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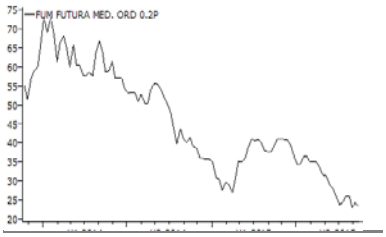
Pharmaceuticals & Biotech



Source: Fidessa

Market data	
EPIC/TKR	FUM
Price (p)	24.8
12m High (p)	45.0
12 Low (p)	22.5
Shares (m)	99.0
Mkt Cap (£m)	24.5
EV (£m)	15.0
Free Float* (%)	98%
Market	AIM

**As defined by AIM Rule 26*

Description

Futura is engaged in the development of drugs and medical devices and their commercial exploitation; products includes condoms, erectile dysfunction, enhanced sexual control, pain relief and delivery technology.

Company information	
CEO	James Barder
CFO	Derek Martin
Chairman	John Clarke

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Next Event	
2015 results	March 2016
MED2002 trial	1H 2016

Analysts	
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Futura Medical

Update following company announcements

FUM has advanced transdermal technology which can be incorporated into formulations of well characterised drugs to improve performance and extend their uses. 2015 was expected to be a busy year for the company and three recent announcements show that management is delivering on these expectations. Clarity of the EU regulatory pathway for the pain portfolio products is an important milestone, and rapid recruitment in the pivotal MED2002 trial, both add to the de-risking of the prodcuts and enhance the prospects of securing commercial partners.

- **Pain portfolio:** FUM announced that a positive meeting with an EU regulatory authority has clarified requirements for regulatory submission of FUM's pain products and indicated that no further clinical trial are likely. This further de-risks the portfolio and should spur the interest of potential commercial partners.
- **MED2002:** FUM is undertaking a pivotal phase III in 192 patients for EU regulatory approval. Recruitment has been at a rapid rate and 118 (61.5%) have been recruited in London alone. Importantly, no adverse events have been observed. Results are due by the end of 1H 2016.
- **Commercialisation**: All these announcements are associated with a further de-risking of the products which increases the prospects of identifying and signing commercial partners. Clarity of requirements for regulatory submission is a major step.
- **Risks:** Clinical trials always carry risk, but considerable clinical experience with the underlying drug, these risk have been minimised. Greatest risk is the timing of licensing deals and commercial, where any delay impacts the time to cashflow breakeven and profitability.
- **Summary:** Regulatory clarity for EU approval of the pain portfolio represents a major achievement. In addition, rapid recruitment for the MED2002 trial augurs well for its regulatory pathway and making the product available as a 'Special' on a 'Named Patient' basis in the UK via Quantum Pharma is helping to maximise shareholder returns. Management is making steady progress on all fronts.

Financial summary and valuation

Year end Dec (£000)	2012	2013	2014	2015E	2016E	2017E
Sales	75	371	0	0	300	345
Royalties	0	0	44	45	500	1,600
Underlying EBIT	-2,327	-2,390	-3,350	-4,539	-4,597	-4,339
Reported EBIT	-2,456	-2,532	-3,527	-4,639	-4,717	-4,479
Underlying PTP	-2,308	-2,381	-3,302	-4,502	-4,510	-4,345
Statutory PTP	-2,437	-2,522	-3,479	-4,602	-4,630	-4,484
Underlying EPS (p)	-2.7	-2.7	-3.2	-4.0	-3.8	-3.4
Statutory EPS (p)	-2.9	-2.8	-3.4	-3.7	-3.9	-3.7
Net (debt)/cash	2,817	991	9,492	5,410	1,520	-1,994
Shares issued	2,163	181	11,555	100	100	100
P/E (x)	-18.3	-18.8	-15.4	-12.4	-13.2	-14.8
EV/sales (x)	nm	nm	nm	nm	nm	nm

Source: Hardman & Co Life Sciences Research

Company update

Pain relief – Regulatory update

Good progress since headline data was announced in July

In July 2015, FUM reported headline data from a complex pivotal trial to assess the efficacy and safety of drugs in its pain portfolio against both topical and oral formulations of their respective gold standards. The trial was a double-blind, randomised, placebo-controlled study in 60 volunteers at a cost of £750k. The results achieved the primary objective of showing that FUM's products were 'non-inferior' to the current marketed gold standard:

- TPR100 (diclofenac) was statistically superior to placebo and gave results which were similar to both gel and oral formulations of the gold standard, Voltaren
- TIB200 (ibuprofen) was statistically superior to placebo and gave results that were at least comparable (non-inferior) to both Nurofen gel and oral Nurofen

DermaSys Gel – Typical packaging

Source: Futura Medical

With these results, management was able to embark upon a number of follow-up steps:

- **Regulatory:** Initiate dialogue with the appropriate regulatory authorities in both the US and EU for both NSAID based products in order to define the optimal route to approval
- **Manufacturing:** Begin optimisation of the manufacturing process and developing commercial packaging
- **Commercial:** Increase the dialogue with potential commercial partners.

In principle, no further clinical trials needed for EU

FUM has announced that, following a meeting with a key European regulator, a positive outcome and clarity of the regulatory pathway has been achieved. Management has been advised that, in principle, no further clinical studies will be required. This is very encouraging and removes any uncertainty, especially in the eyes of potential commercial partners.

EU filing anticipated in 1H 2017

Over coming months, FUM will undertake full-scale validation of the manufacturing process in the final packaging, an artistic impression of which is provided in the picture on the left. Ultimately, of course, this task may be taken over by the eventual commercial partner. Overall, completion of this validation and preparation of the regulatory submission is expected to complete with a regulatory submission during 1H 2017.

FUM seeking similar clarification meeting with FDA

Although no date has been set, FUM is well on-track for a similar meeting with the FDA. While management hopes that the US regulatory pathway will be equally clarified, the overall outcome is unlikely to be as positive given that the products will be prescription-only, a further clinical study in patients in the US is anticipated.

The meeting with the EU regulator has clarified the process required and significantly reduced the risk profile of these products towards commercialisation. It will also provide another spur to potential commercial partners, given that paves the way, just in Europe, to an estimated $750m market. FUM expects to appoint advisors shortly to assist them in this regard.

MED2002 – Trial update

MED2002 is a topical gel of glyceryl trinitrate (GTN) in FUM's proprietary DermaSys technology, which is applied directly to the glans of the penis from where it is rapidly absorbed to increase blood flow giving a fast onset of action, for the treatment of erectile dysfunction. It is considered to be safe to use because of local application, eliminating many of the side effects associated with systemic prescription drugs (eg Viagra), such as headache and flushing.

For regulatory approval, FUM is undertaking a pivotal randomised, double-blind, placebo controlled cross-over trial in 192 patients. The company has announced that trial recruitment is progressing at a rapid rate with 118 (61.5%) London-based patients having joined so far. The trial is recruiting at a rate of ca.10 patients per week in the UK and three centres in Poland will be added early in the new year. This could be revised if UK enrolment remains strong and that appropriate numbers of mild, moderate and severe cases are balanced to power the statistical analysis.

Although the trial is double blind, it is still being carefully monitored for adverse events. To date, no serious side effects have been observed amongst the enrolled patient population.

The primary endpoint is the International Index of Erectile function which was used for the approval of PDE5 inhibitors (eg Viagra). Once enrolled patient testing continues for approximately three months. Therefore, provided all patients are recruited by end of February headline results should be available by the end of 1H 2016.

Available as a 'Special'

Whilst this pivotal trial is being undertaken, FUM has signed a deal with Quantum Pharma (QP.L) to make MED2002 available in the UK as a 'Special'. This is a process whereby doctors in the UK, subject to certain conditions set out by the MHRA, can prescribe unlicensed medicines, which have a proven track record regarding safety, for alternative indications to individual patients on a 'Named Patient' basis only. This deal will provide some income on MED2002 for at least 24 months that would otherwise be lost. Also, it is likely to increase awareness prior to full launch.

Summary

Rapid enrolment of patients coupled with the observation of no adverse events augurs well for the product which, being late stage, carries more weight in FUM's portfolio from a valuation perspective. MED2002 is also being made available on a 'Named Patient' basis in the UK as a 'Special' via Quantum Pharma, which is helping to maximise shareholder returns.

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