

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, 2016**

CYTORI THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware

001-34375

33-0827593

(State or Other Jurisdiction of Incorporation)

(Commission File
Number)

(I.R.S. Employer Identification Number)

3020 Callan Road, San Diego, California 92121
(Address of principal executive offices, with zip code)

(858) 458-0900
(Registrant's telephone number, including area code)

n/a
(Former name or former address, if changed since last report)

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 (*see* General Instruction A.2. below):

- 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))
-

Item 7.01 Regulation FD Disclosure

A copy of an investor slide presentation that Cytori Therapeutics, Inc. (the “Company”) will use during a presentation at the Biotech Showcase™ on Tuesday, January 12, 2016 at 4:30 PM Pacific Time (7:30 PM Eastern Time) in the B-Mission I room at the Parc 55 Wyndham Hotel in San Francisco, is attached to this Current Report on Form 8-K (“Current Report”) as Exhibit 99.1 and is incorporated by reference herein. Additionally, the Company has posted the slide presentation on the Company's Investor Relations website at <http://ir.cytori.com>.

The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Investor Presentation Material

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.

CYTORI THERAPEUTICS, INC.

January 12, 2016

Name: Jeremy Hayden
Title: General Counsel and VP of Business Development

By: /s/ Jeremy Hayden

Exhibit Index

Exhibit
No.

Description

99.1

Investor Presentation Material.

Cytori Therapeutics

Biotech Showcase | January 2016

NASDAQ: CYTX



Forward Looking Statements and Disclaimers

This presentation contains certain 'forward-looking statements' about Cytori Therapeutics, Inc. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

The forward-looking statements included in this presentation, involve known and unknown risks that relate to future events or our future financial performance and the actual results could differ materially from those discussed in this presentation. Some of those forward-looking statements include: our commercialized and pipeline products and technologies; the timing and conduct of our clinical trials, and the associated financial, clinical and regulatory burdens; other parties' abilities to conduct clinical trials involving Cytori Cell Therapy; the various medical indications and markets that may be addressed by Cytori Cell Therapy; the potential effectiveness of Cytori Cell Therapy, including clinical outcomes; our regulatory, reimbursement and commercial strategies and pathways; potential costs and other adverse effects of diseases targeted for treatment by our products, and; anticipated future funding and contract revenues. Some risks and uncertainties related to such forward looking statements include risks and uncertainties regarding the funding, conduct and completion of our clinical trials and other parties' clinical trials involving Cytori Cell therapy, uncertain clinical outcomes, regulatory uncertainties, unfavorable reimbursement outcomes, inability to access sufficient capital on acceptable terms (including inability to fund, or find third party sources to fund, our proposed clinical trials or continued development of our technologies), failure to maintain our substantially reduced cash burn; our partners' failure to launch products in China and other markets where we currently forecast sales; our abilities to service, pay and/or refinance our corporate debt; availability of future government funding and changes in government procurement priorities; the U.S. federal government's ability to reduce, modify or terminate the BARDA contract if it determines it is in its best interests to do so, potential performance issues with our products and technologies, and other risks and uncertainties described under the "Risk Factors" section in our Securities and Exchange Commission Filings on Form 10-K and Form 10-Q. These risks and uncertainties may cause our actual results to differ materially from those discussed in this presentation. We advise reading our most recent annual report on Form 10-K and quarterly report on Form 10-Q filed with the United States Securities and Exchange Commission for a more detailed description of these risks.

The forward-looking statements contained in this presentation represent our estimates and assumptions only as of the date of this presentation and we undertake no duty or obligation to update or revise publicly any forward-looking statements contained in this presentation as a result of new information, future events or changes in our expectations.

Disclaimers

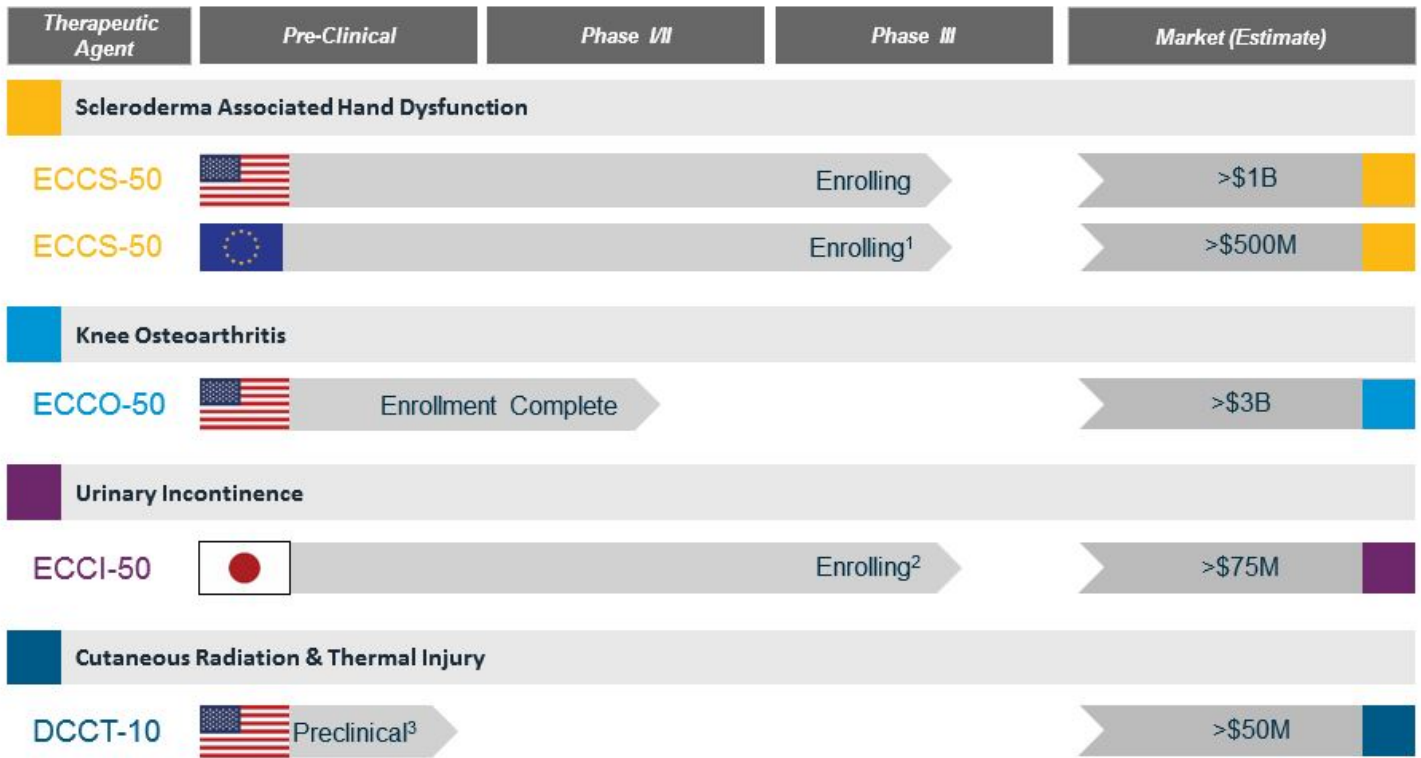
Caution: Within the U.S., the Celution System is an investigational device limited by U.S. law to investigational use.

Celase, Celution, Celution (with design), Cytori Therapeutics, and Cytori (with design) are registered trademarks of Cytori Therapeutics. Cytori Cell Therapy is a trademark of Cytori Therapeutics. All third party trademarks are the property of their respective owners.

Summary

- **Unique cell therapy platform-** clear commercial model, late-stage lead indication and growing development pipeline
- **Completed corporate restructuring-** better positioned to achieve key milestones 2016
- **Substantial clinical data-** indicates Cytori Cell Therapy provides symptomatic benefit, improved quality of life and may impact disease progression
- **Scleroderma product introduction-** 2016 EU managed access program and anticipated US product launch 2018
- **Product & contract revenue growth-** increasingly offset burn through 2018

Cytori Cell Therapy: Late-Stage Clinical Pipeline



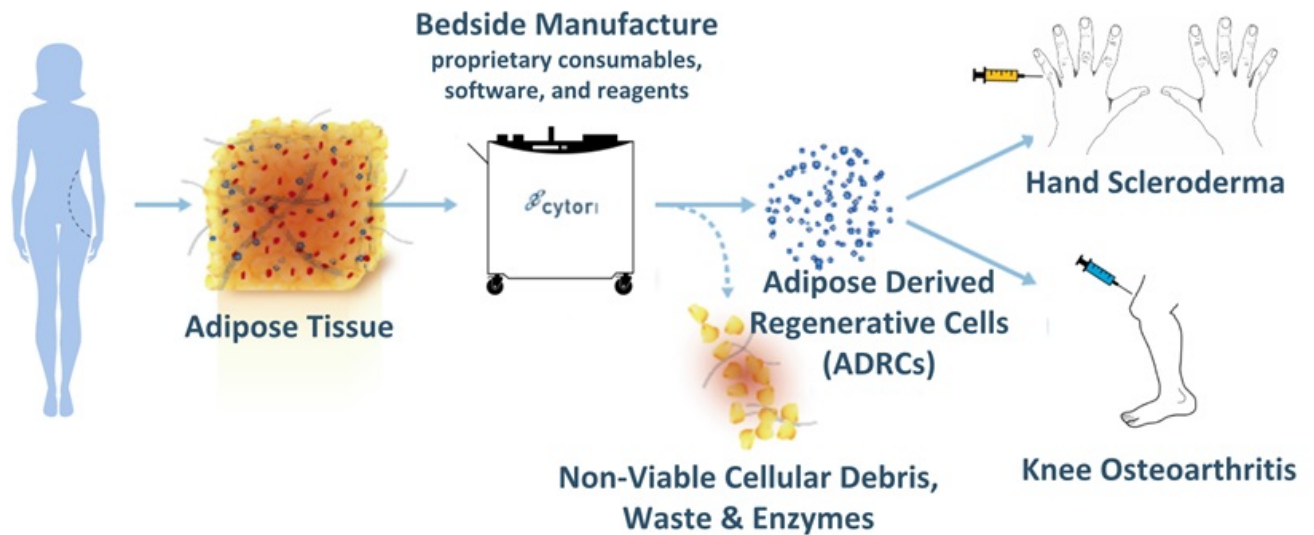
¹ Cytori-funded, Investigator-initiated trial

² Japan Govt Sponsorship

³ Funded by BARDA (US Govt.)

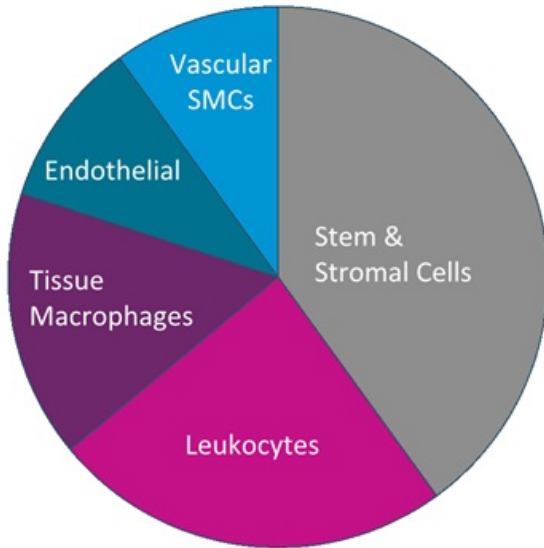
Cytori 3-Step Bedside Process

PROCESS	1 HARVEST Small Volume Liposuction (100-360 mL)	2 PROCESS Celution® System Tissue Processing, Cell Isolation & Dose Preparation	3 DELIVER Cytori® Cell Therapy™ Delivery
TIME	≤ 30 Min	≤ 120 Min	5 - 30 Min



Cytori Cell Therapy: Cellular Composition

A clinical grade, heterogeneous cell population highly-enriched for adipose-derived stem, stromal, vascular, and immunoregulatory cell types

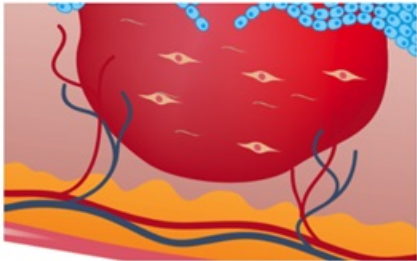


- Cells sourced from autologous adipose tissue
- Therapeutic manufactured in bedside GMP process
- Process yields a diverse, unique cell population
- All consumables are clinical grade

Cytori Cell Therapy: Mechanism of Action

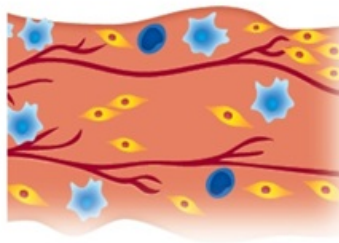
Cytori Cell Therapy beneficially modulates multiple key pathologic processes leading to anticipated sustained reduction in pain and disability and improved quality of life

Angiogenesis/Vasculopathy



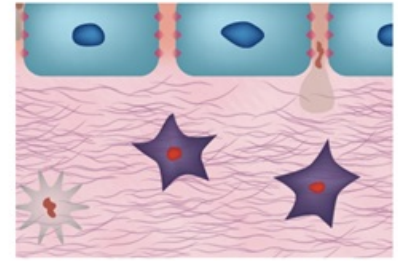
- Promotes angiogenesis
- Normalization of vessel architecture
- Improved vasomotor function¹⁻⁵

Inflammation



- Modulates expression of pro- and anti-inflammatory factors
- Modulates the function of pro- and anti-inflammatory cells^{3, 6-9,}

Fibrosis/Wound Remodeling



- Reduces development of fibrosis
- Remodels existing fibrosis^{2,10,11}

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

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



Raynaud's
Phenomenon



Ulceration
and Edema

Pathophysiology

Endothelial
Dysfunction

Vascular
Damage

Chronic
Inflammation

Fibrosis

Diminished
Hand Function

Ulcers &
Amputation

Cytori Cell Therapy

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

Images reproduced with permission of the nonprofit International Scleroderma Network at sclero.org
Image on left by D Niklas, <https://commons.wikimedia.org/wiki/File:Raynaud-Syndrom.JPG> used under CC license
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Scleroderma: Market Overview

Current Standard of Care

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

Diagnosis

- Average age: 30's-50's

1st/2nd Line Therapies

Inadequately effective or poorly tolerated in ~50% of patients^{1,2}

- 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

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

1. Thompson et al Arthritis Rheum. 2001;44(8):1841-7
2. Herrick (2008) BMJ Clin Evidence 09:1125

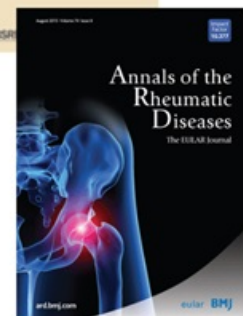
Scleroderma: Treatment Approach

- Ambulatory
- Procedure room
- Local or mild conscious sedation
- Single administration ECCS-50
- 0.5cc injection to each NVB
- No bandage



Pilot/Phase I SCLERADEC I Trial

	SCLERADEC I
Study size	12
Randomization	Open label
Administration	Single administration (~4m cells/finger)
Sites	Single site (IIS) - Marseille, France
Endpoints	<ul style="list-style-type: none">• Cochin Hand Function Scale• Raynaud's Condition Score• Scleroderma Health Assessment Questionnaire• Pain• Modified Rodnan Skin Score• Capillaroscopy• Adverse events• Other
Follow-Up	24 months
Status	Complete

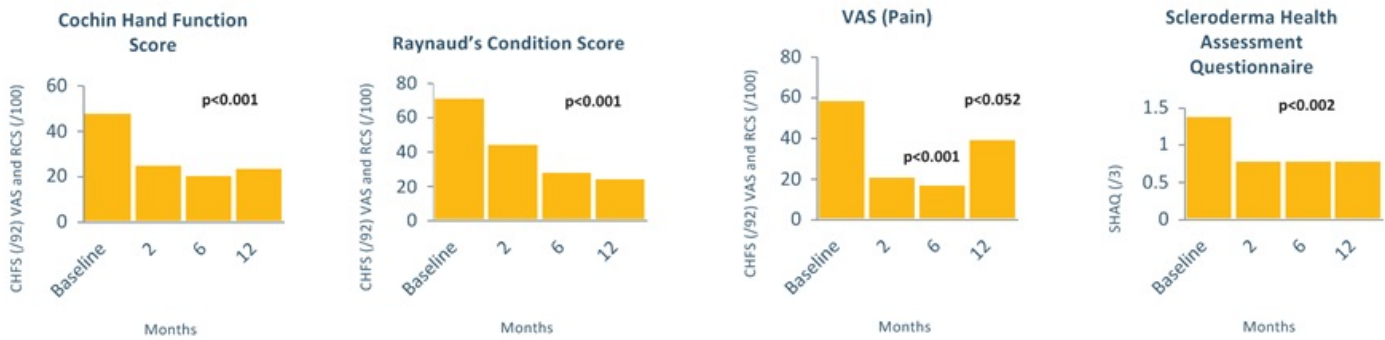


- Six and 12 month data published^{1,2}
- 24 month data to be presented at Systemic Sclerosis World Congress in Lisbon, Portugal, February 19, 2016

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

SCLERADEC I Improved PROs over 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
- Topline data show efficacy sustained to two years following a single treatment

Granel *et al.* Ann Rheum Dis 2014; Guillaume-Jugnot *et al.* Rheumatology 2015
mean \pm std err

SCLERADEC I- Other Endpoints

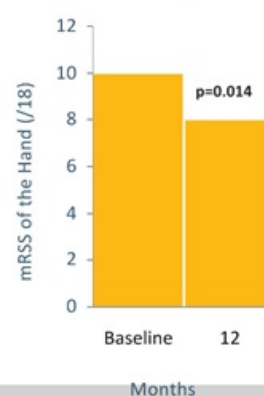
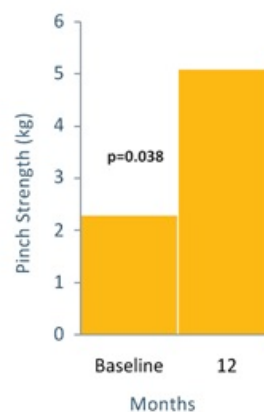
Sustained improvement in hand strength & skin stiffness



- 130% improvement in pinch strength
- 30% improvement in grip strength



- 23% improvement in mRSS of the hand



Granel et al. Ann Rheum Dis 2014; Guillaume-Jugnot et al. Rheumatology 2015
All data presented as mean \pm std err

SCLERADEC I- Other Endpoints

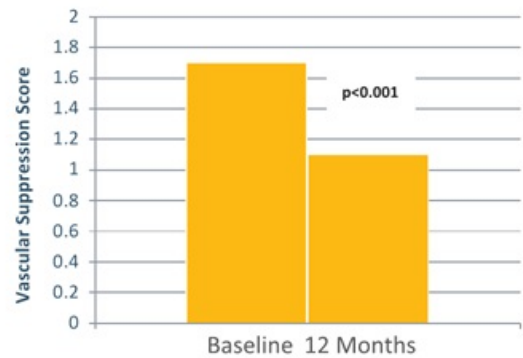
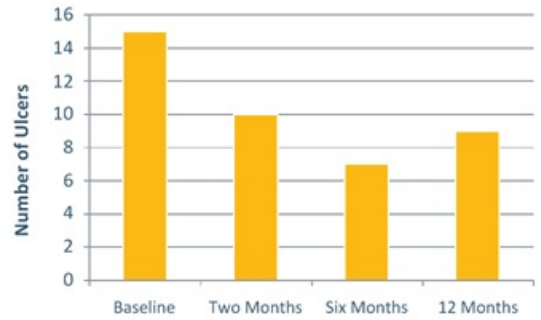
Reduction in digital ulcers, improved microvascular architecture



- **40% improvement in number of ulcers**



- **30-35% improvement in vascular suppression score**





All data presented as mean \pm std err
Granel et al. Ann Rheum Dis 2014; Guillaume-Jugnot et al. Rheumatology 2015
Image at top reproduced with permission of the nonprofit International Scleroderma Network at sclero.org

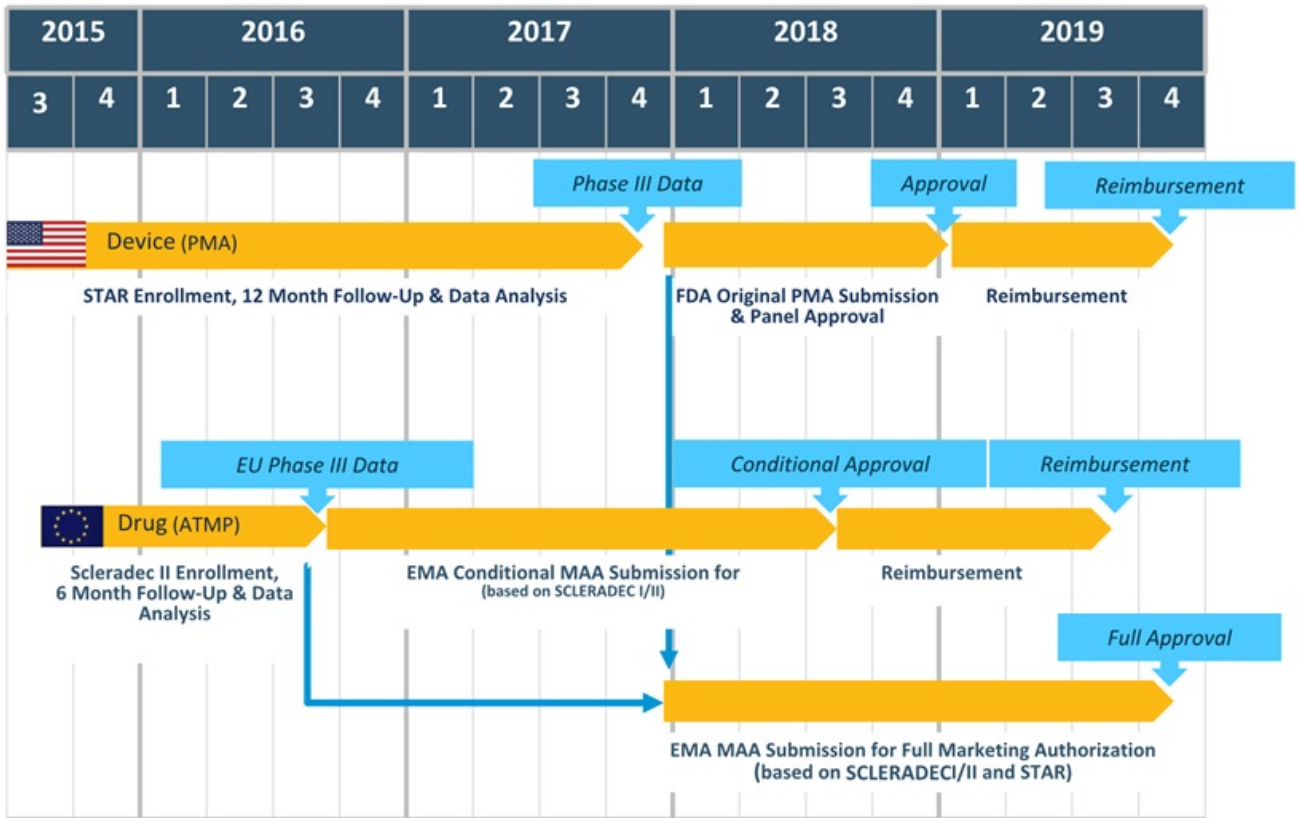
Scleroderma: Ongoing Clinical Trials

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: Anticipated Development Timeline





Situation

- Scleroderma rare disease, orphan designation
- SCLERADEC-I results show positive ECCS-50 risk-benefit ratio
- Two pivotal trials enrolling
- Clear unmet patient needs and verified broad EMEA demand for ECCS-50

Opportunity

- Provide ECCS-50 access to patients unable to participate in clinical trials
- Fulfill company mission

Partner

- IDIS– global market leader with headquarters in UK, NJ
- 22 years of Managed Access Program experience
- > 200 total Programs executed (>74 orphan/rare disease)

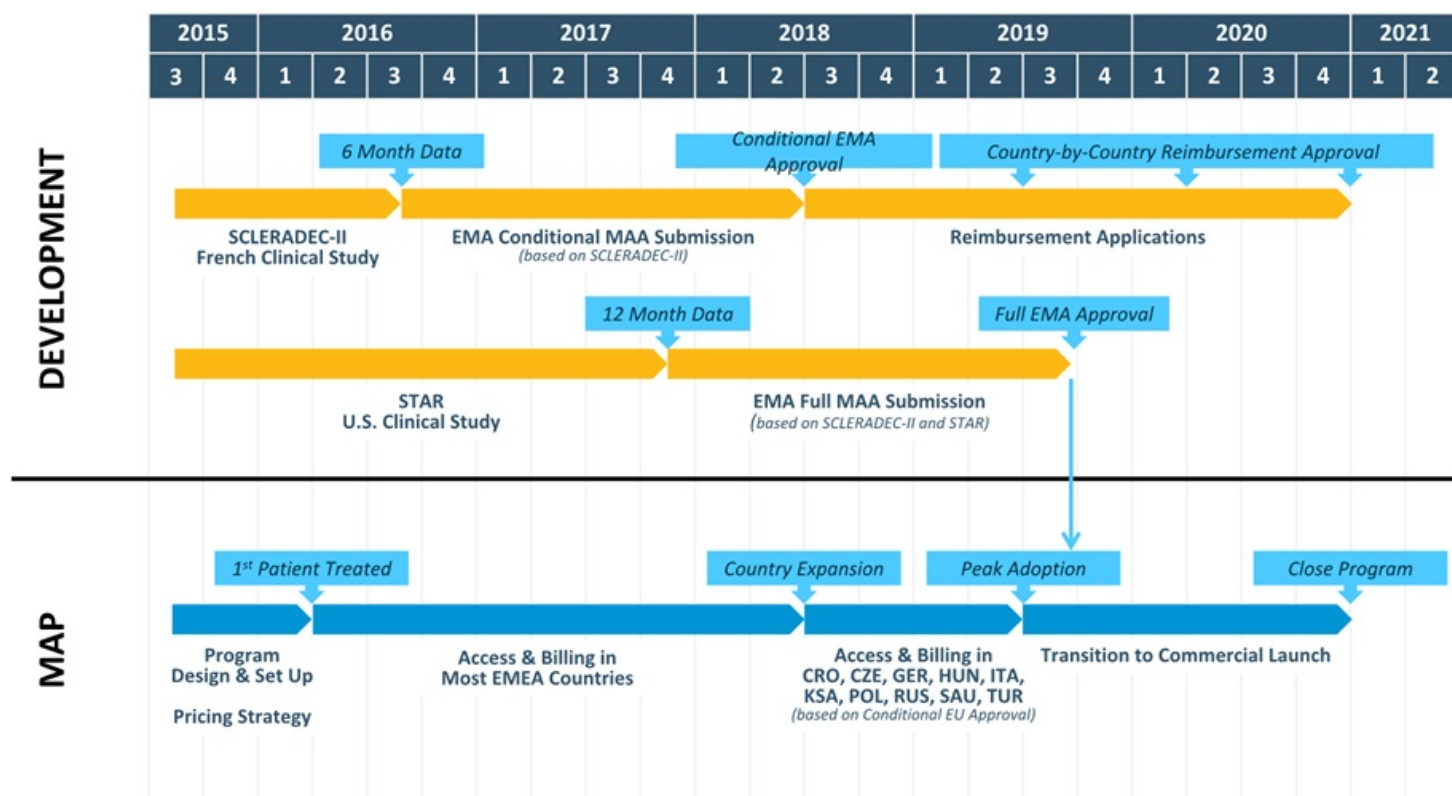




- 1 **Provide ethical and compliant access** to Cytori Cell Therapy™, ECCS-50, for hand scleroderma patients prior to EMA marketing authorization
- 2 **Increase awareness of and facilitate a positive experience** with Cytori Cell Therapy™ among healthcare providers in advance of commercial launch
- 3 **Track and collect key program data and documentation** providing valuable insight regarding the demand for and use of Cytori Cell Therapy™
- 4 **Implement a chargeable program** in EMEA countries where regulations allow
- 5 **Launch the program in Q1 and begin treating patients in Y1** and close the program once reimbursement is attained in each EMEA country



Scleroderma Anticipated Managed Access Program Timeline



Pipeline Indications

Knee Osteoarthritis

Urinary Incontinence

Radiation/Nuclear Burn

Knee Osteoarthritis

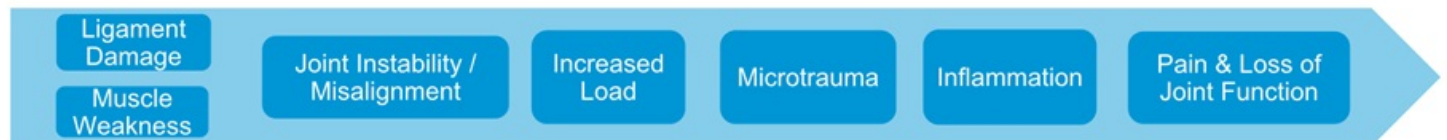
Osteoarthritis

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



Cytori Cell Therapy

Preclinical, veterinary, and in vitro studies report modulation of inflammation and promotion of improved balance between anabolic and catabolic processes within the extracellular matrix of the cartilage

Knee Osteoarthritis: Market Overview

Situation: OA affects 10% of global population and clear unmet need

- Few non-surgical treatments recommended by AAOS
 - Treatment spectrum from oral analgesics/anti-inflammatory meds to total knee replacement
- Health systems are paying for expensive and inadequate treatments that are not recommended by professional bodies

Example:

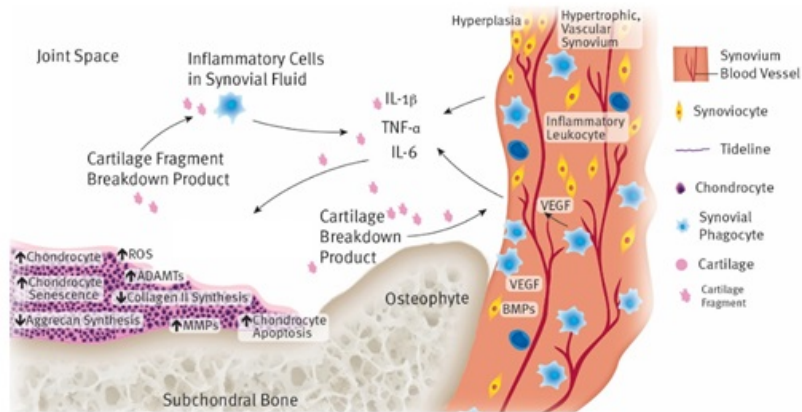
		2014E Market Size: \$2B		
Knee OA Treatment Modality	AAOS Guideline	US	Japan	ROW
Hyaluronic Acid (HA) Injection *	Not recommended	\$900M	\$700M	\$400M

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

- Reduce use of NSAIDs with anticipated reduction in CV/Renal/GI side effects
- Improved pain relief and function
- Delay total knee arthroplasty

*Canaccord Genuity 34th Annual Growth Conference Aug 2014

Rationale for use of Cytori Cell Therapy in OA



- The pathophysiology of osteoarthritis (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
- Clinical feasibility proven

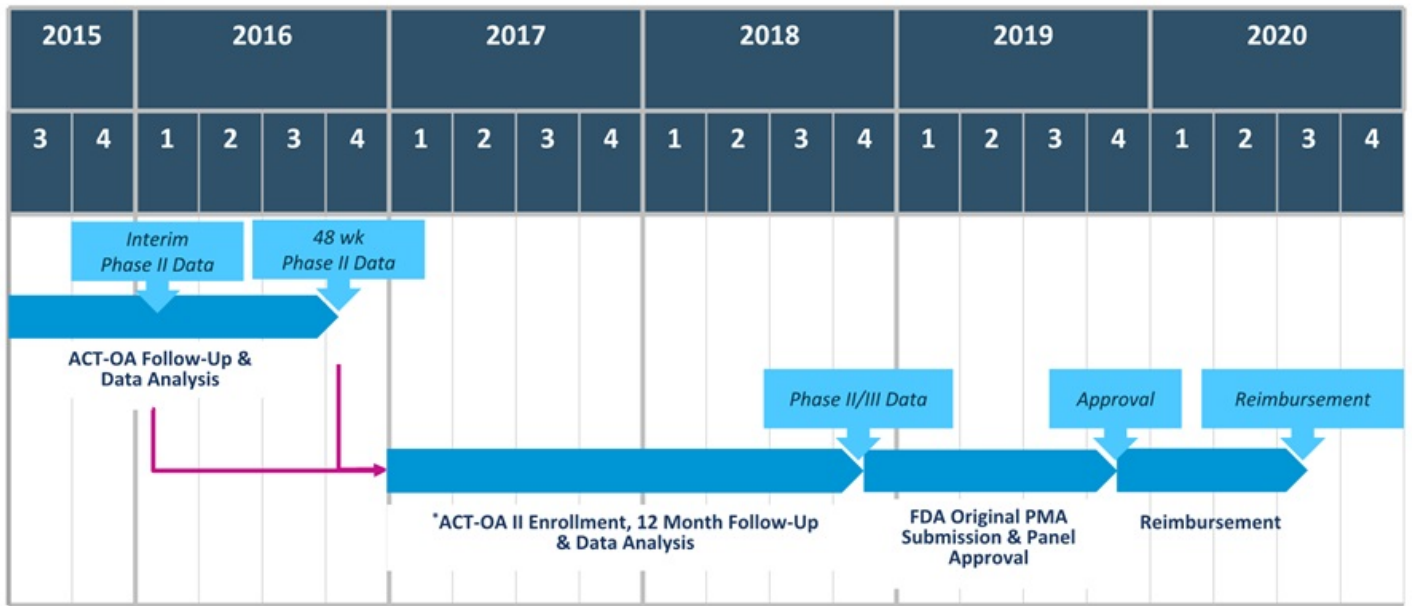
ACT-OA Enrolled Phase II Trial

Clinical/Regulatory Strategy

- US FDA phase II to investigate safety and potential efficacy in key endpoints of single intrarticular administration
- If positive- possible additional phase II, development, or proceed to phase III

	Phase II (ACT-OA)
Study Size	94
Randomization	1:1:1 (low dose, high dose, placebo)
Crossover	None
Sites	12 US
Primary Endpoint	KOOS - pain on walking
Secondary Endpoints	KOOS, pain/function questionnaires, pain meds, SF-36, MRI
Follow-Up	48 weeks
Status	Enrolled 24 wk data Q1/15 48 week data Q4/15

Osteoarthritis Potential Development Path



*Pending 48 week data, funding, and FDA approval

Stress Urinary Incontinence Program: Japan

'ADRESU' Trial Objectives

- Approved, reimbursed therapy for SUI in men following radical prostatectomy
 - Significant unmet need for patients whose symptoms are not responding to conservative methods

Progress/Data

- Pilot clinical trial data published ^{1,2}
 - Increase in mean maximum urethral closing pressure
 - Reduction in mean 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
SCHOOL OF HEALTH SCIENCES

Support

- IIS with support from Cytori and substantial funding via grant from the Japanese Ministry of Health, Labour and Welfare

Development Plan

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

Radiation/Nuclear Burn Program: USA



Objectives

- Development medical countermeasure for mass casualty event involving thermal burn \pm radiation exposure
- Develop 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^{1,2}
- Effective via multiple routes of administration^{1,2}
- Efficacy sustained following substantial exposure to radiation dose³

1. Foubert et al. (2015) Burns doi:10.1016/j.burns.2015.05.004

2. Foubert et al. (2015) Adv Wound Care doi:10.1089/wound.2015.0672

3. Foubert et al (manuscript in preparation)

Support

- Funded by \$106MM contract from Biomedical Advanced Research and Development Authority (BARDA)
 - Part of the Dept. of Health & Human Services
- \$18.7MM of funding allocated through September 2016

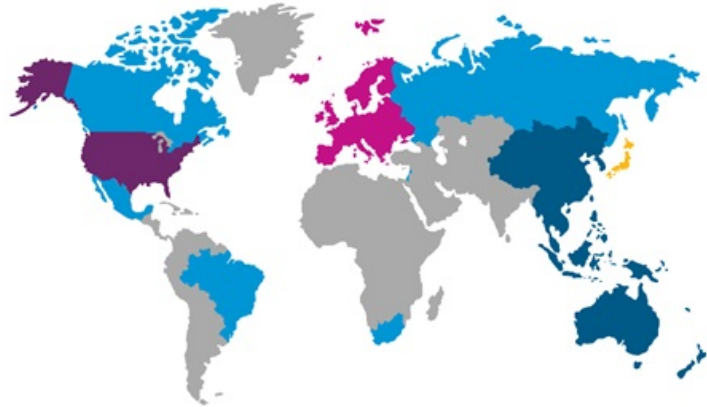
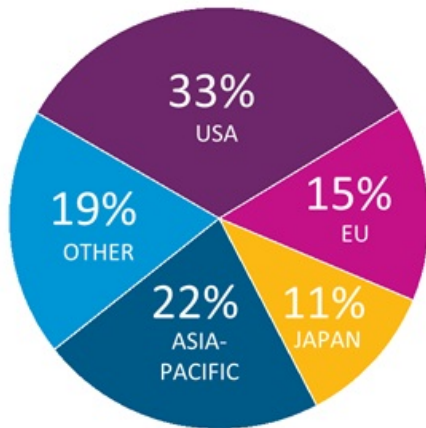
Development Plan

- Submit IDE application in 2016 for a first-in-man clinical trial
- Additional \$8.3 funding preapproved pending receipt of IDE approval for clinical trial

Corporate Information

Cytori Cell Therapy: Global Patent Estate

Over 80 patents issued worldwide; over 55 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, osteoarthritis, SUI and several other pipeline indications

Capitalization Summary

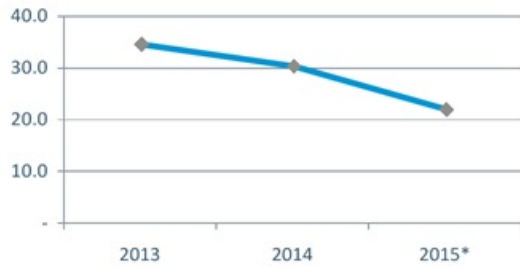
- Q2 2014- Corporate & management restructuring
- Change focus, eliminated/lowered outstanding liabilities and recapitalization

Select Data – as of 12/31/15	
Cash	~ \$19MM*
Senior term loan	~ \$17.7MM
Common Shares outstanding	~ 195MM
Outstanding options, RSAs and warrants	~ 13MM
Fully dilutive share count	~ 208MM
Market capitalization	~ \$35MM

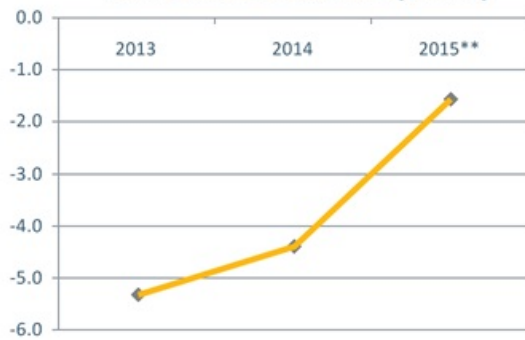
* As of September 30, 2015

Financial & Operational Performance

Annual Operating Cash Burn (\$MM)



Narrowed S&M Loss (\$MM)



* Based on revised guidance of \$22 million in operating cash burn for 2015

** Based on annualized figures from YTD September 30, 2015 financials

Summary

- **Unique cell therapy platform-** clear commercial model, late-stage lead indication and growing development pipeline
- **Completed corporate restructuring-** better positioned to achieve key milestones 2016
- **Substantial clinical data-** indicates Cytori Cell Therapy provides symptomatic benefit, improved quality of life and may impact disease progression
- **Scleroderma product introduction-** 2016 EU managed access program and anticipated US product launch 2018
- **Product & contract revenue growth-** increasingly offset burn through 2018

Review Cytori Corporate Milestones

2016 Milestones

1st Half

- EU MAP program launch
- 24 WK ACT-OA interim data evaluation
- 2 YR follow up data SD-I presented
- Full STAR enrollment
- Full SD-II enrollment

2nd Half

- 48 WK ACT-OA data evaluation
- Japan & MAP progress reported
- SD-II data evaluation

2017 Milestones

- 1 YR follow up STAR evaluation
- File US FDA PMA approval scleroderma
- File EMEA approval scleroderma
- US Phase I Burn enrollment
- Full ADRESU enrollment

Thank You

