#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 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 27, 2017

#### **CELSION CORPORATION**

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation)

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

001-15911 (Commission File Number) 52-1256615 (IRS Employer Identification No.)

997 Lenox Drive, Suite 100, Lawrenceville, New Jersey 08648 (Address of Principal Executive Offices) (Zip Code)

(609) 896-9100 (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

☐ 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.

On January 27, 2017, Celsion Corporation. (the Company) made available corporate presentation materials on the Company's website at www.celsion.com. A copy of the Company's presentation materials is attached hereto as Exhibit 99.1.

#### Limitation of Incorporation by Reference

In accordance with General Instruction B.2. of Form 8-K, this information, including the Exhibit, is furnished pursuant to Item 7.01 and shall not be deemed to be filed for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section 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 specific reference in such a filing. The Company undertakes no duty or obligation to update or revise information included in this Report or any of the Exhibits. The information in this Item 7.01 of this Current Report on Form 8-K will not be deemed an admission as to the materiality of any information that is required to be disclosed solely by Regulation FD.

#### Cautionary Statements

This Current Report on Form 8-K and the presentations include "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including information about the Company's plans and expectations regarding its clinical studies and related FDA and regulatory matters.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Important factors that could impair the Company's business are disclosed in the "Risk Factors" contained in the Company's 2015 Annual Report on Form 10-K and other periodic reports filed with the Securities and Exchange Commission. All forward-looking statements are expressly qualified in their entirety by such factors. We do not undertake any duty to update any forward-looking statement except as required by law.

(d) Exhibits.		
Exhibit No.	Description	
99.1	Corporate Presentation materials	

Item 9.01 Financial Statements and Exhibits.

### **SIGNATURES**

Pursuant to the requirements of the Exchange Act, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

#### **CELSION CORPORATION**

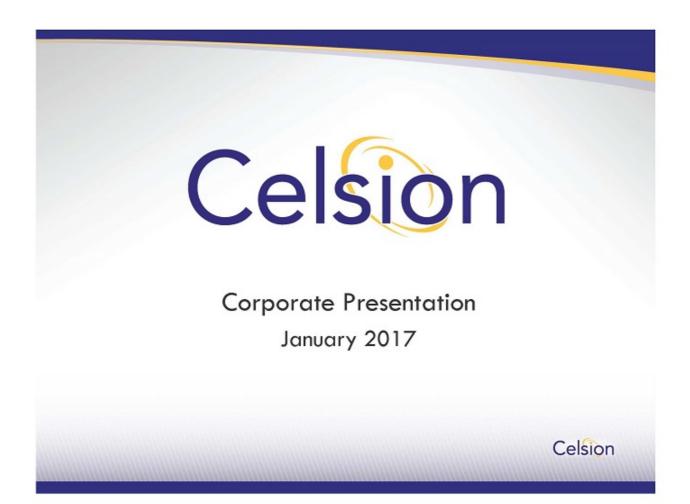
Dated: January 27, 2017

By: /s/ Jeffrey W. Church Jeffrey W. Church Senior Vice President and Chief Financial Officer

#### EXHIBIT INDEX

Exhibit Number Description

99.1 Corporate Presentation materials



### Safe Harbor Statement

This presentation and any statements made for and during any presentation or meeting contain forward-looking statements related to Celsion Corporation ("Celsion") under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected.

These statements may be identified by the use of forward-looking words such as "anticipate," "planned," "believe," "forecast," "estimated," "expected," and "intend," among others. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. Such factors include, among other things, unforeseen changes in the course of research and development activities and in clinical trials; possible changes in cost, timing and progress of development, preclinical studies, clinical trials and regulatory submissions; Celsion's ability to obtain and maintain regulatory approval of any of its product candidates; possible changes in capital structure, financial condition, future working capital needs and other financial Items; changes in approaches to medical treatment; introduction of new products by others; success or failure of our current or future collaboration arrangements, risks and uncertainties associated with possible acquisitions of other technologies, assets or businesses; the ability to obtain additional funds for operations; the ability to obtain and maintain intellectual property protection for technologies and product candidates and the ability to operate the business without infringing the intellectual property rights of others; the reliance on third parties to conduct preclinical studies or clinical trials; the rate and degree of market acceptance of any approved product candidates; possible actions by customers, suppliers, strategic partners, potential strategic partners, competitors and regulatory authorities; compliance with listing standards of The NASDAQ Capital Market; and those risks listed under "Risk Factors" as set forth in Celsion's most recent periodic reports filled with the Securities and Exchange Commission, including Celsion's Form 10-K for the year ended December 31, 2015.

While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Celsion does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

## **Oncology Company**

Capital Efficient Drug Development

Nanoparticle-Based Technology Platforms Driving Growth

Targeted Chemotherapy

Phase III Study in Primary Liver Cancer (The OPTIMA Study)

Phase II Study in RCW Breast Cancer (The Euro-DIGNITY Study)

Gene Mediated Immuno-Oncology

Phase I Neoadjuvant Therapy in 1st Line Ovarian Cancer (The OVATION Study)

Phase I/II Combination Therapy with Avastin  $2^{\rm nd}$  line Ovarian Cancer

## **Our Two Clinical Stage Platforms**



Lysolipid Thermally Sensitive Liposomes Known Chemotherapeutics

### ThermoDox®

## Targeted Doxorubicin Delivery

- · Phase III Study Enrolling in HCC
- Phase II Study in RCW Breast Cancer

## O TheraPlas<sup>™</sup>

Synthetic Non-viral Vector DNA-based Plasmids Therapeutic Proteins

## GEN-1<sup>™</sup>

### Localized IL-12 Immunotherapy

- Neoadjuvant Study in 1st Line Ovarian
- Combination Study with Avastin and Doxil in 2<sup>nd</sup> Line Ovarian Cancer

# **Pipeline of Targeted Therapeutics**

	INDICATION	PRODUCT CANDIDATE	PRE-CLINICAL PHASE 1-2 PHASE 3						
Clinical	Primary Liver	ThermoDox/OPTIMA Study	Phase III enrolling						
Clin	RCW Breast	ThermoDox /Euro-DIGNITY	Phase II initiating						
	Ovarian	GEN-1/OVATION Study	Phase I enrolling						
	MI Bladder Cancer	ThermoDox	Efficacy/Safety/Toxicology Complete						
Pre-Clinical	Glioblastoma	GEN-1	Efficacy/Safety/Toxicology						
	Lung	TheraSilence	Efficacy/Toxicology						

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## Hepatocellular Carcinoma

Large and Deadly Global Cancer

#### 5<sup>th</sup> most prevalent

- 800,000 global incidence growing 5% annually
- By 2020, expected to be the #1 cancer
- China has 50% of new cases; 75% in Asia

#### 4<sup>th</sup> highest mortality

- 5-year survival rate less than 10%
- Median survival from time of diagnosis is less than 3 years<sup>1</sup>
- Curative surgery is possible in less than 20% of patients

#### Local therapies include:

- RFA, TACE and radiation
- PFA is the dominant treatment with local recurrence rates >50% for lesions >3 cm
- ThermoDox + RFA addresses limitations of current standard of care by "Expanding the Treatment Zone"

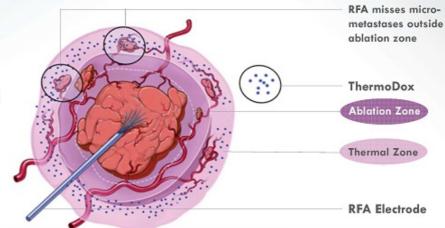
### Market Opportunity >200K Patients

1 Journal of Hepatology 2012 vol. 56 | 908-943

## ThermoDox + RF Liver Ablation

Expanding the Treatment Zone Addresses RFA Limitations

- ThermoDox infused IV
   ~15 minutes prior to
   sRFA
- RFA ablates tumor and creates a "Thermal Zone" in margin surrounding the tumor
- Doxorubicin is released in the "Thermal Zone" expanding treatment area and killing the metastases outside the ablation zone





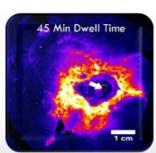
### **RFA Dwell Time Matters!**

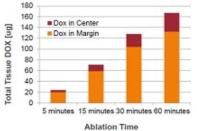
### Learnings from the 700 patient HEAT Study

- Pre-specified analysis of HEAT Study data showed that patients with smaller lesions (3-5 cm) appeared to do better with ThermoDox
- When standardized for dwell time and lesion number, ThermoDox patients demonstrated difference in Overall Survival
- The hypothesis that dwell time increases local doxorubicin concentration was demonstrated in a computational model
- The hypothesis was further tested and demonstrated in an in-vivo porcine model:

More RFA time = More local Dox deposition

15 Min Dwell Time





Multivariate analysis

points to RFA dwell time with ThermoDox as the factor correlating to significant improvement in survival

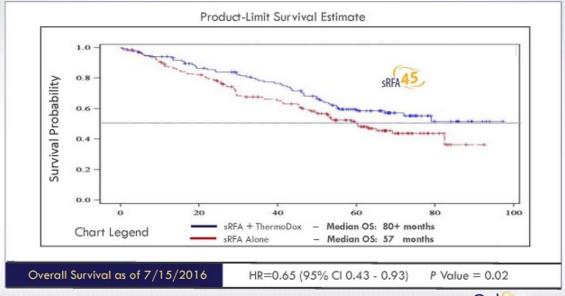


## ThermoDox: HCC

Sub-Group Analysis of HEAT Study Data

#### Greater than Two Years Overall Survival Benefit

285 Patients with Standardized RFA>45 minutes (sRFA)



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### **RFA Dwell Time Matters!**

Independent Confirmation from NIH Analysis of HEAT Study Data

Evaluated RFA burn time per tumor volume (min/ml) for correlation with clinical outcomes

#### Results:

Increase in burn time per tumor volume improves OS in ThermoDox + RFA patients compared to RFA only patients

#### For RFA + ThermoDox patients:

One unit increase in RFA duration per tumor volume improved OS by 20% (p=0.017, HR=0.836, n=227)

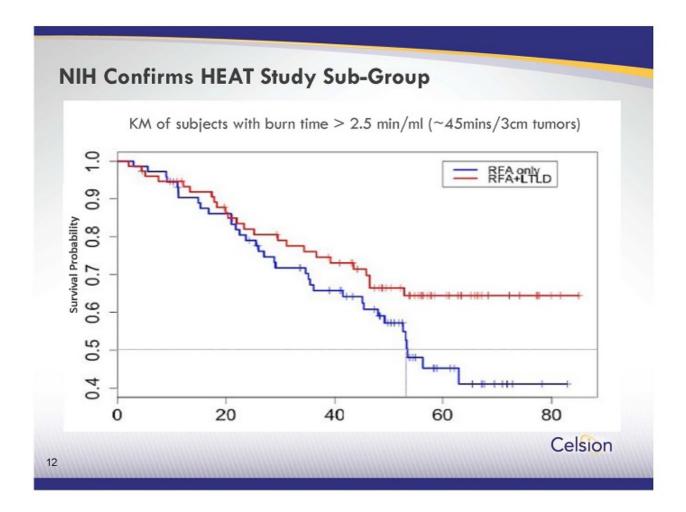
- More dramatic differences in subgroup of patients with RFA burn times per tumor volume > 2.5 minutes/ml
- Cox multiple covariate analysis showed OS to be significant (p=0.038, HR=0.85) - Increase in the burn time per tumor volume improves survival in the RFA + ThermoDox subjects compared to RFA only patients



#### For RFA-only patients:

Burn time per tumor volume did <u>not</u> have a significant effect (p=0.57; HR=0.99; n=210)





## ThermoDox + RFA vs TACE

## Intermediate HCC

Study	Lesion size	N	Median OS (mos.)	Year 1 (%)	Year 2 (%)	Year 3 (%)
HEAT Study ITT Population	Overall: 2.7 - 7.5 cm Mean: 4.2 cm Median: 4 cm	701	53 mos.	85%	76%	64%
ThermoDox + RFA ≥ 45 min.	Overall: 2.7 - 6.9 cm Mean: 4.3 cm Median: 4.2 cm	138	80+ mos.	94%	85%	77%
RFA alone time ≥ 45 min.	Overall: 3 - 6.9 cm Mean: 4.2 cm Median: 3.9 cm	147	57 mos.	88%	79%	69%
Ikeda et al (TACE)	Median: 3.9; range 1-11	99	37 mos.	90%	75%	NR
2013	> 3.0	64	NR	NR	66%	NR
Burrel (DEB TACE)	BCLC A	41	54 mos.	90%	NR	68%
2012	BCLC B	63	48 mos.	88%	NR	64%

DEB TACE - Doxorubicin Eluding Beads

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## The Clinical Management of Hepatocellular Carcinoma in the United States, Europe, and Asia

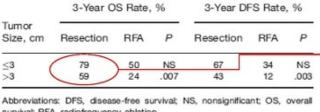
A Comprehensive and Evidence-Based Comparison and Review

Zhi Ven Fong, MD; and Kenneth K. Tanabe, MD

Hepatocellular carcinoma (HCC), the most common primary malignancy of the liver, represents 1 of the leading causes of cancer deaths in the world with an estimated 21,670 deaths in the United States in 2013. In contrast to other malignancies, there is an array of treatment options for HCC involving several specialties in the multidisciplinary care of the patient. Consequently, vast heterogeneity in management tendencies has been observed. The objective of this report was to review and compare guidelines on the management of HCC from the United States (National Comprehensive Cancer Network), Europe (European Association for the Study of the

TABLE 5. Survival Outcomes 3 Years After Surgical Resection and Radiofrequency Ablation of Hepatocellular Carcinoma Based Dichotomized Based on Tumor Size

Cancer September 15, 2014



**HEAT Study showed 3-**Year OS Rate of 77% (July 2015)

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survival; RFA, radiofrequency ablation.

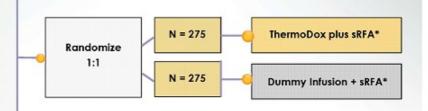
## **Phase III OPTIMA Study Design**

#### **General Eligibility**

- Non-resectable HCC
- Single lesions
- Lesion > 3 cm but not > 7 cm
- Treatment naïve
- · Child-Pugh A

#### Stratification

- Lesion size: 3-5 cm / 5-7 cm
- RFA Technique (Percutaneous, Laparoscopy, or Surgical)



Primary Endpoint Secondary Endpoints	Overall Survival (OS) Progression Free Survival; Safety					
Interim Efficacy Analysis	118 OS Events / HR < 0.61 158 OS Events / HR < 0.70					
Final Efficacy	197 OS Events / HR < 0.75					

First Patient Enrolled Q3 – 2014

~ 75 Clinical Sites in 14 Countries



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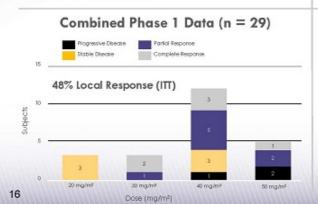
sRFA
 Standardized Radiofrequency Ablation > 45 minutes



## ThermoDox: RCW Breast Cancer

### Difficult to Treat with Severe Complications

- · Breast cancer recurring in the chest wall affects ~35,000 post-mastectomy patients in the US and Europe annually1
- Up to 40% of women undergoing a mastectomy as primary treatment will experience local recurrence
- · Local tumor control is a primary objective in treating these patients







#### Complete Response



#### Phase 2 US DIGNITY Study

Evaluate local-regional breast tumor response. 17 patients enrolled; 12 evaluable for efficacy

- All evaluable patients experienced stabilization of disease; 67% of patients in evaluable population observed local responses - 5 CRs & 3 PRs
- 47% Local Response (ITT)

Agency for Healthcare Research and Quality Celsion 2009; Bian et al. 2008; Clemons et al. 2001



## ThermoDox: Euro-DIGNITY Study

ThermoDox + Hyperthermia + Radiation

#### **Primary Objectives**

 Evaluate complete and partial response after 3 cycles of ThermoDox + Hyperthermia and Radiation Treatment (Tri-Modal Therapy)

 Evaluate loco-regional breast tumor control in patients undergoing Tri-Modal Therapy

70 patients to be enrolled

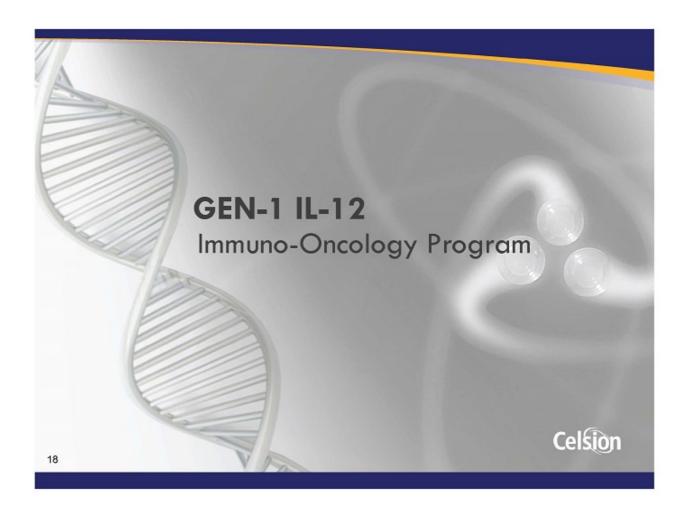
Open Label Design

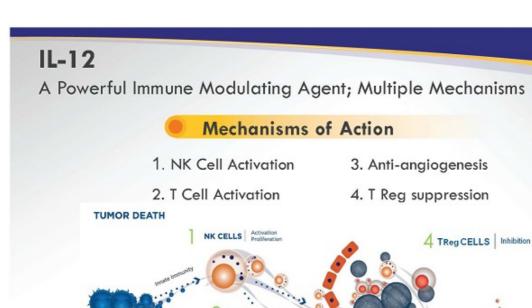
#### **Study Timelines**

- Site Activation: Pending
- Expected Recruitment Period: 2017 – 2018



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7 T CELLS | Maturation Proliferation

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>> TUMOR DEATH

TUMOR

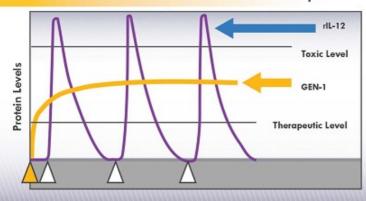
## GEN-1

## Novel Polymer-Plasmid DNA Nanoparticle

### Rationale for Local Therapy with GEN-1 DNA Nanoparticles

- Loco-regional production of potent cytokine IL-12 avoid toxicities and poor pK associated with systemic recombinant IL-12
- Persistent local delivery of IL-12 lasts up to one week and dosing can be repeated
- Ideal for long-term maintenance therapy

#### GEN-1 is an Effective Alternative to rIL-12 Poor pK





100 nm

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### **Ovarian Cancer**

## Large and Deadly Global Cancer

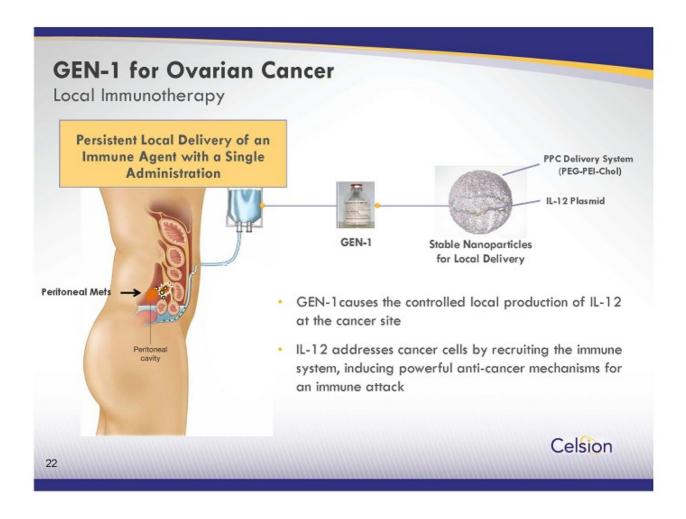
- 8<sup>th</sup> most diagnosed cancer among women
  - 225,000 annual incidence worldwide
  - 22,280 in US and 100,000 in developed countries
  - 14,240 deaths in 2015

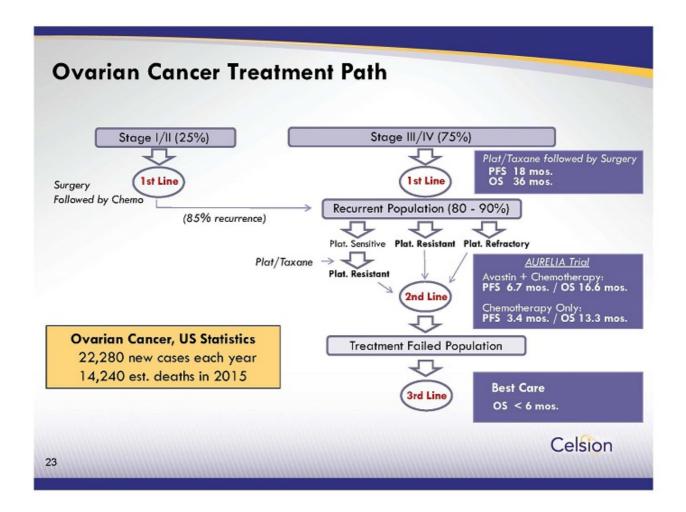
- 5<sup>th</sup> highest mortality among women
  - 5-year survival rate for all stages is >50%
  - Survival rate reduces dramatically if not localized cancer
  - 15% diagnosed with localized cancer, eligible for potentially curative surgery

- Local therapies for ovarian cancer
  - Ovarian cancer is not diagnosed early - spreads to regional/mets requiring combo regimens
  - Most common site of recurrence in abdomen importance of intraperitoneal administered therapy
  - GEN-1 administered IP; ideal adjuvant to SoC therapy

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Sources: Cancer Statistics, American Cancer Society; Globocan; SEER database

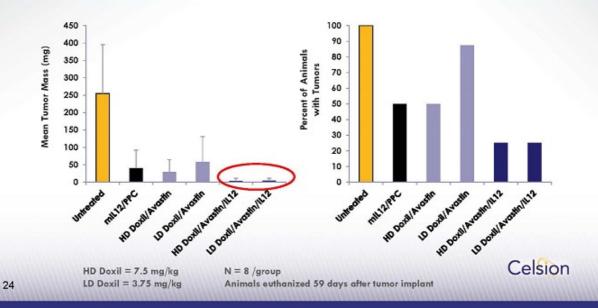




## **GEN-1: Preclinical Studies**

GEN-1 + Doxil + Avastin

- Doxil + Avastin is 2<sup>nd</sup> line SoC for platinum-resistant ovarian cancer.
- Adding Avastin Results in a > 98% Reduction in Tumor Burden



## GEN-1 + Doxil Phase 1b Trial

2<sup>nd</sup> Line

GEN-1 (mg/m²)	Doxil (mg/m²)
24	40
36	40
36	50

#### Clinical Observations

- All doses well tolerated with no DLTs
- Clinical response rate:
  - All doses: > 50%
  - Highest dose: 86%
- Single agent Doxil comparison 4 previous studies:
  - Clinical RR < 50%</li>

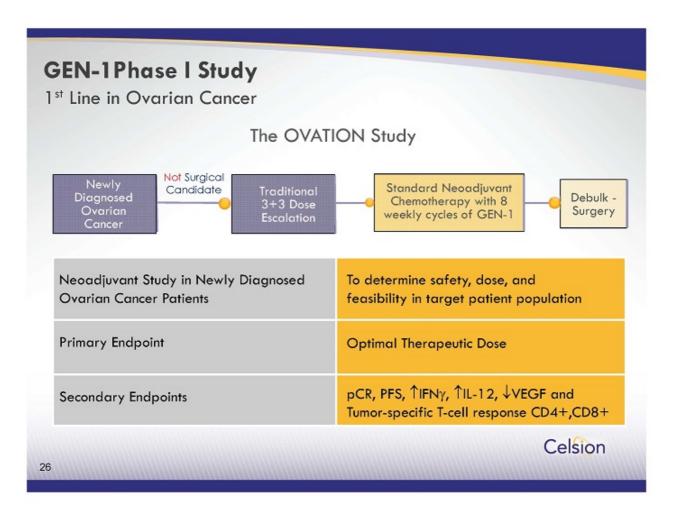
#### **Translational Data Findings**

Significant increase in immunologically active IL-12 levels in peritoneal fluid

- Detectable for at least one week after GEN-1 dosing
- Not detectable or very low in plasma

Significant increase in key downstream mediators of IL-12

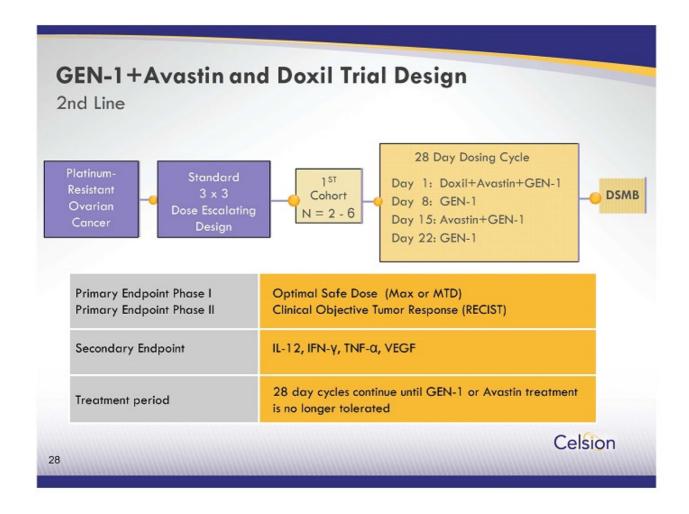
- IFN-γ and TNF-α: ~5-fold increase observed in peritoneal fluid above pretreatment level with the highest increase observed at 77-fold
- Very low to non-detectable levels of IFNγ and TNF-α in plasma

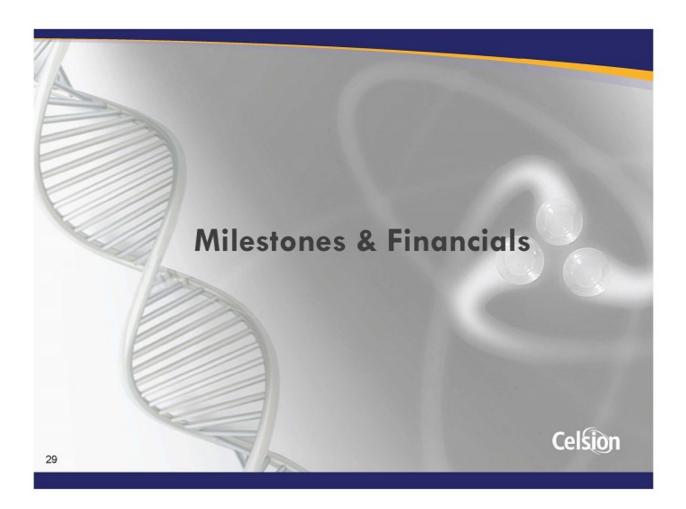


## **OVATION Study**

Totality of Results in the First Four Patient Cohorts, n=12

- 1st 12 patients dosed, there has been a
  - 100% disease control rate (DCR)
  - 75% objective response rate (ORR)
- Of the 11 surgically treated patients:
  - All patients had successful resections of their tumors
  - One patient demonstrated a complete pathological response (PCR) <sup>1</sup>
  - 55% of patients had a RO resection (margin-negative resection)
- All show a greater than 90% drop in their CA-125 protein levels <sup>2</sup>
- Ratio of CD8+/FoxP3+ cells was increased in all four evaluable patients demonstrating a potential shift in tumor environment to favoring immune stimulation following NACT + GEN-1 therapy
- 1 In a 332 patient GOG Study, cPR's were seen in < 6.5% of patients; Strong correlation with improvement in Overall Survival (median OS of 72 mos.) which is a 3 year improvement over patients having a microPR or macroPR (Pvalue = 0.018)</p>
- 2-50% reduction in CA-125 levels from baseline that is maintained for  $\geq 2$  weeks is considered a CA-125 Respondent values of the considered and CA-125 Respondent values of the considered v





# Milestone Events (2016 - 2018)

	2016			2017				2018				
	01	Q2	03	Q4	01	Q2	Q3	04	01	02	Q3	04
ThermoDox												
		Initiate	HEAT Study		OPTIMA					OPTIMA		1st Interim
OPTIMA	- 3	Enrollment in V	OS Data V		50%					Enrollment		Efficacy
STUDY		China	(China cohort)		Complete					Complete		Endpoint
								1st Efficacy				Final Data
Euro-DIGNITY						Initiate		Assessment		Enrollment		Assessmen
STUDY						Enrollment		(24 pts)		Complete		(70 pts)
GEN-1				- 10								
			Translational			Final Efficacy						
		Efficacy Data	Research Data Ef	ficacy Data	Efficacy Data	& TR Data						
OVATION		frem a	from al	from 1	from 1	from Cohorts						
STUDY		Cohorts 1 & 2	from Cohorts 1 & 2	Cohort 3 V	Cohort 4	1-4						
	TR Data from ,						Submit IND				Efficacy & TR	Initiate
Avastin+Doxil	Phase 1b V	Pre-Clin Data					for Ph 1/2	Initiate			data from	Phase 2
Study	Ovarian Study	of AACR V					Study	Enrollment			Phase 1	Study
TheraSilence												
		Pre-Clin Data										
	(	Collaboration ,				Potential Co-						
	100	w/RNA V				Development						
Lung Cancer		company				Collaboration						

√ Achieved to-date

## **Financial Overview**

Cash & Investments (9/30/16)

\$8.7 million

Estimated cash usage per month

~\$1.5 million

Market Capitalization

\$10 million

Common shares outstanding

31 million

Fully diluted shares outstanding

55 million

Avg Daily Trading Volume

~700,000

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