$251	\$38	\$30	\$22	\$20	\$110	\$55	\$28
Stribild (Elvitegravir/Cobicistat/Emtriva/Viread)	\$644	\$96	\$108	\$94	\$71	\$369	\$53	\$59	\$53	\$46	\$211	\$39	\$32	\$30	\$23	\$124	\$62	\$31
Viread (TDF)	\$97	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Genvoya (Elvitegravir/Cobicistat/Emtriva/TAF)	\$4,624	\$1,015	\$980	\$978	\$958	\$3,931	\$824	\$816	\$875	\$885	\$3,400	\$880	\$870	\$855	\$845	\$3,450	\$3,175	\$2,900
Descovy (Emtriva/TAF)	\$1,581	\$342	\$358	\$363	\$437	\$1,500	\$458	\$417	\$450	\$485	\$1,810	\$505	\$525	\$545	\$565	\$2,140	\$2,247	\$2,359
Odeseq (Rilpivirine/Emtriva/TAF)	\$1,598	\$397	\$387	\$436	\$435	\$1,655	\$409	\$382	\$390	\$395	\$1,576	\$390	\$385	\$380	\$375	\$1,530	\$1,010	\$689
Biktarvy (Bictegravir/F/TAF)	\$1,184	\$793	\$1,116	\$1,259	\$1,570	\$4,738	\$1,693	\$1,604	\$1,800	\$1,875	\$6,972	\$1,925	\$1,975	\$2,025	\$2,075	\$8,000	\$8,710	\$9,332
HIV Other (Post Viread Generic 2018)	\$120	\$83	\$99	\$109	\$135	\$426	\$120	\$160	\$140	\$142	\$562	\$149	\$156	\$161	\$165	\$631	\$683	\$739
Other antiviral	\$80	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Product Sales	\$3,205	\$792	\$724	\$640	\$589	\$2,745	\$604	\$619	\$2,215	\$1,824	\$5,262	\$867	\$872	\$891	\$916	\$3,546	\$3,403	\$3,398
Yescarta (CAR-T)	\$264	\$96	\$120	\$118	\$122	\$456	\$140	\$156	\$150	\$160	\$606	\$170	\$180	\$190	\$200	\$740	\$968	\$1,198
Filgotinib (RA)	-	-	-	-	-	-	-	-	-	-	-	\$3	\$5	\$10	\$15	\$33	\$175	\$410
Zydrelig (INH/LCLL)	\$133	\$27	\$26	\$26	\$24	\$103	\$20	\$18	\$16	\$14	\$68	\$12	\$10	\$9	\$9	\$40	\$30	\$30
AmBisome (ex-US)	\$420	\$93	\$105	\$99	\$110	\$407	\$119	\$95	\$75	\$50	\$339	\$30	\$20	\$20	\$20	\$90	\$60	\$40
Letairis	\$943	\$197	\$204	\$121	\$96	\$618	\$83	\$80	\$50	\$25	\$238	-	-	-	-	-	-	-
Ranexa	\$758	\$155	\$19	\$31	\$11	\$216	\$8	\$1	-	-	\$9	-	-	-	-	-	-	-
Vemlidy	\$263	\$101	\$116	\$134	\$137	\$488	\$136	\$151	\$160	\$170	\$617	\$180	\$190	\$200	\$210	\$780	\$900	\$1,000
Viread (TDF)	\$210	\$72	\$75	\$57	\$39	\$243	\$40	\$65	\$40	\$35	\$180	\$30	\$25	\$20	\$20	\$95	\$70	\$60
Other (excludes Sovaldi)	\$214	\$51	\$59	\$54	\$50	\$214	\$58	\$53	\$50	\$50	\$211	\$50	\$50	\$50	\$50	\$200	\$200	\$200
Remdesivir	-	-	-	-	-	-	-	-	\$1,674	\$1,320	\$2,994	\$392	\$392	\$392	\$392	\$1,568	\$1,000	\$1,000
Product Sales (Antiviral Franchise + Other Products)	\$21,677	\$5,200	\$5,607	\$5,516	\$5,796	\$22,119	\$5,467	\$5,067	\$6,901	\$6,482	\$23,917	\$5,554	\$5,560	\$5,578	\$5,607	\$22,299	\$21,534	\$21,924
Royalty, contract and other revenues	\$450	\$81	\$78	\$88	\$83	\$330	\$81	\$76	\$80	\$80	\$317	\$80	\$80	\$80	\$80	\$320	\$325	\$325
Total Revenues	\$22,127	\$5,281	\$5,685	\$5,604	\$5,879	\$22,449	\$5,548	\$5,143	\$6,981	\$6,562	\$24,234	\$5,634	\$5,640	\$5,658	\$5,687	\$22,619	\$21,859	\$22,249
Cost of Sales	\$3,590	\$660	\$714	\$759	\$1,406	\$3,539	\$703	\$798	\$909	\$855	\$3,265	\$733	\$734	\$736	\$740	\$2,943	\$2,799	\$2,850
Operating Expenses	\$7,126	\$1,833	\$1,931	\$1,921	\$2,161	\$7,846	\$2,080	\$2,350	\$2,496	\$2,484	\$9,410	\$2,349	\$2,369	\$2,393	\$2,417	\$9,527	\$9,582	\$9,712
Research and Development (R&D)	\$3,518	\$871	\$916	\$954	\$1,029	\$3,770	\$1,004	\$1,186	\$1,248	\$1,209	\$4,648	\$1,072	\$1,079	\$1,088	\$1,099	\$4,337	\$4,307	\$4,341
Sales, General and Administrative (SG&A)	\$3,608	\$962	\$1,015	\$967	\$1,132	\$4,076	\$1,076	\$1,164	\$1,248	\$1,274	\$4,762	\$1,277	\$1,290	\$1,305	\$1,318	\$5,190	\$5,276	\$5,371
Total Costs and Expenses	\$10,716	\$2,493	\$2,645	\$2,680	\$3,567	\$11,385	\$2,783	\$3,148	\$3,405	\$3,338	\$12,675	\$3,082	\$3,102	\$3,129	\$3,157	\$12,471	\$12,382	\$12,563
Operating Income (EBIT)	\$11,411	\$2,788	\$3,040	\$2,924	\$2,312	\$11,064	\$2,765	\$1,995	\$3,576	\$3,224	\$11,559	\$2,552	\$2,538	\$2,529	\$2,530	\$10,148	\$9,477	\$9,687
Operating Margin	\$1	\$1	\$1	\$1	\$0	\$0	\$0	\$0	\$1	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total Other Income	(\$516)	(\$84)	(\$77)	(\$86)	(\$121)	(\$368)	(\$116)	(\$191)	(\$133)	(\$137)	(\$577)	(\$122)	(\$122)	(\$116)	(\$110)	(\$470)	(\$452)	(\$518)
Pre-tax income	\$10,895	\$2,704	\$2,963	\$2,838	\$2,191	\$10,696	\$2,649	\$1,804	\$3,443	\$3,087	\$10,983	\$2,430	\$2,416	\$2,413	\$2,420	\$9,678	\$9,025	\$9,169
Provision for taxes	\$2,152	\$453	\$637	\$617	\$545	\$2,252	\$523	\$411	\$723	\$648	\$2,305	\$510	\$507	\$507	\$508	\$2,032	\$1,895	\$1,926
Effective Tax Rate (non-GAAP)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net loss attributable to noncontrolling interest	\$5	(\$7)	(\$5)	(\$3)	(\$7)	(\$22)	(\$13)	(\$7)	-	-	(\$20)	-	-	-	-	-	-	-
Net Income (non-GAAP)	\$8,738	\$2,258	\$2,331	\$2,224	\$1,653	\$8,466	\$2,139	\$1,400	\$2,720	\$2,439	\$8,697	\$1,920	\$1,908	\$1,906	\$1,912	\$7,646	\$7,130	\$7,244
EPS Basic (non-GAAP)	\$6.73	\$1.77	\$1.84	\$1.76	\$1.31	\$6.67	\$1.69	\$1.12	\$2.17	\$1.95	\$6.93	\$1.54	\$1.53	\$1.53	\$1.54	\$6.13	\$5.75	\$5.83
EPS Diluted (non-GAAP)	\$6.68	\$1.76	\$1.82	\$1.75	\$1.30	\$6.64	\$1.68	\$1.11	\$2.17	\$1.95	\$6.91	\$1.54	\$1.53	\$1.53	\$1.54	\$6.13	\$5.75	\$5.83
Shares Outstanding - Basic (non-GAAP)	1,298	1,276	1,270	1,267	1,266	1,270	1,262	1,255	1,254	1,252	1,256	1,250	1,249	1,247	1,245	1,248	1,239	1,242
Shares Outstanding - Diluted (non-GAAP)	1,309	1,283	1,277	1,267	1,273	1,275	1,270	1,262	1,254	1,252	1,259	1,250	1,249	1,247	1,245	1,248	1,239	1,242

Source: Jefferies estimates, Company reports

Company Description

Gilead Sciences

Gilead is a leader in the development and marketing of anti-infective drugs, with approved products for the treatment of HIV/AIDS, Hep C, hepatitis B, liver and pulmonology diseases. Gilead is developing a pipeline of antivirals, liver disease, immunology and oncology. The company has an extensive worldwide sales and marketing infrastructure.

Company Valuation/Risks

Gilead Sciences

Our PT is based on a pipeline-adjusted DCF and multiple of our 2020 EPS estimate. Risks: competition, pipeline disappointments, and worse-than-expected sales.

Galapagos

Our Price Target is based on a sum-of-the-parts valuation largely comprising probability-adjusted NPVs for filgotinib, GLPG1690 in IPF, GLPG1972 in osteoarthritis, and Toledo in autoimmune disorders, plus Net Cash. Risks include: (1) regulatory setbacks for filgotinib; (2) upcoming late-stage pipeline catalysts are high risk; and (3) clinical trial failures.

Analyst Certification:

I, Michael J. Yee, certify that all of the views expressed in this research report accurately reflect my personal views about the subject security(ies) and subject company(ies). I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this research report.

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Investment Recommendation Record

(Article 3(1)e and Article 7 of MAR)

Recommendation Published	August 18, 2020 , 21:52 ET.
Recommendation Distributed	August 18, 2020 , 21:52 ET.

Company Specific Disclosures

Jefferies LLC is acting as a financial advisor to Kite Pharma (KITE) on the sale of the company to Gilead Sciences (GILD).

Jefferies Group LLC makes a market in the securities or ADRs of Gilead Sciences, Inc.

Jefferies Group LLC makes a market in the securities or ADRs of Galapagos.

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Buy - Describes securities that we expect to provide a total return (price appreciation plus yield) of 15% or more within a 12-month period.

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The expected total return (price appreciation plus yield) for Buy rated securities with an average security price consistently below \$10 is 20% or more within a 12-month period as these companies are typically more volatile than the overall stock market. For Hold rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is plus or minus 20% within a 12-month period. For Underperform rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is minus 20% or less within a 12-month period.

NR - The investment rating and price target have been temporarily suspended. Such suspensions are in compliance with applicable regulations and/or Jefferies policies.

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Other Companies Mentioned in This Report

- Galapagos (GLPG NA: €156.70, BUY)

Rating and Price Target History for: Gilad Sciences, Inc. (GILD) as of 08-17-2020



Jefferies LLC is acting as a financial advisor to Kite Pharma (KITE) on the sale of the company to Gilad Sciences (GILD).

Rating and Price Target History for: Galapagos (GLPG NA) as of 08-17-2020



Notes: Each box in the Rating and Price Target History chart above represents actions over the past three years in which an analyst initiated on a company, made a change to a rating or price target of a company or discontinued coverage of a company.

Legend:

- I: Initiating Coverage
- D: Dropped Coverage
- B: Buy
- H: Hold
- UP: Underperform

Distribution of Ratings

Distribution of Ratings						
			IB Serv./Past12 Mos.		JIL Mkt Serv./Past12 Mos.	
	Count	Percent	Count	Percent	Count	Percent
BUY	1411	55.64%	121	8.58%	10	0.71%
HOLD	979	38.60%	27	2.76%	5	0.51%
UNDERPERFORM	146	5.76%	0	0.00%	0	0.00%

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