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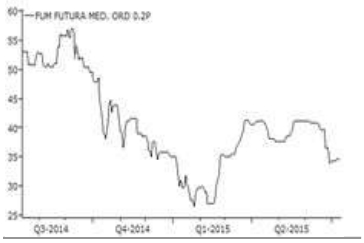
14th July 2015

Pharma & Biotech



Source: Fidessa

Market data	
Price (p)	37.0
12m High (p)	69.0
12 Low (p)	26.0
Shares (m)	99.0
Mkt Cap (£m)	36.6
EV (£m)	27.1
EPIC	FUM
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

Interims	Sep-15
MED2002 trial	1Q/2Q'16

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Futura Medical plc (FUM.L) RNS

Preliminary pain trial results have reduced risk

Futura Medical has proprietary transdermal technology which can be incorporated into formulations of well characterised drugs to improve performance and extend their uses. Headline results from a clinical trial assessing its three pain portfolio products suggest that its anti-inflammatory drugs applied locally are 'not inferior' to formulations of the established gold standards. These should provide a value inflection point, with further potential uplift when management concludes licensing deals with commercial partner(s).

Clinical trial: FUM commissioned a complex pivotal trial to assess the efficacy and safety of all three drugs in its pain portfolio – diclofenac, ibuprofen, methyl salicylate – 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.

Results: TPR100 and TIB200 were both superior to placebo and were 'non-inferior' to gel and oral formulations of Voltarol and Nurofen, respectively. There were no serious adverse events. These preliminary findings were as good as could be expected. SPR300 was no different to placebo, which is unsurprising as this drug is not mainstream for inflammation.

Next steps: FUM has already commenced optimisation of the manufacturing process and outer packaging. Preparations are underway for consultation with US and EU regulators. These results pave the way to concluding commercial deal(s) with pharmaceutical majors.

Valuation: After drifting back recently, we expect these results to produce a re-valuation of the shares and to regain positive momentum. FUM is still forecast to reach break-even and become cashflow positive in 2017. Our risk-adjusted DCF has risen from 110p to 126p per share. Any licensing deal would provide further upside potential.

Risks: Clinical trials always carry risk, but with the 1° end-point being 'non-inferiority', these risks have been minimised. Greatest risk is the timing of licensing deals and commercial, where any delay impacts the time to cashflow breakeven and profitability.

Investment summary: Commercialisation of its first three products is key over the next 18 months and drives the cashflow which could provide a significant valuation uplift. Today's results reduce risk, provide a value inflection point taking the DCF up to 126p and improve the probability of finding an attractive licensing partner from the pharmaceutical majors.

Financial summary and valuation

Year end Dec (£000)	FY12	FY13	FY14	FY15E	FY16E	FY17E
Sales	75	371	44	200	300	345
Royalties	0	0	0	600	1,750	2,800
Underlying EBIT	-2,327	-2,390	-3,350	-3,802	-3,837	-3,124
Reported EBIT	-2,456	-2,532	-3,527	-3,999	-4,054	-3,361
Underlying PTP	-2,308	-2,381	-3,302	-3,604	-3,719	-3,074
Statutory PTP	-2,437	-2,522	-3,479	-3,801	-3,936	-3,310
Underlying EPS (p)	-2.7	-2.7	-3.2	-3.1	-3.0	-2.2
Statutory EPS (p)	-2.9	-2.8	-3.4	-3.3	-3.3	-2.6
Net (debt)/cash	2,817	991	9,492	6,306	3,172	883
Shares issued	2,163	181	11,555	100	100	100
P/E (x)	-18.3	-18.8	-15.4	-15.9	-16.4	-23.1
EV/sales (x)	510.6	103.3	871.8	191.5	127.7	111.0

Source: Hardman & Co Life Sciences Research

Pain portfolio trial

Headline results

It is important to stress that the results published today are preliminary headline data and that full statistical analysis is still being undertaken. However, these results achieved the primary objective of showing that FUM's products were 'non-inferior' to the current marketed gold standard, which will be the main claim when seeking regulatory approval.

- 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
- SPR300 (methyl salicylate) was not statistically different to placebo

Background

While cash was being conserved for products nearer commercialisation, FUM's pain relief portfolio had to play second fiddle to the opportunities in sexual health. With increased capital, management has been able to undertake a pivotal trial investigating the safety and efficacy of all three products in its pain relief portfolio – diclofenac, ibuprofen and methyl salicylate. Results from this trial were announced to the market today, which demonstrated that FUM's anti-inflammatory products were at least as good as could be expected and pave the way for management to maximise shareholder value, probably though licensing deals.

Trial objectives – 'non-inferiority' to gold standards

The aim of this study was to prove the efficacy and safety of the products in FUM's pain relief portfolio and to show that the products are at least as good (non-inferior) as the currently marketed gold standard. A carefully constructed protocol allowed FUM to achieve these objectives for approximately £750k, which is relatively cheap compared to the cost of other clinical trials.

Protocol

The trial was conducted by a CRO with specialist experience in topical pain relief trials. It was a double-blind, randomised, cross-over, placebo-controlled study in 60 subjects using an induced pain model. This model subjected the healthy volunteers to pain in a controlled clinical environment.

Efficacy

Pain was assessed using the following assessments:

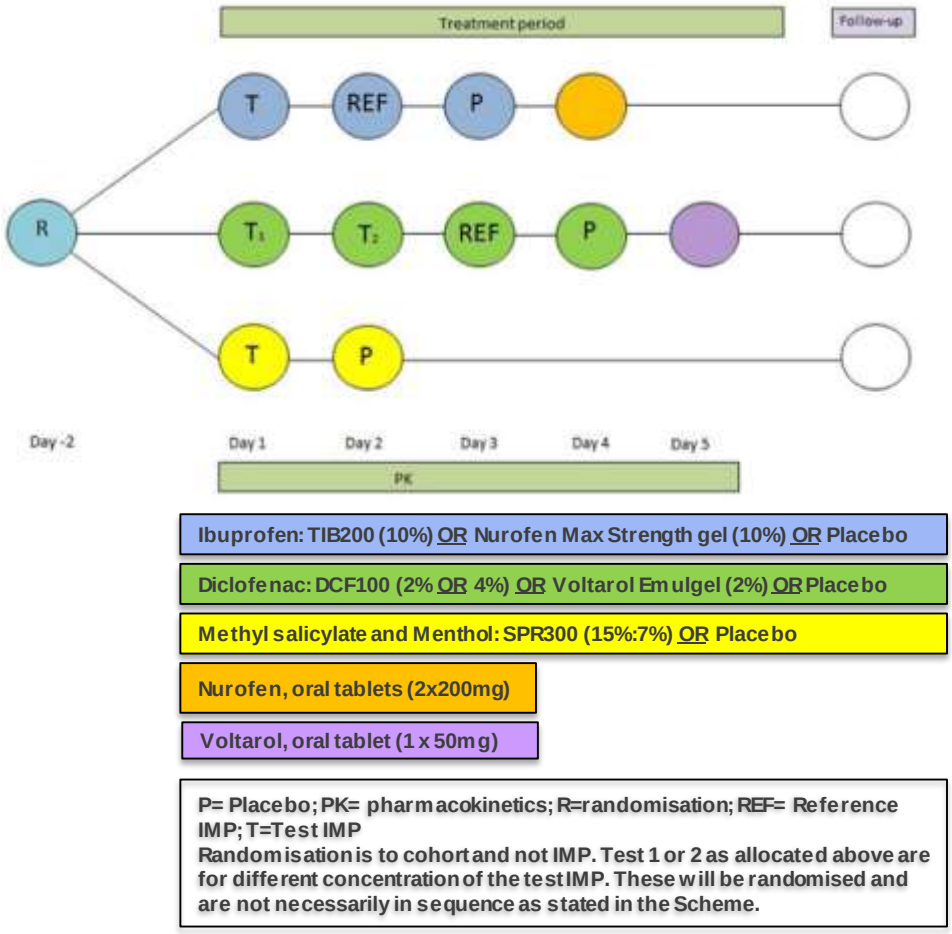
- Heat Pain Tolerance Test
- Erythema (redness of skin) intensity

Safety

Safety was assessed through:

- Local adverse events
- Systemic adverse events

Protocol for clinical trial of pain relief portfolio



Source: Futura Medical

Volunteers were subjected to sun burn through controlled UVB light on two locations on the subject's back. The following day, these volunteers were tested using FUM's products, the gold standard or placebo.

Heat Pain Tolerance Test (HPTT)

Assesses the maximum temperature that the subject could tolerate to induce skin sunburn. A heat probe increases temperature up to a level that the subject finds unbearable. It is a subjective test determined by the volunteer.

Erythema

Erythema was measured using a Doppler ultrasound to score the intensity. This is an objective measurement conducted by the physician.

Measurements were taken over a six hour period for each test, with the erythema measurement being taken at each time point ahead of the HPTT.

Results

TRP100

Diclofenac in FUM's proprietary gel formulation (TRP100) at both strengths (2% and 4%) was shown to be better than placebo, clearly indicating that the drug was having an effect. Moreover, both strengths of TPR100 gave similar results to the gold standard, Voltarol 2% gel, in preventing erythema at all time points from 2-6hrs.

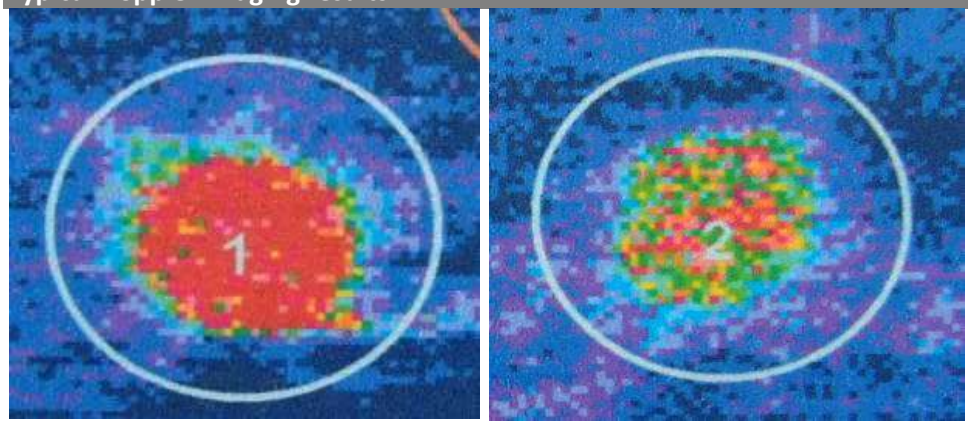
Interestingly, TPR100 also appeared to be equally effective as oral Voltarol 50mg, which could provide the commercial advantage that locally applied gel is unlikely to cause the unwanted gastrointestinal side effects seen with prolonged use of oral NSAIDs. Voltarol gel is the largest selling ant-inflammatory gel for localised pain relief with global sales in 2014 estimated at $300m. Therefore these 'non-inferiority' results were as good as could be expected for FUM.

TIB200

Similar outcomes were seen with ibuprofen 10% gel (TIB200) against both Nurofen gel and against oral Nurofen 400mg. Results for TIB200 in erythema were almost superimposable on those with oral Nurofen at each time point (1-6hrs). Interestingly, the early benefits of branded Nurofen gel seemed to wear off after 2-3hrs, but this observation has not been shown to be statistically different at this stage.

The following graphic shows, typically, the impact of anti-inflammatory drugs on the Doppler imaging scan 2h after administration. There is a noticeable reduction in erythema.

Typical Doppler imaging results



2hr after placebo **2hr after analgesic application**

Source: Futura Medical

SPR300

The only slight disappointment from the study was that SPR300 failed to show any difference compared to placebo. However, 'Deep Heat' (methyl salicylate) is not really targeted at pain relief in the same way as NSAIDs and this result could have been anticipated. Indeed, the use of Deep Heat is not a recognised treatment for sunburn. In order to show non-inferiority to Deep Heat, a different trial would need to be undertaken.

Heat Pain Tolerance Test results

In the subjective HPTT part of the study, volunteers could more easily withstand pain when on the test drugs with anti-inflammatory properties. TPR100 and TIB200 results were significantly better than the vehicle (placebo), and there was no difference between FUMs drugs and the gold standard in both gel and oral formulations.

Summary of results in HPTT

	TPR100 2% (diclofenac)	TPR100 4% (diclofenac)	TIB200 10% (ibuprofen)	SPR300 (methyl salicylate)
Vehicle (placebo)	p = 0.047	P = 0.003	P = 0.007	ns
Gel gold standard	'similar'	'similar'	'similar'	-
Oral gold standard	'similar'	'similar'	'similar'	-

ns = not significant; 'similar' = not powered to show statistically difference
Source: Futura Medical

All the results announced are the headline findings; full publication with complete statistical analysis will be available in September 2015.

Next steps

- **Regulatory:** Management intends to 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:** The process of optimising the manufacturing process and developing commercial packaging is underway
- **Commercial:** Based on pre-clinical data, and prior to these results, management has been in dialogue with potential commercial partners. This process is likely to have greater impetus following publication of these results, given the non-inferiority of the products compared to the high selling gold standards
- More work needs to be done with a different trial to show the benefits of methyl salicylate compared to placebo and non-inferiority to Deep Heat, but this is unlikely to be a priority at this time point

Conclusion

In conclusion, TRP100 and TIB200 have both been demonstrated to be more effective than placebo in both the subjective and objective elements of the study. In addition, these two drugs, in FUM's proprietary gel formulation produced similar (not statistically different) results to their respective active ingredient gold standard in both gel and oral formulations. This was the best possible outcome for these two drugs and paves the way for management to improve shareholder value, probably in the form of licensing deals with commercial partners.

Financials

There has been a modest knock-on effect on future forecasts of the slightly higher R&D investment in 2014 compared with our previous expectation, increasing losses by about £300k per annum for the next two years.

R&D investment will continue for the following reasons:

- Completion of the shelf-life work for CSD500 to get it as close as possible to the two year industry standard to avoid changes to existing supply chains
- Costs associated with the complex double-blind clinical trial of the pain relief portfolio, where success could pave the way to significant licensing deal(s) with major partners
- Costs of the pivotal phase III clinical trial for MED2002 in 192 patients with erectile dysfunction

Profit & Loss account

Year end Dec (£,000s)	2012	2013	2014	2015E	2016E	2017E
Sales	**75**	**371**	**44**	**200**	**300**	**345**
COGS	0	0	0	0	0	0
Gross Profit	**75**	**371**	**44**	**200**	**300**	**345**
SG&A	-964	-785	-1,028	-1,285	-1,478	-1,552
R&D	-1,436	-1,976	-2,366	-3,312	-4,405	-4,713
Deprec & Amortis	-2	-4	-5	-5	-5	-5
Royalties	0	0	0	600	1,750	2,800
Other income	0	0	0	0	0	0
Underlying EBIT	**-2,327**	**-2,390**	**-3,350**	**-3,802**	**-3,837**	**-3,124**
Share based costs	-129	-141	-177	-197	-217	-237
Exceptional items	0	0	0	0	0	0
Statutory Operating profit	-2,456	-2,532	-3,527	-3,999	-4,054	-3,361
Net financial income	18	10	48	197	118	51
Pre-tax profit	**-2,308**	**-2,381**	**-3,302**	**-3,604**	**-3,719**	**-3,074**
Exceptional items	0	0	0	0	0	1
Reported pre-tax	-2,437	-2,522	-3,479	-3,801	-3,936	-3,310
Reported taxation	261	314	481	497	661	707
Minorities	0	0	0	0	0	0
Underlying net income	**-2,048**	**-2,067**	**-2,906**	**-3,131**	**-3,056**	**-2,193**
Statutory net income	-2,177	-2,208	-2,998	-3,304	-3,275	-2,603
Period-end shares in issue (m)	77.4	77.8	99.0	100.0	101.0	102.0
Weighted average shares (m)	74.7	77.6	89.5	99.5	100.5	101.5
Fully dliuted shares (m)	79.0	79.8	94.3	104.9	106.4	107.9
Underlying Basic EPS (p)	**-2.74**	**-2.66**	**-3.25**	**-3.15**	**-3.04**	**-2.16**
U/l Fully-diluted EPS (p)	**-2.59**	**-2.59**	**-3.08**	**-2.99**	**-2.87**	**-2.03**
Statutory Basic EPS (p)	-2.91	-2.85	-3.35	-3.32	-3.26	-2.56
Stat. Fully-diluted EPS (p)	-2.76	-2.77	-3.18	-3.15	-3.08	-2.41
DPS (p)	0.00	0.00	0.00	0.00	0.00	0.00

Source: Futura Medical Annual Reports; Hardman & Co Life Sciences Research

Balance sheet

at 31st Dec (£,000)	2012	2013	2014	2015E	2016E	2017E
Shareholders funds	2,873	988	9,722	6,518	3,342	840
Cumulated goodwill	0	0	0	0	0	0
Total equity	2,873	988	9,722	6,518	3,342	840
Share capital	155	156	198	200	202	204
Reserves	2,718	832	9,524	6,317	3,140	636
Capitalised R&D	4,281	4,952	5,852	7,472	9,809	11,966
Long-term loans	0	0	0	0	0	0
Bank overdrafts	0	0	0	0	0	0
less: Cash & securities	2,817	991	9,492	6,306	3,172	883
Invested capital	**4,337**	**4,949**	**6,082**	**7,684**	**9,979**	**11,922**
Fixed assets	7	8	11	16	24	35
Intangible assets	0	0	0	0	0	0
Capitalised R&D	4,281	4,952	5,852	7,472	9,809	11,966
Stocks	7	35	142	644	966	1,111
Trade debtors	0	12	0	0	0	0
Other debtors	117	107	205	100	150	173
Trade creditors	-165	-187	-396	-300	-450	-518
Tax liability	231	265	481	473	662	881
Other creditors	-141	-243	-212	-673	-962	-1,226
Debtors less creditors	42	-46	77	-432	-796	-1,155
Invested capital	**4,337**	**4,949**	**6,082**	**7,684**	**9,979**	**11,922**

Source: Futura Medical Annual Reports; Hardman & Co Life Sciences Research

Cashflow

Year end Dec (£,000s)	2012	2013	2014	2015E	2016E	2017E
Trading profit	-2,327	-2,390	-3,350	-3,802	-3,837	-3,124
Depreciation	2	4	5	5	5	5
Amortisation	0	0	0	0	0	0
Stocks	1	-28	-107	-30	-35	-35
Working capital	123	139	71	-120	-135	-150
Other	0	0	0	0	0	0
Company op cashflow	**-2,201**	**-2,275**	**-3,380**	**-3,947**	**-4,003**	**-3,305**
Net interest	16	11	21	197	118	51
Tax	260	261	314	473	662	881
Operational cashflow	-1,925	-2,003	-3,046	-3,276	-3,222	-2,373
Capital Expenditure	-4	-5	-8	-10	-12	-15
Free cashflow	**-1,929**	**-2,008**	**-3,054**	**-3,286**	**-3,234**	**-2,388**
Dividends	0	0	0	0	0	0
Other investments	0	0	0	0	0	0
Cashflow after investments	**-1,929**	**-2,008**	**-3,054**	**-3,286**	**-3,234**	**-2,388**
Share repurchases	0	0	0	0	0	0
Share issues	2,163	181	11,555	100	100	100
Change in net debt	**234**	**-1,826**	**8,501**	**-3,186**	**-3,134**	**-2,288**
Opening net cash	2,583	2,817	991	9,492	6,306	3,172
Closing net cash	**2,817**	**991**	**9,492**	**6,306**	**3,172**	**883**
Hardman cashflow/share (p)	-2.6	-2.6	-3.4	-3.3	-3.2	-2.3

Source: Futura Medical Annual Reports; Hardman & Co Life Sciences Research

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