

www.amarantus.com www.avantdiagnostics.com www.theranosticshealth.com Ticker: OTCQB:AVDX Ticker: OTCQX:AMBS

**Proposed 3-Way Business Combination** 

# **Forward-Looking Statements**

This presentation contains "forward-looking statements" within the meaning of the "safe-harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such statements involve known and unknown risks, uncertainties and other factors that could cause the actual results of the Company to differ materially from the results expressed or implied by such statements, including changes from anticipated levels of sales, future international, national or regional economic and competitive conditions, changes in relationships with customers, access to capital, difficulties in developing and marketing new products and services, marketing existing products and services, customer acceptance of existing and new products and services and other factors. Accordingly, although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can be no assurance that such expectations will prove to be correct. The Company has no obligation to update the forward-looking information contained in this presentation.





# **Business Case Moving Forward**

The combined company will offer cutting edge pharma services in the areas of cell cycle biology and signal transduction pathways to assist pharmaceutical companies and medical researchers in identifying treatment pathways for disease.

The combined company will leverage its CLIA/CAP laboratory infrastructure to launch proprietary diagnostic tests in the areas of Ovarian Cancer, Multiple Sclerosis and Alzheimer's disease, and related non-proprietary assays.





## **Proposed Executive Team**

#### **Gregg Linn: Chief Executive Officer & President**

President and Managing Member at Issuers Capital Advisors, LLC

President and CEO at Precision Metal Products, LLC

COO and CFO at Vital Living, Inc. (VTLV)

CFO at Skyline Mutimedia Entertainment, Inc. (SKYL)

CFO at Biomechanics Corporation of Amerca (BCAM)

### Glenn Hoke, PhD: EVP, Chief Scientific Officer

President & CEO at Theranostics Health, Inc.

**EVP & CSO at Dyad Corporation** 

VP Research & Development at Gene Logic

VP at Genetic MediSyn

#### **Ronald Hencin: Vice President Business Development**

VP of Business Development at Theranostics Health

VP BioResearch Sale at Gene Logic

IT Entrepreneur

#### **Gerald E. Commissiong: Member of the Board of Directors**

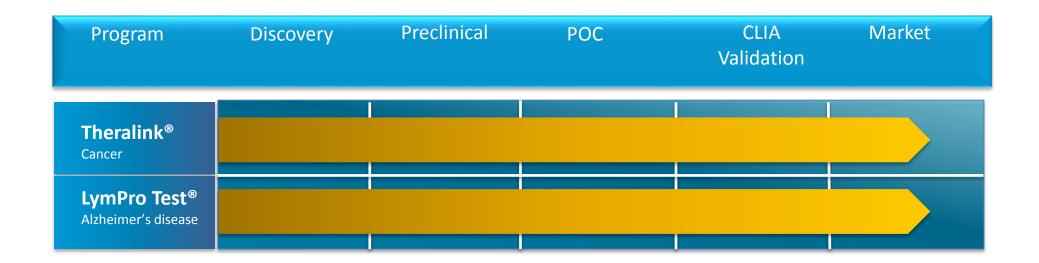
Co-founded AMBS in 2008: Led acquisition of entire AMBS portfolio via over \$40M in capital raised

Professional athlete: CFL Calgary Stampeders

Stanford University, Management Science & Engineering



# Pharma Services Product Pipeline







### **Current Challenges in Cancer Diagnosis & Treatment**

Current diagnostics do not accurately predict response to therapy; patients are thus often subjected to costly treatments with many side effects and low response

#### Current treatments for breast cancer deliver modest benefits relative to costs

Regimen from label

### Trastuzumab

+paclitaxel

#### **Pertuzumab**

+docetaxel +trastuzumab

#### **Everolimus**

+exemestane

#### Lapatinib

+capecitabine

Efficacy (Change in PFS)

2 month increase

6 month increase

6 month<sup>1</sup> increase

5 month increase

**Safety** (key side effects)

- Cardiomyopathy
- Exacerbation of neutropenia

- Left-ventricular dysfunction
- Embryo-fetal toxicity
- Hepatic impairment
- Decreased wound healing
- Renal failure

- Left-ventricular dysfunction
- Hepatotoxicity
- · Cutaneous reactions

Annual Cost





\$100,000

\$120,000

TheraLink® matches patients to their optimal therapy based on individual biopsy results





### **Phospho-Proteomic vs. Genomic Testing**

The TheraLink® Assay provides actionable information beyond what genomic testing provides, enabling oncologists to select more appropriate treatments

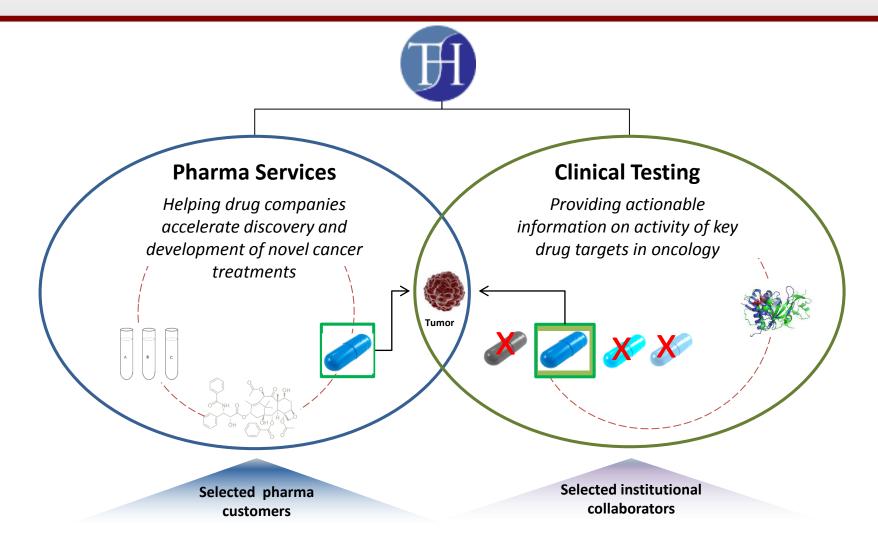
TheraLink <sup>®</sup> Measurements	Why This Matters	How TheraLink® Is Different	KOL insight
<b>Quantity</b> of proteins	<ul> <li>Measuring the quantity of given proteins in a tumor helps distinguish among disease pathways (which create different amounts of proteins) and assess treatment response</li> </ul>	Genomic testing detects defective genes but not which pathway they contribute to	"I like that this addresses pathways that there aren't currently Dx for." —Pathologist/Oncologist
<b>Activity</b> of proteins	<ul> <li>In certain disease pathways, proteins need to be not only present but also activated (i.e., phosphorylated) to be involved in the disease process</li> </ul>	Genomic testing does not evaluate whether proteins are activated	"Mutations do not always yield functional proteins, hence genomics testing is not entirely conclusive"  — Oncologist
Entire pathway of protein signaling	<ul> <li>A diverse range of proteins, some mutated and some not, may be implicated in a given disease pathwayAnalyzing the entire pathway identifies likely drug targets</li> </ul>	Proteins can participate in aberrant signaling pathways despite being genetically normal	"Not all HER2+ patients respond to therapy because there may be resistance downstream. This test could replace IHC and FISH." —Pathologist/Oncologist





### **Company Snapshot**

Theranostics Health offers the TheraLink® Assay phospho-proteomic test to the pharmaceutical and clinical sectors, helping them optimize cancer treatment



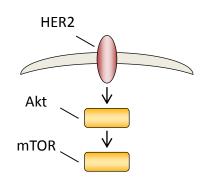


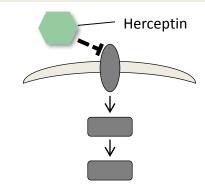


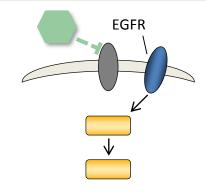
### **Importance of Phospho-Proteomic Testing**

Evaluating downstream signaling activity triggered by cell-surface proteins is critical to identifying the drug most likely to inhibit tumor growth

#### Rationale for TheraLink®: Why is the Signaling Pathway Important?







Cell-surface proteins activate signaling molecules involved in causing cancer

Blocking those proteins with a drug may turn off the pathway

However, compensatory mechanisms may activate the same pathway by other means

For example, in a subset of breast tumors, HER2 activates Akt and, in turn, mTOR

Herceptin disarms HER2 and prevent Akt / mTOR activation

This helps to explain why up to 70% of advanced HER2+ patients fail Herceptin therapy<sup>1</sup>

In this example, the TheraLink® assay would be able to identify that the Akt/mTOR pathway was activated via EGFR and recommend treatment with an EGFR inhibitor



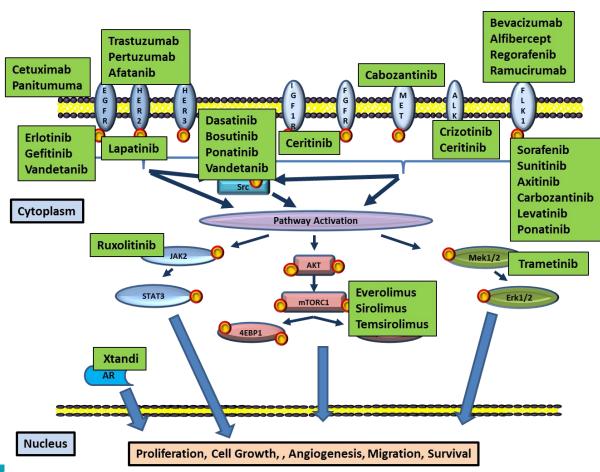




### **Business Overview: The TheraLink® Assay**

The 24 markers analyzed by TheraLink® were chosen for their relevance to treatment – a majority are targets of current cancer therapies

#### Molecular Therapies Targeting TheraLink® Markers (Current)



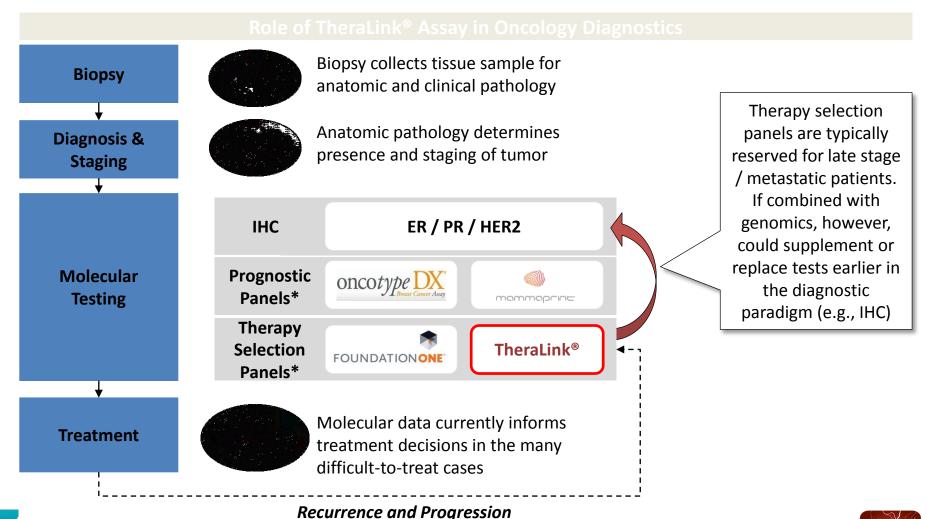
- Most of the markers analyzed by TheraLink® are drug targets
- Hence, TheraLink® identifies therapeutic options most likely to suppress tumor growth for a particular patient





#### **Business Overview: The Role of TheraLink®**

TheraLink® improves on current oncology diagnostics by enabling rapid, actionable insights to help inform treatment decisions







#### **Business Overview: Pharmaceutical Services**

Theranostics Health supports clients' drug development efforts, providing nondilutive capital and strategic insights for product development

#### Allows investigators to analyze **Representative Customers** cell signaling pathways that What drive cancer growth, **Theranostics** #3 Pharma determining which potential Health does drug targets are active #5 Pharma Data provided by Theranostics #2 Pharma Why assays can be used to screen for **Theranostics** compound activity, assess off-Health is #27 Pharma target effects, and analyze valuable responses to treatment #8 Pharma • Theranostics Health partners #1 Pharma with 30 biopharmaceutical Who companies, including 9 of the is a customer 08 09 10 11 12 13 industry's 10 largest Years as a Theranostics Health





customer

### **Growth Opportunities**

Launching from its current efforts, Theranostics Health will expand its range of offerings substantially in the future

# **Efforts**

# Strategic Partnerships

 Identify and pursue valueadding strategic partnerships with various types of companies (e.g., genomics companies, biopharmas)

# New Oncology Indications & Uses

- Continue to expand beyond core indications already being pursued (breast NSCLC, CRC, pancreatic, and ovarian), to additional solid tumors
- Expand to earlier, less severe cancer stages

# Immune Checkpoint Measurement

- Expand panel to include immune system checkpoint molecules PD-1 and PD-L1, relevant across multiple tumor types
- Guide patients to immunotherapies (e.g., Bristol-Myer Squibb's Opdivo, Merck's Keytruda)

### Kit Development

- Develop and seek FDA approval for commercial kit to enable broader access and uptake
- This offering facilitates reaching the sizable ex-US market

# New Indications Beyond Oncology

 Expand to additional indications, beyond oncology, in which intracellular signaling will guide therapy selection





### **Business Overview: Applications of the TheraLink® Assay**

Unlike other Dx (e.g., genomic panels), TheraLink® measures the activity of targets specified on drug labels, empowering clinicians to select the optimal therapy



#### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AFINITOR safely and effectively. See full prescribing information for AFINITOR.

AFINITOR (everolimus) tablets for oral administration Initial U.S. Approval: 2009

#### 12 CLINICAL PHARMACOLOGY

#### 12.1 Mechanism of Action

Everolimus is an inhibitor of mammalian target of rapamycin (mTOR), a serine-threonine kinase, downstream of the PI3K/AKT pathway. The mTOR pathway is dysregulated in several human cancers. Everolimus binds to an intracellular protein, FKBP-12, resulting in an inhibitory complex formation (mTORC1) and thus inhibition of mTOR kinase activity. Everolimus reduced the activity of S6 ribosomal protein kinase (S6K1) and eukaryotic elongation factor 4E-binding protein (4E-BP1), downstream effectors of mTOR, involved in protein synthesis. In addition, everolimus inhibited the expression of hypoxia-inducible factor (e.g., HIF-1) and reduced the expression of vascular endothelial growth factor (VEGF). Inhibition of mTOR by everolimus has been shown to reduce cell proliferation, angiogenesis, and glucose uptake in *in vitro* and/or *in vivo* studies.





### **Business Overview: Value Proposition**

Theranostics Health benefits multiple stakeholders



#### **For Patients**

- Receive the right INDIVIDUALIZED therapy for the best outcome
- Reduce exposure to ineffective, potentially toxic treatments



#### **For Oncologists**

- Identifies appropriate treatment options
- Guides therapies for patients who develop resistance to treatment



#### **For Insurers**

- Reduces cost of ineffective therapies
- Enables channeling of savings to funding of effective therapies



### **For Pharma Companies**

- Reduce clinical trial failures rates and cost
- Increase efficacy rates that can support premium pricing





### **Competitive Landscape: TheraLink® Key Advantages**

TheraLink® offers several key advantages that appeal to community-based oncologists, the key decision-makers in diagnosis and treatment

#### **Focused**

- Targets included in the panel are well-known and clearly linked to drugs
- Panel is targeted for specific tumor types
- Provides only the information that oncologists need to know

"This gives me only information

that I can use - that's a real

advantage."

-KOL Oncologist

"If there's nothing actually going on in the HER2 pathway, why give an inhibitor?"

—KOL Oncologist

#### **Actionable Data**

- The Theralink® report directly supports therapy selection
- Easily helps physicians
   identify which therapies
   to use and which
   therapies not to use

# **Supported by Growing Evidence**

- Body of evidence supporting the underlying technology (RPMA) is growing
- Additional clinical evidence gathering is underway
- Covered by intellectual property

"These are well-validated, known druggable targets."

—KOL Oncologist





# Business Overview: Theranostics Health's Strategy & Vision Expand offerings in both clinical testing and pharma services

#### **Strategy**

#### **Demonstrate Value**

- Develop robust evidence base to demonstrate clinical utility, particularly in breast cancer
- Work with thought leaders to communicate value to the broader oncology community
- Leverage partnerships to expand commercial capabilities and negotiate reimbursement

#### **Drive Awareness & Uptake**

- Launch in new tumor types
- Establish programs to help providers file claims / appeals and assist patients in covering out-of-pocket costs
- Seek more comprehensive reimbursement coverage via unique code

#### **Expand the Offering**

- Expand offering with strategic partnerships to encompass a broader 'Omics approach
- Leverage partnership to shift use earlier in the diagnostic paradigm
- Continue demonstrating value through additional clinical utility studies

#### Vision

Empower the broader cancer community with targeted, actionable molecular information



### **Business Overview: Upcoming Test Releases**

- TheraLink® Assay for Colorectal Cancer
  - Conducting validation in Q3/16
- TheraLink® Assay for Pancreatic Cancer
  - Samples are being collected and conducting validation Q3/16
- TheraLink® Assay for Non-Small Cell Lung Cancer
  - Currently negotiating agreements for access to NSCLC tissues
  - Validation starting after Pancreatic Cancer and likely available by end of year
- TheraLink® Assay for Immune Checkpoints (PD-1, PD-L1, etc.)
  - Q4/2106 timing of studies with multiple pharma partners, and further work on method development

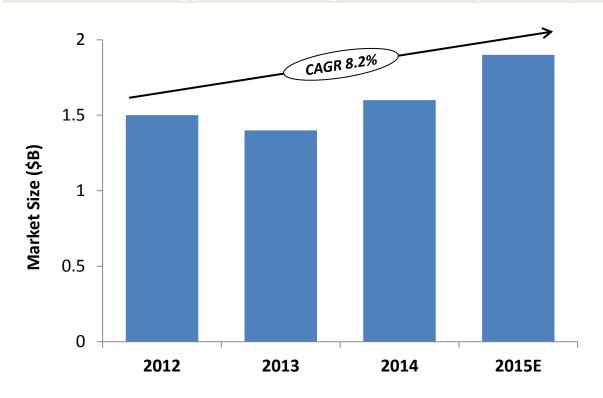




### **Market Assessment: Oncology Diagnostics Market Size**

Within the rapidly-growing molecular diagnostics industry, oncology diagnostics – the segment that includes the TheraLink® assay – have been notably successful

#### Oncology Molecular Diagnostics: Industry Revenue (2012 – 2015, WW, US\$



- The molecular diagnostics industry as a whole has enjoyed robust growth since 2012, with an overall CAGR of 7.8%
- Hematology / oncology diagnostics, the segment that includes the TheraLink® assay, have been among the fastestgrowing in the sector, posting a CAGR of 8.2%





### **Market Assessment: Key Trends in Molecular Diagnostics**

Theranostics Health benefits from major trends in molecular diagnostics, notably the demand for actionability and the rise of proteogenomic testing

Trend	Key Details	Impact on Theranostics Health	
Growth of Personalized medicine	<ul> <li>Cancer is increasingly considered an individual disease driven by a patient's particular abnormalities</li> <li>This trend parallels a broader shift toward developing personalized therapeutics, particularly in oncology (e.g., Dx to identify appropriate treatment for each patient)</li> </ul>	TheraLink® provides otherwise- inaccessible information on an individual patient's disease pathway	
Demand for <b>Actionability</b>	<ul> <li>The number of competitors in proteomic and genomic testing continues to increase</li> <li>As oncologists struggle to differentiate among tests, the actionability of data – its usefulness in guiding treatments – is growing in importance</li> </ul>	Ensuring that TheraLink® results are actionable is an ongoing focus for management	
Rise of <b>Proteogenomics</b>	<ul> <li>Studies have linked genomic and proteomic levels of data (e.g., mapping ~84% of the human proteome)</li> <li>Vendor collaborations have begun to demonstrate serious interest (e.g., the OneOmics partnership of</li> </ul>	Increases in both scientific grounding and vendor interest will strengthen  TH's husiness	

AB Sciex and Illumina)



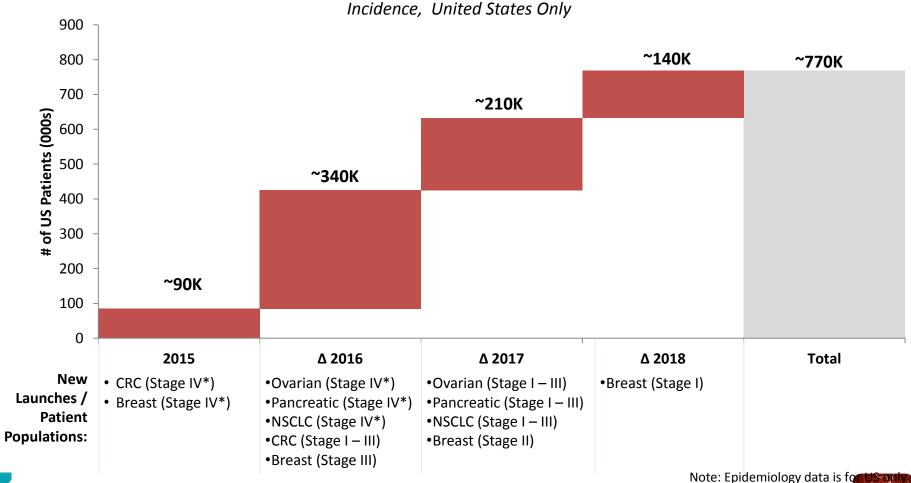


TH's business

#### Market Assessment: Potential Addressable Market

By 2018, TheraLink® assays will serve an addressable market of nearly 800,000 U.S. patients driven by launches in new tumors and use in earlier stage patients









#### **Reimbursement: Current CPT Codes and Definitions**

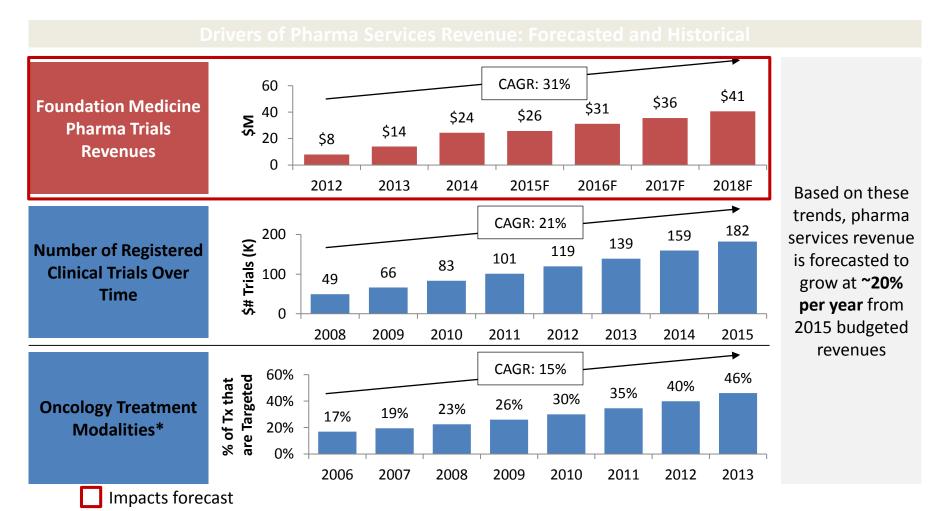
To date, Theranostics Health has successfully obtained reimbursement for the TheraLink® Assay through a combination of codes

Code	Description	Reimbursement Rate <sup>1</sup>	
81479	Unlisted Molecular Pathology Procedure	\$728 - \$1,820	Total of <b>\$990</b> - <b>\$2,495</b>
88325	Pathology consult	\$136 - \$343	7/
88380	Microdissection laser	\$118 - \$304	
G0452	Molecular interpretation	\$8 - \$28	





# Financials: Pharma Services Revenue Model Assumptions Future revenues for pharma services forecasted based on trends in the industry





**Bioscience** 

Source: EvaluateMedTech analyst consensus, clinicaltrials.gov, PhRMA

<sup>\*</sup>CAGR and annual estimates extrapolated based on data from 2003 and 2013; other treatment modalities include cytotoxics, hormonal, and supportive care

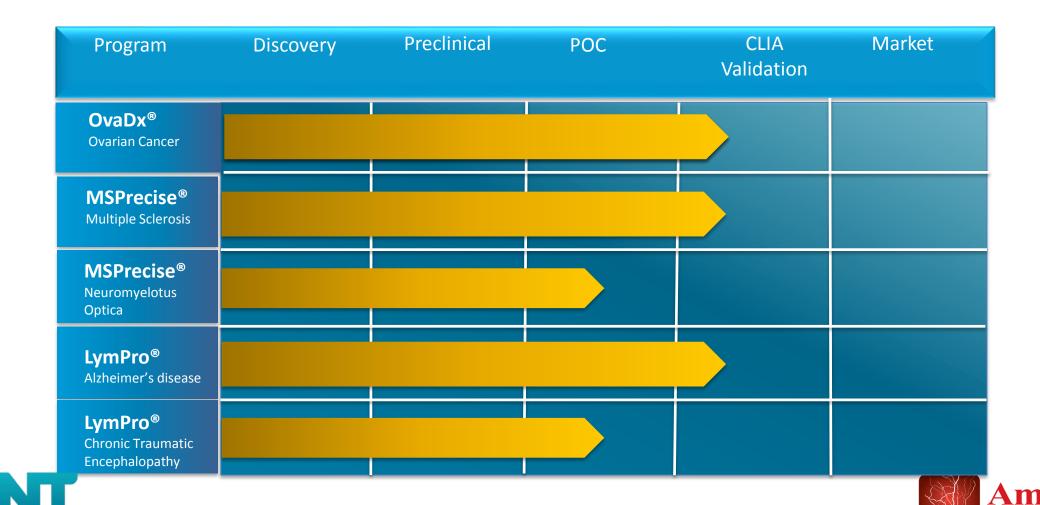
# Business Case for LymPro Test® Pharma Services in Alzheimer's disease

- Interest created from 2014-2015 from same customer list as Theranostics Health
- Major challenges
  - Overall business focus shifted towards therapeutics
  - Scarcity of resources forced Amarantus to devote majority towards diagnostics
  - Balance sheet challenges gave potential customers pause
    - Concern was if Amarantus had financial difficult it could damage customer trials
- Spin-off of Amarantus Diagnostics into Avant/Theranostics allows for clean balance sheet and familiar services provider
- Overall cell cycle biology expertise added bonus
- Amarantus business development to work with Theranostics to take over relationships



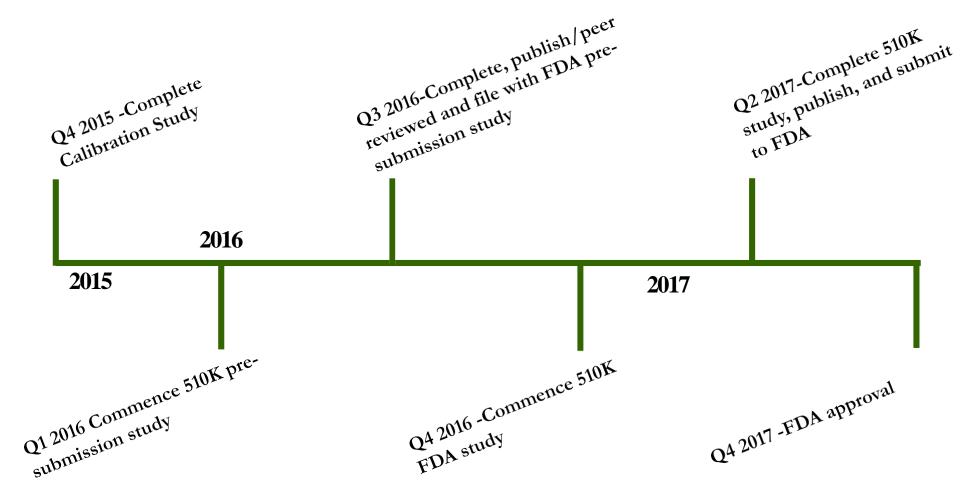


# **CLIA Diagnostics Pipeline Ready for Development**



**Bioscience** 

# OvaDx® Pipeline

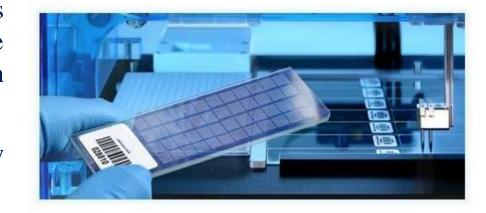






### OvaDx® Overview

- Monitoring test with a performance profile that has the potential to completely transform the diagnosis and treatment of patients with ovarian cancer.
- Based on 10+ years of research and development by leaders in cancer diagnostics and tumor immunology



- OvaDx targets the **tumor-specific antibodies**, which allows for earlier detection of cancers, because the immune system produces large quantities of antibodies in the blood, even when only a few tumor cells are present
- OvaDx uses a **proteomics approach** to test for multiple disease markers simultaneously, which are combined by a sophisticated statistical algorithm that further enhances sensitivity and specificity
- Microarray construction allows for high throughput, low cost sample processing





### Ovarian Cancer – The Silent Killer

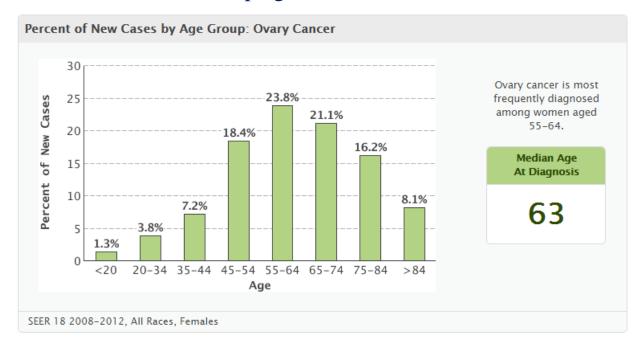
- Known as the "Silent Killer" due to the fact that in its early stage disease symptoms are ambiguous and often ignored by many patients
- With early stage (IA) detection, ovarian cancer can be cured in most patients using a simple surgical procedure and no chemotherapy; 95% of women lead productive lives
- Late stage detection (III and IV) has a poor prognosis and a 5-year survivability of
   <20%</li>
- Because the majority of patients present stage III or IV disease, most patients die within 5 years of diagnosis, making ovarian cancer one of the most deadly cancers
- There is a compelling and unmet medical need for new testing technology that detects ovarian cancer in its pre-symptomatic stages





# Ovarian Cancer By The Numbers

- American Cancer Society estimates that 21,290 new cases of ovarian cancer will be diagnosed and 14,180 women will die of ovarian cancer in the U.S. in 2015.
   Approximately 192,000 women are currently living with the disease
- Fifth leading cause of cancer death among U.S. women
- A woman's lifetime risk of developing invasive ovarian cancer is 1 in 72







# Early testing suggests that OvaDx will vastly exceed CA-125 in every aspect of diagnostic performance

- **Superior technology to CA-125....** 
  - OvaDx tests for autoantibodies, which are found in higher quantities in the blood than proteins like CA-125, which are found within cancer cells themselves
  - ✓ OvaDx tests for 10 different tumor autoantibodies rather than a single cancer cell protein
  - ✓ OvaDx employs a proprietary algorithm that determines a probability score based on the blood level of each of the 10 autoantibodies, significantly increasing overall accuracy
- OvaDx has produced superior results in pre-clinical studies

	OvaDx Te		
	Positive	Negative	Very strong initial performance in the
Ovarian cancer patients	231	22	detection of early a late stage disease
Healthy patients	0	258	

n of early and ge disease

**High sensitivity** of 91.2% despite the fact that samples contained many Stage I and Stage II cancers that CA-125 is known to miss

**ZERO false positives** (100% specificity), which means that OvaDx may one day help avoid unnecessary surgery and chemotherapy in thousands of women due to falsely elevated CA-125





# MSPrecise: First in Class Molecular Diagnostic for MS How Does It Work?

1



CSF sample collection per standard practice by neurologist

 $\left(2\right)$ 



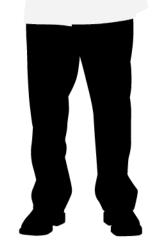
Sample shipped a CLIA lab to measure changes in specific immune cells

Our report is delivered to the neurologist









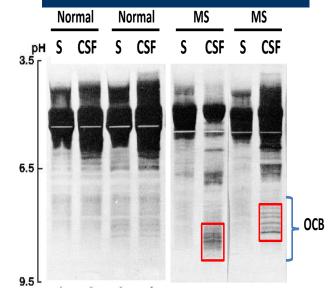




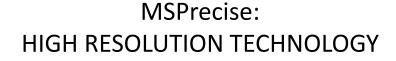
# MSPrecise®: Transforming How Multiple Sclerosis Is Diagnosed

### NOW: LOW RESOLUTION TECHNOLOGY

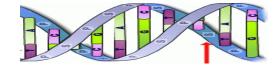
# Oligoclonal Banding of Proteins



+ PREDICTIVE VALUE = 46-64%



**Next Generation Sequence Analysis of Rare Antibody Genes** 



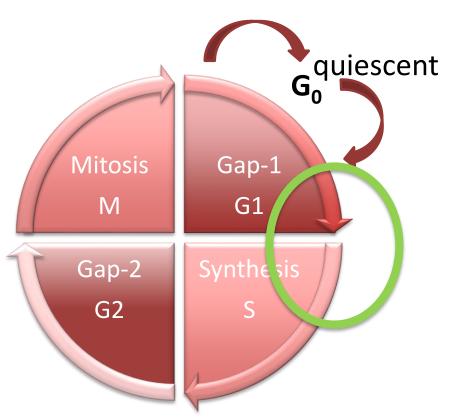
AGT GGG AGC ACC TAC TAC AAC

+ PREDICTIVE VALUE ~ 80%

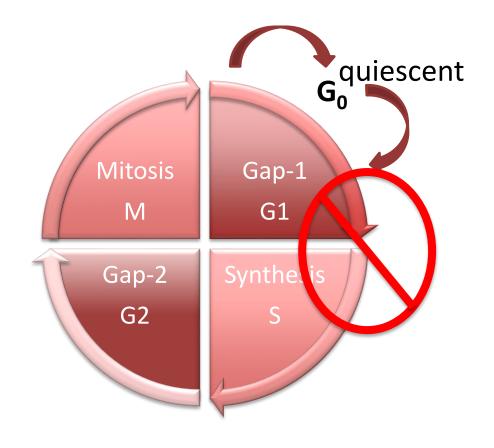




# LymPro Test®: Measuring Cell Cycle Dysfunction in Alzheimer's Disease



Healthy Individuals:
G1-S transition
highly regulated



AD: G1-S 'Brake' is broken



## LymPro: How Does It Work?



Blood sample collected at clinic and sent to lab



In lab, white blood cell samples stimulated to enter cell cycle

Expression of specific cell cycle-related proteins is detected by flow cytometry

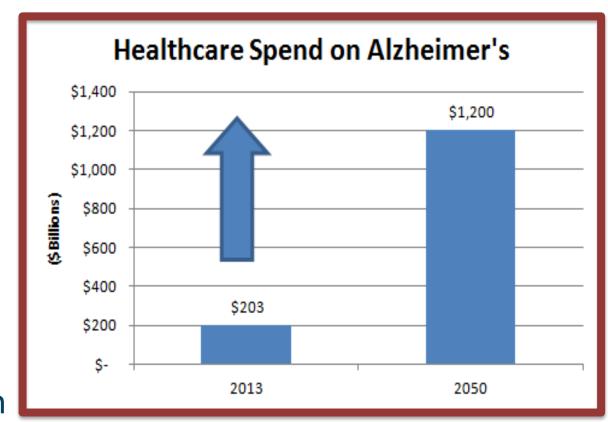
Proprietary algorithm identifies dysfunctional patterns





# Key Unmet Need: Effective Early Diagnostic

- 1 in 9 Americans over 65 has AD
- 5.2 million Americans have AD
- 500,000 new diagnoses per year
- High misdiagnosis rate
- \$200B costs in the U.S. health system
  - 10% of healthcare budget
- Growing rapidly with aging population







# **Corporate Strategy**





## **Investment Highlights**

- Combination of 3 companies with synergies in biology and indications
- 2015 Pharma Services revenue of \$1.5M expected to grow significant
  - Theralink® in breast cancer to expand into other indications
  - LymPro Test® to add significant potential to pharma services revenue potential
  - Leader in cell cycle biology
- CLIA laboratory operating to highest standards
- Introducing proprietary diagnostic tests into market in 2017
  - Ovarian cancer: OvaDx® Market potential of \$2B+ (replacing CA-125)
  - Multiple Sclerosis: MSPrecise® Market potential of \$200M+ (improving Tx intervention)
  - Alzheimer's disease: LymPro Test® Market potential of \$3B+ (65yr Medicare screen)





### **Contact Information**

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