
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **September 25, 2014**

BioTime, Inc.

(Exact name of registrant as specified in its charter)

California
(State or other jurisdiction of incorporation)

1-12830
(Commission File Number)

94-3127919
(IRS Employer Identification No.)

1301 Harbor Bay Parkway
Alameda, California 94502
(Address of principal executive offices)

(510) 521-3390
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Forward-Looking Statements

Any statements that are not historical fact (including, but not limited to statements that contain words such as "may," "will," "believes," "plans," "intends," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Additional factors that could cause actual results to differ materially from the results anticipated in these forward-looking statements are contained in BioTime's periodic reports filed with the SEC under the heading "Risk Factors" and other filings that BioTime may make with the Securities and Exchange Commission. Undue reliance should not be placed on these forward-looking statements which speak only as of the date they are made, and the facts and assumptions underlying these statements may change. Except as required by law, BioTime disclaims any intent or obligation to update these forward-looking statements.

This Report and any accompanying exhibits shall be deemed "furnished" and not "filed" under the Securities Exchange Act of 1934, as amended.

Section 7 - Regulation FD

Item 7.01 - Regulation FD Disclosure

Beginning September 25, 2014, Joseph Wagner, Ph.D., the Chief Executive Officer of BioTime's subsidiary OncoCyte Corporation, will provide an update on product development by OncoCyte in certain private meetings. Dr. Wagner's presentation will include the information in the slides attached to this report as Exhibit 99.1.

Section 9 - Financial Statements and Exhibits

Item 9.01 - Financial Statements and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Slide presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOTIME, INC.

Date: September 25, 2014

By: s/Robert W. Peabody
Senior Vice President,
Chief Operating Officer, and
Chief Financial Officer

Exhibit Number

Description

[99.1](#)

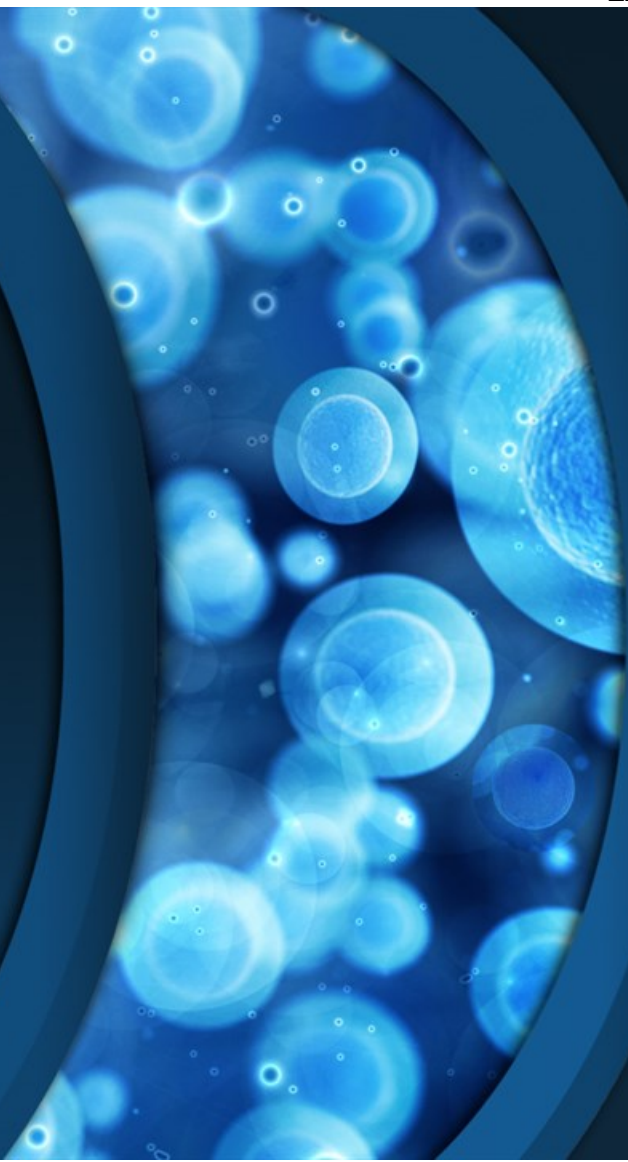
Slide presentation



Joseph Wagner, Ph.D.

Chief Executive Officer

September 25, 2014

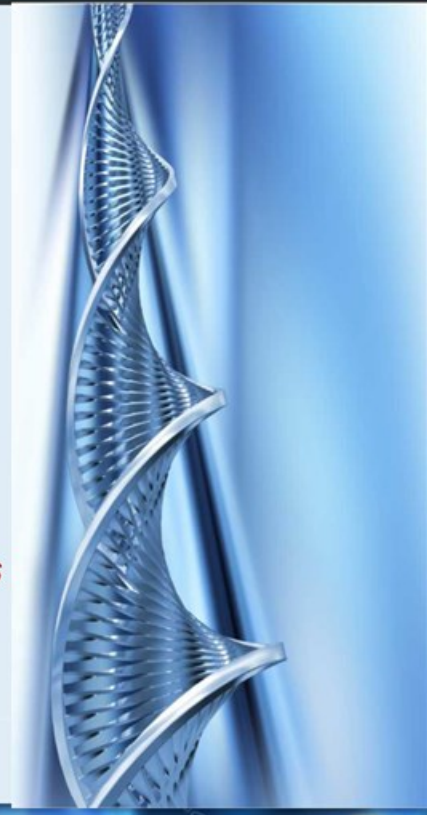


Our mission is to develop novel products for the diagnosis and treatment of cancer in order to improve both the quality and length of life of cancer patients



- Internally developed cancer gene discovery platform
- Platform based on extensive microarray dataset
- Marker discovery principle based on similarity of gene expression in embryonic development and cancer
- Scores of potential targets identified and IP filed
- Multiple product opportunities

Goal: Develop and market low-cost molecular diagnostic tests for major cancers with rapid adoption by initial users followed by widespread use in large patient populations



Multiple clinical studies reporting by year-end 2014, coupled with very large market potential of products may yield large, near-term valuation increases

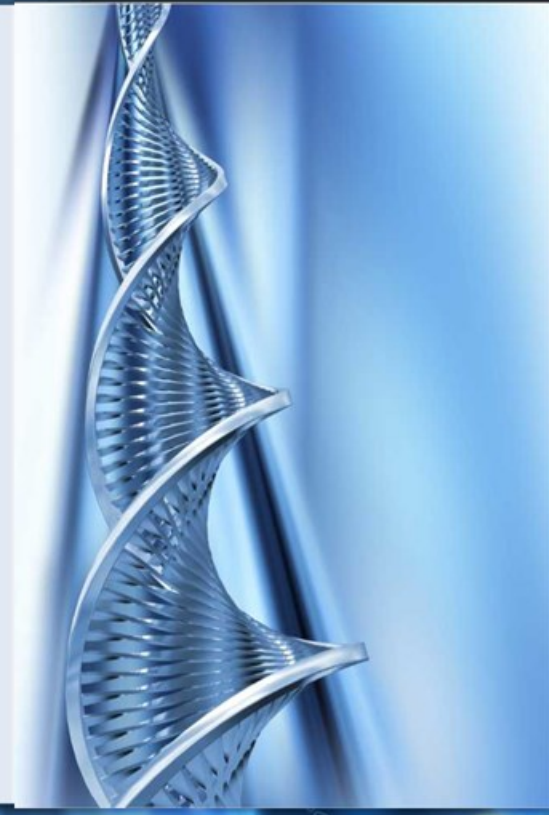


- Initial clinical validation studies on three diagnostic products reporting by year-end 2014
- Novel molecular cancer diagnostics that address major unmet medical needs
- Potential for rapid initial adoption through KOL support and limitations of current diagnostic tests
- Potential for broad eventual adoption due to advantages over current screening diagnostics
- Favorable reimbursement landscape with opportunity for value-based pricing of tests
- Near-term revenue potential (12-18 months)
- Potential for products to achieve “blockbuster” status (>\$1B/year)

OncoCyte Presentation Highlights

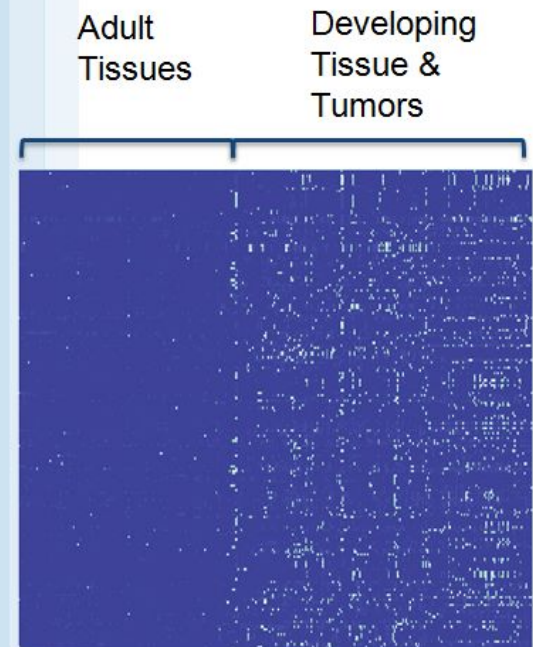
Our mission is to develop novel products for the diagnosis and treatment of cancer in order to improve both the quality and length of life of cancer patients

- **Technology Overview**
- **Business Strategy**
- **Product Development & Marketing Path**
- **Product Programs**
 - **Breast Cancer Diagnostic**
 - **Bladder Cancer Diagnostic**
 - **Lung Cancer Diagnostic**
- **Reimbursement Strategy**
- **Upcoming Milestones**



Many of the same genes that drive embryonic development drive tumor formation and growth

- A substantial proportion of the mammalian genome is exclusively activated during embryonic development
- These embryo-exclusive genes regulate:
 - Cell proliferation
 - Cell signaling
 - Organ formation
 - Angiogenesis
- Many of these genes are accessed/activated by cells after oncogenic mutation & transformation
- Many of these genes have not been previously associated with cancer



Translating proprietary cancer marker platform into near-term revenue opportunities in oncology markets

Cancer Marker Discovery (2011-):

- Assembled >700 sample microarray dataset
- Bioinformatics generated >3000 candidate markers

Protection of Intellectual Property (2011-):

- Aggressive filings protecting all markers and all uses

Cancer Marker Validation (2012-):

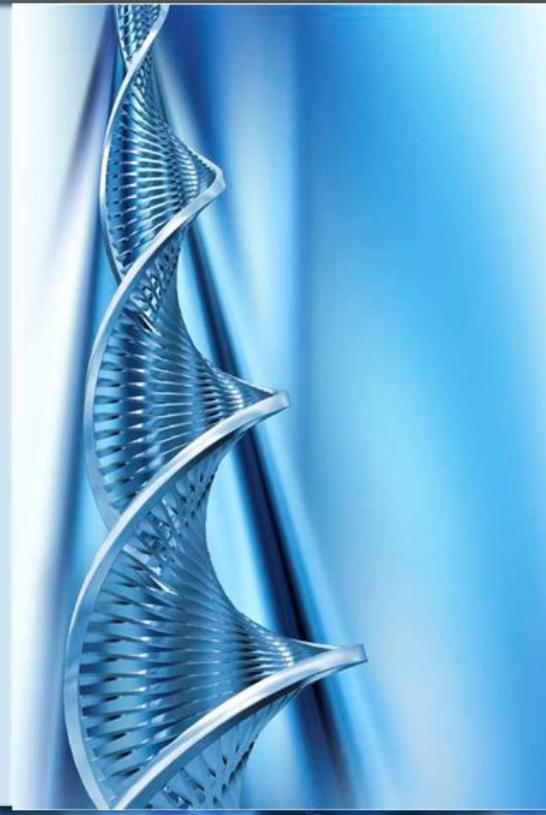
- Verify gene expression using alternate methodologies
- Verify protein expression in tumor tissue

Proof of Concept in Patient Samples (2013-):

- Verify gene/protein expression in retrospective clinical sample banks
- Build candidate multiplex panels for large scale testing

Large Prospective Clinical Studies (2014-):

- Initiate larger studies in target patient populations
- Test performance of multiplex panels using platform-neutral proprietary test kits



Validation of cancer marker biology through peer-review process



Elevated expression of cancer/testis antigen FSIP1 in ER-positive breast tumors

Karen B Chapman^{*1},
Maria J Prendes¹,
Jennifer L Kidd¹,
Hal Sternberg²,
Michael D West²
& Joseph Wagner¹

COL10A1 expression is elevated in diverse solid tumor types and is associated with tumor vasculature

Karen B Chapman^{*1}, Maria J Prendes², Hal Sternberg², Jennifer L Kidd², Walter D Funk², Joseph Wagner¹ & Michael D West²

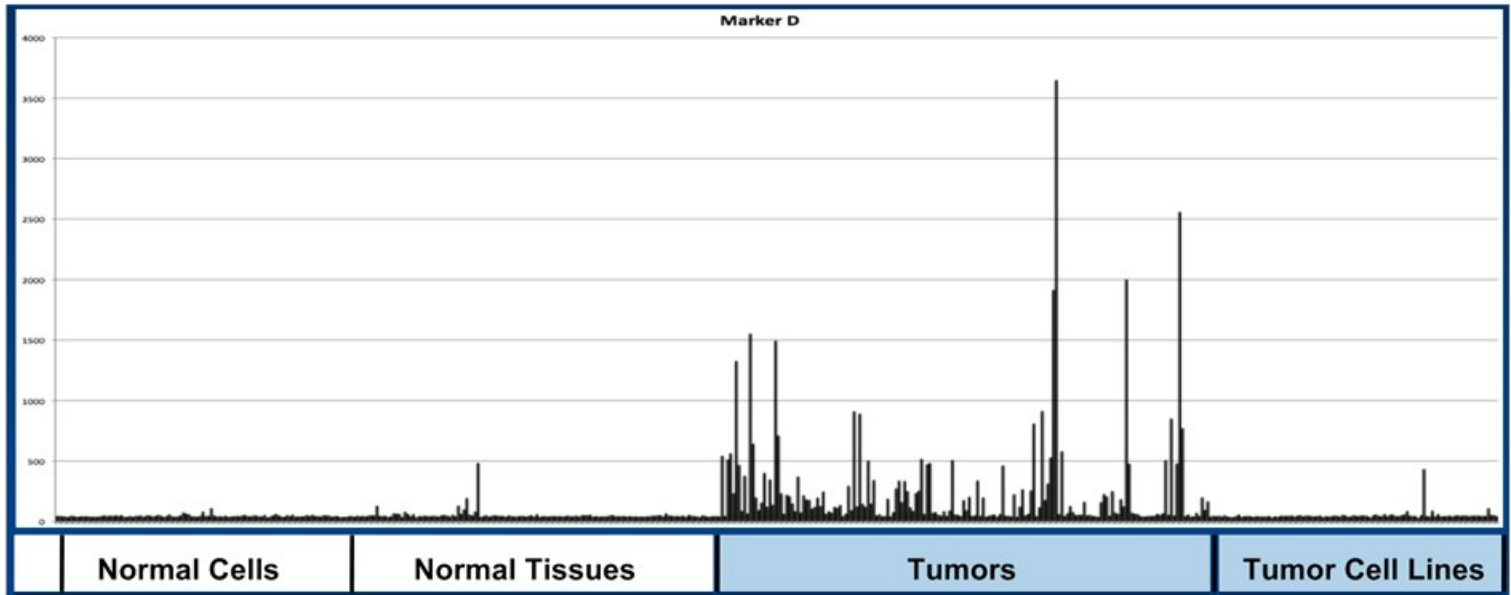
¹OncoCyte Corporation, 1301 Harbor Bay Parkway, Alameda, CA 94502, USA
²BioTime Inc., 1301 Harbor Bay Parkway, Alameda, CA 94502, USA

Many more to come...

Example 1: COL10A1

COL10A1 is normally only expressed during embryonic development and regulates long bone mineralization

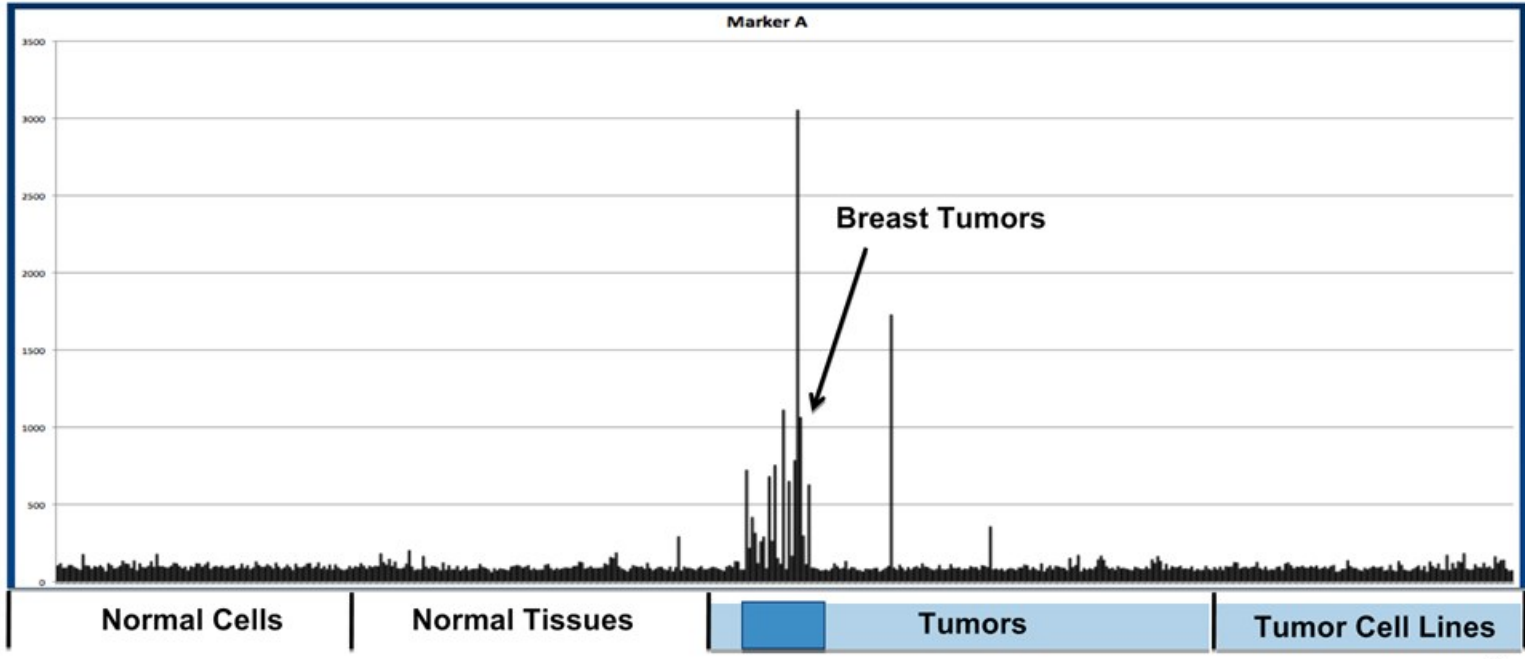
- Data from Illumina microarray shows high levels of COL10A1 expression in a majority of tumor samples tested with little expression in normal tissues
- COL10A1 represents a novel “pan-cancer” biomarker



Example 2: FSIP1

FSIP1 is a protein normally only expressed in the tail of mature male sperm cells

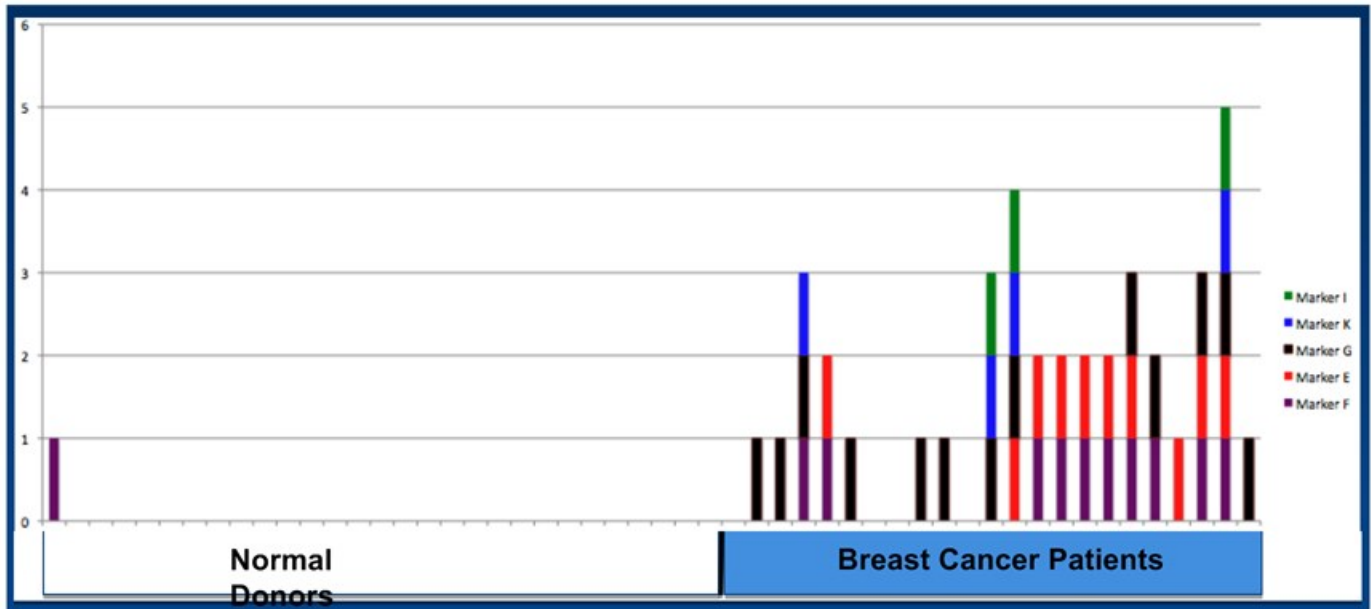
- Data from Illumina microarray shows high levels of FSIP1 expression in a majority of breast cancer samples tested with no expression elsewhere
- FSIP1 represents a novel breast cancer-specific biomarker



Multiplex Breast Cancer Biomarker Panel

Preliminary data compilation shows discrimination between breast cancer patient serum and normal donor serum.

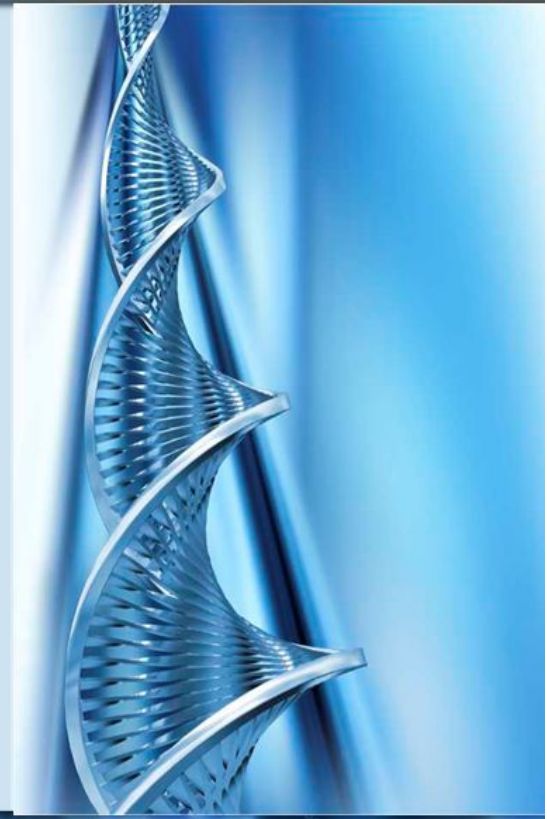
- Individual biomarker expression in patient samples validates microarray data
- Combining individual markers demonstrates high performance of multiplex approach necessary for user adoption



OncoCyte's Business Formula

Designed to translate proprietary cancer marker platform into near-term revenue opportunities

- **“Listen to Your Technology”**
- **“Listen to Your Customers”**
- **Create Scalable Business Model**
- **Early Revenues Fund Larger Trials**



“Listen to Your Technology”

Technology platform defines product opportunities in subsectors of cancer diagnostics

Potential products based on dataset structure:

- Screening diagnostics
- Recurrence diagnostics

Potential products based on markers:

- Breast cancer
- Colorectal/GI cancers
- Bladder/urothelial cancers
- Thyroid cancer
- Lung cancer

Potential products with low cost and ease of use:

- Blood-based tests
- Urine-based tests



Physician adoption is the key barrier to entry for cancer screening diagnostics

User Will Adopt Tests That:

- Key Opinion Leaders support
- Resolve diagnostic dilemmas
- Justify the need for procedures
- Eliminate unnecessary procedures
- Have reasonable cost/reimbursement

User Will Not Adopt Tests That:

- Create diagnostic ambiguity
- Replace procedures
- Create unnecessary costs

Technology alone does not drive user adoption



How does OncoCyte identify and prioritize its products?



Strategically develop diagnostic products that will be rapidly adopted and have short- and long-term revenue potential

Focus on developing products that:

- Fit with proprietary technology
- Are simple to perform and interpret
- Are relatively low cost and easy to use
- Appeal to an immediate user base
- Have long-term large market potential
- Are based on protectable/enforceable IP



Create a scalable business model beginning with an immediate market with early adopters, successively expanding into larger opportunities

Initial Use & Market:

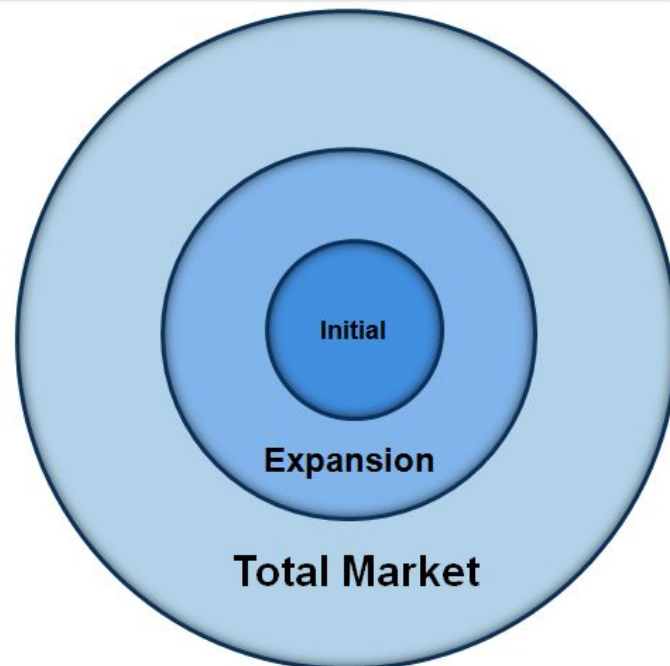
- Early adopters with immediate needs
- Can be addressed rapidly with relatively low cost

Expanded Use & Market:

- Larger markets and user bases
- Requires additional clinical validation

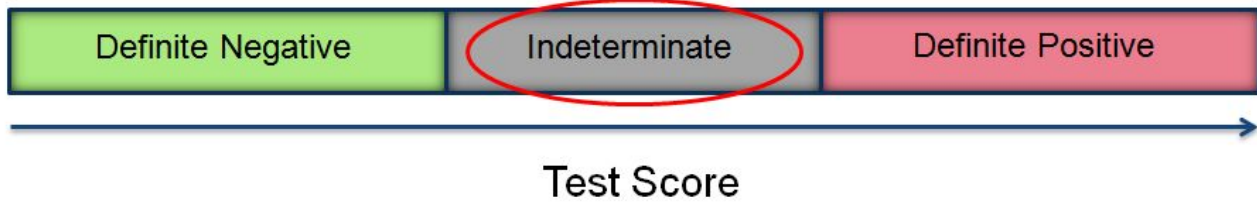
Final Target Use & Market:

- Addresses very large markets and tens of thousands of users
- Requires partnerships to meet ultimate revenue goals



Key Driver: Limitations of Current Tests

Initial users/use will be to clarify diagnostic dilemmas due to uncertainties in imaging and other traditional tests



Current Tests With Significant Limitations Include:

- Mammography for breast cancer
- Urine cytology for bladder cancer recurrence surveillance
- Low-dose CT for lung cancer screening

Current Product Programs

Simple, low cost cancer screens that address current unmet user needs in large patient markets



ONC-BR-001:

- Blood-based breast cancer screen
- Measures sera proteins via ELISA

ONC-BL-002:

- Urine-based bladder cancer screen
- Measures RNA levels via PCR

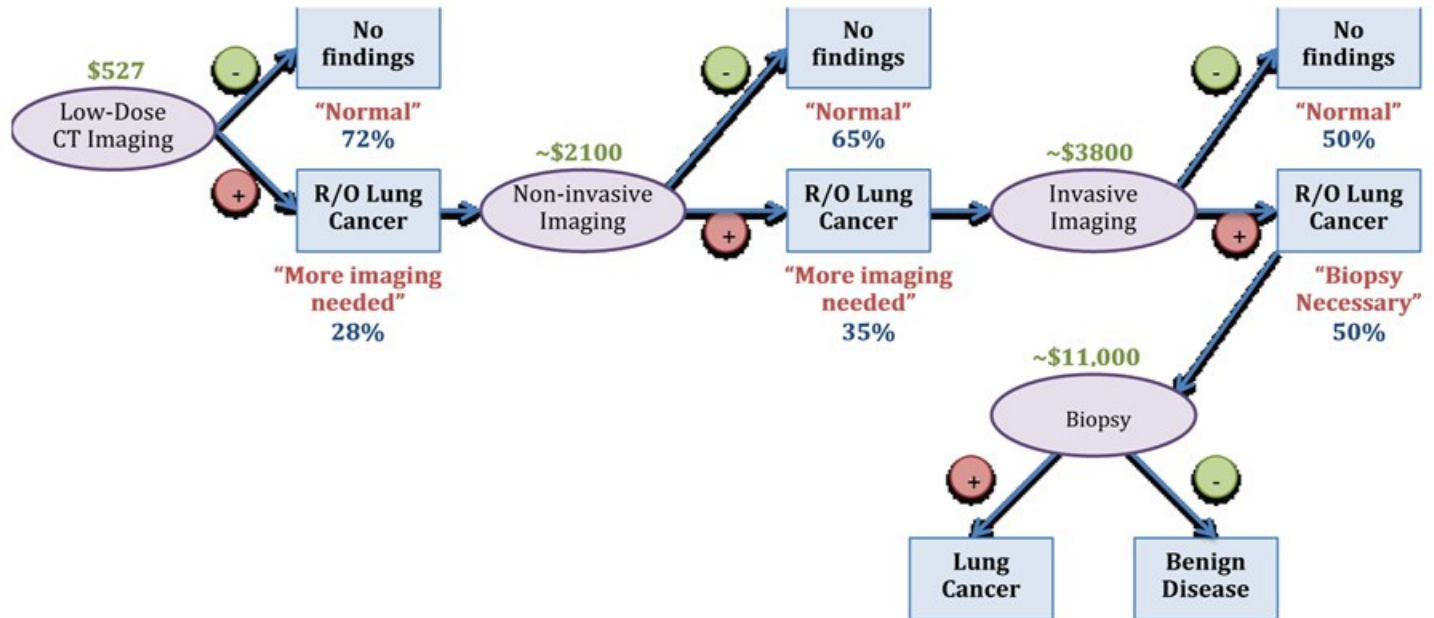
ONC-LN-003:

- Blood-based lung cancer screen
- Measures sera proteins and/or RNA



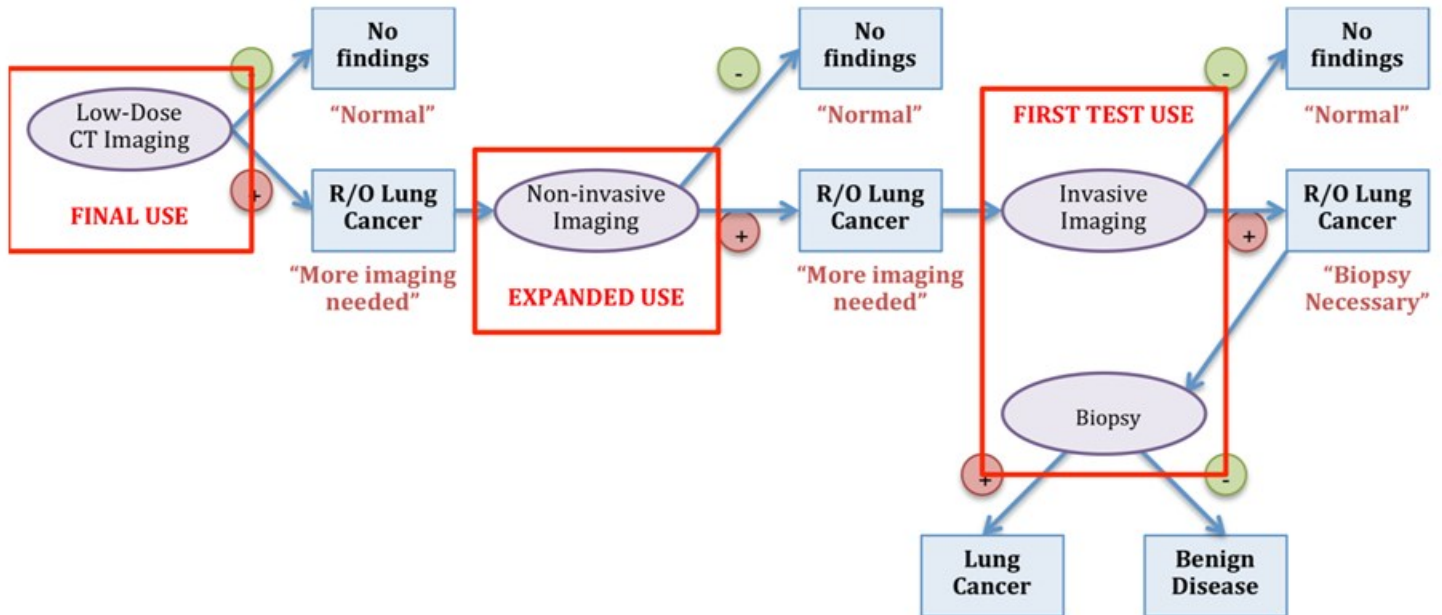
ONC-LN-003: Lung Cancer Product

Initial test use late in diagnostic tree with progressive data driving test use earlier and earlier



ONC-LN-003: Lung Cancer Product

Initial test use late in diagnostic tree with progressive data driving test use earlier and earlier



Initial Use & Market:

- Radiologists/thoracic surgeons: Management of imaging positive patients
- 350K tests/year in US

Expanded Use & Market:

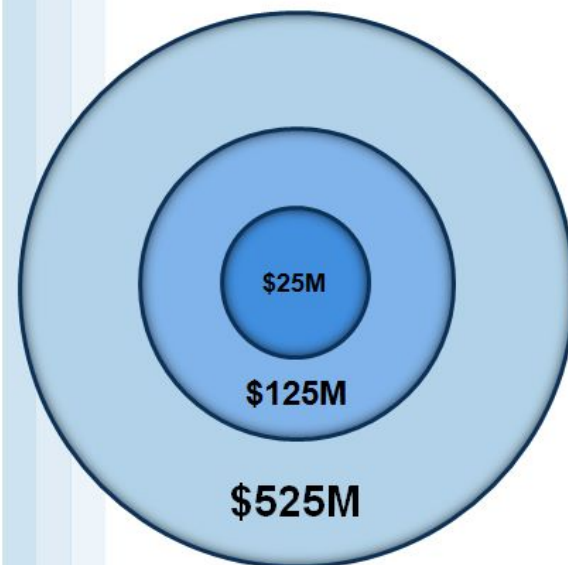
- Radiologists/thoracic surgeons: Management of all LDCT+ patients
- 1.75M tests/year in US

Final Target Use & Market:

- Radiologists/thoracic surgeons: Used in conjunction with/surrogate for LDCT in all high-risk patients
- >7M tests/year in US

Current Status:

- Multi-center study underway
- High interest from KoL's



Ongoing study in target population initiated by collaborators at the Wistar Institute

Subjects:

- N = 600
- All high-risk, includes cancer-free, benign nodules, confirmed cancer patients

Endpoints:

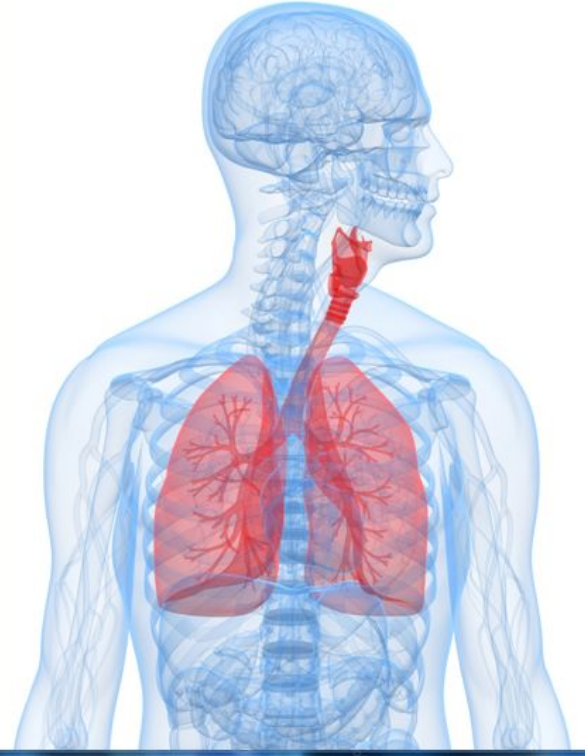
- Primary: Correlation with diagnosis
- Secondary: Correlation with tumor origin, stage, grade

Sites:

- 6 total including NYU, Temple, Penn, Christiana

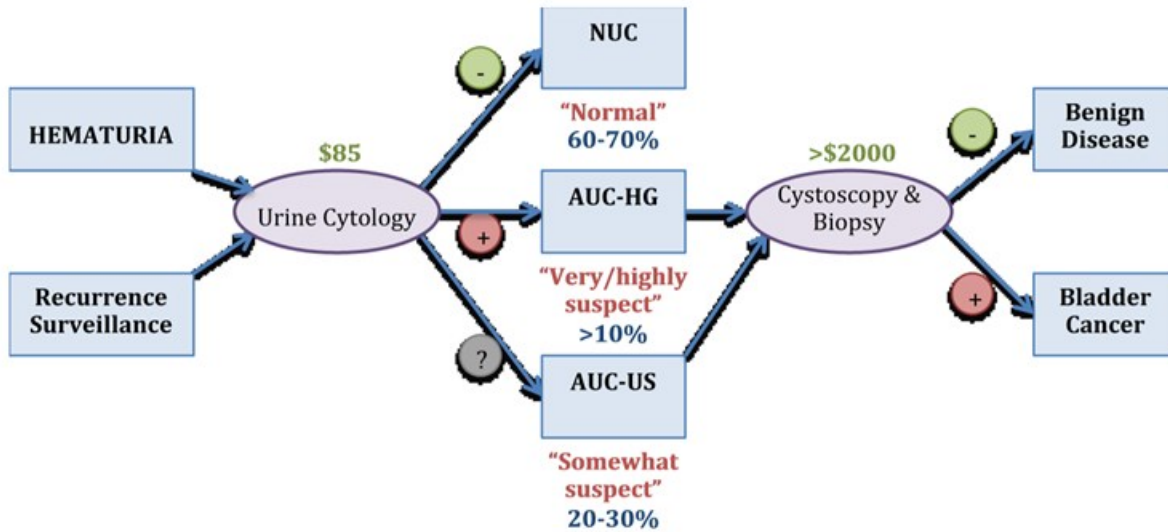
Timing:

- Study completed enrollment May 2014
- Sample analysis completed Sept 2014
- Initial data publication late 2014
- Study data presentations at ATS & ASCO 2015

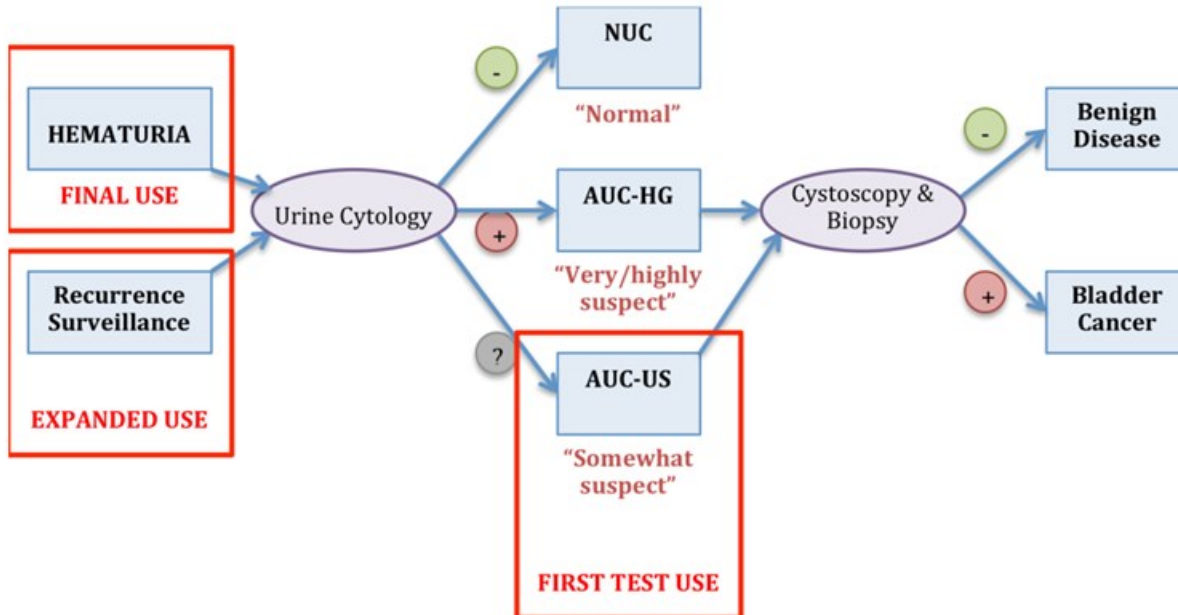


ONC-BL-002: Bladder Cancer Product

Initial test use late in diagnostic tree with progressive data driving test use earlier and earlier



Initial test use late in diagnostic tree with progressive data driving test use earlier and earlier



Urine-based multiplex PCR recurrence diagnostic test



Initial Use & Market:

- Pathologist: Resolution of indeterminate cytology during recurrence surveillance
- 500K tests/year in US

Expanded Use & Market:

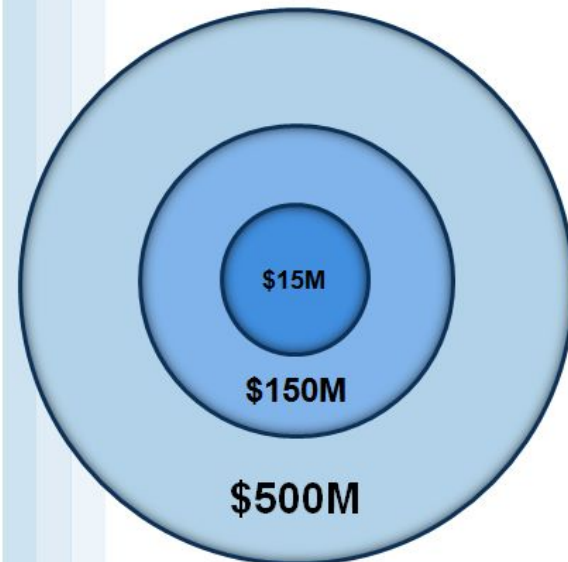
- Oncologist: All recurrence surveillance
- 1.5M test/year in US

Final Target Use & Market:

- Urologist: Management of hematuria
- >5M tests/year in US

Current Status:

- Ongoing patient studies in US, China
- Additional sites to be selected



Multisite clinical studies in setting of surveillance cytology testing or cystoscopy



Subjects:

- N = 100/1200
- At time of surveillance cytology/cystoscopy

Endpoints:

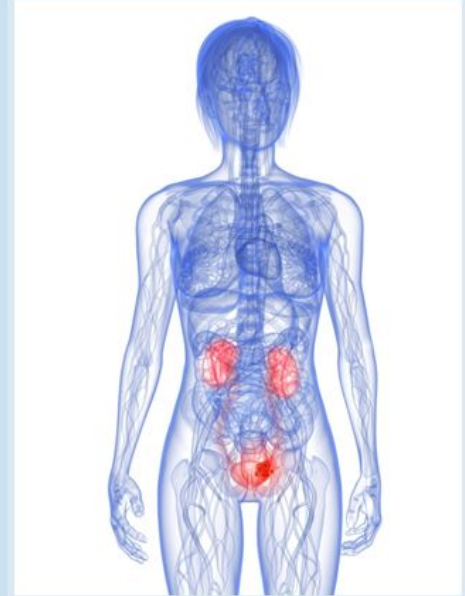
- Correlation of markers to cytology/cystoscopy results

Sites:

- Cytopathology: Johns Hopkins
- Cystoscopy: Four large urology clinics in Texas, Ohio, Indiana and South Carolina

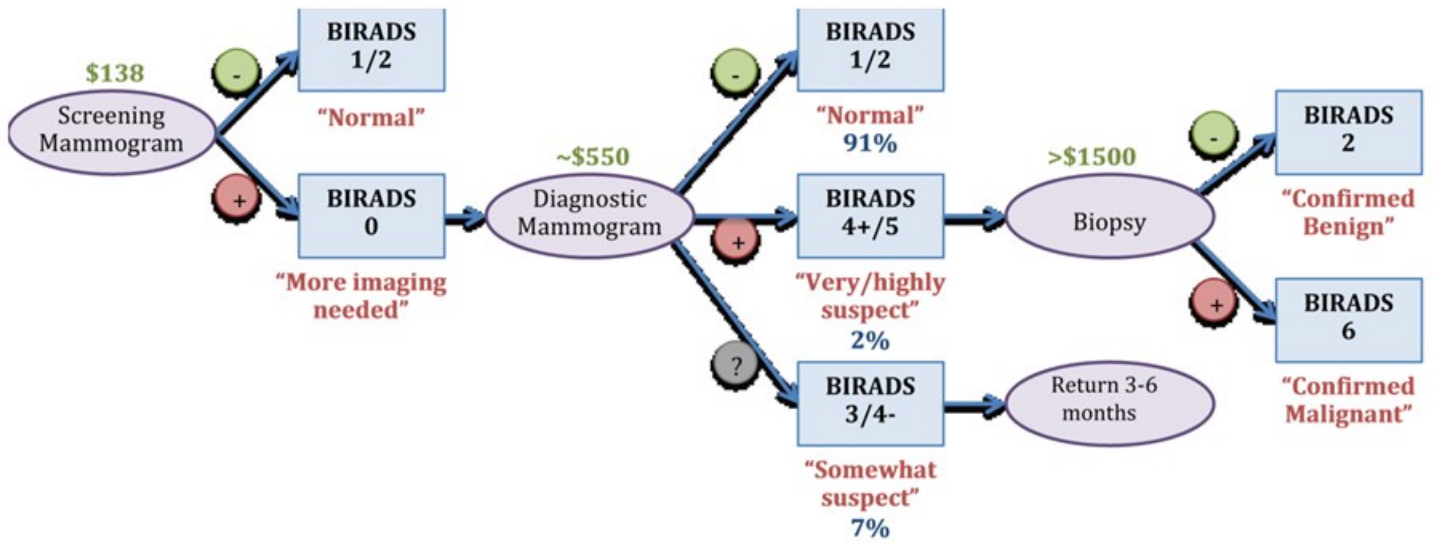
Timing:

- Cytopathology: Complete late 2014
- Cystoscopy: July 2015
- Data presentation at AUA & ASCO in May, 2015

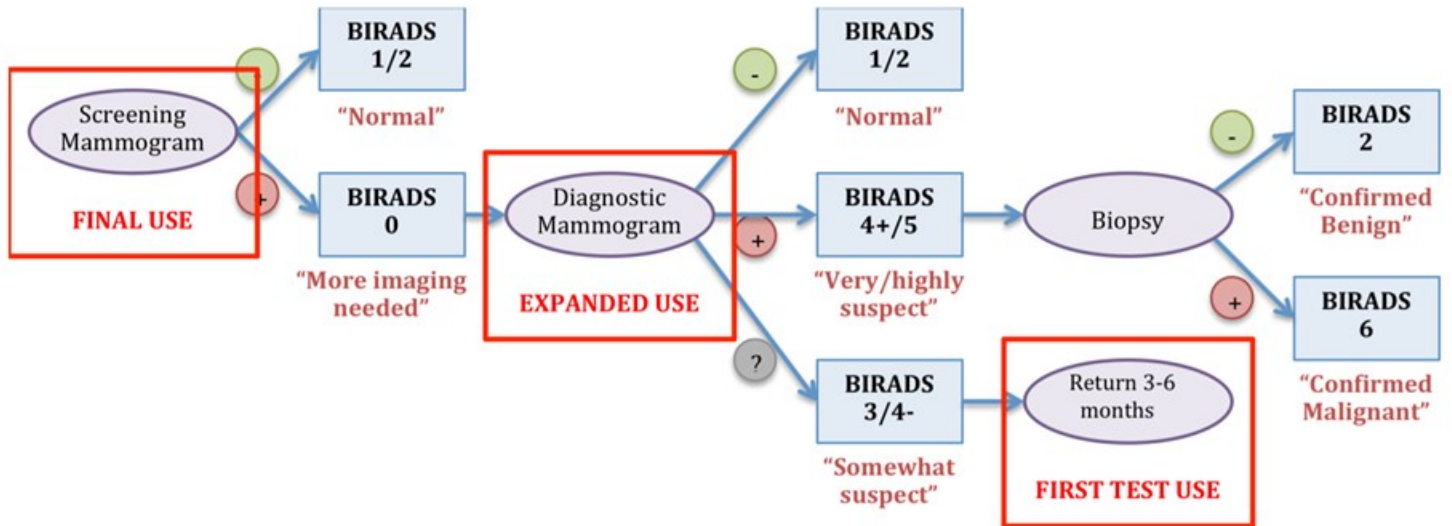


ONC-BR-001: Breast Cancer Product

Initial test use late in diagnostic tree with progressive data driving test use earlier and earlier



Initial test use late in diagnostic tree with progressive data driving test use earlier and earlier



Blood-based screening diagnostic measures sera protein biomarkers using ELISA

Initial Use & Market:

- Radiologist: Management of BIRADS 3-4 patients
- 350K tests/year in US

Expanded Use & Market:

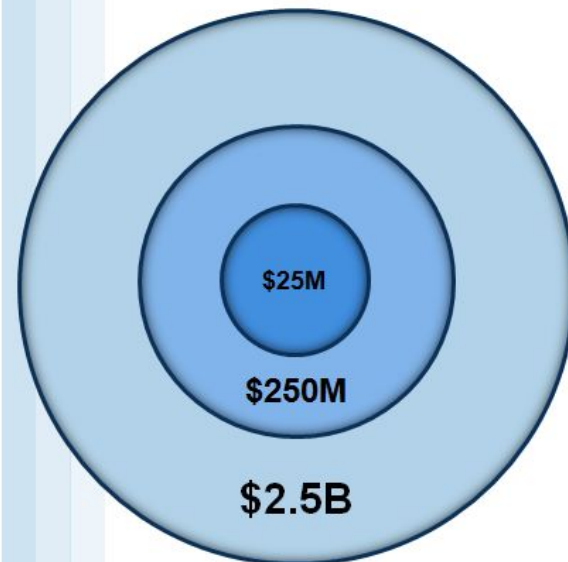
- Radiologist: In conjunction with all diagnostic mammography
- Oncologist: Recurrence surveillance
- 3M tests/year in US

Final Target Use & Market:

- PCP/Radiologists: In conjunction with or surrogate for screening mammography
- >30M tests/year in US

Current Status:

- Clinical study underway
- In discussions with additional sites



Prospective, multisite study in diagnostic mammography patients

Subjects:

- N = 600
- At time of diagnostic mammography

Endpoints:

- Primary: Correlation with BIRADS score
- Secondary: Correlation of biomarker with pathology

Sites:

- Up to 6 total
- Currently enrolling: Ron Korn, SMIL, Scottsdale, AZ
- Abcodia providing additional samples

Timing:

- First subject enrolled early Jan 2014
- Complete study by end of 2014
- Data presentation at ACR & ASCO in May, 2015



Superior product at lower cost to drive rapid adoption in initial markets, followed by widespread adoption

- **KOL endorsements**
 - Drive adoption within KOLs' own practices as well as among other physicians
 - Can lead to medical society recommendations
- **Strong Clinical Trial Data**
 - Supports positive health economics and patient outcomes
- **Cost effectiveness of tests**
 - Drives user willingness to acquire additional data
 - As test volume increases, adoption point becomes earlier as test accuracy gains credibility



Reimbursement Strategy

Favorable reimbursement potential for multiplex molecular tests despite recent CMS changes



Anticipated Reimbursement for Our Tests:

- Each test would receive new 815XX code
- April 2014 Medicare patch exempts molecular tests from pricing cuts
- Potential for value-based pricing is real
- OncoCytte would set price for first 3 quarters after launch, price negotiation with CMS regional contractors (*i.e.* Gap Filling) effective fourth quarter
- Low-cost test technology allows strong gross margins even at low reimbursement rates



Upcoming Development Milestones

Positive clinical trial results will drive commercialization efforts with first test launch in 2015

- **Q4 2014:**
 - Completion of breast, bladder and lung clinical trial enrollment and data analysis
 - Publication of lung trial results; submission of clinical study data for presentation at major oncology meetings
- **Q1 2015:**
 - Initiation of CLIA lab testing certification
 - Expansion of executive management team
- **Q2 2015:**
 - Presentation of breast, bladder and lung clinical trial at major oncology meetings
 - Publication of breast and bladder clinical trial data in peer-reviewed journals
- **Q3 2015:**
 - Assay validation completed for lead test
 - California CLIA certification obtained
- **Q4 2015:**
 - Commercial launch of first diagnostic test to be announced at major oncology meeting



OncoCyte: Investment Highlights

Beginning with an immediate market with early adopters, expanding into large opportunities

- **Broad platform of cancer markers**
- **Low-cost tests using standard methods**
- **Potential for rapid initial adoption and broad eventual adoption**
- **Scalable business model:**
 - **Significant revenue in initial markets**
 - **Early revenues fund studies necessary for broader use**
 - **Very large long-term potential revenue opportunity**

