COWEN

EQUITY RESEARCH

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■ Biotechnology

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QUICK TAKE: INDUSTRY UPDATE

NDA FILING FOR FILGOTINIB IN RHEUMATOID ARTHRITIS EXPECTED THIS YEAR

THE COWEN INSIGHT

GILD announced that following a pre-NDA meeting with the FDA, it will submit an NDA for filgotinib in RA this year. It had been unclear whether the FDA would require results from the Ph. II MANTA safety study in the NDA, which would have delayed the filing until at least 2021. Therefore the 2019 NDA filing timeline represents the best case scenario. We remain Outperform on GILD and partner GLPG.

Filgotinib NDA Submission Timeline As Good As One Could Have Hoped, Placing It On Pace For A U.S. Launch In 2020

The News: This morning GILD ($68) and partner GLPG ($130) announced that following a pre-NDA meeting with the FDA, GILD expects to move ahead with an NDA submission for filgotinib in the treatment of rheumatoid arthritis (RA) this year. The company indicated that it discussed both the results from the FINCH Phase III program and also the ongoing Ph. II testicular tox study MANTA in patients with moderate-to-severe ulcerative colitis or Crohn's disease.

Our Take: We are encouraged by GILD's decision to move forward with the NDA filing for filgotinib in RA during 2019. GILD clearly must believe based on its interactions with the FDA that the safety database generated through the pivotal program is sufficient to support approval. This represents essentially a best-case scenario in terms of NDA timing. While GILD and GLPG had guided to regulatory filings in the EU and Japan during 2019, it had remained unclear whether the MANTA study would need to be completed prior to any regulatory filings in the U.S. The FDA had requested the MANTA study be conducted to assess semen parameters with filgotnib treatment in men with moderately to severely active ulcerative colitis or Crohn's disease following preclinical signals of testicular toxicity in rodents. Per clinicaltrials.gov, the MANTA study has a primary completion date of January 2021, and a full completion date of October 2024. Therefore, should the FDA have required results from the study, an NDA before 2021 would have been unlikely. As no signals of testicular toxicity were observed in men in any clinical trial including all of the FINCH Phase III studies, investors had been hopeful that the FDA would not require the completion of the MANTA studies, though it remained quite possible that the Agency would. Therefore today's announcement represents the best case outcome that puts filgotinib on pace for a 2020 U.S. launch.

Filgotinib has generated encouraging results across its Phase III program that suggest the drug has a profile competitive with other JAK inhibitors in the treatment of RA. For example in FINCH 1, 200mg filgotinib led to an ACR20/50/70 rate of 77%/47%/26% at 12 weeks in RA patients who had an inadequate response to MTX (IR-MTX). These data compare well with the results produced by Xeljanz, Olumiant, and upadacitinib in their Phase III programs. For reference, 5mg Xeljanz produced an ACR20/50/70 rate of 61%/34%/12% at 3 months in the Phase III ORAL-STANDARD trial in IR-MTX patients. In the RA-BEAM trial in IR-MTX patients, 4mg Olumiant (note: only 2mg dose approved in the U.S.) produced an ACR20/50/70 rate of 70%/45%/19% at 12 weeks. In upadacitinib's Phase III SELECT-COMPARE trial in IR-MTX patients, 15mg upadacitinib produced an ACR20/50/70 rate of 71%/45%/25% at 12 weeks. Filgotinib has also fared well in patients with inadequate responses to DMARDs (FINCH 2) and those naive to MTX therapy (FINCH 3). Please see our previously published notes for a full discussion of the FINCH 1 and FINCH 3 results and the FINCH 2 results.

Filgotinib may have a best-in-class safety profile as no imbalances in serious AEs, serious infections, herpes zoster, malignancy, MACE, or death have been shown. This compares to an observed imbalance in DVTs in one of Olumiant's randomized Phase III trials and an imbalance in PEs in a long-term RA safety study of Xeljanz. In aggregated 24 week data from FINCH 1, 2, and 3 only one case of VTE has been observed (in the 200mg filgotinib

cohort in FINCH 1) out of a total of n=2,088 patients treated with filgotinib vs. 3 cases out of a total of n=1,039 patients treated with MTX in these trials. For comparison, there were six cases of PE among 498 RA patients who received upacitinib in the Phase III SELECT-BEYOND trial. Our consultants have noted the difference in DVT rates between filgotinib and the other members of the class, though they are uncertain whether this difference represents a true safety advantage, or if it is a consequence of different populations with different risk factors enrolled in the various trials. Nonetheless, our consultants conclude that filgotinib appears at least as safe as the other JAKs.

We expect filgotinib will be approved in 2020 and will represent a competitive JAK inhibitor across patient populations affected by RA. We estimate peak WW sales of filgotinib of $1.9B in RA alone, yielding $445MM in royalties to GLPG. Filgotinib is also being evaluated in pivotal programs in additional disease indications. Results from the Phase III SELECTION trial in ulcerative colitis are anticipated in Q2:20, and results from the DIVERSITY Phase III trial in Crohn's disease are anticipated in Q3:20. In addition GILD expects to begin a Phase III study is psoriatic arthritis in Q4:19, and a Phase III in ankylosing spondylitis in H1:20.

VALUATION METHODOLOGY AND RISKS

Valuation Methodology

Biotechnology:

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Investment Risks

Biotechnology:

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

ADDENDUM

Stocks Mentioned In Important Disclosures

Ticker	Company Name
GLPG	Galapagos NV (ADR)
GILD	Gilead Sciences

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

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Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Equity Research Rating Distribution

Distribution of Ratings/Investment Banking Services (IB) as of 06/30/19

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	495	63.38%	114	23.03%
Hold (b)	279	35.72%	14	5.02%
Sell (c)	7	0.90%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's equity research rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's equity research ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's equity research ratings definitions. Cowen and Company Equity Research Rating Distribution Table does not include any company for which the equity research rating is currently suspended or any debt security followed by Cowen Credit Research and Trading.

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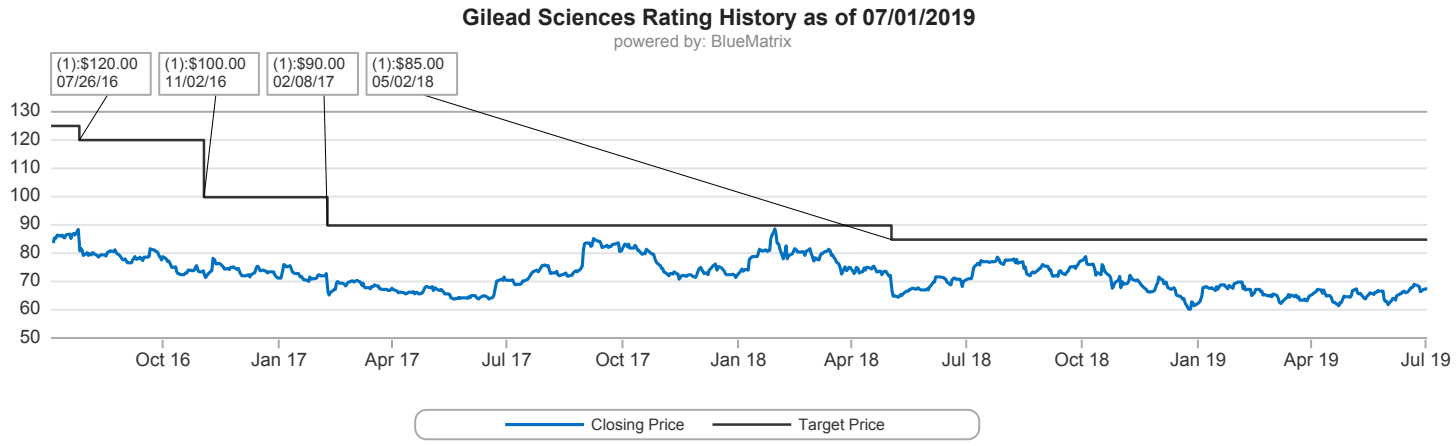

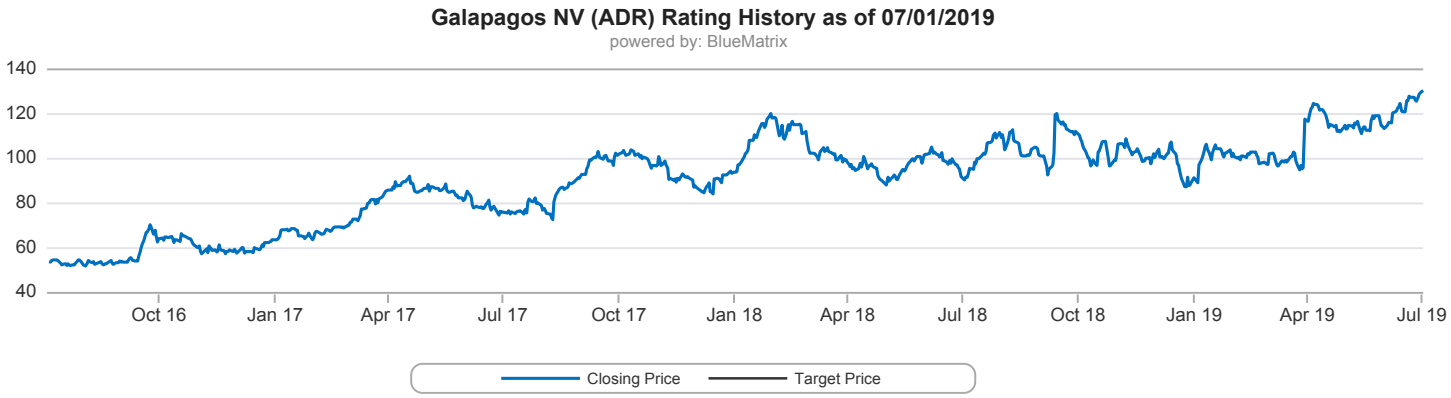

Initiated Coverage - 06/08/2015 - Rating Outperform

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

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