

GALAPAGOS NV (GLPG-NASDAQ)

Biotechnology

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2Q19 Update Keeps Outlook On Track for Filgo Approvals 2H2020

RECOMMENDATION

On Friday before market open, Galapagos presented results for 2Q19 and updated expected goals and drug development milestones. In our view, there were no significant deviations from discussion points recently outlined on the Gilead collaboration announcement. We expect the upcoming R&D day during November to be the next catalyst for GLPG, as the management team will outline key data readouts and milestones for 2020, while also providing looks at earlier stage programs such as Toledo. We remain **Market Perform**, as we look for more clarity regarding the expected clinical and regulatory events during 2020.

Filgotinib filings in EU and US seem on track for potential regulatory approval in RA during 2H2020:

Based upon current commentary, it sounds like filgotinib will file for approval within both the U.S. and EU during 2H2019 for Rheumatoid Arthritis (RA). We have kept revenue expectations for 2020 minimal, but moving away from concerns about MANTA delaying approval is encouraging. Furthermore, it sounded as though the blinded data from MANTA has not shown an imbalance regarding testicular toxicity between the arms, based upon management commentary on the call. Finally, AbbVie indicated on its 2Q19 call this morning that upadacitinib may not have an AdCom meeting prior to approval, and within the context of a new black box warning for Xeljanz on blood clots, this could benefit the commercial positioning of filgotinib, which has not had a DVT/PE signal and is expected to file at a high dose (versus the lower dose sub for upadacitinib within RA). Beyond RA, management noted that the recruitment process of the SELECTION study (Phase 3 UC) has been completed, which hopefully supports a data readout during 2020. Filgotinib in inflammatory bowel disease will be one of the major expansion areas for the franchise (includes Crohn's).

Toledo program target will not be unveiled until 2020, once Phase 2 studies are underway:

Management indicated that topline data from the GLPG3312 compound (Toledo program) should be presented during the planned R&D day in November. That said, besides biomarker and safety data, the mechanism of action is unlikely to be disclosed until the broad ranging Phase 2 program ramps during 2020. The Toledo program has been kept secretive for competitive reasons for an extended amount of time, and management has indicated that they think it is a novel approach for inflammation and auto-immunity.

Conflict resolution agreement between the Galapagos and Gilead teams makes sense:

Galapagos' CEO explained that it would have full control over individual programs within the partnership through a qualifying Phase 2 study and then Gilead could opt-in on the program into Phase 3. Under the scenario that Gilead is not interested to advance a specific program, Galapagos would have rights to develop the program within Europe as a fully owned asset. Alternatively, if Gilead is interested in developing an asset that Galapagos is uninterested in developing, Gilead would have rights to develop in the U.S. as a fully owned asset. The contractual terms of conflict resolution should help to avoid the complications that Galapagos has previously experienced when developing cystic fibrosis assets in collaboration with AbbVie.

JULY 26, 2019 | 12:50 PM EDT
COMPANY COMMENT

Market Perform 3 Target Price NM

Suitability High Risk/Speculation

MARKET DATA

Current Price (Jul-26-19)	\$178.82
Market Cap (mln)	\$9,803
Current Net Debt (mln)	\$(1,344)
Enterprise Value (mln)	\$8,458
Shares Outstanding (mln)	54.8
30-Day Avg. Daily Value (mln)	\$40.3
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)	(59)	(59)	(60)
new	(53) A	(44) A	(67)	(68)
2020E	(57)	(64)	(64)	(53)
new	(57)	(73)	(72)	(61)
2018A 2019E 2020E				
EBITDA (mln) (\$, Dec FY)				
old	(42)	(231)	(239)	
new	(42)	(233)	(264)	
GAAP EPS (\$, Dec FY)				
old	(0.61)	(3.96)	(3.95)	
new	(0.61)	(3.98)	(4.34)	
Revenue (mln) (\$, Dec FY)				
old	318	161	171	
new	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

Please read domestic and foreign disclosure/risk information beginning on page 4 and Analyst Certification on page 5.

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Figure 1 - GLPG 2019 Key Catalysts

	H1		H2
filgotinib	SELECTION Ph3 recruited Sjögren's Ph2 recruited CLE Ph2 recruited FINCH 1 topline wk 24 FINCH 3 topline wk 24 FINCH 2 publication in <i>JAMA</i>	✓ ✓ ✓ ✓ ✓ ✓	Sjögren's PoC topline CLE PoC topline Ph3 PsA start applications for approval in RA
fibrosis	1st dosing NOVESA Ph2 '1690	✓	PINTA Ph2 recruited <i>ERS</i> <i>ACS (structure '1205)</i>
'1972	<i>OARSI symposium</i>	✓	ROCELLA Ph2b recruited ✓
MOR106	GECKO Ph2 start/IND opening	✓	Japan ethnobridging study start
earlier programs	start Ph1 '3312 (1 st gen Toledo) start Ph1 '3121 start Ph1 '2534	✓ ✓	topline '3312 start Ph1 '3667 start Ph1 '3970 (2 nd gen Toledo) start PoC '3312 in IBD

Source: Company Presentations

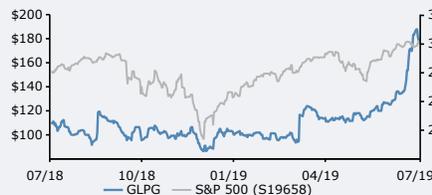
RAYMOND JAMES

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Galapagos NV, Income Statement		EUR €, mm																							
	2015A	2016A	2017A	Mar-18 1Q18A	Jun-18 2Q18A	Sep-18 3Q18A	Dec-18 4Q18A	2018A	Mar-19 1Q19A	Jun-19 2Q19A	Sep-19 3Q19E	Dec-19 4Q19E	2019E	Mar-20 1Q20E	Jun-20 2Q20E	Sep-20 3Q20E	Dec-20 4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E
Total Revenue	60.580	152	156	45	57	103	113	318	40.919	67.590	40	40	188	40	40	40	51	171	301	585	992	1143	1385	1599	1821
Product Revenues								0			0	0	0	0	0	0	11	11	141	425	832	1063	1305	1519	1741
Reimbursement Revenues	40	130	127	38	50	95	106	289	33	59	40	40	172	40	40	40	40	160	160	160	160	80	80	80	80
Other Income	21	22	29	7	7	8	6	29	8	9			17					0	0	0	0	0	0	0	0
Cost of Goods Sold	0.00	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0	-0.6	-1	-7	-21	-25	-32	-39	-46	-52
Gross Profit	61	152	156	45	57	103	113	318	40.919	67.590	40	40	188	40	40	40	52	172	308	606	1017	1175	1424	1644	1873
Gross Margin %																	95%	95%	95%	95%	97%	97%	97%	97%	97%
Operating Expenses	-150.0	-163.1	-245.7	-77	-91	-91	-104	-362.7	-94.162	-111.9580	-108	-108	-422.3	-97	-113	-113	-113	-436.7	-578.4	-701.8	-892.8	-971.6	-1108.2	-1198.9	-1274.9
Research and Development	-130	-140	-219	-70	-82	-80	-91	-323	-83.195	-94	-94	-94	-366	-86	-97	-97	-97	-376	-488	-526	-595	-629	-693	-719	-728
Research and Development % of Sales	-214%																		163%	90%	60%	55%	50%	45%	40%
Sales, General and administrative expenses	-19	-22	-24	-7	-9	-11	-11	-37	-9.221	-13.711	-14	-14	-50	-12	-16	-16	-16	-60	-90	-175	-298	-343	-416	-480	-546
G & A % of Sales	-32%																		30%	30%	30%	30%	30%	30%	30%
Sales and marketing expenses	-1	-2	-3	0			-2	-3	-1.746	-3.875			-6					0	0	0	0	0	0	0	0
Sales and marketing % of Sales	-2%																								
Operating Profit	-89	-11	-90	-32	-34	12	8.708	-45	-53.243	-44.3680	-68	-68	-234	-57	-73	-73	-61	-265	-271	-96	124	203	316	445	599
Operating Profit Margin %	-148%	-8%	-58%	-71%	-59%	12%	8%	-14%	-130%	-66%	-171%	-171%	-124%	-144%	-183%	-183%	-120%	-155%	-90%	-16%	13%	18%	23%	28%	33%
Fair value re-measurement of Share Sub Agreement	-31	57	0	0.00			0	0		0.00			0					0	0	0	0	0	0	0	0
Other financial income	2	10	5	1.61	12.05	2.09	7.67	23	7.00	-1.35			6					0	0	0	0	0	0	0	0
Other financial expenses	-2	-2	-31	-6.79			-1.03	-8	-2.35	-1.47			-4					0	0	0	0	0	0	0	0
Pretax Income	-120	54	-116	-37	-22	14	15.348	-29	-48.589	-47.189	-68	-68	-232	-57	-73	-73	-61	-265	-271	-96	124	203	316	445	599
Income Tax Provision	1	0	0	-0.06	-0.08	0.48	-0.39	0	-0.07	-0.06			0					0	0	0	0	10%	15%	15%	15%
Tax Rate																									
Net Income	-118	54	-116	-37	-22	14.842	14.956	-29	-48.657	-47.249	-68	-68	-232	-57	-73	-73	-61	-265	-271	-96	124	183	269	378	509
Basic Shares Outstanding																									
Diluted Shares Outstanding	-	46.39	49.48	50.97	51.34	54.30	55.39	53.00	54.61	54.82	61.07	61.07	57.89	61.07	61.07	61.11	61.11	61.09	61.13	61.17	61.21	61.24	61.27	61.30	61.32
Basic EPS																									
Diluted EPS		1.16	-2.34	-0.73	-0.42	0.27	0.27	-0.61	-0.89	-0.86	-1.12	-1.12	-3.98	-0.94	-1.20	-1.20	-1.00	-4.34	-4.43	-1.56	2.03	2.99	4.39	6.17	8.30
Diluted EPS Growth % YoY																									
Performance Metrics																									
EBITDA	0.00	-8.17	-86.20	-31.12	-32.80	13.25	8.71	-41.97	-53.24	-44.37	-67.17	-68.14	-232.92	-57.48	-73.14	-72.17	-61.28	-264.07	-269.84	-94.74	125.13	204.32	317.20	446.18	599.59

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
Gilead Sciences, Inc.	GILD	NASDAQ	\$66.32	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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* Columns may not add to 100% due to rounding.

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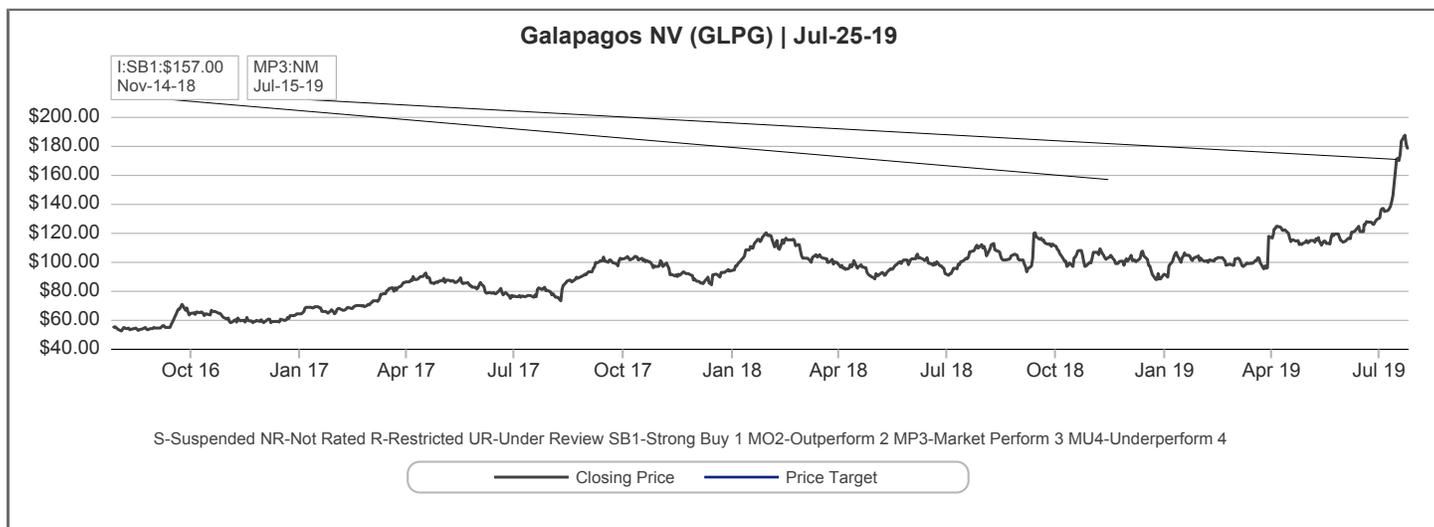
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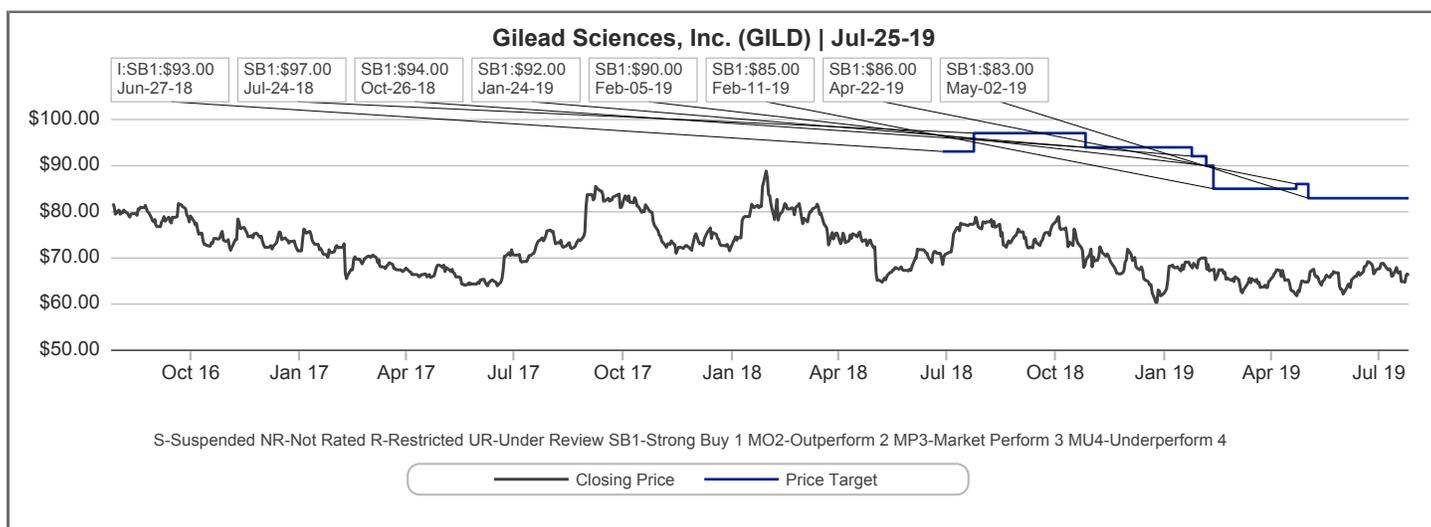
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Target Prices: The information below indicates our target price and rating changes for the subject companies over the past three years.





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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