

BIOPHARMA / IMMUNOLOGY AND METABOLISM

Looking for Seabiscuit: Strategic Assets in Immunology and Metabolism

• **Bottom Line:** We are positive on the immunology sector with its diverse indications, continuous innovation, and deep expertise, and are looking long for opportunities in challenging immuno-metabolism and metabolism sectors, in areas like NASH, obesity and diabetes. We are initiating our coverage with nine companies including GLPG, DERM, EQ, PRVB, CBAY, MDGL, and MNKD rated Outperform, VKTX rated MP and ICPT rated Underperform. Our asset-indication framework incorporates available data as the asset progresses through its lifecycle, bridging development risk to commercial value.

• **Galapagos, OP, \$140 PT.** With a proven track record of success spearheaded by filgotinib, we like the forward momentum GLPG continues to generate with a leading first in/best in class IPF drug in Phase 3 and a pipeline with major optionality in OA and other I&I indications. Their creative success is grounded in their heavily tested RNAi platform, world class in-house chemistry and a cutting edge scientific team backed-stopped by their experienced and seasoned management group.

• **Dermira, OP, \$20 PT.** Dermira is commercializing Qbrexza, targeting primary hyperhidrosis, a largely untapped, but needy market. Qbrexza penetration prior to evolution of the competitive pipeline critical to Dermira's value inflection. Lebrikizumab, an anti-IL13 antibody, acquired from Roche/GNE, is in Phase 2b in atopic dermatitis (AD), with April readout expected. Early proof of concept in Phase 2a, solid biological rationale, and strong market demand suggests Lebri can capture its fair share in growing AD market.

• **Equillium, OP, \$16 PT.** Clinical stage biotech chasing CD6, a surprisingly underdeveloped biological pathway in immunity, to regulate runaway autoimmunity. Antibody asset has proof of concept in humans, has room to move in dosing and is smartly targeted in the right indications and right patients. Team is experienced, moving quickly, and leveraging a non-dilutive unique partnership model to generate value. They are

Key Stats: **Biopharma / Immunology and Metabolism**

S&P 500 Health Care Index: 1,060.16
S&P 600 Health Care Index: 2,930.10

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Ticker	Rating	Price	Price Target Current	Mkt. Cap (MM)	Current Rev Est.		Current EPS Est.	
					2019	2020	2019	2020
CBAY	OP	\$9.97	\$22.00	592	0.0	0.0	(\$1.55)	(\$1.72)
DERM	OP	\$7.46	\$20.00	314	\$21.0	\$50.0	(\$5.73)	(\$4.13)
EQ	OP	\$6.04	\$16.00	105	0.0	0.0	(\$1.09)	(\$1.53)
GLPG	OP	\$101.04	\$140.00	5,486	€153.8	€198.6	(€3.90)	(€3.18)
ICPT	UP	\$99.03	\$70.00	2,936	\$257.6	\$266.3	(\$7.31)	(\$4.68)
MDGL	OP	\$122.99	\$165.00	1,894	0.0	0.0	(\$4.04)	(\$4.61)
MNKD	OP	\$1.47	\$3.00	235	\$119.2	\$125.0	(\$0.17)	(\$0.13)
PRVB	OP	\$2.26	\$6.00	85	0.0	0.0	(\$1.22)	(\$1.17)
VKTX	MP	\$8.77	\$10.00	627	0.0	0.0	(\$0.54)	(\$0.74)

Source: Company Information and SVB Leerink LLC Research
Revenues in MM.

building a portfolio in an asset, with big upside in Asthma, GVHD (graft vs. host disease) and other expected indications.

• **Provention bio, OP, \$6 PT.** Small team of experienced drug developers, aggregating assets through leveraged strategic partnerships. They have built a deep and broad portfolio of late stage I&I assets that have or soon will have proof-of-concept. 2019 is catalyst filled. If successful, the team will have the first drug preempting Type I Diabetes; a first in class celiac drug; the first oral Crohn's drug; a treatment for resistant ulcerative colitis, and a SLE (systemic lupus erythematosus) bispecific targeting pathogenic B cells. While we do not expect all of these assets to meet their goals, the team are operational and development experts, giving them a real shot at success.

• **Intercept, UP, \$70 PT.** Intercept is trailblazing the FXR pathway for PBC (primary biliary cirrhosis) and NASH (non-alcoholic steatohepatitis), leading innovation in both markets. Despite successes, its OCA has challenges, and remains a hard pill to swallow, with pruritus, add-on lipid control, and a marginal efficacy. Intercept will have to manage a pricing quandary without destroying value in their PBC and NASH markets. FDA is likely to give the drug a pass as the lead molecule for the brand new Liver division; however, physicians, payers and patients may ask for more.

• **CymaBay, OP, \$22 PT.** Targeting the PPAR – delta axis with Seladelpar, a potent and selective agonist, CymaBay is demonstrating impressive efficacy and safety profile in PBC and pre-clinically in NASH . We like CymaBay's focused strategy of pursuing PBC as a bridge to NASH, sequentially positioning Seladelpar as a candidate for combination with an anti-obesity backbone. CymaBay has a catalyst-rich next year-and-a-half with two step-up data read-outs in NASH, including upcoming top-line NASH Phase 2 MRI-PDFF results.

• **Madrigal, OP, \$165 PT.** MGL-3196 is chasing a dream of targeting thyroid signaling with a β -selective agonist. THR β -selective agonism is useful for hyperlipidemia and to burn fat in the liver; thinking NASH, Madrigal is all-in for hitting the fibrosis or NASH resolution bars, to gain access to the prize of reversing the hepatic metabolic phenotype. This is a big bet on the pathway, it's a big bet on fatty liver as the major causative driver of NASH fibrosis and it's a big hairy bet on the safety of this one compound. They have patient data, and will accumulate the numbers to prove safety in time.

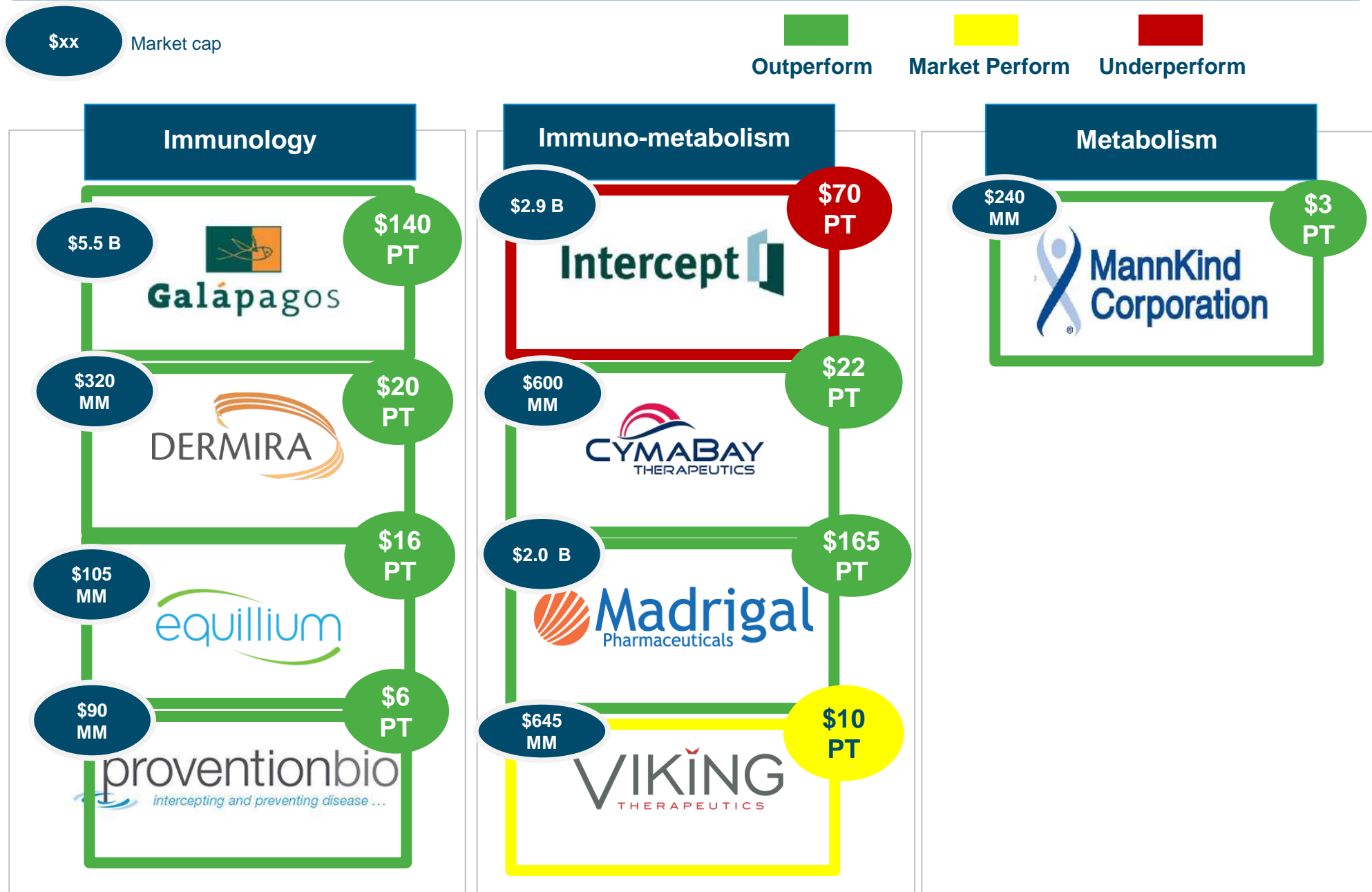
• **Viking, \$10 PT.** Viking is positioning VK2809, a hepatic prodrug, thyroid receptor β -selective agonist for NASH, as they pursue an IND with the GI division, to start Phase 2b trials this year. Early results are directionally promising, but limited. VK2809 has published the most extensive datasets across animal species for any beta selective product to date. VK5211 is a selective androgen agonist. No other drug has demonstrated the magnitude of anabolic effects in aging adults that VK5211 has shown; if Viking can find its way in sarcopenia, they may have a second winner.

• **MannKind Corporation, OP, \$3 PT.** This is a 'do or die' year for MannKind. Our specialists say they have the best fast acting insulin on the market. Period. The company and Afrezza are being relaunched



with new leadership recruiting new blood from big experienced pharma companies, a devoted salesforce, new sales strategy, same patient minded doggedness. With monitors and enormous amount of data becoming available, patients will see how off they are in their postprandial time in range. Afrezza can fix that. The promise of their technosphere inhalation platform was confirmed with the United Therapeutics deal in PAH; MannKind has >20 more assets like them sitting on the shelf. We recommend jumping on their relaunch.

Our coverage



Our take: immunology and metabolism



\$140

OP

\$5.5 B

Our Take:

- Proven track record of success, with one almost in the bag (Filgotinib), with a strong partnership, paving the way into commercial world
- Leading with a first in/best in class IPF drug in Phase 3
- Pipeline with huge optionality in OA and other indications
- I&I focus, creative targeting and world class in house chemistry
- Experienced, seasoned management team; amongst the best European scientific teams in the world



\$16

OP

\$105 MM

Our Take:

- Chasing CD6, a surprisingly underdeveloped biological pathway in immunity, to retune and regulate runaway autoimmune pathways, especially T cells
- Antibody asset has proof of concept, has room to move in dosing and is being smart targeted in the right indications for right patients
- Team is experienced, moving quickly, leveraging non-dilutive unique partnership model to generate value
- Portfolio in asset, with big upside in Asthma, GVHD and other undisclosed indication



\$20

OP

\$320 MM

Our Take:

- Recently approved, best-in-class Qbrexza is commercial stage play in primary hyperhidrosis, an untapped market, with significant unmet need
- Improved visibility on Qbrexza launch with robust market penetration prior to competitive evolution of the current pipeline is critical to Dermira's value inflection
- Lebrikizumab, an anti-IL13, acquired from Roche/GNE is in Phase 2b for atopic dermatitis, with earlies POC with potential to capture its fair share in growing AD market



\$6

OP

\$90 MM

Our Take

- Team of highly experienced developers, aggregating assets through leveraged strategic partnerships
- Built a deep and broad portfolio of late stage I&I assets that have/ will have proof-of-concept
- If successful, they will have first drug preempting Type I Diabetes; best in class celiac drug; first oral Crohn's drug; an asset in resistant ulcerative colitis, and a SLE bispecific
- Team are operational and development authorities; the year is catalyst filled

\$xx

Price Target

\$xx

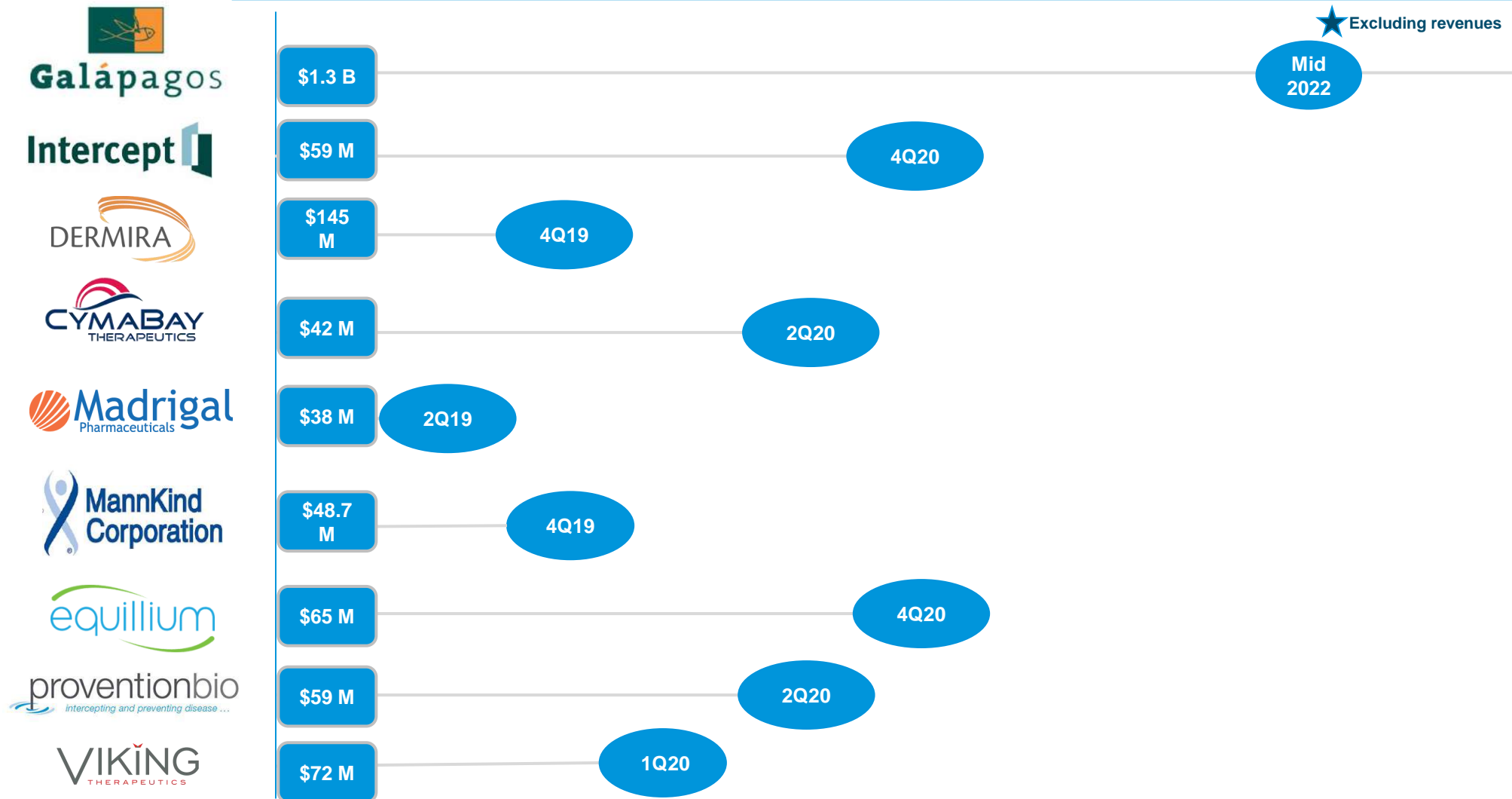
Rating

\$xx

Market cap

Our coverage: immunology and metabolism

Forecasted cash runway



A few perspectives on immunology therapeutic landscape

Lessons learned

- There is an enormous amount of experience in I&I; learnings from failed trials (lupus), creates upside for those with a strong heart

Cancer spillover

- The greatest experiment in medicine is being conducted in IO; learnings will be applied to I&I diseases; in addition overcapacity in oncology is being applied to I&I

New and old modalities

- Antibodies have had a terrific run, but small molecules are making a comeback for I&I, promising oral dosing, ease of travel, transport and safety of dose withdrawal

'Reset' still a dream

- The dream is to reset the dynamics of the immune system. We can tinker with it, but we cannot reset it in a targeted way

New indication landscapes

- The ladder of indications being targeted in I&I is expanding (atopic dermatitis, vitiligo, alopecia), partially because we can, partially because we must

Tip is not the iceberg

- Our ability to fingerprint the immune phenotype is in its infancy; made difficult by the fact that much of the immune system resides in peripheral tissues, inaccessible to sampling

Room for improvement

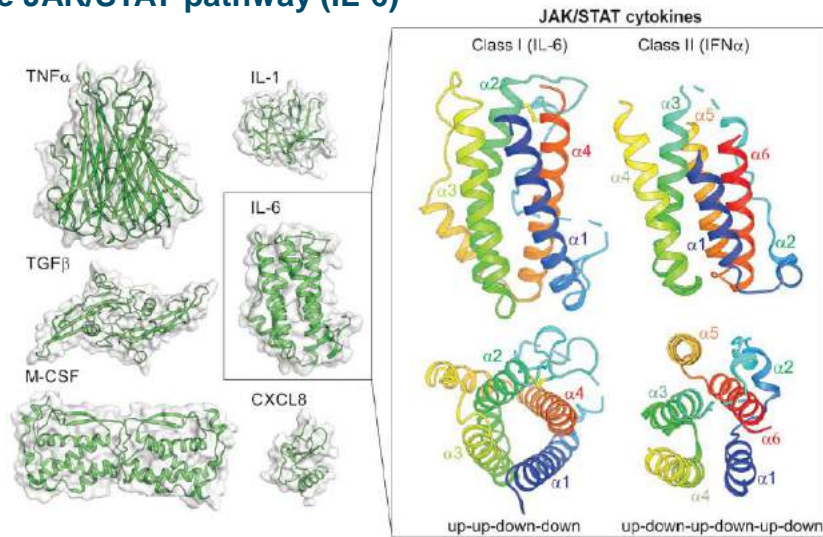
- The best RA drugs last 4-7 years and have to be switched, most RA patients have to take additional medicines to combat pain and stiffness; we can do better for them; combinations make sense but are too dangerous, we need better targets functioning in the right windows

Sharp edge of generic tip-over

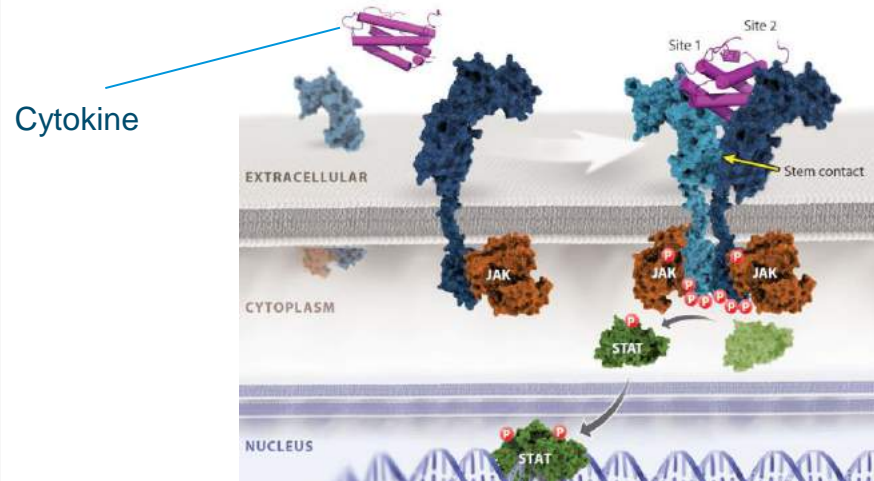
- You remember CV? We are not quite there in I&I but the battle is being raged with biosimilars, payers, asset monoliths, in the frontlines; Forecasting outcomes of these battles are speculation at this point

JAK-STAT signaling at the heart of the immune system

Structures of members of the TNF α -family, TGF β -family, IL-1-like cytokines, chemokines (CXCL8), cytokines that signal through receptor tyrosine-kinases (M-CSF) or the JAK/STAT pathway (IL-6)

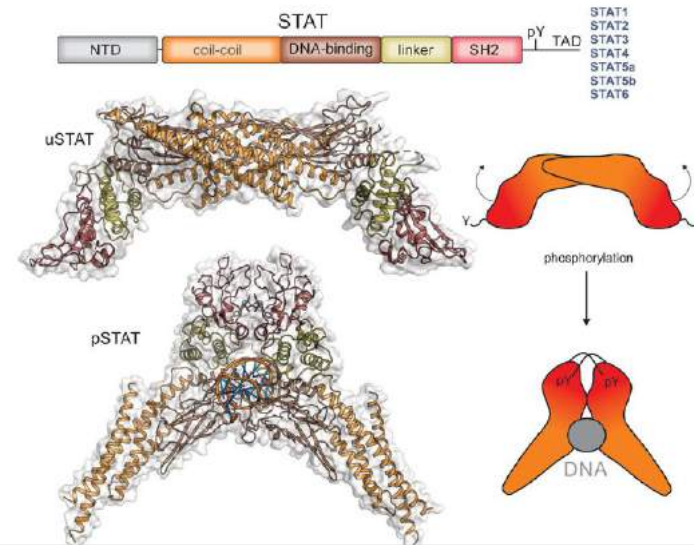
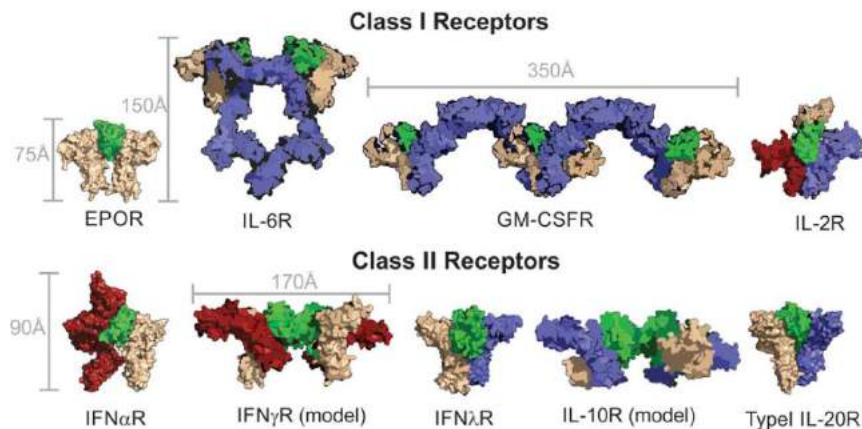


Cytokine receptor–ligand engagement, dimerization, and signaling.



Signal Transducers and Activators of Transcription (STATs) are a family of latent transcription factors that are activated by phosphorylation following cytokine exposure

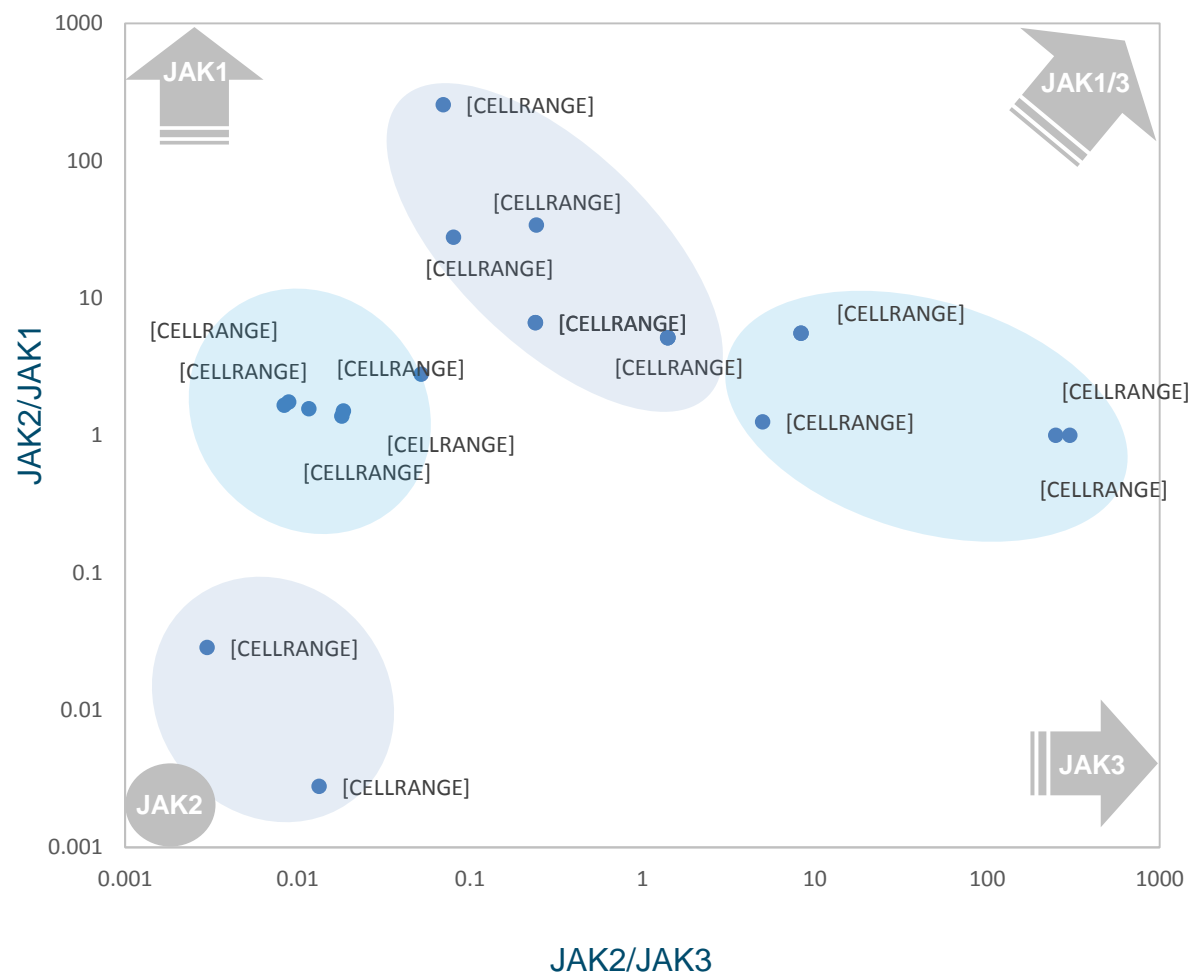
Structures and models of a diverse range of cytokine:receptor complexes



Understanding JAK selectivity

JAK selectivity with an eye for 1 and 3

Ratio of published IC₅₀'s across JAK inhibitors



Most approved or pipeline medicines hit multiple kinases, albeit with varying potencies

While potencies vary it is very difficult to draw conclusions regarding clinical safety and efficacy

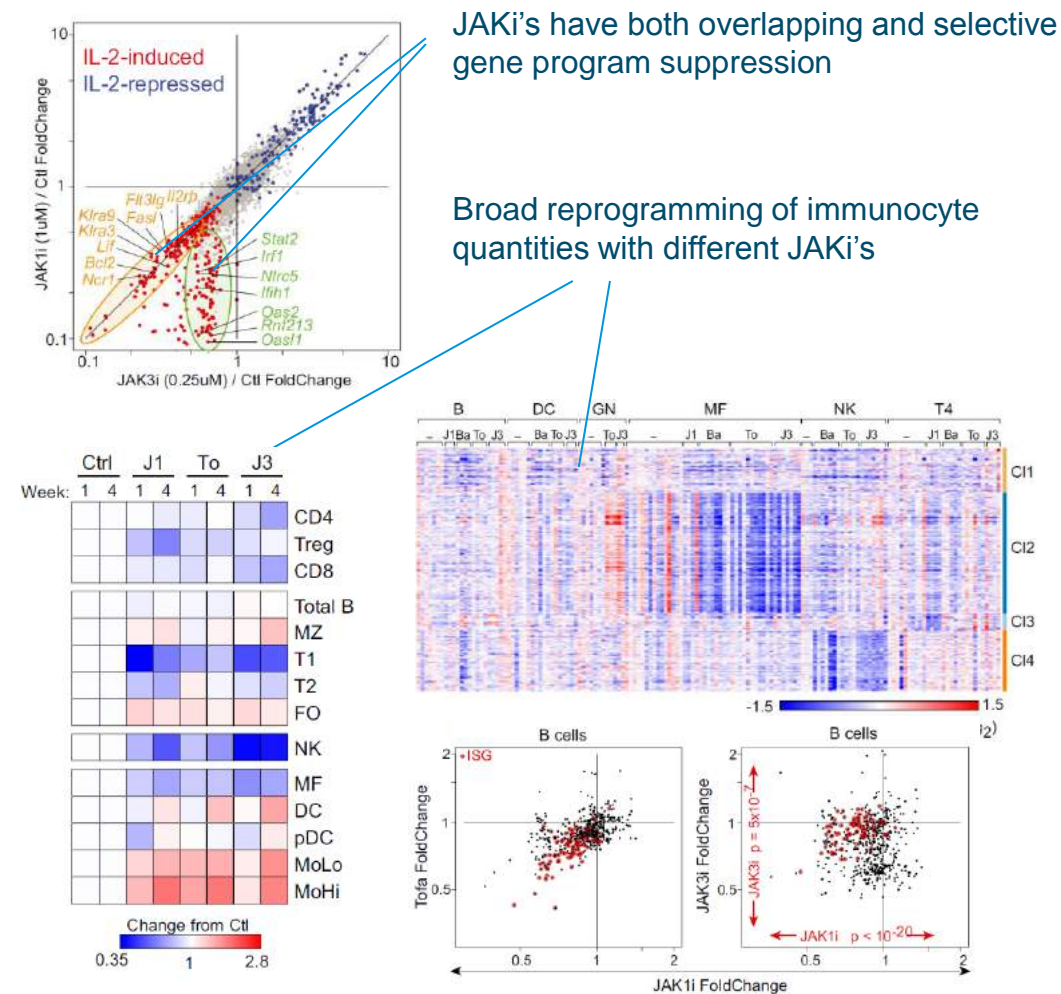
Strategies have veered from expedience to highly selective inhibitors (which are making their way through clinic)

Assays vary, and depending on properly using ATP at cellular Km's vs high ATP (lots of various and misunderstanding of IC₅₀'s due to these disconnects)

Full coverage of a kinase is great but sometimes a weaker profile provides a broader therapeutic window

Understanding JAK selectivity: a network effect with nuances

JAKi's have a profound impact on immunogenomics across cell types; nuances exist that will likely differentiate one inhibitor from another, which are unlikely to be identified in simply enzyme or cellular assays



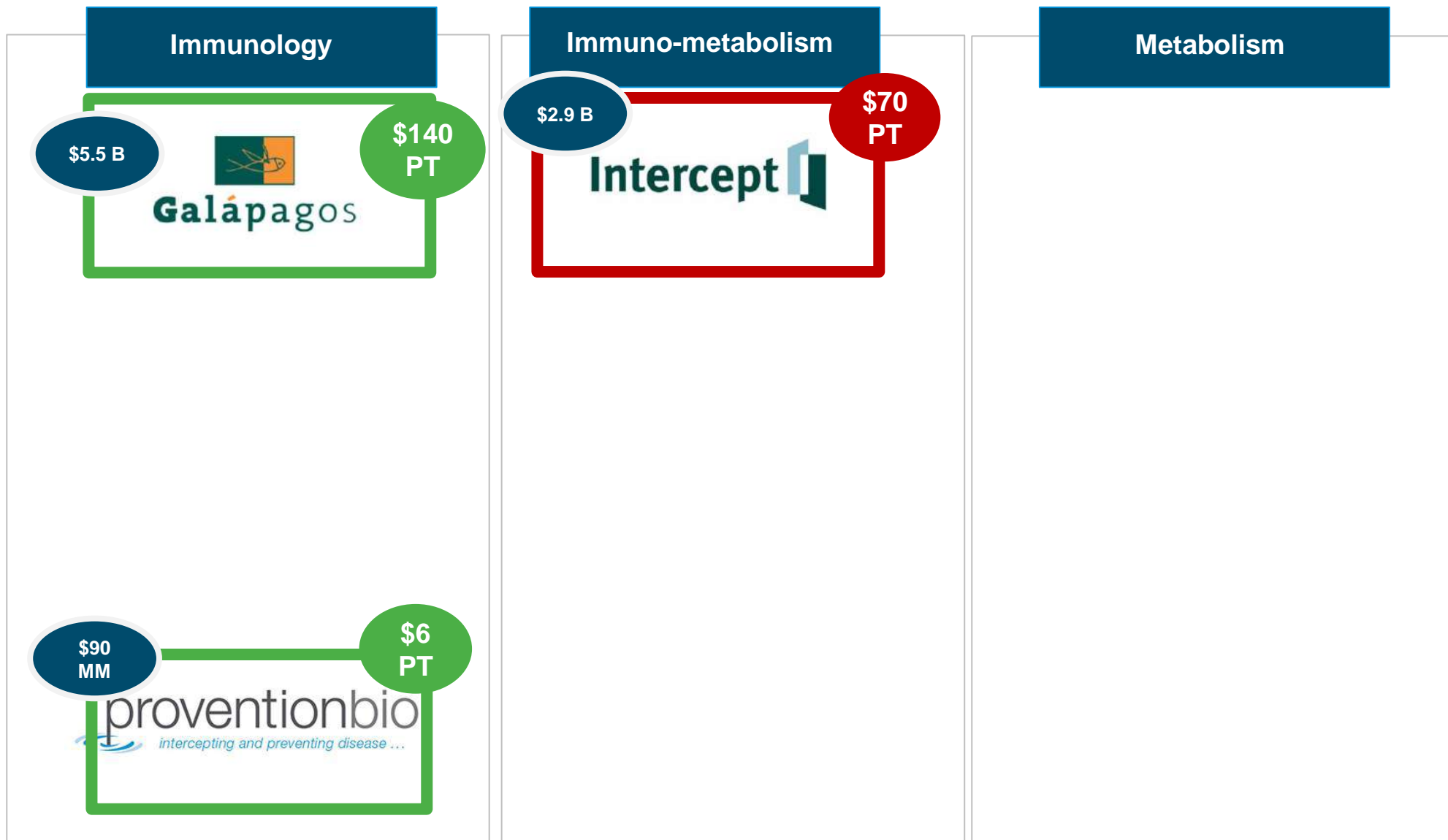
Implications of network effects of JAKi:

1. whether on cells or genes, the effects are broad but subtle, overlapping between compounds, even compounds that target single JAK isoforms with high specificity
2. the signaling and transcriptional network adapts to repeated JAK blockade, with the drug's effect persisting even after the compound has cleared
3. when two JAK isoforms are involved in signals from a given cytokine, selectively blocking one or the other has a different impact on that cytokine's overall signature
4. TH1/17 and T cells are important, but innate mechanisms including NK cells, have a important contribution to observed effects of JAK inhibitors
5. isoform-specific JAKi will not provide sharply delineated blockade of a specific pathway, but quantitative nuances of network-level effects, which may differentiate therapeutic windows relative to adverse events

Our coverage: Highlights

\$xx Market cap

■ Outperform
 ■ Market Perform
 ■ Underperform



GLPG: Pursuing large markets with drug pipeline

	Pre-IND	Phase 1	Phase 2	Phase 3	NDA	Market
Filgotinib	Rheumatoid arthritis, Crohn's disease, Ulcerative colitis					2020 & 2021
Idiopathic Pulmonary Fibrosis	GLPG1690 & GLPG1205					2022
Osteoarthritis	GLPG1972					2025

Drug	Indication	Event	Timing	Importance
Filgotinib	RA	FINCH1 and FINCH3 Phase 3 readout	1Q19	Large
Filgotinib	Sjogren's syndrome	Phase 2 proof of concept data	1H19	Medium
Toledo	Undisclosed	Announce program updates	2H19	Medium
Filgotinib	Crohn's Disease	Complete enrollment in Phase 3 DIVERSITY1 Trial	2H19	Medium
Filgotinib		Program updates at major medical conferences	2H19	Medium
Filgotinib	Ulcerative colitis	Topline results from the Phase 3 SELECTION trial	2H20	Large

PRVB: Pipeline and Catalyst Horizon Forecast

Drug	Preclinical	Phase 1	Phase 2	Phase 3	NDA/BLA	Market (Est. Launch)
PRV-031 teplizumab for Type 1 diabetes	anti-CD3 mAB					2024
PRV-015 Celiac's Disease	anti-IL-15 mAB					2025
PRV-6527 Crohn's Disease (CD)	Oral CSF-1R inhibitor					2024
PRV-300 Ulcerative Colitis (UC)	anti-TLR3 mAB					2025
PRV-3279 Systemic Lupus Erythmatosus (SLE)	CB32B and CD79D DART					2028
PRV-101 Type 1 diabetes and coxsackie virus (CV) infections	CVB vaccine					2029

Drug	Catalyst	Expected Date	Significance
PRV-300	Phase 1b PULSE study top-line results	2Q19	High
PRV-6527	Phase 2a PRINCE study top-line results	4Q19	High
PRV-031	Initiate Phase 3 trial	2H19	Medium
PRV-3279	Initiate Phase 1b/2a trial	4Q19	Medium
PRV-015	Complete GLP Tox studies	4Q19	Low
PRV-101	File IND	2H19	Low
PRV-015	Initiate Phase 2b trial	1H20	Medium
PRV-300	Initiate Phase 2a trial	1H20	Medium
PRV-6527	Initiate Phase 3 trial	1H20	Medium
PRV-101	Initiate Phase 1 trial	1H20	Medium

Strong push into IPF Creates the Path Forward for GLPG Past Filgotinib

Ticker	SVB Leerink Rating	SVB Leerink PT	Date	Close	52-week		Market Cap (B)	Cash/share	Cash & Equiv. (M)
					Low	High			
GLPG	Outperform	\$140	2/20/2019	\$101.04	\$85.00	\$122.28	\$5.6	\$24.78	54,299

Company Overview

Galapagos at a Glance:

- Belgian based company founded in 1999 based on a proprietary drug discovery platform
- Their platform has produced drug candidates targeting IPF, inflammatory diseases, OA, atopic dermatitis, and opened up partnerships with leading pharmaceutical companies.
- Trades on the Euronext (GLPG) and as ADRs on the NASDAQ exchange (GLPG)

Financials:

- €1.3B in cash as of 3Q18
- Market cap €4.9B (\$5.5B)
- €285M projected 12-month cash burn
- Projected cash runway into 2023

Valuation Methodology:

- Sum of the parts valuation applying an 11.95% WACC calculated discount rate and 2% terminal growth rate.
- Each drug's constituent values are determined by a probability weighted scenario analysis based on our independent asset profiles

Investment Thesis

- We believe GLPG has a potential best-in-care drug in GLPG1690 that has the potential to become the standard of care in IPF treatment.
- With limited effective treatments in IPF, GLPG1690 carries blockbuster potential with following its projected 2022 market launch.
- Filgotinib's superior safety profile versus other JAKi's makes it a potentially best-in-class JAKi that has an opportunity to compete with anti-TNF agents in RA and IBD.
- While view gaining approval to treat OA highly unlikely given the history of the clinical efforts, we cannot ignore the massive opportunity should GLPG1972 gain regulatory approval.
- We expect GLPG's proprietary discovery platform to continue to produce uniquely profiled drugs that will keep the doors open to partnership opportunities

Expectations

Value creation:

- With Phase 3 trials being the key intermediate term driver, we anticipate execution updates regarding recruitment status and DMC recommendations
- Announcement of new programs such as the Toledo compound will continue to expand GLPG's pipeline

Likelihood of technical, regulatory, access, and commercial success

- We assign probabilities of regulatory approval of 40.7%, and 68% to GLPG1690 and Filgotinib, respectively. These drugs shift GLPG towards a meaningful commercial market profile

Risks:

- Regulatory and commercial path for filgotinib is under the control of a collaborative partner, Gilead
- Filgotinib fails to be differentiated against other JAK inhibitors
- Path forward for GLPG1690 as combination therapy in IPF leaves the backdoor exposed to monotherapy pursuit by competitors

Pursuing large markets with drug pipeline

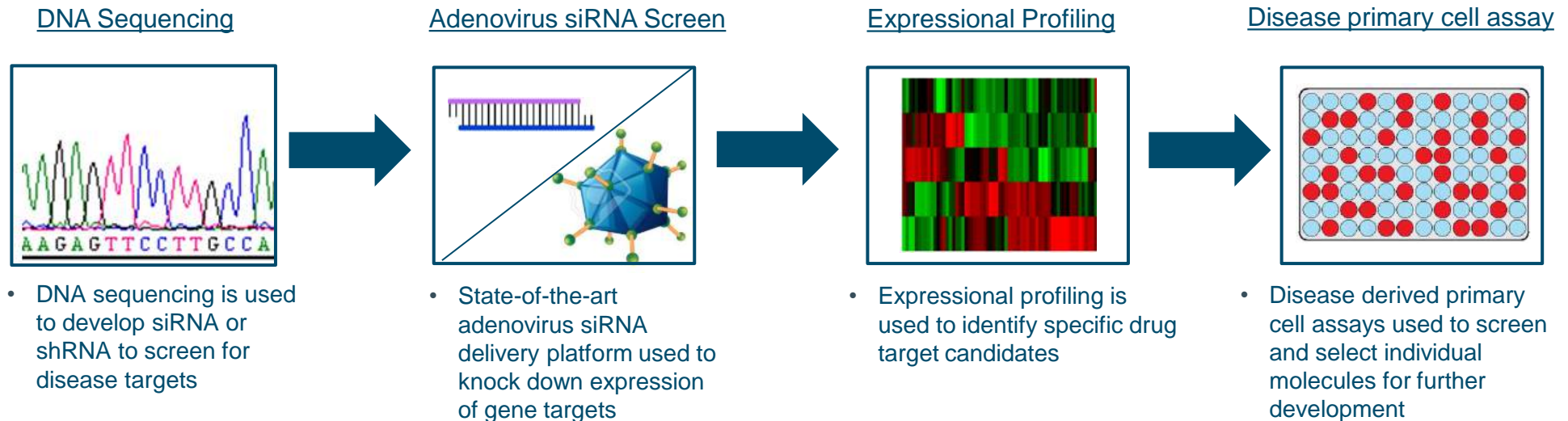
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Filgotinib	Ulcerative colitis	Topline results from the Phase 3 SELECTION trial	2H20	Large

Filgotinib- Pipeline in a drug

Indication	Pre-IND	Phase 1	Phase 2	Phase 3	NDA	Market (Est. Launch)
Rheumatoid arthritis (RA)			Phase 3 FINCH1, FINCH2, and FINCH3			2020
Ulcerative colitis (UC)			Phase 3 SELECTION1			2021
Crohn's disease (CD)			Phase 3 DIVERSITY1			2020
Psoriatic arthritis (PA)			Phase 2 EQUATOR			
Ankylosing spondylitis			Phase 2 TORTUGA			
Small bowel CD			Phase 2 SBCD			
Fistulizing CD			Phase 2 DIVERGENCE2			
Sjögren's disease			Phase 2			
Cutaneous lupus (CL)			Phase 2			
Lupus nephropathy (LN)			Phase 2			
Uveitis			Phase 2 HUMBOLDT			

Proprietary discovery platform creates near limitless drug targeting capabilities



- Discovery approach applicable to a broad range of diseases
- Able to scan thousands of gene targets per disease
- Enables high throughput identification of drug candidates targeting those gene products
- Drug candidates and core molecules can be enhanced using x-ray crystallography and drug target assays to validate chemical optimization of molecular behavior

Adenoviral Vectors Expressing siRNAs for Discovery and Validation of Gene Function

Gert-Jan Arts,¹ Ellen Langemeijer,¹ Rudi Tissingh,¹ Libin Ma,¹ Heidi Pavliska,¹ Kristina Dokic,¹ Richele Dooijes,¹ Emir Mešić,¹ Remko Clasen,¹ Frits Michiels,¹ Jan van der Schueren,² Mark Lambrecht,² Sofie Herman,² Reginald Brys,² Kim Thys,² Marcel Hoffmann,¹ Peter Tomme,² and Helmuth van Es^{1,3}

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Quantification Assays for Total and Polyglutamine-Expanded Huntingtin Proteins

Douglas Macdonald^{1,*,3}, Michela A. Tessari^{2,3}, Ivette Boogaard⁴, Melanie Smith³, Kristiina Pulli², Agnieszka Szynol⁴, Faywell Albertus⁴, Marieke B. A. C. Lamers³, Sipke Dijkstra⁴, Daniel Kordt⁵, Wolfgang Reindl⁵, Frank Herrmann⁵, George McAllister³, David F. Fischer^{4,†}, Ignacio Munoz-Sanjuan^{1,¶}

Functional screening of viral siRNA libraries in human primary cells

By Dr. Kara Bortone,
Dr. Frits Michiels,
Dr. Nick Vandegehuchte,
Dr. Peter Tomme and
Dr. Helmuth van Es

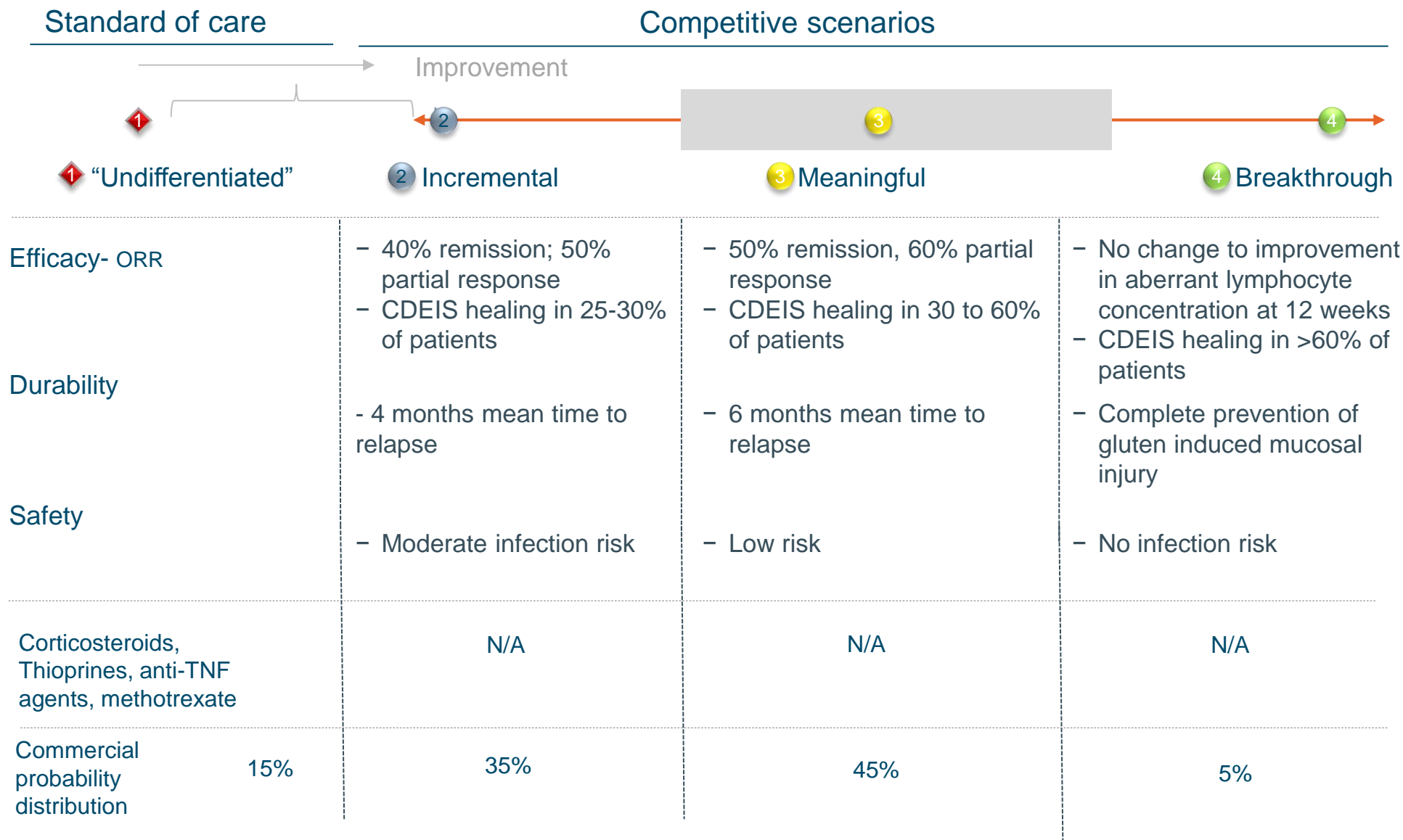
Drug DiscoveryWorld Fall 2004

The Orphan G Protein-Coupled Receptor 3 Modulates Amyloid-Beta Peptide Generation in Neurons

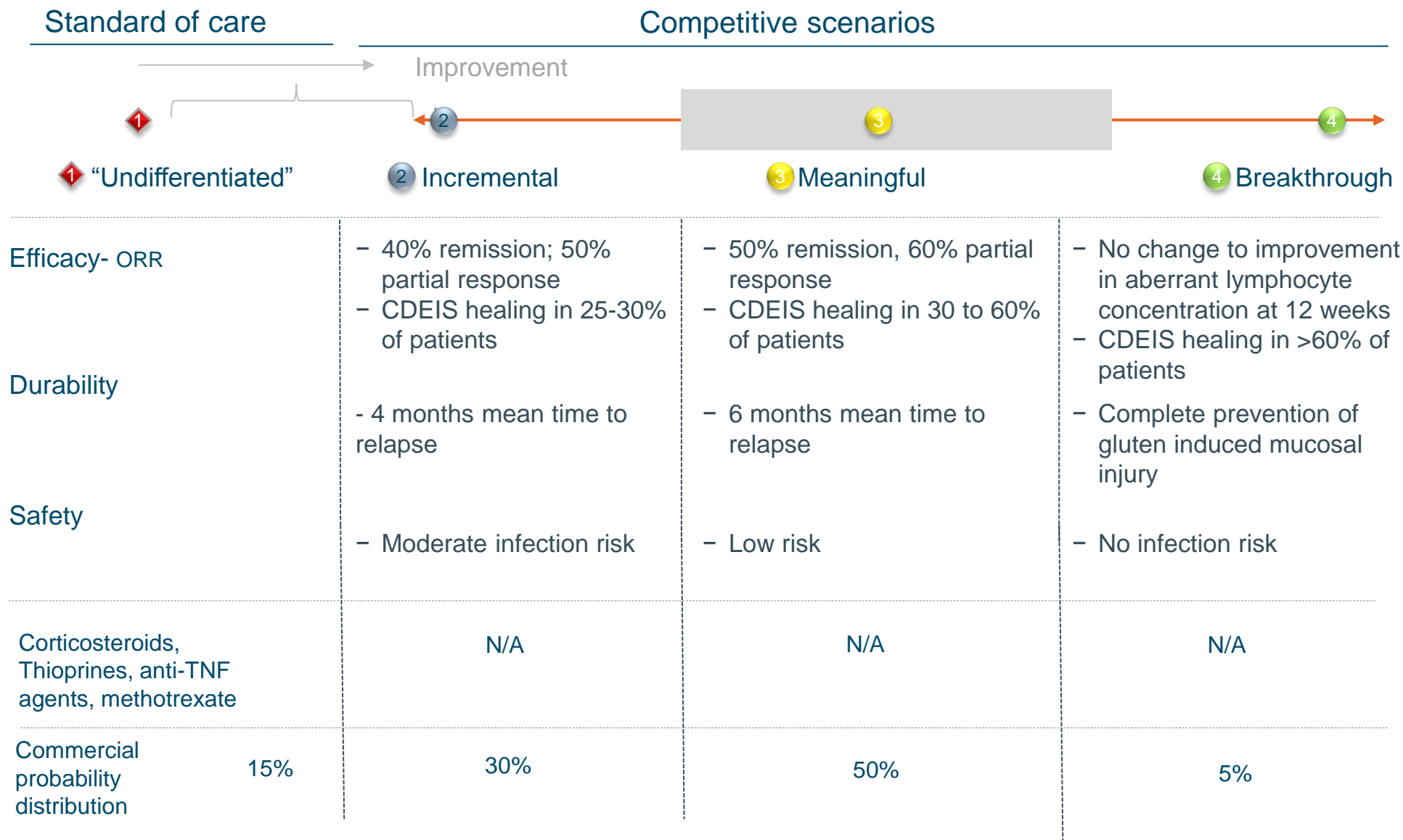
Amantha Thathiah,^{1,2} Kurt Spittaels,^{3*} Marcel Hoffmann,^{3,†} Mik Staes,^{3,‡} Adrian Cohen,^{3,§} Katrien Horré,^{1,2} Mieke Vanbrabant,^{1,2} Frea Coun,¹ Veerle Baekelandt,⁴ André Delacourte,⁶ David F. Fischer,^{2,||} Dirk Pollet,³ Bart De Strooper,^{1,2,||} Pascal Merchiers^{2,||}

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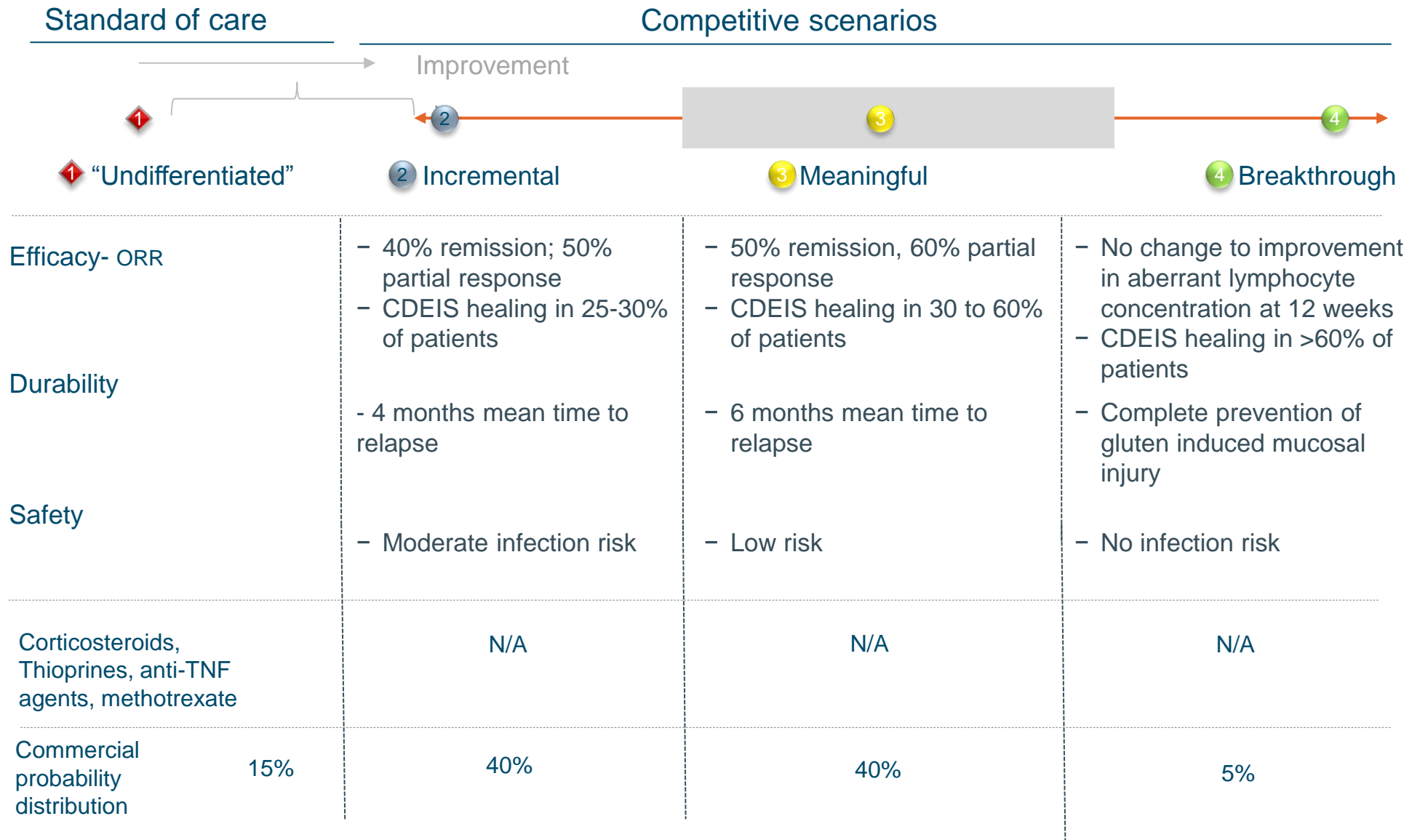
Filgotinib's drug profile in RA places it in potential competition with anti-TNF agents



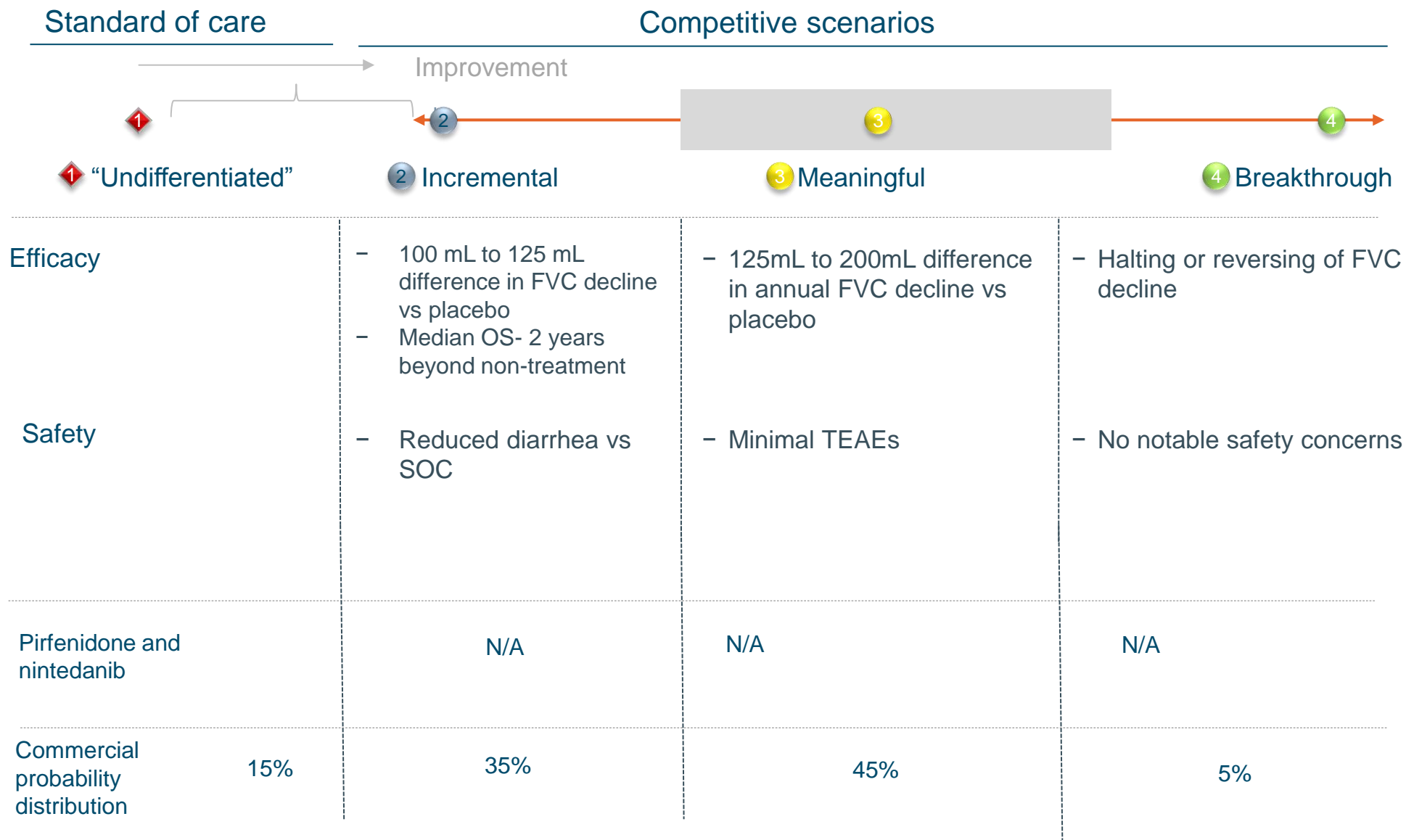
Filgotinib may potentially be the first oral treatment approved to treat CD



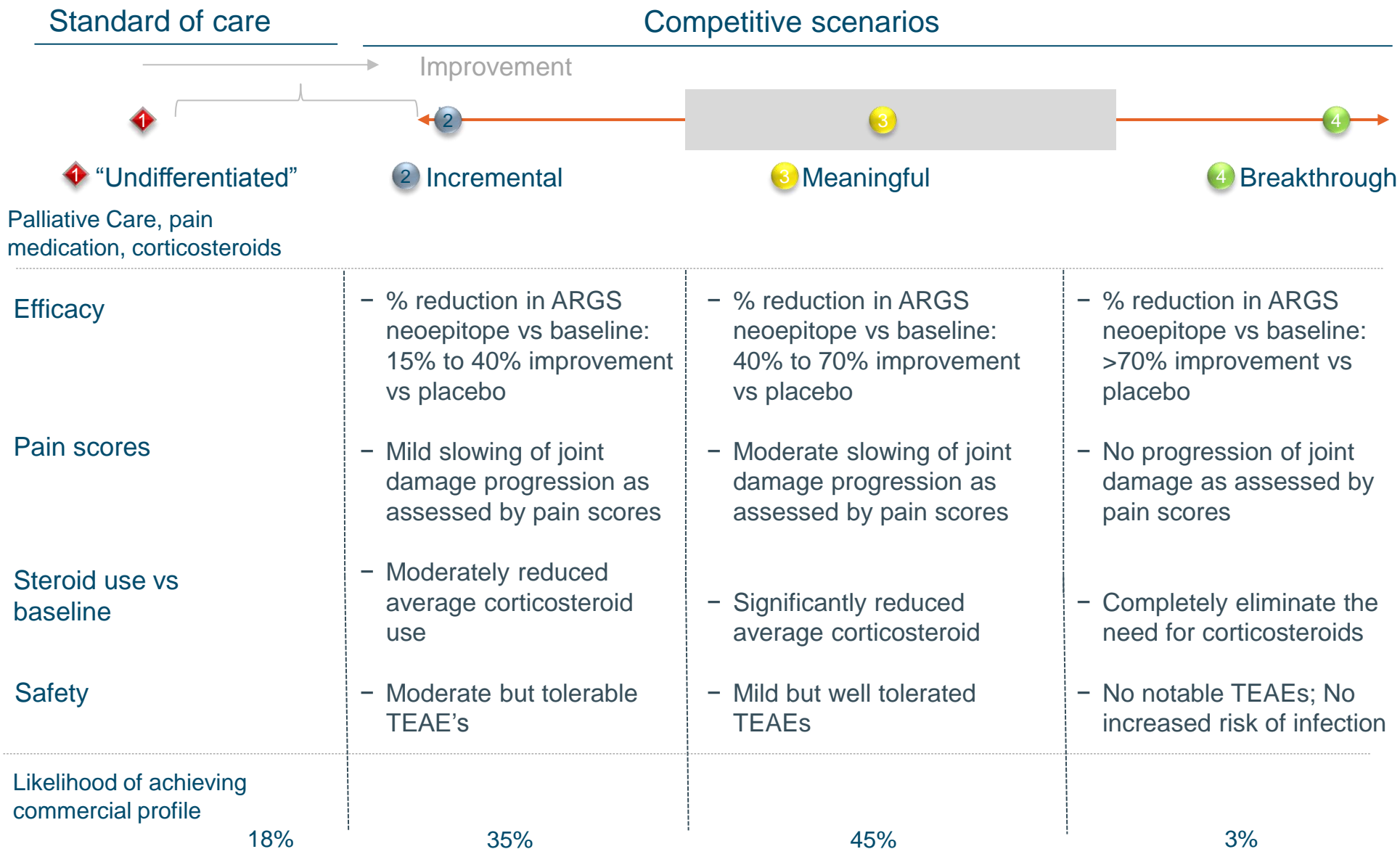
Although not the first JAK inhibitor approved to UC, filgotinib still carries best-in-class potential



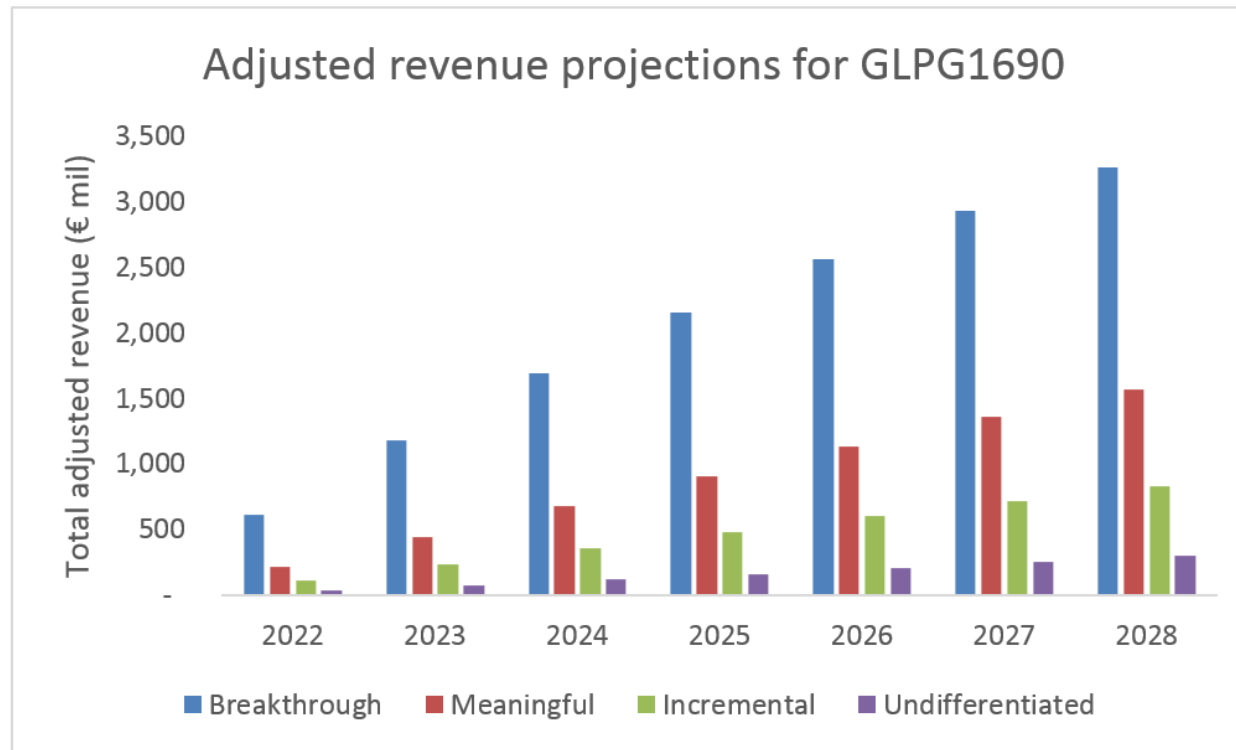
GLPG1690 Positioned to Enter a Weak IPF Market



GLPG1972 Targeting Big Opportunity In OA



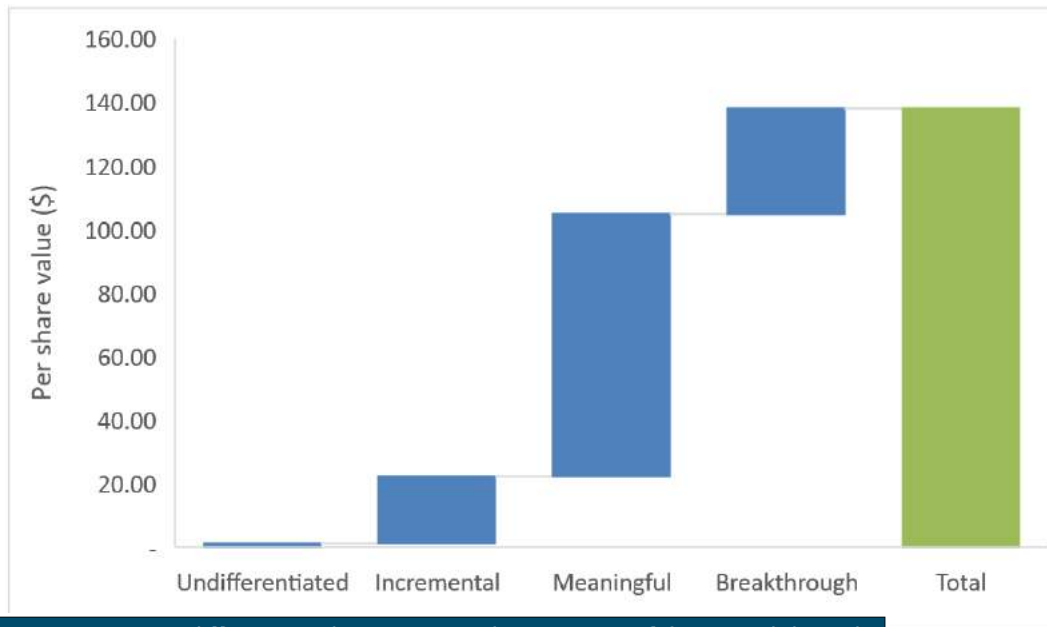
Adjusted revenues for GLPG1690 projected into 2028



	2022	2023	2024	2025	2026	2027	2028
Breakthrough	613	1,178	1,691	2,151	2,563	2,931	3,261
Meaningful	217	446	679	911	1,138	1,359	1,572
Incremental	114	235	357	479	599	715	827
Undifferentiated	36	76	118	162	208	254	300

- Revenues were adjusted based on a 40.7% probability of regulatory approval for an IPF drug in Phase 3
- The breakthrough scenario forecasts revenues in the case GLPG1690 becomes the standard of care and a backbone therapy for all IPF drug combinations
- At the other end of the spectrum, GLPG1690 undifferentiated from pirfenidone and nintedanib becomes relegated to patients who are intolerant to or not responding to standard of care.

IPF Valuation



Per share value (\$)	Undifferentiated	Incremental	Meaningful	Breakthrough
GLPG1690	23.10	69.84	135.63	300.49
GLPG1205	0.92	1.60	2.65	4.59
GLPG1972	3.09	6.71	10.22	15.73
Filgotinib	29.48	55.28	79.74	117.63
MOR106	6.95	6.95	6.95	6.95
Operations	(68.60)	(90.35)	(115.63)	(170.79)
Cash	27.96	27.96	27.96	27.96
Total	22.89	78.00	147.52	302.56
Commercial probability distribution	6.1%	27.1%	55.9%	11.0%
Commercial adjusted total	1.39	21.11	82.45	33.18
Sum of the parts total (\$)	140.00			

- Our \$140 PT was determined by a Sum of the parts valuation that applied a WACC calculated 11.9% discount rate and 2% terminal growth rate to revenues and cash flows projected into 2028.
- Revenues for each asset were adjusted independently twice
 - 1) By probability of regulatory approval
 - 2) By drug-specific
- A commercial probability distribution was determined based on a revenue weighted distribution of independent commercial scenarios projected for each drug candidate.
- GLPG1690 and filgotinib comprise a majority of the valuation.
- Galapagos held €1.3B in cash and cash equivalents as of the end of 3Q18. Pro forma cash was not applied to this valuation.

GLPG Risks to Valuation

Product risk

One or more of the clinical trials for filgotinib or GLPG1690 may fail to meet its primary endpoint necessitating a deeper decision into continued development in that particular indication. Additionally, any safety issues that occur within one trial for filgotinib may read negatively across the entire filgotinib franchise.

Collaboration risk

Multiple products within GLPGs pipeline, including filgotinib and MOR106 are being developed and will be marketed away from GLPG's control. This gives GLPG limited ability to address situational issues surrounding the success of these drugs.

Regulatory risk

The FDA has previously indicated a belief in drug combinations as the likely future for IPF treatment. With this in mind, GLPG has pursued pivotal trial investigating GLPG1690 in combination with standard of care. While we believe this creates a safer path to approval, it nonetheless opens the door to potential competitors pursuing a path to approval as a monotherapy to significantly disrupt expectations for market competition

Financing risk

GLPG currently has no revenue producing products on the market. Though well capitalized over the near term, negative outcomes for any of their asset franchises may significantly impact their ability raise funds in the future.