Precision Therapeutics, Inc.

GeneFx® Lung Commercialization Strategy

September 2014

Precision Therapeutics Overview

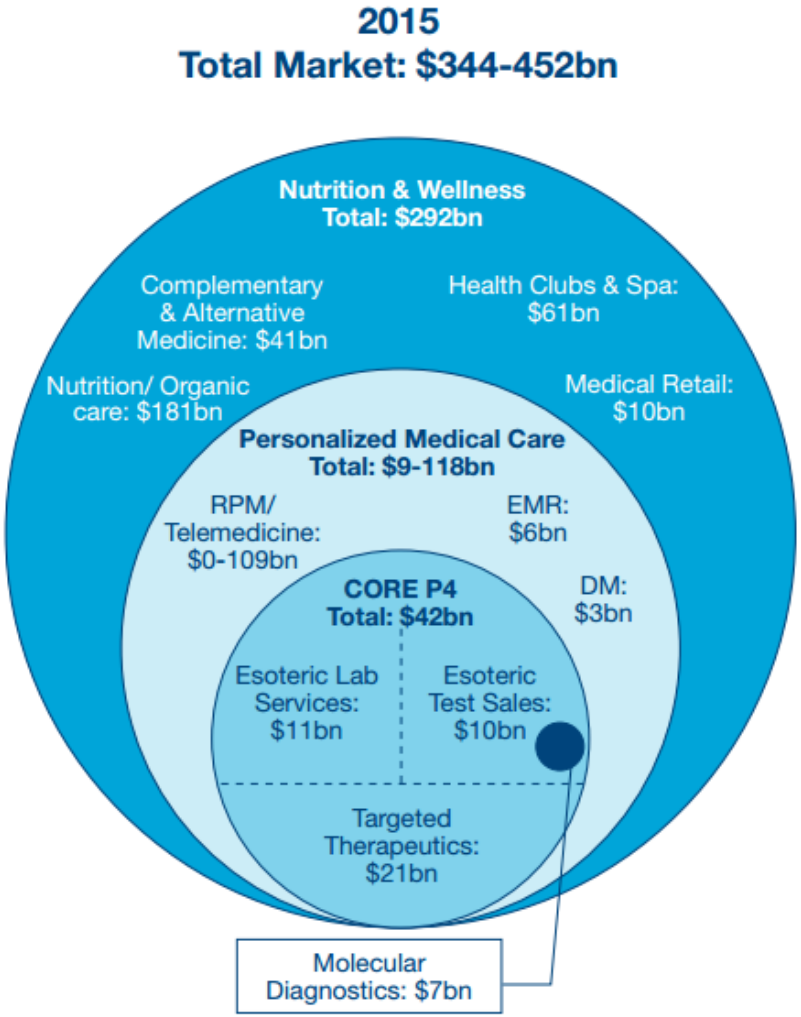
- Precision Therapeutics is dedicated to improving the outcomes of cancer patients by providing personalized medicine solutions that aim to increase quality of life and cancer survival rates.

- Precision offers a portfolio of products, developed to help guide physicians and patients who face difficult clinical decisions, throughout the continuum of cancer care

- Strategically focused on tumor types with large market sizes and unanswered critical clinical questions

Personalized Medicine Market

- Currently, only 1 in 4 cancer patients will respond to standard of care therapy[1]
- Many patients experience unnecessary toxicity from ineffective drugs
  - The likelihood of a patient responding to administered therapy decreases with each ineffective treatment
  - Additionally, subgroups of certain patients may not need chemotherapy
    - Identifying this low-risk population remains a challenge in many tumor types
- Individual patients must receive individualized treatment – empiric choice is not enough



Source: PriceWaterhouse Coopers *The New Science of Personalized Medicine*

Consolidation Opportunity

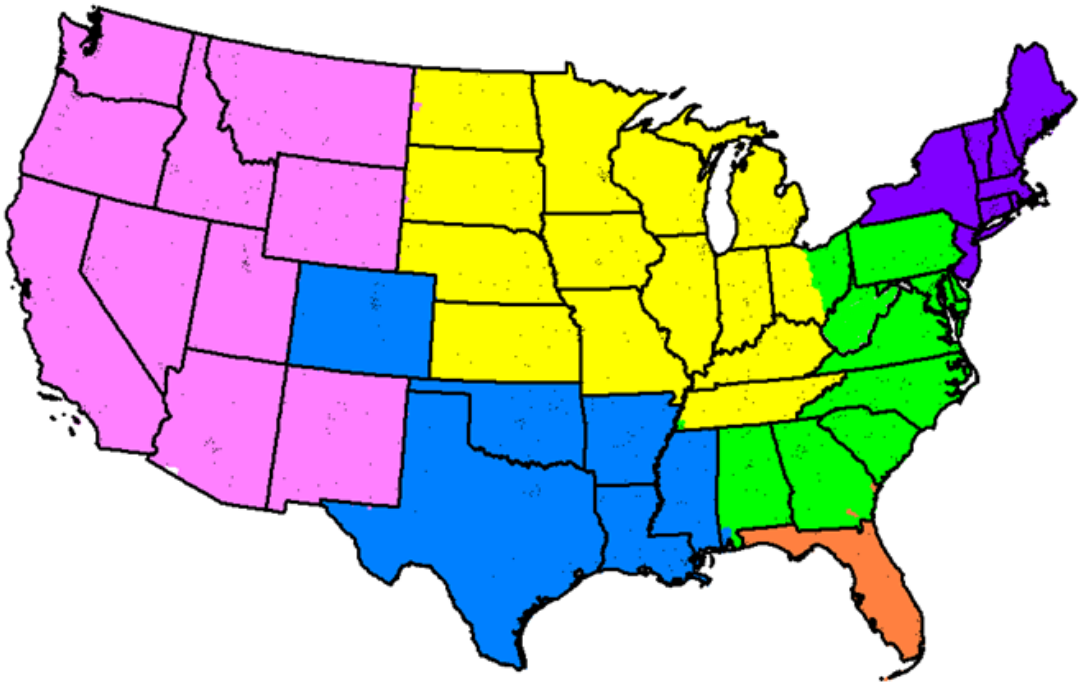
Market Trend	Market Implication
Cancer treatment increasingly evolving into sub-typing, thereby creating smaller patient cohorts	Small market sizes for individual products makes a single product focused direct sales force cost prohibitive
Cost of genomic discovery and innovation decreasing at a rapid pace	Emerging pipeline of promising tests and signatures
Challenging environment for single product companies to finance operations & commercialization efforts	Assets are available at attractive prices and deal structures & an established organization can leverage sales channel and scale operations

Capabilities

- Two CLIA labs capable of multiple technology/assay platforms for a range of specimen types
- Product development and validation – Identify opportunities to develop and commercialize
- Strategic KOL relationships and broad access to surgeons, pathologists and oncologists
- Navigation of Medicare & Private reimbursement landscape
- Biorepository operations
- Experienced Executive Team

Specimen Protocols	Methods	Infrastructure Investments	Assays
Fresh Tissue	Chemoresponse	Full time Pathology	ChemoFx
Tissue in Formalin	H&E	Experienced R&D	BioSpeciFx IHC
FFPE – Tissue Blocks	Immunohistochemistry	Skilled Tech Staff	BioSpeciFx Mutations
FFPE – Tissue Slides	Micro Dissection	Robust Informatics	GeneFx Colon
Tissue in RNALater	RNA Processing Extraction/Amplification	Specialty Automation	GeneFx Lung
Frozen Cells	DNA processing Extraction/Amplification	LIMS/IT	
Raw Nucleic Acids	Microarray	Tech Partners	
	qPCR	Vendor Partners	

Established Sales Channel



- Access to O.R. and Live-Tissue is a unique advantage
- Proven sales force across 6 U.S. districts

Precision Product Strategy

Technology Agnostic – Products answer critical clinical questions

Validated and Proprietary – Supported by strong analytical and clinical validation

Products that can be included in clinical practice guidelines

Clinical utility that changes standard of care and demonstrated economic value to payers

Provide multiple products for each patient using ONE tissue sample – >$4k in revenues per tumor sample received

GeneFx® LUNG

A product of Precision Therapeutics, Inc.

GeneFx® Lung is the only genomic signature for early stage NSCLC that may be <u>both</u> prognostic and predictive for survival benefit from chemotherapy.

GeneFx Lung

- A 15-gene microarray signature developed for early-stage non-small cell lung cancer (NSCLC)
- Critical Clinical Question: Is my early-stage lung cancer patient high or low risk for reduced overall survival? Should they be treated with adjuvant chemotherapy?
- Assesses a patient's risk of reduced overall survival following surgery
  - Helps physicians determine:
    - Whether or not to treat a patient more aggressively/administer chemotherapy
    - Whether to refer a patient to a medical oncologist
- 30-35% of NSCLC patients present at stage I-II
  - 187,000 new NSCLC cases annually
  - 68,000 US cases annually
- Addressable market of $238M

GeneFx Lung: Overall Process Status

PRODUCT LICENSE	☑
Build Out Laboratory	☑
Complete All Analytical Validations	☑
CLIA & NY State Regulatory Approval	☑
Second Clinical Validation Publication (JTO-2014)	☑
Field Experience Study Designed (Clinical Utility)	☑
Pricing Strategy	☑
Sales & Marketing Material	☑
Sales Distribution Model	☑
Clinical Utility Data	☐
Medicare Dossier Submission	☐
Reimbursement Coverage	☐
COMMERCIALIZATION	☐

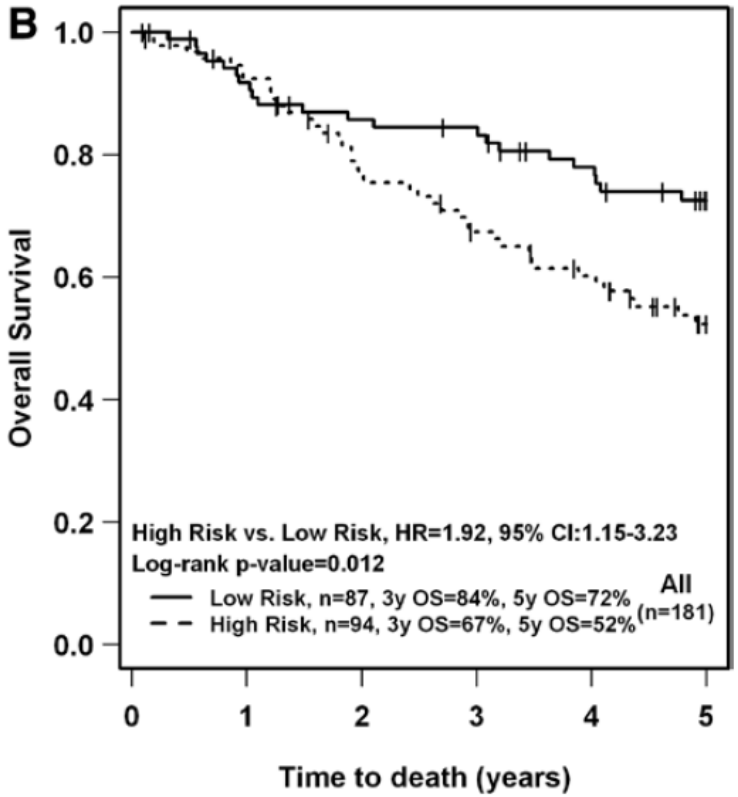
GeneFx Lung: Key Drivers of Commercialization

Clinical Utility Data → Reimbursement Coverage → Commercialization

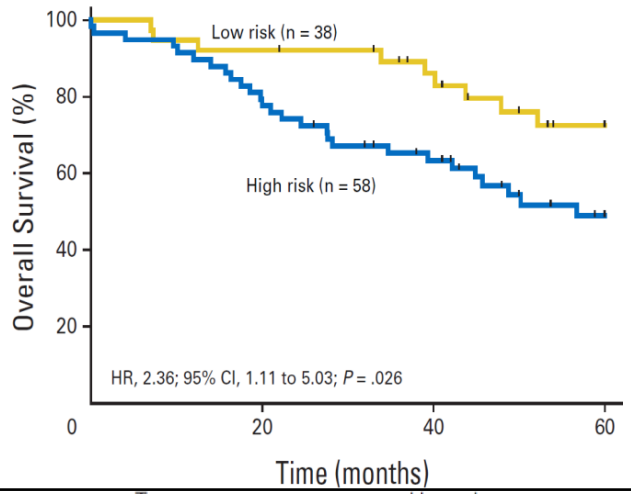
- Medicare population makes up ~75% of Lung Cancer market
- Medicare coverage requires 3 Elements:
  - Analytical Validity ☑
  - Clinical Validity ☑
  - **Clinical Utility** ☐
- Precedent Test is Pervenio Lung Cancer Test (acquired by Life Tech)
  - In 2013, Pervenio was explicitly Non-Covered (LCD) by Medicare for "Lack of Clinical Utility Data"

In 2013, New Guidance was issued for Clinical Utility Requirements:
- Palmetto GBA
- Novitas Solutions
- CMTP

4 Independent Clinical Validation Sets



Kaplan–Meier survival curves for all 181 patients.[1]
B. Low risk versus high risk. HR, hazard ratio; CI, confidence interval; OS, overall survival.



Cohort	Tumor Type	Platform	No.	Hazard Ratio*	95% CI	Adjusted P
Training set						
JBR.10	NSCLC	U133A	62	18.00	5.78 to 56.05	< .001
JBR.10	NSCLC	RT-qPCR	62	2.29	1.06 to 4.94	.034
Validation sets						
DCC	ADC	U133A	96	2.26	1.02 to 4.97	.044
NLCI	NSCLC	44K	133	2.27	1.18 to 4.35	.014
Duke	NSCLC	U133 + 2	48	1.96	0.87 to 4.42	.11
UM-SQ	SQC	U133A	79	3.57	1.48 to 8.58	.005

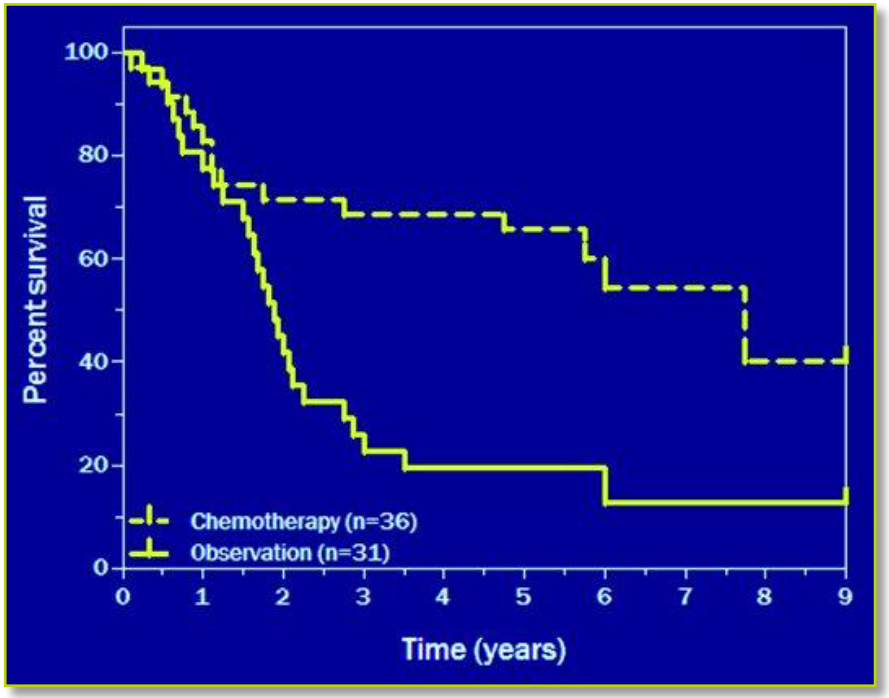
Validated in four independent clinical datasets to significantly predict the risk of mortality following surgery for early stage lung cancer[2]

1. Der, et al. 2013
2. JCO – 2011 Shown: KM for Director's Challenge Consortium adenocarcinoma data set

GeneFx Lung:
Potentially Predictive of Chemotherapy Benefit

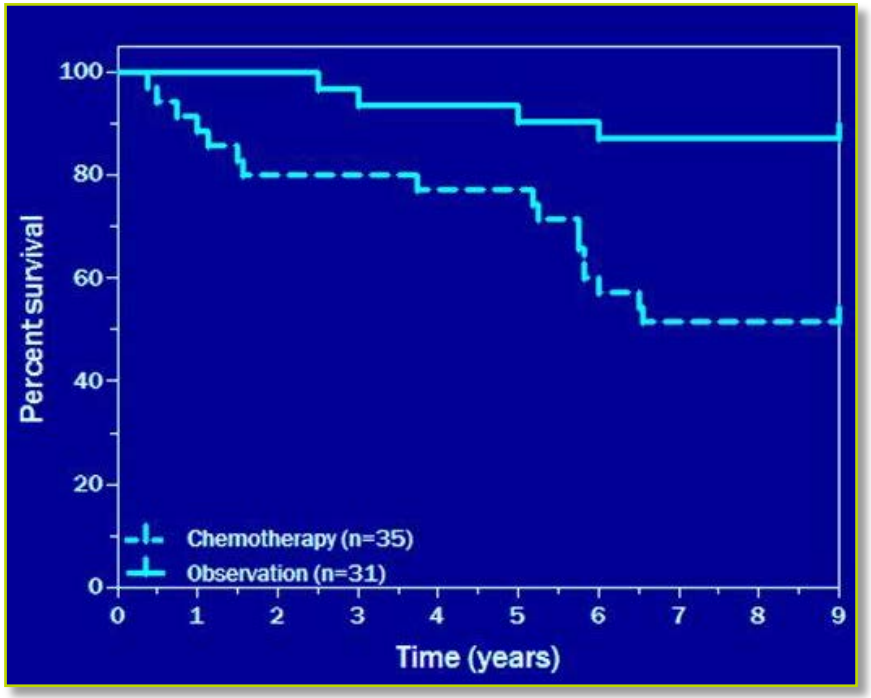
High risk patients who received chemo benefitted while low risk were harmed

High risk (n=67)



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

Low risk (n=66)



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

GENEFX® LUNG
A product of Precision Therapeutics, Inc.

Commercialization Plan

GeneFx Lung

Initial Target Customer
Thoracic Surgeons

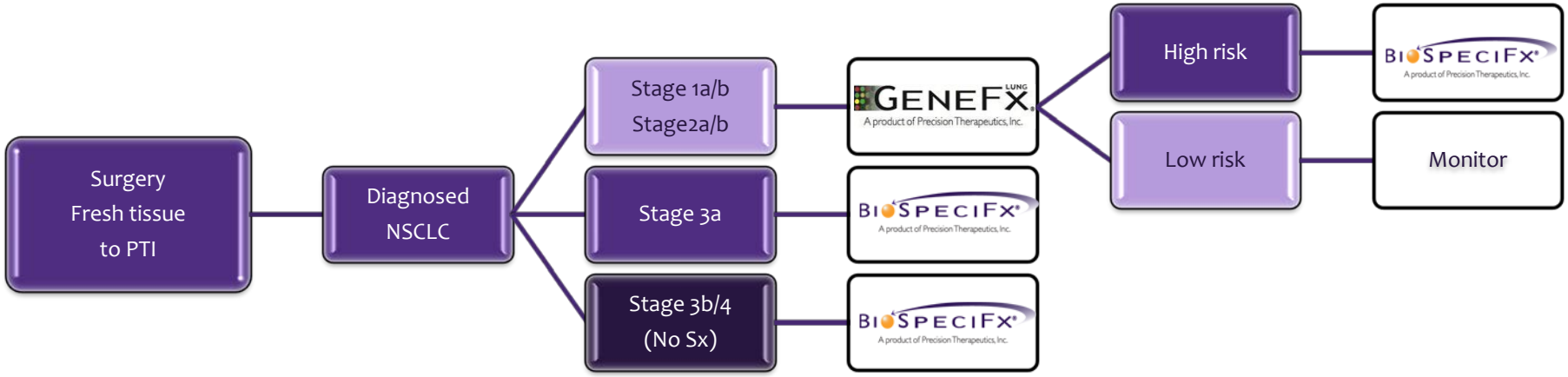
- Thoracic Surgeons and Surgical Oncologists will play a critical part in the initial sale
- Referral to Medical Oncology by Surgeon is Variable Depending on Area of Country
- Density of Cases per Call Point is Better Leveraged at Surgical Point
- "Risk of Recurrence" more important to Surgeons

Care Channel:	Avg Cases per Year
- 4,000 Thoracic Surgeons	15-17 Cases/Year
- 8,200 General Surgeons	
- 9,400 Medical Oncologists	7-10 Cases/Year

Source (1) NCCN (2) PTI Analysis, ABMS, ASCRS

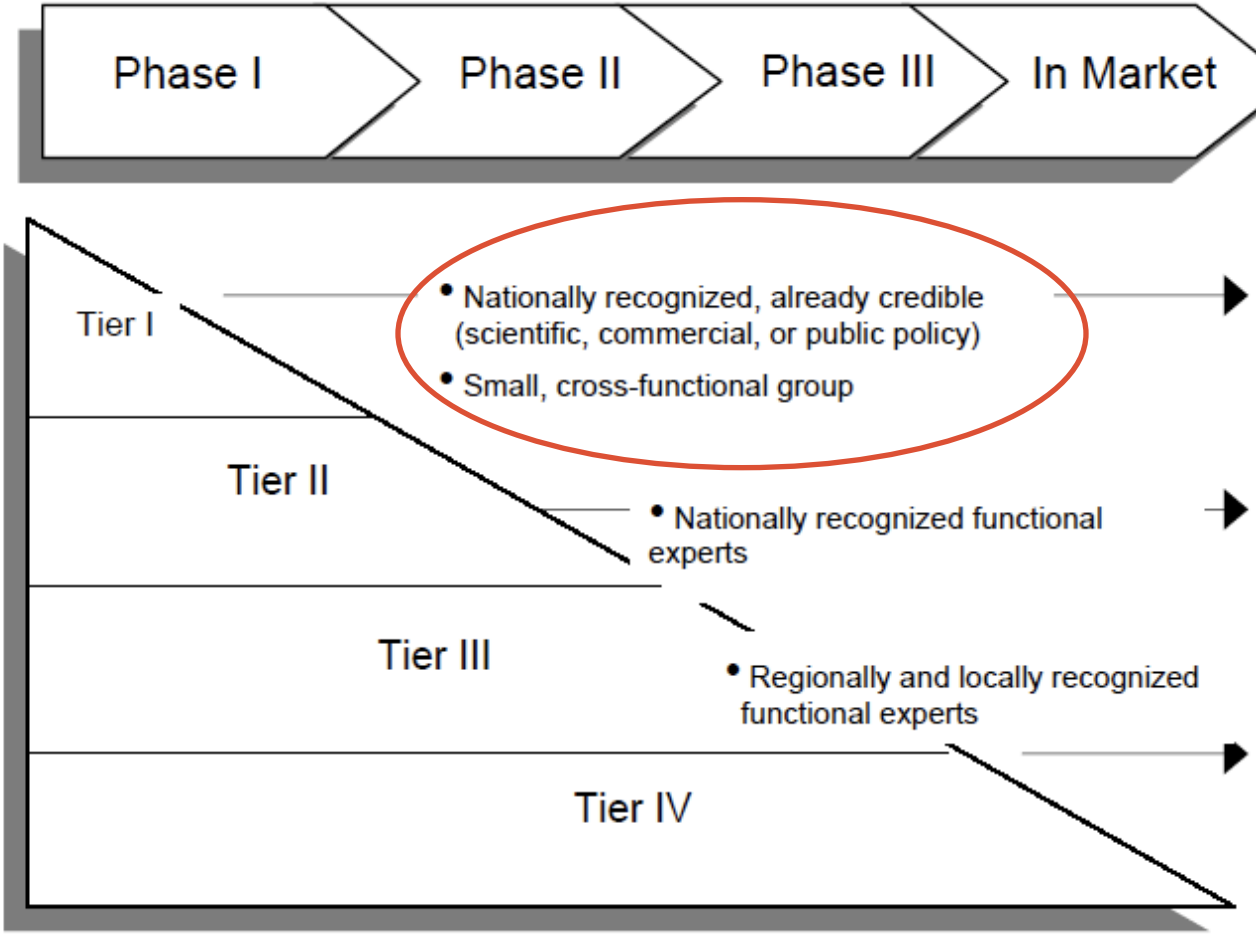
Pathway for Suspected Cancers for NSCLC Surgeons

Incorporating precision therapies across each stage of Non-Small Cell Lung Cancer



PrecisionTherapeutics
The Science of Individualizing Cancer Therapy

KOL Strategy



- Scientific Advisory Board
- Clinical Trials
- P-Development
- Clinical Questions
- Publications Strategy
- KOL Leadership
- Medical Education
- Pricing/Reimbursement
- Commercialization
- Webinars

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Clinical Marketing

- KOL Adoption
- Society Relationships
- Publication Planning
- Medical Education
- Patient Advocacy
- Cooperative Relationships
- PR, Guidelines and Political Strategy
- Social Media

Incidence and Market Volumes

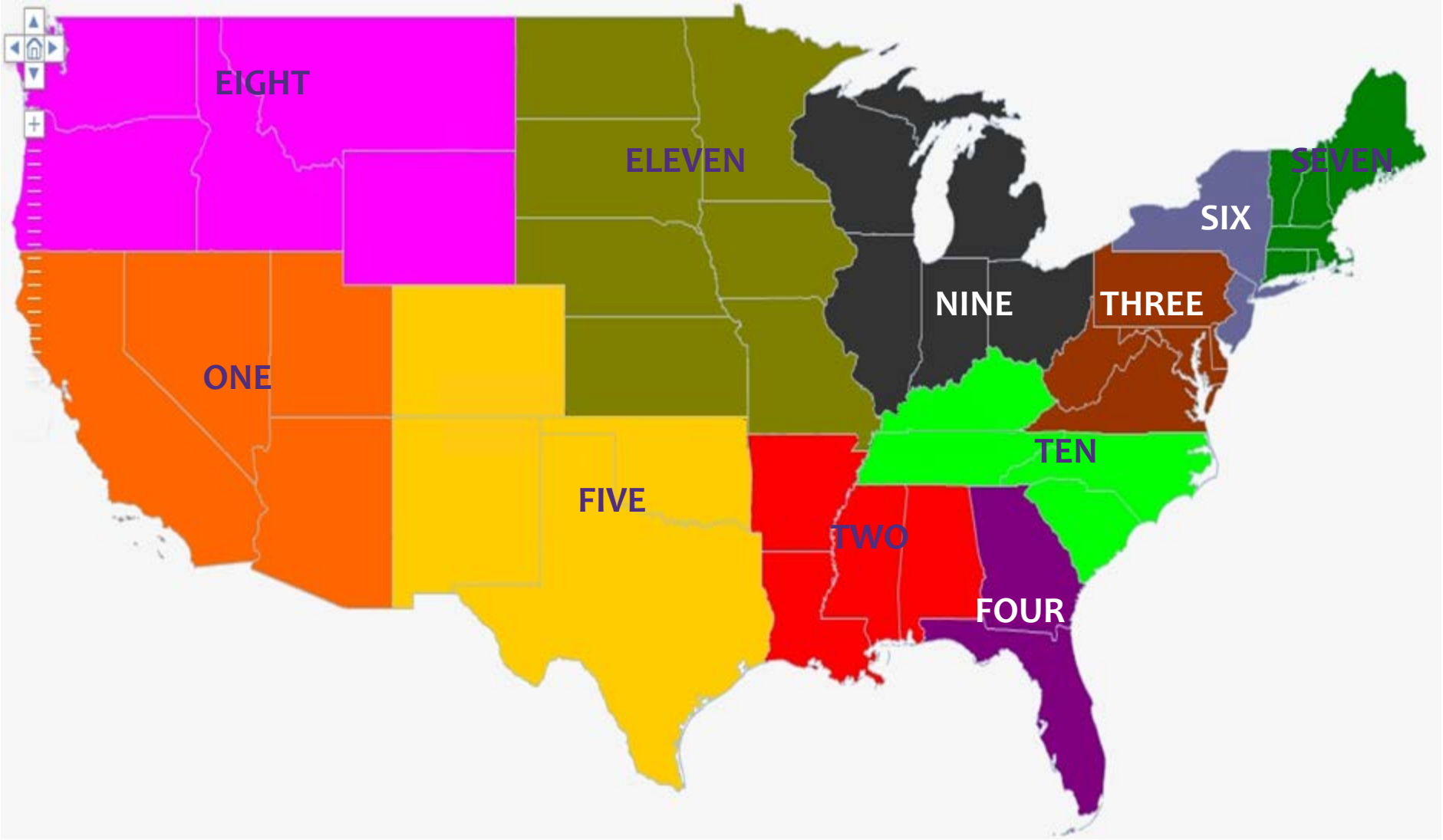
TOP 10 MARKETS FOR NSCLC NATIONALLY

- California – 16,000 plus
- Florida – 15,500 plus
- New York – 13,000 plus
- Texas – 12, 600 plus
- Pennsylvania – 10,600 plus
- Illinois – 9,000 plus
- Ohio – 9,000
- Michigan – 7,700 plus
- North Carolina – 7,000
- New Jersey – 6,000

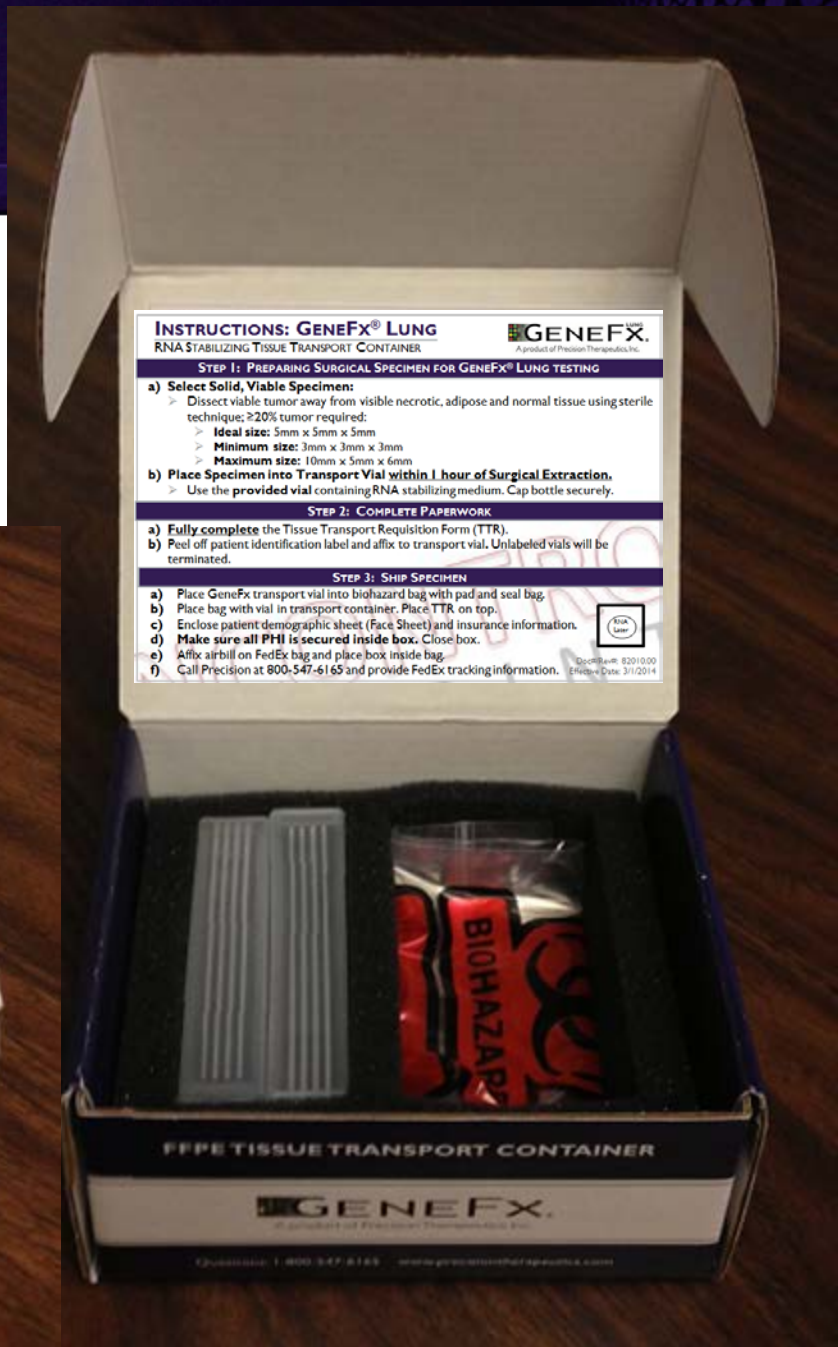
TOP 10 INCIDENCE MARKETS FOR NSCLC NATIONALLY

- Kentucky
- West Virginia
- Arkansas
- Mississippi
- Oklahoma
- Tennessee
- Maine
- Missouri
- Indiana
- Louisiana

KOL SEGMENTATION



GeneFx Lung RNA Later Tissue Transport Kit



GeneFx Lung Final Report

- Patient result easy to find and understand
- Patient-friendly explanation of results
- Summary of clinical validation provided with each report
- Graph clearly plots patient status within high or low risk range
  - Will update with JTO data when available

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The Science of Individualizing Cancer Therapy

GENEFX LUNG PATIENT REPORT

PATIENT INFORMATION

PATIENT NAME:	JANE DOE	PTI ACCESSION #:	XXXXXXXXXXXX
DATE OF BIRTH:	XX/XX/XXXX	PATHOLOGY #:	XXXXXXXXXXXX

SPECIMEN INFORMATION

REQ. PHYSICIAN:	JOHN DOE, MD	FACILITY	CANCER CENTER
PTI RECEIVED DATE:	03/15/2014	TESTING LABORATORY:	PTI- LAWRENCEVILLE
SPECIMEN SITE:	LUNG, RIGHT UPPER LOBE	REPORT DATE:	04/01/2014
TUMOR STAGE:	STAGE II	MATERIALS RECIEVED:	The specimen was received in an RNAlater®-filled container and consists of a sufficient quantity to conduct GeneFx Lung testing.
EXTRACTION DATE:	3/14/2014		

RESULTS

PATIENT SCORE: 0.71

THRESHOLD (LOW RISK/HIGH RISK): - 0.10

RISK CLASSIFICATION:

HIGH RISK

- **Following surgery, GeneFx Lung assesses a patient's risk of reduced overall survival.**
- **Patients classified as high risk by GeneFx Lung were ~2 – 3.5 times more likely to experience reduced overall survival than patients classified as low risk.[1,2]**

1. Zhu CQ, et al. J Clin Oncol. 2010 Oct 10;28(29):4417-24.
2. Der SD, et al. J Thorac Oncol. 2013 Dec 3 [Epub ahead of print].

NOTES:

STUDY DESCRIPTIONS

GeneFx Lung is a 15 gene expression-based signature for early-stage non-small-cell lung cancer (NSCLC).

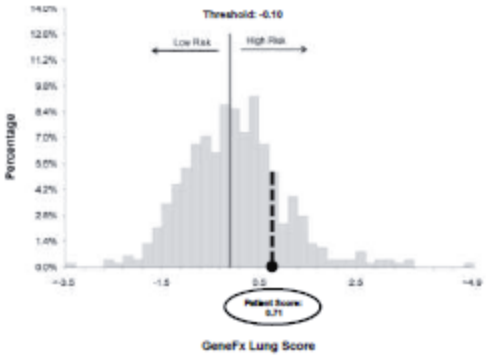
The assay identifies patients at higher risk of reduced overall survival following surgery.

In multiple independent validations totaling 308 untreated early-stage NSCLC patients (Zhu, 2010), GeneFx Lung was validated as a statistically significant independent predictor of reduced overall survival in multivariate analysis (HR = 2.26-3.57, P< 0.05).[1]

An additional independent validation of 181 early-stage patients (Der, 2013) confirmed GeneFx Lung as an independent prognostic marker in multivariate analysis (HR = 1.92; 95% CI, 1.15-3.23; p = 0.012). Clinical sensitivity = 68%; 95% CI, 0.56-0.8; clinical specificity = 56%; 95% CI, 0.47-0.654.[2]

1. Zhu CQ, et al. J Clin Oncol. 2010 Oct 10;28(29):4417-24.
2. Der SD, et al. J Thorac Oncol. 2013 Dec 3 [Epub ahead of print].

PATIENT SCORE DISTRIBUTION



Laboratory Director: Arlette H. Uihlein, MD, FCAP

This test is not to be used independently for purposes of medical diagnosis, prognosis, or as the basis for making therapeutic decisions, but may be used in conjunction with other recognized, standard laboratory and diagnostic tests and procedures, in accordance with current literature and practice guidelines, and with the experience and clinical judgment of a physician. A patient's condition and medical history should always be considered when making any treatment decisions. This test was developed and its performance characteristics determined by Precision Therapeutics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Precision Therapeutics is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing.

PRECISION THERAPEUTICS, INC. | 91 43RD STREET, PITTSBURGH, PA 15201 | 1-800-547-6165 | WWW.PRECISIONTHERAPEUTICS.COM | CLIA: 39D2008653

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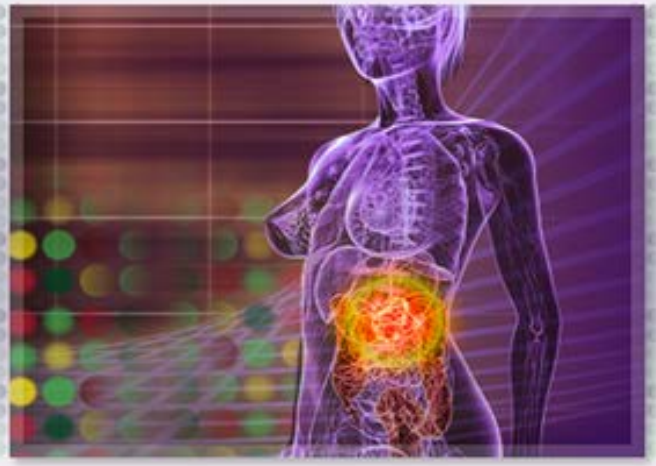
Her physician has more information about her cancer. Before considering chemotherapy.

Precision Therapeutics' GeneFx product line identifies early stage lung and colon cancer patients at higher risk of recurrence following initial surgery.

GENEFX COLON
A product of Precision Therapeutics, Inc.



GeneFx℠ Colon

GeneFx℠ Colon is a microarray-based gene signature developed for Stage II colon cancer patients from FFPE tissue. GeneFx℠ Colon is performed on a small amount of tissue, removed during surgery or a biopsy. The signature identifies patients at higher risk of recurrence within 5 years following initial surgery, providing physicians with more information when making treatment decisions for their patients.

Click Here To Learn More

GENEFX LUNG
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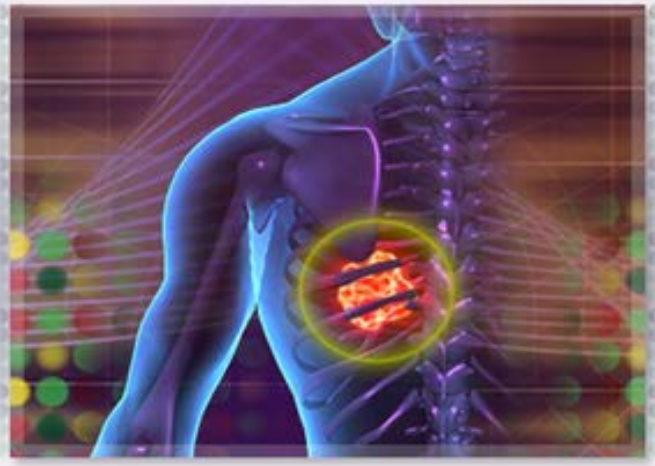

GeneFx℠ Lung

GeneFx℠ Lung is a gene expression-based signature for early-stage non-small-cell lung cancer. GeneFx℠ MLung is performed on a small amount of fresh tissue, removed during surgery or biopsy and preserved in RNAlater®. The signature identifies patients at higher and lower risks of mortality following surgery, and has demonstrated the potential to select early-stage patients most likely to benefit, or be harmed by, adjuvant chemotherapy.

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PTI Business Review for MBI and

GeneFx® Lung Commercialization Strategy

September 2014