BRYAN, GARNIER & CO

25th March 2020

Biotech

Healthcare

A first look at Covid-19 impacts

Accurately measuring the impacts of the prevailing economic crisis is of course somewhat premature.

That said, and barring new developments in coming weeks, we can nevertheless consider that the healthcare sector should be one of the least affected of all. Indeed, large cap pharmaceuticals and diagnostics companies could well rank among the stocks to buy as we move towards the late stages of the Covid-19 impact.

Here we try to address a slightly different objective. Across the different activities that healthcare companies are conducting, clinical and regulatory affairs seem to be more affected than others. A kind of unanimous statement seems to be saying that new trial starts are postponed but also that patient recruitment for trials has become more difficult while follow-up of patients might also be negatively affected. On the other hand, although regulatory agencies have sent reassuring messages to say that the review of medicines would not be impacted by the current situation, we have seen AdCom cancellations and doubt that inspections of manufacturing or R&D sites can take place normally at present.

When the two topics are considered, we estimate that the biotech sector is far more likely to feel the impacts than others and it is unsurprising to see it has already suffered more adversely on the markets. As such, our objective here is to navigate through the sector and discuss the various situations.

In the end, we come up with a selection of two favourite names for an offensive play and two for a defensive play: Innate Pharma and Genfit on the one hand, Genmab and Galapagos on the other hand. All four are Buy ratings and harbour significant upside to their respective FVs.

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BG Coverage

GALAPAGOS | BUY vs. NEUTRAL | EUR230 vs EUR225

GENFIT | BUY - Top Picks | EUR65

CELYAD | BUY | EUR49

GENEURO | BUY | EUR6,0 vs EUR6,3

GENMAB | BUY | DKK1900

INNATE PHARMA | BUY | EUR13,9 vs EUR15,6

MORPHOSYS | BUY | EUR140

NICOX | BUY | EUR19

ZEALAND | BUY | DKK228 vs. DKK260

DBV TECHNOLOGIES | NEUTRAL | EUR10

ABIVAX | CORPORATE | EUR37,5

BONE THERAPEUTICS | CORPORATE | EUR6,7

LYSOGENE | CORPORATE | EUR11

ONCODESIGN | CORPORATE | EUR15

OSE IMMUNO | CORPORATE | EUR7

SENSORION | CORPORATE | EUR2

THERANEXUS | CORPORATE | EUR13

TRANSGENE | CORPORATE | EUR3,2

VALNEVA | BUY | EUR5,2

Last Reports

OSE IMMUNO | 13/01/2020 | Winning by DEALing with early-stage programs
SENSORION | 09/12/2019 | Unique in the hearing loss space
ABIVAX | 03/12/2019 | Will ABX464 be partnered or Abivax acquired?
LYSOGENE | 07/11/2019 | The Genes for Success

Last rating Change:

DBV TECHNOLOGIES | 18/03/2020 | A confusing situation but DBV should have the answers
OSE IMMUNO | 13/01/2020 | Winning by DEALing with early-stage programs
GALAPAGOS | 08/01/2020 | Top Picks Q1 2020: Astrazeneca, Genfit, Korian, Roche
MEDIGENE | 08/01/2020 | Healthcare | Suspension and Dropping of Coverage
CASSIOPEA | 08/01/2020 | Healthcare | Suspension and Dropping of Coverage
GENFIT | 08/01/2020 | Top Picks Q1 2020 Healthcare: Astrazeneca, Genfit, Korian, Roche
CELLECTIS | 08/01/2020 | Healthcare | Suspension and Dropping of Coverage
SUMMIT THERAPEUTICS | 08/01/2020 | Healthcare | Suspension and Dropping of Coverage

Last FV Change:

MORPHOSYS | 20/03/2020 | Even if uncertainty remains, current valuation makes it de facto a BUY
DBV TECHNOLOGIES | 18/03/2020 | A confusing situation but DBV should have the answers
SENSORION | 13/03/2020 | One-year delay for SENS-401 Phase II results
BONE THERAPEUTICS | 12/03/2020 | At the stage to deliver

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Healthcare looks safer than other sectors but …

Sales and manufacturing very mildly impacted

From our interactions with the largest pharmaceutical companies, we understand that the impact of Covid-19 on healthcare is probably one of the smallest across all industries. The vast majority of companies under our coverage that have accepted to share some colour about the situation and the influence on their business are unanimous in saying that so far, it has had minimal if any impact on revenues.

If we try to get deeper into the analysis, then it is fair to underline that some are likely to benefit from the situation, including companies that manufacture diagnostic tests for Covid-19. For instance, Roche which is producing reagents at full capacity to feed public and private institutions equipped with its Cobas 6800 and 8800 Systems (about 850 in total are currently installed around the world). Our understanding is that the company is currently able to produce between 3.5 and 4 million tests per month. We do not know the exact average price of a single test but we can estimate the extra business generated at close to USD1bn mainly over H1 2020. Similarly, pharma companies are conducting trials to fully assess the benefit of marketed drugs for various diseases, in the context of Covid-19. Many are produced and made available for free, some might generate some revenues. Lastly, some companies are being funded by public or private groups to work diligently on vaccines or treatments, and although this is unlikely to generate profits it could result in very positive “halo” effects in terms of reputation and image.

In the other direction, to mention a few, our understanding is that it could be more difficult for companies involved in the CHC business simply because there is much less traffic in pharmacies and stores where these products are sold. Although anti-inflammatory drugs, analgesics and pain killers might be less affected, many other categories are likely to feel an impact. We would expect the vaccines business to be negatively impacted in the short-term, and not only vaccines for travellers, because vaccination can be delayed in many cases by a few months. However, longer-term, the impact could reverse, notably for those making flu vaccines since higher vaccination rates are likely in many geographies on a routine basis. Lastly, in the prescription drug field, we would assume that a hierarchy is likely across the various diseases with a very limited impact on acute care and severe diseases (like stroke, MI, cancer etc…) whereas some impacts could be seen when it comes to the diagnostic or new treatment starts for patients with less serious cases.

Manufacturing capabilities are unaffected, with people allowed to go to work and inventories significant enough to absorb any disruption if needed (weeks in the channels, months for key drugs within companies) but at this point, there is no impact on supply and for some drugs, production has even been ramped up as much as possible to meet demand. Even factories in China, France and Italy are running at normal rates, according to the different companies.

Marketing and promotion are significantly affected and companies have all mentioned a massive switch towards more digital use and less physical interactions, which was already a natural trend in the industry, largely underway in Asia in particular and now more globally implemented. Some time will be needed to see whether this has any influence. Once the entire industry moves in this direction, there is unlikely to be a meaningful change in the relative positions of the drugs in their respective markets. We could imagine however that (i) physicians have even less time than before to spend with sales representatives, which

should be positive for mature products and SoC; (ii) in the same vein, it could be more difficult for a company to promote new drugs.

Meanwhile, smaller companies in the biotech field look more vulnerable and although some might fall into the category of beneficiaries of the situation over the longer term, in the short term we might see more complex situations here and hence our decision to focus on them in this report.

Regulatory and clinical affairs to monitor more closely

A deeper investigation into the sector shows that the two fields where an influence has been noted by companies is:

(i) conduct of clinical trials;
(ii) interactions with regulators.

We look at the two one by one and see how companies might be impacted:

CLINICAL TRIALS AFFECTED BY THE CURRENT SITUATION

Firstly, companies have made public statements (Galapagos, Eli Lilly) to say they are stopping recruitment of patients and new study starts. This may of course impact the length of some clinical development programmes by a few weeks or months.

Most of them are saying that ongoing trials are continuing for patients who are already enrolled in the trials but obviously, there is legitimate questions about the quality of the follow-up although most of the trials are structured in such a way that if some data points are missing, there are approved and accepted methodologies per study design to fill the gap by extrapolating the data in-between two or three visits since it is not unusual in trials.

It is fair to anticipate an increased patient drop-out rate however that may require the extension of the recruitment period and an increase in the number of patients to fulfil the statistical analysis. In most cases, we expect the situation to delay the processes by a few months. However, there could be cases where the trials are not fully recruited yet and with some losses to follow-up in chronic diseases with long treatment duration and here the delay could be longer, with potential financing issues.

INTERACTIONS WITH REGULATORS ARE PROBABLY AFFECTED TOO

The second aspect of the business that is potentially impacted by the current situation concerns interactions with the healthcare authorities. Here also, we have heard cases of cancellations of advisory committees for instance which is unlikely to mean a simplified regulatory process but more probably a delay until a new one can be scheduled.

The EMA has stated quite clearly on its website that the measures implemented “do not impact EMA’s core activities related to the evaluation and supervision of medicines”. That said, if only because each approval requires a visit and inspection of the manufacturing site, we cannot see how it will be possible to approve new drugs in the current environment since travel is banned.

Filing, acceptance of filing and work on documents are activities that should not suffer too much but the final part of the approval process does not seem able to work at a steady pace. This again should be appreciated on a case by case basis.

Part 1: What is the situation for biotechs?

Unsurprisingly, biotech companies have taken a huge hit on the financial markets compared with large cap pharma companies, albeit with significant discrepancies across the sector and performances vs the peak in 2020 of between -25% and -70%. That said, it is fair to mention that some of the companies had troubles before the Covid-19 outbreak and with no link to the virus, which is just adding to a negative situation in some cases.

We have tried to contact all these companies. The feedback we have had has been very mixed in quality and in terms of the extent of answers provided.

That said, we have started out by making some comments on each situation and then attempted to pick three companies in each of the offensive and defensive categories that could be the winners and those to have among all European biotech companies.

But before we do this, we would like to stress and report here what the CFO of J&J stated in a recent interview: “Given the strength of its balance sheet, the current economic environment may even work in the company’s favour, allowing it to supplement or accelerate its development portfolio and pipeline”. The way we read into this sentence is that J&J might well opportunistically use the situation to undertake BD or M&A activity and especially, to buy biotech companies whose share prices have suffered too negatively from the crisis. He added: “As this lingers on, that may be a good opportunity for us to strike deals that were maybe at an impasse, where now maybe there’s less of an impasse because there’s a need on the seller side”. In other words, it is difficult to imagine that a full due diligence can be run in the current situation but if discussions were already ongoing, then some biotechs could have less negotiating power and be compelled to accept offers that would otherwise be rejected.

This is an aspect we should not forget. Some share prices are so low now that it might attract interest from buyers and notably from pharma companies.

Our two favourites in a defensive mode

GENMAB LOOKS LIKE A CLEAR WINNER IN THE CURRENT ENVIRONMENT

Genmab’s valuation is mostly based on a best-in-class multi-blockbuster oncology product (Darzalex), which is now considered as SoC in its indication (Multiple Myeloma). Even if marketing efforts are hindered by the Covid-19 outbreak, it should comfortably rely on its already established status. On top of that, the main catalyst this year will be the approval of the subcutaneous formulation of the drug, which is expected for the first half of this year, and unlikely to be impacted by the ongoing situation. In the end, this situation could even help Genmab by compromising the launch of isatuximab by Sanofi, a potential competitor to Darzalex.

The rest of the pipeline should remain largely untouched, especially since it is fully focused on oncology, a life-threatening condition, less impacted by the reallocation of hospital resources. Furthermore, it appears that the ongoing phase II of tisotumab vedotin is now fully recruited meaning that it should not be affected at all. The only cloud on the horizon is the approval of ofatumumab (with Novartis in the driving seat),

which could be slightly delayed. However, and given its small stake in Genmab's valuation (less than 10% of EV), a delay of even more than six months would not fundamentally impact the investment case. We are reiterating our Buy rating and our FV of DKK1,900. Genmab is a "must have" at the current price.

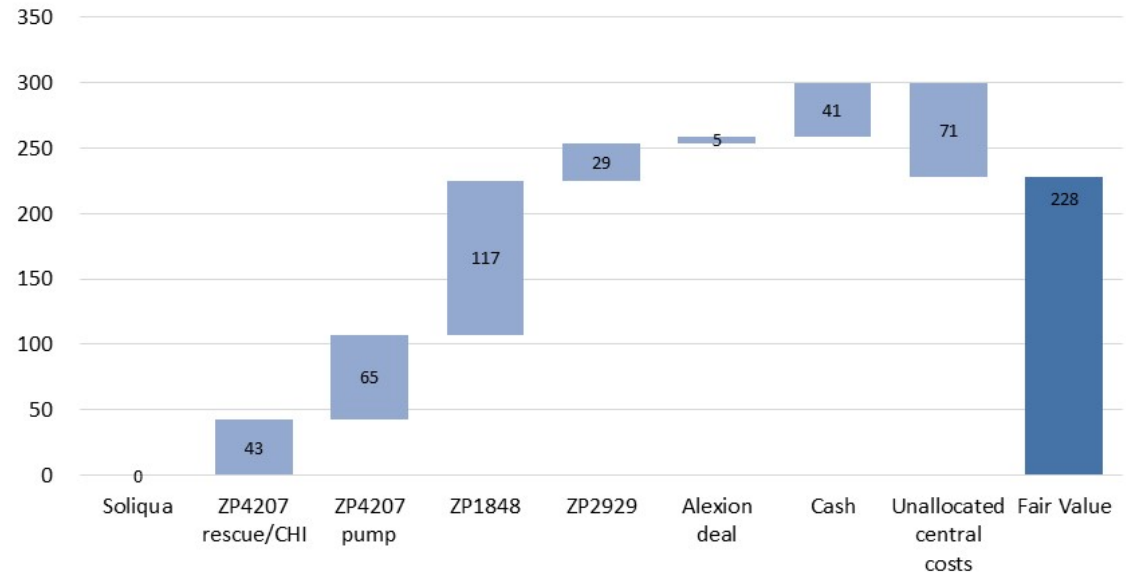
GALAPAGOS BACK TO AN ATTRACTIVE ENTRY PRICE

On Sunday, Galapagos announced that it had decided to pause recruitment for the filgotinib trials until further notice to help protect patient safety. Note above all that this does not impact the phase III SELECTION programme in ulcerative colitis the results of which are still expected in the second quarter of this year. However, no mention was made of the ongoing regulatory process for filgotinib. With a PDUFA date set for 17th July, the whole process could be affected by the ongoing outbreak. Even if our contacts with the company give us reason to believe that everything is going as planned, we estimate that a general shift in timeline could cost up to EUR15/share. To reflect the impact on the other filgo trials, we have already reviewed our central scenario, decreasing our FV from EUR235/share to EUR230/share. The heavy discount to FV therefore prompts us to adopt a Buy rating again (vs Neutral).

Others in the category would include:

Zealand: the group is another European biotech at a critical stage concerning the Covid-19 situation since several compounds are in late-stage clinical development and the most advanced asset is even on the verge of entering the regulatory phase. Our interactions with the company suggest no impact for dasiglucagon which ended its development as a rescue therapy for hypoglycemia and should be filed by the end of March, as planned. An approval is not expected before early 2021, giving plenty of time to the FDA to conduct all the required inspections and carry out the review. In CHI, given the small size of the trial, it is not expected to face delays either. The company was more cautious about glepaglutide in SBS, since the phase III trial is not fully recruited yet and some delays might be experienced to get the full number of patients in the trial. Today, we adjust our FV downwards to reflect higher-than-expected operating expenses in Q4 2019 and for 2020, communicated recently by the company and we also factor in a six-month delay for glepaglutide's review process (DKK9 per share) to be on the safe side.

Fig. 1: Waterfall Zealand Pharma

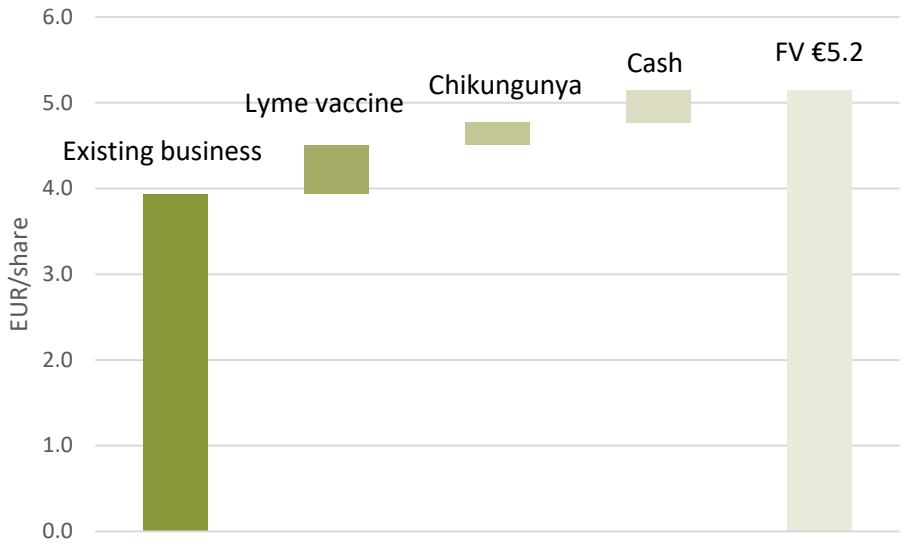


Source: Bryan Garnier & Co

Morphosys: the group is overly dependent on one asset, Tafasitamab. However, while Darzalex has been marketed for the past five years, Tafa is approaching the critical step of its approval. In the light of the recent postponement by the FDA of all routine facility inspections, we are not ruling out a potential impact on the ongoing process which was supposed to lead to a decision by 30th August. If so, this could delay the launch by few months, potential milestones to be paid by Incyte accordingly while most of the costs going forward will remain the same. In the meantime, we are not expecting any impact on the European process, given that approval is expected only around mid-2021. Overall, we estimate that a six-month+ delay could impact our FV by as much as EUR10 per share. If so, our FV would stand at EUR125/share, still representing significant upside to the current stock price.

Valneva: The company announced yesterday that the Covid-19 crisis would affect sales of its two vaccines on the market, i.e. Ixiaro and Dukoral. Since they are prescribed mainly for travellers, the negative impact on sales is obvious and will be between -EUR20m and -EUR40m (FY 2020 original guidance was of total sales between EUR125m and EUR135m). The impact will mainly occur in Q2 2020 since the outbreak really started in March. We have decided to factor in the maximum negative impact on sales since we do not know how long the Covid-19 outbreak will last. However, like many other healthcare companies, Valneva will also face a delay in the phase III initiation for the Chikungunya vaccine with a positive impact on associated costs. This will mitigate the impact on EBITDA. As such, Valneva expects 2020 EBITDA of -EUR50m (vs previous guidance for -EUR35m). With no delay in Chikungunya phase III costs, we estimate EBITDA would have been -EUR74m. We have made no changes to our sales figures for next year and after. The gross cash position should be EUR35m to EUR40m at year-end. Therefore, these changes lead to a decrease in our FV to EUR5.2 vs EUR6. We keep our Buy rating.

Fig. 2: Waterfall Valneva



Source: Bryan Garnier & Co

Lysogene: The vast majority of patients have been recruited and injected for the phase II/III AAVance (Sanfilippo syndrome). Only two patients remain to be injected according to our information. The company confirmed that they are already identified and since it is a one-day procedure for injection, we are confident that the trial will be fully recruited by mid-year as scheduled. The only disturbance from the Covid-19 outbreak will be for efficacy (every six months) and safety (every three months) visits, including some scheduled in April. Lysogene is looking at two options: 1/use of local centres close to patients' homes to perform these evaluations, or 2/a one/two-month delay for these visits. Since it is a two-year trial, these visit delays should not be of major concern if well discussed and documented with the agencies. Sanfilippo syndrome is a rare disease with no available treatment and we believe the FDA may agree to some modest protocol deviations. Last but not least, Lysogene has enough drug in stock to treat all the patients and recently raised EUR7.7m providing it enough cash until 2021. For this reason, we are ranking it in the "defensive" category.

Our two favourites in an offensive mode

GENFIT IS OUR TOP PICK AND WE REMAIN CONFIDENT IN ELAFIBRANOR'S PHASE III DATA

Genfit should have an answer from the FDA by 26th March regarding the addition of a new secondary endpoint to the phase III trial before any statistical analysis and readout can be completed. According to the company, no special message has been received from the FDA to alert over potential delays. The positive phase IIB clinical results published recently by Cymabay with seladelpar, a PPARδ, gave us more confidence that elafibranor should meet its primary endpoint of NASH resolution without worsening of fibrosis in the phase III study RESOLVE-IT. If the FDA is on time to give a green light regarding the addition of the new secondary endpoint, we believe the top-line interim results of RESOLVE-IT could be published in the first half of April. Finally, we estimate the gross cash position at EUR270m at the end of 2019.

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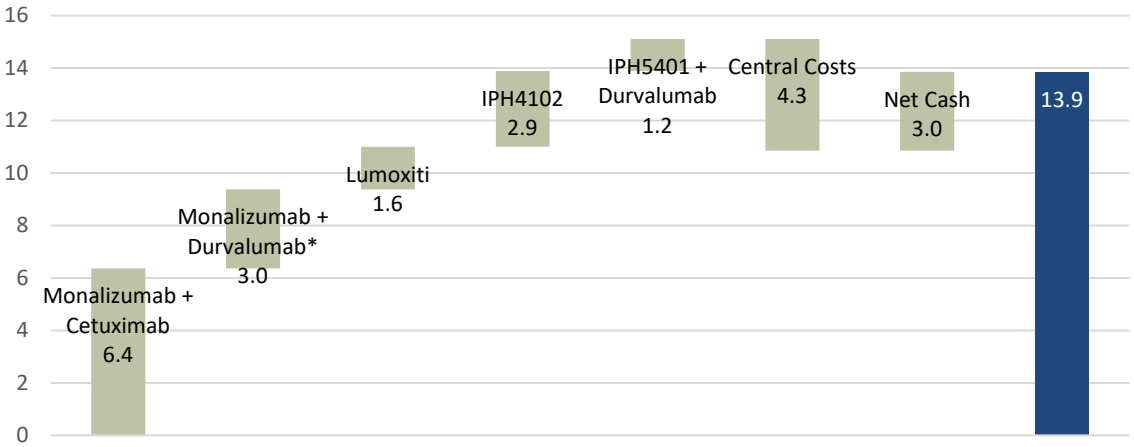
INNATE PHARMA BACK TO A VALUATION CLOSE TO ITS CASH

Innate Pharma might be impacted by the current situation. However, we have had limited feedback so far and our comments are therefore quite speculative. Since Innate Pharma is mainly working in the rare oncology space, we do not expect meaningful delays in the development of its drugs. The main negative consequence could actually be an incremental delay in the decision by AZ to start recruiting the first patient in the monalizumab SCCHN phase III trial, since most new trial starts are postponed until after the end of the Covid-19 outbreak period. This event triggers a USD100m milestone payment by AZ to Innate. Another six-month delay is estimated to have an impact of about EUR0.5 per Innate share, not so much because the milestone is perceived later in the year but because the filing, approval and launch would also be delayed by the same magnitude. Beyond this, we are also factoring in some delays in Lumoxiti's ramp-up to reflect the comments made by the company recently about its learning curve with the product. Despite this downward adjustment to our FV from EUR15.6 to EUR13.9, we are still well above the current share price which has recently tested all-time lows again. At the current levels, we are only a touch above the cash situation, especially if the upcoming USD100m from AZ is factored in. And it is therefore a legitimate question to ask AZ again: when could it be worth considering buying Innate Pharma rather than still paying millions in milestones?

Fig. 3: Waterfall Innate Pharma



Source: Bryan Garnier & Co

Others in the category would include:

Abivax: we have no feedback from the company about any potential delay in trials but of course, what Galapagos said in its press release resonates for Abivax because the two groups are operating more or less in the same fields with anti-inflammatory drugs. Of course, filgotinib is in the review process in RA and is expected to have phase III data in UC shortly and so only CD is truly impacted whereas ABX464 is in ongoing phase II trials in RA and UC and might face some delays, although the company stated recently that it was on track. The strength of the phase IIa data in UC does not prevent discussions with potential partners to move on and reach an agreement. This is still our central scenario because otherwise the clock is ticking and Abivax could face cash constraints, having said that visibility is limited to the end of Q2 2020.

The statement from J&J regarding opportunities to undertake M&A resonates particularly with Abivax since it is no secret that the company could be for sale if a good price is offered by a third party. Back in early December 2019 when we initiated the stock, we made various calculations about the price a bidder might be prepared to pay for access to ABX464 and although the high-end of the range may not be reachable anymore in the current context, we would say that our FV of EUR37.5 still represents a reasonable target. If nobody emerges however, then we see no other option for Abivax than a financial bridge in one form or another to obtain coverage of its operations at least until the end of the year.

DBV Technologies: The FDA Adcom scheduled for 22nd May has been cancelled. Before any new AdCom can take place, the FDA needs to visit the manufacturing site. Since this type of site inspection is on hold, we would forecast about three months' delay for the potential approval (PDUFA originally set for 5th August 2020). As a reminder, we downgraded our rating to Neutral (from Buy) and our FV to EUR10 (from EUR46) when the company announced the cancellation on 18th March. There is no reason at this point to further adjust our assumptions.

Geneuro: the group was among the very first to comment on a Covid-19 impact with the delay in the initiation of the last phase II with temelimab by the Karolinska Institutet in Stockholm due to an adverse allocation of resources in the hospital. We are assuming a six-month delay and have therefore reduced our FV to EUR6 per share.

Pixium: the company announced the postponement of its Feasability study both in Europe and in the US and explained there could be a delay (which we are convinced of) in the initiation of the pivotal trial PRIMAvera scheduled for the end of this year since the filing of the IND with the health authorities is scheduled by mid-year. We believe this filing will be delayed. Now, the hottest topic for Pixium with the existing situation is cash management. Pixium will benefit from French government measures for delayed payments. In addition, the company will seek non-dilutive financing. As a reminder, Pixium's cash position was close to EUR7m at the end of 2019 and we estimate that Pixium has enough cash until mid-2020.

OSE Immunotherapeutics: the company has both oncology and autoimmune disease franchises, with clinical studies at the recruitment stage. We currently expect the readout from the first step of the phase III study of Tedopi in CPI-refractory NSCLC patients, with OS at 12 months. While all patients in this first part of the study have already been enrolled, the company is expecting 12-month follow-up data, which also has to be reviewed by IDMC. In our view, this readout could still be announced in H1 2020, although, if successful, the potential expansion of the study (step 2) could be impacted more significantly. We also acknowledge that the timeline of the phase I/II basket study of BI 765063, initiated in April 2019, could be stretched due to potential delays in patients screening and recruitment. BI 765063 is in-licensed by B.I., and we expected a significant milestone for OSE in 2021 in association with the initiation of the phase II trial, which could now be postponed. However, we also note that oncology studies could remain a priority for clinical sites compared with trials in less severe chronic diseases. As such, in our view, the expected start of phase II studies of OSE-127 in UC and Sjogren syndrome (SS), could be delayed more significantly. OSE-127 is being co-developed with Servier, which recently amended an in-licensing agreement to include an early payment of EUR5m on enrolment of the first patient with SS and we previously projected the full exercise of the licensing option (and EUR15m payment) for 2022. These potential milestone payments could therefore be postponed, although most of the OSE-127's value in our financial valuation is back-loaded (late-stage milestones and tiered royalties). Additionally, in H2 2020-H1 2021, OSE could secure another partnership agreement for FR104, a phase-II-ready immuno-suppressive therapy, in kidney transplant. In our view, the out-licensing activities are not hugely impacted by the outbreak, as was evidenced by two recent

agreements between CytomX and Astellas and Immatics and GSK. We also acknowledge that OSE currently lacks visibility on the potential impact of Covid-19 and intends to issue an update as soon as the situation becomes clearer. Pending management's guidance, we are therefore making no change to our FV.

Fig. 4: Overview in figures

	Share price	YTD perf.	Spread vs Max. 2020	Upside to FV	Changes
Abivax	13.92	-38%	-41%	169%	
DBV	7.65	-61%	-67%	31%	
Galapagos	144.50	-23%	-42%	59%	Buy vs Neutral - FV EUR230 vs EUR235
Genfit	12.80	-27%	-32%	408%	
Genmab	1343.00	-11%	-21%	41%	
Innate	4.77	-22%	-33%	191%	FV EUR13.9 vs EUR15.6
Lysogene	2.45	+36%	-53%	349%	
Morphosys	84.30	-34%	-38%	60%	
Valneva	2.35	-7%	-32%	155%	FV EUR5.2 vs EUR6
Zealand	189.80	-10%	-35%	20%	FV DKK228 vs DKK260

Source: Bryan Garnier & Co

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Bryan Garnier stock rating system

For the purposes of this Report, the Bryan Garnier stock rating system is defined as follows:

Stock rating

BUY	Positive opinion for a stock where we expect a favourable performance in absolute terms over a period of 6 months from the publication of a recommendation. This opinion is based not only on the FV (the potential upside based on valuation), but also takes into account a number of elements that could include a SWOT analysis, momentum, technical aspects or the sector backdrop. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.
NEUTRAL	Opinion recommending not to trade in a stock short-term, neither as a BUYER or a SELLER, due to a specific set of factors. This view is intended to be temporary. It may reflect different situations, but in particular those where a fair value shows no significant potential or where an upcoming binary event constitutes a high-risk that is difficult to quantify. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.
SELL	Negative opinion for a stock where we expect an unfavourable performance in absolute terms over a period of 6 months from the publication of a recommendation. This opinion is based not only on the FV (the potential downside based on valuation), but also takes into account a number of elements that could include a SWOT analysis, momentum, technical aspects or the sector backdrop. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.

Distribution of stock ratings

BUY ratings 46,6% NEUTRAL ratings 45,3% SELL ratings 8,1%

Research Disclosure Legend

For some of the companies mentioned in this report, Bryan Garnier & Co has acted as a financial advisor over the last 12 months

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