UK | Healthcare | FUM LN | Market Cap £66m | 28 November 2019^

Futura Medical*

December data could be game-changing

Graham Doyle
+44 (0) 20 3100 2095
graham.doyle@liberum.com

BUY **Target price £0.60**
Publication price £0.32

*Corporate Broking Client of Liberum

Next events

P3 read-out	Dec 2019
RoW outlicensing	Anytime

Stock performance

Source: Bloomberg

Summary financials & valuation (£m)

Dec Year end

	2018	2019E	2020E
Market cap	£65.5m	£65.5m	£65.5m
Net cash	£9.2m	£1.4m	£4.1m
EV	£56.3m	£64.0m	£61.4m

Source: Liberum, Bloomberg

MED2005 valuation	Risk adjusted	Value to Futura (£m)	Per share
Highly Successful	15%	281	1.37
Successful	25%	195	0.95
Modest Success	35%	67	0.33
Failure	25%	0	0.00
Risk adjusted		114	0.57
RX to OTC switch	38%	24	0.12
Risk adjusted		9	0.04
Futura valuation		**123**	**£0.61**
Central cost		-3	-£0.01
Per share		**£0.01**	**0.60**

Source: Liberum estimates

Futura is set to report headline data from its P3 FM57 study in erectile dysfunction (ED) in December. We believe that the trial is significantly de-risked and hence estimate a >70% probability of some form of positive outcome. Given the complexity of the study the range of potential outcomes is wide. In this note we detail what the likely scenarios will mean for valuation. Assuming a positive outcome implies an NPV range of £0.45-1.49 per share. Hence while failure remains a risk, the risk/reward is very attractive. BUY.

FM57 data due in December

With the last patient's final dose delivered in mid-October the study is on track for a mid-December read-out. This data is pivotal to the equity story.

Study has been de-risked

Just replicating the P2 data would be positive. But, Futura has added higher doses and more endpoints while also lengthening the study, which raise the chances of success.

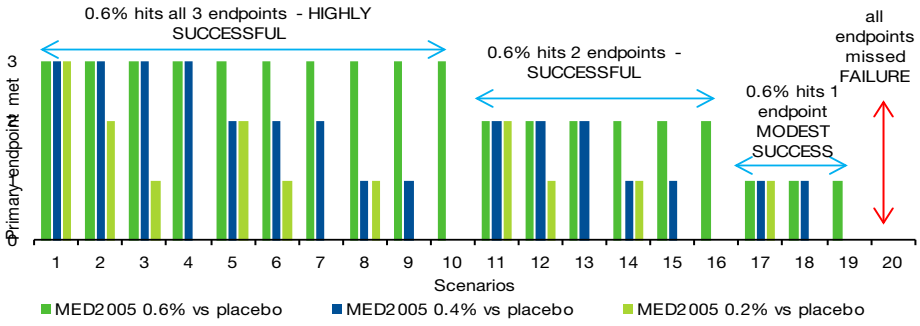
Outcome not binary

We believe there are 20 feasible outcomes of which just 1 would represent failure and leave no chance of approval. We forecast a >70% chance of a positive outcome.

Positive outcome implies £0.45-1.49 per share

We assume peak sales potential of £240-500m depending on the outcome which is worth £0.45-1.49 per share implying 41-366% upside.

19 of 20 potential outcomes deliver a positive result in P3 study



Source: Liberum estimates

Contents

Company dashboard

What it does

Futura Medical is a UK-based pharmaceutical business developing a portfolio of innovative products for sexual health and pain, based on its proprietary, transdermal DermaSys® drug delivery technology. Its lead asset is MED2005, a topical therapy for erectile dysfunction that is currently in P3 studies.

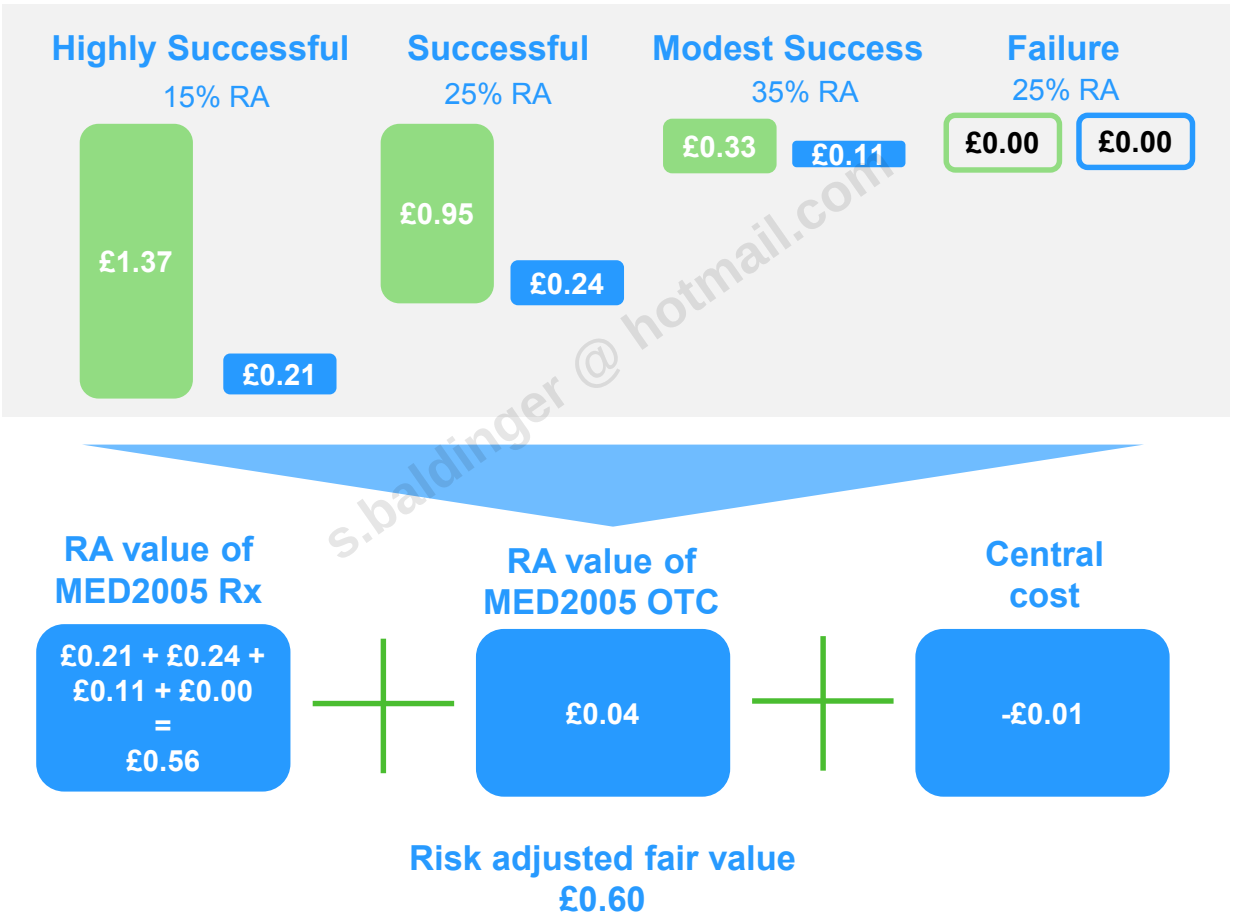
Bull case

- FM57 delivers a positive outcome
- Company secures outlicensing deal
- TPR100 is outlicensed beyond the UK

Bear case

- FM57 delivers an unequivocally negative outcome
- Cash burn exceeds that in our forecasts
- Company cannot secure funding post data release

How the target price is generated



Source: Liberum, Bloomberg, [Company]

Investment summary

- **What to expect from FM57:** We expect Futura's P3 FM57 study for its investigative treatment for erectile dysfunction, MED2005 to read-out in mid-December. The study builds on a positive P2 trial but is more complex with 3 actives doses, 3 co-primary endpoints and 3 reasonably distinct patient populations. That said, the key focus will be whether or not at least one of the MED2005 doses can show superiority to placebo in at least one of the primary endpoints. In this note we detail what to look out for in such a complex dataset.
- **Why FM57 is low risk:** We believe that Futura has learned from its P2 study, FM53. This established a minimal effective dose, taught the company about best practice for patient recruitment and informed its decision around key secondary endpoints that will be relevant for commercialisation, in our view. As a result of this, it has made some crucial changes that best position FM57 for success, most importantly adding two higher doses of MED2005. In addition, the high enrolment in the open label extension study also at least bodes well from a side-effect profile perspective
- **A positive outcome is highly likely:** Most P3 studies are binary in nature with only success or failure as the potential outcomes. However, FM57 is not. We believe that there are a range of 20 feasible outcomes. More importantly, just 1 of these outcomes could be viewed as complete failure and prohibit future approval. In fact, on a probability weighted basis we believe that there is a >70% chance of some form of positive outcome for Futura that could enable the second P3 study and eventual approval. In this note we band these 20 outcomes into 4 broad categories that allows us to assess the potential impact of December's data on Futura's valuation.
- **Positive outcome delivers 50-400% upside:** Assuming some degree of positive outcome we believe MED2005 can generate peak sales of £240-500m. Applying a 12% WACC to this and assuming that Futura will only get 40% of the overall economics if it out-licenses the drug drives an NPV range of £0.45-1.49 per share. Even at the low end of the range there is 41% upside.

What to expect from FM57

Futura's P3 FM57 study for its investigative treatment for erectile dysfunction, MED2005 is due to read-out in mid-December. The study is complex with 3 actives doses, 3 co-primary endpoints and 3 reasonably distinct patient populations. However, ultimately at least one of the doses needs to show superiority to placebo in at least one of the primary endpoints. In this section we provide more detail on the structure of the trial and the key things to look out for when the company releases the headline data.

P3 with multiple doses and multiple endpoints

This is a relatively complex P3 study and we believe designed appropriately in order to mitigate against a high placebo effect which can often be the case in this therapeutic area. The key design points of the FM57 study are:

- **There are 3 doses of FM57:** The P2 study had a 0.2% dose but the P3 study includes a 0.4% and 0.6% dose.
- **There are 3 co-primary endpoints:** Rather than a single endpoint which could lead to a higher placebo effect in our view, management have included 3. This includes:
  - **IIEF score:** Questions 1-5 and 15 on the IIEF erectile dysfunction questionnaire
  - **SEP 2 (Sexual Encounter Profile):** A further question of "Were you able to insert your penis into your partner's vagina?
  - **SEP 3 (Sexual Encounter Profile):** A last question of "Did your erection last long enough for you to have successful intercourse?
- **Patient population includes all types of ED:** Futura have enrolled patients with mild, moderate and severe ED in proportion to the believed prevalence of each (59% mild, 28% moderate and 13% severe).

Headline data due in mid-December

Management has said that it expects FM57 to read-out in mid-December. We are confident that this timeline will be delivered as the last patient in the study had received their final dose in mid-October. This implies that it was tracking in-line with the timeline suggested on clinicaltrials.gov which expected a 1 November primary completion. Factoring-in a month of data cleaning and statistical analysis, this leaves room for a mid-December read-out.

Headline data will test each dose against the primary endpoints

The study hierarchy means that each dose will be individually tested against the primary endpoint to decide if they have shown statistical significance. For this to be the case the difference between the MED2005 dose and placebo for each endpoint must be large enough to deliver a p-value of less than 0.017.

It is important to note that the primary endpoint is tested against the entire population, so even showing a major benefit in mild but not in the entire population would not constitute meeting the primary endpoint. Put simply, on average a patient in a MED2005 arm must have a more positive outcome for at least one primary endpoint (with a p-value of less than 0.017) in order for that dose to have worked.

There are a range of important secondary endpoints including speed of onset of action and duration of action. However, first and foremost at least one of the primary endpoints must be met by at least one of the doses.

What to look out for in mid-December

Taking all of the above into context we think investors should be looking for the following (in this order of priority) from any Futura RNS related to the FM57 read-out:

- Did any of the doses show superiority to placebo on any primary endpoint?
- If they did, which dose hit the largest number of primary endpoints?
- Was the percent of systemic adverse events competitive with Cialis and Viagra?
- How did the most successful dose perform on the secondary endpoints? Specifically, was the onset of action within the 10-minute timeframe aimed for by the company?

The above questions are the first ones we would look to address on release of the RNS however we provide a more detailed analysis further-on in this note where we assess what scenarios are likely to emerge and what they mean commercially.

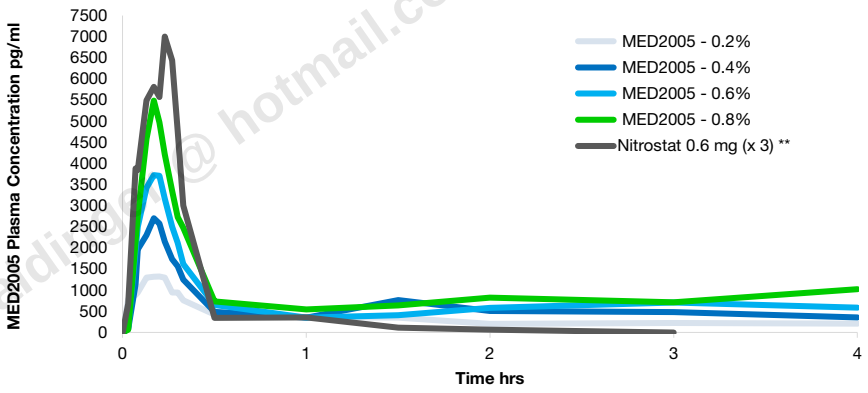
Why FM57 is low risk

We believe Futura has learned from FM53 which established the minimal effective dose, taught the company about the intricacies of effective patient recruitment and helped to better define the most relevant endpoints to include in the P3. As a result of this, it has made some crucial changes that best position FM57 for success. In addition, the high enrolment in the open label extension study also at least bodes well from a side-effect profile perspective.

Higher doses added

Futura has added a 0.4% and 0.6% dose to the 0.2% studied in the P2a. We believe that there is a rationale to support the view that these higher doses should deliver greater efficacy. This is driven by a recent P1 pharmacokinetic study FM58. It demonstrated dose-proportionate absorption levels (higher dose equated to more active ingredient in the blood), but the absorption rate was broadly similar with all doses first detected in the bloodstream within four-to-five minutes with 78% of GTN absorbed through the penis after five minutes.

Figure 1: Plasma concentration



Source: company

Three co-primary endpoints

FM53's primary endpoint was change in efficacy based on the IIEF erectile function questionnaire. These questions are shown below, and the answer can be quantified on a scale of 0-5 with 5 being positively inclined. As such the maximum score available is 30 for Futura's analysis.

1. How often were you able to get an erection during sexual activity?
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?
3. When you attempted intercourse, how often were you able to penetrate (enter) your partner?
4. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?
5. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?
6. How do you rate your confidence that you could get and keep an erection?

For FM57, it has expanded this by adding two additional endpoints, both questions from the sexual encounter profile:

1. Were you able to insert your penis into your partner's vagina?
2. Did your erection last long enough for you to have successful intercourse?

The problem with an ED study is that it is not binary in terms of outcomes for the patients. Hence we believe the more detail and aspects of these outcomes that are tested, the more accurate they are likely to be, in our view. This should help to reduce variability and again the placebo effect.

It is important to note that these endpoints are clinically relevant and have been validated by the FDA in the past (Cialis, Levitra and Stendra were approved on this basis).

Duration of study extended

The initial study involved four weeks on treatment per patient. In our view, a shorter study period will result in a greater placebo effect. FM57 will be run over 12 weeks, and hence we would expect the placebo responses to dissipate over time.

Recruitment from more appropriate countries

FM57 will be trialled almost exclusively in Central and Eastern Europe, where we think the inclusion criteria can be more accurately achieved than in the UK. We suspect that this decision was driven by the performance of the trial centres in FM53.

Sample size modestly increased

The sample size has been increased to 250 patients per active arm versus 230. This modest increase should help at the margins to improve the chances of capturing a genuine efficacy improvement.

Open label enrolment encouraging from safety perspective.

As required by the regulator Futura is running a year-long, open label extension study for the highest MED2005 dose (0.6%). The company stated in September that over 500 patients had completed the blinded study and 80% of these had chosen to enrol in the open label study. Clearly reading anything into this with regards to the implications for efficacy is of little value, however it does at the very least suggest that 80% of patients are willing to take the highest dose available on an open label basis implying that they view the side-effect profile as tolerable.

A positive outcome is highly likely

Unlike most P3 studies we believe success or failure for the FM57 trial is not binary, rather there are a range of 20 feasible outcomes when factoring-in the dosing regimen. More importantly, there is just 1 of these outcomes that could be viewed as complete failure and prohibit future FDA approval. In fact, on a probability weighted basis we believe that there is an >70% chance of some form of positive outcome for Futura that could enable the second P3 study and eventual approval. In this section we band the potential outcomes into 4 broad categories, explaining which result would fall into which category. This enables us to then forecast the broad economic significance of a particular read-out in the following section.

Multiple positive potential outcomes, not binary

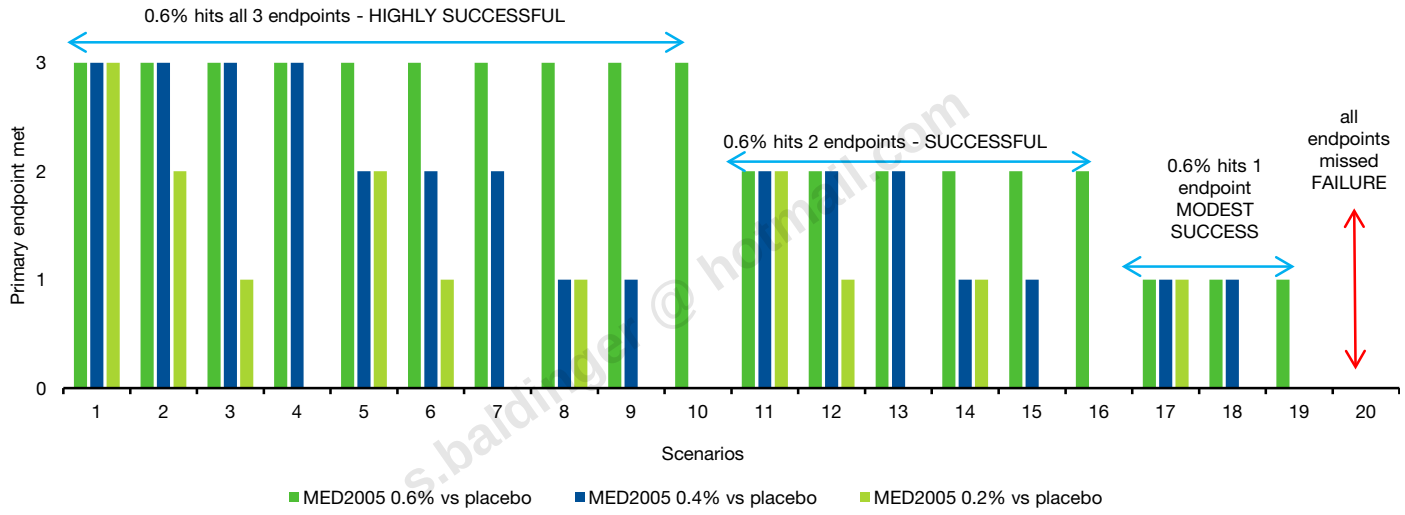
Many investors view FM57 as binary, but we believe there are 20 realistic outcomes (mathematically there are 512). Of these 20, only one would mean that MED2005 has no chance of progressing to approval, and we believe the potential of that happening is highly unlikely.

To simplify the analysis, we think it is fair to assume that Futura will ultimately look to reduce the doses from three to two for the confirmatory P3 study to follow this one. We assume this as we expect that it will want to target the majority of the Rx market with one of the 0.6% and 0.4% doses, and then also get approval for the 0.2% for the benign end of the Rx market to allow for an eventual OTC switch. In practice, we do not see why it would look to have all three doses approved. We believe there are four broad bands of outcomes:

- **0.6% dose hits all 3 co-primary endpoints – HIGHLY SUCCESSFUL:**
  - **All doses meet 3 co-primary endpoints:** We would expect Futura to choose between the 0.6% and 0.4% for the follow-up study, and to get eventual approval. We would also expect the 0.2% dose to be approved.
  - **0.6% dose meets all 3 endpoints, 0.4% and 0.2% meet at least one endpoint:** In this scenario, we would expect Futura to prioritise the 0.6% dose over the 0.4% dose and to gain eventual approval. For the 0.2% dose, we would strongly expect approval if it hit two endpoints, and see approval with just one endpoint met as a 50/50. The cause for this optimism is the clean side-effect profile that has seen modestly efficacious drugs approved recently (Plenity earlier this year in obesity).
  - **0.6% dose meets all 3 endpoints, 0.4% meets 0, 1 or 2 endpoints and 0.2% does not meet any endpoint:** In this scenario, we would expect the 0.6% to be prioritised and ultimately approved. We would not expect the 0.2% dose to be approved.
- **0.6% dose hits 2 co-primary endpoints – SUCCESSFUL:**
  - 0.6% dose meets two endpoints, 0.4% and 0.2% meet at least one endpoint: We would expect Futura to prioritise the 0.6% dose if the 0.4% only meets one endpoint, if the 0.4% meets two endpoints then further analysis will be needed which can be done ahead of the second confirmatory P3 study. We would expect whichever asset is prioritised to gain approval. For the lowest dose, we would expect approval if it hit two endpoints and see approval with just one endpoint met as a 50/50.

- **0.6% dose hits 1 co-primary endpoint – MODEST SUCCESS:**
  - 0.6% dose meets one endpoint, 0.4% and 0.2% meet one endpoint: We would not expect the 0.6% dose to get approval, but see a good chance for the 0.2% given the likely safety benefits relative to PDE-5s. Commercial success would be driven by mild patients.
  - 0.6% dose meets 1 endpoint, 0.4% meets 1 endpoint and 0.2% does not meet any endpoint: We think this would be an unsuccessful outcome, as we would not expect the 0.2% dose to gain approval given the lack of efficacy, while we would not expect the 0.4% or 0.6% to gain approval given the relative lack of efficacy and likely only moderately better safety profile vs PDE-5s.
- **0.6% dose misses all endpoints – FAILURE:**
  - This is a worst case, total failure outcome. Here no dose would have shown efficacy, and hence we would not expect approval.

Figure 2: Summary of potential outcomes assuming linear probability



Source: Liberum estimates

Probability of success > 70%

A paper published by Wong et al in 2018 showed that the average P3 success rates across all indications excluding oncology is about 70%, and for genitourinary indications (relating to genital and urinary organs) it is 69%. These P3 studies will usually have come on the back of a thorough P1 and P2 programme. Given Futura has delivered such a programme and shown compelling P2a data, we see no reason to assign a lower chance of success here. In fact, we believe there are a few reasons to believe that this is lower risk and therefore has a higher chance of success than the typical study analysed in the Wong et al paper.

1. **Safety unlikely to be an issue:** A McKinsey study on P3 failures found that 30% during the period 1990-2002 were driven by safety concerns. For MED2005, this should not be an issue as GTN is a well understood API with a long safety record. As such, we view a failure of the study due to side-effect issues as highly unlikely. This could in theory lift the probability of success by almost 10ppt above the 70% typical rate.
2. **MED2005 is not a NME:** A study conducted by BioMedTracker showed that from 2004-2014 new molecular entities (novel mechanisms) were 30%

more likely to fail in P3 than non-NMEs. GTN is a well understood molecule, and has been approved for over two decades.

3. **Replicating P2 would deliver a positive outcome:** Simply replicating the efficacy seen in the P2a study would deliver a positive outcome, albeit towards the lower end of that scale.
4. **Improvements on P2 further de-risk study:** As detailed in the previous section, Futura has made a number of key changes that increase the probability of success in this study, in our view.

While P3 studies are always risky, we believe that FM57 is significantly lower risk than the average P3 study.

Positive outcome delivers 41-366% upside

Having grouped the likely outcomes into 4 categories, in this section we assess the likely peak sales for each scenario and hence the valuation implications for Futura immediately post the release of the headline data. In a positive scenario we forecast a peak sales range of £240-500m and an NPV per share of between £0.45 and £1.49.

RX peak sales range of £240-500m depending on level of success

We have built a bottom-up model of the US and RoW markets on a volume basis for each positive scenario. This combined with our pricing assumptions, that reflect a genericised market, drive our forecast peak sales range of £240-500m. Note this is for the prescription market only, we have assumed very little for the OTC opportunity which represents significant optionality.

10-25% volume share depending on clinical outcome

As we have outlined earlier, we believe there are three likely outcomes in a successful scenario:

- **HIGHLY SUCCESSFUL:** Here the highest dose of MED2005 meets all three co-primary endpoints, while also showing a better safety profile when compared to the PDE-5s. This data would allow it to compete head-to-head with the PDE-5s given the efficacy would be likely to be similar but with a faster onset of action and better side-effect profile. We estimate that MED2005 could take a peak volume share in the US of 25% with this data, and 15% in the EU (where pricing is likely to be more of a barrier).
- **SUCCESSFUL:** Here the highest dose hits two co-primary endpoints, while also showing a better safety profile when compared to the PDE-5s. We believe that this would allow MED2005 to carve out a niche in patients who have not stayed on PDE-5s due to the side-effect profile as well as those new patients who want a faster onset of action. Based on market research conducted by Cello Health, this amounts to almost half of the market. Thus although there is a less compelling efficacy argument versus the PDE-5s, there is still a substantial market opportunity. We estimate that MED2005 could achieve a 17% peak volume share in the US (or c.35% of this population that is not happy with PDE-5 therapy), and a 15% share in the EU.
- **MODEST SUCCESS:** 0.6% dose hits co-primary endpoint. Clearly this result would leave MED2005 unable to compete on efficacy terms with the PDE-5s. Rather, we suspect it would be used by new starters who want to retain spontaneity and have the lowest side-effect profile – in essence the least invasive therapy possible. It would also be a useful therapy for those patients contraindicated on nitrates. As such, we still believe that MED2005 could capture a 10% US and EU5 market share.

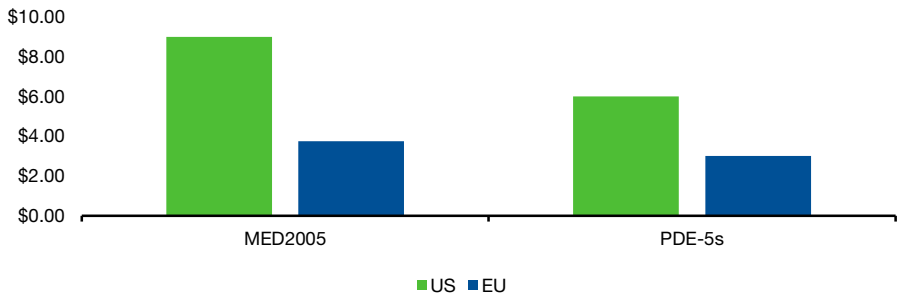
We assume premium pricing in the US for novel administration

We believe that MED2005 is a differentiated product and will warrant a premium to the genericised PDE-5s in the US. We assume a price of $8.50 per dose or a 50% premium over the US. While this is a substantial premium,

it is exaggerated to some extent by the collapsing price of the PDE-5s following recent patent expiries.

For the EU, we assume a more modest 25% premium over the $3.00 per dose that we estimate to be the average price across the EU5. Given most of the European market is out of pocket and that this is a relatively small ticket price, we think there is a relatively inelastic price elasticity of demand and our assumption could prove overly conservative.

Figure 3: EU vs US pricing for MED2005



Source: Liberum estimates, Bloomberg

Shares worth up to £1.49 when fully de-risked

To work out the value of each scenario to Futura immediately post the data read-out we assume:

- The company will ultimately outlicense asset and retain 40% of the total potential value from MED2005. This is similar to what we have seen for other assets that have been outlicensed post P3 success, and broadly mirrors an outlicensing deal whereby Futura received a 20-25% royalty on future sales.
- That a 12% WACC is a fair discount rate.
- That MED2005 is not approved until 2021 in the EU and early 2022 in the US with exclusivity running until 2028.
- That there is a limited chance of an Rx to OTC switch.

This yields a valuation range of £0.45 to £1.49 per share in a positive scenario. On a risk weighted basis this equates to £0.60 per share.

Figure 4: Summary of Futura assumptions and implications for our scenario analyses

Scenario	Peak sales	Peak margin	WACC	TG	DCF value	To Futura	Per share	Risk adjustment	Value per share
Highly successful	£535m	71.7%	12.0%	-25%	£701m	£281m	£1.37	15%	£0.21
Successful	£440m	68.6%	12.0%	-25%	£487m	£195m	£0.95	25%	£0.24
Modest Success	£242m	57.2%	12.0%	-25%	£167m	£67m	£0.33	35%	£0.11
Failure	£0m	0.0%	12.0%	-25%	£0m	£0m	£0.00	25%	£0.00
OTC switch	£78m	24.4%	12.0%	5%	£308m	£123m	£0.12	38%	£0.04

Source: Liberum estimates

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LIBERUM

Research

Alternatives
Conor Finn
+44 (0)20 3100 2257
conor.finn@liberum.com
James Shields
+44 (0)20 3100 2266
James.shields@liberum.com

Business Services, Building, Leisure & Travel
Building Materials, Equipment Hire & Housebuilders
Charlie Campbell
+44 (0)20 3100 2090
charlie.campbell@liberum.com
Marcus Cole
+44 (0)20 3100 2092
marcus.cole@liberum.com

Support Services & Special Situations
Joe Brent
+44 (0)20 3100 2272
joe.brent@liberum.com
Sanjay Vidyarthi
+44 (0)20 3100 2278
sanjay.vidyarthi@liberum.com
James Allen
+44 (0)20 3100 2088
james.allen@liberum.com

Transport
Gerald Khoo
+44 (0)20 3100 2195
gerald.khoo@liberum.com

Leisure
Anna Barnfather
+44 (0)20 3100 2176
anna.barnfather@liberum.com
Andrew Wilkinson
+44 (0)20 3100 2068
andrew.wilkinson@liberum.com

Consumer
Consumer Discretionary
Adam Tomlinson
+44 (0)20 3100 2174
adam.tomlinson@liberum.com

Consumer Goods
Anubhav Malhotra
+44 (0)20 3100 2197
anubhav.malhotra@liberum.com
Nico von Stackelberg
+44 (0) 20 3100 2074
nico.vonstackelberg@liberum.com

Roving
Wayne Brown
+44 (0) 20 3100 2082
wayne.brown@liberum.com

Financials
Financial Services
Ben Williams
+44 (0)20 3100 2274
ben.williams@liberum.com
Jamie Donald
+44 (0)20 3100 2164
jamie.donald@liberum.com
Rahim Karim
+44 (0)20 3100 2271
rahim.karim@liberum.com

Healthcare
Graham Doyle
+44 (0)20 3100 2095
graham.doyle@liberum.com
Alistair Campbell
+44 (0)20 3100 2096
alistair.campbell@liberum.com

Industrials
Capital Goods
Daniel Cunliffe
+44 (0)20 3100 2086
daniel.cunliffe@liberum.com
Ryan Gregory
+44 (0)20 3100 2071
ryan.gregory@liberum.com
Christian Hinderaker
+44 (0)20 3100 2275
christian.hinderaker@liberum.com

Real Estate
Tom Musson
+44 (0)20 3100 2067
tom.musson@liberum.com

Resources
Agriculture & Nutrition
Sophie Jourdier
+44 (0)20 3100 2072
sophie.jourdier@liberum.com

Mining
Richard Knights
+44 (0)20 3100 2087
richard.knights@liberum.com
Ben Davis
+44 (0)20 3100 2083
ben.davis@liberum.com

Speciality Chemicals & New Energy
Adam Collins
+44 (0)20 3100 2075
adam.collins@liberum.com

Technology, Media & Telecommunications
Media
Ian Whittaker
+44 (0)20 3100 2089
ian.whittaker@liberum.com
Harry Read
+44 (0)20 3100 2093
harry.read@liberum.com

SMID Technology & Services
Andrew Bryant
+44 (0)20 3100 2277
andrew.bryant@liberum.com

Technology
Janardan Menon
+44 (0)20 3100 2076
janardan.menon@liberum.com
Olivia Honychurch
+44 (0)20 3100 2081
olivia.honychurch@liberum.com

Strategy & Stock Selection
Andrew Coury
+44 (0)20 3100 2091
andrew.coury@liberum.com

Convertibles

Simon Smith
+44 (0)20 3100 2171
simon.smith@liberum.com

Richard Tomblin
+44 (0)20 3100 2172
richard.tomblin@liberum.com

Equity Sales – London

Julian Collett (Head of Equity Sales)
+44 (0)20 3100 2113
julian.collett@liberum.com
David Parsons (Head of Equities)
+44 (0)20 3100 2125
david.parsons@liberum.com
Edward Blair
+44 (0)20 3100 2117
edward.blair@liberum.com
Nicholas Lee
+44 (0)20 3100 2129
nicholas.lee@liberum.com
Oliver Baxendale
+44 (0)20 3100 2193
oliver.baxendale@liberum.com
Alistair Smallwood
+44 (0)20 3100 2124
alistair.smallwood@liberum.com

Sebastian Fernandez
+44 (0)20 3100 2242
sebastian.fernandez@liberum.com

Specialist Sales

Diversified Financials
Steve Keeling
+44 (0)20 3100 2120
steve.keeling@liberum.com

Real Estate
John Mozley
+44 (0)20 3100 2115
john.mozley@liberum.com

Consumer & Leisure
Lucy Sharma
+44 (0)20 3100 2236
lucy.sharma@liberum.com

Alternative Funds
Anastasia Mikhailova
+44 (0) 20 3100 2259
anastasia.mikhailova@liberum.com
Andrew Davies
+44 (0) 20 3100 2269
andrew.davies@liberum.com
Jack Kershaw
+44 (0) 20 3100 2253
jack.kershaw @liberum.com

Equity Sales – New York

Mark Godridge
+1 212 596 4823
mark.godridge@liberum.com
Julian Plant
+1 212 596 4824
julian.plant@liberum.com
Peter Penha
+1 212 596 4808
peter.penha@liberum.com
Sarah Port
+1 212 596 4818
sarah.port@liberum.com
John Churchill
+1 212 596 4807
john.churchill@liberum.com

Sales Trading

Graham Smith (Head of Execution)
+44 (0)20 3100 2101
graham.smith@liberum.com
Dominic Lowres (Head of Execution Strategy)
+44 (0)20 3100 2103
dominic.lowres@liberum.com
Nina Dixon
+44 (0)20 3100 2109
nina.dixon@liberum.com
Nick Worthington
+44 (0)20 3100 2106
nick.worthington@liberum.com
David Thompson
+44 (0)20 3100 2062
david.thompson@liberum.com
Scott Leslie
+1 212 596 4813
scott.leslie@liberum.com
Mark O'Hara (Head of Sales Trading)
+44 (0)20 3100 2061
mark.o'hara@liberum.com
Scott Briant
+44 (0)20 3100 2118
scott.briant@liberum.com
William Wood
+44 (0)20 3100 2119
william.wood@liberum.com
Tim Mayo (Execution)
+44 (0) 20 3100 2127
tim.mayo@liberum.com

Trading

Giles Johnston (Head of Trading)
+44 (0)20 3100 2203
giles.johnston@liberum.com
Simon Warrener
+44 (0)20 3100 2108
simon.warrener@liberum.com

Market Making

STX 77440
+44 (0)20 3100 2200

Liberum Capital Limited / Ropemaker Place, Level 12, 25 Ropemaker Street, London, EC2Y 9LY / T +44 (0)20 3100 2000 / F +44 (0)20 3100 2299 / www.liberum.com
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