GALAPAGOS NV (GLPG-NASDAQ)

Biotechnology

Dane Leone, CFA | (212) 856-4374 | dane.leone@raymondjames.com
Steven Seedhouse, Ph.D. | (212) 885-1837 | steve.seedhouse@raymondjames.com

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COMPANY BRIEF

Market Perform 3

Suitability	High Risk/Speculation

MARKET DATA

Current Price (Aug-16-19)	$172.06
Market Cap (mln)	$9,432
Current Net Debt (mln)	$(1,275)
Enterprise Value (mln)	$8,157
Shares Outstanding (mln)	54.8
30-Day Avg. Daily Value (mln)	$44.3
Dividend	$0.00
Dividend Yield	0.0%
52-Week Range	$85.00 - $191.63

KEY FINANCIAL METRICS

	1Q	2Q	3Q	4Q
EBITDA (mln) ($, Dec FY)				
2018A	(31)	(33)	13	9
2019E	(53) A	(44) A	(67)	(68)
2020E	(57)	(73)	(72)	(61)

	2018A	2019E	2020E
EBITDA (mln) ($, Dec FY)	(42)	(233)	(264)
GAAP EPS ($, Dec FY)	(0.61)	(3.98)	(4.34)
Revenue (mln) ($, Dec FY)	318	188	171

Source: Thomson One, Raymond James & Associates. Quarterly figures may not add to full year due to rounding.

Upcoming Catalyst

Annual R&D Day: November 14th, 2019 in NYC

RINVOQ Approved Label Turns Focus on Filgotinib to Differentiate

On Friday, the U.S. FDA approved AbbVie's upadacitinib (RINVOQ) for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), who have had an inadequate response or intolerance to methotrexate. The drug label may be somewhat disappointing for the ability of filgotinib to differentiate on safety, as the black box warning (pasted below) seems to read as a class label for Janus kinase inhibitors (JAK), versus a specific risk with upadacitinib (tofacitinib label is more specific). There still could be a margin of possibility that DVT/PE is not a black box warning for filgotinib, given that the signal has not appeared within the clinical studies, but we think that probability is a bit lower now based upon the RINVOQ label. Interestingly, based upon animal tox studies, RINVOQ becomes teratogenic at much lower doses versus Xeljanz (above max recommended human dose 1.6x vs. 146x in rats, respectively). We are still optimistic that filgotinib could differentiate on dosage, as only the low dose (15mg) RINVOQ tablets were approved, and we think that the FINCH datasets support the approval of filgotinib 200mg (high dose). High dose filgotinib would differentiate versus the rest of the approved JAK class, as the current 3 on-market JAKs are all only approved at low dose formulations (tofacitinib, baricitinib and upadacitinib) for the treatment of RA, and this has been a key complaint from the rheumatology community. **Filgotinib filings in EU and U.S. seem on track for 2H19, with potential regulatory approval in RA during 2H20.**

Figure 2 - RINVOQ Label

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use RINVOQ safely and effectively. See full prescribing information for RINVOQ.

RINVOQ™ (upadacitinib) extended-release tablets, for oral use
Initial U.S. Approval: 2019

WARNING: SERIOUS INFECTIONS, MALIGNANCY, AND THROMBOSIS

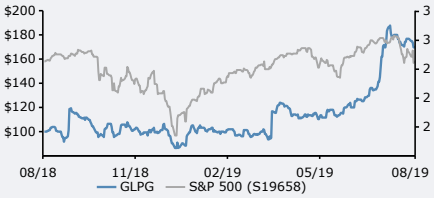
See full prescribing information for complete boxed warning.

- **Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving RINVOQ. (5.1)**
- **If a serious infection develops, interrupt RINVOQ until the infection is controlled. (5.1)**
- **Prior to starting RINVOQ, perform a test for latent tuberculosis; if it is positive, start treatment for tuberculosis prior to starting RINVOQ. (5.1)**
- **Monitor all patients for active tuberculosis during treatment, even if the initial latent tuberculosis test is negative. (5.1)**
- **Lymphoma and other malignancies have been observed in patients treated with RINVOQ. (5.2)**
- **Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with Janus kinase inhibitors used to treat inflammatory conditions. (5.3)**

Source: FDA

COMPANY DESCRIPTION

Galapagos NV is a clinical-stage biotechnology company that is researching and developing novel small molecules to treat indications such as rheumatoid arthritis and inflammation. It was founded in 1999, and is headquartered in Mechelen, Belgium. Its diverse pipeline consists of multiple programs that are in Phases 1-3, and also has preclinical developments. Its most advanced program is filgotinib, a selective JAK1 inhibitor, which is targeting multiple indications including rheumatoid arthritis, ulcerative colitis, and Crohn's disease. Besides filgotinib, Galapagos has four current primary areas of interest: IPF, atopic dermatitis, OA, and inflammation fibrosis.



Company Citations

Company Name	Ticker	Exchange	Closing Price	RJ Rating	RJ Entity
AbbVie Inc.	ABBV	NYSE	$62.98	S	
Gilead Sciences, Inc.	GILD	NASDAQ	$62.87	SB1	Raymond James & Associates

Prices are as of the most recent close on the indicated exchange. See Disclosure section for rating definitions. Stocks that do not trade on a U.S. national exchange may not be registered for sale in all U.S. states. NC=not covered.

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Strong Buy and Outperform (Buy)	55%	62%	21%	26%
Market Perform (Hold)	41%	36%	11%	16%
Underperform (Sell)	4%	2%	3%	0%

** Columns may not add to 100% due to rounding.*

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Medium Risk/Income (M/INC) Lower to average risk equities of companies with sound financials, consistent earnings, and dividend yields above that of the S&P 500. Many securities in this category are structured with a focus on providing a consistent dividend or return of capital.

Medium Risk/Growth (M/GRW) Lower to average risk equities of companies with sound financials, consistent earnings growth, the potential for long-term price appreciation, a potential dividend yield, and/or share repurchase program.

High Risk/Income (H/INC) Medium to higher risk equities of companies that are structured with a focus on providing a meaningful dividend but may face less predictable earnings (or losses), more leveraged balance sheets, rapidly changing market dynamics, financial and competitive issues, higher price volatility (beta), and potential risk of principal. Securities of companies in this category may have a less predictable income stream from dividends or distributions of capital.

High Risk/Growth (H/GRW) Medium to higher risk equities of companies in fast growing and competitive industries, with less predictable earnings (or losses), more leveraged balance sheets, rapidly changing market dynamics, financial or legal issues, higher price volatility (beta), and potential risk of principal.

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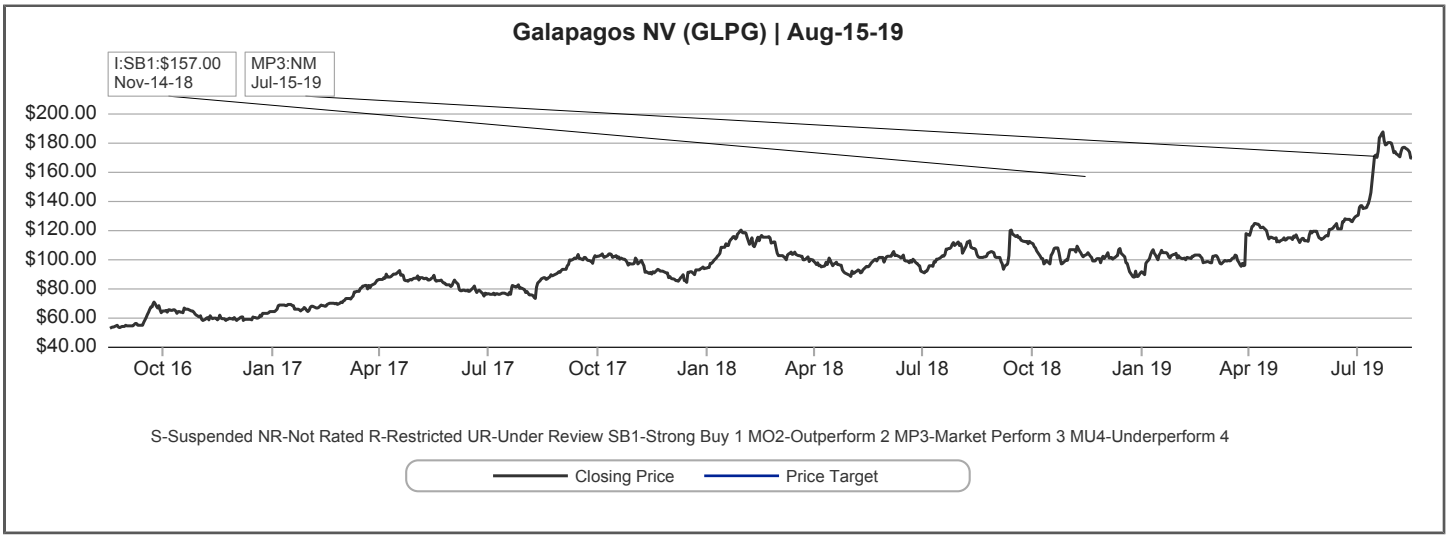

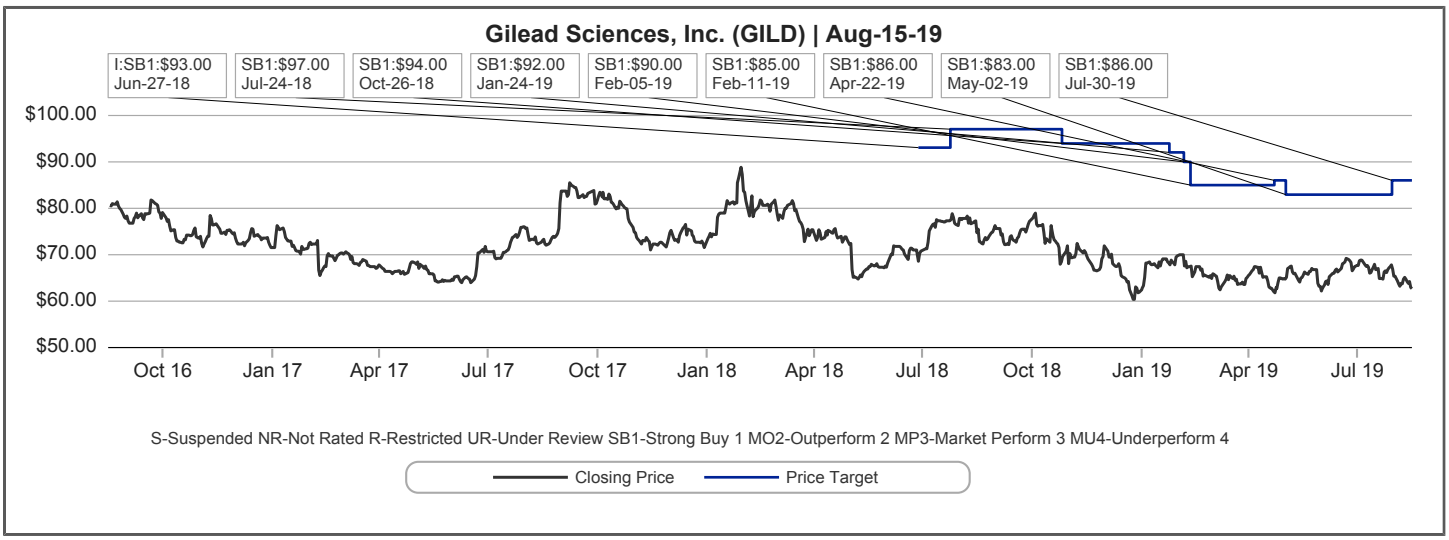

Valuation Methodology

Gilead Sciences, Inc.:
Our valuation is based on our discounted cash flow (DCF) analysis.

Galapagos NV:
We value based on 5 year forward EV/sales.

Risk Factors

General Risk Factors: Following are some general risk factors that pertain to the business of the subject companies and the projected target prices and recommendations included on Raymond James research: (1) Industry fundamentals with respect to customer demand or product/service pricing could change and adversely impact expected revenues and earnings; (2) Issues relating to major competitors or market shares or new product expectations could change investor attitudes toward the sector or this stock; (3) Unforeseen developments with respect to the management, financial condition or accounting policies or practices could alter the prospective valuation; or (4) External factors that affect the U.S. economy, interest rates, the U.S. dollar or major segments of the economy could alter investor confidence and investment prospects. International investments involve additional risks such as currency fluctuations, differing financial accounting standards, and possible political and economic instability.

Company-Specific Risks

Gilead Sciences, Inc.:
Generic Competition and Loss of Exclusivity: Key Gilead products are coming off patent in the U.S. and EU and will continue to come off patent over the next 10-15 years. If loss of market share and pricing power is greater than we currently model, there is risk to our and Street's estimates. Moreover, Gilead (like all biotech companies) is potentially subject to litigation risk (including inter partes reviews) which can affect patent life for key products.
HCV Competitive Risk: If AbbVie's Mavyret continues to take market share from Gilead or new competitors enter and drive pressure to market share and net pricing, there is risk to our HCV estimates. Every ~$1B in annual HCV revenue in out years on a recurring basis is worth about ~$3/share in our model.
HIV Competitive Risk: HIV is a highly competitive field and competitors continue to develop new HIV treatments (e.g., GSK's two drug combination pills, MRK's Delstrigo). If competitors generate favorable clinical data or are able to gain a commercial advantage via pricing or marketing, our HIV estimates could be at risk.
CAR-T Commercial and Development Risk: The field of CAR-T therapies for cancer is relatively new. Any difficulties as it relates to reimbursement or ability to effectively sell the therapies to a wide enough group of treatment centers could create risk to consensus estimates. Moreover, next generation CAR-T approaches including allogeneic treatments and CAR-Ts for solid tumors are less proven and may not yield successes. If the development and commercial headwinds for CAR-T therapies are not navigated, Gilead may not be able to get an appropriate return on its ~$12B acquisition of KITE.
Risk of Pipeline Assets Failing (NASH / Filgotinib): Gilead has several assets in Phase 3 trials including selonsertib for NASH and filgotinib in inflammatory diseases such as RA, UC, and Crohn's. In general, revenues for late stage assets are reflected in our and consensus estimates. Therefore, failure of any or all of the ongoing Phase 3 programs represents a risk to estimates.
Sector Risk: Gilead is a large cap biotech company with many commercialized products in both the U.S. and worldwide. Political headlines and sentiment related to drug developers or drug companies, in particular as it relates to drug pricing, could have an adverse effect on Gilead's market valuation.
High Risk Suitability. We assign a High Risk/Growth suitability rating given the unpredictability and volatility of the biotech space.

Galapagos NV:
We assign a **High Risk/Speculation Suitability** rating as the company is currently not profitable, and is not anticipated to be profitable for a number of years. As such, if the company is unable to secure financing for its activities, it could cease operations.
Stronger data from competitors to filgotinib could reduce our optimism for the program, along with our current commercial sales estimates.
Filgotinib may not be approved by the U.S. FDA for rheumatoid arthritis, which could significantly alter our revenue forecasts for the company, and endanger the Gilead partnership.

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