

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 10, 2017**

CYTORI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-34375
(Commission File
Number)

33-0827593
(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))
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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 10, 2017 at 4:00 PM Pacific Time (7:00 PM Eastern Time), in Room 3 (Ballroom Level) at the Hilton San Francisco Union Square, 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 10, 2017

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

Exhibit Index

Exhibit
No.

Description

99.1 Investor Presentation Material.

Cytori Therapeutics

Update | January 2017



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 statements regarding: our financial condition and prospects; our commercialized and pipeline products and technologies; the timing and conduct of our clinical trials and other parties' clinical trials involving Cytori Cell Therapy, including associated financial, clinical and regulatory burdens and projected timing for trial approval, enrollment and completion; the various medical indications and markets that may be addressed by Cytori Cell Therapy; the potential effectiveness of Cytori Cell Therapy, including clinical outcomes; conduct of our European managed access program; anticipated uses of clinical trial data; regulatory, reimbursement and commercial strategies and pathways; potential costs and other adverse effects of diseases targeted for treatment by our products, including the Celution system, 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; our ability to successfully execute our managed access program; uncertain clinical outcomes; regulatory uncertainties (including potentially adverse decisions regarding our existing and expected regulatory registrations, approvals and authorizations), 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; failure to achieve projected product revenue and contract revenue growth; our and our partners' failure to launch products and grow revenues in 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; increasing or unanticipated competitive pressures; potential performance issues with our products and technologies; lack of customer acceptance of our technologies; inability to find commercial partners for our therapies; 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 reports on Form 10-Q filed with the U.S. 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. **Caution: Within the U.S., the Celution System is an investigational device limited by U.S. law to investigational use.** The following trademarks are owned by Cytori Therapeutics: Celase, Celution, Celution (with design), Cytori Therapeutics, Cytori (with design) and Cytori Cell Therapy. All third party trademarks are the property of their respective owners.

Cytori Overview

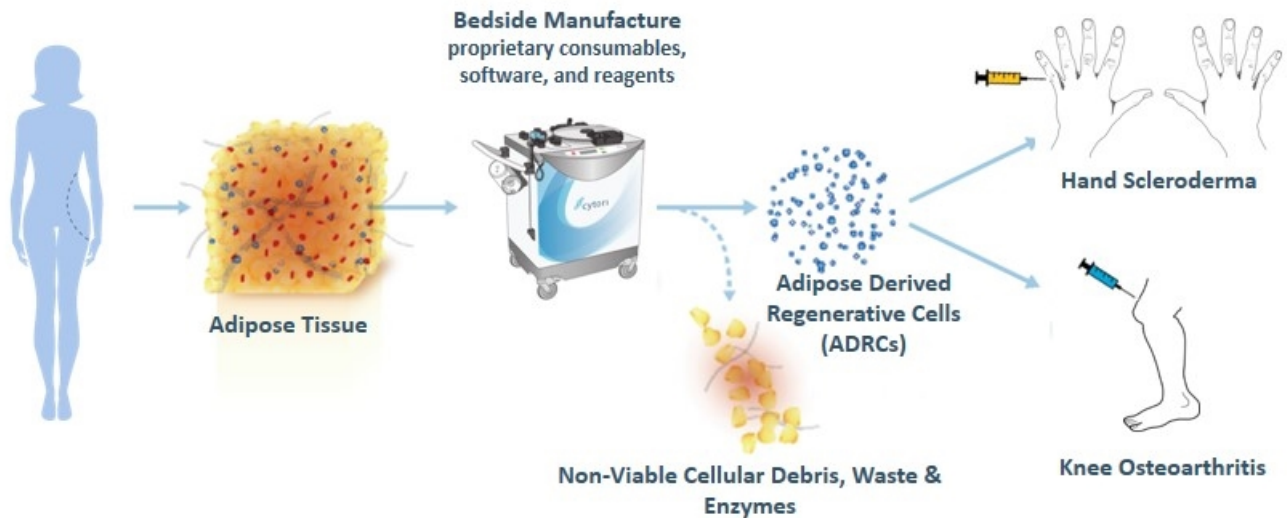
- Late stage cell therapy company
- Three phase III trials complete or enrolling
- Fully enrolled US phase III scleroderma trial, data mid-2017
- Recent US Phase II trial readout in knee osteoarthritis
- Up to \$106m US government (BARDA) contract, anticipate clinical trial milestone 2017
- Product & contracting revenue- narrowing burn

Cytori Cell Therapy: Clinical Pipeline

Therapeutic Agent	Pre-Clinical	Phase I/II	Phase III	Est. Peak Sales Potential
Autoimmune & Inflammatory Conditions of the Hand				
		Hand Dysfunction in Scleroderma	Fully Enrolled (88pts/Data Q3/17)	>\$480M (US)
		Hand Dysfunction in Scleroderma	Enrolling (12/40pts; Data Q3/17) ¹	>\$80M (EU)
		2 ^o Raynaud's Phenomenon		>\$1.6BN (WW)
Orthopedics				
ECCO-50		Knee OA Data Analysis (94 pts)		\$3.4BN (WW)
ECCO-50		Bone Repair Pilot Publ. ²		\$300M (WW)
Urology/Breast Reconstruction				
ECCI-50		Male Urinary Incontinence: Enrolling (21/45pts; Data 2018) ³		>\$75M (JP)
ECCI-50		Breast Reconstruction ⁴		\$130M (JP)
Wounds				
DCCT-10		Rad/Burn ⁵		>\$60M (US)

Cytori Cell Therapy: Same Day Procedure

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

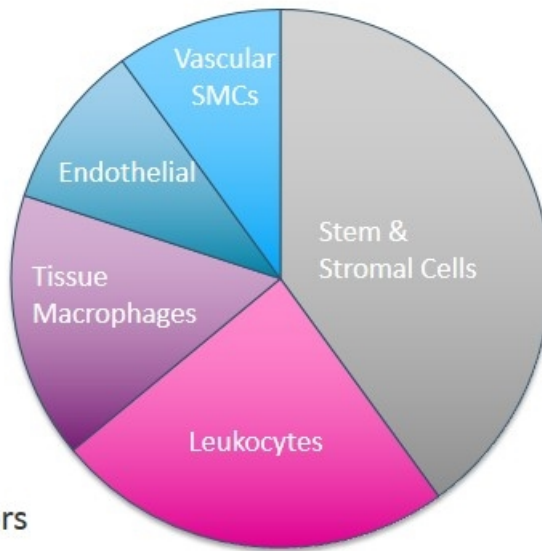


Cytori Cell Therapy: Why Adipose?

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



- Metabolic reservoir
- High baseline angiogenic potential
- Immune organ
- Stem cells & progenitors

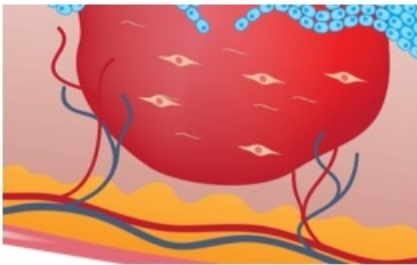


- Cells sourced from **autologous** adipose tissue
- **Heterogeneous and uncultured-** ADRC potency advantage
- Cell therapeutic manufactured in **bedside GMP process**

Cytori Cell Therapy: Mechanism of Action

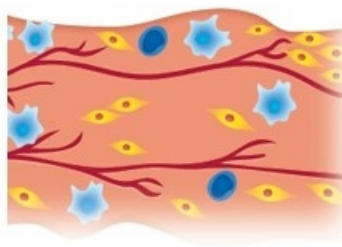
Cytori Cell Therapy is being developed with the goal of beneficially modulating multiple key pathologic processes which are anticipated to reduce pain and disability and improve quality of life

Angiogenesis/Vasculopathy



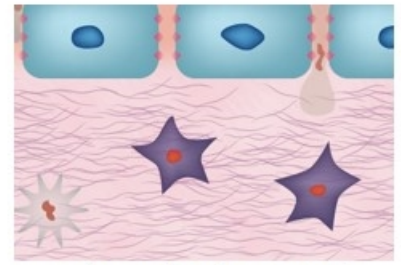
- Promotes angiogenesis
- Normalization of vessel architecture
- Improved vasomotor function¹⁻⁵

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
Image on right reproduced with permission of the nonprofit International Scleroderma Network at sclero.org

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/or 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 and/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

- 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

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 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"> • 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

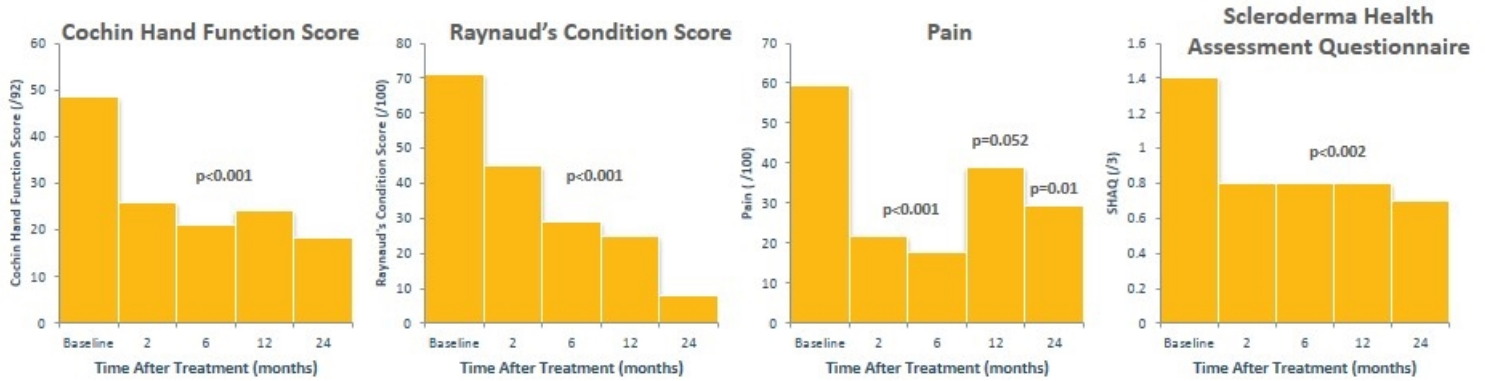


- Six , 12 and 24 month data published^{1,2,3}
- 24 month data presented at Systemic Sclerosis World Congress in Lisbon, Portugal, February 19, 2016
- 36 month follow up data showing sustained benefits materially consistent with those shown on two-year data

SCLERADEC | Improvement Through 24 months



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



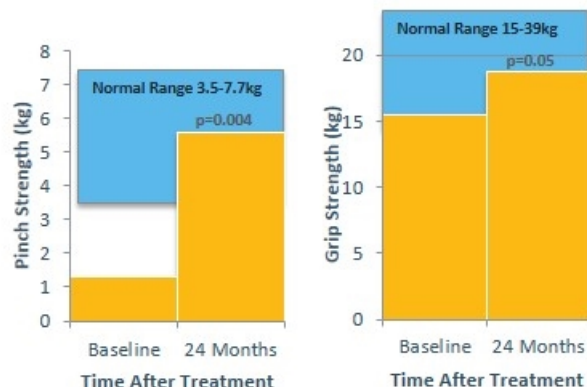
1. 6-month data: Granel et al (2014); Ann Rheum Dis Aug 11; doi: 10.1136/annrheumdis-2014-205681
2. 12-month data: Guillaume-Jugnot et al (2015) Rheumatol. 10.1093/rheumatology/kev323
3. Magalon Systemic Sclerosis World Congress in Lisbon, Portugal, February 19, 2016

SCLERADEC I- Other Endpoints

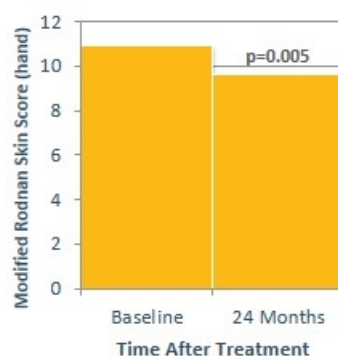
Sustained improvement in hand strength & skin stiffness



330% improvement in pinch strength
20% improvement in grip strength



12% improvement in mRSS of the hand

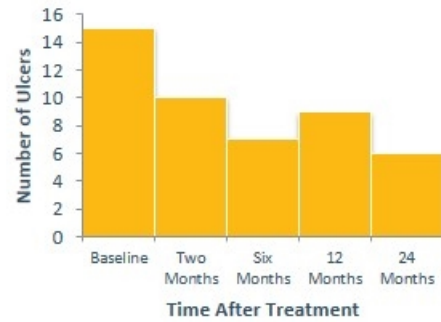


SCLERADEC I- Other Endpoints

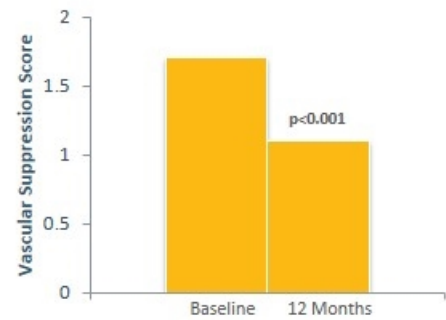
Reduction in digital ulcers, improved microvascular architecture



40% improvement in number of ulcers



30-35% improvement in vascular suppression score





VSS data at 24 months not available

Image at top reproduced with permission of the nonprofit International Scleroderma Network at sclero.org

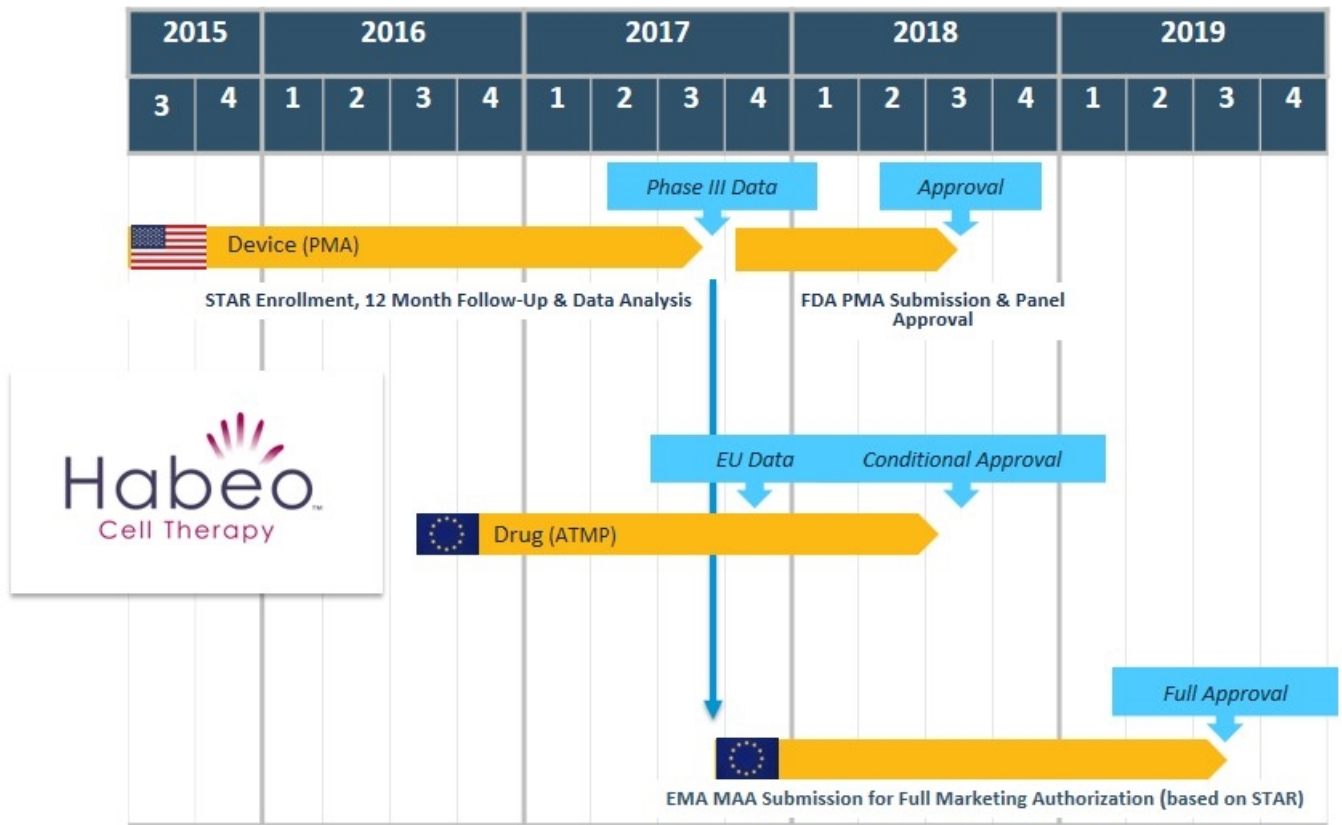
Scleroderma: Ongoing Clinical Trials

Clinical/Regulatory Strategy

- EU SCLERADEC I trial data used to support US FDA STAR trial approval, 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)* 
Study size	88	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	Enrolled, Data in mid-2017	Enrolling

Habeo™ for Scleroderma - Projected Development Timeline



Actual timelines may materially differ from current projections based on a variety of factors, including patient enrollment, regulatory issues and timelines (including EMA and FDA approval timelines), clinical results of the contemplated trials and other factors. Cytos cannot guarantee that it will receive conditional or normal EMA market authorization or FDA Actual timelines may PMA approval for its ECCS-50 therapy.



- 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



Pipeline Indications

Knee Osteoarthritis

Urinary Incontinence

Radiation/Thermal Burn

Knee Osteoarthritis

Osteoarthritis

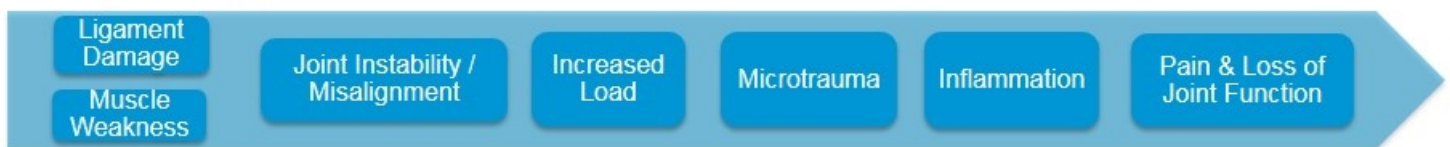
- Progressive loss of joint function
- Imbalance between anabolic (cartilage-forming) and catabolic (cartilage-destroying) processes driven by synovial inflammation
- Distinct from RA

Epidemiology

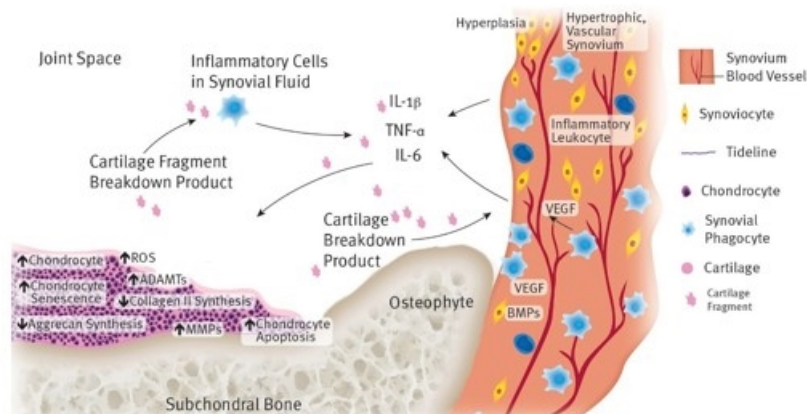
OA is the most common form of arthritis

- 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

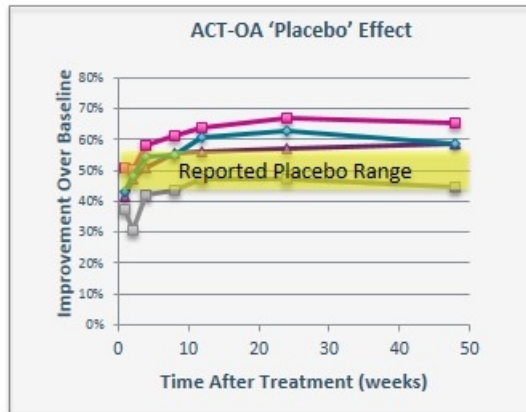


- Pathophysiology of OA (persistent synovial inflammation leading to cartilage destruction) overlaps with other clinical indications in which Cytori Cell Therapy shown to have impact
- Combination of veterinary, preclinical, *in vitro*, and pilot clinical data indicate significant potential for symptomatic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

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

	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, not powered
Secondary Endpoints	KOOS, pain/function questionnaires, disease activity pain meds, SF-36, MRI@ 48 weeks
Follow-Up	48 weeks
Status	Enrolled, completed 48 week topline assessment
Next Steps	Partnership discussion ongoing for Phase III/commercial

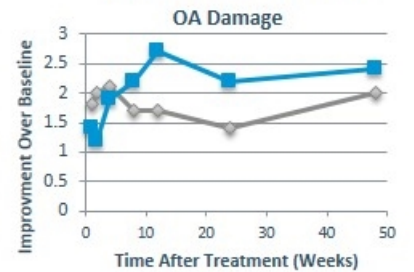
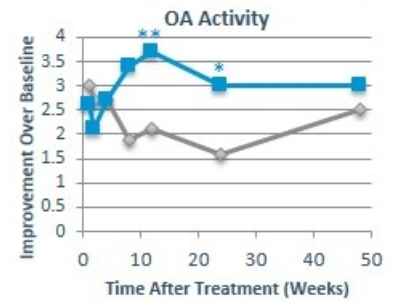
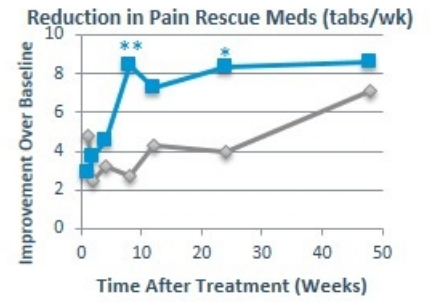
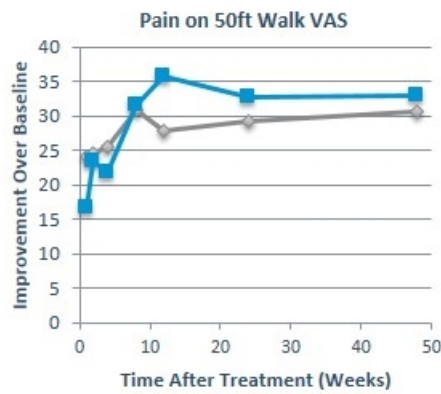
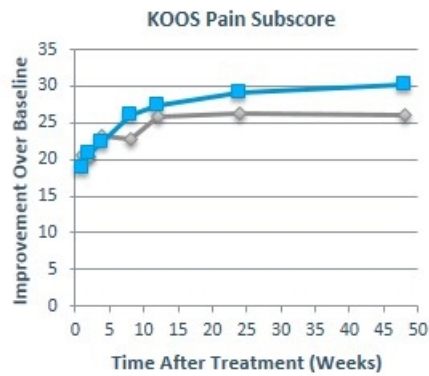
ACT-OA Trial Preliminary Top-line 48 Week Data, Patient Reported Outcomes



- KOOS Pain on Walking
- KOOS Pain Subscore
- ▲— Pain Standing on Target Leg
- ◆— Pain Standing on Both Legs

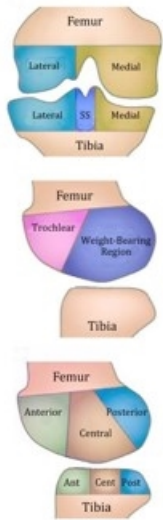
- Placebo
- Treated

* $p \leq 0.1$
 ** $p \leq 0.05$
 *** $p \leq 0.01$

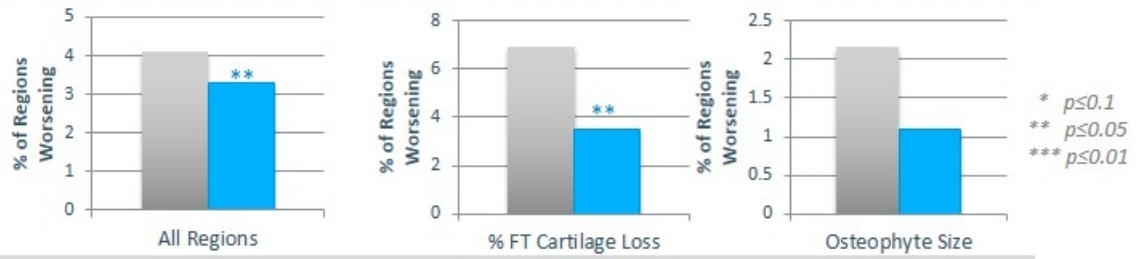


ACT-OA Trial Preliminary Top-line 48 Week Data, MRI or MOAKS

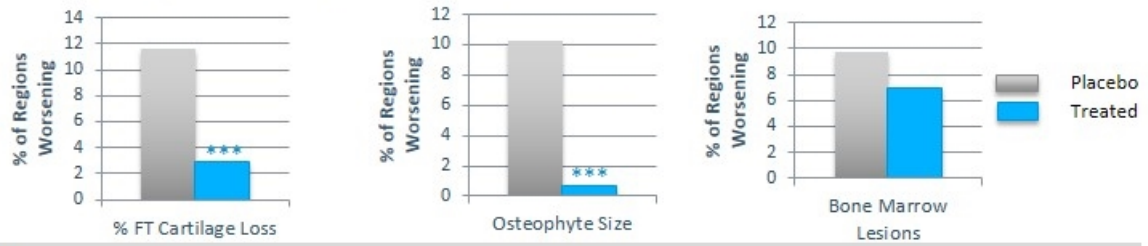
MRI Regional Segmentation



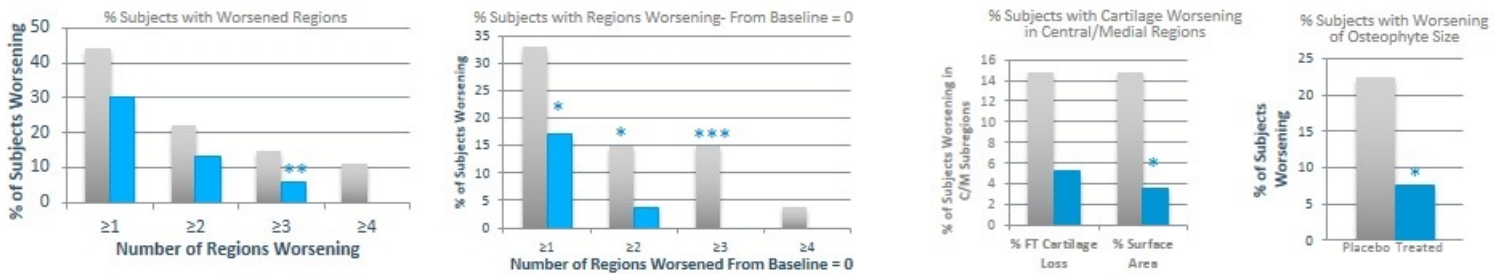
Percentage of Total Regions With Worsening



Percentage of Regions Worsening From a Baseline of Zero



Percentage of Subjects With Worsening



	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, not powered
Secondary Endpoints	KOOS, pain/function questionnaires, disease activity pain meds, SF-36, MRI@ 48 weeks
Follow-Up	48 weeks
Status	Enrolled, completed 48 week topline assessment
Next Steps	Partnership discussion ongoing for Phase III/commercial

48 Week Preliminary Data- Top-line Results

- No SAEs related to cell therapy or procedure
- Consistent 12, 24, 48 week trends favoring cell therapy effect in patient reported outcomes
- Pain PROs, pain on walking question @12 weeks- trends not reaching statistical significance
- Substantial effect from baseline to 12, 24, 48 week, active vs. placebo smaller on relative basis
- Consistent effect in MOAKS/MRI imaging in several parameters at 48 weeks



'ADRESU' Trial Objectives

- Approved, reimbursed therapy for SUI in men following prostate intervention
 - Unmet need for patients
- Support proof of concept in female incontinence

Progress/Data

- Pilot clinical trial data published ^{1,2}
 - Increase maximum urethral closing pressure
 - Reduction 24-hour pad weight
 - Increased blood flow
- Ongoing 45 pt. Multicenter Pivotal Trial
 - Anticipate >50% enrollment by YE 2016
 - Anticipate enrollment completion 2017

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

Support

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

Development Plan

- Ongoing pivotal trial sufficient for approval/reimbursement – 50% enrolled
- Assuming positive data, seek approval and reimbursement based on 12 month assessment
- Potential partnering opportunity



Objectives

- Development medical countermeasure for mass casualty event- thermal burn \pm 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^{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 contract of up to \$106MM from Biomedical Advanced Research and Development Authority (BARDA)
- \$18.7MM of funding allocated through September 2016

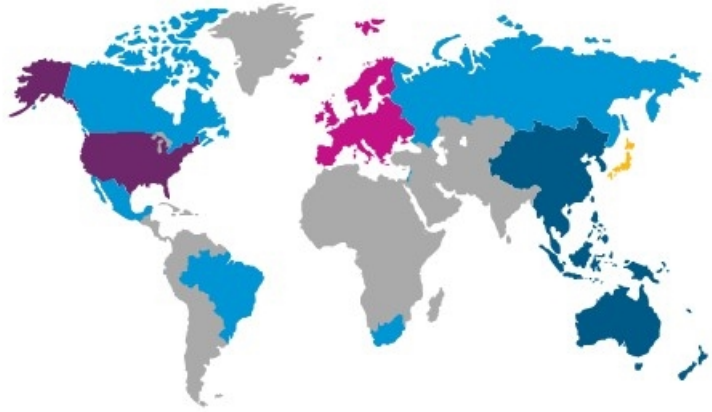
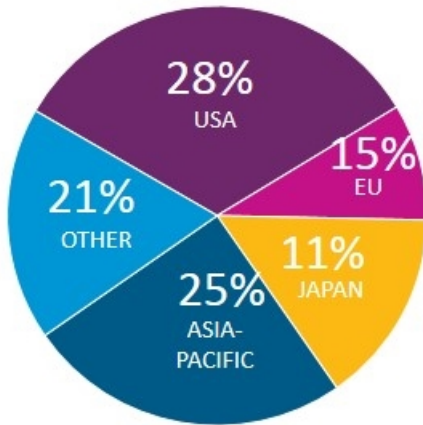
Development Plan

- Submit IDE application in 2016 for a pilot clinical trial
- Enrollment begins 2017
- Additional funding anticipated, pending receipt of IDE approval for clinical trial

Corporate Information

Cytori Cell Therapy: Global Patent Estate

102 patents issued worldwide; over 65 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.

Capitalization Summary

Select Data – as of 9/30/16	
Cash	~ \$15MM
Senior term loan	~ \$17.7MM
Common Shares outstanding	~ 20.5MM
Outstanding options, RSAs and warrants	~ 4.3MM
Fully diluted share count	~ 24.8MM
Market capitalization	~ \$32MM*

* Based on share price of \$1.55 at closing on January 6, 2017.

Update- Key Corporate Objectives & Milestones

2017 Objectives & Milestones

- STAR Phase III one year follow-up data
- SCLERADEC-II 24 WK follow-up data
- Submit for US FDA PMA approval for Habeo™ for scleroderma
- Submit for EMA marketing authorization for Habeo™ for scleroderma
- US Phase I BARDA-funded trial enrollment
- Full ADRESU enrollment
- IDE for for Habeo™ for secondary Raynaud's

Thank You

