Galapagos Big Partnership Filgotinib Before Year End 2015

Galapagos' (listed on Nasdaq) own Filgotinib inflammatory diseases program, 100% proprietary, is part of the negotiations between Galapagos and 5-10 Big Pharma companies since late September 2015.

These Big Pharma companies from both USA and EU which are part of the negotiations realized net medical /pharma revenue of $ 70-20 billion in fiscal year 2014 and fair values of these companies surpasses by far the value of Galapagos.
Well known is the interest of Johnson & Johnson (J&J) and Amgen (mentioned by CEO Galapagos at BNR Nieuwsroom 5 oktober 2015).

The purpose of Galapagos is to engage a partnership before the end of 2015 so the development of the Filgotinib program will evolve, which is expressed by a planned start Phase 3 trial in April 2016, after approval by FDA/EMA's meeting in March.

After successful Phase 3 and registration, first medicine to reach the market is the JAK1 tablet pills for Rheumatoid Arthritis > anticipated in early 2019.

The Filgotinib program (JAK1) technology is now focusing on Rheumatoid Arthritis (read: RA) and Crohn's disease (IBD); current sales represent a worldwide annually revenue of +$30 billion (Anti-TNF Alpha and Interleukin), an attractive market for Galapagos and the new Partner to gain market share .

Part of Filgotinib program:
-RA Study (DARWIN 1 and 2) : efficacy was excellent in Phase 2b study and safety/tolerance scores were fantastic (no other RA study come close > regarding hemoglobin, anemia, high Cholesterol or high level of infections).
-Crohn Study (FITZROY): 10-week follow up scores are provided within two weeks but is expected in early December 2015 > 'Primary Completion date' at website Clinical Trials is 19 November, so final data collection for now is completed and clinical remission is well known.

The collaboration between Galapagos and a Big Pharma company results in a **Win-Win situation** (further information: *see additional information*).

The financial conditions of the Filgotinib partnership, described in draft Term Sheets, will have a big impact on Galapagos. The management's purpose is to agree on better financial terms than the previous opt-in-license deal with Abbvie (instead of royalties > profit-sharing/Co-development and marketing) .

Abbvie earlier in the year 2012 entered into a collaboration with Galapagos, to start Phase 2b studies in RA and Phase 2 Crohn's. Total deal value consisting of $ 1.35 billion milestone payments and 12-22% royalties on future sales.
Abbvie paid $ 150 million in advance and later $ 50 million for an extension of the RA-study.
With the decision of AbbVie 25 September 2015 they saved $ 1.2 billion for RA and also $50 million for Crohn's. (Further motivation of Abbvie: *see additional information).*

Galapagos CEO, Mr. Onno van de Stolpe recently stated repeatedly that negotiations are proceeding according to schedule, "we are on track to do so". **Partnership Deal before the end of 2015 (Link 1).**

Term sheets to finalize the deal have been prepared, which includes good Crohn-scores (see transcript Conference Call 13 November, Link: 2), and after completion of safety-scores Crohn study in early December (see Bullish rapport Morgan Stanley, Link: 3, *and additional information*) the Partnership negotiation will enter the last phase.

Galapagos market value is € 1.82 billion and the Partnership deal alone has a potential value of +$ 1.25 billion (ditto milestones: AbbVie deal) regarding success in Phase3/4 plus sharing profit*.

*Ratio of profit sharing: development/marketing/sales I assume 30/70 or 40/60 > Galapagos / Partner.

Future sales of RA and Crohn's Filgotinib program are forecasted at $2-3.75 billion per year (Bryan Garnier, Jeffries, Morgan Stanley).

The risks in short term: (A) no agreement with negotiate partners, Galapagos on it's own in Phase 3 development (€150 million cost).
(B) Crohn-Study (10-weeks) Phase 2 is no success in terms of efficacy, safety/tolerability.

<u>In my opinion the risk-indication is low because:</u>

a) Great interest of Big Pharma companies, such as Johnson & Johnson, also known as J&J, and Amgen plus other Big Pharma with interest in inflammatory diseases, because the Filgotinib-program is proven the 'most selective JAK1 inhibitor'.

Filgotinib in this manner can offset cannibalization of blockbuster medicines which faces patent loss, for example Remicade (J&J) in late 2018, and faces competition of Biosimilairs and better medicine treatment (JAK and IL-6/17 technology)

b) Excellent scores Filgotinib RA DARWIN Phase 2b studies (efficacy, safety/ tolerability)

c) Management Galapagos for Crohn Study is concerned with the examination of patients who received treatment during the 10-week treatment and management Galapagos proclaimed in the C-Call 11/13 that they rely on good Crohn scores, included in drafted Term Sheets.

When Galapagos finalizes the Partnership (Deal) before year end, it will generate a lot of exposure and their Target Discovery Platform will be valued at fair price; a peerless achievement for a European Biotech company, which will bring Galapagos share price in a new motion (all time high Nasdaq $65,70).
For example, Morgan Stanley bull case scenario from 16th November issued a 12-month target price of $ 107, in case of good Crohn-scores and completion of Filgotinib Partnership deal under the right financial conditions. Note: Morgan Stanley has 0.17% shares of Galapagos.

<u>My conclusion (no rights to be obtained)</u>:
The market value of Galapagos will strongly be affected by the Crohn 10 weeks scores to be published in December and the anticipated Filgotinib Partnership Deal also in December 2015.

By success the Company is well positioned* to become a specialty Pharma Company, which in 5-10 years probably be able to market their own orphan drug (such as Idiopathic Pulmonary Fibroses disease (IPF) > see link: 1).
Risks are mentioned.

**Cash position year end 2015 approximately € 350 million and other promising programs such as Cystic Fibrosis (collaboration with AbbVie on Triple Combo treatment , Ulcerative Colitis and Osteo-Arthritis are also included in judgment.*

(Note: Position in Galapagos shares).

Links

1. http://pharmaboardroom.com/interviews/interview-onno-van-de-stolpe-ceo-galapagos-the-netherlands/
2. http://seekingalpha.com/article/3683636-galapagos-glpyy-ceo-onno-van-de-stolpe-on-q3-2015-results-earnings-call-transcript
3. http://www.twitlonger.com/show/n_1snsdcj

Additional information:

After the decision of Abbvie per 25/9 all rights of the Filgotinib-program are fully owned by Galapagos. This is a program which identifies targets and after preclinical success the molecules go into clinic. The development of targets mainly covers the inflammatory diseases but also Cystic Fibrosis .

The Filgotinib program is known for it's JAK-technology (Janus Kinase Inhibitor).

Inflammatory Diseases (immunology) include: Rheumatoid Arthritis (read: RA), Crohn's disease, Ulcerative Colitis, Psoriasis, Osteo Arthritis.
Galapagos has completed an extensive Phase 2B with RA patients (877 in total), and these results regarding efficacy were excellent and the safety and tolerability gave fantastic scores.

Abbvie made it's decision (not license the program) based on:
1) Financial conditions ($ 1.25 billion payment in three years to Galapagos) > while their own JAK research-program (ABT-494) also had excellent efficacy scores, but the safety scores were inferior (regards Filgotinib Galapagos (see Link: 4) and they decide to test a modified release version

2) Anti-Trust authorities would probably not allow two identical programs simultaneously start phase 3. The delay for Filgotinib would at least take 6 months.

3) Collaboration in Cystic Fibrosis is important and could be affected if AbbVie had frustrated development of Filgotinib.

4) Humira (anti-TNF alpha) is world's best selling RA product with annual revenue of $ 12-14 billion. They have +70 patents till year 2022 to protect the (IP), intellectual property of Humira, against the rise of biosimilairs.

ABT-494 study is a JAK1 and the assumption is that this orally treatment first will be launched as a alternative for patients who do not benefit from Humira. In the future ABT-494 maybe will be a first line treatment (also applies for Filgotinib RA) and can replace Humira, which faces biosimilair competition after 2022 (pricing pressure).

The new mode of actions/mechanisms within RA, but also other inflammatory diseases like Crohn's and Psoriasis, will gain market share. The advantages of JAK regarding Anti-TNF is that orally treatment is less painful, easier to use/absence of injection needle and fewer side effects

Conclusion decision Abbvie: not related to the quality of Filgotinib program Galapagos, but economically driven.
The quality of the Filgotinib program is further underlined by the interest of +10 Big Pharma companies from both the US and EU to negotiate with Galapagos regarding the Filgotinib program.

Investors Galapagos
60-70% shares Galapagos is permanently owned by large investors, especially after NASDAQ IPO.

The list of investors contains:
-Fidelity, Federated, Vanguard, Capital World, Wellington Management, Hartford, Baker Bros, Gilder Gagnon, Adage, Deerfield, Orbimed, BlackRock and Morgan Stanley, Goldman Sachs, JP Morgan, Merrill Lynch, Deutsche Bank and UBS + the Big Pharma companies J&J, AbbVie and GSK.

For both Galapagos and Big Pharma companies a Partnership is a win-win situation.

Galapagos:
1) No further delay in development JAK1 inhibitor (Phase 3 on it's own is a risk)
2) Does not have the marketing power, salesforce and experience regarding meetings FDA/EMA going into Phase 3.

Big Pharma (Negotiation Partners):
1) No JAK in development (for example J&J and Amgen).
JAK1/2 baricitinib has already proven itself in Phase 3 and is superior to existing anti-TNF agents (see Link: 5), of which the top three drug Humira (AbbVie), Remicade (J&J) and Enbrel (Amgen) represents 70-80% of the worldwide sales (except from MTX).

2) Cannibalization (partially) Anti-TNF medicines
Biosimilairs, IL-6/17 and JAKs threaten the position of Anti-TNF on the RA-market .
-**AbbVie** has made his choice> JAK1 to realize $4 billion in sales (Link: 6), especially at first as alternative treatment for people who do not benefit from Humira.
-**Pfizer** Is working on a improved version of its JAK1/3 Xeljanz;
-**Incyte/Eli Lilly's** baricitinib JAK1/2 probably will enter market at the end of 2016.

-**Galapagos' Filgotinib most selective JAK1** safety is fantastic and efficacy is very good.
After 24-weeks LOCF scores Galapagos in 100mg BID and 200mg QD is best so far (AbbVie perhaps comes close, given the 12-week scores, but improvement ABT-494 to realize in week 13-24 for doses 24mg in ACR50/70 compared to 200mg QD Galapagos is probably a bridge to far.

The imminent need for a Partner by year-end 2015 is a goal for Galapagos, because speed is essential to bring Filgotinib program in both RA and Crohn's to the next level > Phase 3.

The Crohn's study (Phase 2) is still in progress and scores are published in December 2015.
There is currently no cure for Crohn's disease (inflammatory bowel disease).

Galapagos Crohn's JAK1 development is in front (+nearly 2 years) of other Big Pharma Crohn studies (for example: AbbVie) and this is a huge advantage (read: good scores) in negotiation with partners Filgotinib program > increased value.

Partnership Deal before 23rd of December?

1) Lot of work to do on Doc's/Filing to EMA / FDA early January 2016 (recommendations partner).

2) Exceptional General Meeting of Shareholders at December 22nd 2015: warrants granted to CEO and other non executives (warrants on behalf of success IPO Nasdaq and progress company) and this must boost performance of board.

3) Term sheets are ready and probably partners will be informed about the Crohn scores in short term and then progress to finalize Partnership deal will speed up, although it requires a lot of expertise of both parties, represented by : directors, auditors, business development managers, clinical experts, legal experts and lawyers (corporate law, competition law, contract law), tax consultants, notaries and communication to finalize the Partnership.

Galapagos CEO words: "it will be exciting weeks for the Biotech company Galapagos"
and therefore to the value of the share.

Links

4. http://www.twitlonger.com/show/n_1snrbk0
5. http://w.ptjournal.com/news/2015-10-14-000000/baricitinib-superior-adalimumab-ra-patients
6. Words CFO AbbVie Bill Chase: Jeffries Conference 11/19 C-Call