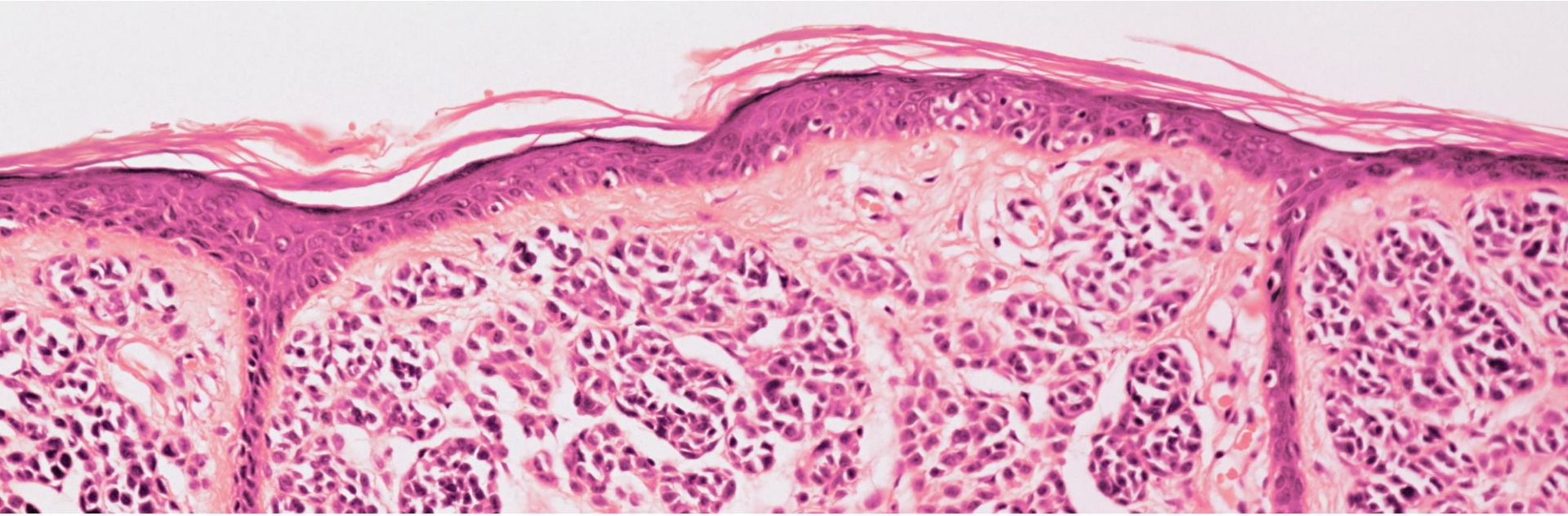
Futura Medical

Advanced Transdermal Technology



Results for the six months ended 30 June 2016

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About Futura

What we do

- Apply advanced transdermal science to generic compounds
- Develop products with compelling commercial potential

Our key strengths

- Clinically proven innovation of generic compounds
- Sexual health and pain relief product focus
- Experienced management team
- Products entering commercial phase with strong development pipeline
- Low cost base

DermaSys®

- Optimised drug delivery through the skin
- 7 core patent families around DermaSys®

2016 Interim Results Highlights

Interim Highlights – Products

MED2002 – Erectile dysfunction gel

- Clinical primary endpoints achieved
- Potential First line therapy – fast and safe
- Projected $500+ million opportunity*

CSD500 – Erectogenic condom

- Approvals expected shortly on modified manufacturing process
- First licensee production complete ahead of H2 launch
- Two new distribution agreements announced
  - Milsing – marketing & distribution rights for Southeast Europe
  - TTK – marketing & distribution rights for India

TPR100 & TIB200 – NSAID topical gels

- Opportunity to be considered "best in class"
- Significant interest from potential commercial partners
  - Out-licensing across both TPR100 & TIB200, EU & USA
  - Strong demand for 12-hour ibuprofen gel
  - Commercial negotiations continuing

** Decision Resources report on MED2002*

Interim Highlights – Financials

- **Net loss of £1.89 million in the period**
  (2015: net loss of £2.47 million)

- **Cash resources of £2.90 million at 30 June 2016**
  (30 June 2015: £7.23 million)

Sexual Healthcare

MED2002 – Gel for Erectile Dysfunction

Sexual Healthcare

Product

- Topically applied gel containing 0.6mg of glyceryl trinitrate
- Utilises Futura's DermaSys® drug delivery technology

Market research

- Market research highlighted significant potential for MED2002
  - ~7.5% of men with ED are contra-indicated for PDE5 inhibitors[1]
  - Strong demand by patients for safe, fast & efficacious treatment

Intercourse is not initiated ~22% of the time PDE5 inhibitors taken by sufferers[1]

Futura trademark and patents

- MED2002 branded Eroxon®
- Patent protection until 2025 in key territories and 2028 for USA

1. Decision Resources market assessment

MED2002 – Clinical Development

Sexual Healthcare

- **Pre-clinical, early stage development complete**

- **MED2002 pivotal efficacy study recently completed**
  - Randomised, placebo controlled, double blind, home use, crossover design in a minimum of 192 ED patients
    - Headline data 6 September, full analysis expected Q4 2016
  - Primary clinical endpoint
    - Improvement in patient erectile function*
  - Secondary clinical endpoints
    - Evaluate efficacy of MED2002 using other IIEF domains, sexual encounter & global assessment questionnaires between mild, mild/moderate, moderate & severe ED patient groups
    - Key secondary endpoint – speed of onset
    - Assess safety & acceptability of MED2002

- **Actual recruitment**
  - 232 randomised males
  - 230 ED patients in full set analysis ("Intention to Treat" set)
  - 209 ED patients that adhered to required study protocol

** As determined by change in International Index of Erectile Function*

MED2002 pivotal study – Headline Data

Sexual Healthcare

Primary clinical endpoint met

- Statistically significant improvement in the International Index of Erectile Function domain (IIEF-EF) between MED2002 & placebo P = < 0.0132 across all ED patients

Secondary analyses of IIEF-EF in ED patients

- Defined by Rosen et al 2011 and recognised industry standard
- Difference between baseline and active score in IIEF-EF domain
- Headline secondary analysis target of > /= 4
- Post hoc analysis planned for
  - Mild: IIEF-EF increase > /= 2, Moderate: IIEF-EF increase > /= 5 & Severe: IIEF-EF increase > /= 7

All ED patient groups (IIEF-EF>/=4)

- Statistically significant improvement in the IIEF-EF domain from baseline for MED2002 vs placebo P = < 0.0272

MED2002 pivotal study – Headline Data

Sexual Healthcare

Mild ED patient group (IIEF-EF>/=4)

- Highly statistically significant improvement in the IIEF-EF domain for MED2002 vs placebo P = < 0.0001
- Rapid speed of onset
  - 82% of patients with onset of < 10 minutes
  - 54% of patients with onset of < 5 minutes
  - 76% of patients lose tumescence < 10 minutes after sexual intercourse
- Excellent safety profile
  - No Serious Adverse Events or serious adverse reactions*
  - No withdrawals from ED patient group due to safety
  - Less than 2% of patients with adverse events of mild headache* (not QC'd yet)

Moderate & Severe ED patient groups (IIEF-EF>/=4)

- Sub group improvement in the EF domain for MED2002 vs placebo not sufficient to achieve significance
  - FM53 was a single dose strength study of 0.6mg of GTN
  - Moderate &/or severe group may respond to higher dose strength

** Across all ED patient groups in FM53*

MED2002 pivotal study

Sexual Healthcare

"The positive data from this study provides an exciting new innovation with the potential to be a first line therapy in erectile dysfunction.

"MED2002 has the required efficacy, speed of onset and safety profile consistent for an over-the-counter as well as prescription use product.

"MED2002, for the first time in the treatment of ED, has the potential to meet the needs of primary care providers and of patients."

Mr David Ralph
Consultant Urologist
St Peter's Andrology Centre & The Institute of Urology, UCLH, London
Past President European Society for Sexual Medicine

MED2002 – Commercial

Sexual Healthcare

- **$5 billion estimated global market***
  - $4.3 billion PDE5 inhibitor sales **
  - Contraindicated market of 7.5% estimated at over $300 million
  - Balance made up with intra-urethral, injection & non-invasive devices
- **MED2002 potential opportunity of over $0.5 billion**
  - Based on Decision Resources research commissioned by Futura
  - $300 million if positioned for the contra-indicated market alone at premium price
  - $600 million if positioned as a first line therapy treatment at forecasted market price
    - Potential to be the fastest ED treatment
    - Excellent safety profile
    - Patient preferred gel application
  - OTC switch potential 25%-30% increase in sector value

** Directors estimate based on combined sales of PDE5 inhibitors and Decision Resources report on MED2002*
*** MSP; total combined sales of PDE5 inhibitors: Viagra, Cialis and Levitra, 2015 Annual reports from Pfizer, Lilly and Bayer*

CSD500 – Erectogenic Condom

Sexual Healthcare

Product

- Lubricated condom with Zanifil® gel incorporated inside teat
- Zanifil® clinically proven claims to give:
  - Increased penile firmness
  - Longer lasting sexual experience
  - Improved sexual performance

Only *over the counter* clinically proven sexual performance claims

Regulatory status

- EU approved medical device & further approvals expected to
  - Extend shelf life
  - Provide second manufacturer
- Ongoing regulatory approvals in non-EU territories

blue diamond® - Futura's own brand

- Selling online and in 600 drug stores in Holland
- 2 SKUs – 3 pack and 6 pack introduced March 2016

CSD500 – Out-licensing

Sexual Healthcare

Global out-licensing strategy

- Seven distribution agreements in place
- All milestone and royalty based, for lifetime of patents
- Ongoing discussions with further licensees

Launch timelines

- First licensee launch on track for Q4 2016
- Next order already placed for 2nd licensee launch
- Further launches planned for 2017

Futura trademarks and patents

- Zanifil® brand logo required on all licensee products
- Existing patents already granted in 36 territories
- New patent filed to extend protection until 2033

Topical Pain Relief

Topical Pain Relief – The Market

Demand for safe, effective, long lasting topical pain relief

- Current topical pain relief is often ineffective
- Significant commercial partner interest
  - Strong permeation claims and 12 hour duration

Global and US sales of topical analgesics

- Global sales of topical over the counter NSAIDs > US$2.9 billion (2015)
- US sales of topical prescription only (Rx) NSAIDs > US$1 billion (2015)

PRODUCT	2015 (mil)	2014 (mil)
PENNSAID	$423	-
VOLTAREN (1%)	$400	$425
FLECTOR PATCH	$127	$167

Regulatory classifications

- Topical NSAIDs in EU available OTC or Rx depending on indication
- In USA only topical diclofenac is available, on Rx basis

1. *Non steroidal anti-inflammatory drug (i.e. ibuprofen and diclofenac)*

TPR100 – Diclofenac

Pain Relief

Product

- 2% diclofenac gel for symptomatic relief of pain and inflammation
- Market leaders
  - EU – GlaxoSmithKline: Voltarol® (1% & 2% gel)
  - US – Horizon Pharma: Pennsaid® (2%) – Rx

Clinical study development

- Pharmaco-kinetic and pharmaco-dynamic studies completed
  - Superior drug delivery over market leaders
  - Primary endpoint met of superiority over placebo
  - Non-inferior to market leader
- No further clinical studies expected for initial EU regulatory approval

Regulatory

- EU – Target submission date by 31 December 2016
  - Initial submission to be novated to commercial partner
- US – Hybrid application
  - Pre-IND review with FDA in Q4 2016

TIB200 – Ibuprofen

Pain Relief

Product

- 10% ibuprofen gel for relief of pain and inflammation
- Market leaders
  - UK – Nurofen® and Ibugel ®
  - US – None approved

Clinical study development

- Pharmaco-kinetic and pharmaco-dynamic studies completed
  - Superior drug delivery over market leaders
  - Primary endpoint met of superiority over placebo
  - Non-inferior to market leader
- Strong demand for 12 hour ibuprofen – efficacy study required

Regulatory status

- EU – Dependent on commercial licensee agreement
- US – Hybrid application

Topical Pain Relief – Commercial

Pain Relief

Improved delivery with DermaSys® technology

- Improved drug delivery claims give consumer point of difference
- NICE[1] guidance requires prescribing of topical NSAID before oral NSAID for osteoarthritis of the knee or hand
- Potential to be considered "best in class" for both TPR100 and TIB200

Out-licensing advisors appointed

- Significant commercial partner interest
- Heads of terms advanced stage with several potential parties
- Anticipate further agreements and announcements in Q4 2016

3 core patent groups specific to NSAIDs

- One patent group approved in all key territories until 2028
- Two further patent groups in application stage

1. National Institute for Health and Care Excellence

Outlook

News Flow and Outlook

Expected news flow during 2016

- CSD500 – 18-month shelf life regulatory approvals
- CSD500 – first distributor launch
- Pain relief – at least one partner agreement
- MED2002 – regulatory guidance over remaining regulatory pathway

Outlook for 2017

- CSD500 – further distributor launches and agreements
- Pain relief – further agreements
- MED2002 – commercialisation strategy and potential agreements

Vision and Objectives

- **To build upon our recognised status as a transdermal innovation specialist in the pharmaceutical industry**

- **Three to five year corporate objectives**
  - CSD500 becoming the market leading premium condom worldwide
  - Successful licensing and launch of pain relief products in key territories
  - Successful commercialisation of MED2002 as a topical treatment for ED
  - Expand the application of our DermaSys® technology
  - Build and enhance strong pipeline of internally developed innovation
  - Build shareholder value