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.
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 #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**
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 erythematosis, 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® for every patient
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
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<tr>
<th>PK Demonstrated successfully</th>
<th>PD study 2014</th>
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<td>3,000+ Patient safety Data base</td>
<td>PD Study designed to Show APIs do not Interfere with each other</td>
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No pivotal trial risk