### INVESTOR DECK

PAXEROL™ for NOCTURIA

100M people in the US suffer from a problem for which we have a strong solution. The patents are issued. We are raising funds for EU launch and FDA trial.





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# NOCTURIA is the #1 urology complaint of men and women 55-84

100M sufferers in US (2.2B worldwide)

65% of people ages 55-84



#### Misery associated with nocturia

Insomnia, fatigue, depression, lower quality of life

US lost work time \$60B/year

Incontinence care currently 25% of the costs of nursing home care

Heart disease, stroke, brain damage, hip fractures

NO DRUG TREATS LOW NOCTURNAL BLADDER CAPACITY



#### INTRODUCING

# Paxerol

A unique 8 hour extended release formulation providing increased nocturnal bladder capacity (NBC +50-100%)

**HOW IT WORKS:** For 76% of nocturia sufferers, low NBC is a key issue. The cause is excess Prostaglandins (PGE2) that irritate the bladder.

For sufferers of Nocturia and Over Active Bladder, a low dose combination of APAP & ibuprofen inhibits PGE2 production through 3 different mechanisms to increase bladder capacity significantly. People are informally using the combination of already approved drugs: 80% success rate. Our next step is to prove efficacy in a Phase 2 clinical trial.

**UNIQUE:** Low dose, combination, extended release, orally disintegrating formulation, label, and advertising

APAP + time release + ODT

ibuprofen



Paxerol has three synergistic mechanisms of action (MOA)



### **World Class Team**

David Dill, CEO, IBM, CFO of 7 firms, 35 years as manager

#### **SCIENTIFIC ADVISORS**

**Frank Rauscher**, **III**, **Ph.D.**, Chief Scientist: Dep. Director, Wistar Inst. **Khurshid Iqbal**, **Ph.D.**, Pharma Chemist, J&J, Hoffmann-LaRoche

#### LEADING CLINICAL EXPERTS

Tony DelConte, MD, led Novartis Enablex FDA trials
Thomas Garvey III, MD, NIH, FDA, drug safety expert
PharmaTrials, successfully completed trials for many big and small pharma
Numoda, trial and data management firm

#### LICENSING AND LEGAL

Joy Barton, Ph.D., Novartis, Marquant Licensing Agent Ed Allera, Buchanan Ingersoll, FDA Focused Lawyer Ping Wang MD, Andrews Kurth, (named top 1000 patent Lawyer)



#### **OVERACTIVE BLADDER DRUGS**

Vesicare, Enablex, Myrbetriq

- Effects often take months
- Large % do not respond
- Severe side effects
- 43–83% stop in < 30 days</li>
- 10-15% fewer bathroom trips
- Treats annoying problem
- Significant competition

2M patients (0.1%)

\$2B SALES

# **Paxerol**

- Effects in as little as 30 mins.
- 80% positive (anecdotal)
- No side effects
- 20% drop out (anecdotal)
- 33-100% fewer nightly trips
- Treats dangerous problem
- No current competition
- 6 US patents issued

\$2-8B SALES? Proving effective for OAB, but focused on nocturia



### **Ethicor Short-term Revenues**

Almost all regulatory bodies outside US permit use of unlicensed drugs ("Specials"). We have an agreement for such distribution of Paxerol.

Contract signed April 2014 with Ethicor Pharma, Ltd. (UK). Plan to launch Paxerol Q1'15 with support of key opinion leaders, education sessions, and published articles. Partnered with UDG, UK's largest prescription drug distributor.

Top end price target – \$5/dose controlled by Ethicor Gross profit estimate – 98%

Only ages 60+, EU, MENA, and SA, with no advertising

\$k Projected Net Income from Ethicor							
2015	2016	2017	2018	2019	TOTAL		
\$832	\$6,611	\$26,949	\$50,538	\$73,161	\$151,091		



# **Big Pharma License**

Protocol feedback and indications of interest from key global leaders

13 week double-blind Crossover Trial run by experts

Licensee to complete trials, patents, and launch Paxerol. Expect upfront payment after Phase 2 trial (mid-2015), milestone payments, 15% royalty





















pharma

## **Use of Funds**

Primary use of funds will be in the management of the trial process and preparations for Ethicor launch

		2015				
	2014	Q1	Q2	Q3		
Ethicor GP Rev Share		\$42	\$125	\$221		
Expenses						
Mfg. Testing	\$300	\$120	_	_		
Clinical Trials	\$356	\$596	\$296	_		
Business Dev.	\$108	\$29	\$33	\$38		
Patents/ Legal WW	\$415	\$130	\$130	\$100		
G&A / other	\$427	\$45	\$40	\$40		
TOTAL Expenses	\$1,606	\$920	\$499	\$178		
Net Income	(\$1,606)	(\$878)	(\$374)	\$43		

Figures expressed as \$k

Profits in Q3 2015



## **Projections**

Figures \$Millions	2014	2015	2016	2017	2018	2019	2020	2021
Ethicor GP Rev Share		\$1	\$7	\$27	\$51	\$73		
Big Pharma Milestones	_	\$13	\$5	\$5	\$38			
Big Pharma Royalties	_	_	_	_	\$15	\$77	\$307	\$768
TOTAL Revenue	\$0	\$13	\$12	\$32	\$103	\$150	\$307	\$768
Expenses	\$2	\$3	\$1	\$2	\$5	\$8	\$16	\$39
Net Income	(\$2)	\$11	\$11	\$30	\$98	\$142	\$291	\$729
%	_	79%	93%	94%	95%	95%	95%	95%

### **Key Assumptions**

- 1. FDA approval 2018 (no accelerated approval designation)
- 2. \$0.30 retail (\$0.15 wholesale) in 2018
- 3. 15% License fee (15-18% tiered structure would add \$120M in 2021)
- 4. Licensing Agent 5% fee
- 5. A \$5B big pharma drug by 2021 (no OAB or bedwetting solution)



# Strengths of This Investment



Not a new chemical entity. Proof with a simple, relatively inexpensive trial. Avoid Phase 1 Trial safety tests and years of risk from unexpected side effects.



Strong Ethicor validation. International sales begin before trial completion, mitigates risk. Late-2015 worldwide big pharma license. Tight patent barrier through 2030.



\$3.4M to positive cash flow 12-15 months Strong ROI @ up to 95% net profit (400X cash return)



\$827K raised so far primarily through pooled due diligence of Keiretsu Forum; \$2.6M needed



World class team, rock solid science, huge unmet need, massive investor returns

