GALAPAGOS NV (GLPG-NASDAQ)

Biotechnology

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COMPANY BRIEF

Market Perform 3

Suitability	High Risk/Speculation

MARKET DATA

Current Price (Oct-27-20)	$127.74
Market Cap (mln)	$8,347
Current Net Debt (mln)	$(6,224)
Enterprise Value (mln)	$2,123
Shares Outstanding (mln)	65.3
30-Day Avg. Daily Value (mln)	$20.5
Dividend	$0.00
Dividend Yield	0.0%
52-Week Range	$112.00 - $274.03

KEY FINANCIAL METRICS

	1Q	2Q	3Q	4Q
EBITDA (mln) ($, Dec FY)				
2019A	(53)	(44)	491	(23)
2020E	(45) A	(86) A	(139)	(139)
2021E	(129)	(137)	(145)	(156)
2022E	(114)	(96)	(95)	(92)

	2019A	2020E	2021E	2022E
EBITDA (mln) ($, Dec FY)	370	(408)	(567)	(396)
GAAP EPS ($, Dec FY)	2.49	(6.82)	(8.73)	(6.10)
Revenue (mln) ($, Dec FY)	896	312	224	438

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

Key Take-Away from TOLEDO Update: Y-Axis Not Included

On Tuesday, the Galapagos management team hosted a roundtable discussion of the TOLEDO program. The discussion was the first time that the key target of the program had been disclosed - salt inducible kinase (SIK). The update focused mostly around pre-clinical models and the expected milestones for 2021. Partner Gilead has opt-in rights to the program once Phase 2 studies are completed, which could occur by YE2021 for the GLPG3970 program. Based upon our discussions with investors, presentation of clinical data is likely needed before excitement around the program develops, as the historical shifting timelines have made TOLEDO more of a *show-me* story.

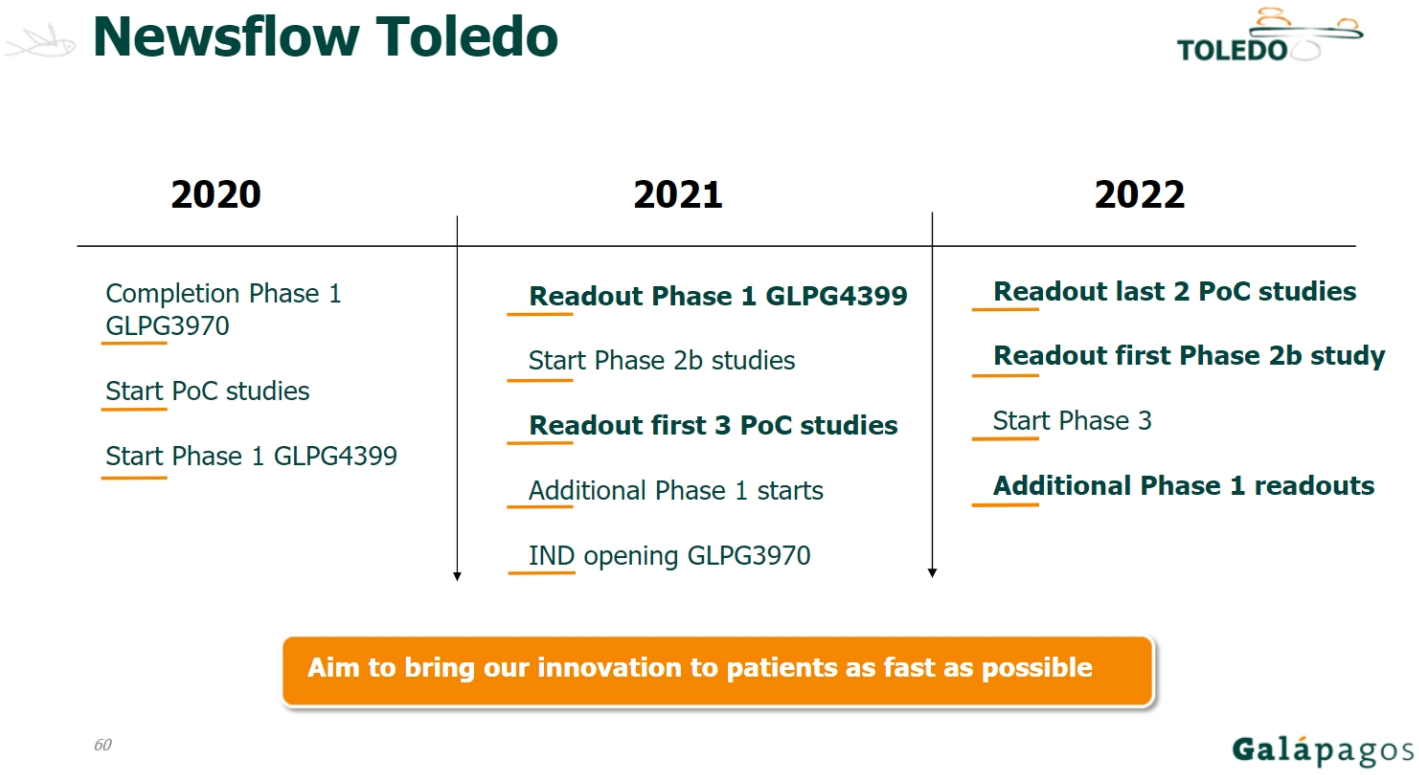
Top-line data had been expected during 2019 with GLPG3312 in IBD: During the 4Q18 conference call, the management team had outlined a plan to start Phase 1 studies of GLPG3312 and then topline the data during 2H2019. The 2019 R&D Update (November 2019) did not include clinical data from the TOLEDO program, but provided an outlook for data from a GLPG3312 ulcerative colitis study during 2020, and also focused on plans for GLPG3970 to start multiple Phase 2 proof-of-concept studies during 2020. The update from the roundtable discussion (today) did not include clinical data from the TOLEDO program, but eliminated GLPG3312 from the development pipeline, and focused on GLPG3790.

Pre-clinical work from TOLEDO program builds upon published work by *Lombardi et al. during 2016:* The work by *Lombardi et al* thankfully included Y-axis scalars and labeling, which helped to understand the relation of SIK1/2/3 expression and cytokine activation. Concordantly with the Galapagos experiments, SIK inhibition was found to *reduce IL-1β-mediated production of proinflammatory cytokines by macrophages and dendritic cells,* and specifically decrease TNF-α while increasing IL-10 secretion. Interestingly, ARN-3236 was used for some of the experiments, which was a Pan-SIK (potent on SIK2, IC50 1nM SIK2/ 21.63nM SIK1/ 6.63nM SIK3) compound explored for use against tumors that had elevated SIK expression (ovarian cancer cells were noted to have elevated SIK2 expression). The pertinence of experiments with ARN-3236 (Arrien Pharma) in oncology may shed light on potential side effects of SIK2 inhibition (why is it favorable for cancer cells to have upregulation of SIK?). Data from a study of ARN-3236-exposed ovarian cancer cells supported a view that blockade of SIK2 inhibits centrosome splitting in mitotic cells (and delay in mitotic progression and accumulation of tetraploid cells). A study evaluating SIK2 inhibition within the context of triple-negative breast cancer (cell lines) suggested that SIK2 "*functions in breast tumor and normal cells to restrain autophagic flux*". **What does this mean? There is clear plausibility for a real clinical effect within auto-immune disorders that respond to anti-TNF biologics, but the safety aspect of SIK inhibition needs to be elucidated.**

What do we actually know about GLPG3970? Not much clinically. From the limited data disclosed during the roundtable discussion, plasma concentration of GLPG3970 hit some peak (Y-axis not provided) two hours post dosing and fell relatively rapidly to hour 7 (management stated once-daily dosing could be effective). *Ex vivo* analysis from whole blood supports some reduction in TNF levels (Y-axis not provided) and some elevation of IL-10 (ditto). Evaluation of GLPG3970 in healthy volunteers has included 59 subjects exposed to at least one oral dose, and was "well tolerated."

GLPG3790 is currently scheduled to complete Phase 1 clinical testing (healthy volunteer) and start proof-of-concept studies before YE2020 (psoriasis, ulcerative colitis, rheumatoid arthritis), with read-outs of the first 3 PoC studies during 2021 (and open an IND).

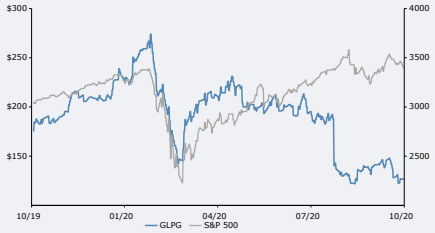
Figure 1 - Toledo Catalyst Calendar



Source: Corporate Presentation

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.



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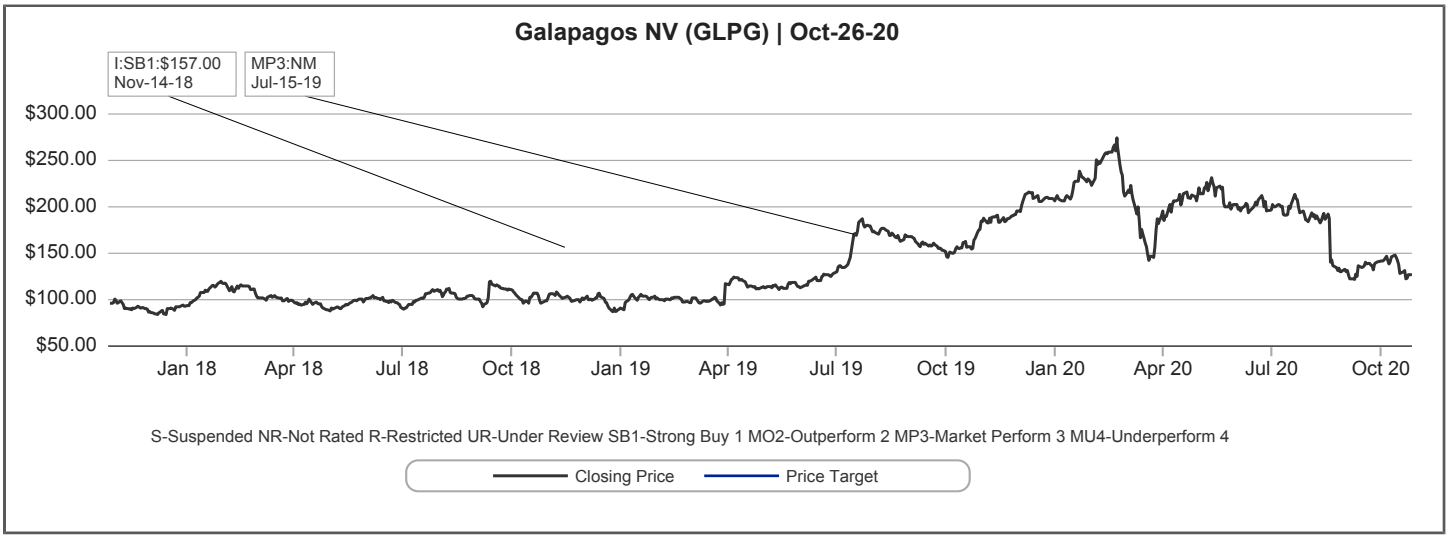

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Galapagos NV
We value based on 5 year forward EV/sales.

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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.
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