#### **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): January 12, 2015

# **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 belov	w if the Form 8-K filling is intended	i to simuitaneousiy satisiy	tne ming obligation of the	ne 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))

#### 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 the accompanying Exhibit 99.1 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 January 12, 2015, Michael D. West, our Chief Executive Officer, will provide an update on product development by BioTime and its subsidiaries in certain private meetings. Dr. West's presentations 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: January 12, 2015 By: s/Robert W. Peabody

Senior Vice President and Chief Financial Officer Exhibit Number 99.1

<u>Description</u> Slide presentation



## Safe Harbor Statement

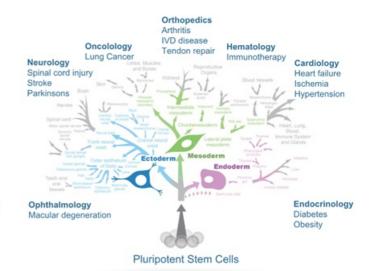


The matters discussed in this presentation include forward looking statements which are subject to various risks, uncertainties, and other factors that could cause actual results to differ materially from the results anticipated. Such risks and uncertainties include but are not limited to the success 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.

# Leading Regenerative Medicine



- Pluripotent stem cell platform provides competitive barriers:
  - Potential to manufacture all human cell types on an industrial scale
  - Regenerative vs. palliative therapy
  - Targeting large degenerative disease markets
  - 600 patents/patent applications worldwide
  - Attractive manufacturing costs
  - Long asset life no FDA pathway for generics or biosimilars
- Anticipating multiple near-term clinical milestones
- Building board and management for initial commercialization



# Near-Term Value Creation



Over the next 12 months, BioTime and its subsidiaries are positioned to increase shareholder value by...

- 1. Announcing results from six clinical studies
- 2. Commercializing cancer screening diagnostics
- 3. Completing Renevia pivotal clinical trial
- 4. Implementing clinical and financial de-risking strategies
- 5. Unlocking subsidiary company value for BioTime shareholders
- 6. Building management & Board for commercial phase

## Clinical Milestones in 1H 2015



- Publication and presentation at major scientific meetings on results of clinical studies of the PanC-Dx family of diagnostics addressing lung, bladder and breast cancer
- 2. **Interim data** from the pivotal trial of *Renevia*, a therapeutic product addressing a large market opportunity in lipoatrophy
- Completion of enrollment of first cohorts in two Phase 1/2a clinical trials (OpRegen and OPC1) each addressing multi-billion dollar market opportunities

# **Product Pipeline**



## Multiple products, each addressing large market opportunities

Product	Medical Need	Market Opportunity
OPC1	Spinal cord injury	> \$20B economic impact in U.S.
VAC2	Non-small-cell lung cancer	> \$38B economic impact in U.S.
OpRegen	Dry AMD	> \$5B annual spend on wet AMD maintenance therapies
Renevia	Lipoatrophy	> 3M HIV patients
PanC-Dx	Cancer diagnostics	\$7B annual cost of mammography in U.S.

# **Subsidiary Strategy**



## Maximizing shareholder value in a broad platform company

- Increases financial flexibility at both the corporate and subsidiary level
- Limits direct dilution to existing shareholders of BTX
- Attracts talented executives with focus on diverse fields of medicine
- Allows investors to focus on opportunities that most interest them
- Enables development of more products using our broad technology platforms
- Limits downside risk by spreading investments among multiple opportunities
- Maintains upside potential as subsidiaries address large market opportunities

# **Major Therapeutics**



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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 NeuroSciences Ltd.					
OpRegen					
Dry AMD	7.3 million prevalence				





Developing Breakthrough
Technologies for
Regenerative Medicine
(NYSE MKT: AST)

Pedro Lichtinger, CEO

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



# OPC1 - Phase 1 Results



#### Feasible and Safe



- Five subjects received 2 mil AST-OPC1 cells, followed for 2-3 years
- Clean safety profile observed to date:
  - No serious adverse events related to surgery, AST-OPC1, or immunosuppression
  - Monitoring through one year shows no evidence of immune responses to AST-OPC1
- Potential evidence of biological activity:
  - MRI results in 4 of 5 subjects are consistent with prevention of lesion cavity formation
- Cleared to enter Phase 1/2a trial in target population for initial indication: complete cervical SCI



## OPC1 - Phase 1/2a Trial





# Indication: Complete Cervical Spinal Cord Injury

- High level of unmet medical need no approved therapies, high level of disability & lifetime cost of care
- Clear path to market endpoint measurements established by SCOPE initiative

### Objectives:

Safety and preliminary efficacy

- Establish safety of AST-OPC1 in cervical sensorimotor complete
   SCI
- Assess effects on upper extremity motor function
- Investigate effects on additional measures of neurological function

### Trial Design:

Sequential cohort, dose escalation

- · Dose three pts with two million AST-OPC1 cells
- After 30 days, dose five pts with 10 million AST-OPC1 cells
- · After 30 days, dose five pts with 20 million AST-OPC1 cells
- First patient enrollment anticipated in second guarter of 2015

# 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>	Significant increase in 12-month DFS in high-risk group (N=11) compared to published historical controls

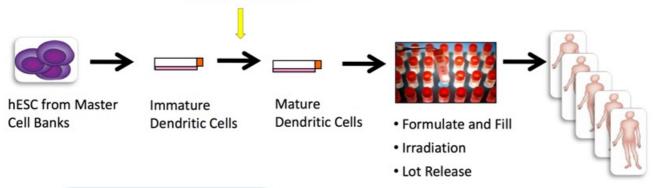
# VAC2 - Unmet Medical Needs



## 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

# AST-VAC2 - Trial Design





# Indication: Non-small Cell Lung Cancer

- Immune blockade inhibitor trials demonstrate sensitivity of lung cancer to immunotherapy
- Proof of concept for telomerase antigen in lung cancer
- · High level of unmet medical need with current therapeutic regime

#### Objectives:

Safety and preliminary efficacy

- Establish safety of AST-VAC2 in resected and advanced disease settings
- Assess generation of anti-telomerase and anti-VAC2 immune responses
- · Investigate initial measures of clinical activity

# Trial Design:

- 5 pts w/ resected NSCLC: 6 vaccinations of 1 million AST-VAC2 cells
- 12 pts w/ resected NSCLC: 6 vaccinations of 10 million AST-VAC2 cells
- 12 pts w/ advanced NSCLC: 6 vaccinations of 10 million AST-VAC2 cells

# 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

Source: Cancer Research Technologies
 Source: National Institutes of Health

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





## Advancing Medicine Through Stem Cell Therapies

Charles Irving, Ph.D., CEO





## AMD and Loss of RPE Cells

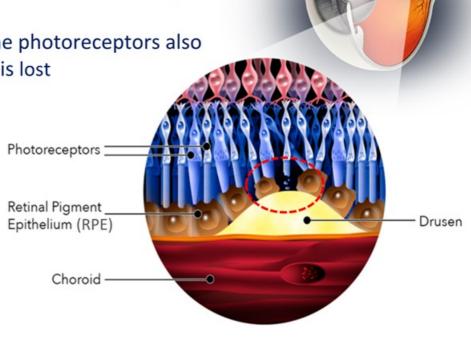


 Photoreceptors depend on RPE cells for nourishment, recycling of visual pigment and waste disposal

 When RPE cells die, the photoreceptors also die and central vision is lost

Geographic Atrophy





## OpRegen



## Therapy for Dry-AMD



- OpRegen®: Cell replacement therapy for the dry form of age—related macular degeneration (dry-AMD) utilizing a suspension of animal product-free RPE cells produced from human embryonic stem cells.
- Indication: Geographic atrophy (the severe dry-form AMD)
- Formulation: Cell suspension in BSS Plus; ready for injection
- Delivery Route: Subretinal administration
- Mechanism of Action: Integration into subretinal space and replacement of missing or diseased RPE cells
- Planned Clinical Trial: Phase I/IIa trial in progressive dry-form AMD with GA
- Study Site: Hadassah Univ Medical Center, Jerusalem
- Stage of Development: FDA & Israel Ministry of Health authorization received





## OpRegen



## **Trial Design**



- Phase I/IIa Dose Escalation Safety and Efficacy Study of OpRegen® Transplanted Subretinally in Patients with Advanced Dry-Form AMD (Geographic Atrophy)
- Open label, non-randomized, sequential, single center trial
- Study Site: Hadassah University Medical Center, Jerusalem, Israel
- Dose and Administration: Single injection of 50,000-500,000 viable cells in saline delivered via a cannula through a small retinotomy into the subretinal space.
- Part 1
  - Cohort 1: 3 Patients, BCVA 20/200 or less, 50,000 OpRegen® cells
  - Cohort 2: 3 Patients, BCVA 20/200 or less, 200,000 OpRegen® cells
  - Cohort 3: 3 Patients, BCVA 20/200 or less, 500,000 OpRegen® cells
- Part 2
  - Cohort 4: 6 Patients, BCVA 20/100, 500,000 OpRegen® cells

# Device & Diagnostic Pipeline



#### **BIOTIME**

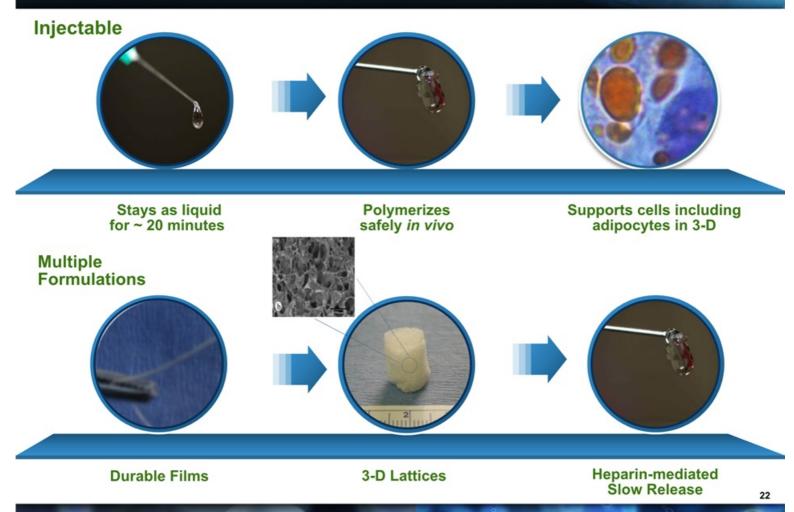
		Design control /	Clin	ical developme	ent	
Platform	Pre-Clinical	IND enabling	Safety	Efficacy	Pivotal	Regulatory Pathway
HyStem® Renevia	Injectable for the tr	reatment of lipoatrophies		Pivotal		CE Mark as a medical device
<i>HyStem</i> ® ReGlyde	Protection followin	g surgery	N/A	N/A	N/A	510 (k) device
<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	2015
Bladder	Screening/Recurre	ence Setting	Clinical Studies in Progress	2015
Lung	High Risk Screening	ng	Clinical Studies in Progress	2015

# HyStem - Unmet Medical Needs





## Renevia™ Pivotal Trial



- Renevia<sup>™</sup> is an injectable matrix designed to safely produce 3-D tissue in vivo, keeping cells where the surgeon places them. It is expected to have numerous applications in multiple tissue types
- BioTime initially is seeking a CE mark for use in HIV-associated lipoatrophy in combination with autologous fat cells.
- An estimated 33M people worldwide have HIV. Number on HIV treatment has tripled in five years – now ~10M, target of 15M by the end of 2015.
- An estimated 35-50% of patients on ARV therapy have lipoatrophy.
- A greater number of people in the US have lipoatrophy due to wounds and age.



**Age-Related Lipoatrophy** 

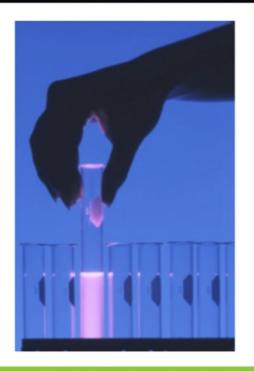
# Renevia<sup>TM</sup> Pivotal Trial



## **Trial Design**

Multicenter, randomized, controlled, single blind trial				
Treated vs. delayed treatment control	25 - 92 subjects in each group with treatment effect measured at 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			
Sites	2 sites in Palma de Mallorca, Spain			





## 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 Announced
Breast cancer	\$2.5 billion	Clinical study underway	1H 2015
Bladder cancer	\$500 million	Clinical study underway	1H 2015
Lung cancer	\$525 million	Clinical study underway	1H 2015

## **Balance of Near-Term Products**



### Three Diagnostic Products to be Commercialized within 12 Months

#### PanC-Dx™ Breast Cancer Diagnostic:

- Blood-based screening diagnostic
- Panel of protein markers
- \$25M initial market opportunity, \$2.5B expanded opportunity

#### PanC-Dx™ Bladder Cancer Diagnostic:

- Urine-based screening diagnostic for recurrence
- Panel of RNA markers
- \$15M initial market opportunity, \$500M expanded opportunity

#### PanC-Dx™ Lung Cancer Diagnostic:

- Blood-based screening diagnostic
- Panel of RNA markers
- \$25M initial market opportunity, \$525M expanded opportunity

# Clinical De-Risking Strategies



- OPC1: Initiative to accelerate current timelines for clinical program by about six months to obtain safety and efficacy readouts more rapidly
- OPC1: Accelerated trial by six months and announced intent to strengthen robustness of proof of concept by seeking FDA permission to expand the number of patients from 13 to 40
- PanC-Dx<sup>™</sup> and Renevia are judged by the company to be relatively low-risk products



#### **AST-OPC1**



#### \$14.3 Million Grant

- Includes funding for:
  - Execution of Phase 1/2a study
  - Process and assay development activities to prepare for pivotal trials and commercialization
  - Facilities and indirect costs
- Potential follow-on grants to expand and accelerate trial

#### **AST-VAC2**



#### **Clinical Development Partnership**

- Asterias performs scale-up and tech-transfer of AST-VAC2 manufacturing process
- CRUK provides personnel and funding for cGMP manufacturing, regulatory filing, Phase 1/2a trial
- Asterias has first option to reacquire program on preset, reasonable terms; majority revenue share on partner's development if does not choose to reacquire

Estimated ~\$40 Million of Total Non-dilutive Funding

# **Unlocking Subsidiary Value**



Asterias Biotherapeutics is the first of BioTime's subsidiaries to be publicly traded

	Timeline
1	Created subsidiary to acquire Geron stem cell assets
2	Closed acquisition of assets
3	Hired a seasoned management team
4	Appointed Pedro Lichtinger as CEO, a leader with significant commercialization expertise
5	Executed clinical and financial de-risking strategies
6	Executed spin-off to public company
7	Listed on NYSE MKT under symbol "AST"

- BTX owns 72% of ~\$120M AST Market Cap
- BTX has 7 other subsidiaries whose value could be unlocked
- Goal: Unlock value of one additional subsidiary in 2015

## **Building Commercialization Team**



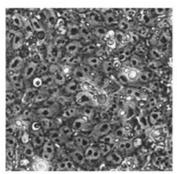
Focused on adding biopharmaceutical industry executives with expertise in clinical development and commercialization

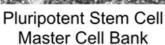
- Appointed Pedro Lichtinger as President and Chief Executive Officer of Asterias, a former Pfizer senior executive with successful drug development and commercialization experience
- Adi Mohanty, former Shire executive, appointed COO of BioTime
- Michael H. Mulroy and Stephen L. Cartt joined BioTime's Board of Directors. Mr. Mulroy and Mr. Cartt both had successful careers in senior management at Questcor Pharmaceuticals, Inc.
- Angus C. Russell, former Chief Executive Officer of Shire plc, appointed to BioTime's Board of Directors

# Improved Product Manufacture



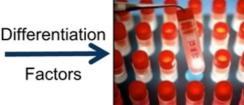
## Advantages of Pluripotency Platform







- Limitless expansion
- · Source of every cell type
- · Centralized production
- Uniform genetics
- Reduced COGs
- Improved QC



Frozen Inventory





Point of Use

#### Clinical:

- Oligodendrocyte progenitors (SCI)
- RPE cells (AMD)

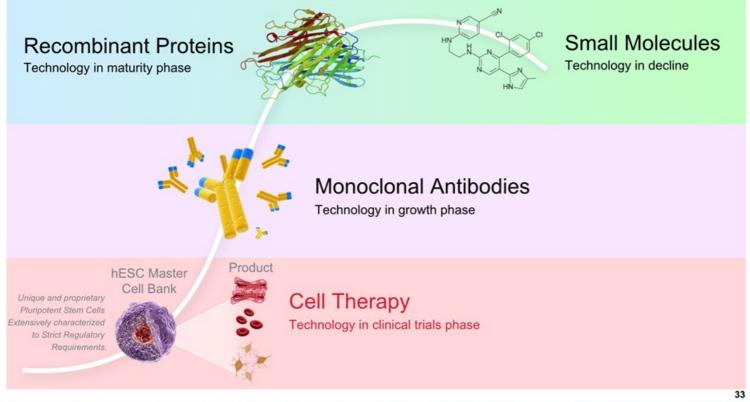
#### Preclinical:

- Dendritic cells (Cancer)
- Brown adipocytes (Type 2 diabetes)
- Vascular cells ischemic disease
- Cartilage cells (spinal disc repair)
- Bone cells (spinal fusion)

# Value of the Pluripotent Platform



Cell therapy: the next wave - with a potentially long lifespan due to lack of regulatory pathway for generics or biosimilars



## BioTime (NYSE Market: BTX)



### Strong Board, Management, and Financial Structure

#### **Key Statistics:**

- \$156M liquid assets: ~\$36M in cash, \$3M in registered BTX shares held by subsidiaries, & \$117M AST shares held by BTX
   (as of October 16, 2014)
- BTX market cap approx.
   \$290M, owns approx. 70% of AST (market cap approx.
   \$130M (as of January 9, 2015)
- No debt

Long-term investors hold approx. 45% of BTX stock

## Summary



- Balance of near- and long-term products
- Emphasis on degenerative diseases with relatively large market potential
- Significant milestones in 2015
- Executing clinical/financial de-risking strategies
- Building commercially-focused management team and Board
- Unlocking subsidiary value (AST first listing on NYSE)
- Powerful pipeline based on pluripotent stem cells
- Long potential asset life due to lack of biosimilars