

Cytori Therapeutics

May 2017



NASDAQ: CYTX

San Diego | San Antonio | Tokyo | Wales

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# Business Highlights- 2017 Focus











Habeo Cell Therapy for Scleroderma  
US phase III enrolled  
Trial read out mid 2017

Profitable Growth in Japan  
Cytori Cell Therapy approved under new law  
Fully enrolled SUI phase III trial 2017

\$106m BARDA Thermal/Radiation Contract  
US clinical milestone pending  
Anticipated 2017

Azaya Acquisition- Nanoparticle Company  
Nanoparticle Doxorubicin bioequivalent to RLD  
Complete bulk manufacturing in 2017

# Cytori Pipeline

Therapeutic	Market	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Launch/Note
<b>Cytori Cell Therapy™</b>							
Habeo™		Scleroderma	██████████	██████████	██████████	██████████	2018/2019
Habeo™		Scleroderma/Cryo*	██████████	██████████	██████████	██████████	2019
Habeo™		2' Raynauds	██████████	██████████	██████████	██████████	2020
ECCO-50		Knee Osteoarthritis	██████████	██████████	██████████	██████████	Available JPN
ECCI-50		Male SUI*	██████████	██████████	██████████	██████████	2019
DCCT-10		Thermal Burn/Radiation#	██████████	██████████	██████████	██████████	Phase I 2017
<b>Cytori Nanomedicine™</b>							
ATI-0918		Breast, Ovarian, Kaposi's	██████████	██████████	██████████	██████████	2019
ATI-0918		Breast, Ovarian, Kaposi's	██████████	██████████	██████████	██████████	
ATI-1123		Multiple	██████████	██████████	██████████	██████████	
CRM-2100		Scleroderma	██████████	██████████	██████████	██████████	

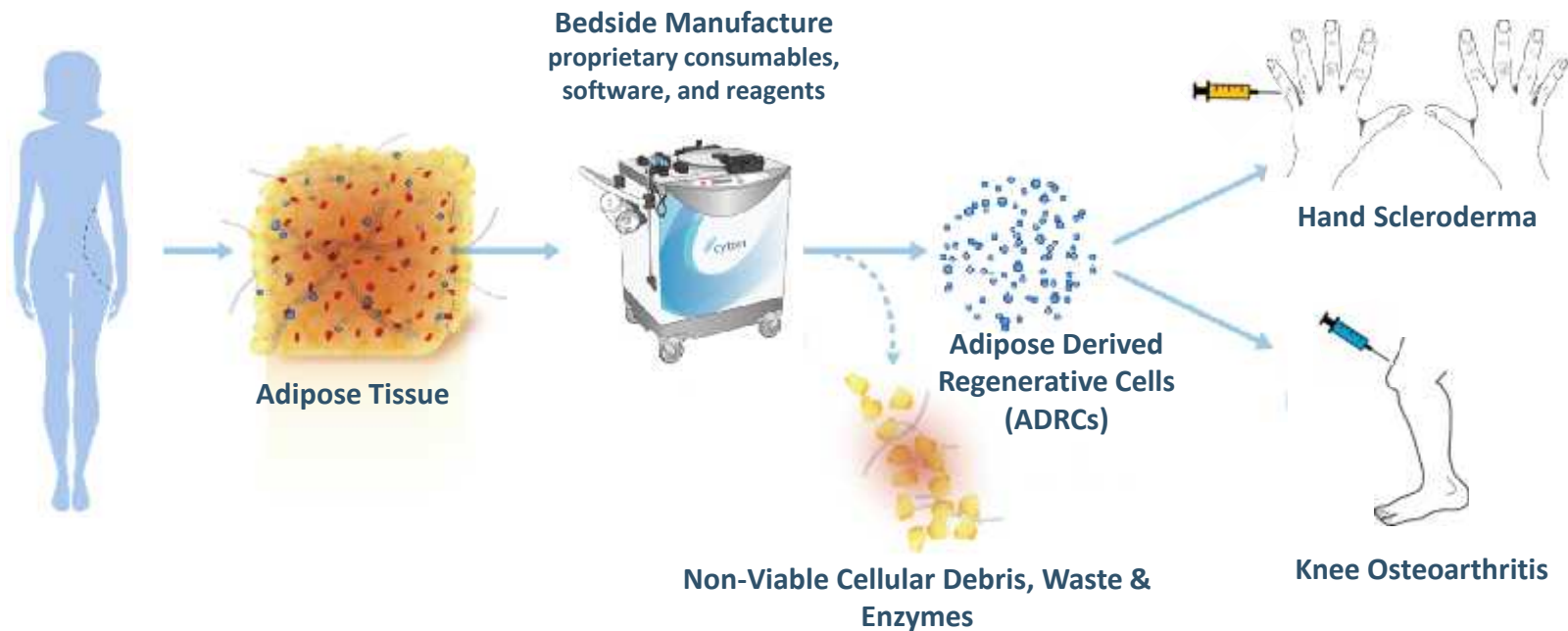
\*Cytori supported, investigator initiated trial  
# BARDA funded program



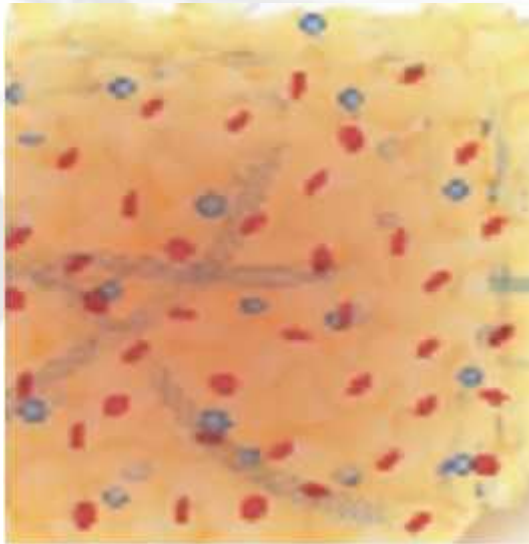
Actual timelines may materially differ from current projections.

# Cytori Cell Therapy: Same Day Procedure

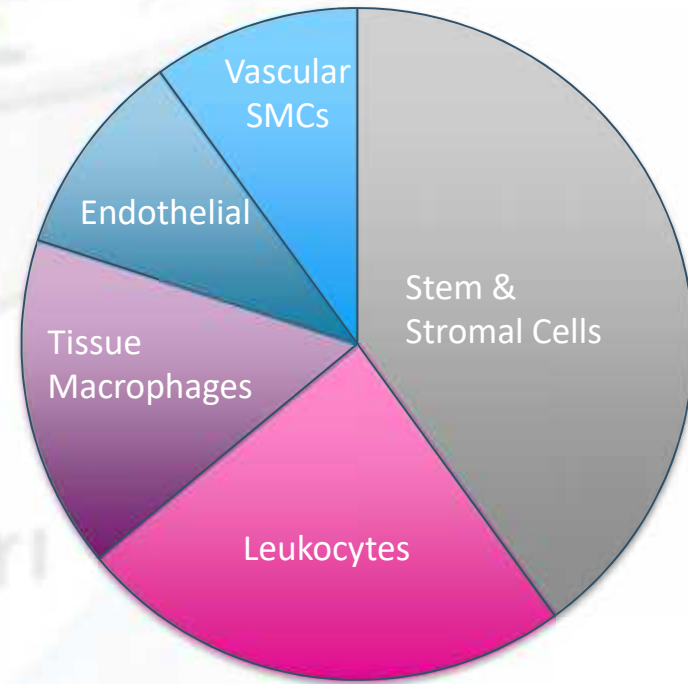
PROCESS	<b>1</b> HARVEST Small Volume Liposuction (100-360 mL)	<b>2</b> PROCESS Celution® System Tissue Processing, Cell Isolation & Dose Preparation	<b>3</b> DELIVER Cytori® Cell Therapy™ Delivery
	TIME	£ 30 Min	£ 120 Min



# Cytori Cell Therapy™



- *Autologous adipose tissue*
- *No cell culture*
- *Manufactured in bedside GMP process*



## Adipose-Derived Regenerative Cells

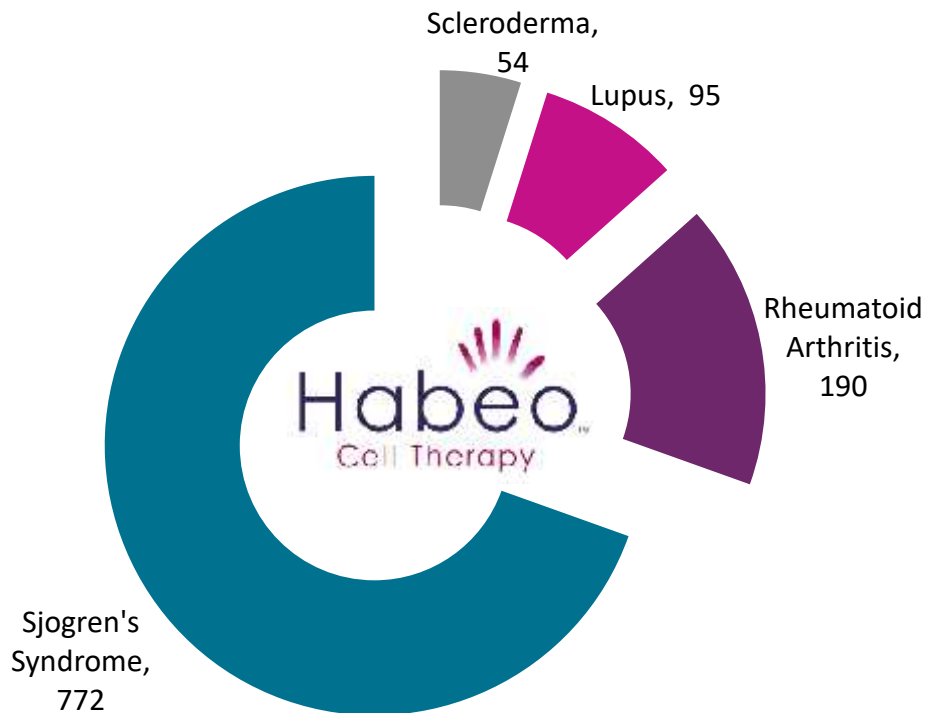
*Autologous, heterogeneous cell population highly-enriched for adipose-derived stem, stromal, vascular, angiogenic and immunoregulatory cell types*



# Habeo Cell Therapy™

## Autoimmune Conditions with Large Unmet Needs

WW Prevalence (000s)\*



### Lead Product Candidate, Scleroderma

No FDA approved treatments for hand dysfunction in scleroderma patients\*

Goal- Habeo positioned as first-in-class therapy with \$600M WW annual peak revenue\*\*

### Label Expansion Opportunity

Raynaud's Phenomenon affects a significant population with connective tissue disease

Goal- Habeo positioned as therapy to reduce duration, frequency, and severity of attacks with \$1.6B WW annual peak revenue\*\*

# Scleroderma

## Scleroderma or Systemic Sclerosis

- Rare autoimmune condition
- Affects Women: Men, 4:1
- US Prevalence: 50,000 patients
- >90% of patients have hand disability
  - Fibrosis, pain, and edema result in diminished mobility and hand function even with standard medical care
  - Severe vasomotor symptoms

### Pathophysiology

*Endothelial Dysfunction*

*Vascular Damage*

*Chronic Inflammation*

*Fibrosis*

*Diminished Hand Function*

*Ulcers & Amputation*



**Raynaud's Phenomenon**



**Ulceration and Edema**

## Cytori Cell Therapy

Preclinical and in vitro studies reported modulation of perivascular inflammation, improved endothelial function, and reduction of extracellular matrix (fibrosis)

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Image on left by D Niklas, <https://commons.wikimedia.org/wiki/File:Raynaud-Syndrom.JPG> used under CC license  
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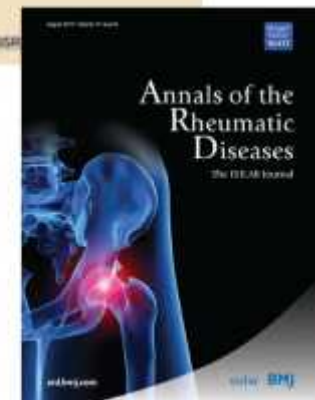
# Habeo Cell Therapy™ Treatment Approach

- Ambulatory
- Procedure room
- Local or mild conscious sedation
- Single administration Habeo
- 0.5cc injection to each NVB
- 4m cells/digit



# Pilot/Phase I- SCLERADEC I Trial

	SCLERADEC I
Study size	12
Randomization	Open label*
Administration	Single administration (~4m cells/finger)
Sites	Single site - Marseille, France
Endpoints	<ul style="list-style-type: none"> <li>• Cochin Hand Function Scale</li> <li>• Raynaud's Condition Score</li> <li>• Scleroderma Health Assessment Questionnaire</li> <li>• Pain</li> <li>• Modified Rodnan Skin Score</li> <li>• Capillaroscopy</li> <li>• Adverse events</li> <li>• Other</li> </ul>
Follow-Up	36 months
Status	<b>Complete</b>



- **Six , 12 and 24 month data published<sup>1,2,3</sup>**
- **24 month data presented at Systemic Sclerosis World Congress in Lisbon, Portugal, February 19, 2016**
- **36 month follow up data showing sustained benefits materially consistent with those shown on two-year data**

# SCLERADEC I Clinical Data Summary

Pilot clinical data show concordant & sustained benefit across multiple endpoints



Parameter	Baseline	Three Years	% Improvement	p value*
<b><u>Patient-Reported Outcomes</u></b>				
Cochin Hand Function Score (/92)	48.5±10.8	21.3±13.5	56%	<0.0001
Raynaud's Condition Score (/10)	7.2±0.9	0.7±1.6	90%	<0.0001
Pain (VAS/10)	59.4±17.2	26.3±25.9	56%	0.0015
Scleroderma Health Assessment Questionnaire (/3)	1.36±0.3	0.83±0.6	39%	0.005
<b><u>Objective Hand Function</u></b>				
Strength: Pinch (kg)	3.3±0.9	4.4±1.8	42%	0.05
Strength: Grip (kg)	15.4±6.0	18.8±6.8	22%	0.012
Extension: Max. Stretch Index Finger to Thumb (mm)	110.7±24.6	123.5±26.3	12%	<0.0001
Modified Rodnan Skin Score (hand)	10.92±4.85	6.25±4.88	43%	<0.0001
<b><u>Capillaroscopy</u></b>				
	<b><u>Baseline</u></b>	<b><u>12 Months</u></b>		
Vascular Suppression Score	1.7±0.8	1.1±0.7	35%	<0.001
Number of Giant Capillaries (total)	41.4±34.1	17.8±22.0	57%	0.0034
Number of Ramified Capillaries (total)	45.0±47.9	26.2±22.2	42%	0.110

SCLERADEC-I: 12 patient, open label single site study conducted in Marseille, France (Granel et al, 2014; Guillame-Jugnot et al, 2016)

# Habeo Cell Therapy™ Ongoing Clinical Trials

## Clinical/Regulatory Strategy

- EU SCLERADEC I trial data used to support US FDA STAR trial approval, potential EU Conditional Marketing Authorization
- US FDA STAR trial for US PMA approval
- US STAR trial ± SCLERADEC II to obtain Full Marketing Authorization

	STAR (Phase III) 	SCLERADEC II (Phase III)* 
<b>Study size</b>	88	40
<b>Randomization</b>	1:1, active: placebo	1:1 (dose from Pilot, placebo)
<b>Crossover</b>	Placebo, crossover at 48 weeks	Placebo, crossover at 24 weeks (cryo)
<b>Sites</b>	Up to 20 in USA	Up to 6 sites in France
<b>Primary Endpoint</b>	Cochin Hand Function Score (CHFS) at 6 months	Cochin Hand Function Score at 3 months
<b>Secondary Endpoints</b>	CHFS, Raynaud's Condition Score, Scleroderma Health Assessment Questionnaire, Pain, Modified Rodnan Skin Score, Hand Mobility in Scleroderma Test, Adverse events	CHFS, Raynaud's Condition Score, Scleroderma Health Assessment Questionnaire, Pain, Modified Rodnan Skin Score, Capillaroscopy, Adverse events
<b>Follow-Up</b>	48 weeks	24 weeks
<b>Status</b>	<b>Enrolled, Data in mid-2017</b>	<b>Enrolling</b>

# Habeo Cell Therapy™ - Market Overview & Positioning

## Current Standard of Care

- No therapies approved for treatment of hand dysfunction in scleroderma patients
- Existing 1<sup>st</sup> and 2<sup>nd</sup> line treatments for treatment of Raynaud's Phenomenon or other aspects of scleroderma are often inadequate and/or poorly tolerated
- Existing 3<sup>rd</sup> line treatments are costly (\$30-\$100k) and often very poorly tolerated

### 1<sup>st</sup>/2<sup>nd</sup> Line Therapies

**Inadequately effective and/or poorly tolerated in ~50% of patients<sup>1,2</sup>**

- Calcium channel blockers (eg: nifedipine)
- PDE5 inhibitors (eg: sildenafil)
- Topical nitrates
- Side effects: headache, dizziness, flushing, tachycardia and edema

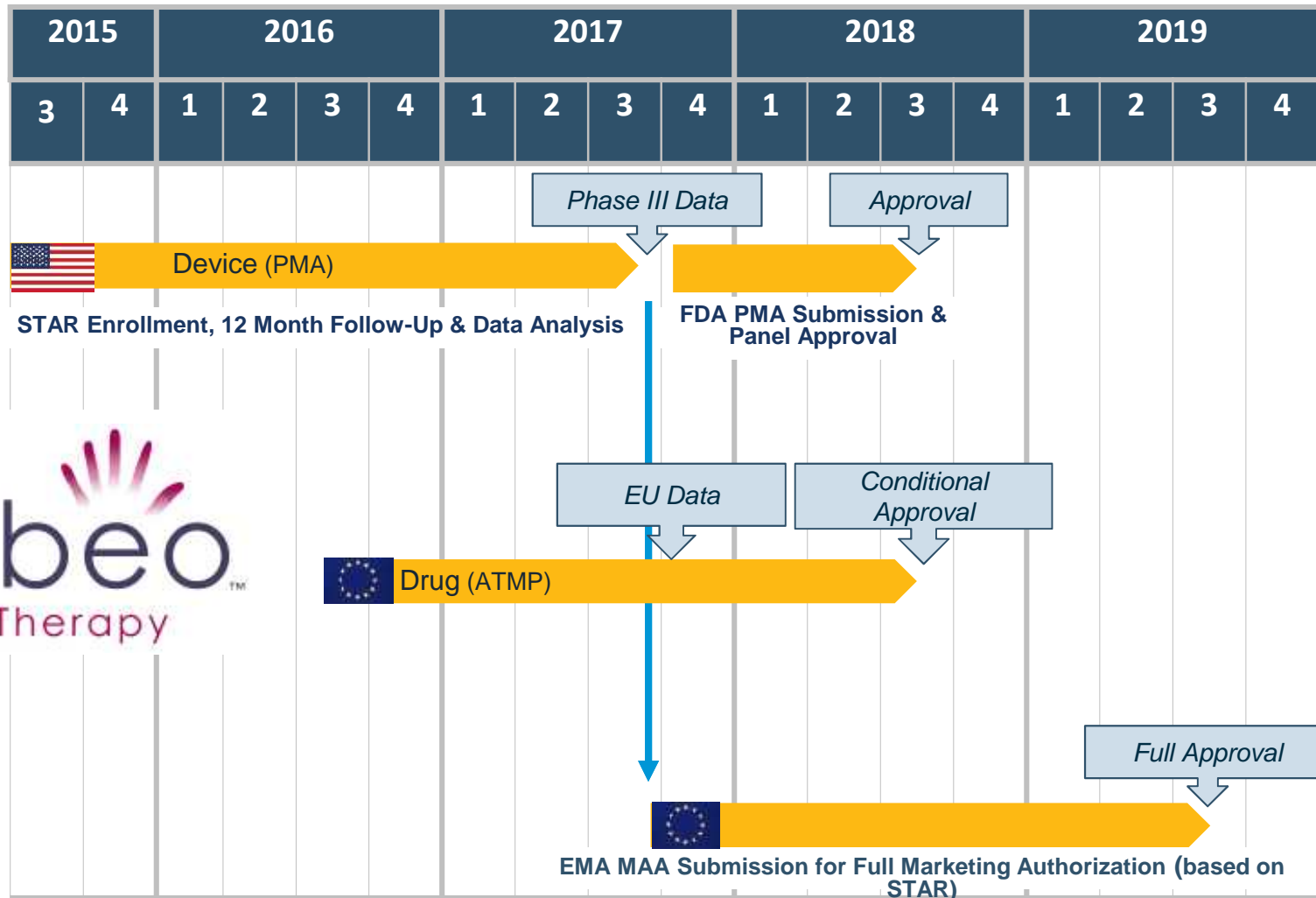


### 3rd Line Therapies

**Expensive, often poorly-tolerated; doses titrated to tolerance rather than to symptom relief**

- Endothelin-1 receptor antagonist (eg: Bosentan)
- Intravenous (IV) prostaglandin (PG) analog (eg: Iloprost)
- Pain due to severe ischemia may require the use of analgesics
- Immunosuppressive agents (eg: methotrexate, cyclophosphamide, azathioprine, mycophenolate)
- Surgical sympathectomy

# Habeo™ for Scleroderma- Projected Development Timeline





# Cytori- US Government Contract



## Contract goal- to develop national countermeasure to treat radiation in conjunction with thermal burn

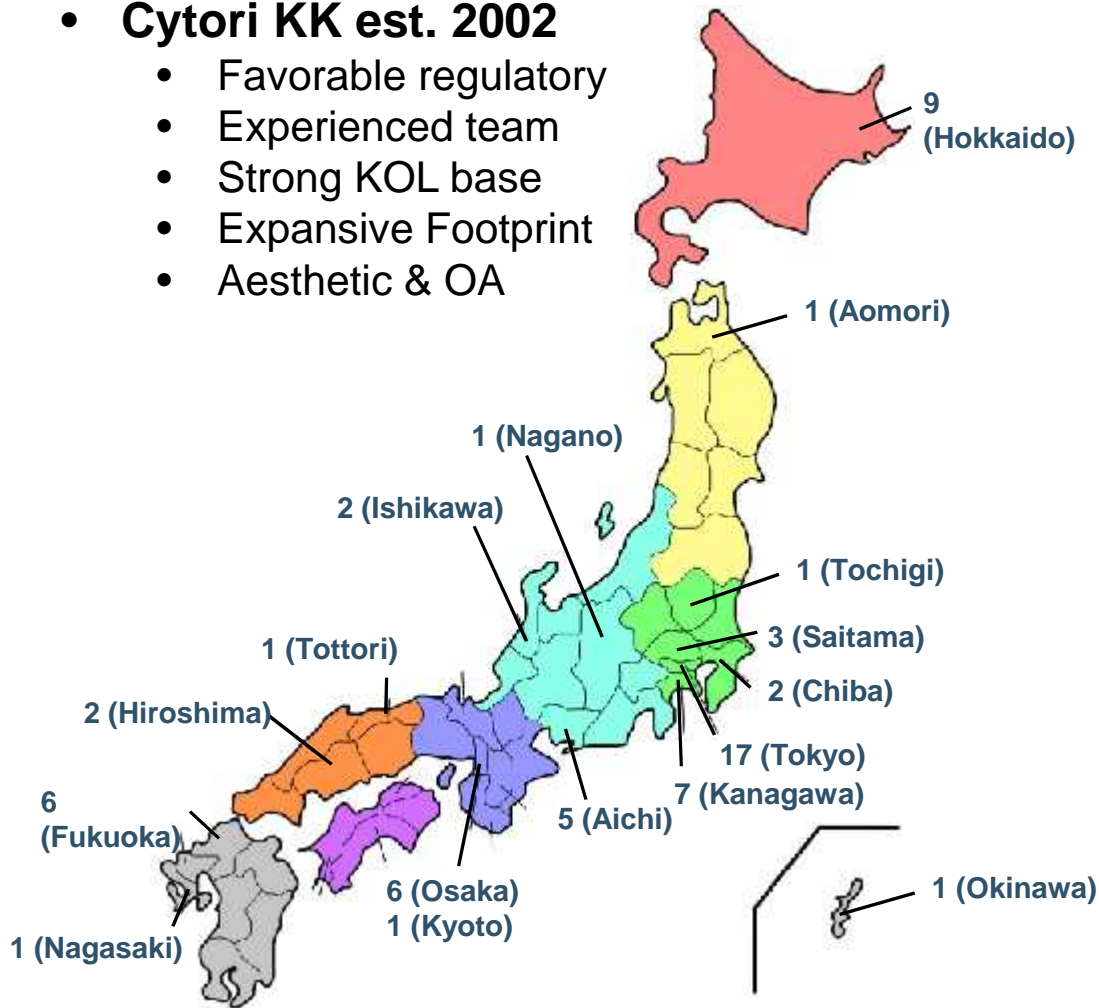
- Funded by contract of up to \$106MM
- \$20.7MM of funding allocated through 1st H 2017
- Successfully completed key rad/burn R&D milestones for clinical introduction
- 2017 Goal- milestone award of ~\$8-12M, contingent upon FDA approval/BARDA review
- 'RELIEF' pilot clinical trial to assess safety and feasibility in patients with large 3rd degree burns undergoing skin grafting
  - Assess patients with 20%-50% total body surface area burn
  - Assess healing of meshed skin grafts
  - Utilize systemic (intravenous) delivery
    - Potential to improve generalized healing- grafted site, partial thickness burns, and skin graft donor site



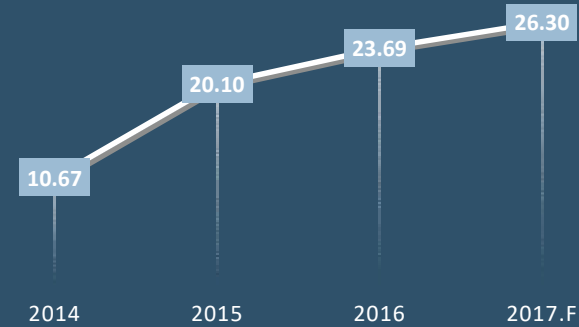
# Japanese Business

- **Cytori KK est. 2002**

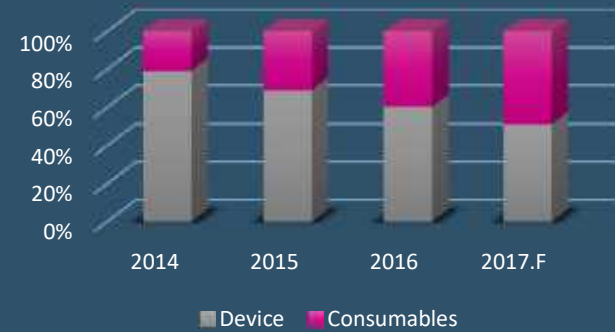
- Favorable regulatory
- Experienced team
- Strong KOL base
- Expansive Footprint
- Aesthetic & OA



UTILIZATION PER ACTIVE DEVICE



Device : Consumable Revenue



**Profitable growth forecasted in 2017**

# 'ADRESU' Phase III Approval Trial



- **Current status**

- Enrolling - 50%+ patients treated

- **Pilot trial data**

- Increase maximum urethral closing pressure
- Reduction 24-hour pad weight
- Increased blood flow
- Pilot clinical trial data published <sup>1,2</sup>

- **ADRESU details**

- Investigator-initiated, 45 pt. multicenter pivotal trial, substantial institutional and governmental support
- Primary endpoint: rate of patients with improvement in urinary leakage volume with greater than 50% reduction from baseline as measured by 24 hour urinary pad weight

- **Development Plan**

- Anticipate enrollment completion 2017
- Assuming positive data, seek approval and reimbursement based on 12 month assessment
- Partnering opportunity



GRADUATE SCHOOL OF MEDICINE  
SCHOOL OF HEALTH SCIENCES

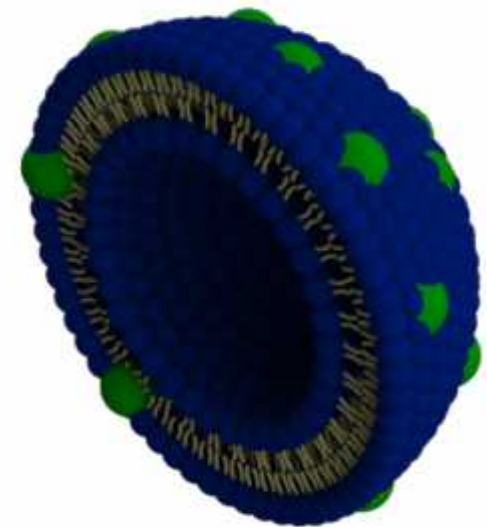


1. Gotoh *et al.* (2014) *Int J Urology* 21 (3) 294-300  
2. Yamamoto *et al.* (2012) *Int J Urology* 19 (7) 652-9

# Cytori Nanomedicine

- **Recent acquisition of proprietary nanoparticle platform technology**
- **US R&D and manufacturing plant**
- **3 Pipeline additions**
  - ATI-0918- complex generic oncology drug- bioequivalent to RLD- Caelyx™
  - ATI-1123- NCE oncology drug- phase II ready asset
  - CRM-2100 nanoparticle based regenerative drug for scleroderma

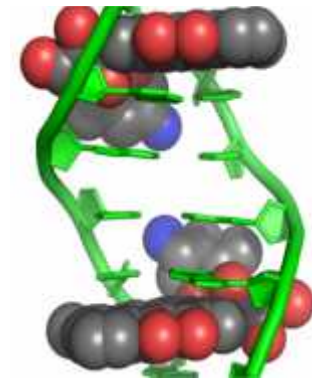
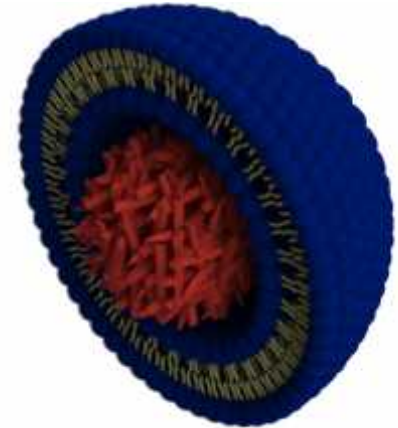
**PSL or Protein Stabilized  
Liposomal Nano Particle  
Technology**



- Sustained release
- Shield toxic drugs
- Deliver molecules and GFs
- Reformulation
- Cell & Tissue Targeting

# ATI-0918 Nanoparticle Encapsulated Doxorubicin

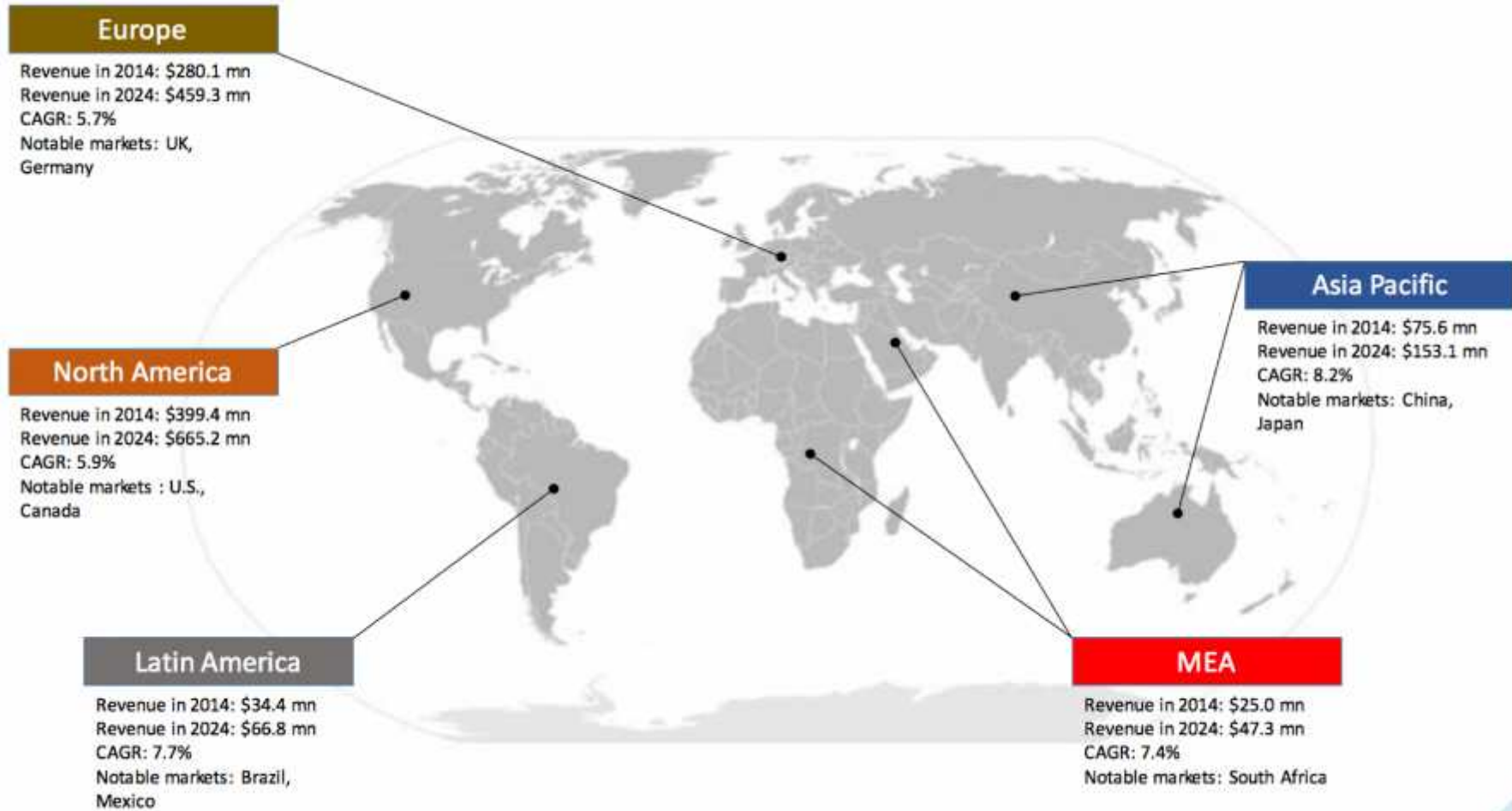
- **Generic nanoparticle, pegylated liposomal encapsulated form of chemotherapeutic, Doxorubicin**
  - Anthracycline topoisomerase II inhibitor
  - Activity via DNA intercalation
- **Encapsulated doxorubicin- much lower cardiotoxicity vs. non-encapsulated doxorubicin**
- **Dx: Breast Ca, Ovarian Ca, Kaposi's Sarcoma, Multiple Myeloma**
- **Market subject to recent global supply shortages**
- **ATI-0918 data is consistent with BE to J&J product, Caelyx™**





# Liposomal Doxorubicin- Estimated Market Growth

## Global market potential growing to 1.4B by 2024



Source: WHO, U.S. CDC, FDA, NIH Journals, Investor Presentations, Primary Interviews, Grand View Research

\*Source: Grand View Research



# ATI-0918 Nanoparticle Encapsulated Doxorubicin

## Regulatory Approval for Generics- ANDA

- **FDA- same process as NDA except bio equivalency (BE) trial substitution for animal studies, clinical studies & bioavailability**
- **ATI-0918 clinical trial data consistent with BE to Caelyx®**
- **Next steps**
  - **File for EMA approval following stability testing**
  - **Discussion with FDA, PMDA (Japan), CFDA (China) to clarify utility of current BE data for approval - ongoing**

# Cytori Nanoparticle Manufacturing Facility in United States



## San Antonio, Texas Facility

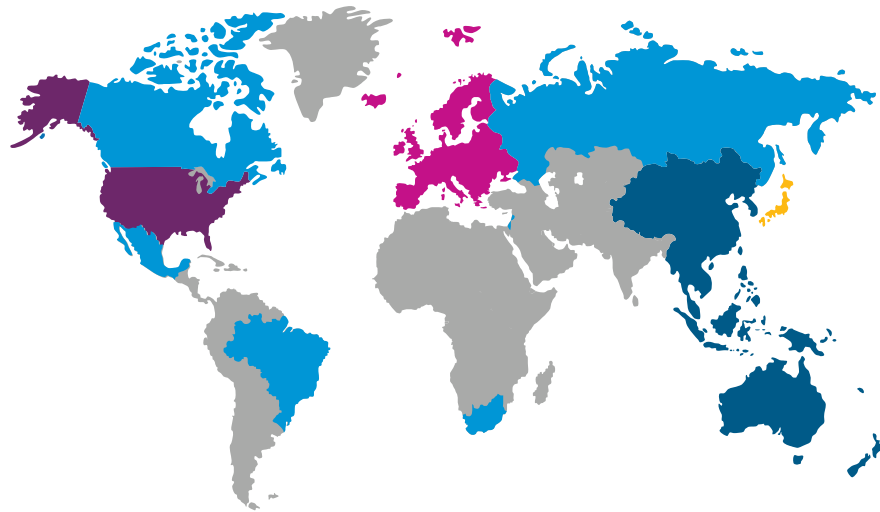
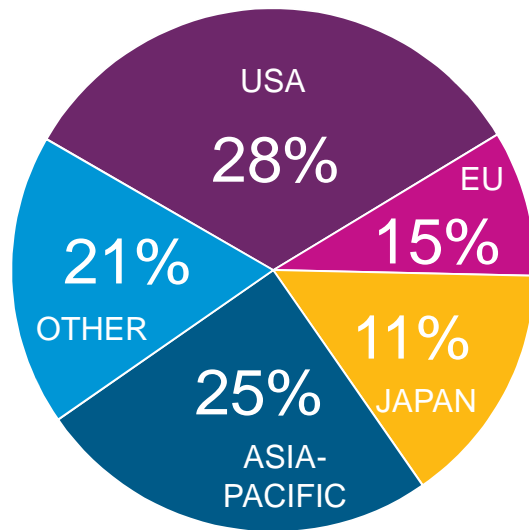
- ✓ Experienced team, 2 positive trials
- ✓ 10 year track record in R&D, manufacture
- ✓ Proprietary processes & controls
- ✓ State-of-the-art GMP manufacturing plant
- ✓ Full in-house analytical lab capability

## Key Milestones

- ✓ Complete- Bioequivalence trial
  - Q4 2017- Initiate stability testing
  - 2017/18 Partnering
  - 2019- EU launch

# Cytori Global Patent Estate

**102 patents issued worldwide; over 65 applications pending**



*Goal: Protect Cytori's proprietary methods and devices for cell therapy & nanoparticle technology as well as methods of using Cytori technology in the treatment of scleroderma, and several other indications.*

# Capitalization Summary

## Select Financial Data – as of 3/31/17

Cash	~ \$15MM (proforma)
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Senior term loan	~ \$15.9MM
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Common Shares outstanding	~ 32.5MM
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Outstanding options, RSAs and warrants	~ 4.8MM
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Fully diluted share count	~ 37.3MM
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Market capitalization	~ \$35MM*
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\* Based on share price of \$1.08 at closing on May 23, 2017

## 2017 Objectives & Milestones

- STAR Phase III one year follow-up data
- Submit for US FDA PMA approval for Habeo™ in scleroderma
- Submission ready for EMA authorization for Habeo™ in scleroderma
- US Phase I BARDA-funded trial initiation
- Full ADRESU enrollment
- IDE for for Habeo™ for secondary Raynaud's
- Complete bulk manufacturing of nanoparticle doxorubicin for EMA approval
- EU commercial partner for nanoparticle doxorubicin

**Thank You**