FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

September 6, 2018

Jefferies

Gilead Sciences (GILD)

Filgotinib thoughts - Pros and Cons to think about?

BUY
Bloomberg NASDAQ: GILD
Price target $95.00
Price $74.53^

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

EQUITY RESEARCH AMERICAS

Key Takeaway

Filgotinib remains a pot'l important drug for GILD and general expectations are for multi-billion peak sales over time especially if the efficacy/safety equation play out over the next year...we are probably more balanced and cautiously optimistic long-term on the program within our other factors for a GILD buy thesis.

GILD remains a top large-cap "value" idea based on a relative medium/longer-term turn around thesis insofar they will trough out on revenue and EPS this year (Q1 was actually possibly the trough already), HCV will stabilize and revs/earnings won't miss again this year to prove that, sentiment is the most negative of all the large cap biotechs and it's the most under-weight of all the large caps (hence most room to turn around), and there's a big call option on the Phase III NASH ASK-1 study in early 2019 and it's not in consensus but yet biggest large cap catalyst in the sector over next 6-8 months, in our view (though only a 30% confidence on our part). That said, we understand Street needs some visibility on Q3 numbers to comfort recent mgmt change surprises and may need a new CEO by year-end to get Street comfortable and stock more "ownable" too.

Phase II Filgotinib data today in ankylosing spondylitis (AS) is incremental "positive" for the franchise and helps bolster pot'l multi-billion peak sales. Note strong efficacy is very notable and helps bolster the RA efficacy question a tad but a pot'l headline safety question will arise on one case of DVT however per GLPG (Buy, covered by P. Welford) commentary (note here) the one patient had an inherited risk of thrombosis (Factor V Leiden gene mutation) and the DVT occurred in the follow-up period post-treatment, hence was later assessed to not be treatment-related. We await upcoming Phase III RA data (FINCH-2 study) and while expectations are not low on efficacy (to be ballpark similar to competitors), focus will be on safety and ensuring no major issue with DVT or other SAEs or serious infections or concerns (though these are known issues esp minor risk of serious infections). See our filgotinib preview on this here looking for a ACR-20 placebo-adjusted 20-25% delta for low dose and 25-30% for high dose to be positive in the ballpark of competitors with ACR-50 and ACR-70 possible add'l differentiation.

On the other hand, our longer term "questions" we are watching and weighing on filgotinib have to do with the ultimate risk/reward of the franchise for GILD given: (1) it ultimately is still tracking to be a fourth-to-market JAK that while may possibly be theoretically best-in-class, may or may not be totally differentiated from third-to-market but pretty clean-so-far ABBV upadacitinib, which also claims to not increase platelets (less DVT risk) and/or hasn't had pooled DVT rates above natural history and does not claim to have decreased hemoglobin or lymphocytes either; so will GILD filgotinib differences matter enough to the managed care formularies if rebating is ultimately the deciding factor and it's 1-2 years behind ABBV? (2) investor uncertainty around the "male toxicity" (sperm count) study (link here) which is growing a bit noisier for Street...and ultimately FDA acceptability for the actual data eventually to support high dose 200mg though in EU they seem to be fine with the high dose. A study has been enrolling for a year but still not completed enrollment (n=250), GILD mgmt has said they need to address it, and GILD may need the 6-mo study completed before they can file. It's possible this just falls into a 2020 filing.

Indeed, on the Q2 EPS call, GILD nicely noted "In terms of filgotinib and the male safety study, we're enrolling the study it's something that we have to address. We believe our margin is adequate above and beyond the minor histological abnormalities that we're seeing in the pre-clinical models and we'll evaluate the data as it comes in"...(also): "And thirdly, we need to submit data from the male safety study, which is enrolling. And, you know, these are tough studies to do. You've got to have men with ulcerative colitis and they have to be on the drug for six months and have multiple sperm collections. So we're doing everything we can to enhance enrollment and we will announce the details when it's appropriate in terms of the filing time...."

Michael J. Yee *
Equity Analyst
(415) 229-1535 michael.yee@jefferies.com
Andrew Tsai *
Equity Associate
(415) 229-1566 atsai@jefferies.com
Kelechi Chikere, Ph.D. *
Equity Associate
(415) 229-1570 kchikere@jefferies.com
Arshad Haider *
Equity Associate
(415) 229-1521 ahaider@jefferies.com
* Jefferies LLC / Jefferies Research Services, LLC

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 $95 PT is based on a pipeline-adjusted DCF and 16x our 2019 EPS estimate. Risks: competition, pipeline disappointments, and worse-than-expected sales.

AbbVie

Our $110 PT is supported by DCF, PE and PEG-relative valuations. Risks: Humira; R&D; reimbursement; M&A.

Galapagos

Our Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for filgotinib, the cystic fibrosis alliance, GLPG1690 in IPF, GLPG1972 in osteoarthritis, and MOR106 in atopic dermatitis, plus Net Cash. Risks include: (1) efficacy, safety, or regulatory setbacks; (2) need to execute future out-licensing and alliances; and (3) clinical trial failures.

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Investment Recommendation Record

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

Recommendation Published	September 6, 2018 , 08:15 ET.
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Company Specific Disclosures

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Steven DeSanctis owns shares of AbbVie Inc. common shares.

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Michael J. Yee, Equity Analyst, (415) 229-1535, michael.yee@jefferies.com

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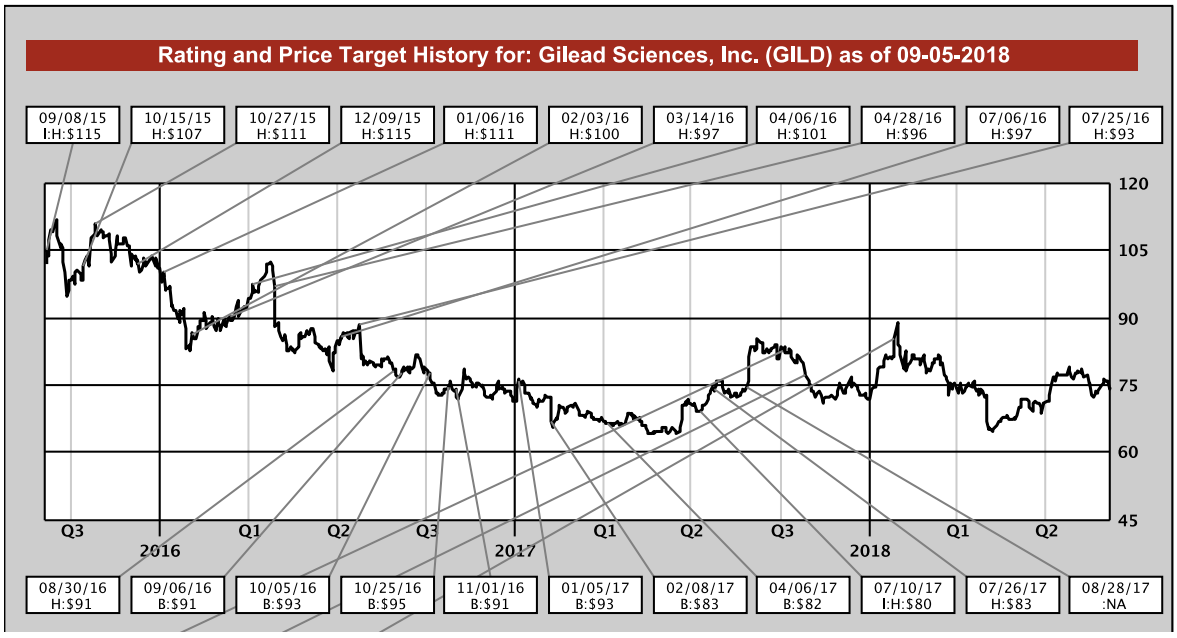
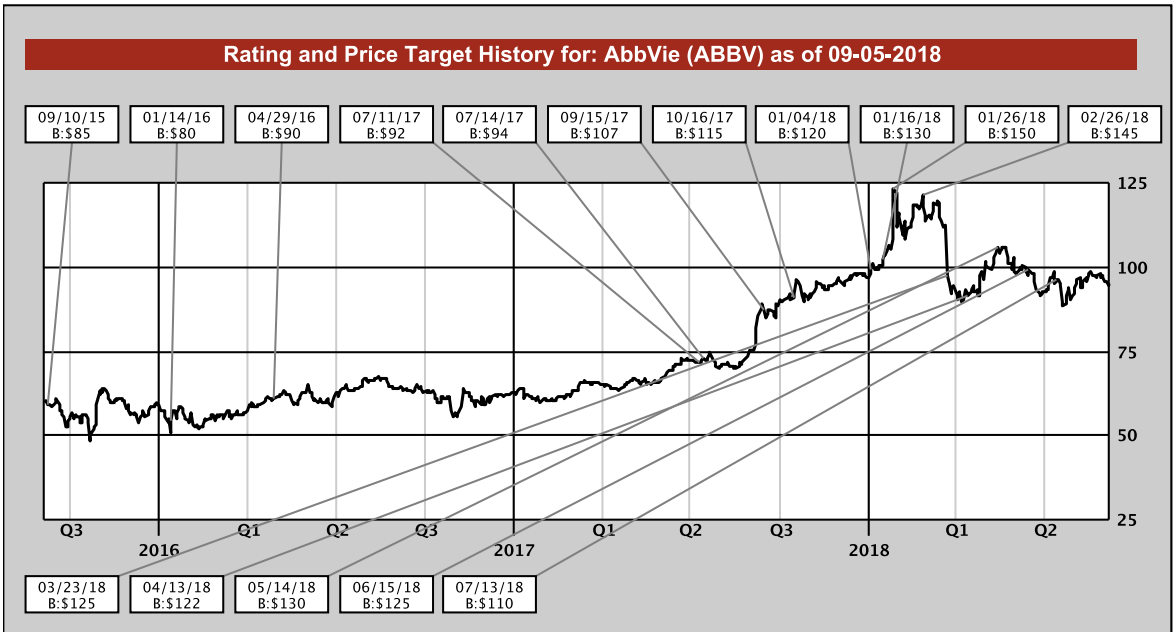
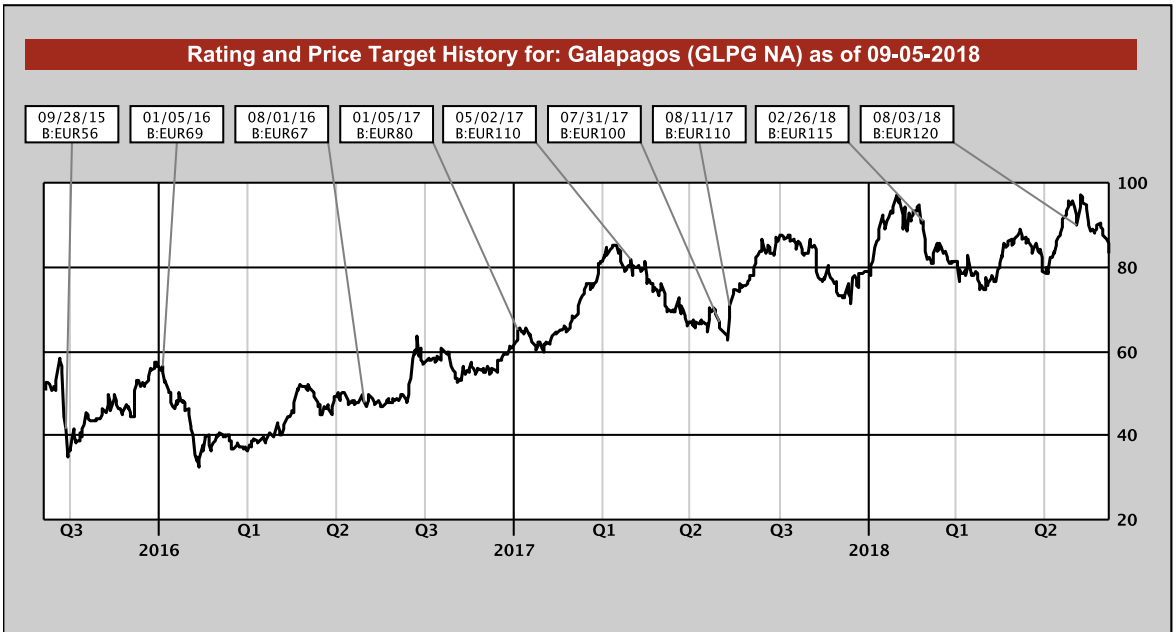
- AbbVie (ABBV: $95.19, BUY)
- Galapagos (GLPG NA: €83.48, BUY)



Michael J. Yee, Equity Analyst, (415) 229-1535, michael.yee@jefferies.com





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UP: Underperform

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Michael J. Yee, Equity Analyst, (415) 229-1535, michael.yee@jefferies.com

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HOLD	833	39.95%	18	2.16%	1	0.12%
UNDERPERFORM	124	5.95%	0	0.00%	0	0.00%

Michael J. Yee, Equity Analyst, (415) 229-1535, michael.yee@jefferies.com

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Michael J. Yee, Equity Analyst, (415) 229-1535, michael.yee@jefferies.com

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Michael J. Yee, Equity Analyst, (415) 229-1535, michael.yee@jefferies.com