Med BioGene LungExpress Dx™

October 2009

Med BioGene

- Personalized medicine & molecular diagnostics company
- Located in Vancouver, Canada
- Founded in 2003
- Projects in oncology and cardiovascular disease
- Primary focus since 2008: Lung cancer
  - *Collaboration with the University Health Network at University of Toronto (Drs. Frances Shepherd and Ming-Sound Tsao)*
  - *3- and 6 gene prognostic signatures for early-stage NSCLC*
  - ***LungExpress Dx™**: 15 gene prognostic signature with predictive indications of adjuvant chemotherapy benefit*

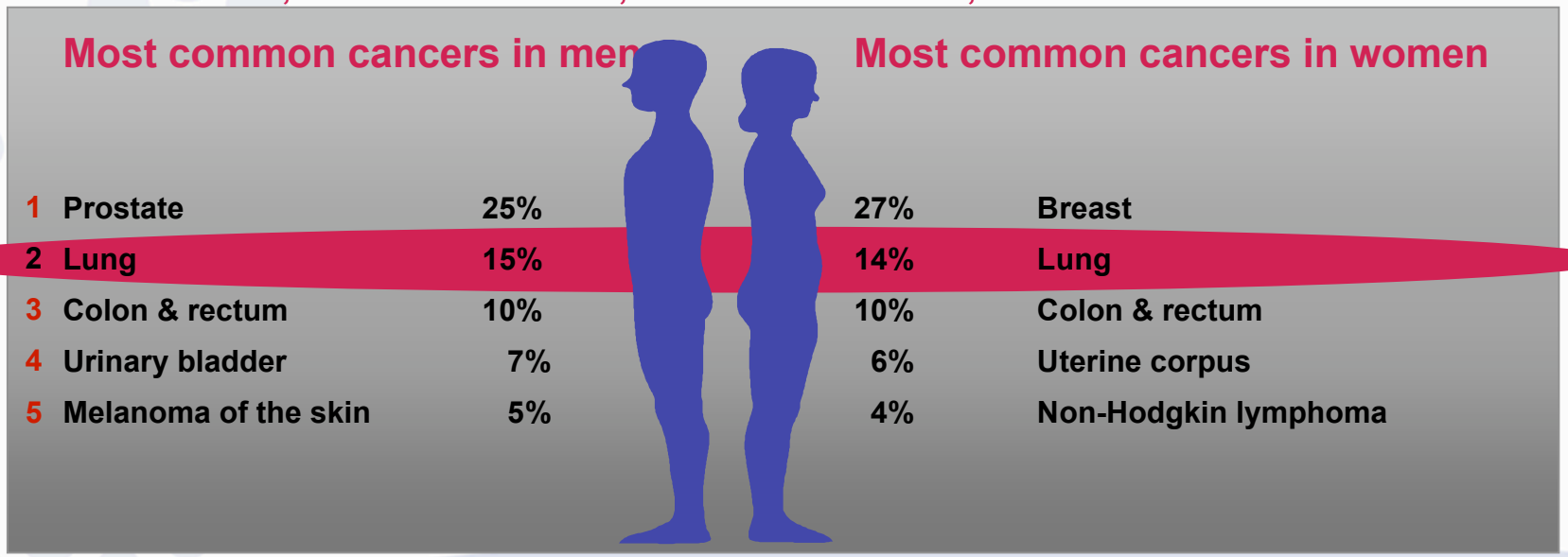
Highlights

Lead test under development is *LungExpress Dx™*

- 15 gene expression-based test prognostic for survival and predictive of chemotherapy benefit in early NSCLC
- Expected to change the standard of care for selecting patients who may benefit from adjuvant chemotherapy
- Potential to increase the five-year cure rate by up to 33%, decrease costs by up to 18%
- Over 200,000 early stage lung cancer patients annually in US and EU alone may benefit from the use of the test
- Abstract included in the distinguished ASCO 2008 Annual Meeting *Official Press Program*

Lung cancer: leading cause of cancer death, second most common cancer

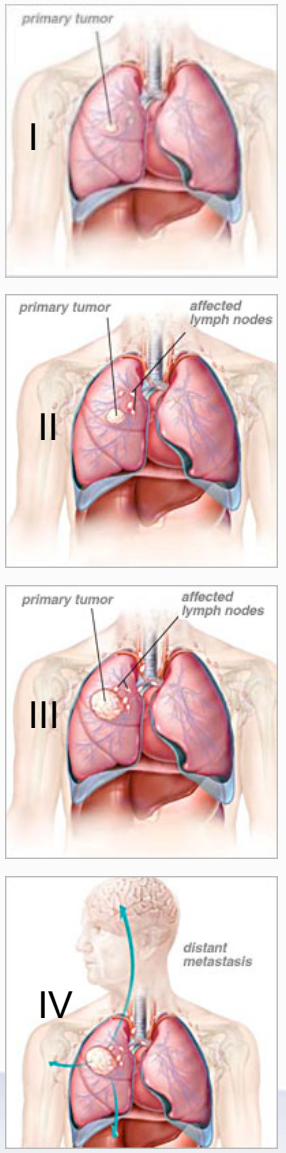
- Leading cause of cancer death in the western world; 219,000 new cases and 159,000 deaths in the US annually (2009)*
- Non-small-cell lung cancer (NSCLC) comprises 85% of all lung cancers
- Lung cancer incidence in US is projected to increase**:
  - 2010: 220,000→2020: 280,000 →2030: 338,000



*Jemal, Cancer Statistics, 2009
** Smith, JCO, 2009

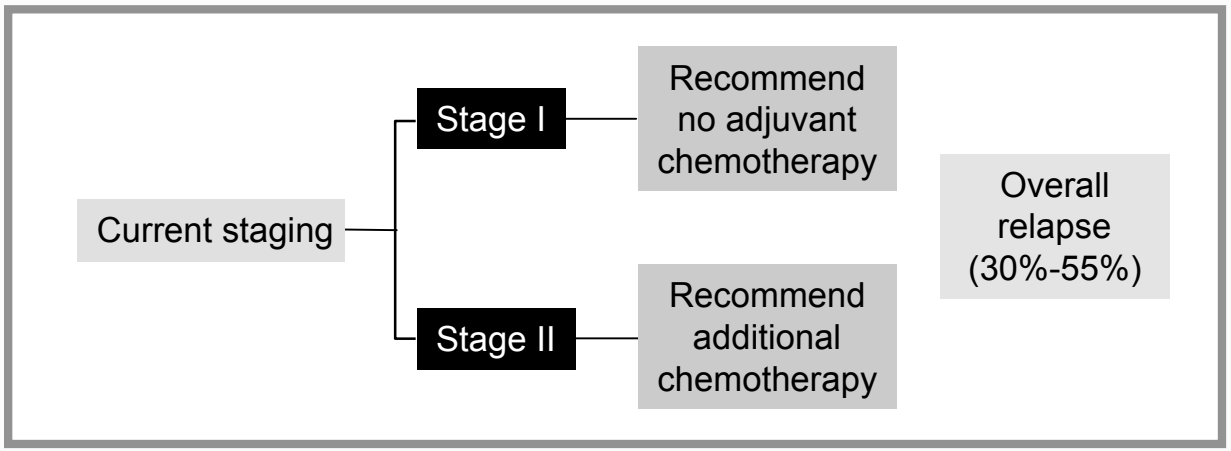
Improvements in lung cancer patient management are urgently needed

- Currently, standard of care and patient prognosis are primarily determined by stage of disease
- Staging based **only** on a combination of clinical characteristics of tumour size, node involvement and metastatic status (TNM)
- Standard of care for early-stage NSCLC:
  Stage I: surgery
  Stage II: surgery + adjuvant chemotherapy
- Significant number of stage I and II patients relapse and die of the disease within 5 years:
  - Marginal benefit of adjuvant chemotherapy: Many patients refuse treatment (only 70-75% compliance)
  - Stage I patients only receive ACT at physician's discretion: tumor size (large stage IB) and ability to tolerate ACT

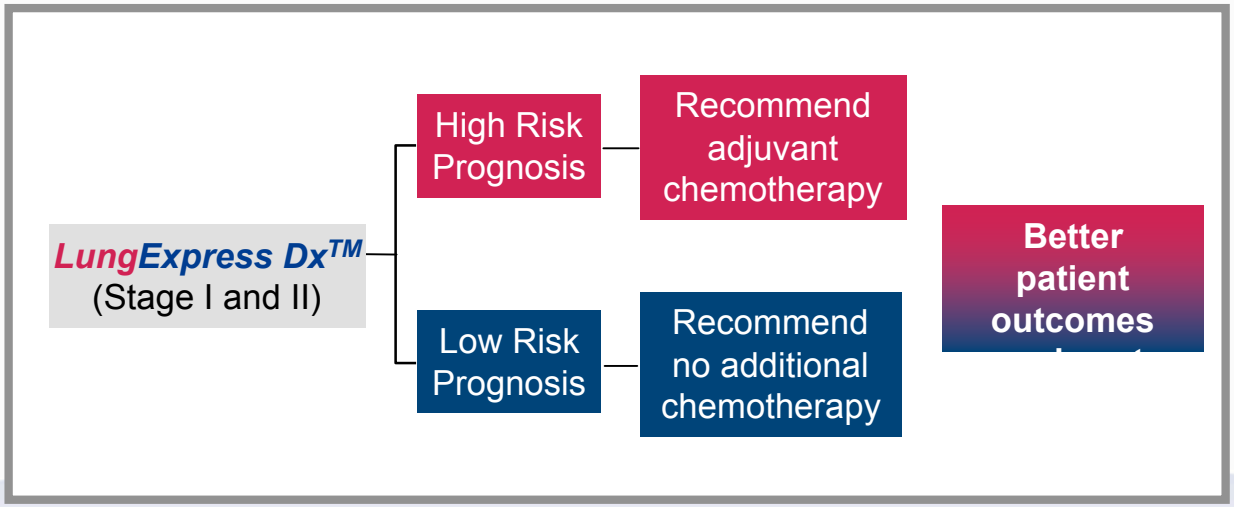


LungExpress Dx™ may change standard of care, improving patient outcome

Current staging paradigm



Future molecular paradigm, with *LungExpress Dx™*



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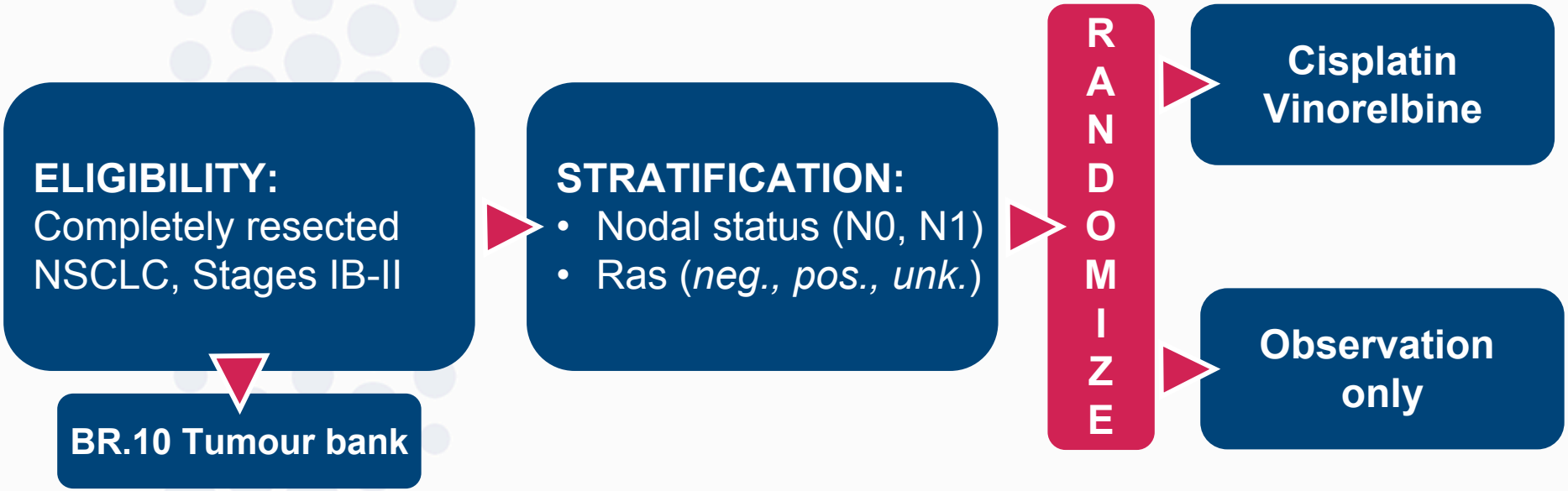
LungExpress Dx™

Development and Validation

JBR.10 Clinical Trial

"Phase III prospective randomized study of adjuvant chemotherapy with vinorelbine and cisplatin in completely resected non-small cell lung cancer with companion tumour marker evaluation" *(Winton et al., (2005) NEJM 352:2589)*



Development of *LungExpress Dx™:* Signature optimization

JBR.10 Clinical Trial (NSCLC IB and II)
n=133 profiled (microarray)

↓

Observation patients n=62

↓

Univariate analysis

172 genes
p<0.005

↓

Stringent gene selection

Leave one out cross validation

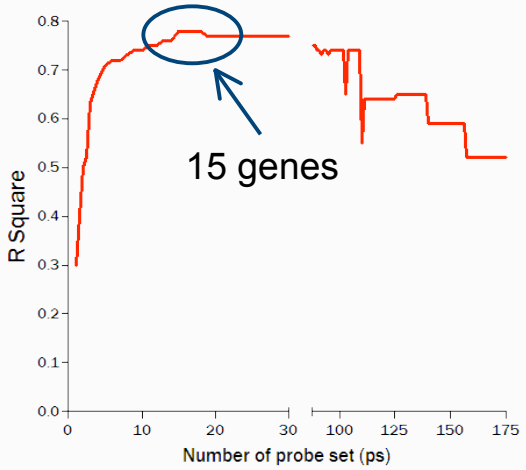
↓

15 genes optimized signature

Principal Component Analysis and Risk Score (PCA/RS)

Risk Score = 0.557***EC1**+0.328***EC2**+0.43***EC3**+0.335***EC4**

Signature optimization

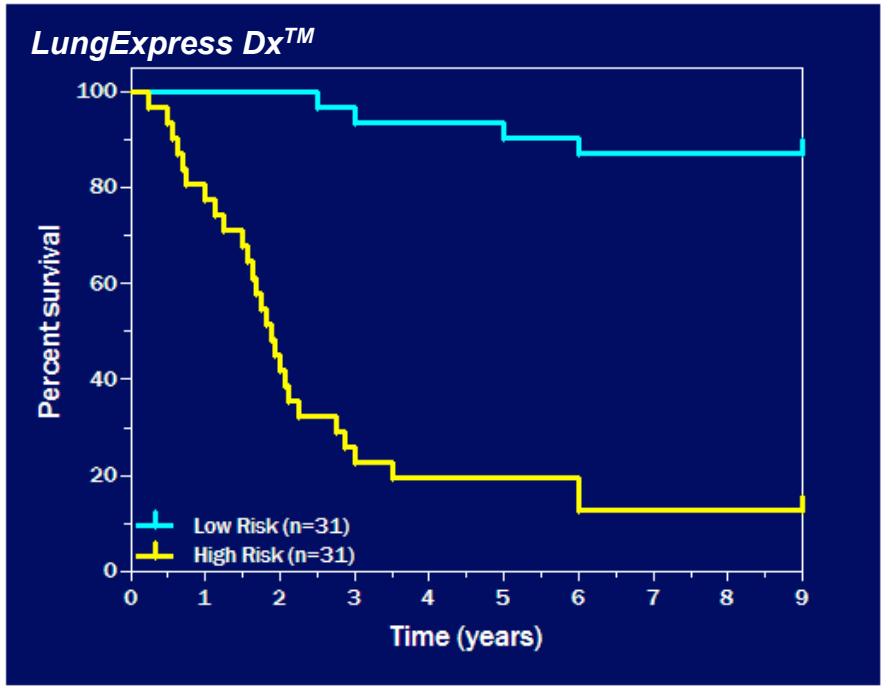


LungExpress Dx™:
RS ≥ -0.1: High risk
RS < -0.1: Low risk

Expression Component (EC): Weighted expression of the 15 genes in of each of the first 4 principal components

High and low risk patients have significantly different prognosis

Observation (n=62)



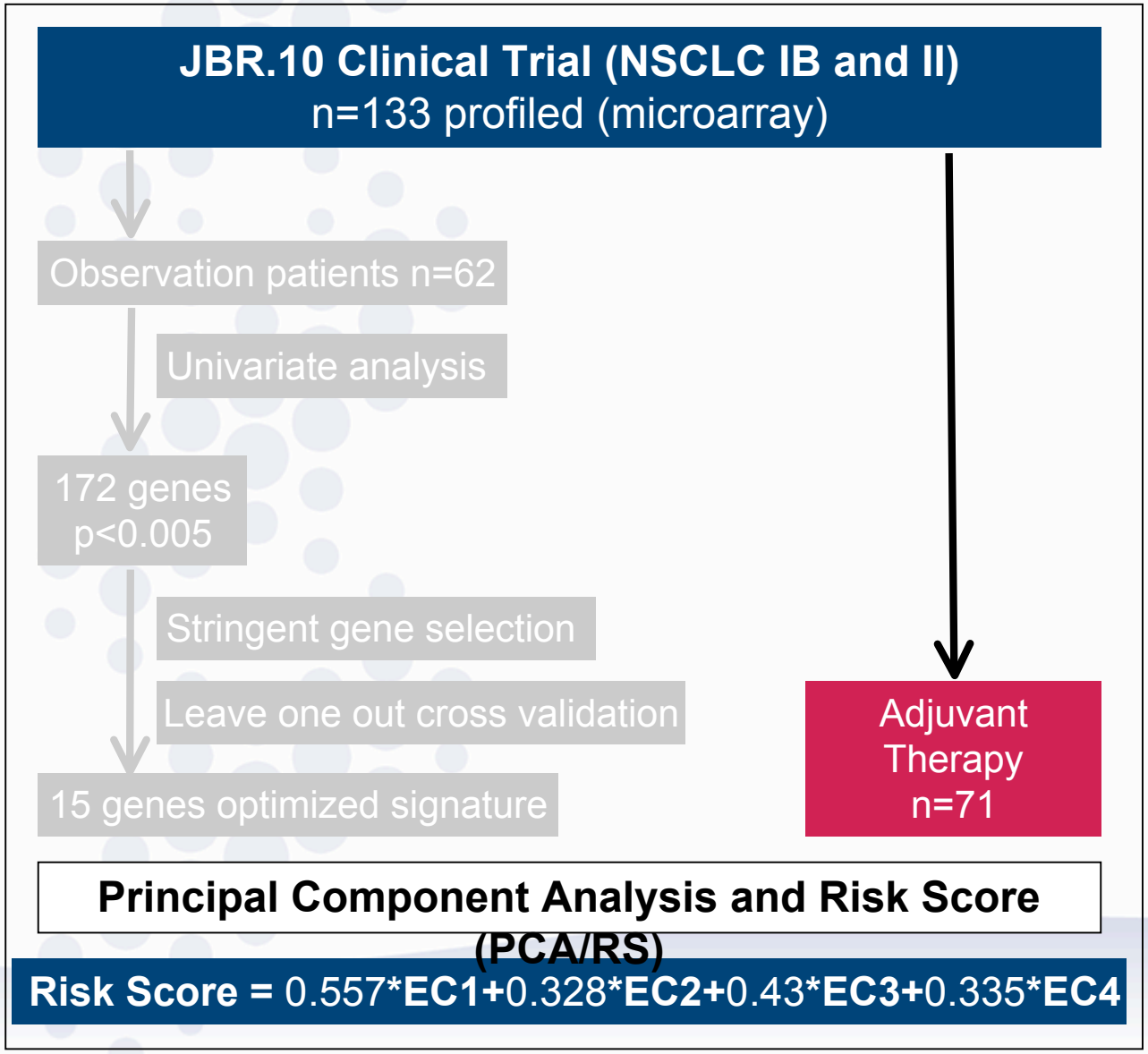
No. at Risk				
Low Risk	31	28	20	1
High Risk	31	9	3	0

HR 15.02 (95% CI 5.12-44.04)
p<0.0001

LungExpress Dx™ validated in independent patient cohorts

Study	# Patients	HR	95% CI	P value
University Health Network *Adenocarcinoma/squamous cell carcinoma / other (Publication pending)*	**183**			
Director's Challenge, *Adenocarcinoma (Shedden 2008)*	**169**	**3.2**	**1.69 – 6.11**	**0.0002**
Netherlands Cancer Institute, *Adenocarcinoma/squamous cell carcinoma (Roepman 2008)*	**133**	2.3	**1.2 – 4.4**	**0.014**
University of Michigan, *Squamous cell carcinoma (Raponi 2006)*	**106**	**2.3**	**1.1 - 4.7**	**0.026**
Duke University, *Adenocarcinoma/squamous cell carcinoma (Potti 2006)*	**85**	**1.5**	**0.81 - 2.89**	**0.19**
TOTAL	**676**			

Development of *LungExpress Dx™:* Testing of predictive utility

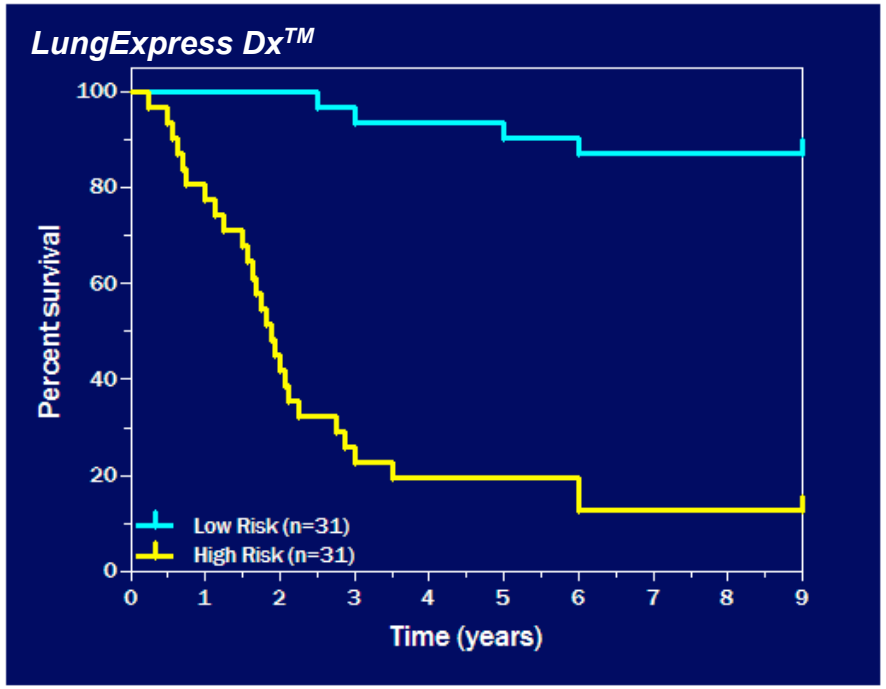


LungExpress Dx™:
RS ≥ -0.1: High risk
RS < -0.1: Low risk

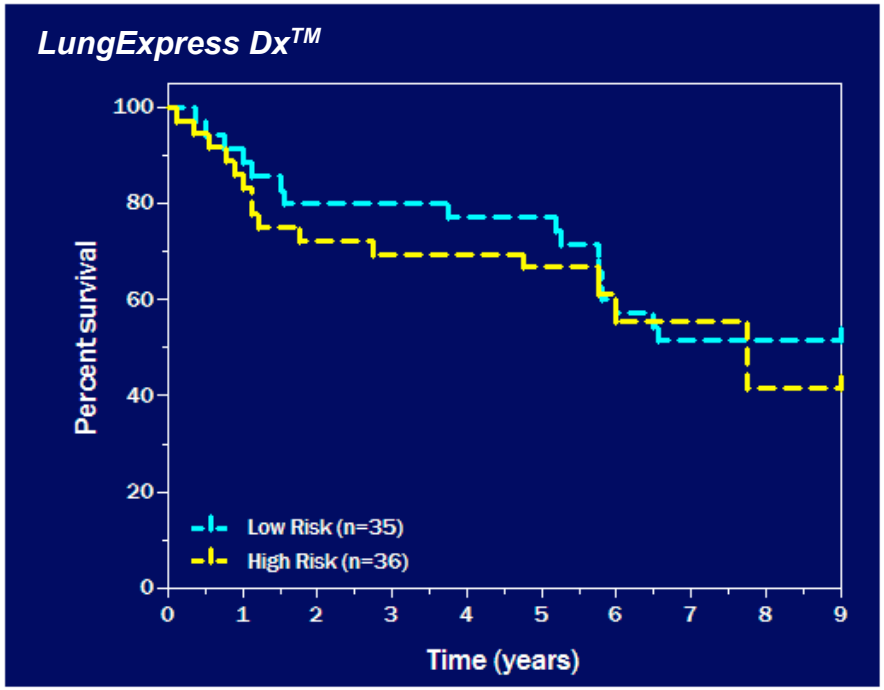
Expression Component (EC): Weighted expression of the 15 genes in of each of the first 4 principal components

High and low risk patients have significantly different prognosis; differences in outcome eliminated by chemotherapy

Observation (n=62)



Chemotherapy (n=71)



No. at Risk								
Low Risk	31	28	20	1	35	28	19	3
High Risk	31	9	3	0	36	25	15	1

HR 15.02 (95% CI 5.12-44.04)
p<0.0001

HR 1.15 (95% CI 0.56-2.37)
p=0.6942

High risk patients benefit significantly from, and low risk patients may be harmed by, chemotherapy

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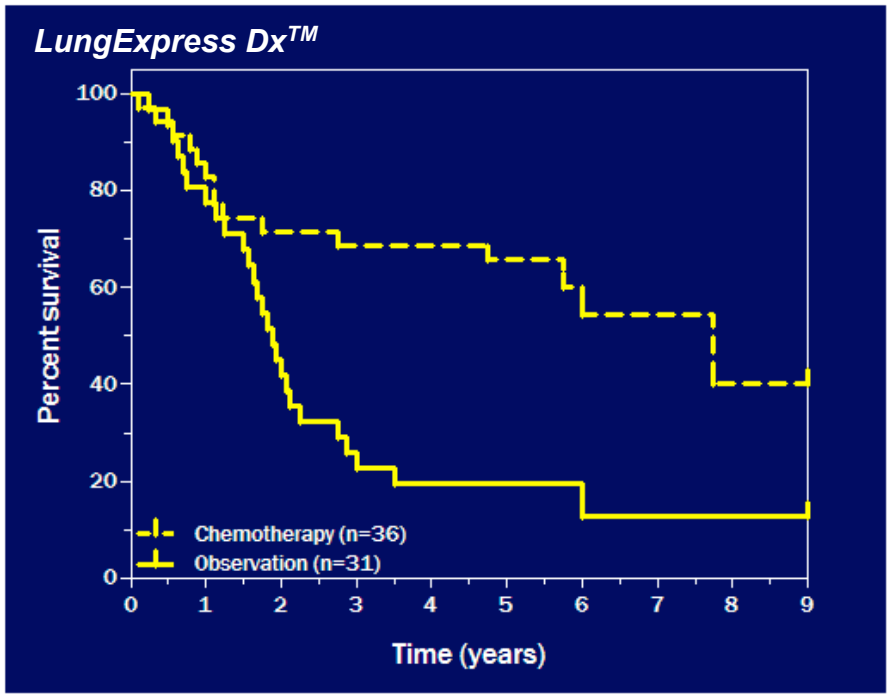
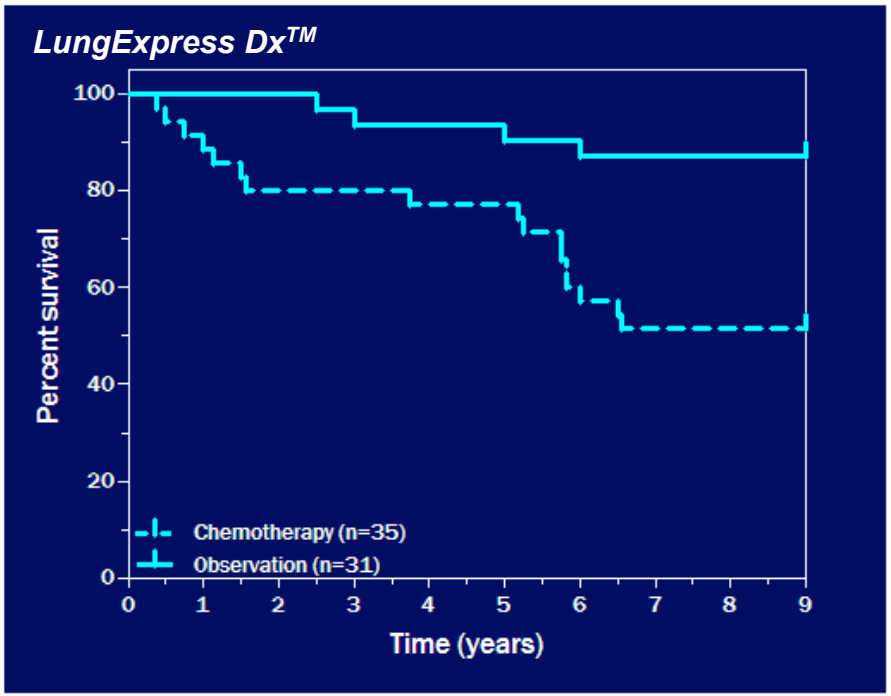
High risk (n=67)



Low risk (n=66)

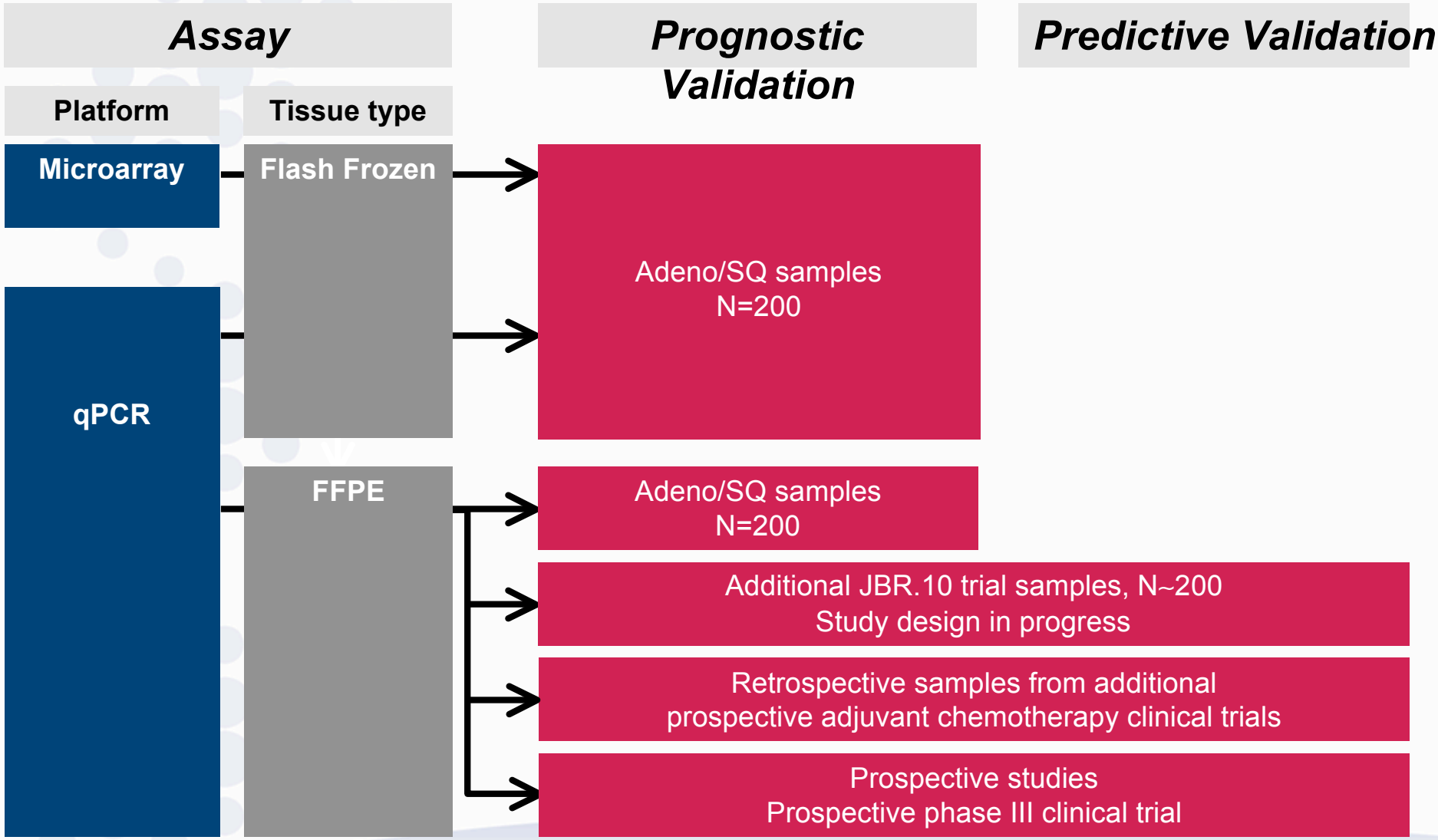


No. at Risk								
Observation	31	9	3	0	31	28	20	1
Chemotherapy	36	25	15	1	35	28	19	3

HR 0.33 (95% CI 0.17-0.63)
p<0.0005

HR 3.67 (95% CI 1.22-11.06)
p=0.0133

Development of *LungExpress Dx™*



Increases cure rate by up to 33%, decreases costs by up to 18.5%

	Current standard of care	Care including *LungExpress Dx™*	Difference
Surviving patients[1]			
5 yrs post diagnosis	61	81	+20
Costs, US$			
Direct medical costs[2]	672,000	2,100,000	+1,428,000
Direct medical costs treatment failure[3]	5,850,000	2,850,000	-3,000,000
Test[4]	0	382,000	+382,000
Total	6,522,000	5,332,000	-1,190,000
	Δ cost/ Δlives = -59,500 US$		

***LungExpress Dx™* has the potential to save annually up to 14,800 lives and $880 million in healthcare costs in the United States**

annually

[1] NCCN TNM staging. Based on 100 patient cohort of stage I and stage II NSCLC, 15-gene classifier OS data.
[2] US$42,000, incl. hospitalization, outpatient visits etc.
[3] US$150,000; costs for first, second and third line treatment of recurrent disease and/or terminal care.
[4] Based on list price of US$3,820 of Genomic Health's Oncotype Dx Breast Cancer Assay.

LungExpress Dx™ Commercialization Strategy:

- Company focus on commercialization of *LungExpress Dx™* and achieving early profitability
- Initial launch in US under CLIA
- Actively pursuing/considering business development opportunities for US and EU
  - Considering pure out-licensing and sub-contracting alternatives (dual-CLIA type model)
- Considering non-US countries for entry through out-licensing (EU, Japan, ROW)

Summary

- ***LungExpress Dx™*** will be used at the early stages of lung cancer to identify those patients at high risk for cancer recurrence
- Critical clinical intervention point which may lead to:
  - Improved survival
  - Personalized, more effective treatment
  - Improved cost-effectiveness of current treatment regimes
  - minimized risk of recurrence
- Only test to predict adjuvant chemotherapy benefit; robust performance in predicting prognosis
- Physicians may use this test to assist in treatment decisions
- Patients may use this test to gain more comfort with their treatment plan
- Test developed by world-leading clinicians
- First mover advantage – expect test to be launch ready by end of 2009
- Initial revenues in the US to begin in 2010, and forecast to reach $140 million by 2014

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Thank you!