



# ***Commercialization of High Value Molecular Diagnostic Tests***

**AusBiotech  
October 2009**

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# Agenda

- Basics for commercial success
- Sales and marketing
- Reimbursement
- US regulatory challenges
- Med BioGene Inc.
  - Lead product under development is **LungExpress Dx™**, a 15 gene expression-based test prognostic for survival and predictive of adjuvant chemotherapy benefit

## Basics for commercial success

- **Demonstrated clinical utility**  
/addressing of a significant unmet need
- **Favourable health economics**
- **Significant market opportunity**
- **Commercial-friendly platform**



## **Sales and marketing**

- **Sales and marketing team must be appropriate in light of price, complexity of test and nuances of patient population**
- **No replacement for the personal touch**
- **Must manage the value perception of the product in relation to competition and status quo**
- **Reinforce clinical utility with continued research and validation studies**

# Reimbursement

- **Clinical adoption in the US depends upon extent of reimbursement**
- **Two cornerstones: clinical utility and health economics**
- **High value molecular diagnostic tests face reimbursement challenges in the US:**
  - **Expensive (US\$4000)**
  - **Need to demonstrate improvement in patient outcome and cost efficiencies compared to incumbent techniques**
  - **Face a complex payor landscape – Medicare and private payors**
  - **Coding: miscellaneous CPT code versus code stacking of known procedures**

## US Regulatory Challenges

- Regulatory pathway for diagnostics was straightforward . . . until recently
- LDTs traditionally regulated by CMS under CLIA
- In 2006 FDA issued its draft guidance for In Vitro Diagnostic Multivariate Index Assays (IVDMIAAs)
  - Status unclear
  - FDA appears to be maintaining the integrity of LDT / CLIA, but narrowing definition of LDT
  - LabCorp / Ovasure example provides good insight
- IVD kits are regulated as Medical Devices by the FDA and need 510(k) or PMA clearance

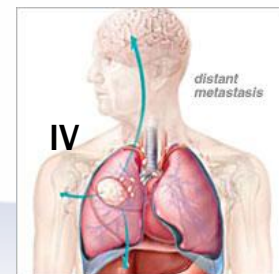
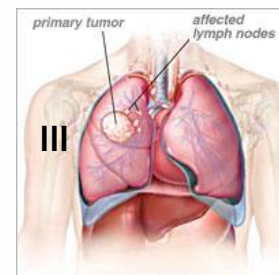
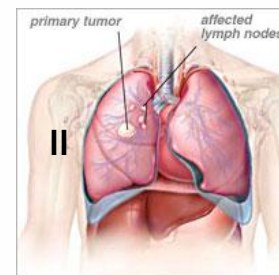
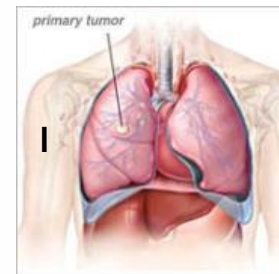
## Med BioGene Inc.

- Personalized medicine and molecular diagnostics company
- Located in Vancouver, Canada
- Projects in oncology and cardiovascular disease
- Primary focus: non-small cell lung cancer (NSCLC)
- Collaboration with leading clinicians at the University Health Network / University of Toronto (Drs. Frances Shepherd and Ming-Sound Tsao)
- Lead product under development is **LungExpress Dx™**, a 15 gene expression based test prognostic for survival and predictive of adjuvant chemotherapy benefit



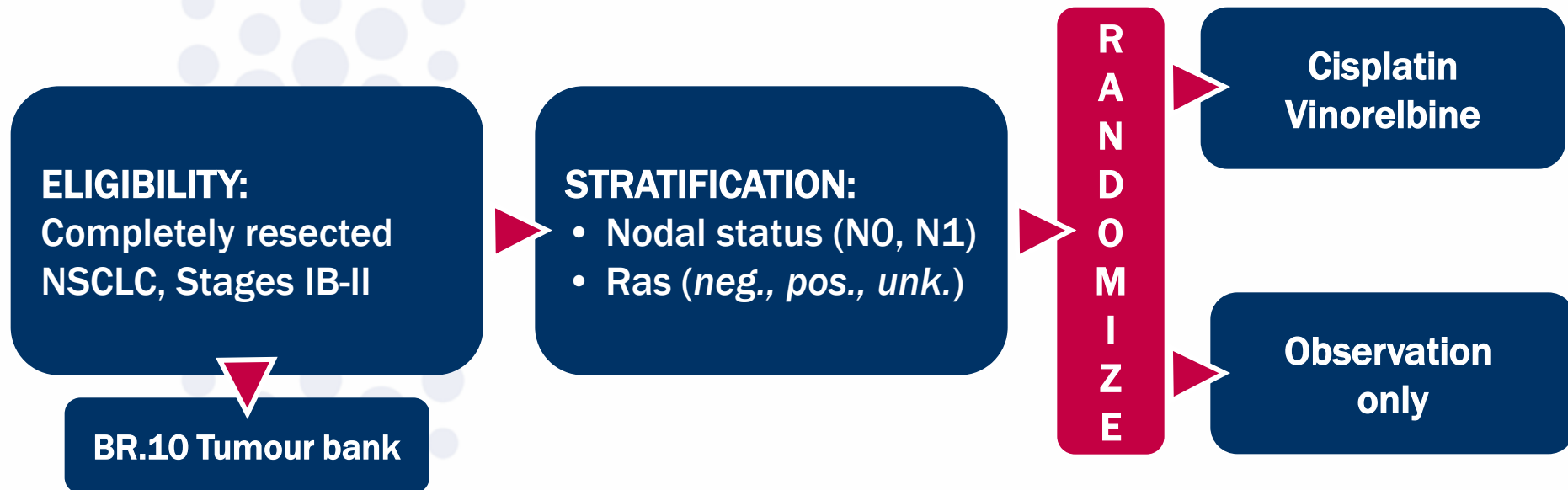
# Improvements in lung cancer patient management are urgently needed

- 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:
  - Stage I patients only receive chemotherapy at physician's discretion: tumor size (large stage IB) and ability to tolerate
  - Many Stage II patients refuse treatment (only 70-75% compliance)



# 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*<sup>TM</sup>: 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

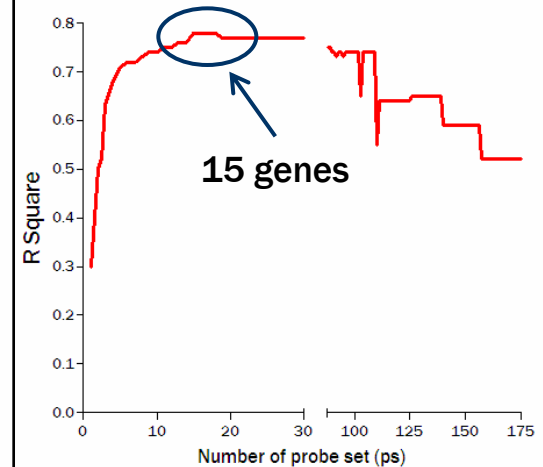
Leave one out cross validation

15 genes optimized signature

Principal Component Analysis and Risk Score (PCA/RS)

$$\text{Risk Score} = 0.557 \cdot \text{EC1} + 0.328 \cdot \text{EC2} + 0.43 \cdot \text{EC3} + 0.335 \cdot \text{EC4}$$

Signature optimization



*LungExpress Dx*<sup>TM</sup>:

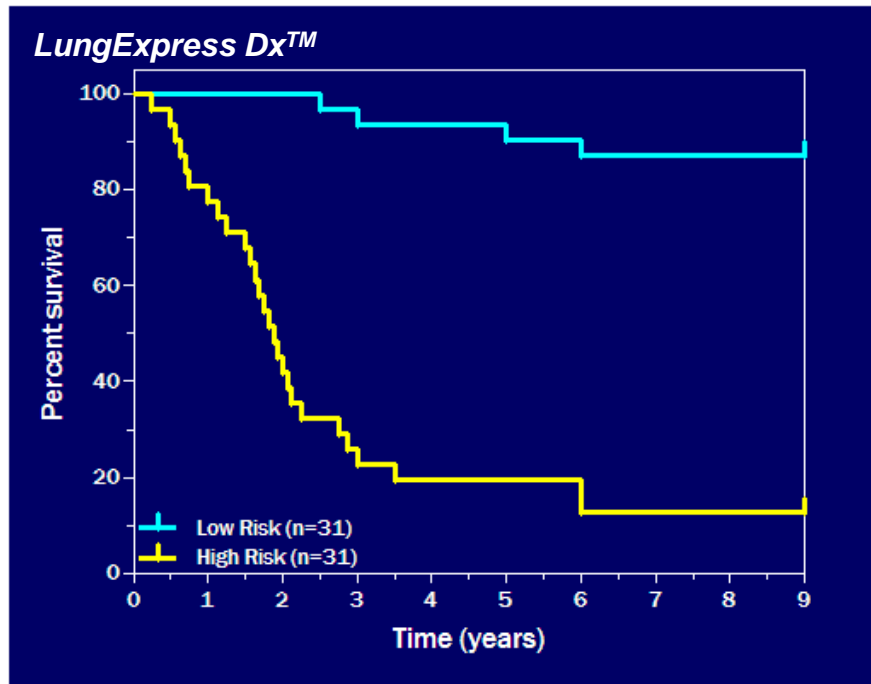
RS ≥ -0.1: High risk

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)

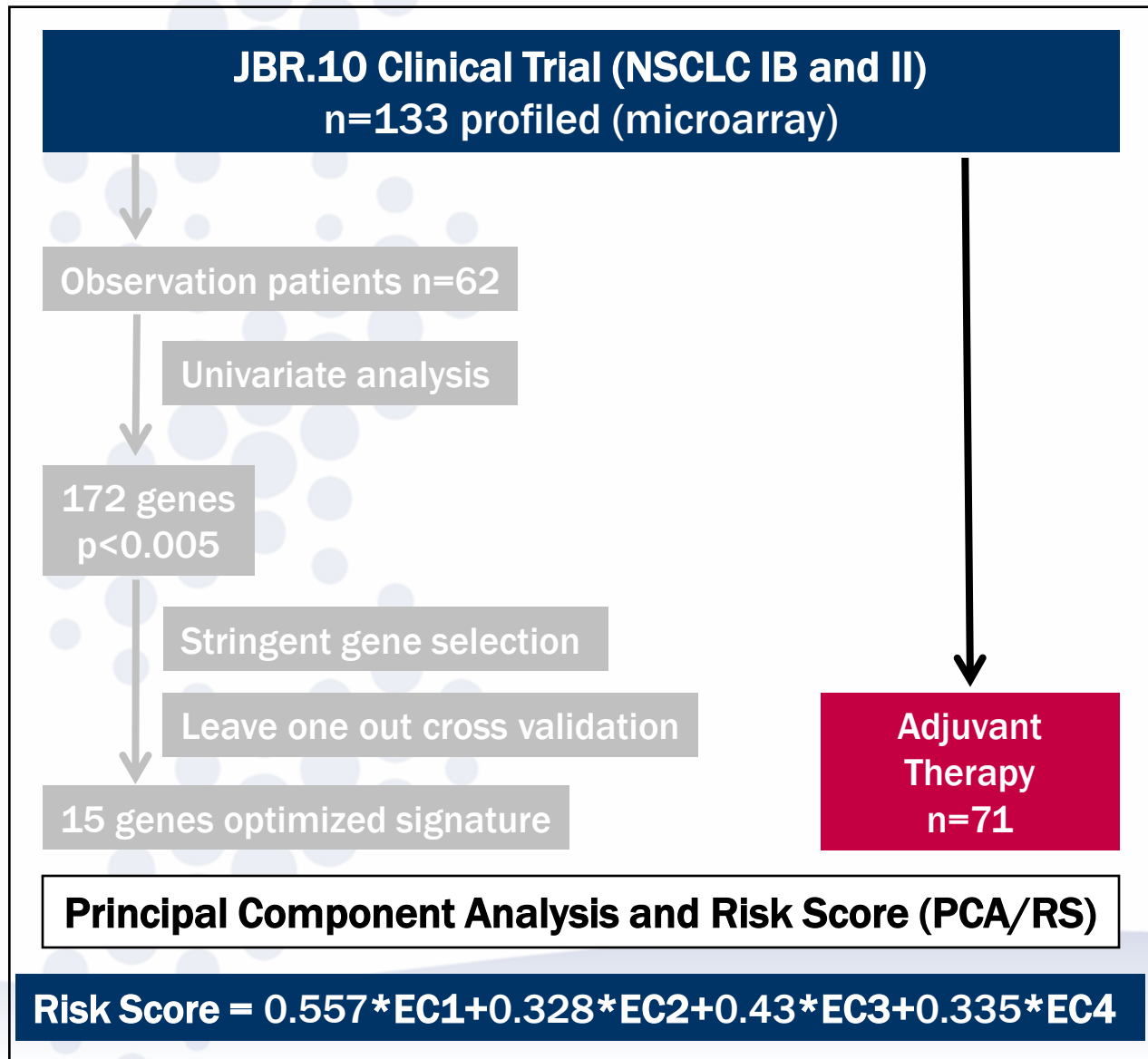


**LungExpress Dx™**  
validated in five independent patient cohorts, and meta-analysis, totaling 675 patients.

No. at Risk	0	1	2	3	4
Low Risk	31	28	20	1	
High Risk	31	9	3	0	

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

# Development of *LungExpress Dx*<sup>TM</sup>: Testing of predictive utility



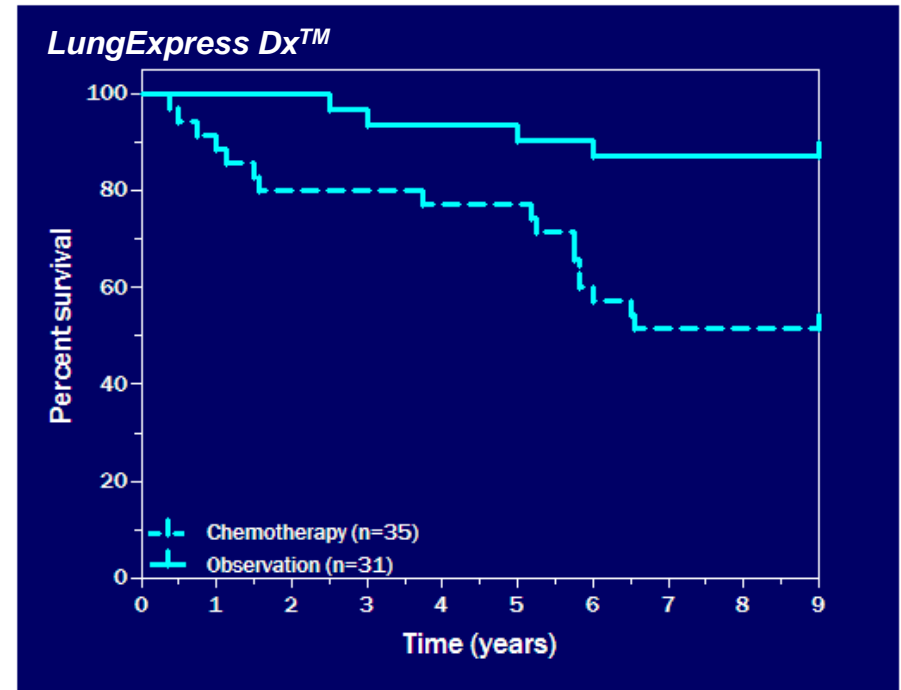
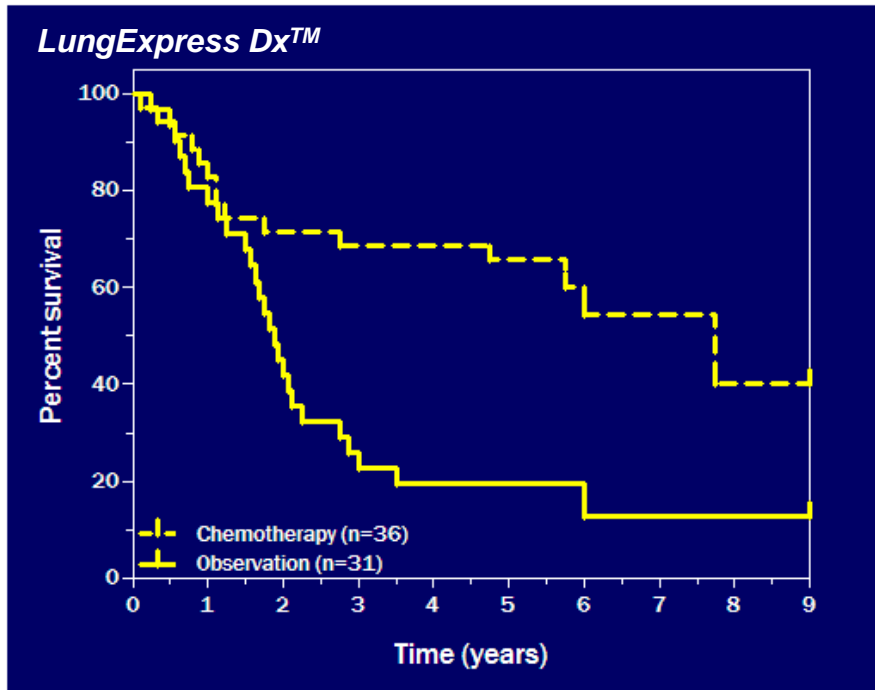
***LungExpress Dx*<sup>TM</sup>:**  
RS ≥ -0.1: High risk  
RS < -0.1: Low risk

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

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

High risk (n=67)

Low risk (n=66)



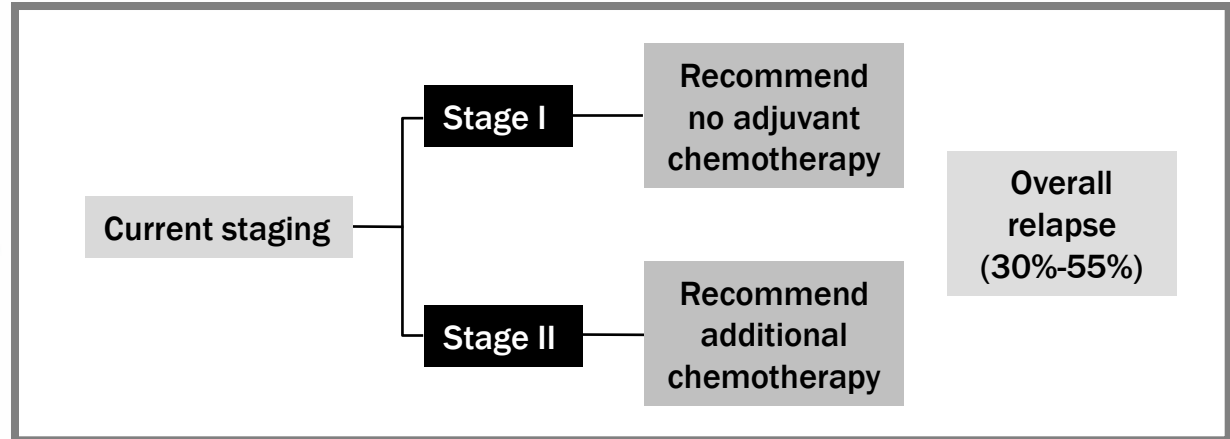
No. at Risk		High Risk (n=67)				Low Risk (n=66)			
	0	1	2	3	0	1	2	3	
Observation	31	9	3	0	31	28	20	1	
Chemotherapy	36	25	15	1	35	28	19	3	

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

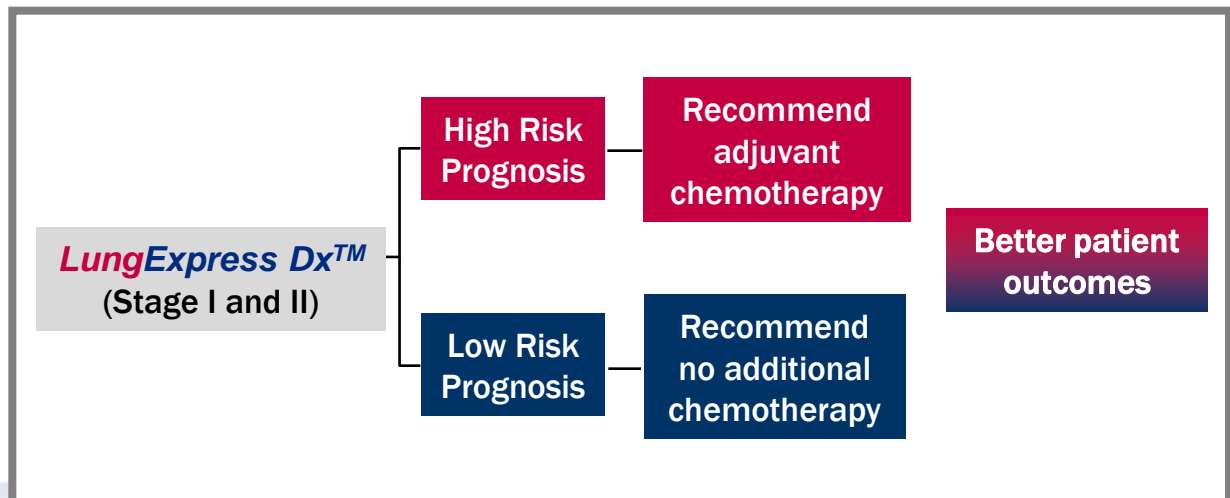
**HR 3.67 (95% CI 1.22-11.06)**  
**p=0.0133**

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

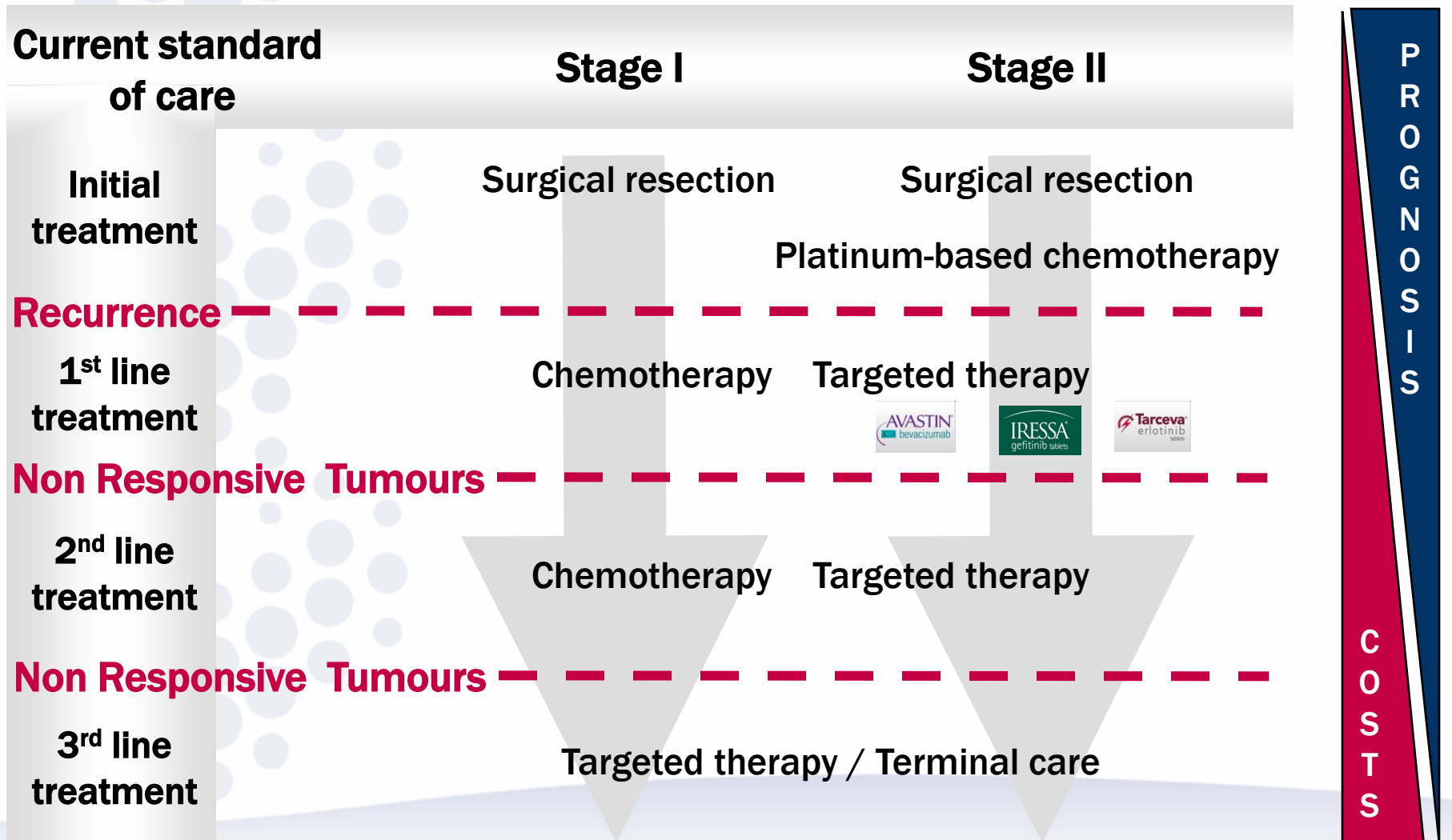
## Current staging paradigm



## Future molecular paradigm, with LungExpress Dx™



# Effective initial treatment of patients may improve treatment outcomes and lower costs





***Med BioGene***

***Thank you***