SkyePharma

making good drugs better

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Smith Barney 4th Annual

Speciality Pharmaceuticals Conference

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This presentation includes certain forward-looking statements with respect to certain development projects, potential collaborative partnerships, results of operations and certain plans and objectives of SkyePharma including, in particular, the statements regarding potential sales revenues from Paxil CR™, targeted sales revenues from other products both currently marketed and under development, possible launch dates for new products, and our revenue and profit guidance for the 2003 financial year. By their very nature forward-looking statements involve risk and uncertainty that could cause actual results and developments to differ materially from those expressed or implied. The significant risks related to SkyePharma's business which could cause our actual results and developments to differ materially from those forward-looking statements are discussed in SkyePharma's SEC filings under the caption "Risk Factors".

SkyePharma reports under UK GAAP. Where US dollar equivalents have been provided for convenience in this presentation, a fixed exchange rate of $1.89 = £1 has been used throughout. **These dollar equivalent numbers do not imply restatement from UK GAAP to US GAAP**.

This presentation was updated on 17th February 2004

SkyePharma in brief

- UK-domiciled speciality pharmaceutical company
- originally founded 1983, IPO 1996
- listed London (“SKP”), New York (ADR, “SKYE”)
- market capitalisation £420/$795 mn

  (17 Feb: 68p/share $13.10/ADR)

Drug delivery – making good drugs better

We normally work on drugs already proven safe and effective

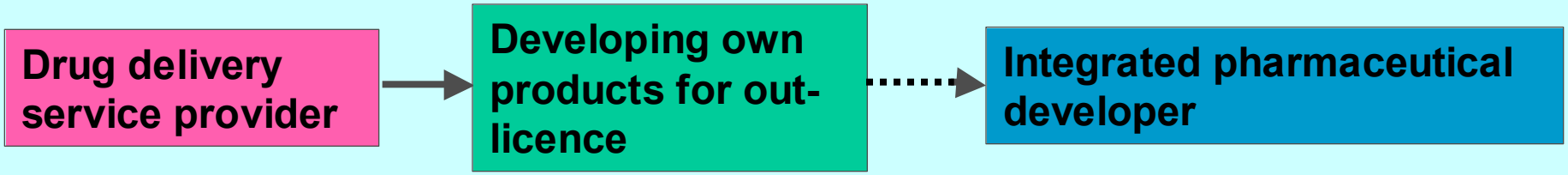
- **low risk of clinical failure**
- **short development times**
- **low development cost**

We rely on partners for sales and marketing

Two business models

	Contract drug delivery project *Example: Paxil CR™*	**Self-funded project** *Example: DepoMorphine™*
Risk	Low	Medium *NB much lower than for a NCE*
Return	Low	High
Out-licence stage	Start of project	Late-stage clinical trials
R&D costs	Partner (reimburses SkyePharma) $5-10 mn	SkyePharma $25-50 mn
Milestone payments	Modest <$10 mn	High $50-100 mn
Royalty rate	Low 3-7%	High 20-50%

A transforming business



Nine approved products

FDA approval validates three of our five delivery technologies

Foradil® Certihaler "approvable" letter (Oct '03) validates fourth (pulmonary)

Strong clinical pipeline

2 Filed, 4 x Phase III, 3 x Phase II

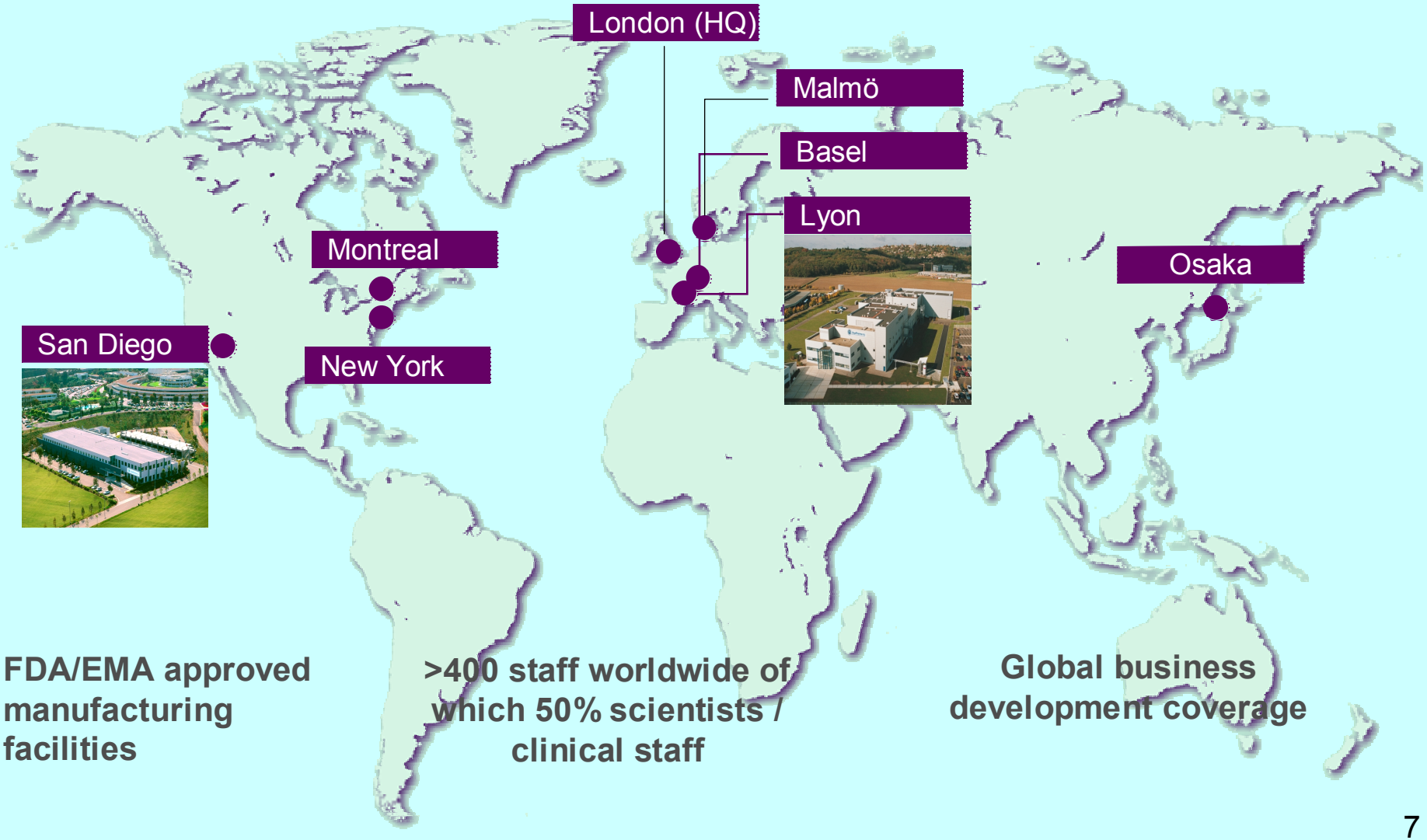
Changing **quality of earnings:**

Royalty income replacing milestones as main revenue source, driven by

Now: Paxil CR™, Xatral® OD/UroXatral®, Solaraze®, DepoCyt®

Future: Foradil® Certihaler, DepoMorphine™, HFA-formoterol, Propofol IDD-D™

Global infrastructure



FDA/EMA approved manufacturing facilities

>400 staff worldwide of which 50% scientists / clinical staff

Global business development coverage

Two lead marketed products

Paxil CR™

Xatral® OD/UroXatral®

Paxil CR™

GlaxoSmithKline

Geomatrix™ oral formulation of GSK's SSRI antidepressant Paxil® (paroxetine)

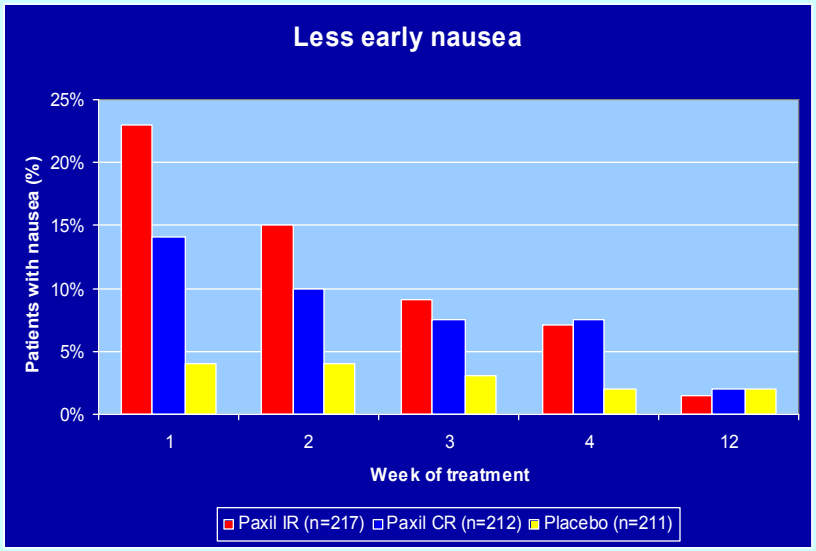
Paxil CR™ is clinically differentiated from Paxil®

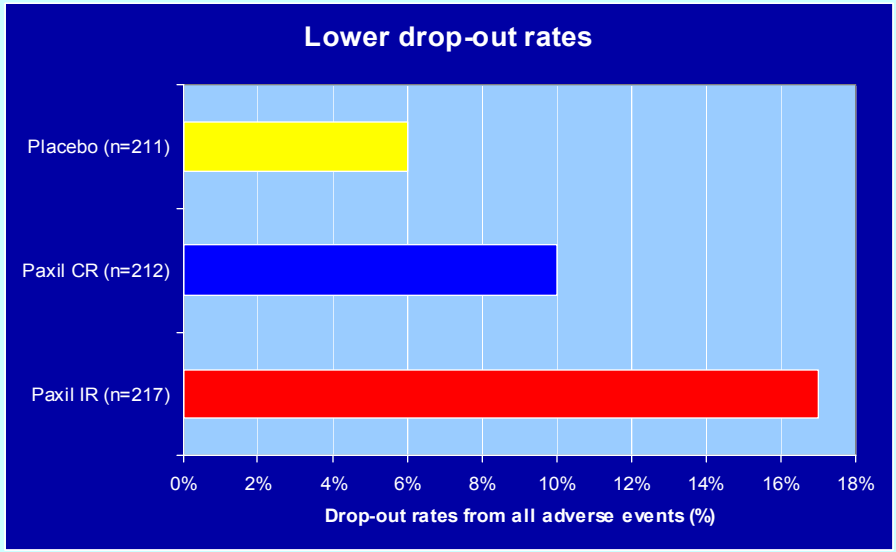
- **reduced incidence of nausea leads to improved compliance, better efficacy**

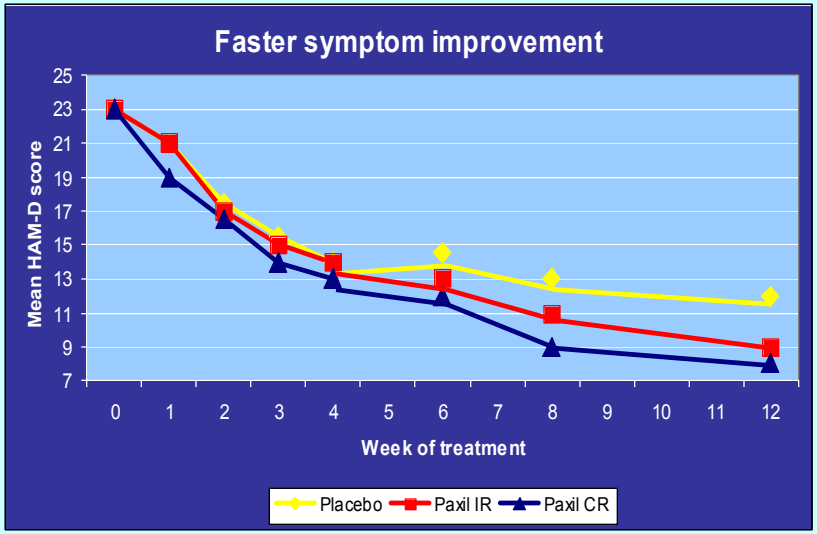
GSK still investing in development of new indications for Paxil CR™

- **depression** — **approved**
- **panic disorder** — **approved**
- **social anxiety disorder** — **approved 17 Oct '03**
- **PMDD (Paxil® never approved for this indication):**
  - **continuous:** — **approved 2 Sep '03**
  - **intermittent:** — **filed**
- ***post-menopausal symptoms*** — ***Stearns et al., JAMA, 4 June 2003***

Paxil CR™ – a clinically differentiated product







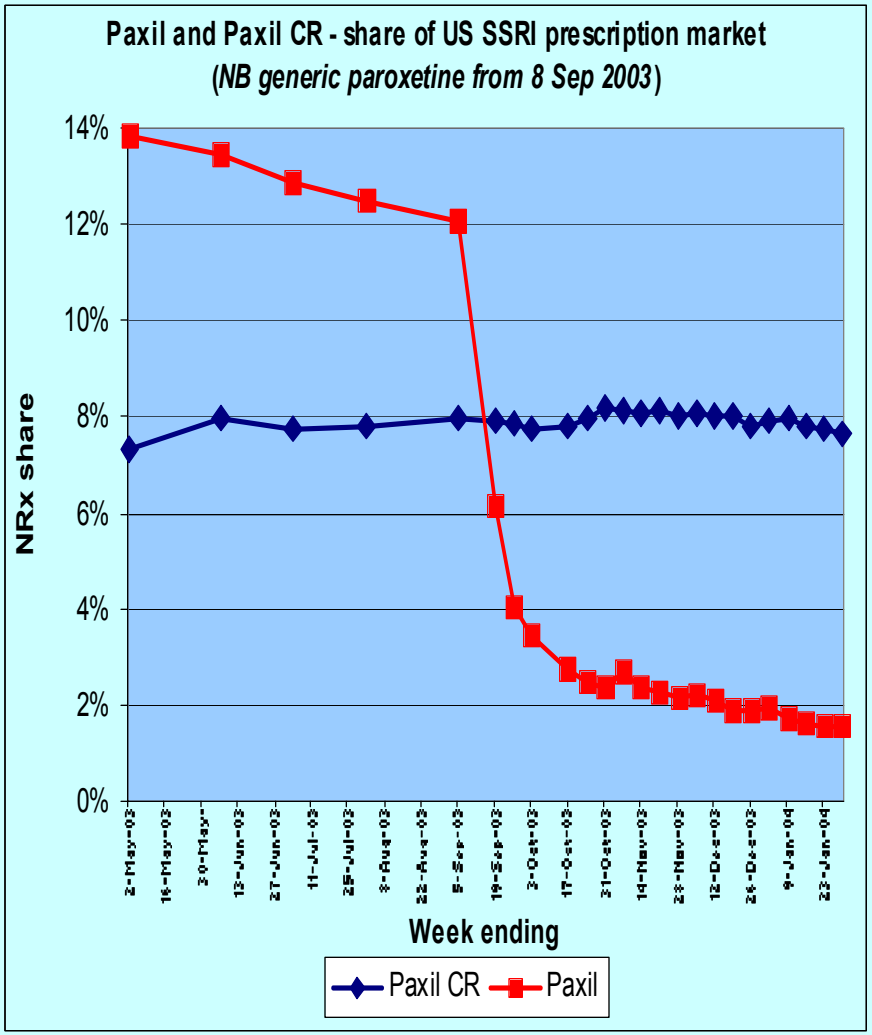
Source: Golden et al., J. Clin. Psych. (July 2002)

Paxil CR™ – defending the Paxil® franchise

Paxil CR™ has captured ~8% of the US SSRI antidepressant prescription market

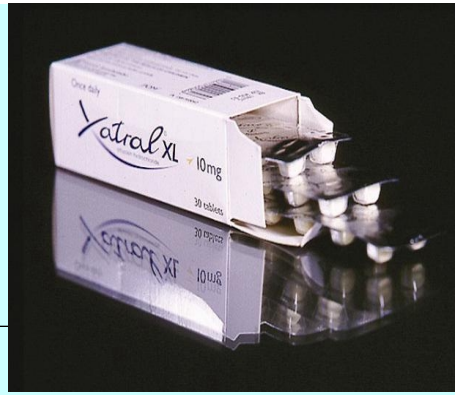
- **first US generic competition for Paxil® started 8 September**
  - a prescription for Paxil CR™ cannot be substituted with generic paroxetine…
  - …but some indirect price pressure
  - GSK still actively promoting Paxil CR™

  "It is very important to keep the sales effort behind Paxil CR™" John Coombe (GSK's CFO) Feb 2004
  - GSK aggressively defending last patent for Paxil® (expires end-2006)
- **Paxil® CR US sales:**
  - 2002: ~$300 mn
  - 2003: ~$650 mn
  - 2004: ~$800 mn (est – likely peak)
- **SkyePharma royalty rate: low single digits**
  - possible increase from start of US generic competition



Xatral® OD/UroXatral®

Sanofi-Synthélabo



Once-daily Geomatrix™ formulation of alfusozin

- uroselective alpha-blocker
- indication: urinary symptoms of BPH

On market in Europe & ROW since 2000

- replacing multidose versions

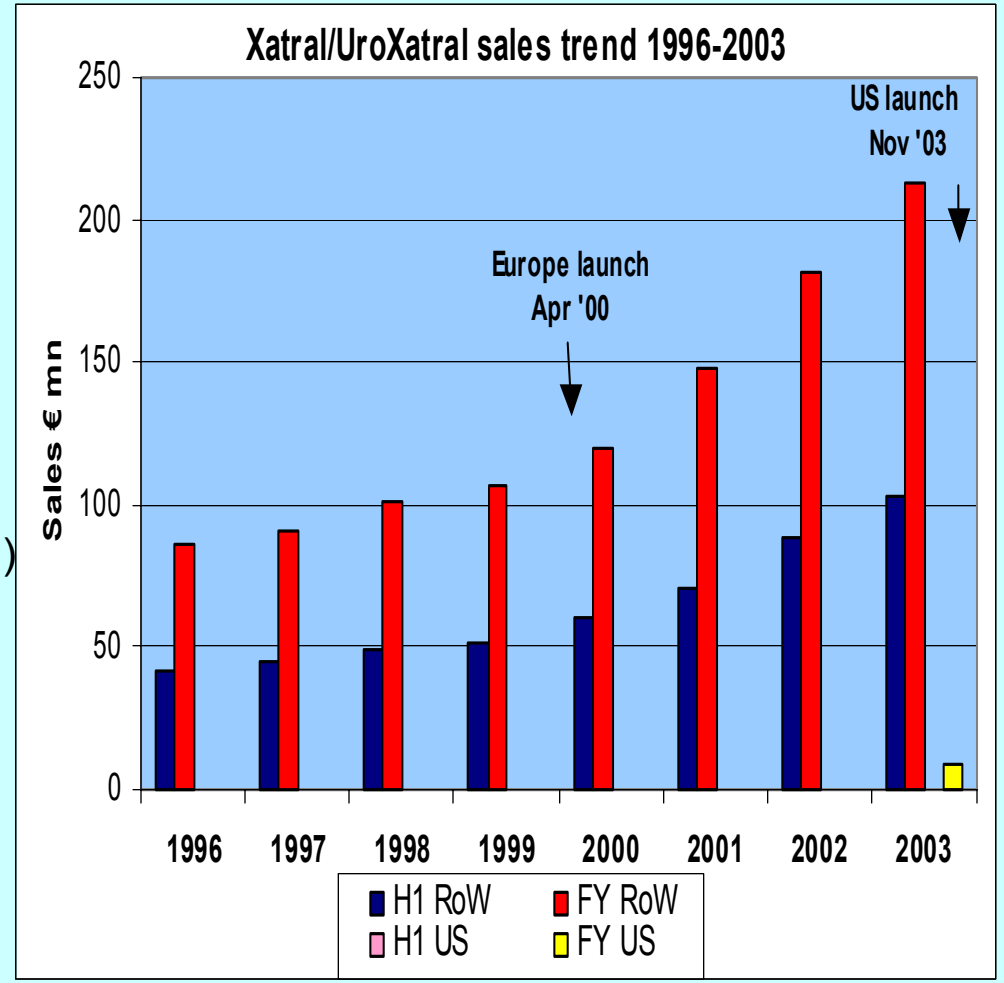
USA: UroXatral® launched 3 Nov '03

- new product on US market
- USPs:

uroselection (avoids postural hypotension)
no ejaculatory side-effects

Second indication: acute urinary retention (approved Europe; Ph III US)

2003 sales €222 mn (+25% CER)
2006 forecast: €500 mn (*Sanofi-Synthélabo*)
SkyePharma royalty rate: mid-single digits



Three key pipeline products

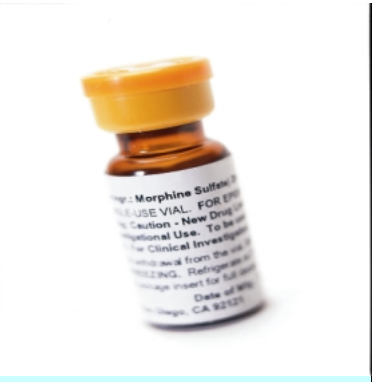
DepoMorphine™

Foradil® Certihaler™

Propofol IDD-D™

SkyePharma

DepoMorphine™ Endo, SkyePharma



Sustained-release morphine for relief of pain after surgery

- given as a single epidural injection before/during operation
- morphine released evenly over 48 hours (period of peak post-op. pain)
  - minimizes breakthrough pain
  - with conventional PCA, patient must react to pain
- no need for catheters and infusion pumps (= savings for hospital)

Disadvantages of conventional morphine

- effective analgesic – but short-acting
- repeat doses need a catheter and an infusion pump
- catheter problems main barrier to wider use of **epidural** analgesia
- epidural route desirable (delivers direct to brain, needs less morphine than IV)

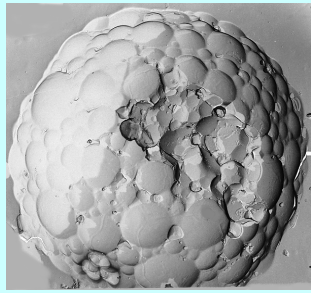
Clinical trials (~1000 patients) highly statistically significant

- hip/knee surgery, lower abdominal surgery, caesarean section

US: **filed with FDA Jul '03 (*PDUFA date 18 May '04*)**

Europe: **filed Nov '03 (UK, then mutual recognition procedure)**

DepoMorphine™ - potential market



- knee replacements & revisions
- hip replacements & revisions
- major abdominal surgeries
- caesarean sections
- thoracic
- vascular

- **~12 million** key target surgeries a year across the US and major Europe
- surgeries associated with an ageing population are **growing at 6-7% per annum**
- market research indicates potential for **25% - 40% patient share** in major territories. Assumes pricing equivalent to IV PCA or epidural infusion **($125 per surgical procedure)**
- est. sales potential: $250 mn
- exploring scope for **premium pricing**

DepoMorphine™ - potential endorsed by Endo deal

$120m deal (Dec '02)

- US/Canada rights for **DepoMorphine™** and **Propofol IDD-D™**
- option on related pipeline products including **DepoBupivacaine**

Deal terms:

- $25 million upfront payment
- SkyePharma's share of sales **20-60%** on combined sales volume of DepoMorphine™ and Propofol IDD-D™
  - >50% share if combined sales >$250 mn

Rights for rest of world still available for licence

- European rights to be licensed early '04

Foradil®

Novartis / Schering Plough

Active ingredient formoterol

- fast-onset, long-acting bronchodilator for asthma
- recent major study on maintenance use of formoterol raises value
- SkyePharma developed both Certihaler™ **device** and **formulation**
  - formulation keeps powder dry, ensures accurate dose
  - now also being used in second collaboration with Novartis (**QAB149**)

Schering-Plough to market in key US market, Novartis elsewhere

Filed US & Europe Dec ‘02 (launches expected in H2 ‘04)

- FDA “approvable” letter issued Oct ‘03

SkyePharma return on sales: ~10% (royalty + manufacturing return)

Propofol IDD-D™ Endo, SkyePharma

- improved version of AstraZeneca's injectable anaesthetic *Diprivan*
- SkyePharma's formulation unique - cannot support microbial growth
  - no need for a preservative
  - 2% emulsion (= lower injection volume and less lipid)
  - **not a generic**
- designed for <u>continuous uninterrupted 24-hour sedation</u>
  - ICU sedation is fastest-growing segment of *Diprivan* market
- Ph III to start Q1'04; target filing: end-2004; target launch: 2006
- **North America**: Endo (same terms as DepoMorphine™)
- **Europe/Japan**: licensees to be appointed
- est. sales potential for Propofol IDD-D™: $200 mn

Other major pipeline products

HFA-formoterol (SkyePharma)

- Fast onset, long-acting bronchodilator in HFA metered-dose inhaler (MDI)
- Value enhanced by recent major study on maintenance use of formoterol
- Ph II trial complete – Ph III to commence 2004
- Filing end 2005; launch 2006/7

Pulmicort® HFA-MDI (AstraZeneca for Europe)

- Pulmicort® (budesonide) inhaled steroid (for asthma)
- Ph II study complete - bioequivalent to CFC MDI
- Ph III trial ongoing
- Filing early 2005

DepoBupivacaine (SkyePharma)

- Long-acting injectable formulation of local anaesthetic
- Designed to provide 48-72 hours of local pain relief after out-patient surgery
- Target indications: knee arthroscopy; laparoscopic surgery; plastic surgery
- Ph I trial started in Europe Sep ’03; Ph II to start mid-2004

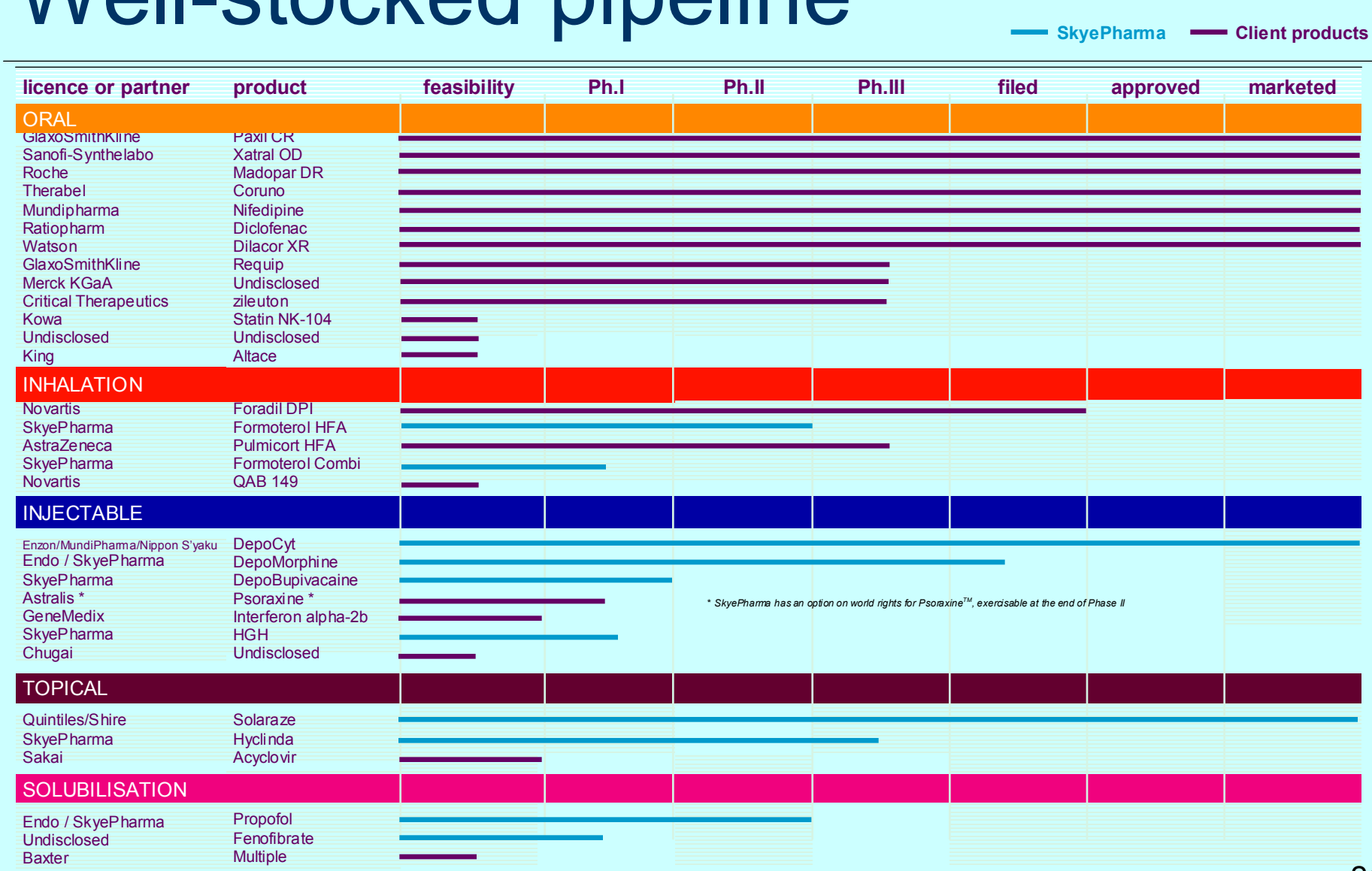
Requip® (GlaxoSmithKline)

- Once-daily oral formulation of ropinirole (for Parkinson’s disease)
- Therapeutic benefits + improved compliance
- SkyePharma managing clinical studies for GSK
- Ph III started Jun ‘03
- Filing 2005

2003 - new corporate developments

- licensing agreement signed with **King** for **Altace®** (ramipril)
  - ACE inhibitor with ~US$600m sales in 2003
- option agreement with **unnamed** partner in **pulmonary** area
- agreement with **Critical Therapeutics** to develop **zileuton** for asthma/COPD
  - once-daily version previously developed for Abbott
  - completed Phase III for asthma but never filed
- agreement with **Novartis** to co-develop **QAB149**
  - ultra-long acting bronchodilator for asthma/COPD
- agreement with **GlaxoSmithKline** to use **pulmonary** formulation technology
- **Astralis** commenced US Phase I clinical trial for **Psoraxine™** for psoriasis
- strategic stake in **Micap** plc – UK yeast technology specialist
  - successfully completed IPO on AIM in August
- strategic stake in **Vital Living** Inc.
  - development of pharmaceutical-grade nutriceuticals

Well-stocked pipeline



Newsflow 2003 – promises delivered

Filings

- DepoMorphine™ US ✓
- DepoMorphine™ Europe ✓
- Paxil® CR Social Anxiety – *FDA approval 17 Oct*
- Paxil® CR PMDD intermittent ✓

(Paxil® CR PMDD continuous – *FDA approval 2 Sep)*

Corporate & commercial agreements

- European licensing of DepoMorphine™
- European licensing of Propofol IDD-D™
- European licensing of DepoCyte® ✓
- Licensing of Pulmonary product package
- Licensing of Dermatology products
- Licensing deal with King – Altace® ✓
- Micap floated on AIM ✓

Product approvals/launches

- US launch of UroXatral® (Sanofi-Synthélabo) ✓
- European launch of DepoCyte®
- US approval of Foradil – *FDA "approvable" 22 Oct*

Clinical trial progression

- Requip® (GlaxoSmithKline) – Ph III start ✓
- Propofol IDD-D™ – Ph II end ✓
- Propofol IDD-D™ – Ph III start
- Pulmicort® HFA-MDI (AstraZeneca) – Ph III start ✓
- Psoraxine™ (Astralis) - Ph I start ✓

Clinical data publications

- DepoMorphine™ – Ph III
- Foradil® DPI – Ph III
- UroXatral® – Ph III

Newsflow 2004 – further progress

Filings

Pulmicort® HFA-MDI (AstraZeneca, Europe)

Requip® OD (GlaxoSmithKline)

Licence agreements

Deferred from 2003:

DepoMorphine™ (Europe)

Pulmonary product package

Unnamed pipeline product

Others:

Dermatology products

Propofol IDD-D™ (Europe)

DepoBupivacaine™ (Europe)

Product approvals/launches

Paxil® CR PMDD intermittent (US)

DepoMorphine™ (US) *(PDUFA date 18 May)*

Launch of DepoCyte® (Europe) ✓

Foradil® CertiHaler™ (US) *("approvable" Oct '03)*

Clinical trials (initiation)

Propofol IDD-D™	Ph III
Formoterol HFA-MDI	Ph III
Formoterol+fluticasone HFA-MDI	Ph II/III
Zileuton (Critical Therapeutics)	Ph III (COPD)
Psoraxine™ (Astralis)	Ph II
DepoBupivacaine™	Ph II

Clinical data publications (by partners)

DepoMorphine™ – Ph III

Foradil® CertiHaler™ – Ph III

UroXatral® – Ph III

Investment highlights

Evolving from a **technology** focus to a **product** development focus

Nine approved products validate drug delivery technologies

Changing **quality of earnings** driven by **Paxil CR™, Xatral® OD/UroXatral®, Solaraze™, DepoCyt®**

- with **Foradil® Certihaler, DepoMorphine™, HFA-formoterol & Propofol IDD-D™** close behind

Strong **clinical pipeline**

2 Filed, 4 x Phase III, 3 x Phase II

Royalty growth drives move to sustained and rising **profitability**

SkyePharma

making good drugs better

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