



cardio dx

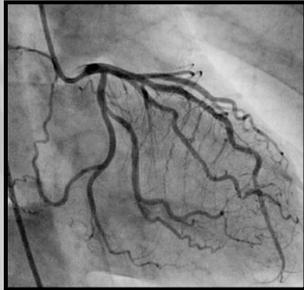
***IVDMIA Public Forum
Comments***

February 2007

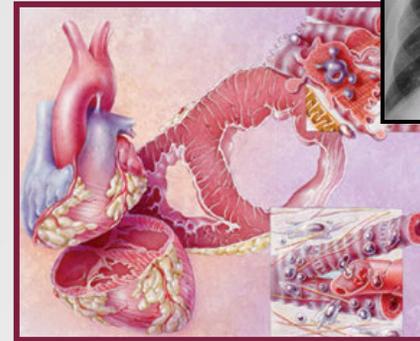
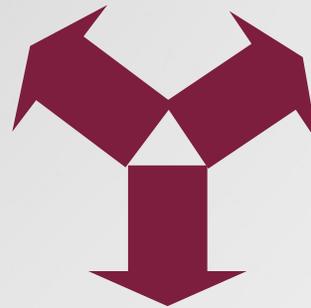
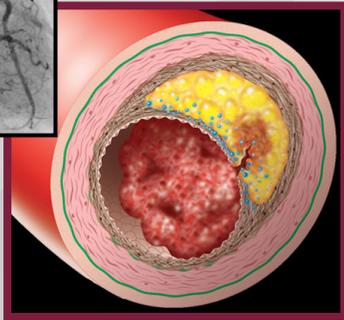
CardioDx Summary

- *Molecular diagnostics company based in Palo Alto, CA*
 - *Launched 2005*
 - *Leading venture investors*
- *Focused on improved targeting of advanced / invasive cardiovascular therapies*
- *Three clinical programs in development*
- *First commercial launch expected in 2008*
- *CLIA lab model for initial product offerings*

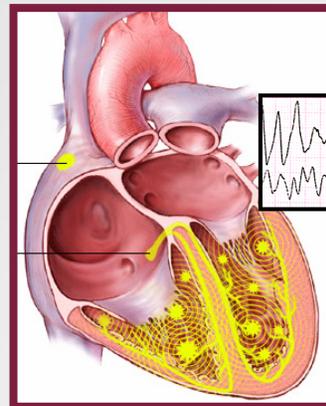
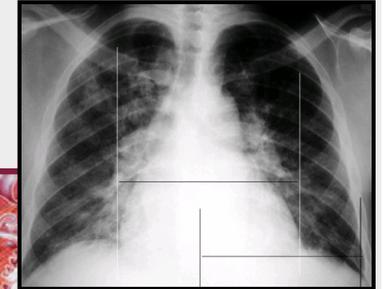
Exclusive Focus on CVD



Coronary Disease & ACS



Congestive Heart Failure



Arrhythmias & SCD

Large Patient Populations

- *Heart Failure*

- *5,500,000 patients in the U.S.*
- *On complicated drug regimens*
- *Adherence to guidelines is challenging*

- *Coronary disease*

- *7,000,000 heart attack survivors in the US*
- *6,500,000 angina / chest pain patients in US*
- *Significant overuse of invasive procedures*

- *Sudden Cardiac Death*

- *300,000 sudden cardiac deaths per year in US*
- *2,500,000 heart failure patients at risk for SCD (EF<35%)*
- *Lifesaving therapies available (ICD and CRT-D)*
- *Very limited ability to choose high risk patients*

Need for better patient stratification

CardioDx Approach

- *Focus on important clinical decision*
 - *Intensive discussions with clinicians*
- *Collect large number of samples*
 - *20,000 samples under contract*
 - *Collaborations with leading academic centers*
 - *Full IRB and patient consents*
 - *Extensive clinical data collection*
- *Using multiple technologies to find biological signals*
 - *Gene expression, SNPs, proteomics, etc.*

Development Path

	<u>Discovery</u>	<u>Development</u>	<u>Validation</u>
Goal	<i>Proof of Concept / Candidate markers</i>	<i>Training, Testing, Tuning Algorithm Development</i>	<i>Validation</i>
Samples	<i>N = 1,000 – 2,000</i>	<i>N = 500 - 1,000</i>	<i>N = 1,000 - 2,000 Multiple validations</i>
Processes	<i>Re-sequencing, SNP discovery, microarrays, exploratory analysis</i>	<i>Genotyping, quantitative PCR, biostatistics</i>	<i>Genotyping, quantitative PCR, formal hypothesis testing</i>
Time Frame	<i>6 – 12 months</i>	<i>6 – 12 months</i>	<i>3 – 6 months</i>

Focus on Publication and Reproducibility

CardioDx Products

- *Validated in multiple cohorts*
- *Targeting peer reviewed publications*
- *Positive health economic benefits*
- *All communications through physicians*
 - *No direct to consumer testing*

Adding novel information to the physician's decision making process

Impact on CardioDx of IVDMA Guidance

- *Difficult to raise additional capital*
- *No parallel product development*
 - *Three clinical programs down to one*
 - *Lead program delayed 1+ years*
 - *Other programs delayed 3-5 years*
- *Longer development timelines*
 - *Diagnostics require shorter timelines to reflect current clinical setting*

Millions of patients lose the opportunity to receive more appropriate care

Why Innovation Will Slow

- *Today's tools of genetics, genomics, proteomics require new companies to drive new diagnostic products*
- *Large labs are great developers, but do not focus on research*
- *Academic labs do not have the resources to conduct the large scale development and validation trials*
- *New IVDMA's will come from small companies*

***FDA should encourage companies like
CardioDx to develop new tests***

What We Would Like To See

- *Work with the FDA individually or through coalitions*
- *Allow new products to come to market under CLIA*
- *Use criteria to determine regulatory path*
 - *Test volume, Peer reviewed articles, etc.*
- *Establish pilot test registry*

Regulation that fosters innovation



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Thank You

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