

## Formycon

Pharma & biotech

11 May 2017

### Building a pipeline of third-wave biosimilars

Formycon has reported FY16 financial results that highlight the progress of its biosimilars pipeline. During 2016 partner Bioeq IP AG started a global Phase III study of Lucentis biosimilar FYB201 for neovascular age-related macular degeneration (nAMD); US and EU launches are planned for 2020 and 2022. Formycon disclosed that FYB203 is a proposed biosimilar of Eylea in preclinical studies. It targets all biologics in the nAMD market, which had revenues of \$8.2bn in 2016. The company recently disclosed that FYB202 is a biosimilar of Stelara. Cash at end 2016 was €14m.

### Global Phase III trial of Lucentis biosimilar underway

Formycon and its partner Bioeq IP AG are running a global Phase III clinical trial of lead asset FYB201, a biosimilar of Lucentis (2016 revenues \$3.2bn). Development, regulatory and commercial milestones could be over three-digit million euros. The company aims for US launch in 2020 and the EU in 2022 on patent expiries. We view FYB201 as a potential first-to-market mover, as competitors are behind.

### Biosimilar candidate for Eylea's growing market

In February 2016 Formycon disclosed FYB203 is a proposed biosimilar of Eylea for nAMD (2016 sales \$5bn). It is in preclinical studies and partnered with Santo Holding in a deal that involves an upfront payment of single-digit million euros (received) and ongoing payments for its product development activities up to regulatory approval; sales revenue may reach double digits. Eylea patents expire in 2023 in the US and 2025 in the EU. With no other known competitors, we believe that Formycon is uniquely positioned in the growing Eylea market.

### FYB202 disclosed as a biosimilar of Stelara

Formycon has disclosed that FYB202 is a biosimilar candidate of Stelara (ustekinumab, 2016 sales \$3.2bn) in pre-clinical stage. Stelara is indicated for psoriasis and Crohn's disease. Consensus forecasts predict a market of \$4.5bn in 2020 (EvaluatePharma). Patent protection ends in 2023 in the US and 2024 in the EU. Additionally, Formycon has an undisclosed biosimilar FYB205. It plans to partner both FYB205 and FYB202 in the future.

### Valuation: Building a pure-play biosimilars pipeline

Formycon's market cap is c €298m and its enterprise value (EV) is c €284m. Progression of the pipeline and additional partnerships should unlock further value.

#### Consensus estimates

| Year end | Revenue (€m) | PBT (€m) | EPS (€) | DPS (€) | P/E (x) | Yield (%) |
|----------|--------------|----------|---------|---------|---------|-----------|
| 12/15    | 16.92        | 0.60     | 0.07    | 0.0     | N/A     | N/A       |
| 12/16    | 19.53        | (4.06)   | (0.45)  | 0.0     | N/A     | N/A       |
| 12/17e   | 30.80        | 3.40     | 0.03    | 0.0     | N/A     | N/A       |
| 12/18e   | 29.80        | (1.10)   | (0.22)  | 0.0     | N/A     | N/A       |

Source: Bloomberg, Formycon data

**Price** €32.8  
**Market cap** €298m

#### Share price graph



#### Share details

|                  |                      |
|------------------|----------------------|
| Code             | FYB                  |
| Listing          | Deutsche Börse Scale |
| Shares in issue  | 9.1m                 |
| Cash at end 2016 | €14m                 |

#### Business description

Formycon is a biotechnology company focused on biosimilars. The lead product is FYB201, a Lucentis biosimilar in Phase III. FYB203 is an Eylea biosimilar in the preclinical stage. They are both partnered. It also has two unpartnered biosimilars: FYB202, a biosimilar candidate of Stelara; and FYB205, an undisclosed biosimilar.

#### Bull

- Leading biosimilars company addressing an \$11-12bn market.
- Two partnered products in multi-million euro deals.
- Potential first-to-market advantage for FYB201.

#### Bear

- No EMA guidance for intraocular biosimilars.
- US biosimilar market immature.
- Lucentis market declined in 2014-16.

#### Analysts

|                    |                     |
|--------------------|---------------------|
| Juan Pedro Serrate | +44 (0)20 3681 2534 |
| Jonas Peculis      | +44 (0)20 3077 5728 |

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)  
[Edison profile page](#)

Edison Investment Research provides qualitative research coverage on companies in the Deutsche Börse Scale segment in accordance with section 36 subsection 3 of the General Terms and Conditions of Deutsche Börse AG for the Regulated Unofficial Market (Freiverkehr) on Frankfurter Wertpapierbörse (as of 1 March 2017). Two to three research reports will be produced per year. Research reports do not contain Edison analyst financial forecasts.

## Financials: FY16 results released

Formycon's revenues increased to €19.53m in 2016 from €16.92m in 2015, mainly from out-licensing activities. The company is guiding for 2017 revenues of €25m, which could increase if FYB202 or FYB205 are partnered. Expenses increased from €16.6m in 2015 to €23.7m in 2016 in part associated with research and development as the number of employees increased from 53 to 70. According to Formycon, R&D will continue its expansion during 2017. EBITDA was a loss of €3.37m in 2016 vs a gain of €1.47m in 2015. The net loss was €4.07m in 2016 vs net income of €0.60m in 2015. Cash burn in 2016 was €6.4m. Cash and equivalents were €14m at end December 2016. The company has no financial debt.

### Exhibit 1: Financial summary

| Year end 31 December (€m)                     | 2012          | 2013          | 2014          | 2015          | 2016          |
|---|---------------|---------------|---------------|---------------|---------------|
| <b>Income statement</b>                       |               |               |               |               |               |
| Revenue                                       | 0.60          | 0.40          | 12.70         | 16.9          | 19.53         |
| Profit before tax (as reported)               | (2.40)        | (7.77)        | 0.87          | 0.60          | (4.06)        |
| <b>Net income (as reported)</b>               | <b>(2.40)</b> | <b>(7.77)</b> | <b>0.87</b>   | <b>0.60</b>   | <b>(4.07)</b> |
| EPS (as reported) (€)                         | N/A           | N/A           | N/A           | N/A           | N/A           |
| Dividend per share (€)                        | 0.00          | 0.00          | 0.00          | 0.00          | 0.00          |
| <b>Balance sheet</b>                          |               |               |               |               |               |
| Total non-current assets                      | 7.19          | 6.25          | 4.03          | 3.74          | 4.40          |
| Total current assets                          | 0.45          | 10.90         | 12.88         | 23.41         | 20.80         |
| <b>Total assets</b>                           | <b>7.64</b>   | <b>17.20</b>  | <b>16.91</b>  | <b>27.15</b>  | <b>25.19</b>  |
| Total current liabilities                     | (3.38)        | (2.70)        | (3.26)        | (1.61)        | (3.58)        |
| Total non-current liabilities                 | 0.00          | (0.50)        | (0.53)        | (0.66)        | (0.72)        |
| <b>Total liabilities</b>                      | <b>(3.38)</b> | <b>(3.19)</b> | <b>(3.80)</b> | <b>(2.28)</b> | <b>(4.30)</b> |
| Net assets                                    | 4.26          | 13.90         | 13.11         | 24.87         | 20.89         |
| <b>Shareholders' equity</b>                   | <b>4.26</b>   | <b>13.90</b>  | <b>13.11</b>  | <b>24.87</b>  | <b>20.89</b>  |
| <b>Cash flow statement</b>                    |               |               |               |               |               |
| Net cash from operating activities            | 2.16          | (16.62)       | (0.03)        | 0.52          | (5.04)        |
| Net cash from investing activities            | (4.15)        | (0.04)        | (0.57)        | (0.60)        | (1.35)        |
| Net cash from financing activities            | 1.52          | 17.43         | (0.01)        | 11.15         | 0.06          |
| <b>Net cash flow</b>                          | <b>0.50</b>   | <b>0.68</b>   | <b>(0.61)</b> | <b>11.07</b>  | <b>(6.33)</b> |
| <b>Cash &amp; cash equivalent end of year</b> | <b>0.21</b>   | <b>0.90</b>   | <b>0.29</b>   | <b>20.30</b>  | <b>13.97</b>  |

Source: Formycon accounts

## Valuation

Formycon's market cap is c €298m and enterprise value (EV) is c €284m. The company has two assets targeting the entire biologics nAMD market, which had total sales of \$8.2bn in 2016 and is projected to reach c \$10bn in 2020 (EvaluatePharma). Assuming a 50% discount and 50% penetration for biosimilars, the target market for Formycon's nAMD products would be c \$2.5bn, on which Formycon may receive royalties and milestones. Stelara had sales of \$3.2bn in 2016 and EvaluatePharma's consensus forecast is c \$4.5bn in 2020. Using the same assumptions, the potential market for a biosimilar of Stelara would be c \$1.13bn. The company plans to partner this product and the undisclosed biosimilar FYB205 in the future. We also believe that the valuation reflects the background, expertise and successful track record of the company's management. Progression of the pipeline in the clinic and additional partnerships should unlock further value.

In our view, the closest peers are Pfenex (market cap €111m; EV €35.7m at a \$1.09/€ exchange rate), Xbrane (market cap €17m; EV €13.7m at a SEK9.6/€ exchange rate) and Coherus BioSciences (market cap €1bn; EV €1bn at a \$1.09/€ exchange rate); however, relative valuation metrics, such as P/E, are difficult to assess, given the early-stage and often loss-making nature of these development companies. Furthermore, all are at different stages of development with multiple other assets in the pipeline, further complicating any peer group comparison.

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisors and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. Edison is authorised and regulated by the [Financial Conduct Authority](#). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. [www.edisongroup.com](http://www.edisongroup.com)

#### DISCLAIMER

Any Information, data, analysis and opinions contained in this report do not constitute investment advice by Deutsche Börse AG or the Frankfurter Wertpapierbörse. Any investment decision should be solely based on a securities offering document or another document containing all information required to make such an investment decision, including risk factors.

Copyright 2017 Edison Investment Research Limited. All rights reserved. This report has been commissioned by Deutsche Börse AG and prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2017. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.