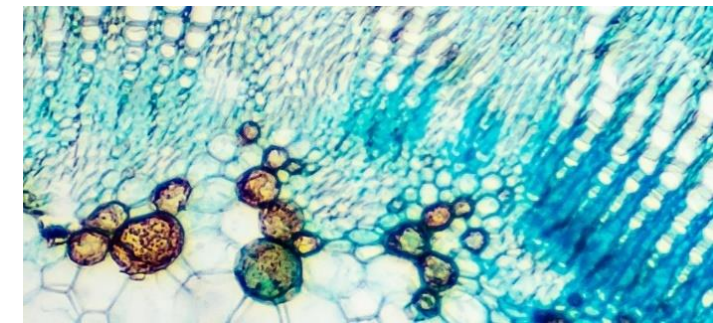


# INTERIM RESULTS

Six months to 30 June 2019

11 September 2019

Strictly Private and Confidential



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# A CORPORATE OVERVIEW



# ABOUT FUTURA - A CORPORATE OVERVIEW



## FUNDAMENTALS

Futura is listed on AIM and located at the Research Park, Guildford

- 'Virtual' organisation with 15 staff and low overheads
- Significant outsourced infrastructure with over 30 consultants

## DERMASYS®

Clinically proven transdermal science

- Drug delivery through the skin of existing pharmaceutical drugs for improved or new indications
- Excellent safety profile - no harsh permeation enhancers

## TRACK RECORD

Clinically proven innovation using existing pharmaceutical compounds

- Sexual health and pain relief focus
- Late stage products with experienced Management Team

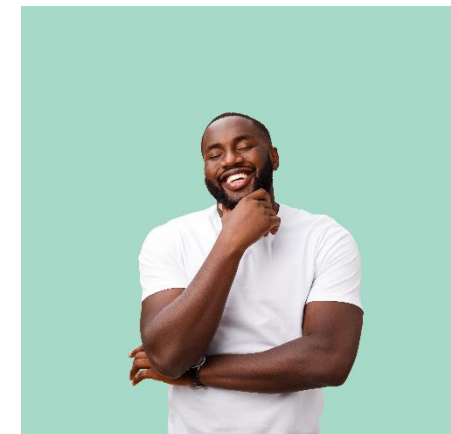
## KEY PORTFOLIO PRODUCTS

**MED2005 – Topical gel for the treatment of erectile dysfunction (ED)**

- Highly differentiated treatment including potential 5-minute speed of onset
- Positive Phase 2 data, excellent PK results & 1st Phase 3 headline data due by end of 2019

**TPR100 – Topical gel for the treatment of pain relief**

- UK regulatory dossier submitted and first round of questions received with response due Q1 2020
- Further out-licensee interest pending UK regulatory approval



# SIX MONTH HIGHLIGHTS – PRODUCTS, ORGANISATION & FINANCIAL



- Strategic decision to focus on maximising R&D pipeline value by de-risking assets
- Priorities are MED2005 Phase 3 trial completion and further realisation of value from pain portfolio
- Increased awareness of MED2005 within scientific and pharmaceutical communities

## MED2005

- First Phase 3 “FM57” recruitment complete and on track for headline data in December 2019
- 500 patients completed FM57 so far<sup>1</sup> with 80% electing to continue into Open Label Extension
- Planning for second confirmatory Phase 3 “FM59” underway

## PAIN RELIEF

- Initial feedback received, supporting Thornton & Ross on its responses expected during Q1 2020
- Interest from other EU licensing partners post MHRA approval
- Development agreement for topical Cannabidiol gel signed



- Net loss in the period: £4.46 million (Net loss 30 June 2018: £1.95 million)
- Cash resource at 30 June 2019: £ 5.63 million (with tax credit of £1.36 million received in August 2019)



MED2005 – AN  
INNOVATION IN  
THE TREATMENT  
OF ED

LEAD PRODUCT



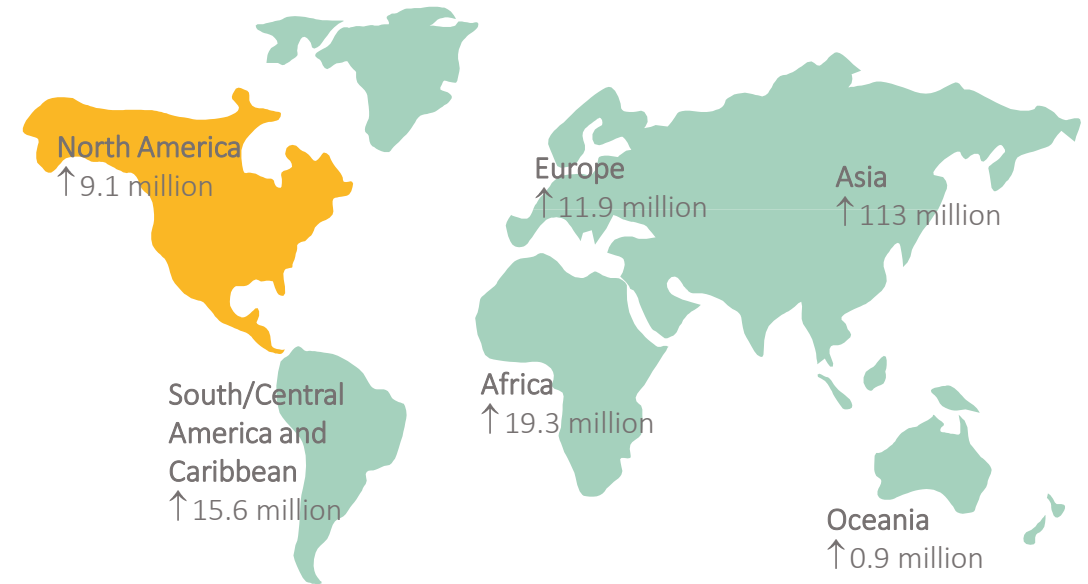


# ERECTILE DYSFUNCTION – QUALITY OF LIFE & SIZE OF THE PROBLEM



- 1 Sexual activity is beneficial<sup>1</sup>
- 2 Low self esteem and confidence
- 3 Partner concerns
- 4 Loss of intimacy
- 5 Affects work and family
- 6 Depression

☰ The number of men with ED will increase from 152 million men in 1995 to 322 million men by 2025<sup>2</sup>



- Growing population
- Ageing population
- Growth in obesity
- Increased awareness/acceptance

1. Early cessation of sex associated with premature death – Swedish study 1981; 50% reduction in cardiac death with more than two orgasms per week – Caerphilly Cohort Study BMJ 1997

2. Adapted from McKinlay JB. Int J Impot Res. 2000;12(suppl 4):S6-S11

# ED MARKET SIZE AND TREATMENT OPTIONS

**Erectile Dysfunction prescription (Rx) market worth over US\$ 5 billion in 2018<sup>1</sup>**

But no real innovation for 10+ years



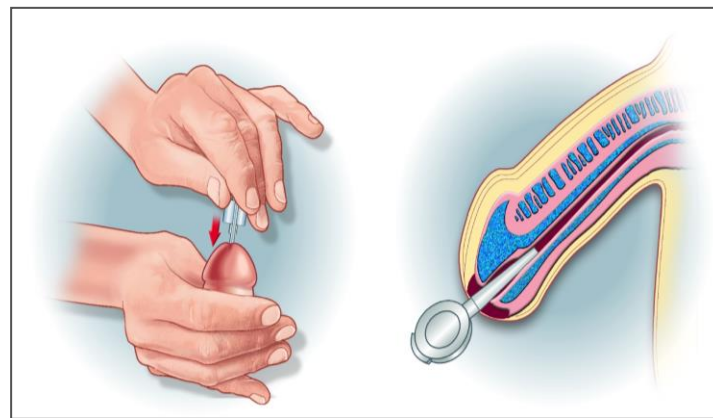
## PDE5 inhibitors



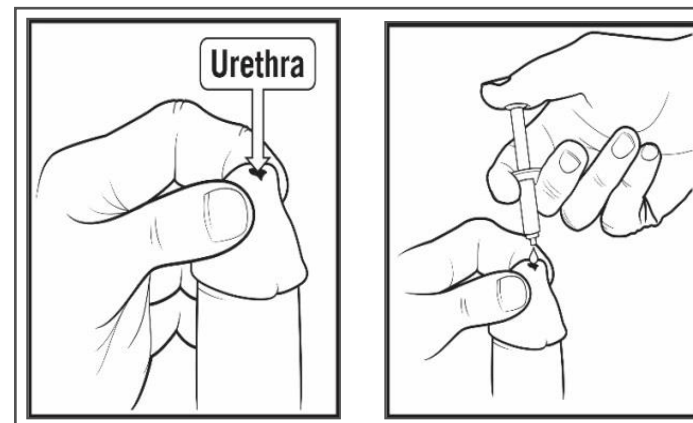
### Caverject®



### Muse®



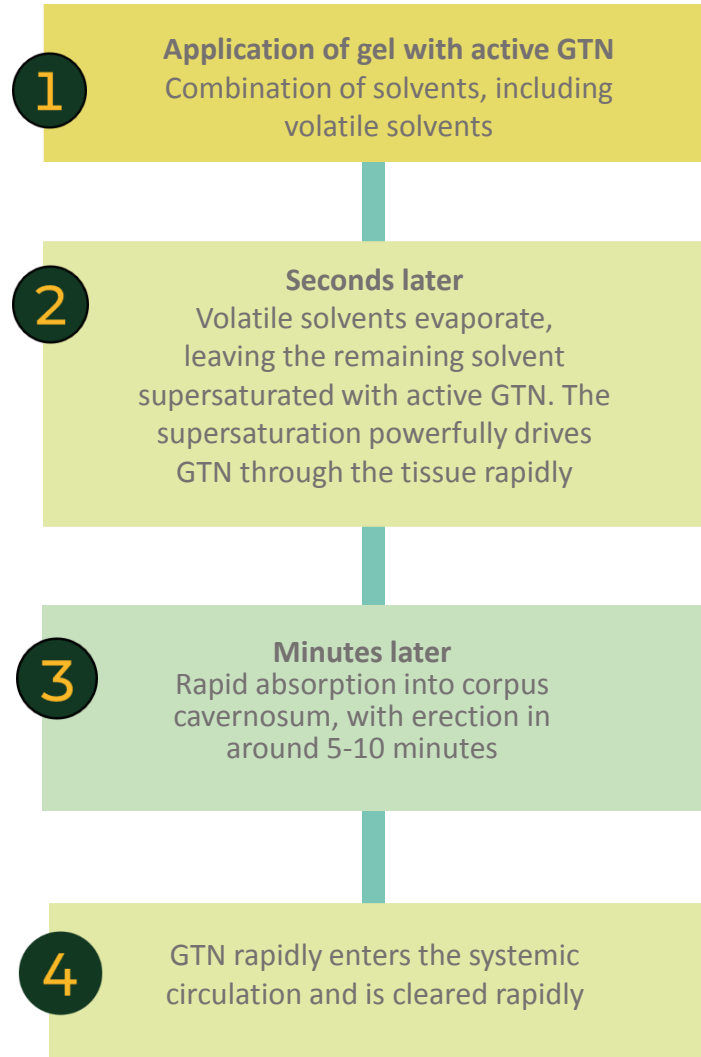
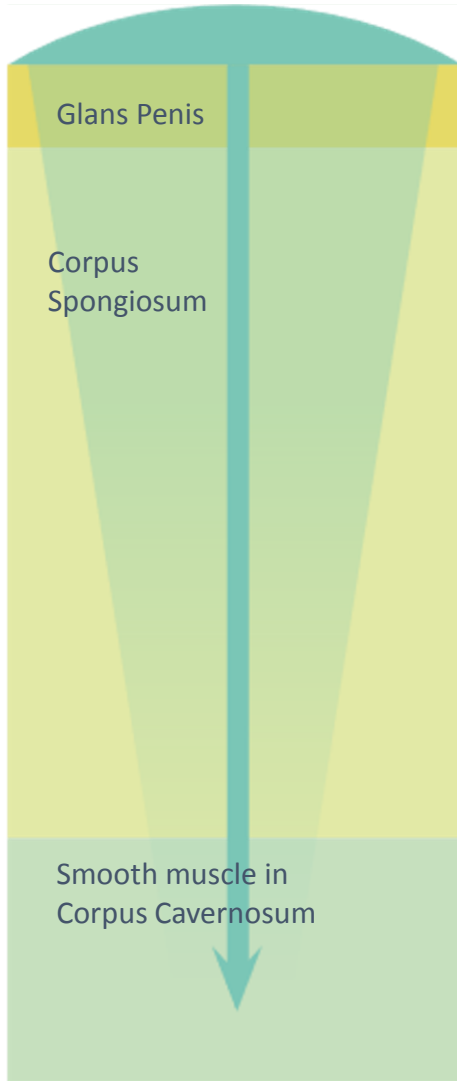
### Vitaros®



<sup>1</sup> Market size with sales based on Manufacturers' Selling Prices 2018: Sales from 75 countries. IQVIA  
<sup>2</sup> Excludes sales of Sildenafil through the Pfizer / Teva generic deal.



# MED2005 & THE DERMASYS<sup>®</sup> TRANSDERMAL TECHNOLOGY



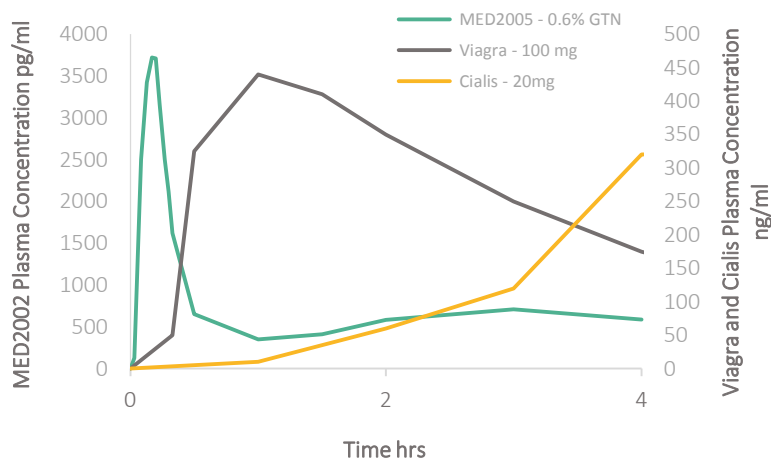
MED2005 uses **unique DermaSys<sup>®</sup> technology**, which enables **targeted and rapid delivery** of GTN through the tissue to achieve and maintain an erection

# MED2005 – FIRST TOPICAL GEL TO TREAT ED WITH KEY DIFFERENTIATORS

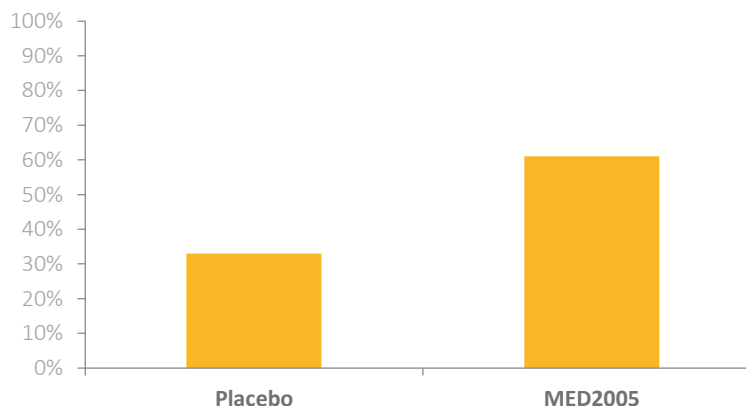


- MED2005 is a **topical gel** containing from 0.2% up to 0.6% of **glyceryl trinitrate (GTN)**
- Utilises Futura’s proprietary **drug delivery technology** DermaSys®
- Is applied directly to the exterior of the head (glans) of the penis **by the male or sexual partner**
- Has a rapid onset of action **5-10 minutes**
- Enables** either partner to initiate **sexual intimacy and spontaneity**

Comparative Dual Axis Pharmacokinetic Graph  
Comparing MED2005 (0.6% GTN) vs Viagra (100 mg)  
and Cialis (20mg) Over 4hrs<sup>1</sup>



Clinically important improvement (Rosen) in mild and mild to moderate ED patients MED2005 0.2% (FM53)



## 2019 UK focus group research results

- Women with partners suffering from ED
- Both pre and post menopausal women
  - Strong interest in MED2005 unique attributes
  - Helps restore a shared sexual experience
  - Women as interested in restoring intimacy and spontaneity to their sex lives
  - KOLs consistently state that ‘Treating couples is more effective than the individuals’

# MED2005 VALUE PROPOSITION



MED2005's unique proposition could become a preferred treatment option for many men with ED and their partners. It will also present a new treatment option for those for whom PDE5is are unsatisfactory or unsuitable.

## Alternative first line treatment

MED2005 is an **effective alternative first line** treatment for couples looking for a **spontaneous and more intimate solution** to erectile dysfunction

50% of physicians consider MED2005 a significant treatment improvement<sup>1</sup>

## Unable to use PDE5is

MED2005 represents a **treatment option** for those patients on nitrates therefore **contra-indicated to PDE5is**

At least 10% of ED patients are contraindicated from using oral PDE5is<sup>1</sup>

## Dissatisfied PDE5i users

MED2005 represents a **new treatment option** for patients who have discontinued treatment and for those who find PDE5i side effects **unacceptable**

Up to 50% of ED patients discontinue current ED treatments within a year<sup>1</sup>



**"MED2005, for the first time in the treatment of ED, has the potential to meet the needs of primary care providers and of patients...."**

**"The treatment of ED has not seen any new clinical products for nearly two decades...."**

Prof David Ralph who is Consultant Urologist at St Peter's Andrology Centre & Institute of Urology, UCLH, London and Past President of the European Society of Sexual Medicine

Dr Wayne Hellstrom who is Professor of Urology and Chief of Andrology at Tulane University School of Medicine in New Orleans and member of the Futura Medical Advisory Panel,

# MED2005 REPRESENTS A POTENTIAL US\$1 BILLION OPPORTUNITY<sup>1</sup>

1

- ED prescription (Rx) market worth over US\$5.6 billion in 2018<sup>2</sup>
- Research by Cello suggests a > 20% patient share for MED2005 (Branded Eroxon®)

2

- PDE5i now generic ED prescription (Rx) market worth US\$5.6 billion in 2018<sup>2</sup>
- Rx US\$ sales down by 15% since 2016 however volumes up by over 25%

3

- \$660 million potential 'Over the Counter' sales at \$5 per dose with 70% incremental to prescription sales
- Research and forecast provided by Ipsos Mori for Futura

4

- Strong commercial out-licensing interest in particular with Phase 3 headline data expected December 2019

5

- Strong interest from women whose partners have ED
- UK research conducted on both pre and post menopausal women

6

- Further patent filed in 2017 progressing and entering PCT national phase in Q1 2020
- Potential to extend patent protection, if application successful, out to 2037





# MED2005 – CLINICAL DEVELOPMENT PROGRAMME

LEAD PRODUCT



# CLINICAL STUDY PROGRAMME



Study Code	Study Phase	Number of Subjects	Test Article	Study status
FM33	Phase 1 – PK.	16	0.025%, 0.033% , 0.083% & 0.166% MED2003, 0.25% MED2004 and 0.4% MED2005	✓ Complete
FM35	Phase 1– PD.	15	0.0033% , 0.025% & 0.083% MED2003 and 0.2% MED2005	✓ Complete
FM53	Phase 2a – headline data Sep 2016 & peer-reviewed journal publication early 2018	231	0.2% MED2005 vs Placebo	✓ Complete
FM58	Phase 1 – PK.	40	0.2%, 0.4%, 0.6% & 0.8% MED2005 and Nitrostat	✓ Complete
FM57	Phase 3 – Safety and efficacy dose ranging. <b>Top-line results Dec 2019</b>	1,000	0.2%, 0.4% & 0.6% MED2005 and Placebo	Ongoing
FM59	Phase 3 – Safety and efficacy Confirmatory study. <b>Study completion by end of 2020</b>	690	0.2%, 0.4% & 0.6% MED2005 and Placebo (likely choosing two of three doses from FM57)	H2 2019 start <sup>1</sup>

Studies FM02 to FM07, FM22, FM23, and FM27 were early phase exploratory studies using previous MED formulations and are not presented here

PK = pharmacokinetic      PD = pharmacodynamic  
 PLO = Placebo (identical gel to MED2005 but without the active pharmaceutical ingredient glyceryl trinitrate)  
 1. Regulatory and ethics submissions expected in H2 2019 to allow patient enrolment to commence H1 2020

# FM53 (PHASE 2A EFFICACY STUDY) – COMPLETED SEP 2016

## FM53

A randomized double blind, placebo-controlled, home use, cross-over clinical trial of topically-applied glyceryl trinitrate, MED2005, 0.2% for the treatment of erectile dysfunction in 231 patients

## OBJECTIVES

**Primary endpoint:** Evaluate efficacy of MED2005 using the International Index for Erectile Function (IIEF) questionnaire

**Secondary endpoints:**

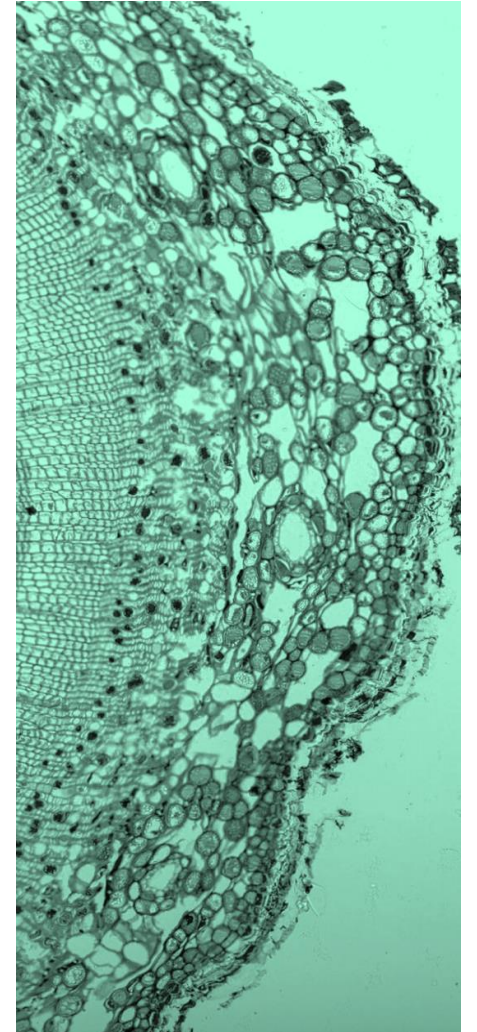
- Evaluate efficacy of MED2005 using the other domains of the IIEF, the Sexual Event Profile (SEP) and the Global Assessment Questionnaire (GAQ), mild/moderate, moderate & severe ED patient groups
- Assessment of speed of onset
- Assess safety and acceptability of MED2005

## DURATION

8-week treatment period (4 weeks active + 4 weeks placebo)

## RESULTS

- Primary end point and number of secondary endpoints were met
- Efficacy in mild and mild/moderate patients; minimum effective dose
- Extremely favourable side-effect profile in patients and female partners
- Patients experienced erections in 5-10 minutes
- Product used for spontaneous intercourse; in 33% of couples, the female applied to the male



# FM57 – PHASE 3 STUDY DESIGN



FM57	A Phase 3, dose-ranging, multi-centre, randomized, double-blind, placebo-controlled, home use, parallel group clinical trial of topically applied GTN for the treatment of ED in 1,000 male subjects with ED & their female partners								
OBJECTIVES	<p><b>Primary objective:</b></p> <ul style="list-style-type: none"><li><input type="checkbox"/> To demonstrate the efficacy of MED2005 versus placebo in male subjects self-diagnosed with ED using the erectile function domain of the International Index for Erectile Function (IIEF), the Sexual Encounter Profile (SEP) Question 2 &amp; 3.</li></ul> <p><b>Secondary objective:</b></p> <ul style="list-style-type: none"><li><input type="checkbox"/> To evaluate the efficacy of MED2005 in male subjects using Self-Esteem And Relationship Questionnaire (SEAR) for men, the Global Assessment Questionnaire (GAQ), the additional domains of the IIEF as well as subjective measures of the time of onset and duration of action (erection) and additional questions on usage and application of MED2005.</li><li><input type="checkbox"/> To evaluate the safety of MED2005 using Adverse Events (AEs) and standard assessments</li><li><input type="checkbox"/> Assess safety and acceptability of MED2005 in nitrate contraindicated patients</li></ul>								
STUDY SITES	Central and Eastern Europe								
PRODUCTS TESTED*	MED2005 <b>0.2% GTN</b> , 300 mg gel = 0.6mg GTN; MED2005 <b>0.4% GTN</b> , 300 mg gel = 1.2mg GTN; MED2005 <b>0.6% GTN</b> , 300 mg gel = 1.8mg GTN; and Placebo vehicle;								
STUDY UPDATE	<table><tr><td>End of June 2019:</td><td>Fully recruited</td></tr><tr><td>End of August 2019:</td><td>500 patients completed 3 month double blind phase to-date</td></tr><tr><td>End of August 2019:</td><td>80% of patients elected to-date to continue into Open Label extension and receive highest MED2005 dose</td></tr><tr><td>By end of 2019:</td><td>FM57 on track to deliver headline results</td></tr></table>	End of June 2019:	Fully recruited	End of August 2019:	500 patients completed 3 month double blind phase to-date	End of August 2019:	80% of patients elected to-date to continue into Open Label extension and receive highest MED2005 dose	By end of 2019:	FM57 on track to deliver headline results
End of June 2019:	Fully recruited								
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End of August 2019:	80% of patients elected to-date to continue into Open Label extension and receive highest MED2005 dose								
By end of 2019:	FM57 on track to deliver headline results								
OPEN LABEL EXTENSION	Approximately 450 subjects will also participate in a 6-month open label extension (150 of these for a further 6 months – totalling 12 months) to confirm long term safety of MED2005.								



# FM57 – RISK MITIGATION

- 1  Strong evidence of efficacy from 232 patient Phase 2a study (FM53) especially for men with mild and mild to moderate erectile dysfunction
- 2  Broad regulatory consensus<sup>1</sup> on remaining clinical programme (Phase 3)  
 Regulatory recommendations included into Phase 3 study design and analysis
- 3  FM58 PK study data suggests higher doses will increase efficacy whilst maintaining adverse events at an acceptable level for patients & their partners
- 4  Design of Phase 3 studies enhanced by seeking world leading expert opinion  
 Potential commercial partner feedback also incorporated into the Phase 3 design
- 5  FDA confirmed US Regulatory Pathway – US 505(b)2 using Nitrostat<sup>®</sup> as reference drug<sup>2</sup>  
 MEB confirmed EU Regulatory Pathway – Article 8(3) of Directive 2001/83/EC<sup>3</sup>

 All Regulatory Agencies open to OTC after period of Rx marketing

1. Meetings held with FDA, MEB and MHRA, United States, Netherlands (on behalf of EU) and UK regulators respectively  
2. Nitrostat<sup>®</sup> contains the same active pharmaceutical ingredient as MED2005. Used Nitrostat<sup>®</sup> in FM58 PK study as a pre-existing Listed Drug(reference drug) to simplify safety requirements.  
3. Likely to be same pathway for UK or MHRA equivalent pathway following Brexit.

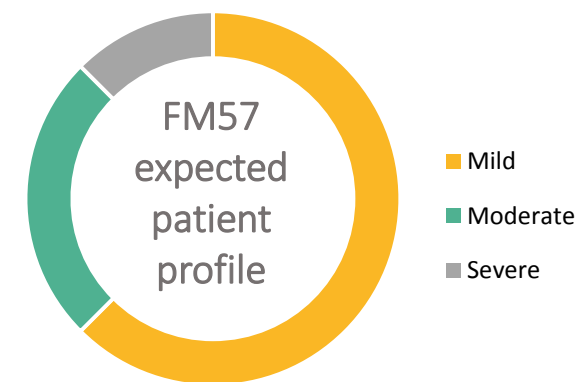
# FM57 – RISK PROFILE AND POSSIBLE OUTCOME SCENARIOS

## Possible outcome scenarios

- FM57 has been designed to study a number of scenarios – Outcome is not binary
- 3 different doses (0.2%, 0.4% & 0.6%) trialed in 3 types of ED (mild, moderate & severe)
- Highly successful clinical result is where at least one dose meets all primary endpoints
- Successful clinical result is where some primary endpoints are met in some types of ED<sup>1</sup>
- The better the clinical result the more the 2nd Phase 3 (FM59) will be de-risked
- A ‘highly compelling’ clinical result may allow us to seek EU approval ahead of FM59 results<sup>2</sup>

## Mild and moderate ED represents largest opportunity

- Commercial opportunity largely lies with men with milder ED who tend to be younger and more sexually active
- KOLs want a safe, locally applied product especially for men with mild and mild to moderate ED with performance anxiety issues
- FM57 expected patient profile reflects the key commercial opportunity



1. FM53 could be considered 'Successful' as it met the Primary Endpoint of FM53 with excellent side-effect profile but not at all ED severities at MED2005 0.2% dose.

2. If data compelling second Phase 3 may not be required for EU regulatory approval. In certain circumstances may submit ahead of completion of 2nd Phase 3 but timed that 2nd Phase 3 data would be available if required subsequent to initial submission. Second Phase 3 data at time of submission isNON-CONFIDENTIAL mandatory for FDA regulatory approval





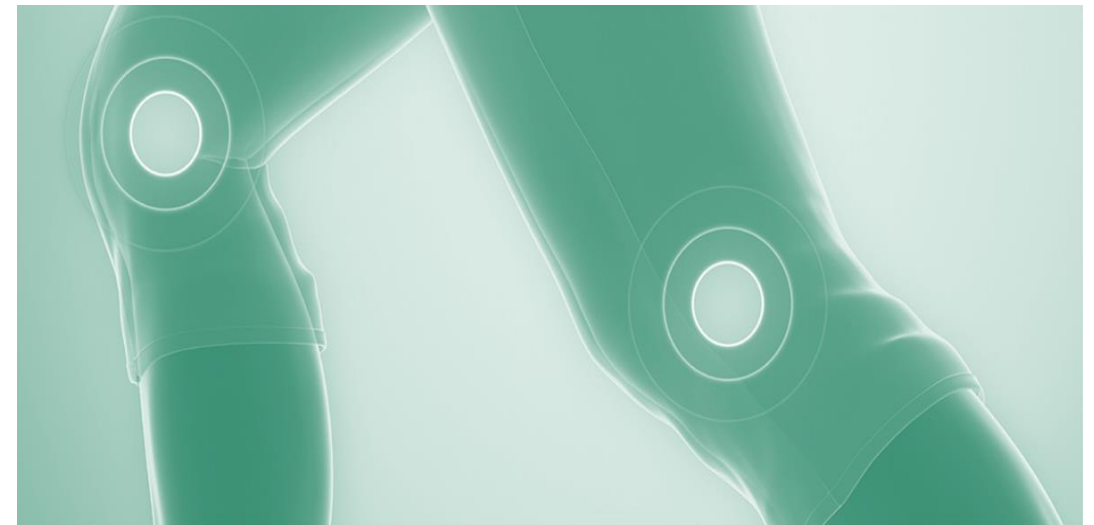
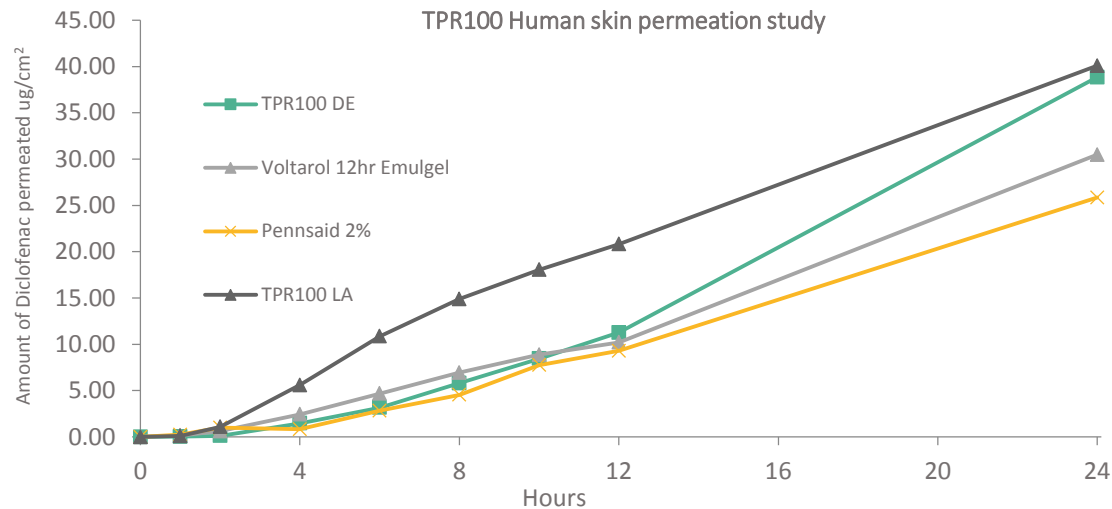
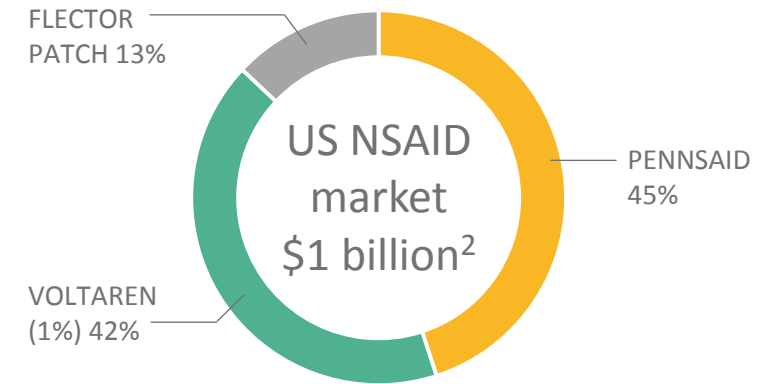
FUTURAMEDICAL

# TOPICAL PAIN RELIEF



# TOPICAL PAIN RELIEF

- 1 Global sales of topical over the counter non steroidal anti-inflammatory drugs (“NSAIDs”) > US\$ 2.9 billion<sup>1</sup>
- 2 Demand for safe, effective and long lasting topical pain relief  
DermaSys® provides **faster drug permeation**, a key point of difference
- 3 **TPR100** is a Diclofenac gel that utilises Futura’s DermaSys® technology  
**Improved permeation** compared to market leaders at same dosage



# TOPICAL PAIN RELIEF

1

Agreement signed with Thornton & Ross (part of STADA) for UK rights in 2017  
UK regulatory submission first responses received in Q2 2019  
Futura assisting Thornton & Ross preparing responses by Q1 2020

2

Commercial discussions ongoing with other potential distributors  
TPR100 - USA will require further clinical data to support regulatory submission



## TPR100 – USA strategy

- FDA Pre-IND response given
  - Simplified new drug application 505(b)(2) filing route
  - 700 patient, placebo controlled 12-week efficacy study required
- Futura looking for partner commitment before progressing clinical expenditure

## Illustrative positioning only



## TIB200 – 10% ibuprofen gel

- Opportunity to move from current 3-4 times to twice a day dosing
- Placebo controlled efficacy study required prior to EU regulatory filing
- Futura require partner commitment before progressing clinical expenditure

# CBD100 – TOPICAL CANNABIDIOL GEL USING THE POWER OF DERMASYS®

- Early development programme underway
- Exploiting Futura's **DermaSys® transdermal technology**
- Targeting **Cannabidiol** – one of 113 Cannabinoids found in Cannabis

1

Joint venture signed with CBDerma Technology  
15 months initial development programme to optimise CBD100

2

Cannabidiol is a non-psychoactive cannabinoid with many anecdotal reports of therapeutic activity in a variety of conditions suitable for topical treatment such as pain relief

3

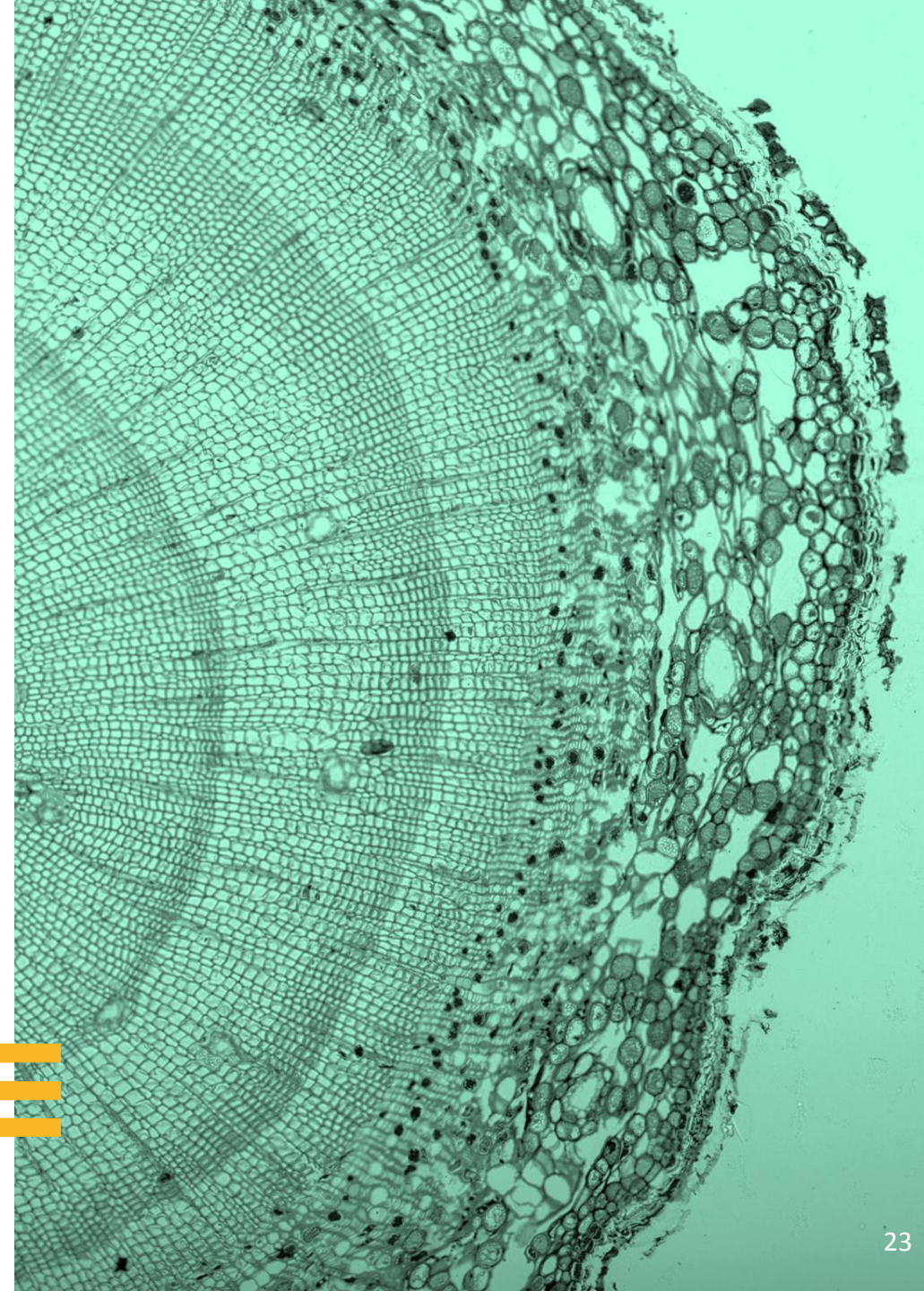
Initial commercial opportunity as a cosmetic product exploiting DermaSys® transdermal technology

4

Possible pharmaceutical applications however will be subject to extensive clinical development

5

Costs in the region of US\$ 1 million shared between parties Futura exploiting existing internal expertise and resources





# FINANCIAL RESULTS & OUTLOOK



# INTERIM HIGHLIGHTS – ORGANISATION & FINANCIALS

- ❑ **Net loss of £4.46 million in period**
  - ❑ (30 June 2018: net loss of £1.95 million)
- ❑ **Cash resources of £5.63 million at 30 June 2019** (30 June 2018: £6.03 million)
  - ❑ Plus Tax Credit of £1.36 million received in August 2019
- ❑ **Funding**
  - ❑ Current cash sufficient to complete FM57 study
  - ❑ Exploring a number of funding options including non-dilutory funding sources to complete second study (FM59)
  - ❑ Funding will place the Company into a position of strength so can continue capitalising on product development and for negotiating any out-licensing agreements for MED2005
  - ❑ Results of the FM57 trial will have an impact on these funding options



# OUTLOOK

1

Headline data of first Phase 3 for MED2005 by end of December 2019  
Start up activities commencing H2 2019 and last patient last visit expected by end of 2020

2

Increasing awareness of MED2005 through scientific advisory meetings involving high profile US and EU key opinion leaders ('KOLs') in addition to increasing scientific and general publicity

3

Progress/approval on TPR100 MHRA regulatory submission with further out-licensing discussions  
Further out-licensing discussions on MED2005 with Rx and OTC companies

4

Updates on development of CBD100 – topical cannabidiol formulation using DermaSys®

