

CoreTherm® – Individualized Treatment for BPH



CoreTherm[®] – Individualized Treatment for BPH

Benign Prostate Hyperplasia

Ulf Rosén
President & CEO
since mid June 2006

Last previous positions:
Senior Partner LSM group AB
President & CEO NeoPharma AB
(Baxter, Pharmacia and Fresenius)

Current commissions of trust:
Chairman of the board: TFS International AB
Board member, Cartela AB and Scibase AB



Symptoms

Every other man is affected

- difficulty starting urination
- weak urinary stream
- difficulty postponing urination
- sense of incomplete bladder emptying
- frequent urination, even at night
- dribbling of urine

Gradual worsening, often over a period of several years



Treatment Alternatives for BPH

Estimated in EU/US = > 21,2 million men with BPH and 5,3 million treated

- Drugs

- Lifelong treatment
- Alleviates the symptoms
- Efficacy 20-40%

EU/US = 4,7 million patients



- Minimal invasive method

- Thermotherapy with microwaves – CoreTherm / PLFT
- Efficacy 80%

EU/US = 0,14 million patients



- Surgery

- An operation via the urethra, TURP
- Efficacy 80%

EU/US = 0,36 million patients



- Watchful waiting

EU/US = 15,9 million patients

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CoreTherm:

CE mark

FDA approved 2002 (PMA)

> 20 000 patients treated

Treatment Alternatives for BPH

Important distinctions

- Treat the symptoms
 - Drugs
 - MSD
 - GSK
 - MIT's
 - Medtronic
 - Boston Scientific
 - AMS
- Treat the problem
 - Surgery
 - TURP (Gold standard)
 - Makers of surgical instruments
 - Supplier of endoscopic equipment
 - Lasers
 - AMS
 - Biolitec
 - MIT's
 - CoreTherm from ProstaLund

Considerations for a US launch

Time, costs and risks of entering the market...

- **Regulatory process** 510K, De Novo, PMA, - clear position in your claims
- **Reimbursement** CPT code? –application/process/decision, HE-data
- **IP position** Co-existence, cross-license/license agreement,
- **Choice of sales and distribution channel**
 - “Change of behavior”
- **Product positioning, market conditions**
- **Competitors “whom are we up against”**
- **Market entry & Key opinion leader support**

Market Introduction

- Basic assumptions and learning points from the current status of the company and previous experience:

Position of the CoreTherm system

Major changes in behavior and flow of patients
 Significant technical differentiation
 New technology, educate the market.
 Specialists, small customer base
 Frequent follow up, customer training and service

No changes in behavior and flow of patients
 No or little technical differentiation
 Commodity
 Broad use, large customer base
 No follow up or maintenance

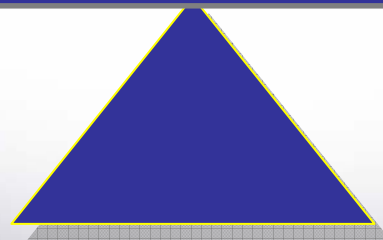
Own organization

Distributor

Specialized distributor
 with fully dedicated staff

General distributor
 with partly dedicated staff

General distributor
 with fully dedicated staff



Choose a distributor...

Key questions

- On what level in the organization do you have your champion?
- Financial resources, private/listed company?
- Strategic goals and how do your product fit into this picture?
- “House of brands” or industrial partner with own product line?
- Is your product going to be a primary or complementary brand?
- Competence and track record?
- Geographical presence and priority?
- Remuneration of the sales organization?
- Potential asset or liability at exit?

Do you like and trust these people?

Do they add considerable value to your product?

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SWOT, FAB, PDS etc. “What value do you bring to the market and for whom” →Money is a strong force for “change of behavior”
- **Competitors “whom are we up against”**
Who will gain or loose by your presence on the market?
- **Market entry & Key opinion leader support**
A US voice is important, guidelines, recommendations from professional associations

The ProstaLund story

- PMA approval in 2002 with excellent clinical results in par with TURP, the gold standard
- Existing CPT code, CoreTherm included into the reimbursement system
- Successful but cumbersome and expensive patent litigation initiated by Urologixs
- Missed the main window of opportunity with ACMI, mainly due to delays in the PMA process.
 - Unrealistic expectations on time needed.
- Product champion at ACMI on lower levels and change of management left CoreTherm “in the air”

The ProstaLund story

- CoreTherm secondary to own brands and product lines
- Salesforce highly dependent on monthly commissions, focus on low hanging fruits...
- Customers were poorly trained on how to get maximum benefit from CoreTherm leading to poor results and declining sales
- Focus on selling the technology rather than customer and patient benefits
- Product was positioned improperly against other MITs rather than against where we have a competitive advantage –TURP and other curative treatments

The ProstaLund story

- ProstaLund Inc. established late 2005
 - Managed from Sweden
- Bought back the distribution rights to CoreTherm, last payment in February 2006
- Took over a customer base shattered across the US, with very little information
- Hired a US (native) CEO in May
- Recruit and train clinical instructors
- Retraining of customers
- Start the cumbersome and time consuming process of repositioning CoreTherm as a curative, office based, method with favorable reimbursement in contrast to hospital based alternatives. (TURP/Laser)

The ProstaLund story

- Back to basic
 - Focus on most important and profitable customers
 - Peer selling and endorsement
 - Marketing programs implemented locally, working together with our client base to attract more patients into the system
 - Strong geographical focus, “big fish in a small pond”, demographics is important
 - Main customer base in Florida or South East
 - Cut cost, seeking profitability and grow from there...
 - Redirect resources and focus on new products
 - US will not be the first market...

Final reflections..

- Do you have your act together for a US launch?
- Do you have the time, financial strength and endurance for a US adventure?
- EU or very selected parts of EU might be the best market to commercially validate your product
 - Gives also the opportunity to upgrade your product based on regular clinical experience and early sales - you become a blip on the radar screen
- Having VCs onboard, maybe the next owner of the company shall take the product to the US...??

Cash is King..... thanks for your attention!