### 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 10, 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)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### 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

On September 10, 2014, our Chief Executive Officer Michael D. West, Ph.D. will provide an update on product development by BioTime and its subsidiaries at the Rodman & Renshaw 16th Annual Healthcare Conference in New York City. Dr. West'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.

Exhibit Number Description
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 10, 2014

By s/Robert W. Peabody

Senior Vice President, Chief Operating Officer, and Chief Financial Officer Exhibit Number 99.1

<u>Description</u> Slide presentation



### Safe Harbor Statement



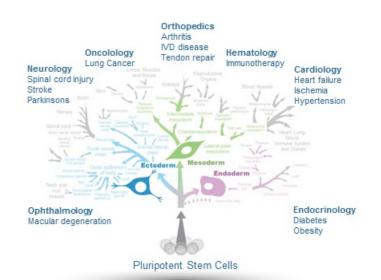
The matters discussed in this presentation include forward looking statements which are subject to various risks, uncertainties, and other factors that could cause actual results to differ materially from the results anticipated. Such risks and uncertainties include but are not limited to the success of BioTime in developing new stem cell products and technologies; results of clinical trials of BioTime products; the ability of BioTime and its licensees to obtain additional FDA and foreign regulatory approval to market BioTime products; competition from products manufactured and sold or being developed by other companies; the price of and demand for BioTime products; and the ability of BioTime to raise the capital needed to finance its current and planned operations. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. As actual results may differ materially from the results anticipated in these forward-looking statements they should be evaluated together with the many uncertainties that affect the business of BioTime and its subsidiaries, particularly those mentioned in the cautionary statements found in BioTime's Securities and Exchange Commission filings. BioTime disclaims any intent or obligation to update these forward-looking statements.

## Investment Highlights



### The Technology Leader in Regenerative Medicine

- Poised to commercialize one of the largest revolutions in medicine
- Targeting large markets in degenerative diseases (\$billion markets)
- Multiple clinical milestones in 2H2014
- Balance of near-term and longerterm products in development
- Leader in core pluripotent stem cell technology with >600 patents/ patent applications worldwide
- No approval pathway for generics or biosimilars to our cell therapies



# **Advent of Regenerative Medicine**



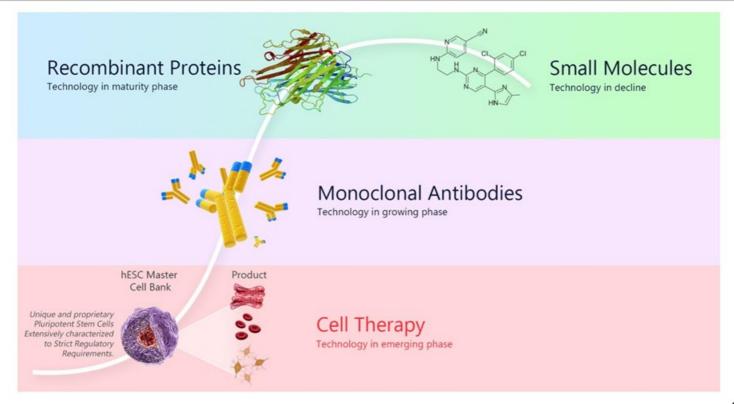
# Biotech revolutions often take 15-20 years from conception to commercialization

Recombinant DNA	Monoclonal Antibodies	Regenerative Medicine
Advent: 1974: Gene cloning technology developed Hurdle: 1976: moratorium on rDNA research Launch: 1989: EPO is first billion dollar product  • 2014: products using rDNA technology are ubiquitous  • >140 clinical trials  • \$75bn current global market	Advent: 1975: Hybridoma technology developed Hurdle: HAMA response Launch: 1997: Rituximab is first billion-dollar product  • 2014: 8 of the 20 best-selling biotechnology drugs are therapeutic monoclonal antibodies  • >200 clinical trials  • \$44bn current global market	Advent: 1998: Isolation of pluripotent stem cells  Hurdle: 2001: U.S. federal funding restriction (reversed in 2009)  2010: First-in-human trial of OPC1  Future: First billion-dollar product

# Value of the Pluripotent Platform



Cell therapy: In growth phase – potentially long lifespan due to lack of regulatory pathway for generics or biosimilars



## **Targeting High Medical Need**



**VAC2** – Cancer, telomerase immunotherapy

- \$38B economic impact of non-small-cell lung cancer in the U.S
- Targeted by Asterias Biotherapeutics (BioTime owns 70.6%)

**OPC1** – Spinal cord injury, oligodendrocytes

- \$20B annual economic impact of spinal cord injury in the U.S.
- Developed by Asterias Biotherapeutics (BioTime owns 70.6%)

**OpRegen** – Dry AMD, retinal pigment epithelial cells

- >\$5B annual spend on drug therapies for wet AMD
- Cell Cure Neurosciences (BioTime owns 62.5%)

PanC-Dx - Cancer diagnostic, breast, lung, bladder CA

- \$7B annual cost of mammography in the US
- Targeted by OncoCyte (BioTime owns 75.3%)

Renevia – HyStem, device for lipoatrophy

- >3M HIV+ patients with lipoatrophy
- Renevia developed by BioTime (owns 100%)

### **Recent Milestones**



- 3Q14: FDA clearance to initiate Phase 1/2a clinical trial of OPC1 for complete cervical spinal cord injury
- 3Q14: ASTY becomes first publicly-traded subsidiary of BioTime
- 3Q14: FDA premarket notification clearance for Premvia<sup>™</sup>
- 3Q14: OncoCyte initiates large multi-site clinical trial for PanC-Dx<sup>™</sup> bladder cancer diagnostic
- 2Q14: ASTY awarded \$14.3MM research grant from CIRM to fund Phase 1/2a clinical trial of OPC1
- 2Q14: OncoCyte partners with Weill Cornell for expanded lung cancer diagnostic clinical study
- 2Q14: ASTY presents OPC1 Phase 1 clinical data at ASGCT scientific meeting
- 2Q14: ASTY raises \$13MM through sales of equity
- 1H14: BTX raises \$10MM through sales of equity

## **Rapid Cadence of Milestones**



- 2H14: ASTY anticipates completing negotiations for partnership to fund Phase 1/2a of VAC2 development
- 2H14: Cell Cure Neurosciences files OpRegen® IND with FDA
- Late 2014: Three clinical trials for OncoCyte's PanC-Dx<sup>™</sup> (bladder, breast, and lung cancers) expected to be completed
- 4Q14: Renevia<sup>™</sup> pivotal clinical trial
- 4Q14-2Q15: results of OncoCyte's three PanC-Dx<sup>™</sup> trials expected to be published in peer-reviewed journals and presented at major scientific meetings
- 1Q15: OPC1 clinical trial patient enrollment expected to begin
- Mid-2015: Potential PanC-Dx<sup>™</sup> commercialization
- Late 2015: Potential Renevia<sup>™</sup> commercialization

# **Major Therapeutics**





OPC1	Potential patients in U.S.	Research	Preclinical	Phase 1	Phase 2
Spinal cord injury	12,000/year				
Multiple sclerosis	180,000 prevalence				
Stroke	800,000/year				
VAC1					
Prostate cancer	240,000/year				
AML	12,000/year				
VAC2					
Lung cancer					
CellCure					
OpRegen					
Dry AMD	7.3 million prevalence				





### Developing Breakthrough Technologies for Regenerative Medicine

Pedro Lichtinger, CEO

Former CEO Optimer Pharmaceuticals, and President of Pfizer's Global Primary Care Unit



## OPC1 – Unmet Medical Needs



#### The First hESC-Derived Product in the Clinic



#### AST-OPC1

- Safe and feasible in world's first clinical trial of human embryonic stem cell-derived therapy
- Extensive data in non-clinical animal studies demonstrates:
  - -- Engraftment periods of > 1 year
  - -- Extensive cavity filling and myelination
  - -- Improved locomotor function
  - -- No observed toxicity, immunogenicity
- Cleared to enter Phase1/2a study in target population for initial commercial indication (complete cervical SCI)
- Follow-on opportunities in MS, Stroke, other neurodegenerative diseases



### OPC1 - Phase 1/2a Clinical Trial



Indication: OPC1 is a cryopreserved cell product containing human embryonic stem cell (hESC) derived oligodendrocyte progenitor cells (OPCs) for the treatment of subacute spinal cord injury (SCI). OPC1 has three reparative functions (production of neurotrophic factors, induction of remyelination, & induction of vascularization) that promote tissue repair & return of function in the injured spinal cord.

- Multicenter, open-label, dose escalation trial
- Three consecutive dose cohorts, 13 total subjects
- Treatment effect measured at 6 and 12 months
- · Primary endpoint:
  - Safety with respect to: OPC1, the surgical procedure for administration, and the transient immunosuppression
- Secondary endpoint:
  - Neurological function as measured by upper extremity motor scores and motor level in the cervical spinal cord
- 3-4 sites in the United States
- Duration (enrollment and follow up): About 36 months

# OPC1 Opportunity: SC Injury



#### Significant Unmet Medical Need

- Highly debilitating condition with no currently approved therapies
- Lifetime cost of care \$3-4M for complete cervical injury patients
- High economic burden: estimated \$14.5 billion cost of care plus \$5.5 billion lost productivity in US alone

### Attractive Firstto-Market Opportunity

- Incidence of 12,000 per year in US alone
- Low therapeutic dose facilitates manufacturing, reduces COGS
- Concentrated market with most patients treated at <100 US sites

# Focused Path to Market

- · Initial efficacy readout within 2 years
- Defined clinical endpoints to support approval with <300 patient trial
- Potential for breakthrough therapy & orphan designations

# VAC2 - Proof of Concept



Telomerase is expressed in ~95% of cancer types

VAC1 was safe and stimulated anti-telomerase immune responses in two clinical trials with improved or stabilized biomarkers

	Phase 1: prostate cancer Duke J. Immunol 2005, 174:3798	Phase 2: acute myelogenous leukemia Multi-center Khoury ASH 2010
Patients treated	20	21
Tolerability	Excellent	Excellent
Patients immunized against telomerase	95%	55%
Laboratory & clinical impact	<ul> <li>Highly significant increase in PSA doubling times</li> <li>Clearance of circulating immune complexes</li> </ul>	<ul> <li>Significant increase in 12-month DFS in high-risk group (N=11) compared to published historical controls</li> </ul>

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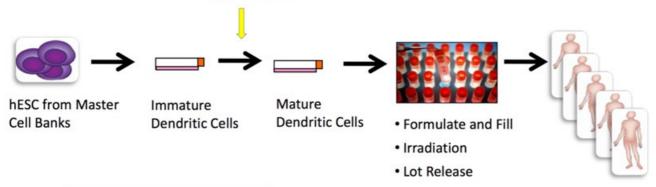
# VAC2 - Unmet Medical Needs



### Advantages of VAC2 Platform







#### Mechanism of Action

- Present antigen on restricted HLA
- Participate in indirect antigen presentation
- Adjuvant allogeneic effect

- Hundreds of doses
- · Off-the-shelf availability
- Treat a large patient pool

# VAC2 Opportunity: NSC lung cancer



#### Significant Unmet Medical Need

- 5 year survival rates of <20% for Stage 3 & 4 disease, <50% for Stage 2 disease<sup>1</sup>
- Estimated annual costs in US alone of \$12.1 billion, plus \$36.1 billion in lost productivity due to early death<sup>2</sup>

#### Substantial Market Opportunity

- 400,000 new cases per year in the seven major markets<sup>3</sup>
- \$4.6 billion market in 2011, despite significant use of generic chemotherapies<sup>3</sup>
- Precedent for high value treatments (e.g. Xalkori, Zykadia, Avastin)

#### Existing Proof of Concept for Immunotherapy

Multiple published studies in animal models an human clinical trials

<sup>1</sup> Source: Cancer Research Technologies

<sup>2</sup> Source: National Institutes of Health

<sup>3</sup> Source: Decision Resources





### Advancing Medicine Through Stem Cell Therapies

Charles Irving, Ph.D., CEO



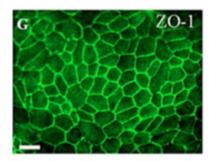
# OpRegen® – Unmet Medical Needs

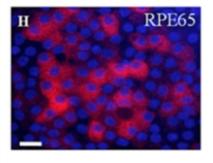


### Current wet AMD market estimated at > \$5B



- 7.3 million have early stage <u>dry</u> AMD in US (10x wet form)
- Any effective treatment expected to achieve blockbuster sales
- OpRegen® Suspension of retinal pigment epithelial (RPE) cells for dry age-related macular degeneration (AMD)
- OpRegen® Plus Matrix bound RPE cells for dry AMD
- Partnered with TEVA





http://www.amd-therapy.de/en/investment/market-and-competition

# OpRegen® – Phase I/IIa Clinical Trial **EBIOTIME**

Indication: OpRegen® is a suspension of allogeneic human retinal pigment epithelium (RPE) cells intended to replace diseased or missing RPE cells in patients with geographic atrophy, the severe stage of dry form age-related macular degeneration. OpRegen® is intended to be transplantated subretinally using existing surgical skills.

- Dose escalation safety trial
- 15 patients divided into three cohorts each of three legally blind patients, followed by a fourth cohort of six patients with better vision that will receive the maximum dose. All patients will be followed up for 12 months post-transplantation.
- Primary endpoint:

Safety and tolerability of OpRegen®

- Secondary endpoint:
  - Measure of the ability of OpRegen® cells to engraft, survive, and moderate disease progression
- Single site Hadassah Medical Center, Jerusalem
- Duration (enrollment and initial follow up): 23-26 months

# OpRegen Opportunity: Dry AMD





#### Significant unmet medical need

- 7.3 million U.S. patients with early-stage dry AMD (age-related macular degeneration)
- · No cure: any effective treatment would likely achieve blockbuster sales
- Current treatment market estimated at \$5-10 billion<sup>1</sup>

# Novel technological approach

- OpRegen®: suspension of RPE (retinal pigment epithelial) cells for dry AMD
- OpRegen® Plus: matrix-bound RPE cells for dry AMD

# Cost-efficient partnership approach

· Partnered with TEVA

<sup>&</sup>lt;sup>1</sup> Source: http://www.amd-therapy.de/en/investment/market-and-competition

# Device & Diagnostic Pipeline



### **BIOTIME**

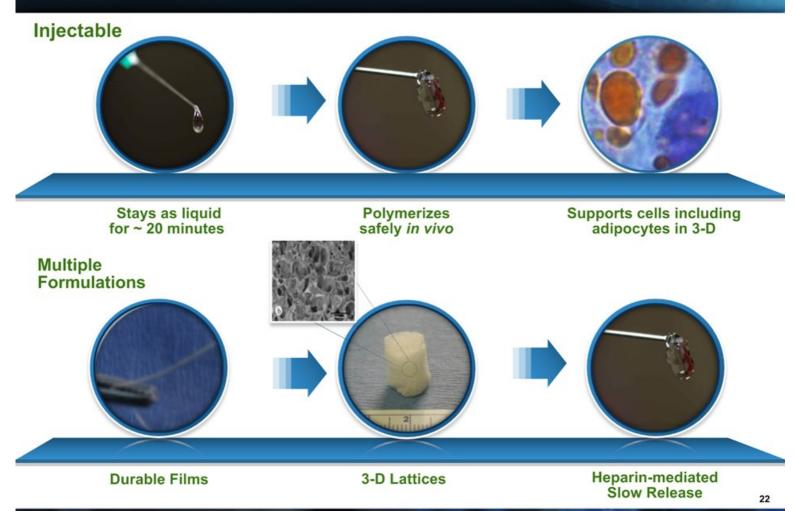
		Design control /	Clinical development			
Platform	Pre-Clinical	IND enabling	Safety	Efficacy	Pivotal	Regulatory Pathway
HyStem® Renevia	Injectable for the tr	eatment of lipoatrophies		Pivotal		CE Mark as a medical device
<i>HyStem</i> ® ReGlyde	Protection following	g surgery	N/A	N/A	N/A	510 (k) device
<i>HyStem</i> ® Premvia	Wound Manageme	ent				Cleared Class II device August 2014

### ONCOCYTE

Indication	Research	Development	Clinical Validation	Commercialization
Breast	Screening/Recurre	ence Setting	Clinical Studies in Progress	
Bladder	Screening/Recurre	ence Setting	Clinical Studies in Progress	
Lung	High Risk Screening	ng	Clinical Studies in Progress	

# HyStem - Unmet Medical Needs





## Renevia - Medical Need



- Based on animal studies Renevia<sup>TM</sup>
  is expected to have numerous
  applications in the stable engraftment
  of CNS, heart, osteochondral, liver,
  adipose, and other cell types.
- BioTime initially is seeking a CE mark to apply the technology to HIVassociated lipoatrophy using autologous ASF cells.
- An estimated 33M people worldwide have HIV
- An estimated 35% of patients on ARV therapy have lipoatrophy
- A greater number of people in the US have age-related lipoatrophy



Age-Related Lipoatrophy

### Renevia<sup>TM</sup> – Pivotal Clinical Trial



Indication: Renevia™ is a resorbable matrix to be used for the delivery of autologous adipose derived cells for the treatment of HIV-related facial lipoatrophy. Renevia™ serves as a temporary 3-dimentional matrix in which the implanted cells can attach, proliferate and differentiate into adipocytes.

- Multicenter, randomized, controlled, single blind, trial
- Treated vs. delayed treatment control, 25 45 subjects in each group with treatment effect measured a 1, 3, and 6 months
- Primary endpoint:
   Increase in skin thickness as measured by ultrasound at 6 months
- Secondary endpoint:
   Mid-face volume deficit score, Global Aesthetic Improvement

   Score
- Two sites in Palma de Mallorca, Spain
- Duration (enrollment and follow up): 18 24 months

# 2014 Milestones – HyStem









- Initiation of Renevia<sup>™</sup> pivotal clinical trial
- 510(k) clearance for Premvia™
- 2014-15 file 510(k) application for ReGlyde™

## Renevia Opportunity: Lipoatrophy



#### Significant Unmet Medical Need

- Current standard of care utilizes dermal fillers<sup>1</sup>
- · Most dermal fillers have suboptimum aesthetic properties

#### Substantial Market Opportunity

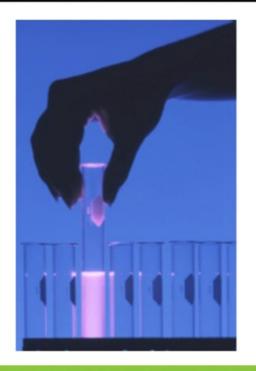
- · 33 million cases of HIV infection worldwide
- Up to 35% of people with HIV on ARV therapy have lipoatrophy1
- Precedent for injectibles (e.g. HA, Calcium hydroxylapatite)

#### Existing Proof of Concept for Lipotransfer

 Cell-assisted lipotransfer already widely used clinically, and demonstrates need for matrix to increase uniformity of graft

<sup>&</sup>lt;sup>1</sup> Source: AIDS Care Vol. 21, No. 5, May 2009, 664-671





### Advanced Noninvasive Cancer Diagnostics

Joseph Wagner, Ph.D., CEO



# PanC-Dx - Cancer Diagnostics





- Novel products for the diagnosis and treatment of cancer in order to improve both the quality and length of cancer patients' lives
  - Internally developed cancer gene discovery platform
  - Platform based on extensive microarray dataset
  - Market discovery principle based on similarity between embryonic development and cancer
  - Scores of potential targets identified
  - Multiple product opportunities
- Develop and market low-cost molecular diagnostic tests for major types of cancer

PanC-DX™	Potential market size	Status	Results expected
Breast cancer	\$2.5 billion	Clinical study underway	Late 2014
Bladder cancer	\$500 million	Clinical study underway	Late 2014
Lung cancer	\$525 million	Clinical study underway	Late 2014

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## PanC-Dx – Breast Cancer Study



Proposed Use: The  $PanC-Dx^{TM}$  breast cancer diagnostic is a multi-analyte, blood-based test designed to i) detect presence of malignancy in otherwise asymptomatic patients, and ii) detect recurrence of disease in patients with a past history of breast cancer

- Single multicenter cohort-design study
- Up to 800 patients will be enrolled at time of diagnostic mammography (including 200 cancer-positive)
- Primary endpoint:
   Correlation of biomarkers with BI-RADS score
- Secondary endpoint:
   Correlation of biomarkers with pathology
- Currently enrolling at Scottsdale Medical Imaging
- Anticipated completion: late 2014

### PanC-Dx – Bladder Cancer Study



Proposed Use: The PanC-Dx™ bladder cancer diagnostic is a multi-analyte, urine-based test designed to detect i) recurrence of disease in patients with a past history of bladder cancer, and ii) presence of bladder cancer in patients presenting with hematuria

- Two multicenter cohort-design studies
- Up to 1100 patients will be enrolled at time of cystoscopy (including at least 150 cancer-positive)
- Primary endpoint:
   Correlation of biomarkers with cystoscopy and cytology results
- Secondary endpoint:
   Correlation of biomarkers with pathology
- First study underway in US; sites currently being selected for second study
- Anticipated completion first study: late 2014
- Anticipated completion second study: mid 2015

## PanC-Dx – Lung Cancer Study



Proposed Use: The *PanC-Dx*™ lung cancer diagnostic is a multi-analyte, blood-based test designed to distinguish benign from malignant nodules in high-risk patients undergoing surveillance low-dose CT

- Two cohort-design studies at 7 total sites
- Approximately 730 patients have been enrolled to date (including over 300 cancer positive)
- Primary endpoint:
   Correlation of biomarkers with pathology
- Secondary endpoint:
   Correlation of biomarkers with stage, tumor type
- Studies being conducted in collaboration with the Wistar Institute and Weill Cornell Medical College
- Anticipated completion both studies: mid 2014

### PanC-DX<sup>™</sup> - Opportunity #1: Breast CA



Blood-based screening diagnostic measures sera protein biomarkers using ELISA. Clinical study underway & in discussions with additional sites



# Initial use and market

- Radiologists: management of BIRADS 3-4 patients
- · 350k tests per year in the U.S.
- · Estimated at \$25 million

# Expanded use and market

- Radiologists: in conjunction with all diagnostic mammography
- Oncologists: recurrence surveillance
- 3 million tests per year in the U.S.
- · Estimated at \$250 million

# Final target use and market

- PCP/radiologists: in conjunction with—or surrogate for—screening mammography
- >30 million tests per year in the U.S.
- · Estimated at \$2.5 billion

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### PanC-DX<sup>™</sup> - Opportunity #2: Bladder CA



Urine-based multiplex PCR recurrence diagnostic test. Ongoing patient studies in U.S. & China with additional sites to be selected



# Initial use and market

- Pathologists: resolution of indeterminate cytology during recurrence surveillance
- 500k tests per year in the U.S.
- Estimated at \$15 million

# Expanded use and market

- Oncologists: all recurrence surveillance
- 1.5 million tests per year in the U.S.
- Estimated at \$150 million

# Final target use and market

- Urologists: management of hematuria
- 5 million tests per year in the U.S.
- Estimated at \$500 million

# PanC-DX<sup>™</sup> - Opportunity #3: Lung CA



Blood-based lung cancer screen for high-risk population Multi-center study underway with high interest from KOLs



# Initial use and market

- Radiologists & thoracic surgeons: management of LDCT+ patients
- 1.75 million tests per year in the U.S.
- · Estimated at \$125 million

# Final use and market

- Radiologists & thoracic surgeons: used in conjunction with or as surrogate for LDCT in all high-risk patients
- >7 million tests per year in the U.S.
- · Estimated at \$525 million

## BioTime (NYSE Market: BTX)



### Strong Board, Management, and Financial Structure

### **Key Statistics:**

- \$24.8 MM available: ~\$8.5 MM available in cash plus \$16.3 MM in registered BTX shares held by subsidiaries that are available for sale (as of September 5, 2014)
- No debt

- Revenues of \$1.1 MM and \$2.2 MM during the three and six months ended June 30, 2014, respectively
- BTX market cap approx. \$223 MM, owns 72% of ASTY (market cap approx \$191 MM (as of September 5, 2014)

Long-term investors hold approx. 40% of BTX stock

# Long-Term Value Creation Strategy BIOTIME

	BioTime	Traditional Biotech
Potential to be the overall leader in the next generation of biotech?	YES	NO
Broad technology base with many product opportunities?	YES	NO
Products not easily vulnerable to generic or biosimilar competition?	YES	NO
Broad IP portfolio?	YES	NO
Spinoff technologies with near-term market potential?	YES	NO
Frugal spending history?	YES	NO
History of funding programs partially through non-dilutive research grants?	YES	NO
Not primarily a binary bet on a single product in clinical trials?	YES	NO

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# BioTime – Investment Opportunity



Positioned as the technology leader in the coming regenerative medicine revolution



