SkyePharma

making good drugs better

Jefferies Life Sciences Conference 2006

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27 June 2006

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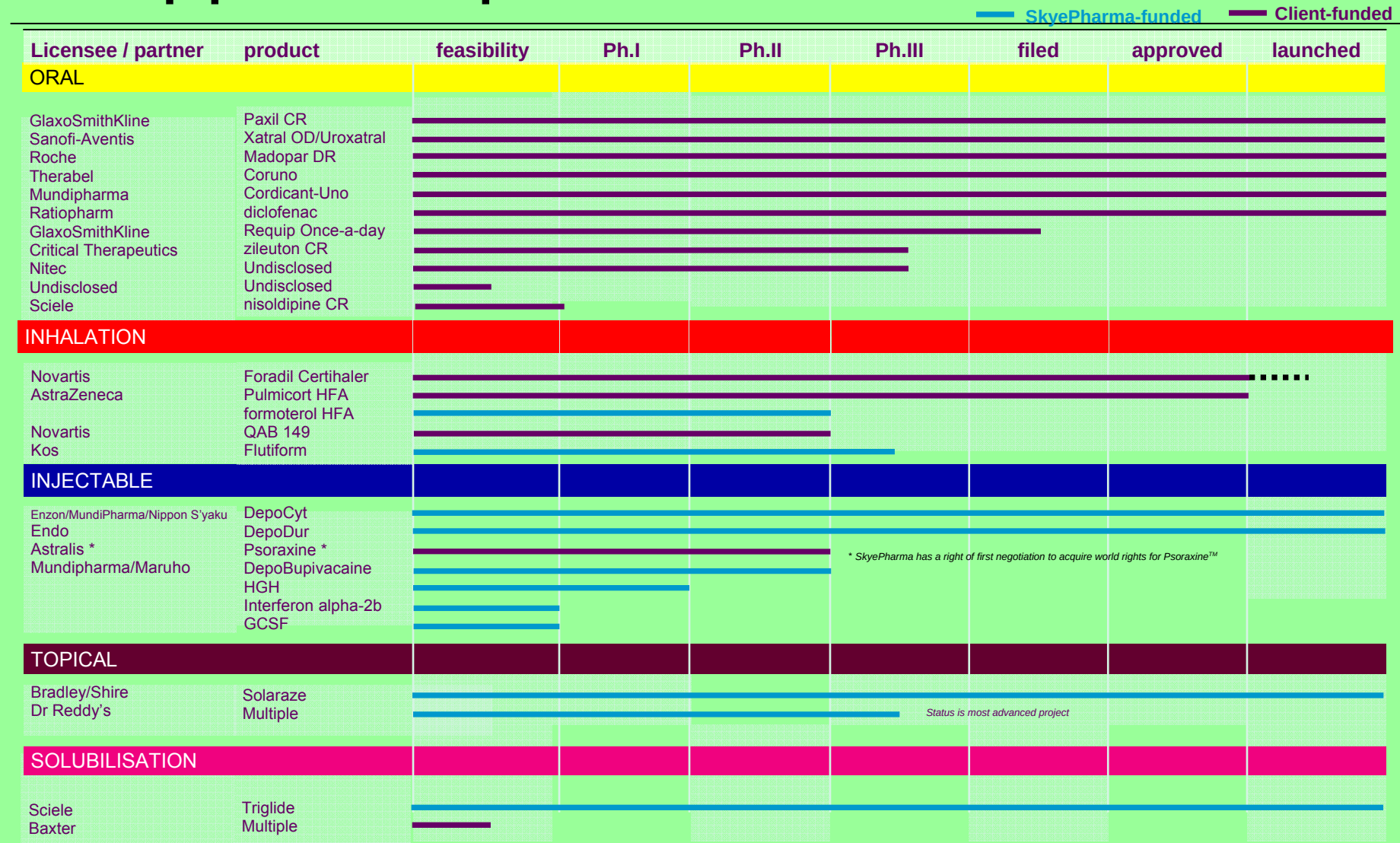
SkyePharma reports under IFRS. Where US dollar equivalents have been provided for convenience in this presentation, a fixed exchange rate of $1.85 = £1 has been used throughout. These dollar equivalent numbers do not imply restatement from IFRS to US GAAP.

This presentation was updated on 19 Jun 2006

SkyePharma in brief

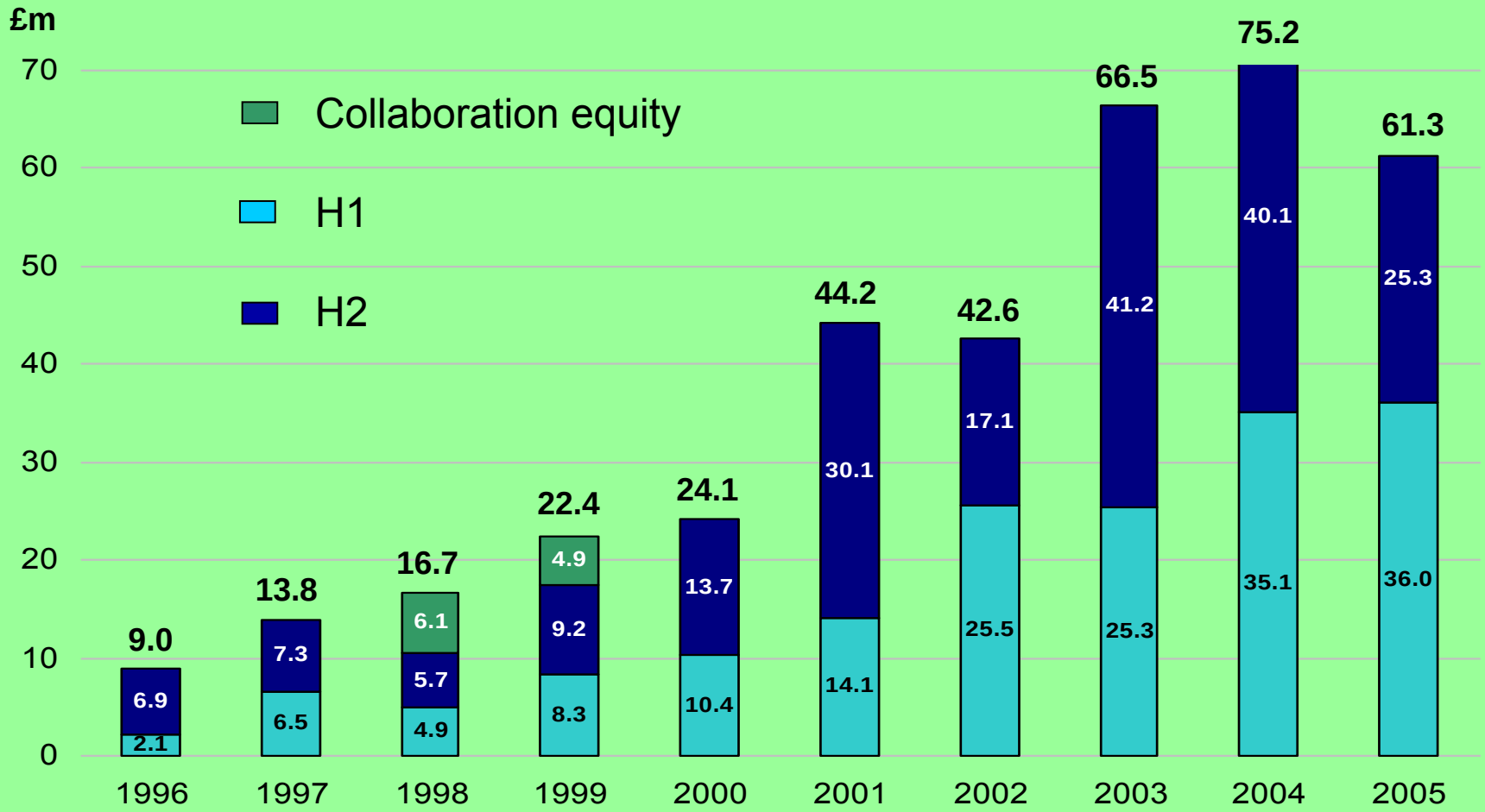
- UK-domiciled speciality pharmaceutical company
- technology focus: drug delivery
- originally founded 1983, IPO 1996
- listed London (SKP), New York (ADR, SKYE)
- 2005 revenues £61 mn ($115 mn)
- market capitalisation £234 / $435 mn
  - 19 Jun: 31p/share, $5.80/ADR, 754 mn shares in issue
- largest investors HBM (11%), Insight (10%)

12 approved products

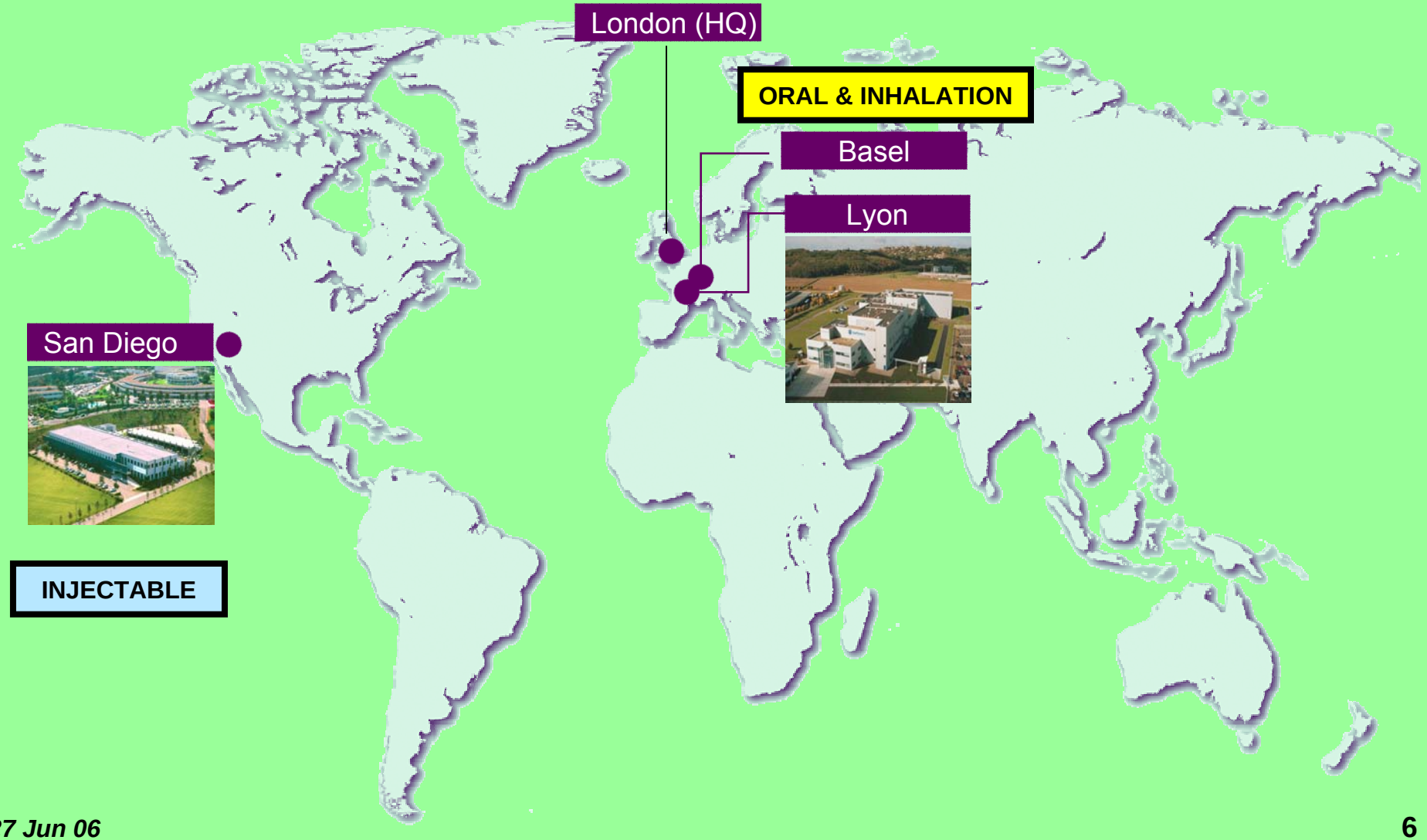


Turnover record

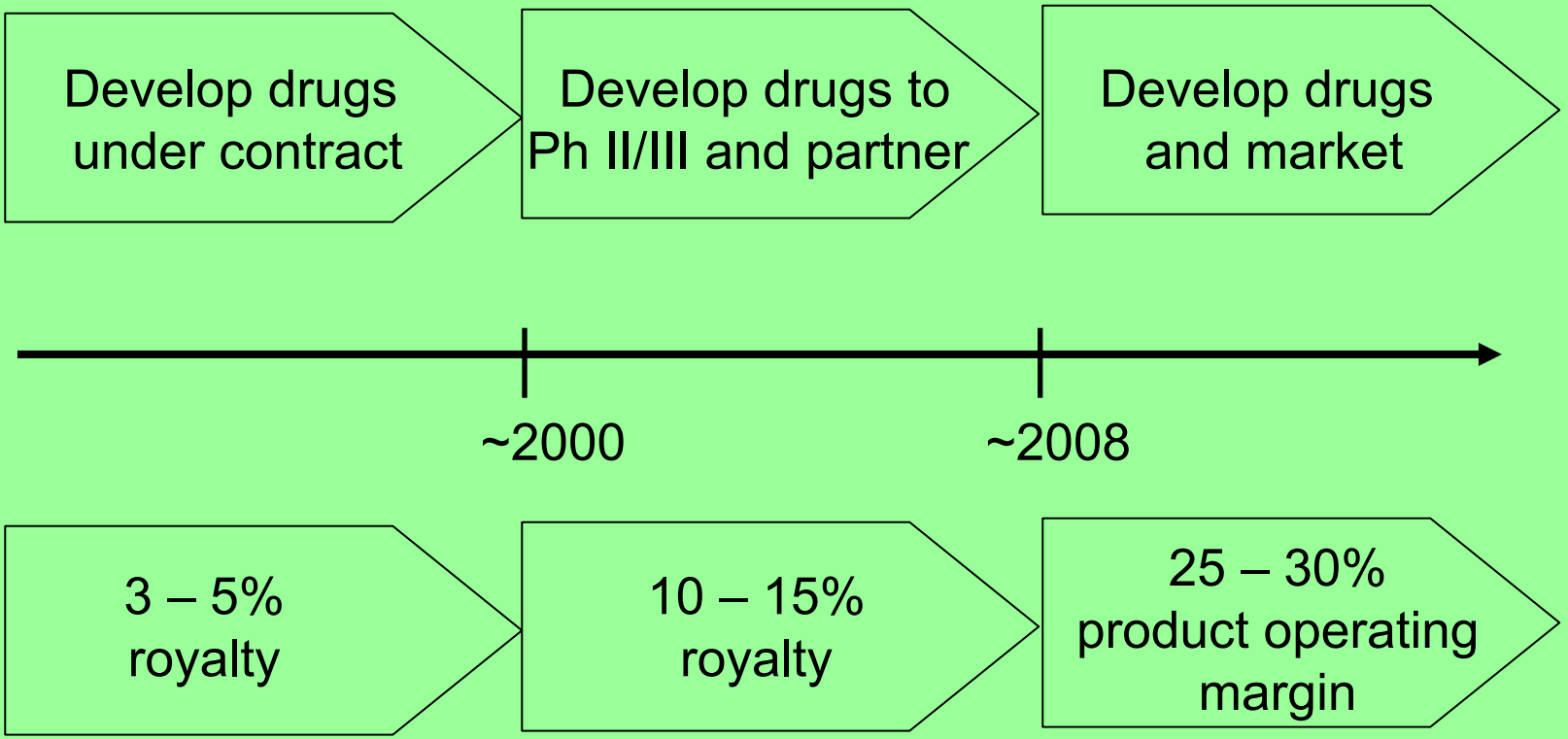
- Compound annual growth rate 1996-2005: 24%



Two main business units



Strategy evolution



Strategic plan 2006

- new leadership
- divest injectables unit
- continue Phase III for Flutiform™ and outlicense this year
- focus on core oral/inhalation unit and expand pipeline
- improve operational efficiency
- longer term aim to market own products in selected therapeutic area

New leadership

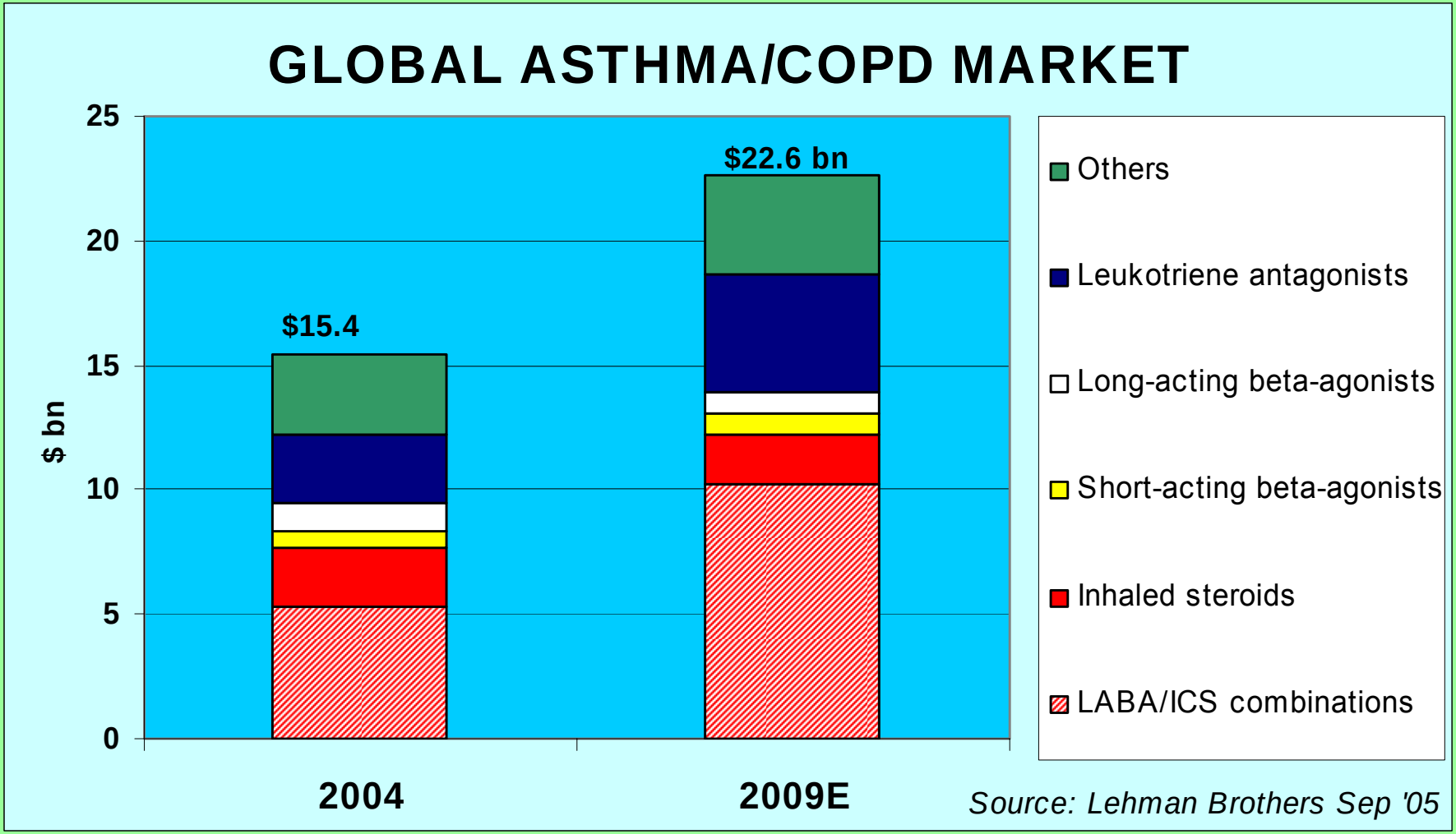
Dr Jerry Karabelas	Non-executive Chairman	Novartis; SmithKline Beecham
Frank Condella	Chief Executive	IVAX; Faulding; Roche
Dr Ken Cunningham	Chief Operating Officer	Arakis; Alza; Sequus
Donald Nicholson	Finance Director	Boehringer-Mannheim; Wellcome
John Murphy	General Counsel	Celltech; Medeva
Dr Francesco Patalano	President, Europe	Novartis; CIBA; Fisons

Flutiform™

SkyePharma's major pipeline project

SkyePharma

Flutiform™ - market opportunity



Flutiform™ - product details

- formoterol (LABA) and fluticasone (ICS) in a fixed-dose combination
  - formoterol 5 µg with fluticasone 50 µg or 125 µg per actuation ("puff")
  - two actuations per dose
  - dosed twice a day (morning and night)
- proprietary HFA-powered MDI with dose counter
- covered by SkyeDry™ patent (2019 expiration)
  - unique proprietary formulation technology
  - uses DSCG (cromolyn sodium, *Intal*) at sub-therapeutic dose as excipient to stabilize formoterol
  - maintains dose-to-dose consistency
- target indication: asthma in adults and adolescents ≥ 12
  - COPD and paediatric asthma to follow

Flutiform™ - product profile

- **formoterol** LABA (long-acting beta-2 agonist)
- 12 hours bronchodilation = twice-daily dosing
- faster onset of action (1-3 mins) than salmeterol (30-45 mins)
  - gives rapid relief from common symptom of wheeziness on waking
  - patient confidence that medication is working
  - enhances compliance
  - less risk of over-dosage
- **fluticasone** ICS (inhaled corticosteroid)
- low level of systemic uptake
- physician-preferred ICS in the US
  - US physicians in particular are concerned by the risk of systemic uptake of inhaled steroids

Source: TVG market research 2004 (commissioned by SkyePharma)

FlutiForm™ - Phase III trials

- trial design approved by FDA
- 3 double-blind pivotal trials
  - primary end-point : FEV_1
  - patient population: mild-moderate asthmatics age >12
- one open-label 12-month safety study
  - conducted in parallel with pivotal trials
- total number of patients N = 1700
- started as planned in Feb ’06
- target filing: **H2 ‘07**

Flutiform™ - competitive landscape

Company	Product	Current phase	Estimated FDA approval date	Likelihood of FDA approval
GlaxoSmithKline	*Advair* fluticasone + salmeterol	Marketed as DPI in US and EU	n/a	n/a
AstraZeneca	*Symbicort* budesonide + formoterol	Marketed EU as DPI MDI filed with FDA Sep 05	2008	High *FDA known to have issues with AZN's MDI - may require additional clinical data*
SkyePharma	*Flutiform* fluticasone + formoterol MDI	Ph III Feb 06	2009	High
Altana with Sanofi-Aventis	ciclesonide + formoterol DPI	Ph II	2012	Moderate *ciclesonide once-daily formoterol twice-daily*
Novartis (with/without Schering-Plough?)	once-daily ICS + QAB149 DPI mometasone + formoterol MDI	Preclinical "Ph III to start in '06"	2012 ?	Moderate *NCE development* Unknown *mometasone once-daily formoterol twice-daily*
GlaxoSmithKline	once-daily ICS + once-daily LABA DPI *both are NCEs*	Early Ph II	2011/12	Moderate *NCE development*

Source: SkyePharma

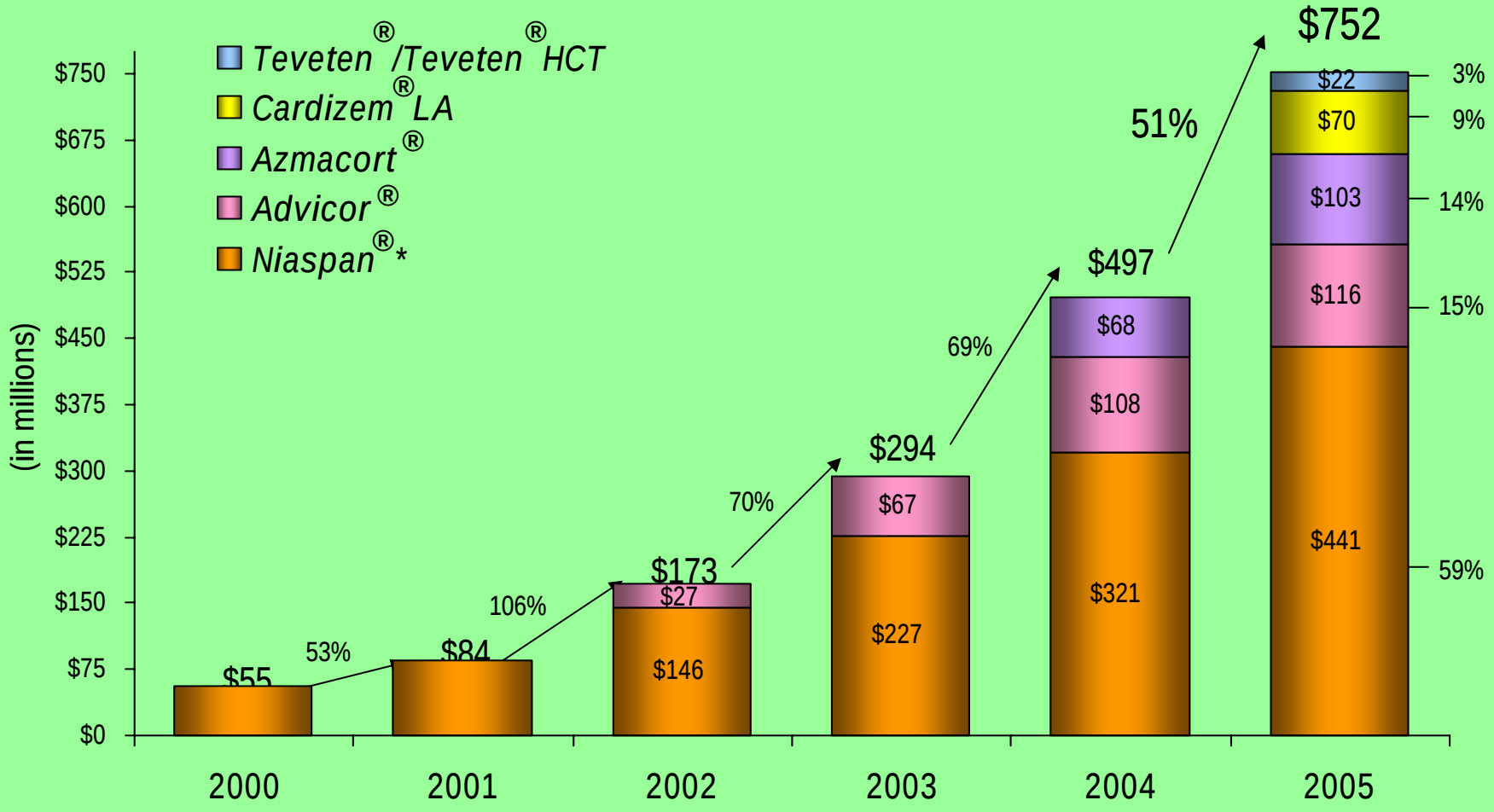
Flutiform™ US licence – Kos (May 2006)

- Kos has exclusive marketing rights for Flutiform™ in US
  - right of first negotiation for Canada
- SkyePharma receives up to $165 mn in milestone payments on regulatory & sales targets
  - includes $25 mn upfront
- SkyePharma royalty rate starts in mid-teens
  - rate escalates on sales targets
- SkyePharma and Kos share development of Flutiform™ for asthma and COPD
  - SkyePharma funds trials needed for approval in adult asthma
  - Kos funds trials for all other indications and marketing/post-approval studies
- SkyePharma supplies product to Kos

US partner for Flutiform™ – why Kos?

- successful, fully integrated US Specialty Pharmaceutical company
  - strong financial position, no debt, excellent long-term outlook
- strong commercial capabilities, proven track record
  - 750 person sales force (>1000 by Flutiform™ launch), broad managed care, medical affairs and customer services functions
  - established presence in cardiovascular & asthma areas
  - track record of respiratory market performance with Azmacort
  - proven success in creating and building markets supported by quality medical and patient education
- excellent, therapeutically aligned R&D capabilities
  - clinical, regulatory, safety and surveillance strengths in CV, metabolic and respiratory disease areas
- **both partners see high potential in the product**
  - superior product concept
  - differentiated from competing combinations
  - clear window of opportunity

Kos revenue growth record



*Includes international sales royalty (licensing revenue)

Major objectives 2006

- divest injectable unit
- outlicense Flutiform™ ✓
  - negotiations for non-US territories ongoing
- complete modifications to Certihaler™ and relaunch in EU
- expand oral / inhalation pipeline
- work with licensing partners to drive revenues of marketed products

The new SkyePharma

- new leadership
- drive for sustainable profitability
  - accelerated by sale of injectables unit
- core business is oral and inhalation
- potential blockbuster in Flutiform™
- strong cashflow from existing royalties

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Appendix

Core Oral / Inhalation Business

Major marketed products

Oral/inhalation:

Paxil CR™ (GlaxoSmithKline)

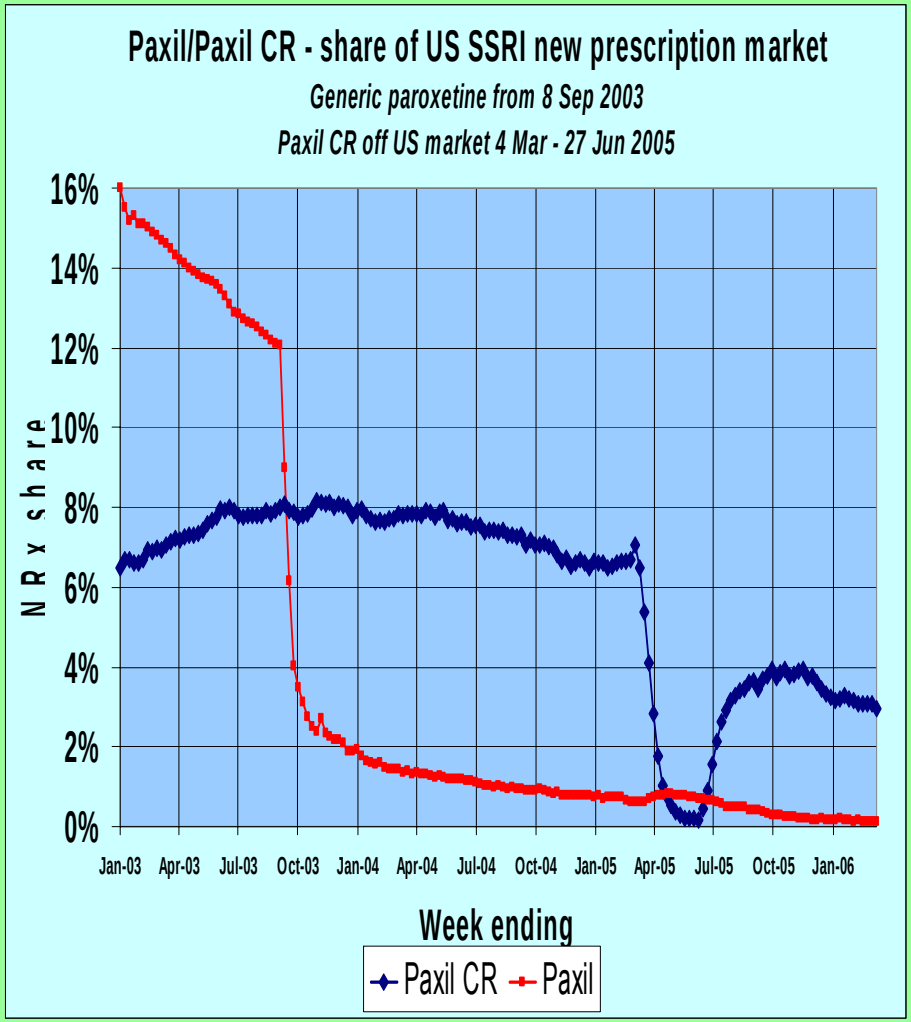
Triglide (Sciele)

Xatral® OD / Uroxatral® (Sanofi-Aventis)

Solaraze® (Bradley; Shire)

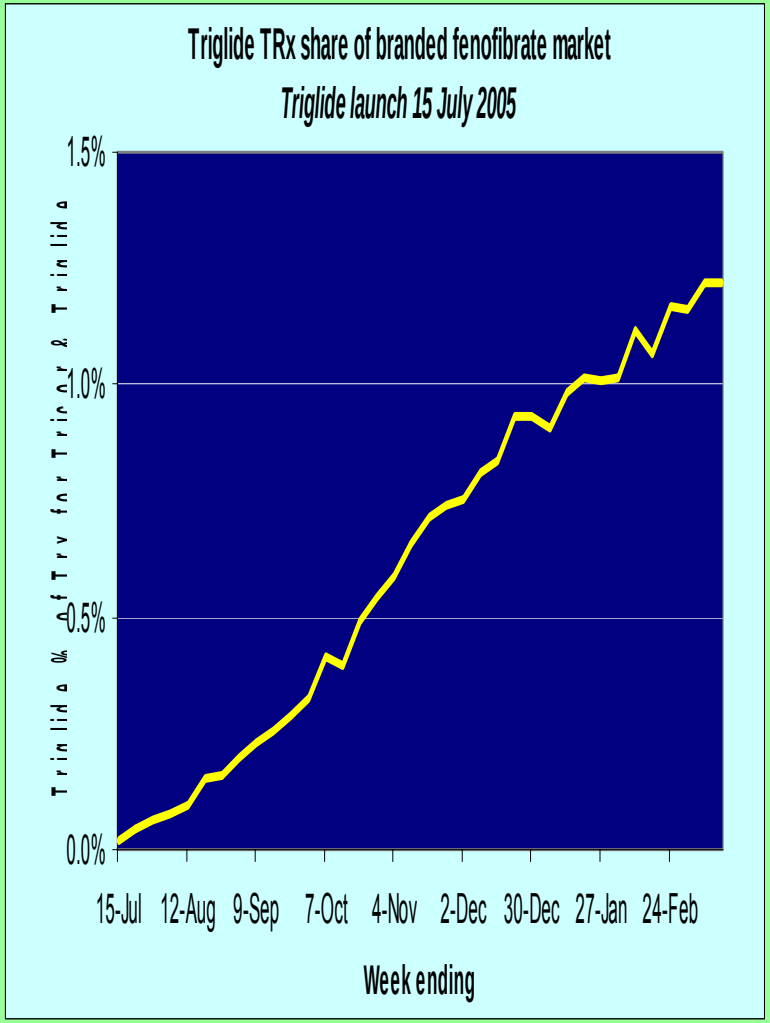
Paxil CR™ GlaxoSmithKline

- Geomatrix™ version of GSK's SSRI Paxil® (paroxetine) for **depression**
  - targets release to lower intestine
  - reduces nausea (issue with all SSRIs)
  - improves compliance
- manufacture problems at GSK led to product being taken off US market for 4 months in 2005
  - supply restrictions since re-introduction
- Mylan filed Para IV certification 2005
  - GSK has not challenged, so no 30 month stay of approval
  - generic expected after Jun 2007
- SkyePharma royalty: 4% since April '05
  - previously 3%



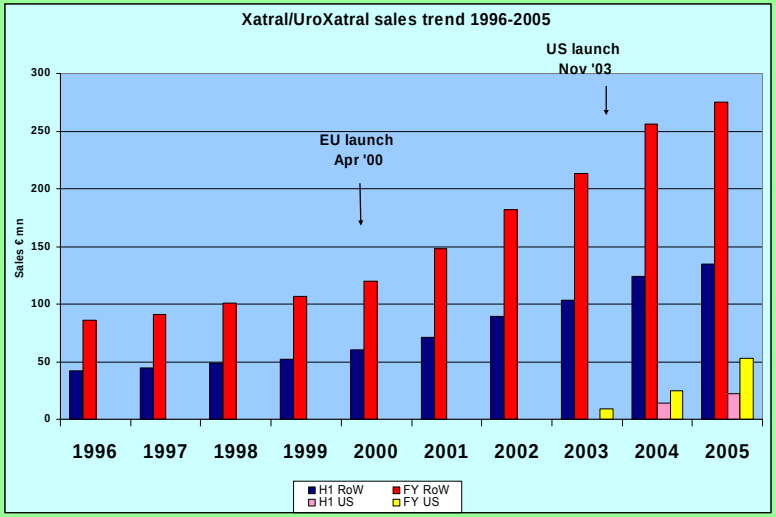
Triglide™ Sciele

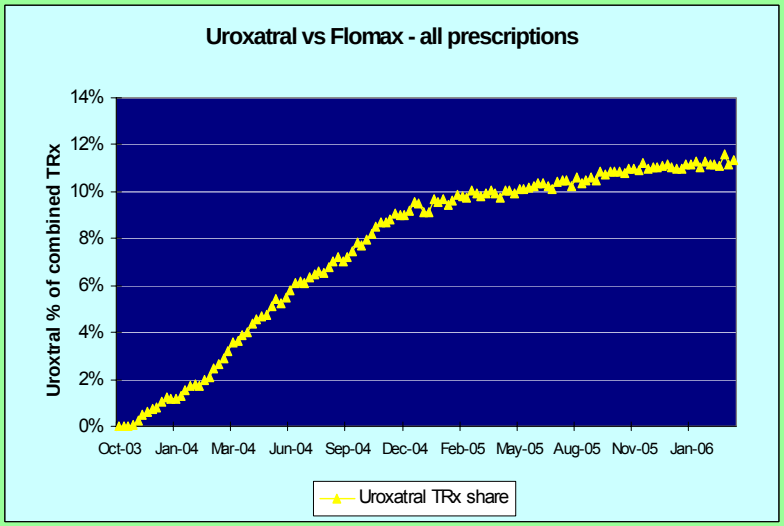
- SkyePharma oral formulation of fenofibrate – avoids food interaction problems
- fenofibrate a key treatment for **lipid disorders**
- beneficial **dual** lipid-modulating effects – TG & LDL-C ↓ but HDL-C ↑
  - highly unsatisfied market – most patients with elevated lipids are either untreated or under-treated
- launched in US July '05 by Sciele (successful specialty pharma company)
- Triglide™ 2005 sales $5m (5 months only)
  - now holds ~2% NRx share
- SkyePharma receives up to $50m in milestones and 25% share of sales



Xatral® OD/Uroxatral® Sanofi-Aventis

- once-daily Geomatrix™ formulation of alfusozin for **BPH**
- marketed in Europe & ROW since 2000 and in US since 2003
- main competitor Flomax (tamsulosin)
  - in US, Uroxatral® now holds >11% of combined NRx for Flomax and Uroxatral®
- 2005 sales of Xatral (all versions) €328m +18% CER
  - US sales €53m ($66m) +121% CER
  - Xatral® OD/Uroxatral® now >90% of Xatral® sales reported by Sanofi-Aventis
- SkyePharma return on sales: mid-single digits





Solaraze® Bradley / Shire

- topical gel formulation of diclofenac for **actinic keratosis**
  - AK is early form of squamous cell carcinoma
  - alternative treatments for AK are painful and disfiguring
  - SkyePharma HA formulation retains high concentration of active in upper skin layers
- marketed by **Bradley** in North America, **Shire** in Europe / Australasia
  - 2005 global in-market sales $27.5 mn (+78%)
  - US $10m in 9M '05 (*latest data reported by Bradley*) – FY '05 est $15m
    - vs $6m in 2004 (for 4 months)
  - Europe/RoW $12.5m (+32%)
- progress towards Australian marketing authorisation
  - Australia is major market for skin cancer products
- SkyePharma royalty: double digit

Key near-term pipeline products

Oral/inhalation:

Foradil® Certihaler®

Pulmicort® HFA

Requip Once-a-day

Flutiform™

Foradil® Certihaler™ Novartis / Schering-Plough

- long-acting bronchodilator formoterol in multi-dose dry-powder inhaler
- Foradil® Certihaler™ now approved in 24 markets (Europe, Mid-East, S America…)
- launched in Germany Sep ’05 and Switzerland Oct ’05 but recalled by Novartis from both markets Jan ’06
  - a few patients misused device and experienced accidental incorrect dose
  - SkyePharma working with Novartis to investigate cause and correct
- FDA “approvable” letter Apr ’06 – device modifications will be required for final approval
- SkyePharma return on sales: ~10% (royalty + manufacturing return)

Pulmicort® HFA-MDI AstraZeneca (for Europe)

- Pulmicort® (budesonide) in CFC-free MDI
  - inhaled steroid for asthma
- will allow AZN to withdraw CFC-MDI version (Montreal protocol requirement)
- SkyePharma developed formulation and conducted clinical development for AZN
- filed on country-by-country basis in Europe mid ’05
- first European approval (Finland) Feb ’06
- double digit royalty

Requip Once-a-day GlaxoSmithKline

- once-daily oral dosage formulation of ropinirole (dopamine agonist) for Parkinson's disease
- dopamine agonists increasingly recommended as first-line therapy
- once-daily version should deliver efficacy and provide convenience
- filed by GSK Dec '05
  - national applications filed in Europe and New Zealand
  - US filing had to be withdrawn for technical reasons – should be resubmitted H2 '06
- GSK's 2005 sales of Requip® $284m (+34%)
  - majority of sales currently for RLS indication
- mid-single digit royalty rate