

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**

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 Monday, January 12, 2015 at 3:30 PM Pacific Time (6:30 PM Eastern Time) in the C-Mission II 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.

Date: January 12, 2015

By: /s/ Tiago Girao

Tiago Girao

VP Finance and Chief Financial Officer



Cytori Therapeutics

NASDAQ: CYTX

Investor Update
January 2015

Restoring Lives

Forward-looking Statements

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 ability to successfully initiate the planned clinical trials in the United States, Japan and Europe, as well as the financial, clinical and regulatory burdens associated with those trials, and our ability to complete the trials in the time frames referenced, the various medical indications that may be addressed by Cytori Cell Therapy, the potential effectiveness of Cytori Cell Therapy, our ability to maintain a substantially reduced cash burn and increase our percentage of R&D expenditures compared to prior years, Our partners ability to launch products in China and Europe, our ability to refinance our corporate loan, and the anticipated BARDA funding of approximately \$8.3 million to cover the costs of the pilot clinical trial for thermal burn. Some risks and uncertainties related to such forward looking statements include: risks in the collection and results of clinical data, final clinical outcomes, regulatory uncertainties, financing uncertainties, dependence on third party performance, future Government funding and procurement priorities, the Government's sole discretion in determining funding timing and amounts, the Government's ability to reduce, modify or terminate the BARDA contract if it determines it is in the Government's best interests to do so, the performance of our products, 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.

Corporate Overview

Cytori Cell Therapy™

- Differentiated, adipose-based therapeutics platform with extensive clinical experience
 - Autologous therapeutic- uniquely regulated as FDA Class III device
 - Primary disease targets: immuno/inflammatory and ischemic disease
 - Strong global intellectual property position
-

Lead Indication in Late Stage Clinical Development

- Scleroderma, rare rheumatologic condition
 - Pilot data indicative of disease modification & symptom improvement
 - Entering U.S. Phase 3/pivotal trial 2015
 - 80 patient, double blind trial with crossover arm
-

Global Pipeline, with External Funding

- E.U. Phase 3/pivotal trial for scleroderma
- U.S. Phase 2/pilot trial in osteoarthritis, heart failure
- U.S. Phase 2/pilot trial planned for thermal wounds- funded by U.S. government
- Japanese Phase 3/pivotal trial for urinary incontinence- funded by Japanese government

Cytori Cell Therapy™ Pipeline



Scleroderma Assoc. Hand Dysfunction

	ECCS-50		Initiate 2015
	ECCS-50		Initiate 2015

Knee Osteoarthritis

	ECCO-50		Enrolling 2015
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Chronic Heart Failure

	OICH-D3		Enrollment Complete
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Cutaneous Thermal Injury

	DCCT-10		Preclinical Planning
		US Govt Sponsorship	

Urinary Incontinence

	ECCI-50		Enrolling 2015
		Japan Govt Sponsorship	

Cytori's Autologous Cell Therapy Solution



- Stem cells
- Mesenchymal progenitor cells
- Endothelial Cells
- Endothelial progenitor cells
- Lymphatic cells
- Lymphatic progenitor cells
- Treg cells
- Type 2 macrophages
- Vascular smooth muscle cells
- Pericytes

Therapeutic Agent

Primary Mechanism

ECCS-50



- Modulation of the innate immune system and inflammation through down-regulation of pro-inflammatory factors incl. IL-6 and CXCL-2

OICH-D3



- Increased angiogenesis and arteriogenesis through up-regulation of factors such as VEGF and PlGF

DCCT-10



- Modulation of ECM deposition through modulation of MMP expression and activity

Point of Care Platform

- Multifaceted & expandable
- Extensive automation
- Approximately 1 hour

Adipose-Derived Regenerative Cells

- Unique perivascular and interstitial cells from adipose

Versatile Therapeutic Derivatives

- Therapeutics regulated as FDA class III device (RFD# 090013)
- Multiple therapeutic formulations

Cytori Cell Therapy for Scleroderma Hand Dysfunction

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6



Scleroderma Associated Hand Dysfunction (SAHD)

Systemic sclerosis (SSc) or scleroderma

- Rare Autoimmune condition
- Affects women:men, 4:1
- Cutaneous and visceral fibrosis
- Obliteration of the lumen of small vessels
- $\geq 90\%$ patients hand disability

Hand manifestations principal source of functional impairment and reduced quality of life

- Fibrosis, pain, and edema result in diminished mobility and hand function even with standard medical care



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

Pathophysiology

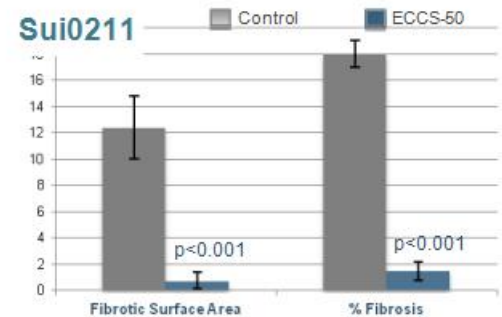
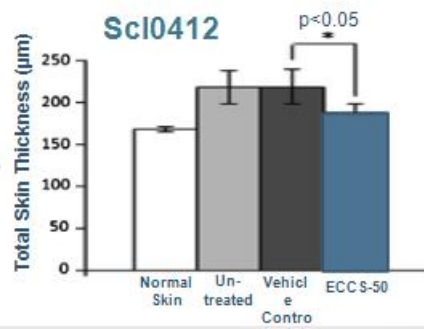


Development of ECCS-50 for Scleroderma (SAHD)

Study	Phase	Approach	Status	Key Findings	Ref
Scl0101	Preclin. (human)	Feasibility	Complete	Preparation of ADRCs from scleroderma patients is feasible [§]	1
Scl0412	Preclin. (murine)	Drug-induced cutaneous fibrosis	Complete	Reduced skin thickness [§]	2
Sui0211	Preclin. (porcine)	Urethral fibrosis	Complete	Reduced fibrosis [§]	3
Scl102	Clinical Phase I (Pilot)	12 patient, single arm	Complete	Good safety profile; Sustained improvement in hand function, pain, and quality of life [§]	4
Scl103	Clinical Phase III (Pivotal)	80 patient USA randomized, controlled trial	FDA-approved Projected to begin enrollment in Q1, 2015		
Scl104	Clin. Phase II/III	40 patient multi-center EU randomized, controlled trial	Pending French regulatory approval (ANSM)		

1. Unpublished Data on file at Cytori // 2. Serratrice et al 2014; Stem Cell Res. & Ther. 5: 138- // 3. Unpublished Data on file at Cytori // 4. Granelet et al (2014); Ann Rheum Dis Aug 11
[§] Study executed by Cytori collaborator

Preclinical studies demonstrate consistent reduction in fibrosis



NASDAQ: CYTX

8





Study Design

- Single center (Marseille, France), open-label trial of 12 patients (NCT01813279)
- Funded by Groupe Francophone de Recherche de la Sclérodémie

Population

- Men and women with diagnosis of limited or diffuse scleroderma
- Age \geq 18 years
- Functional disability of the hand
 - Cochin Hand Function Score >20

Treatment/Dosing

- ECCS-50: 1 mL s.c. into each finger (4 million cells/finger)

Study Endpoints

- Primary endpoint: Cochin score
- Secondary endpoints:
 - Hand symptoms and function (other than Cochin)
 - Health-related quality of life (S-HAQ questionnaire)
 - Raynaud's & vasculopathy
 - Safety



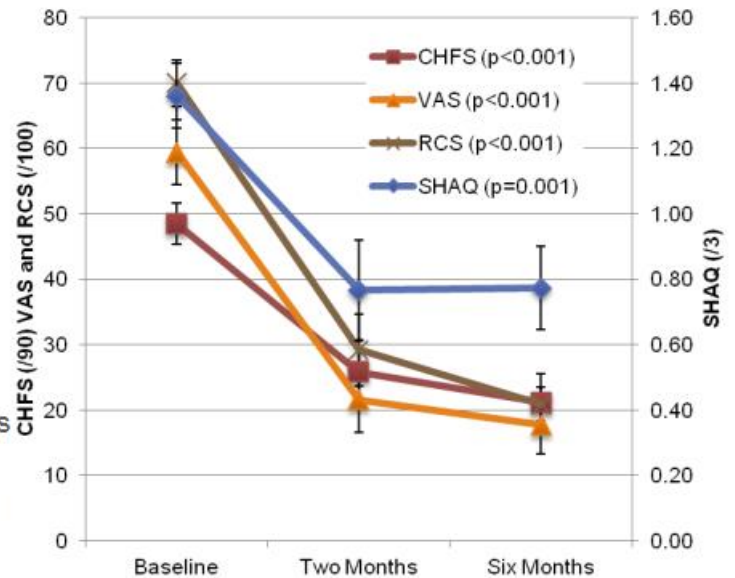
Scleradec I Results

• ECCS-50 Safety

- No serious AEs during follow-up
- Four minor AEs reported by four patients
 - All resolved spontaneously within 15d

• ECCS-50 Efficacy

- Hand Function
 - Average 57% improvement in Cochin Hand Function Score at 6 months
 - Improved grip and pinch strength
- Pain
 - Average 64% improvement in pain at 6 months
- Vasculopathy
 - 69% reduction in Raynaud's score (frequency and intensity) at 6 months
 - Reduced edema (finger size)
- Ulcer Healing
 - 53% reduction in number of ulcers and 90% reduction in average ulcer area at 6 months

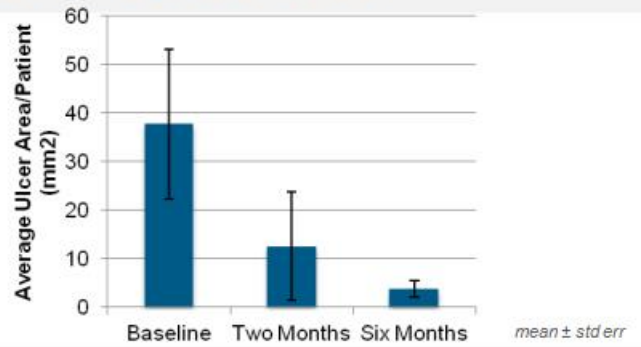
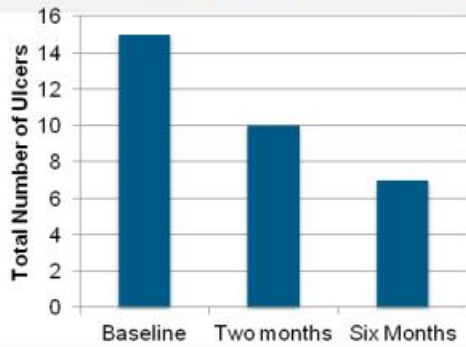


CHFS = Cochin Hand Function Scale
 VAS = Visual Acuity Scale (Pain)
 RCS = Raynaud's Condition Score
 SHAQ = Scleroderma Health Assessment Questionnaire
mean ± std err; p values shown for 6 month data

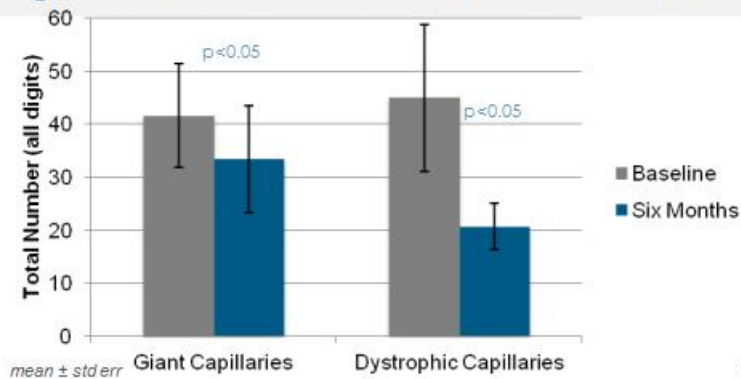
Graell et al (2014); Ann Rheum Dis Aug 11



ECCS-50 Treatment led to a progressive decrease in the number of ulcers and average ulcer area





...and significant normalization of microvasculature



Granel et al (2014); Ann Rheum Dis Aug 11

Phase 3/Pivotal Trial Design for Scleroderma (SAHD)

	STAR Trial (US Pivotal) 	Scleradece II (EU Confirmatory) 
Study Design	Randomized, double blind, 48 weeks	Randomized, double-blind, 6 months (+6 months open label)
Control	Placebo, crossover 48 weeks*	Placebo, crossover after 24 weeks (cryopreserved)*
Sample size	80 (1:1 randomization)	40 (1:1 randomization)
Sites	10 to 12 USA	6 France
Key Inclusion	Cochin > 20	Cochin > 20
Initiation	2015	2015
Primary endpoint	Cochin Score at 6 months	Cochin Score at 3 months
Key Secondary endpoints	Cochin at other visits Raynaud's Condition Score S-HAQ VAS Modified Rodnin Functional hand assessment HAMIS Adverse events	Cochin at other visits Raynaud's Condition Score S-HAQ VAS Modified Rodnin Functional hand assessment Capillaroscopy Adverse events
Regulatory Strategy	PMA approval, under CBER	Additional CE Mark labeling

*after all patients have completed the noted time point

Rare Disease Basis for Scleroderma (SAHD) & Therapeutic Analogue

Scleroderma

Definition

An autoimmune disorder causing collagen overproduction leading to fibrosis and impaired vasculature. Most commonly effects the hands but often affects multiple organ systems.

Epidemiology

- Prevalence: 50 - 75,000
(242/million adults)
- Incidence: 4,400
(18.8/million adults)
- Predominance in women 20 to 50 years old

Therapeutics

- Focus on vasodilation/vasoconstriction
 - Calciumchannelblockers
 - NO pathway
 - Endothelin1 receptor antagonists
 - Prostanoids

Analogous Disease

Rheumatoid Arthritis (RA)

Definition

An autoimmune disorder causing a systemic inflammation which manifests itself in multiple joints of the body. Primarily affects lining of the joints but can also affect other organs.

Epidemiology

- Prevalence: 1,500,000
(30x more common than SSc)
- Incidence: 131,000
(410/million)

Therapeutics

- NSAIDS
- Disease modifying drugs
 - Methotrexate
 - Biologics
- RA biologics can cost over \$30k/year

Comparison of Scleroderma and RA Hand Disability

Published studies confirm that SSc disability is similar to or worse than RA

Metric	Outcomes	Source
Work disability (WD)	WD was observed in 56% of SSc patients vs. 35% of RA patients	Ouimet 2007
	"...the prevalence of work disability in SSc is substantially higher than other common rheumatic conditions."	Sharif 2011
HAQ-DI	"QOL in patients with SSc, as indicated by their level of physical function, was significantly reduced compared to healthy controls, but similar across groups of rheumatology patients... Joint involvement in SSc is more disabling than joint involvement in [psoriatic arthritis]; and patients with SSc experience more severe pain than patients with RA"	Johnson 2007
	"...patients with dSSc have more functional impairment than patients with RA or other CTDs [connective tissue diseases]"	Morita 2007
Cost (health care utilization)	"...indirect comparison with RA in Canada suggests that SSc's average costs are higher (RA: 10 459; SSc: 12 585 euros/patient/year)"	Minier 2010
	"...average annual cost of SSc per patient may be as high as that of RA (the equivalent of \$16,141 in 2007 Canadian dollars, based on RA cost estimates from one study [31]), and in diffuse SSc the average annual cost per patient may very well exceed the cost of RA."	Bernatsky 2009

Cytori Cell Therapy for Knee Osteoarthritis

NASDAQ: CYTX

15



Knee Osteoarthritis

Osteoarthritis (OA) Definition

Disease of the entire joint involving the cartilage, joint lining, ligaments, and underlying bone. The breakdown of tissues leads to pain and joint stiffness

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



Current Therapies

Treatment Modality	2014E		
	# Patients / Treatments	ASP	Market Size
Celebrex/NSAID	3,900,000**	\$564	\$2.2B
Knee Viscosupplement Injection	898,000*	\$935	\$0.8B
Total Knee Arthroplasty	780,000	\$4,402	\$3.4B

* Includes sales of packages for multiple indications: OA, RA, Ankylosing Spondylitis, Acute Pain Management.

** Represents a particular course of therapy performed in the U.S. (i.e., one single injection or multiple injection treatment).

Development of ECCO-50 for Knee Osteoarthritis

Study	Phase	Approach	Status	Key Findings	Ref
OA0103	Preclinical (human)	Demonstration of <i>in vitro</i> differentiation towards chondrocytes	Complete	Expression of multiple markers characteristic of chondrogenesis	1
OA0203	Preclinical (caprine)	Injured-induced osteochondral defect	Complete	Improved healing at 4 months [§]	2
OA0205	Preclinical (canine)	Injection into injured intervertebral disc	Complete	Improved disc biochemistry and matrix production	3
OA0501	Veterinary (canine)	21 animal randomized, double-blind trial of OA in the hip	Complete	Improvement in lameness, pain, and range of motion [§]	4
OA0502	Veterinary (canine)	Open-label multi-center study of 14 animals with elbow OA	Complete	Improvement in lameness, pain, and range of motion [§]	5
OA104	Clinical Phase I (Pilot)	25 patient, single arm; OUS	Complete	Improvement in activity and knee function (Lysholm) ¶	6
OA105	Clinical Phase I (Pilot)	18 single arm; OUS	Complete	Improvement in pain and knee function (Lysholm and WOMAC) ¶	7
OA106	Clinical Phase I (Pilot)	Higher dose; 25 patient, single arm with 2 nd look arthroscopy at 2yrs; OUS	Complete	Improvement in pain and knee function; 64% positive or very positive on 2 nd look; only 12.5% 'failed' ¶	8
OA107	Clinical Phase II (Pilot)	Multi-center, USA randomized, double-blind placebo-controlled trial	FDA- IDE approved Projected to begin enrollment in Q1, 2015		

1. Huang *et al* 2004; *Plast Reconstr Surg*. 113(2):585-94
2. Jurgens *et al* 2013; *BioResearch* 2 (4) pp. 315-25
3. Ganey *et al* 2009; 34 (21) 2297-304
4. Black *et al* 2008; *Vet Ther*. 8 (4) pp. 272-84
5. Black *et al* 2008; *Vet Ther*. 9 (3) pp. 192-200
6. Koh *et al* 2012; *The Knee* 19: 902-7
7. Koh *et al* 2013; *Arthroscopy* 29 (4) 748-55
8. Koh *et al* 2013; *Knee Surg Sports Traumatol Arthrosc*

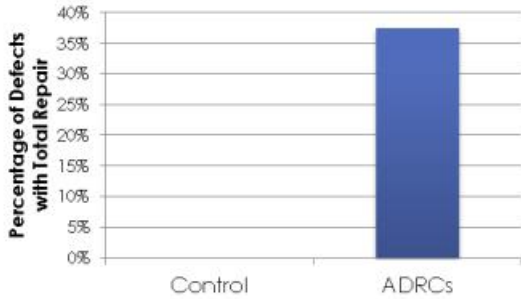
§ Study executed by Cytori collaborator

¶ Study executed independently of Cytori

Development of ECCO-50 for Knee Osteoarthritis

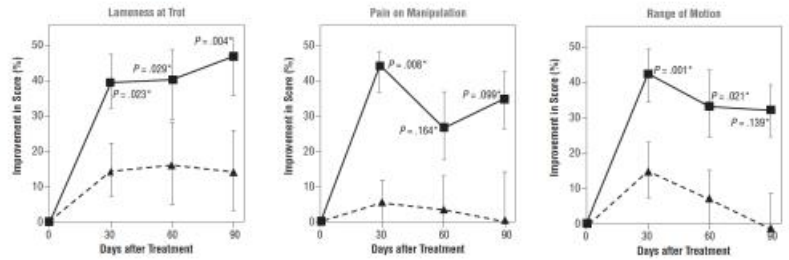
Goat Injury Model

Treatment led to greater healing of cartilage 4 months after injury



Canine veterinary model (randomized, controlled)

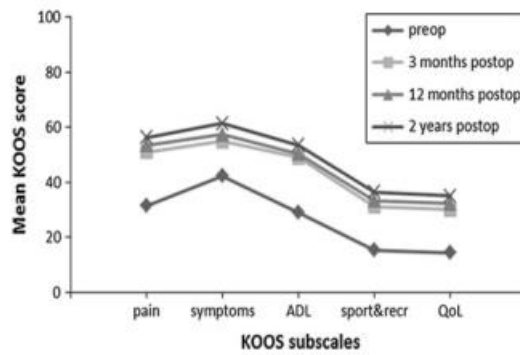
Treatment led to improvements in lameness, pain, and range of motion²



Clinical Pilot

Treatment led to reduced pain, increased function, and potential cartilage repair³

- Jurgens *et al* 2013; *BioResearch* 2 (4) pp. 315-25
- Black *et al* 2008; *Vet Ther.* 8 (4) pp. 272-84
- Koh *et al* 2013; *Knee Surg Sports Traumatol Arthrosc*



U.S. Pilot/Phase 2 Trial for Knee Osteoarthritis

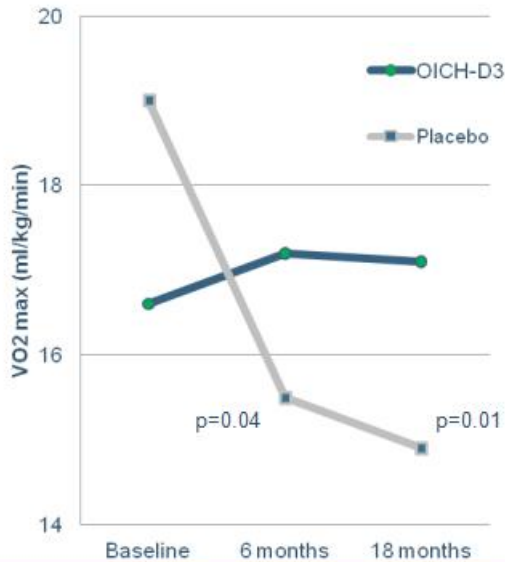
ACT-OA (US Phase II) 

Study Design	Randomized, double blind, 48 weeks duration, dose escalation (low and high dose cell ECCO-50 therapy)
Control	Placebo, no crossover
Sample size	90 (1:1:1 randomization)
Sites	Up to 15 in USA
Key Inclusion	OA of Knee, pain \geq 6 months, pain on walking \geq moderate, KL score 2-3,
Initiation	2015
Primary endpoint	KOOS - Pain on Walking at 12 Weeks
Key Secondary endpoints	Observed Pain Scores on 50-foot Walk Test Number of Observed OARSI30 Responders Using the 50-Foot Walk Test Knee injury and Osteoarthritis Outcome Score (KOOS) VAS Assessments (0-100 mm scale) Patient global assessment Number of tablets of rescue medication Short-Form (SF)-36 questionnaire MOAKS scoring (MRI Osteoarthritis Knee Score) at Week 48 Adverse events
Regulatory Strategy	Phase III study leading to PMA (under CBER) and approval in EU, Canada and other markets as appropriate

Development of OICH-D3 for Heart Failure

PRECISE Study

Randomized, DB, PC trial of OICH-D3 treatment in 27 pts. with chronic heart failure.



E.U. Phase II Trial

Associated with significantly greater maximum oxygen consumption capacity (VO₂ max) at both six and 18 months

ATHENA Trials Summary

Randomized, DB, PC trial in US of OICH-D3 treatment in patients with chronic heart failure - primary endpoint VO₂ max.

ATHENA I

28 ● ●

2:1 active:control
lower dose

ATHENA II

3 ● ●

2:1 active:control
higher dose

STATUS

- Enrollment stopped after 31 patients for safety review
- Thorough safety review conducted, permission to proceed with protocol amendments
- Cytos decision - truncate enrollment, evaluate 6 and 12 month data
- Further decisions on investment based on analysis of data, optimization of protocol (as per amendments) and incorporation of next generation technology

TIMELINES

- 6 month data analysis 1Q2015
- 12 month data analysis 4Q2015

Cytori-U.S. Government Collaboration for Thermal Burn Countermeasure



US Government Contract # HHSO100201200008C

- **Goal**

- Develop a medical countermeasure for use following mass casualty attack involving thermal burn & radiation injury
- Contract value: up to \$106m

- **Status**

- **\$4.7m- proof-of-concept phase completed**
- **\$14m- contract option 1 for additional development activities ongoing**
- **\$8.3m- contract option 2 to fund US Phase I/II clinical trial pre-reviewed and approvable, subject to FDA IDE approval**
- \$79m additional contract options for Phase III clinical trial and for development of countermeasure for combined radiation & thermal injury
- Other medical countermeasure options possible outside current contract

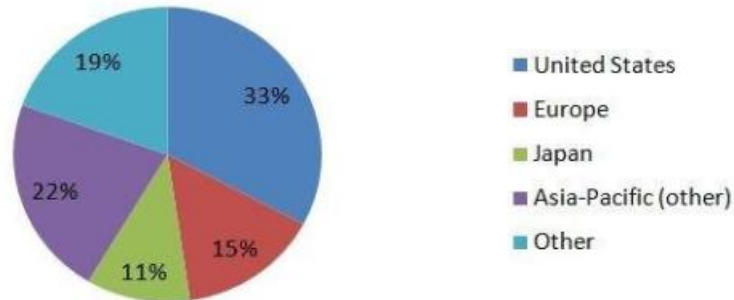
Long term goal-

United States Government acquisition contract for Cytori Cell Therapy

Cytori's Global Patent Estate

75 patents issued worldwide; 45 applications pending

Geographic Distribution of Cytori's Patents & Applications



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, and several other pipeline indications

Commercial Opportunities and Revenue Outlook

Direct sales- Japan



- Nov 2014, Regenerative Medicine Law in effect
- Expand Cytori's ability to sell product under Class I approval
- Cytori KK has operated in Japan for more than 10 years

Licensing partners



Lozem Vascular - in SE Asia, Australia and China (launch in 2015 upon CFDA approval)

Bimini - Puregraft & Celution for hair re-growth (EU launch in 2015)

US BARDA contract revenue



Revenue Outlook

- 2015
 - Modest growth from product sales, BARDA & royalty/licenses
 - Positive contribution margin
- 2016
 - Continued growth from product sales, BARDA & royalty/licenses
 - Growing positive contribution margin

Financials & Expenses

Select Data - as of 9/30/14

Cash	~ \$8M (~ \$20M pro-forma)
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Senior Term Loan	~ \$25M (Matures 2017)
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- Spend focus and reductions
 - 2014 reduction in FT headcount from peak of 119 to 77, severance impact mostly complete by YE 2014
 - Operating cash burn ~ \$35M in 2013, ~ \$31M estimated in 2014, to a forecasted operating cash burn of ~\$25M in 2015 (\$10M reduction from 2013)
 - Strengthened our focus on R&D activities- expected to be at least 55% of total operating expenses as compared to 40% for 9ME 9/30/2014.

Anticipated 12 Month Milestones

Clinical Milestones

• Trial Enrollment

- Osteoarthritis: ACT-OA, data 2016
- Scleroderma: STAR, data 2016
- Scleroderma: E.U. SCERADEC-II, data 2016
- Japan male urinary incontinence trial: timeline announced & begin enrollment

• Clinical Data

- Cardiac: ATHENA 6 and 12 month data
- Scleroderma: SCLERADEC-I, 12 month data

• Preclinical Data

- Burn/wound healing: presentation at American Burns Association

Business/Operational Milestones

- Partner: Chinese FDA approval & Chinese product launch
- Partner: European product launch for hair re-growth
- Growing impact of reduced cash burn and loan refinance
- Increase out licensing platform and in licensing immunology/ inflammatory and ischemia area



Cytori Corporate Overview

NASDAQ: CYTX

Thank you!

QUESTIONS, please contact ir@cytori.com