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# CardioPharma

**CP-101 CardiaPill®**  
The Game Changer  
in Treating CVD



# Forward looking statements



This presentation includes forward-looking statements including statements regarding the timing and outcome of clinical trials, potential regulatory approvals, future demand for and sales of our products and the future development of new products.

These statements are not guarantees of future performance and the Company's actual results could differ materially and adversely from those expressed in any forward looking statements.

CardiaPill® is a registered trademark, but has not been approved yet by the US FDA for commercial use.

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# Corporate Strategy



- Bring the first US and EU patented CVD polypill CP-101 successfully through the US FDA NDA process.
- Use the US FDA Approval data and process to help move the product through the various international regulatory processes.
- Make CP-101 available to the global community at appropriate prices.



# CVD - Leading cause of death



# >81M

cardiovascular patients in the US

# 1/3

deaths in the US each year

# >\$500B

in costs to the US health care system



# Standard of care for cardiovascular disease



Platelet inhibitor

Cholesterol  
lowering agent

Anti-hypertensive

**3** Classes of medicines  
have an enormous  
positive impact

Yet, CVD remains the leading  
cause of death



**785,000**

experience a **first** heart  
attack each year

**470,000**

experience a **repeat**  
heart attack each year

## The Problem – Non-Compliance



The #1  
problem  
in medicine is  
**non-compliance**

**>60%**

of cardiovascular patients  
are non-compliant with  
their medications\*

**CP-101 is a solution**



\* Circulation 2010;121:1455-1458.

**CP-101** CardiaPill®  
**Uniting**  
the standard of care



# CardiaPill - Ideal Combination for CVD



## CP-101 CardiaPill®

Once-a day, dose variable, color coordinated capsule containing the 3 most prescribed cardiovascular drugs

### Anti-hypertensive:

**lisinopril**

- leading ACE inhibitor

### Cholesterol lowering agent:

**simvastatin**

- leading statin

### Anticoagulant:

**aspirin**

- leading platelet inhibitor



# Global Standard of Care

# Target Doctor Perception



- 2014 American College of Cardiology – Primary Research
  - Data collected from 100s of cardiologists:
    - 96% would like the drug available today
    - 94% would put existing patients on the drug today
    - 87% would prescribe it for naïve patients
    - 93% would like to see more combinations



# More Important? *Compliance or Economics*



- CP-101 answers both questions
- Once-a-day combination immediately promotes:
  - Increased convenience = better acceptance
  - Improved patient compliance = better outcomes
- Reduced costs at all levels = better economics

*“The concept is simple. Several different drugs are available (generically and thus inexpensively)... So, combining them in one pill could reduce heart disease by 80%. This approach has obvious appeal, and vast implications for global health...” (Lancet, April 18, 2009; 1313)*



# Intellectual Property



- The Brigham and Women's Hospital, Inc. is the original owner of the two patents that protect the Drug. The Liang Patent protects the concept of combining (or even placing in the same package) aspirin, any ACE inhibitor and any statin. The Chungi Patent protects the Drug from a competitor being able to formulate the three drugs described in the Liang Patent into one pill.
- CardioPharma has exclusively licensed the global rights to the intellectual property surrounding CardiaPill®. CardiaPill® is predicated on two issued patents:
  - a) The Liang Patent was issued to Harvard researchers. It claims the use of four classes (any cholesterol-modifying compound, any blood pressure medicine, an antiplatelet product, and, optionally, effective B vitamins) to prevent cardiovascular events. These drugs do not have to be in single dosage unit, but could be co-packaged. In addition to the standard risk factors and prior cardiovascular events, the Liang Patent singles out systemic lupus erythematosus, patients on hemodialysis or with transplants, and smokers as additional populations; and
  - b) Two of Liang's colleagues at the Massachusetts College of Pharmacy gained approval for a method of formulating three or more effective drug classes listed in Liang's patent into a single pill (the Chungi Patent). Like the Liang Patent, the Chungi Patent also provides for a co-packaged product.



# Intellectual Property



- **Strong patent protection**
  - Issued patents: US, Canada, Australia, New Zealand, SA, Israel, EU
    - Covers method of use, method of formulation (single pill)
  - Patents pending: Japan, China, India and other international markets
- **IP is Platform-based – allows multiple combinations of multiple proven CV drugs:**
  - Anti-hypertensives (e.g. ACEIs, ARBs,...)
  - Cholesterol lowering agents (e.g. niacin, statins, newer agents)
  - Platelet inhibitors (e.g. ASA, clopidogrel,...)
  - Next generation products already in development
- **Independent corroborating FTOs and KSR tested**





## Wide range of potential products

Proprietary platform protects and enables numerous combinations of proven CVD drugs...

- Anti-hypertensive:  
e.g. ACEs, ARBs
- Cholesterol lowering agent:  
e.g. niacin, statins, newest agents
- Platelet inhibitor:  
e.g. ASA, clopidogrel

... targeting multiple patient-specific formulations:

- Diabetics
- Smokers
- Clinically obese
- Resistant to drug class
- Lupus

Multiple combinations for  
broad market coverage



These triple  
combinations  
have been  
requested by  
the FDA

high statin / low pril / fixed ASA

low statin / high pril / fixed ASA

high statin / high pril / fixed ASA

low statin / low pril / fixed ASA

A CardiaPill<sup>®</sup> for every patient

# Rapid Market Entry



# Regulatory Pathway



- Strong documented FDA support from inception
- product treated by FDA as a new drug, not a generic copy, providing first to market exclusivity protection
- Expected NDA filing: 2015
- International Registrations in process building off the US submission



# Bio bioequivalency and Non-interference



**PK Demonstrated  
successfully**

**PD study 2014**

3,000+ Patient safety  
Data base

PD Study designed to  
Show APIs do not  
Interfere with each other

**No pivotal trial risk**