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- This presentation highlights basic information about us and the offering. Being a summary document, this slide deck does not contain all the information that you should consider before investing.
- We have filed a registration statement (including a preliminary prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the preliminary prospectus in the registration statement (including the risk factors described therein) and other documents, including the Company's Form 10-Ks and Form 10-Q, that we have filed with the SEC for more complete information about us and the offering.
- You may get these documents for free by visiting the "Search EDGAR" section on the SEC web site at http://www.sec.gov. The preliminary prospectus, dated May 11, 2016, is available on the SEC website. Alternatively, we or the dealer-manager for this offering, Maxim Group LLC will arrange to send you a preliminary prospectus if you contact Maxim Group LLC, Prospectus Department, 405 Lexington Ave., New York, NY, 10174; Telephone: (212)-895-3745; Email: syndicate@maximgrp.com.



## Cytori Overview

- Cell therapy technology with viable commercial model
- Multiple programs in phase III
- Lead Indication- Scleroderma therapy EU introduction 2016 via early access program, anticipated US phase III data in 2H 2017 with goal for FDA approval in 2018
- Product & contract revenue growth- increasingly offsetting burn
- Completed substantial corporate repositioning



## Cytori Cell Therapy: Clinical Pipeline

Therapeutic Pre-Clinical Agent	Phase I/II	Phase	<i>III</i>	Marl	ket (Estimate)	
Scleroderma Associated Hand Dysfund	ction					
ECCS-50		Enrolling			>\$1B	
ECCS-50		Enrolling <sup>1</sup>			>\$500M	
Knee Osteoarthritis						
ECCO-50 Enrollme	ent Complete				>\$3B	
Urinary Incontinence						
ECCI-50		Enrolling <sup>2</sup>			>\$75M	
Cutaneous Radiation & Thermal Injury	1					
DCCT-10 Preclinical <sup>3</sup>					>\$50M	
<sup>a</sup> Cytori-supported, Investigator-initiated trial <sup>2</sup> Japan Govt Sponsorship <sup>3</sup> Funded by BARDA (US Govt.)						
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## Cytori 3-Step Bedside Process



## Cytori Cell Therapy: Why Adipose?

Adipose-derived regenerative cells- Clinical grade, heterogeneous cell population highly-enriched for adipose-derived stem, stromal, vascular, and immunoregulatory cell types



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## Cytori Cell Therapy: Mechanism of Action

### Cytori Cell Therapy is being developed with the goal of beneficially modulating multiple key pathologic processes which are anticipated to reduce pain and disability and improve quality of life

#### Angiogenesis/Vasculopathy



- Promotes angiogenesisNormalization of vessel
- architecture
- Improved vasomotor function<sup>1-5</sup>

#### Inflammation



 Modulates expression of proand anti-inflammatory factors
 Modulates the function of proand anti-inflammatory cells<sup>3, 6-9,</sup>

#### Fibrosis/Wound Remodeling



- Reduces development of fibrosis
  Remodels existing
- fibrosis<sup>2,10,11</sup>

1. Foubert et al (2015); 2. Koh et al (2011); 3. Premaratne (2011); 4. Morris et al (2015); 5. Eguchi et al (2015); 6. Feng et al (2010); 7. Hao et al (2014); 8. Dong et al (2013); 9. Data on file (Cytori); 10. Serratrice et al (2014); 11. Data on file (Cytori)



# Lead Indication: Scleroderma



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# 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





Raynaud's Phenomenon

Ulceration and Edema

Endothelial Dysfunction	Vascular Damage Inflammation	Fibrosis	Diminished Hand Function	Ulcers & Amputation	
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### Cytori Cell Therapy

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

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## Scleroderma: Market Overview

### **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

Diagnosis • Average age: 30's-50's	<ul> <li><u>1st/2nd Line Therapies</u></li> <li><i>Inadequately effective and/or poorly tolerated in ~50% of patients</i><sup>1,2</sup></li> <li>Calcium channel blockers (eg: nifedipine)</li> <li>PDE5 inhibitors (eg: sildenafil)</li> <li>Topical nitrates</li> <li>Side effects: headache, dizziness, flushing, tachycardia, and edema</li> </ul>	<ul> <li>3<sup>rd</sup> Line Therapies</li> <li>Expensive, often poorly-tolerated; doses titrated to tolerance rather than to symptom relief</li> <li>Endothelin-1 receptor antagonist (eg: Bosentan)</li> <li>Intravenous (IV) prostaglandin (PG) analog (eg: Iloprost)</li> <li>Pain due to severe ischemia may require the use of analgesics</li> <li>Immunosuppressive agents (eg: methotrexate, cyclophosphamide, azathioprine, mycophenolate)</li> <li>Surgical sympathectomy</li> </ul>
Pcytori	1. Thom 2. Herri	pson et al Arthritis Rheum. 2001;44(8):1841-7 5/11/2016 1 :k (2008) BMJ Clin Evidence 09:1125

## Scleroderma: Treatment Approach

- Ambulatory
- Procedure room
- Local or mild conscious sedation
- Single administration ECCS-50
- 0.5cc injection to each side of each finger





# Pilot/Phase | SCLERADEC | Trial

	SCLERADEC I	
Study size	12	
Randomization	Open label	
Administration	Single administration (~4m cells/finger)	
Sites	Single site (IIS) - Marseille, France	
Endpoints	<ul> <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	24 months	
Status	Complete	



- Six and 12 month data published<sup>1,2</sup>
- 24 month data presented at Systemic Sclerosis World Congress in Lisbon, Portugal, February 19, 2016

1. Granel et al (2014); Ann Rheum Dis Aug 11: doi: 10.1136/annrheumdis-2014-205681 2. Guillaume-Jugnot et al (2015) Rheumatol. 10.1093/rheumatology/kev323

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## SCLERADEC | Improvement Through 24 months

### ECCS-50 Treatment led to improvement in hand function, Raynaud's phenomenon, and pain



### **Key Observation:**

- Concordant reduction (~50%) in four key symptomatic patient reported outcomes
- Efficacy sustained to two years following a single treatment



 1. 6-month data: Granel et al (2014); Ann Rheum Dis Aug 11: doi: 10.1136/annrheumdis-2014-205681
 5/11/2016

 2. 12-month data: Guillaume-Jugnot et al (2015) Rheumatol. 10.1093/rheumatology/kev323
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## **SCLERADEC I- Other Endpoints**

### Sustained improvement in hand strength & skin stiffness



# **SCLERADEC I- Other Endpoints**

### Reduction in digital ulcers, improved microvascular architecture



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1. 6-month data: Granel et al (2014); Ann Rheum Dis Aug 11: doi: 10.1136/annrheumdis-2014-205681 5/11/2016 2. 12-month data: Guillaume-Jugnot et al (2015) Rheumatol. 10.1093/rheumatology/kev323

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# Scleroderma: Ongoing Clinical Trials

### **Clinical/Regulatory Strategy**

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

	STAR (Phase III)	SCLERADEC II (Phase III)
Study size	80	40
Randomization	1:1, active: placebo	1:1 (dose from Pilot, placebo)
Crossover	Placebo, crossover at 48 weeks	Placebo, crossover at 24 weeks (cryo)
Sites	Up to 20 in USA	6 France
Primary Endpoint	Cochin Hand Function Score (CHFS) at 6 months	Cochin Hand Function Score at 3 months
Secondary Endpoints	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
Follow-Up	48 weeks	24 weeks
Status	Enrolling	Enrolling



## Scleroderma - Projected Development Timeline







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Managed Access

## Scleroderma Managed Access Program Timeline



# **Pipeline Indications**

Knee Osteoarthritis Urinary Incontinence Radiation/Nuclear Burn



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# **Knee Osteoarthritis**

### Osteoarthritis

Progressive loss of joint function Imbalance between anabolic (cartilage-forming) and catabolic (cartilage-destroying) processes driven by synovial inflammation

### Epidemiology

OA is the most common form of arthritis

- 13.9% of adults **>25** years
- 33.6% (12.4 million) ≥65 years
- Estimated 26.9 million US adults (2005)

### Pathophysiology



## Scientific Rationale: Cytori Cell Therapy in OA



- Pathophysiology of OA (persistent synovial inflammation leading to cartilage destruction) overlaps with other clinical indications in which Cytori Cell Therapy shown to have impact
- Combination of veterinary, preclinical, *in vitro*, and pilot clinical data indicate significant potential for symptomatic improvement and perhaps disease modification

## Opportunity: Biologic/Cell Therapy to better address gap between oral analgesics and surgical management

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## ACT-OA Trial & Top-line 24 Week Interim Analysis

	Phase II (ACT-OA)		
Study Size	94 enrolled		
Randomization	1:1:1 (low dose, high dose, placebo)		
Sites	12 US		
Primary Endpoint	KOOS - pain on walking @ 12 weeks		
Secondary Endpoints	KOOS, pain/function questionnaires, disease activity pain meds, SF-36, MRI@ 48 weeks		
Follow-Up	48 weeks		
Status	Enrolled- 48 week data Q3/16		
	24 Week Interim Data- Top-line Results From Partial Unblinding		
	<ul> <li>Patient allocation equal</li> <li>No safety concerns</li> <li>Pain on walking endpoint @12 weeks- not statistically significant</li> <li>Consistent 12, 24 week trends favoring cell therapy effect</li> <li>Strong placebo response ~50% in certain endpoints</li> <li>Cell therapy benefit over and above placebo effect</li> </ul>		



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## **Osteoarthritis Development: Anticipated Next Steps**

- Full un-blinding & complete analysis after 48 week data collected (~ Q3 2016)
  - · Evaluation of individual responder rates & patient subset analyses
  - · Evaluate continued symptomatic improvement vs. placebo
  - 48 week MRI assessment for effect on cartilage



\*Pending 48 week data, phase 3 funding, and FDA approval

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## **Stress Urinary Incontinence Program**



### 'ADRESU' Trial Objectives

- Approved, reimbursed therapy for SUI in men following radical prostatectomy
  - Significant need for patients not responding to conservative methods
- Support proof of concept in female incontinence

#### **Progress/Data**

- Pilot clinical trial data published <sup>1,2</sup>
- Increase maximum urethral closing pressure
- Reduction 24-hour pad weight
- Increased blood flow
- Ongoing 45 pt. Multicenter Pivotal Trial
  - Enrollment started Q3/2015
  - 2 years to enroll

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





GRADUATE SCHOOL OF MEDICINE NAGOYA SCHOOL OF HEALTH SCIENCES

#### Support

- Investigator initiated with Cytori support
- Substantial funding via Japanese Ministry of Health, Labour and Welfare

#### **Development Plan**

- Ongoing pivotal anticipated as approval/reimbursement trial
- Assuming positive data, seek approval and reimbursement based on 12 month assessment
- Seeking commercial partnership with Japanese company

## **Radiation/Nuclear Burn Program**



### **Objectives**

- Development medical countermeasure for mass casualty event- thermal burn ± radiation exposure
- Proof of concept clinical data for use of Cytori Cell Therapy in wound healing

### **Progress/ Preclinical Data**

- Improvement in multiple tissue repair parameters following administration of Cytori Cell Therapy<sup>1,2</sup>
- Effective via multiple routes of administration<sup>1,2</sup>
- Efficacy sustained following substantial exposure to radiation dose<sup>3</sup>

Foubert et al. (2015) Burns doi:10.1016/j.burns.2015.05.004
 Foubert et al. (2015) Adv Wound Care doi:10.1089/wound.2015.0672
 Foubert et al (manuscript in preparation)



### Support

- Funded by \$106MM contract from Biomedical Advanced Research and Development Authority (BARDA)
- \$18.7MM of funding allocated through September 2016

#### **Development Plan**

- Submit IDE application in 2016 for a proof-of-concept clinical trial
- Additional \$8.3 funding pending receipt of IDE approval for clinical trial

# **Corporate Information**



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# Cytori Cell Therapy: Global Patent Estate

### 85 patents issued worldwide; over 75 applications pending



Goal: Protect Cytori's proprietary methods and devices for manufacturing Cytori Cell Therapy, as well as methods of using Cytori Cell Therapy in the treatment of scleroderma, and several other indications, including osteoarthritis and SUI.

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# **Capitalization Summary**

Q2 2014- Corporate & management restructuring

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• Change focus, eliminated/lowered outstanding liabilities and recapitalization

Select Data – as	s of 3/31/16	
Cash	~ \$9.4MM	
Senior term loan	~ \$17.7MM	
Common Shares outstanding	~ 13.3MM*	
Outstanding options, RSAs and warrants	~ 1.1MM*	
Fully diluted share count	~ 14.4MM*	
Market capitalization	~ \$50MM**	
After giving effect to a 1:15 reverse stock split * As of May 9 <sup>th</sup> , 2016, based on closing share pr	ice of \$3.95*	

# **Anticipated Key Corporate Milestones**

2016 Milesto	ones
1 <sup>st</sup> Half	<ul> <li>✓ EU MAP program launch</li> <li>✓ 24 WK ACT-OA interim data evaluation</li> <li>✓ 2 YR follow up EU scleroderma trial</li> <li>Full STAR phase III trial enrollment</li> </ul>
2 <sup>nd</sup> Half	<ul> <li>48 WK ACT-OA data evaluation</li> <li>Japan &amp; MAP progress reported</li> <li>Full SD-II enrollment</li> </ul>
2017 Milesto	nes
	<ul> <li>1 YR STAR Phase III data</li> <li>SD-II data evaluation</li> <li>File US FDA PMA approval scleroderma</li> <li>File full EMEA approval scleroderma</li> <li>US Phase I Burn enrollment</li> <li>Full ADRESU enrollment</li> </ul>



# Thank You

