

**PROLOR
BIOTECH**

Protein . Longevity . Redefined

Corporate Presentation

May 2011

NYSE Amex: PBTH

Safe Harbor Statement

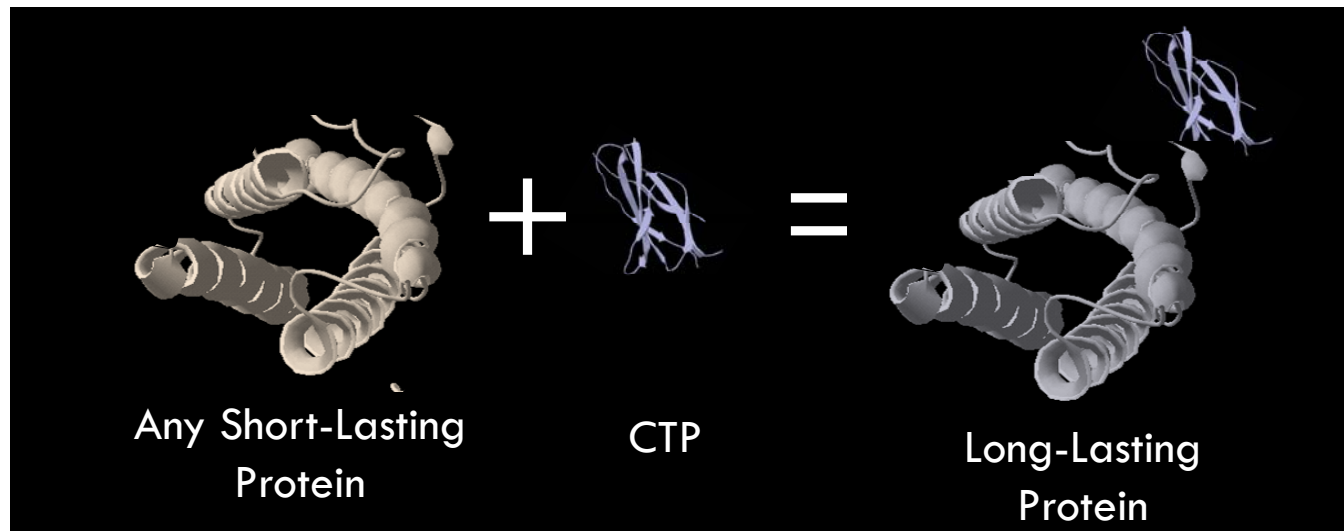
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This presentation contains forward-looking statements, including statements regarding the results of current studies and pre-clinical experiments and the effectiveness of PROLOR's long-acting protein programs and are made pursuant to the safe harbour provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that forward-looking statements involve risks and uncertainties that may affect PROLOR's business and prospects, including the risks that PROLOR Biotech may not succeed in developing any commercial products, and that ongoing studies may not continue to show substantial or any activity; and other risks and uncertainties that may cause results to differ materially from those set forth in the forward-looking statements. In addition to the risks described above, investors should consider the economic, competitive, governmental, technological and other factors discussed in PROLOR Biotech's filings with the Securities and Exchange Commission.

PROLOR: Leader in BioBetter Drugs

- Developing CTP-enhanced biobetter proteins and peptides
 - ▣ Dramatically reduce injection frequency, drug load and potentially side-effects for most proteins, peptides or antibodies
- Validated platform technology – safe and effective
 - ▣ Based on natural human peptide providing protein longevity
 - ▣ Preclinical & clinical proof-of-concept in multiple compounds
 - ▣ Merck's CTP-based Elonva[®] has received EU marketing approval
- Current pipeline targets \$62B total market
 - ▣ Lead product hGH-CTP in Phase II -- \$3B market
 - ▣ Obesity, IFN- β , Factor IX, Factor VIIa, others
- Poised to achieve significant clinical milestones
- Strong leadership team, IP position and balance sheet

CTP Increases Circulation Time



CTP Is Nature's Long-Acting Solution

- CTP was discovered at Washington University
- CTP is already in our system
 - ▣ Part of hCG
- CTP was added to hCG **during evolution** to provide hCG with an extended circulation time in the body
- Evolution selected CTP as the optimal way to extend the circulation time, without affecting the biological activity
- Superior safety and efficacy profile vs. man-made options



CTP: Clinically Validated Technology

- Merck 's long-acting FSH-CTP (Elonva®) received EU marketing authorization in 2010
 - ▣ Single FSH-CTP injection replaces 7 daily FSH injections in fertility treatment
- Two licensees of CTP technology: PROLOR and Merck
 - ▣ Merck holds license for 4 fertility-focused proteins (FSH, hCG, LH and TSH)
 - ▣ PROLOR holds license for **all other human therapeutics** of natural or non-natural sequence

CTP Competitive Advantages

PEGylation

- Increase size
- Slow enzymatic cleavage

DNA Mutations

- Add sugar chains
- Increase negative charge

Protein Fusion

- Increase size
- Slow enzymatic cleavage

Best Of Breed Combination

CTP

- Increase size
- Slow enzymatic cleavage
- Add sugar chains
- Increase negative charge
- Built-in modularity – number and placement of CTP cassettes

PROLOR's Pipeline of Market Leaders

Product / Indication	Market Size	Preclinical	Phase I	Phase II
hGH	\$3 billion			
Factor IX/VII	\$2 billion			
Obesity	\$10 billion			
IFN-B	\$11 billion			
Atherosclerosis	\$20 billion			
Rheumatoid Arthritis	\$16 billion			



Lead Product: hGH-CTP BioBetter to Reduce Injection Frequency

- 
- \$3 billion market
 - Growing at 7% annually
 - Requires daily injections

hGH Effect in hGH Deficient Adults

Proper hGH treatment results in:



Decrease in fat mass



Increase in lean body mass



Increase in bone density

Improved cardiac function, lower risk of cardiac diseases

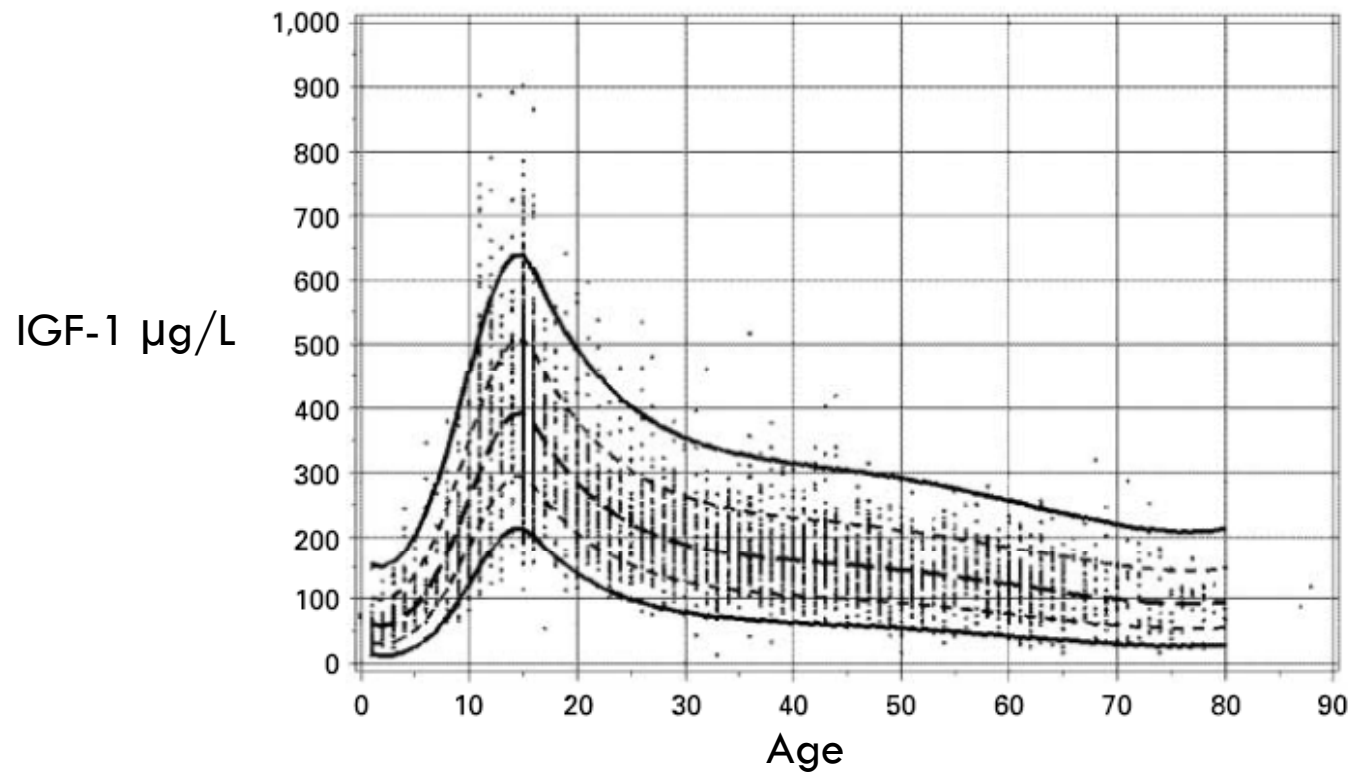


Improved overall physical performance



hGH → IGF-I Cascade

IGF-1 is the clinically monitored primary indicator of hGH biological activity in adults



Source: Serum IGF-1 Reference Values For An Automated Chemiluminescence Immunoassay System: Results From A Multi-Center Study, Hormone Research, 2003;60:53-60

hGH-CTP Phase II Study Design

- **Efficacy Objective**: Identify range of doses of hGH-CTP that can provide hGH-deficient adults with IGF-1 levels within the normal range.
- **Safety Objective**: Evaluate safety of hGH-CTP in low and high doses
- **Patients**: Recruit hGH-deficient adults who are already on daily hGH treatment and are within the normal range of IGF-1
- **Design**: Switch these patients to single weekly injections for a duration of one month, measuring safety, tolerability & IGF-1
 - ▣ Period long enough for evaluating IGF-1 trend

hGH-CTP Phase II Study Design (continued)

- **Phase II Efficacy Endpoint**: mean number of hours of IGF-1 within ± 1.5 SD after the last injection
 - ▣ SD is the statistical standard deviation from the average IGF-1 level for normal population
 - ▣ The clinically defined normal range that endocrinologists use is ± 2.0 SD
 - ▣ In the Phase II trial we used ± 1.5 SD , which is a very conservative definition
- Patients are divided into 3 main cohorts and receive single weekly injections, each containing 30%, 45% and 100% , respectively, of the cumulative net hGH dose they would get over 7 days of daily injections
 - ▣ An experimental group will be receiving 100% dose administered once every two weeks

hGH-CTP Phase I Conclusions

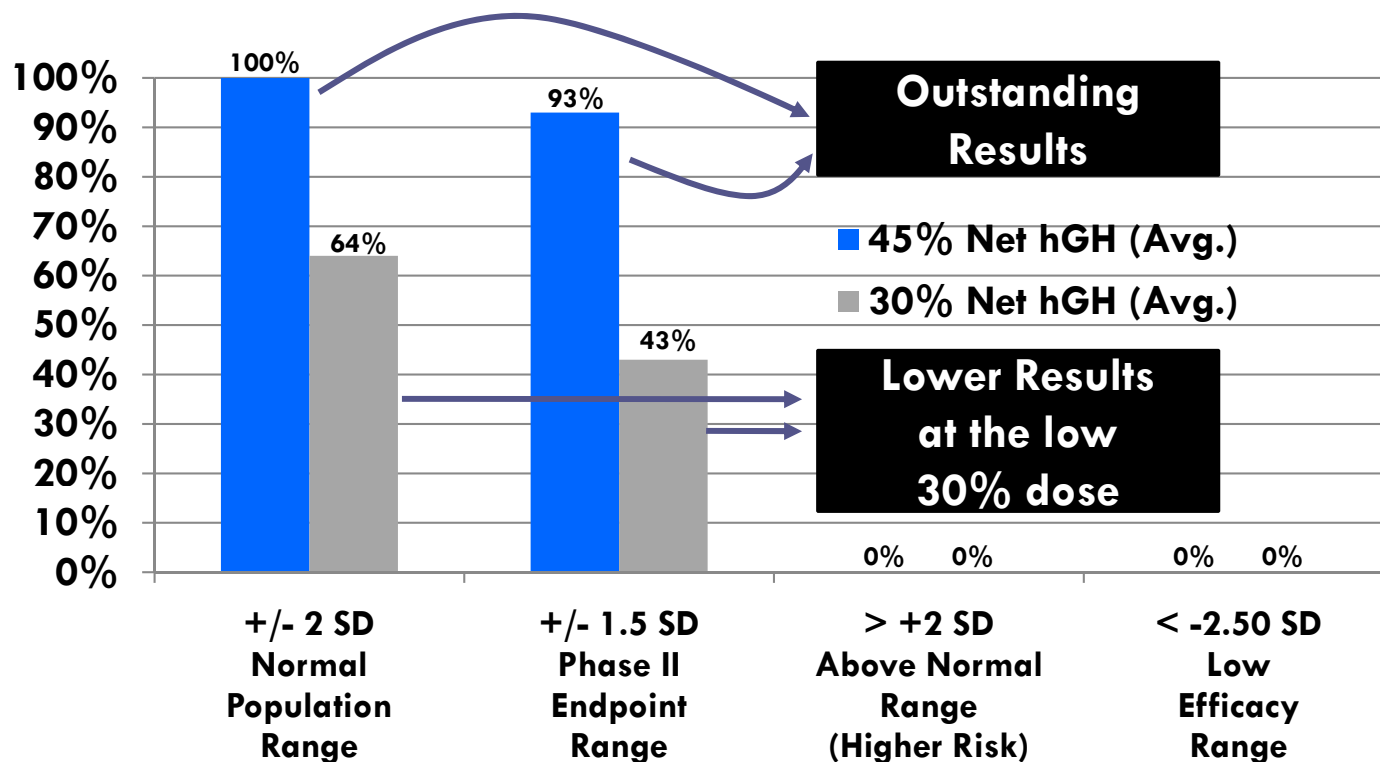
- Data from Phase I (healthy volunteers) show:
 - ▣ hGH-CTP is a very potent hGH
 - ▣ hGH-CTP has 7x the $\tau^{1/2}$ (half life) of commercial hGH
 - ▣ Potential injection interval of 7-14 days
 - ▣ Faster clearance of IGF-1 at the high dose injected
- hGH-CTP potency and IGF-1 stimulation
 - ▣ Question for Phase II: Would IGF-1 levels significantly exceed the normal range in patients ?

How many hours during a week following a single hGH-CTP injection would the IGF-1 be above the upper limit of the normal range (+2 SD) ?

Positive Interim hGH-CTP Phase II Results (30% & 45% Cohorts)

Single Injection of hGH-CTP Can Replace 7 Daily Injections of hGH

IGF-1: Percent of hours within and outside normal range during 7 days post last injection of hGH-CTP to hGH-Deficient adults



hGH-CTP Phase II Positive Interim Data

-- Analysis --

- The 30% to 45% dose range can provide hGH-deficient adults with IGF-1 levels within the normal range for sufficient amount of time during 7 days via a single weekly injection
- Positive dose response between the 30% and 45% groups
 - Physicians will have flexibility to choose the best dose based on individual patient IGF-1 response to hGH-CTP
 - Clinically valuable, as endocrinologists vary in their “desired” IGF-1 target level
- Interim data do not indicate that hGH-CTP has potential to cause excessive IGF-1 levels in patients
- Good safety & tolerability profile, No antibody formation

Single Injection of hGH-CTP Can Replace 7 Daily Injections of hGH

hGH-CTP Phase I to Phase II

Expectations vs Findings

- | □ <i>Data from Phase I</i> | □ <i>Phase II Interim</i> |
|--|---------------------------|
| □ <i>hGH-CTP is a very potent hGH</i> | □ ✓ |
| □ <i>hGH-CTP has 7x the $T_{1/2}$ (half life) of commercial hGH</i> | □ $10 \times T_{1/2}$ |
| □ <i>Potential injection interval of 7-14 days</i> | □ 7 days * |
| □ <i>Faster clearance of IGF-1 at the high dose</i> | □ NO |
| □ hGH-CTP potency and IGF-1 stimulation | |
| □ Would IGF-1 levels significantly exceed the normal range in patients ? | □ NO |

* Twice-a-month cohort's data is not available yet for analysis

hGH-CTP Phase II/III Status

- Phase II enrolling & dosing of 100% single-weekly injection cohort on track
- Phase II completion expected mid-year, assuming no unexpected delays
 - 100% twice-monthly experimental cohort's data will be available thereafter, pending speed of recruitment
- Q3-Q4 filing for pediatric Phase II trial approval on track
- Q1/Q2 2012 filing for adult Phase III trial approval on track

hGH-CTP Competitive Landscape Update

- *Orphan drug designation obtained in U.S.*
 - Granted for treatment of growth hormone deficiency-- covers GH deficiency in both adults and children
- *Novo Nordisk update*
 - Announced Oct 31 2010 that PEG-hGH program was terminated due to expected administration profile requiring more than one injection per week.

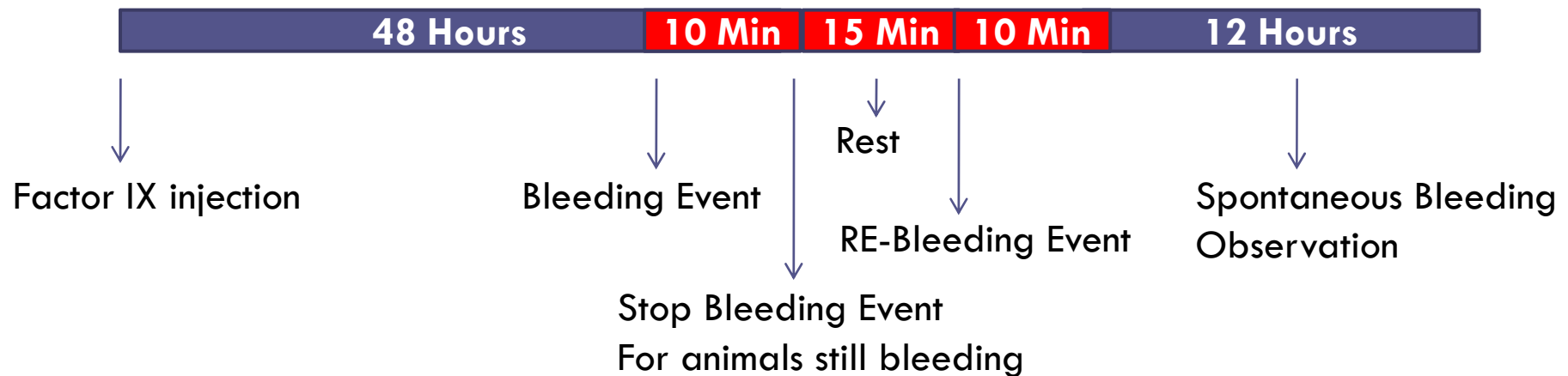


Factor IX BioBetter to Reduce Hospitalization

- Hemophilia B – \$700 million market
- Growing at 14% annually
- Bleeding events require hospitalization
- Prophylactic treatment requires 2-3 weekly IV infusions administered in hospital

Factor IX-CTP Efficacy

- Comparative Study in Factor IX-depleted mice



- Designed to test
 - Duration of clotting activity
 - Quality of clotting activity
 - Compared with BeneFIX [Pfizer/Wyeth] (the FDA-approved commercial Factor IX)

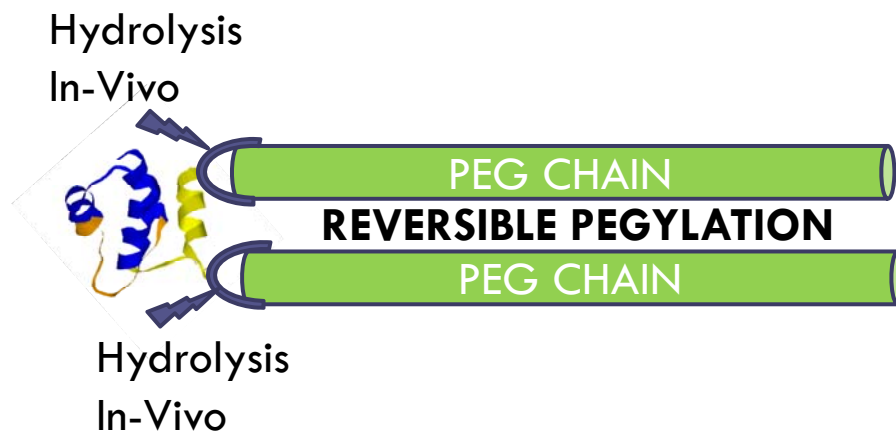
Factor IX-CTP Showed Superior Efficacy and Longevity [Preclinical]

	1 st Bleeding Event Clotting Activity	2 nd Bleeding Event Long Acting Clotting Activity		12h Post 2 nd Bleeding Event Long Acting Clotting Activity
	Blood Loss Compared to FIX-CTP	Blood Loss Compared to FIX-CTP	Bleeding Duration Compared to FIX-CTP	Bleeding Episodes (Spontaneous)
Untreated Control vehicle	x2.8	x4.6	x3.1	83%
BeneFIX	x2	x3.8	x3.1	50%
FIX-CTP	/	/	/	0

Added 2nd drug delivery technology platform for peptides & small molecules – Reversible PEGylation



- PEG chain too large for small peptide, rendering it inactive, or must be used in very high doses

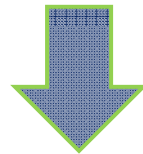


- PEG chain hydrolyzed from small peptide, leaving authentic peptide to perform its intended activity
- Slow, controllable and predictable hydrolysis achieves desirable PK profile
- Unique linkers, patent protected
- Demonstrated in animal models for long-acting versions of exendin-4, PYY, ANP, gentamicin

Obesity Epidemic Demands New Safe & Effective Therapies

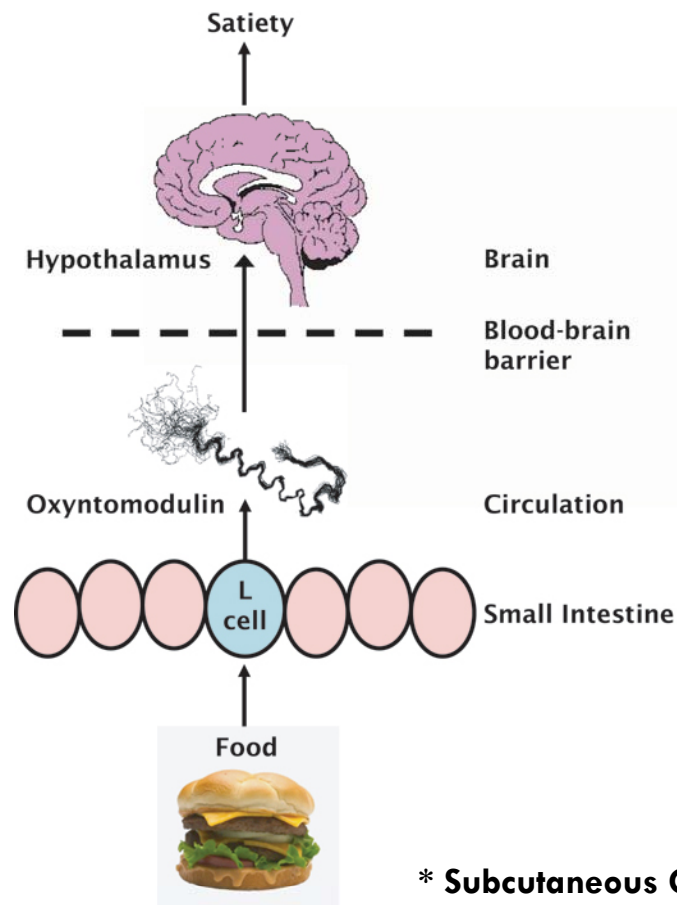
Recent FDA rejections focus on safety issues

- *Vivus* – Risk of major adverse cardiovascular events; Risk of birth defects
- *Arena* – Risk of heart-valve disease, psychiatric and memory problems and cancerous tumors in rats
- *Orexigen* – Risk of major adverse cardiovascular events



***Tremendous need for anti-obesity drugs that have
good efficacy and side effect profile***

Oxyntomodulin – Nature's Appetite Control Mechanism



- Natural appetite suppressant mechanism
- Can be over-expressed in very high quantities with no side effects
- Clinically achieved 0.5kg per week weight loss over 4 weeks along with signs of adipose tissue loss*
- Half-life the major problem – subjects injected 3 times daily
- PROLOR's reversible-PEGylation product for oxyntomodulin designed for **once-weekly administration**

* **Subcutaneous Oxyntomodulin Reduces Body Weight in Overweight and Obese Subjects** -- A Double-Blind, Randomized, Controlled Trial, Bloom et al., DIABETES, VOL. 54, AUGUST 2005

2011 Pipeline Development Focus

Anticipated activities:

- *Oxyntomodulin*
 - Complete further animal efficacy and tox studies
 - File for regulatory clearance to initiate Phase I
- *Factor IX, Factor VII*
 - Complete further animal efficacy and tox studies
 - File for regulatory clearance to initiate Phase II
- *Atherosclerosis, Rheumatoid Arthritis*
 - Produce large quantities for preclinical testing
 - Conduct animal models to test efficacy, injection profile

Anticipated Milestones

Event	Timing
Obesity: Complete efficacy studies in small animals	Q2 2011
hGH-CTP: Phase II adult clinical trial completion	Q2 2011
Factor VII-CTP: Complete efficacy studies in small animals	Q3 2011
hGH-CTP: File for Phase II pediatric study regulatory clearance	Q3-Q4 2011
hGH-CTP: File for Phase III adult study regulatory clearance	Q1-Q2 2012
Obesity: File for Phase I study regulatory clearance	Q2-Q3 2012
Factor IX-CTP: File for Phase II study regulatory clearance	Q2-Q3 2012

Robust IP Portfolio

28

- Exclusive license to a series of CTP patents issued by the USPTO covering the basic platform
- Issued patents covering hGH-CTP and EPO-CTP (July 2009)
- Seven other pending patent applications covering CTP innovations: configurations, compositions & methods
- Exclusive license to a series of Reversible PEGylation patents issued by the USPTO covering the basic platform
 - Excluding insulin and hemophilia drugs

Leadership

Phillip Frost, MD.
Chairman



Abraham Havron, Ph.D.
CEO



Jane Hsiao, Ph.D., MBA
Director



OPKO
Corporation

Marian Gorecki, Ph.D.
Director



Steve Rubin, J.D.
Director



OPKO
Corporation

Shai Novik, MBA
President



Financial Profile

- NYSE-Amex and TASE listed (PBTH)
- 54 million common shares outstanding, 60 million fully diluted, 27 million shares in the float
- \$22 million cash balance Mar 31, 2010
- Cash expected to last through 2012