
**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): March 14, 2019

CELSION CORPORATION
(Exact name of registrant as specified in its Charter)

Delaware

(State or other jurisdiction
of incorporation)

001-15911

(Commission
File Number)

52-1256615

(IRS Employer
Identification No.)

997 Lenox Drive, Suite 100, Lawrenceville, NJ

(Address of principal executive offices)

08648-2311

(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 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

Celsion Corporation (the “Company”) will be making corporate presentations over the next several weeks, including a presentation at the Oppenheimer & Co. 29th Annual Healthcare Conference on Tuesday, March 19, 2019, in New York, NY. In connection with the presentations, the Company intends to discuss the slide presentation attached as Exhibit 99.1 hereto, which is incorporated herein by reference.

The slide presentation attached as Exhibit 99.1 to this Current Report on Form 8-K includes “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the slide presentation or in the press release are “forward-looking” rather than historical.

The Company undertakes no duty or obligation to update or revise information included in this Current Report on Form 8-K or Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Celsion Corporate Presentation dated March 2019

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.

CELSION CORPORATION

Dated: March 14, 2019

By: /s/ Jeffrey W. Church

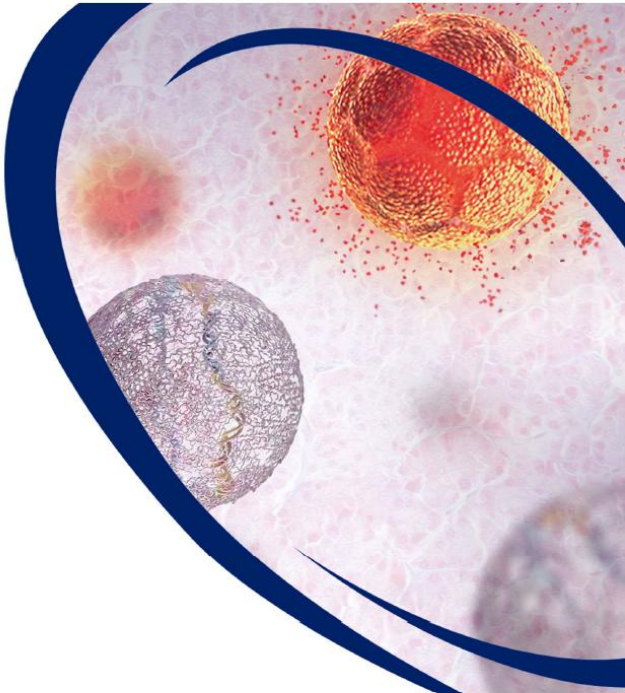
Jeffrey W. Church

Executive Vice President and Chief Financial Officer

Celsion

Corporate Presentation

March 2019



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 filed with the Securities and Exchange Commission, including Celsion's Form 10-K for the year ended December 31, 2017.

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.



2019: A Year of Opportunity



LARGE
COMMERCIAL
OPPORTUNITY

Two distinct and innovative technology platforms at clinical stage

Billion dollar commercial opportunities each in HCC/Primary Liver and Ovarian Cancer where the need for effective treatments remains



SIGNIFICANT
MILESTONES

OPTIMA Study, a global Phase III trial in HCC/Primary Liver Cancer, with 1st interim data expected in second half of 2019

OVATION 2 Study, a Phase I/II trial in Ovarian Cancer with Phase I data expected in second half of 2019



FINANCIAL
STABILITY

\$30 million in cash provides 2-year operating runway

Clean Cap Structure

- Less than 20 million shares outstanding
- Minimal warrant overhang

Two Novel Nanoparticle-Based Technology Platforms

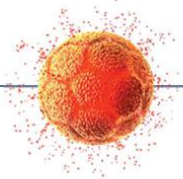
Both Poised for Success

LTSL

Lysolipid Thermally Sensitive Liposomes for Delivery
of Known Chemotherapeutics

ThermoDox®

Targeted Doxorubicin Delivery



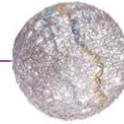
Orphan Drug Designation: US and EU
Fast Track for HCC in US

TheraPlas

Non-Viral Vector Delivers DNA Plasmids Coded
for Therapeutic Proteins

GEN-1 Immunotherapy

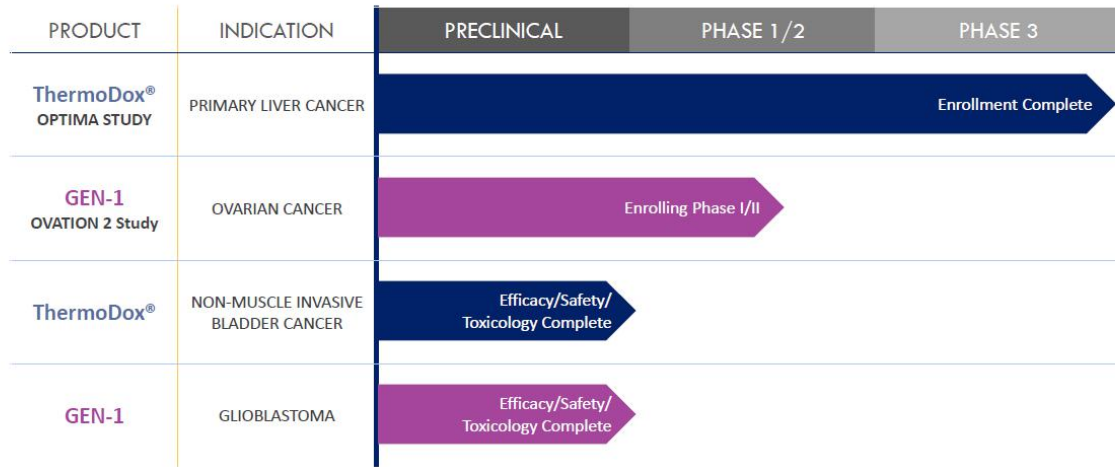
Localized Interleukin-12 (IL-12) Immunotherapy



Orphan Drug Designation: US
EU Filing in Progress

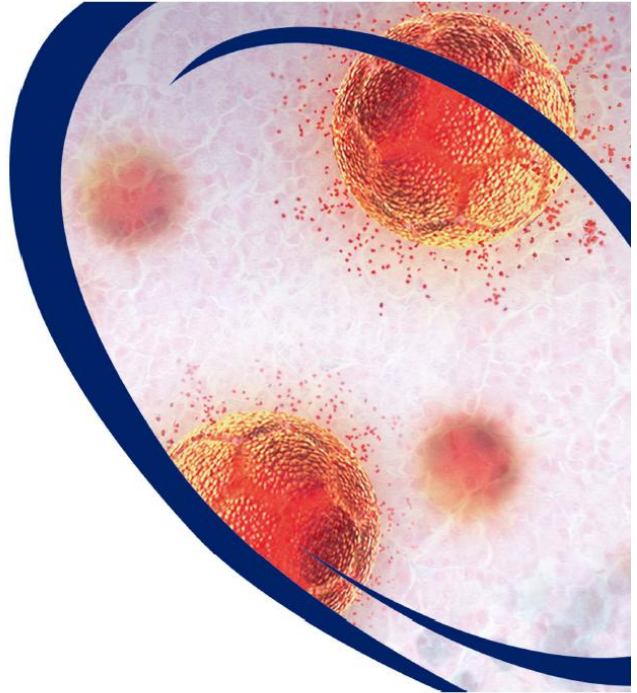
Celsion Pipeline

Focused Drug Development Strategy



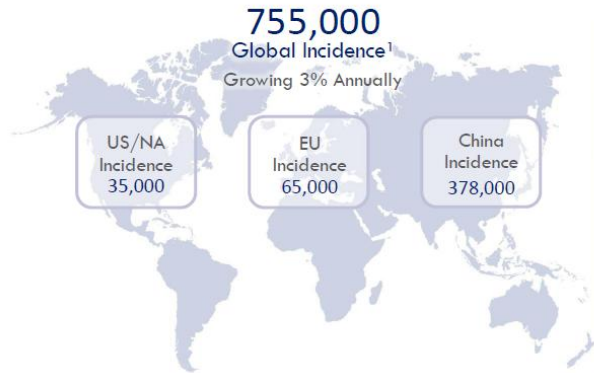
Celsion

ThermoDox[®]
CHEMOTHERAPY



First Target: Hepatocellular Carcinoma

High Global Incidence With High Mortality



4th Highest Mortality of all Cancers

Median survival from
time of diagnosis **< 3 years²**

5-year survival rate **< 10%**

Early- and Intermediate-stage
patients eligible for curative
surgery **< 20%²**

**Few curative treatment options in
early- and intermediate-stage patients**

Addressable Market Opportunity for ThermoDox: > 200K Patients across US, EU, and Asia*

¹ Incidence Data Source: GLOBOCAN 2018; <http://gco.iarc.fr/>

² *J Hepatol.* 2012; 56: 908-943.

*Based on study design, HCC staging criteria, and regional market dynamics.

Locoregional Therapies (LRT) - A Mainstay Treatment for Unresectable Patients

Multiple Procedures; Limited Long-term Effect

Radiofrequency Ablation: A dominant treatment

- Effectiveness decreases with increasing tumor size
- Local recurrence rates > 50% for lesions > 3 cm

Most other LRTs require:

- Multiple procedures
- Hospitalization
- High treatment costs

Other therapies include:



Microwave Ablation (MWA)



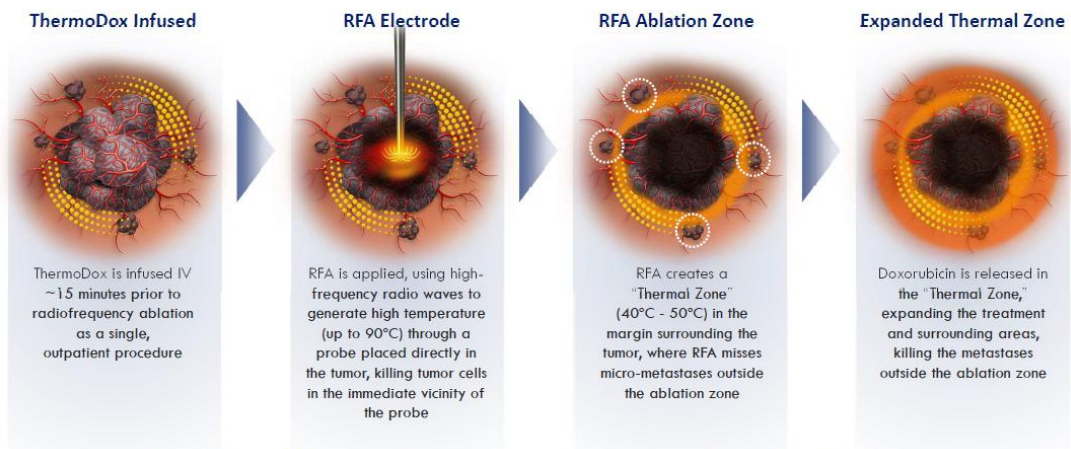
Transarterial
Chemoembolization (TACE)



Radiation

ThermoDox + Radiofrequency Ablation (RFA) Expands the Treatment Zone

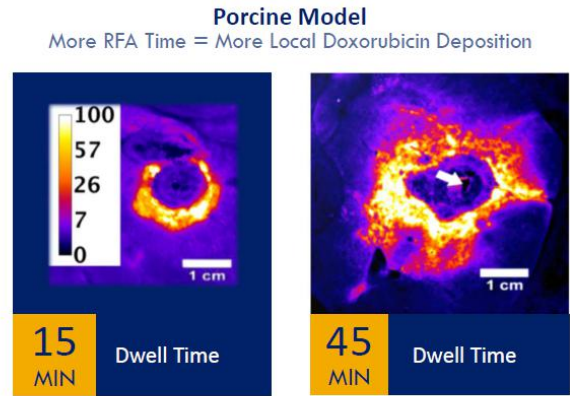
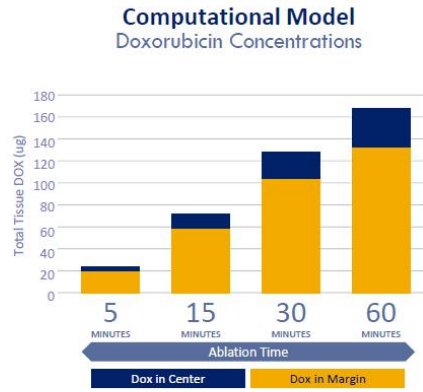
Benefits larger, unresectable tumors



ThermoDox delivers **25x** more doxorubicin into tumors versus doxorubicin IV infusion alone¹

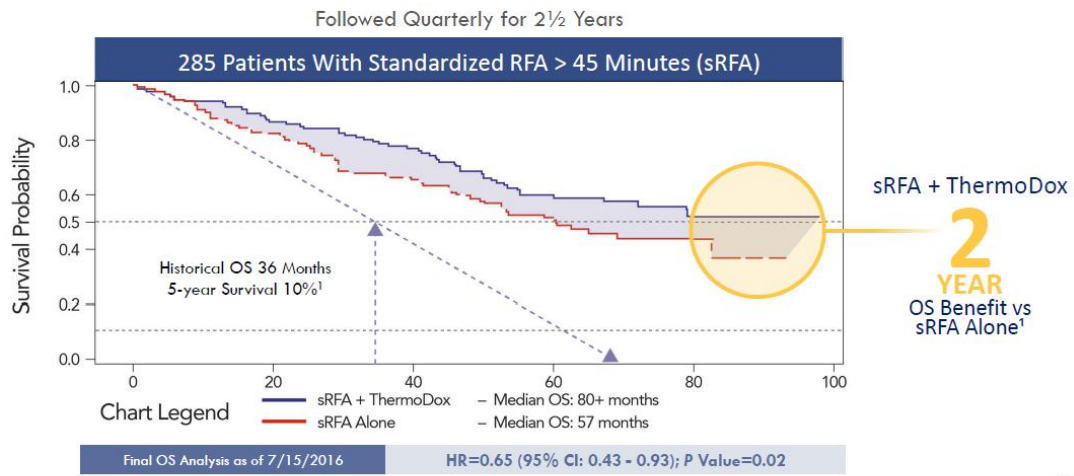
HEAT Study: Results Inform Phase III OPTIMA Study Design

Multivariate Analysis Suggests RFA Dwell Time with ThermoDox was the Key Factor
Correlating to Significant Improvement In Overall Survival



ThermoDox + RFA Demonstrated a 2-year Improvement in Overall Survival

HEAT Study Subgroup Survival Analysis With Standardized Dwell Time and Number of Lesions



HEAT Study Subgroup

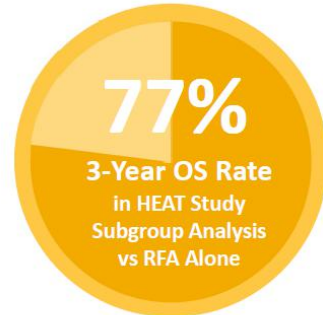
Transcends Historic Survival Rates

Cancer Therapy: Clinical

Phase III HEAT Study Adding Lyso-Thermosensitive Liposomal Doxorubicin to Radiofrequency Ablation in Patients With Unresectable Hepatocellular Carcinoma Lesions

Won Young Tak, Shi-Ming Lin, Yijun Wang, Jiasheng Zheng, Aldo Vecchione, Soo Young Park, Min Hua Chen, Stephen Wong, Ruocai Xu, Cheng-Yuan Peng, Yi-You Chlou, Guan-Tarn Huang, Jianqiang Cai, Basri Johan Abdullah, June Sung Lee, Jae Young Lee, Jong Young Choi, Julieta Gopez-Cervantes, Morris Sherman, Richard S. Finn, Masao Omata, Michael O'Neal, Lukas Makris, Nicholas Borys, Ronnie Poon, and Riccardo Lenzi

DOI: 10.1158/1078-0432.CCR-16-2433



ThermoDox + sRFA: Transformative Results

Widespread Data Dissemination



Radiology

Future ONCOLOGY

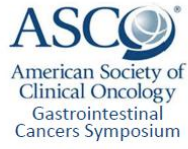


Hepatic Oncology



Results Presented at Numerous Conferences

Not Celsion's Opinion Alone!



Independent NIH Analysis Confirms the Importance of RFA Dwell Time



Evaluated RFA burn time per tumor volume (min/mL) for correlation with clinical outcome

Overall Findings

Increase in burn time per tumor volume improved overall survival (OS) in ThermoDox + RFA patients compared to RFA-only patients, n=437

For all single-lesion RFA + ThermoDox patients

One unit increase in RFA duration per tumor volume improved OS by 20% (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)

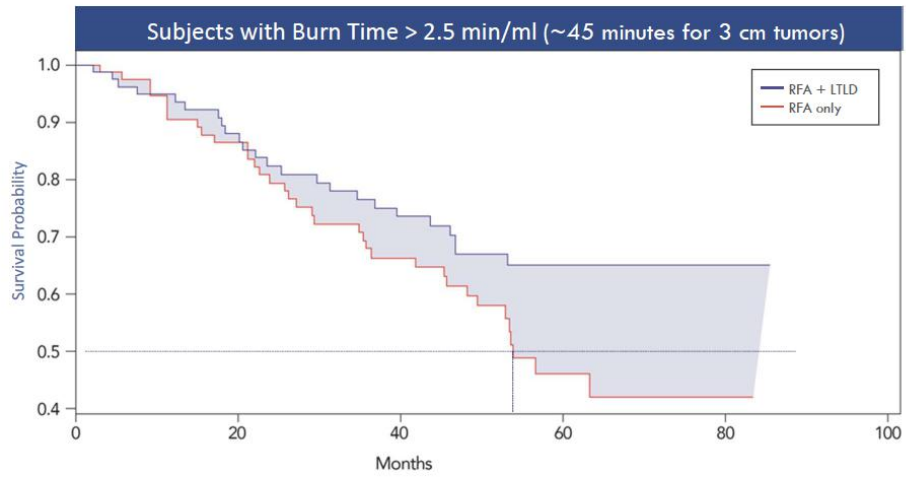
For all single-lesion RFA-only patients

Burn time per tumor volume did not have a significant effect (n=210)

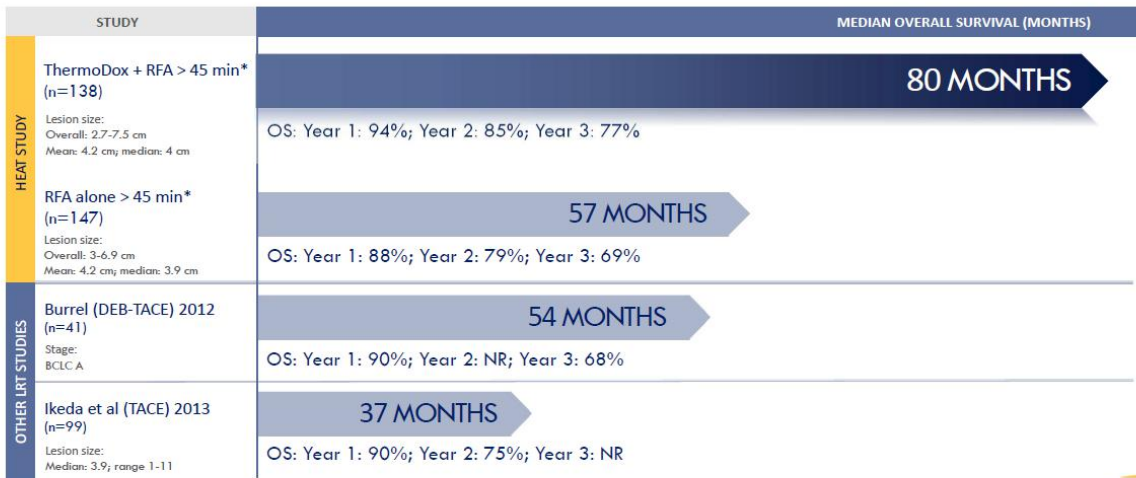


NIH Analysis Correlates Dwell Time and Volume to OS Benefit

Confirmatory Results and Basis of HCC OPTIMA Study Design



ThermoDox + sRFA Demonstrates Significant OS Benefit versus Other Locoregional Therapies



ThermoDox + sRFA Results

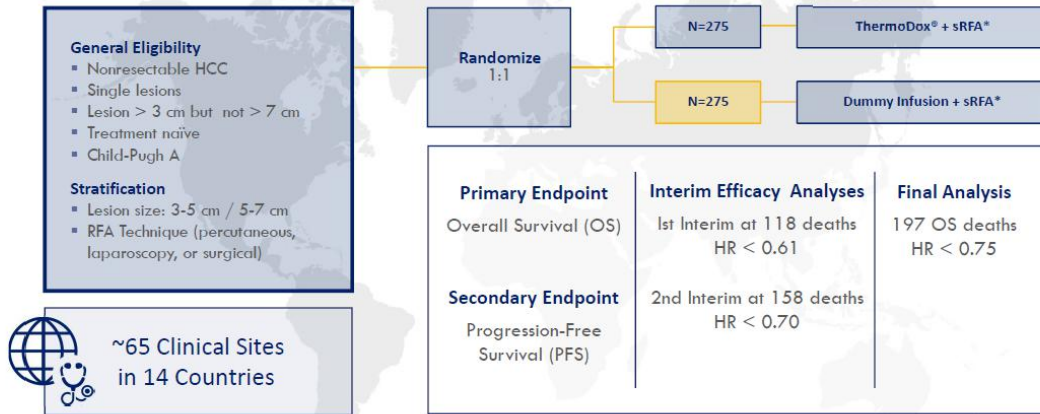
High Survival Rates for Patients With Intermediate Size Lesions



Phase III OPTIMA Study Design

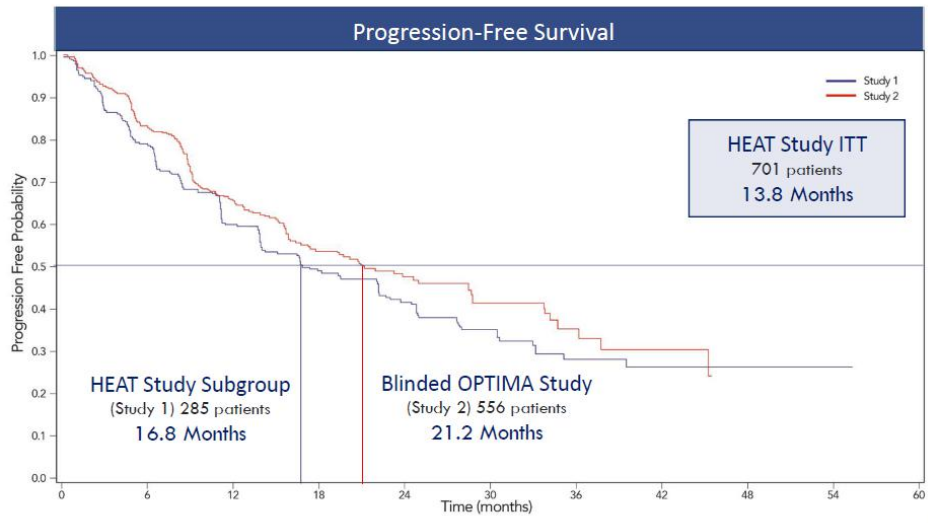
Applying Broad-based Learnings to OPTIMA Study

Enrollment Completed
Q3 2018



OPTIMA Study: Blinded PFS Data Consolidated for Both Arms

PFS and OS Tracking with Results of HEAT Study Subgroup



ThermoDox Summary



**OPTIMA Study addresses the largest global unmet medical need remaining in oncology
HCC Cancer: A \$ Billion+ Commercial Opportunity**



**Published HEAT Study subgroup analysis demonstrates ability to deliver clinically
meaningful results for early-stage and intermediate-stage HCC patients**



Addressable patient population offers a “Blockbuster” market opportunity



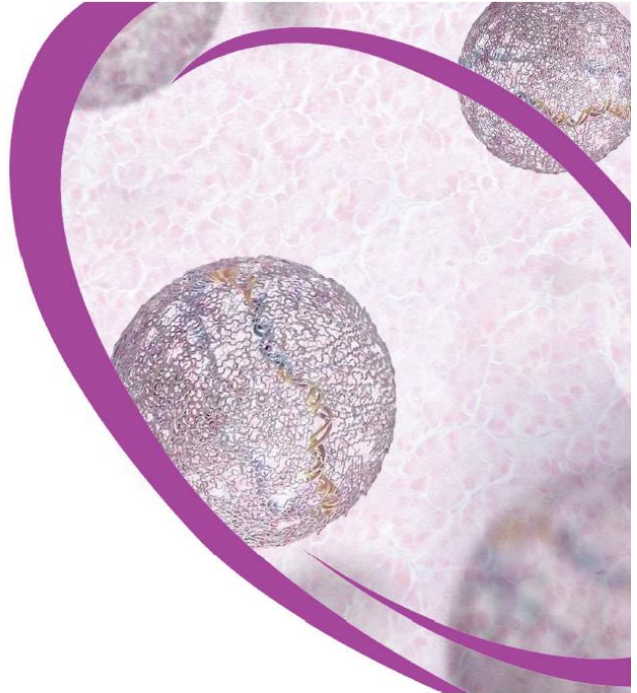
PFS and OS Data is on track with expectations



First look at interim data: 2nd half of 2019

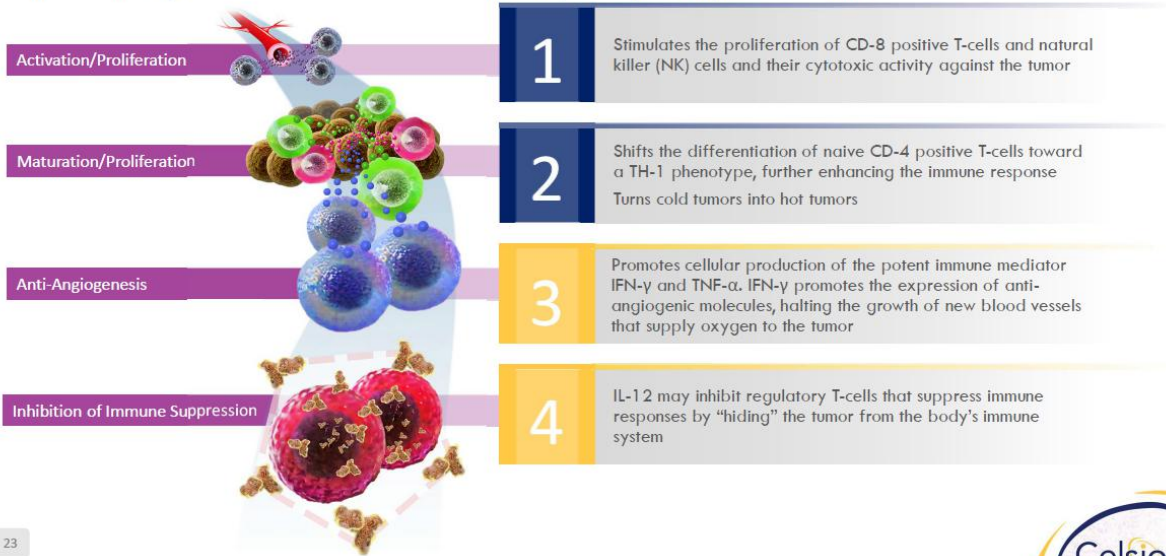
Celsion

GEN-1 IL-12
IMMUNO-ONCOLOGY
PROGRAM



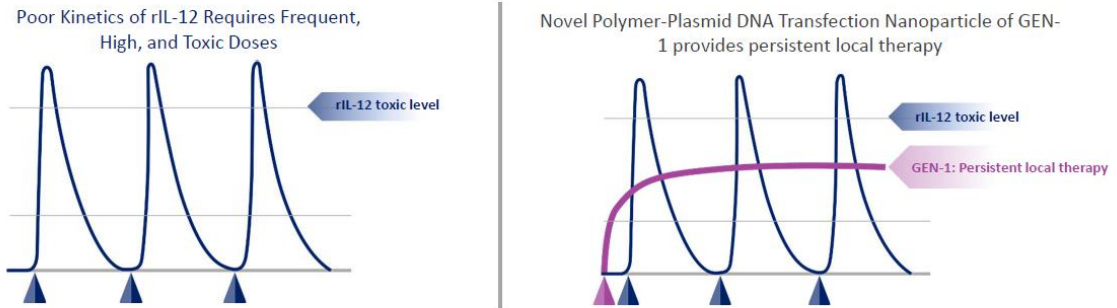
IL-12: A Powerful Immune-Modulating Agent

Interleukin 12 (IL-12) Can Induce Anti-cancer Immunity Through Multiple Mechanisms



GEN-1 Addresses IL-12 Toxicity and Poor Pharmacokinetics (pK)

First-In-Class IL-12 Novel Delivery



Locoregional production avoids toxicities and poor pK associated with systemic recombinant protein IL-12 (rIL-12)

Persistent local delivery lasts up to 1 week, with ability for repeat dosing

Potential for long-term maintenance therapy

GEN-1 Clinical Development Program Published in Peer-Reviewed Journals



Anwer et al, *Gene Therapy*, Phase I Monotherapy

Anwer et al, *Gynecol Oncol*, Combination with Plat/Doxil

Alvarez et al, *Gynecol Oncol*, Phase II monotherapy

Thaker et al, *Gynecol Oncol*, Combination with Doxil

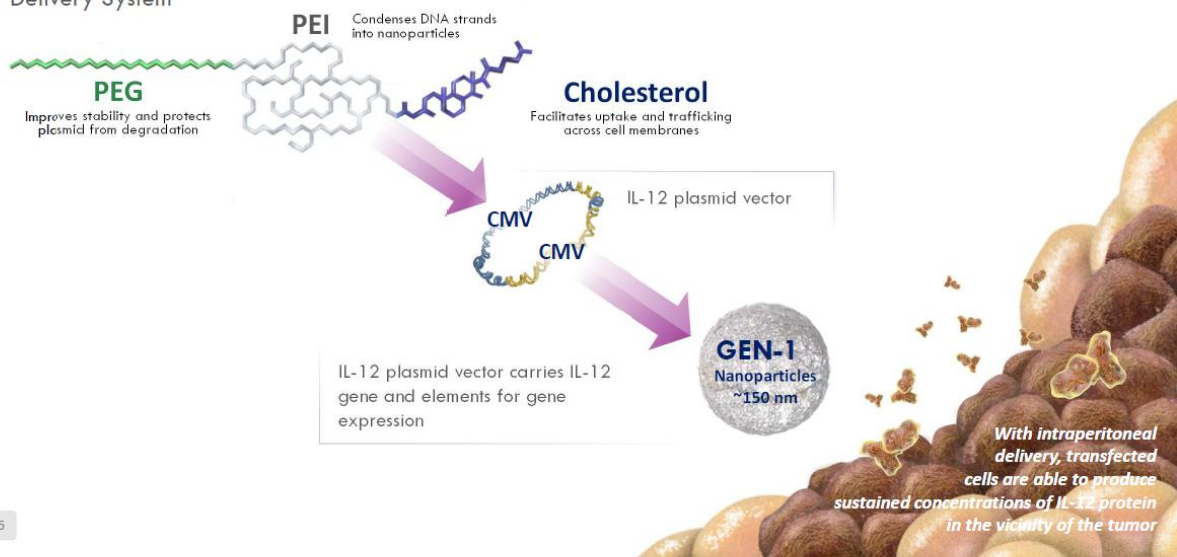
Thaker et al, *Future Oncol*, Gen-1 Review

Transformative Results Presented at Numerous Conferences

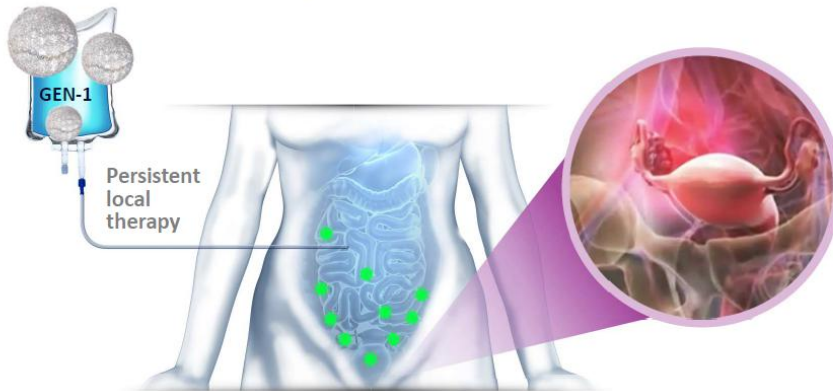


GEN-1 Composition

Three Components of Polyethylene Glycol (PEG) Polyethyleneimine (PEI) Cholesterol Delivery System



GEN-1 Targets Ovarian Cancer Metastases Throughout the Peritoneal Cavity



Local Expression of IL-12 Favors
Immune Modulation in Tumor Microenvironment

Intracavity infusion
of GEN-1 produces durable
and local expression of
IL-12 in the peritoneum

Peritoneal-plasma barrier
minimizes systemic exposure
of IL-12, thereby improving
safety profile of GEN-1

First Target: Ovarian Cancer

High Global Incidence and Mortality

8th Most Diagnosed Cancer Among Women



5th Highest Mortality Among Women

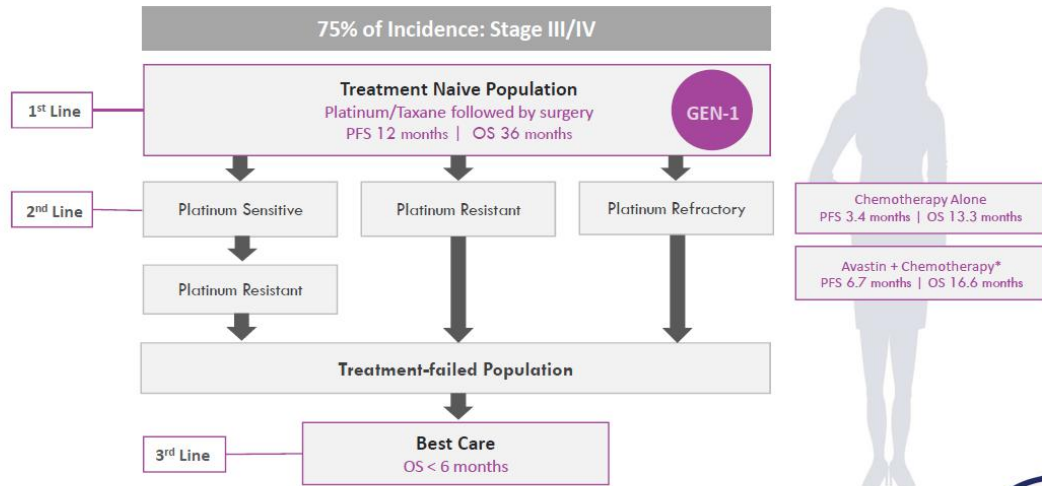
- 5-year survival rate for all stages is < 50%
- > 70% of women are diagnosed in advanced stages (III/IV)
- Only 15% diagnosed with localized cancer eligible for potentially curative surgery
- Survival rate dramatically reduced if not localized cancer
- Most common site of recurrence is in the abdomen
- Intraperitoneal-administered therapy is an important clinical strategy

Addressable Market Opportunity


> 100,000 Patients

Treatment Options in Advanced Ovarian Cancer Are Limited


Recurrence Rates are High and Survival Rates Low



Five Completed Trials of GEN-1 in Patients With Ovarian Cancer

 **SAFETY** Well tolerated in all completed studies to-date
Maximum tolerated dose (MTD) has not been reached

 **BIOLOGIC & CLINICAL EFFECTS** Evidence of biological activity and clinical benefits have been demonstrated

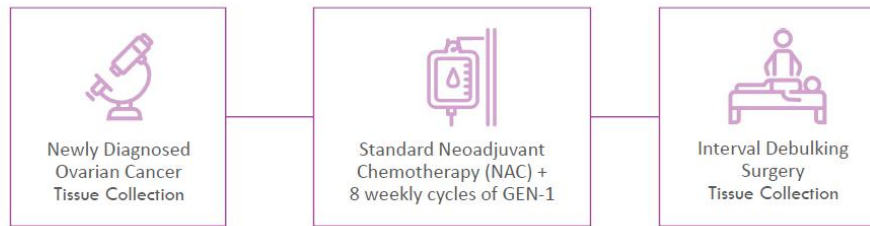
 **FITS INTO STANDARD CHEMO REGIMENS** Peritoneal administration
Adjuvant to standard-of-care therapy

5 Completed Trials

Study	Mono/Combo	Study Phase	Disease	N
GEN-1-101	Monotherapy	I	Platinum-Resistant	13
GOG-170Q	Monotherapy	II	Platinum-Resistant	20
GEN-1-201	+ Carboplatin/ Docetaxel	I	Platinum-Sensitive	13
GOG-9928	+ Doxil	Ib	Platinum-Resistant	14
OVATION I	+ Carboplatin/Taxol	Ib	Treatment Naive Newly Diagnosed	14

OVATION I Ovarian Cancer Study

Phase I to Determine Dose, Efficacy, and Biological Activity With NAC in Stage III/IV Patients



Ovarian Cancer Patients (FIGO IIIc & IV)

3 + 3 Dose Escalation
Starting at 36 mg/mm

Final Dose at 79 mg/mm
6 patients

Primary Endpoint

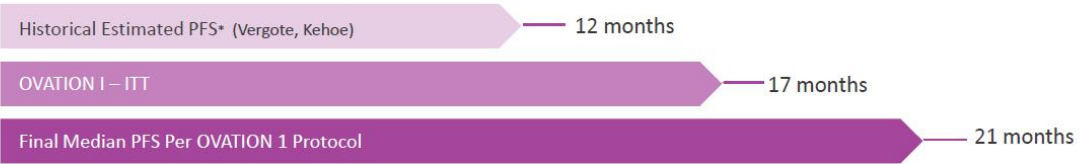
Safety
Optimal Dose

Secondary Endpoints

Clinical Response, PFS
Pathological Response,
Surgical Response,
Biological Response

OVATION I Study: Improved Progression-Free Survival with GEN-1

vs Historic Outcomes in Comparable Patient Populations



Similar Baseline Patient Characteristics in the OVATION I Study vs Large NAC Trials

Name of Study	# of Patients	Age	Histology	Stage
OVATION I	18	Median: 63 Range: 48-79	Serous: 95% Clear Cell: 5%	IIIC: 67% IV: 33%
Vergote	670	Median: 63 Range: 33-81	Serous: 65% Undiff: 27%	IIIC: 76% IV: 24%
Kehoe	550	Median: 65 Range: 34-88	Serous*: 83% Clear Cell: 6%	II, IIIA/B: 12% IIIC: 71% IV: 15%

32 *Includes high-grade and "not specified"

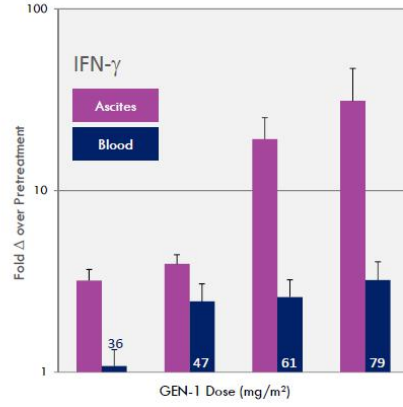


OVATION I Study

Clinical and Molecular Dose Responses Demonstrated

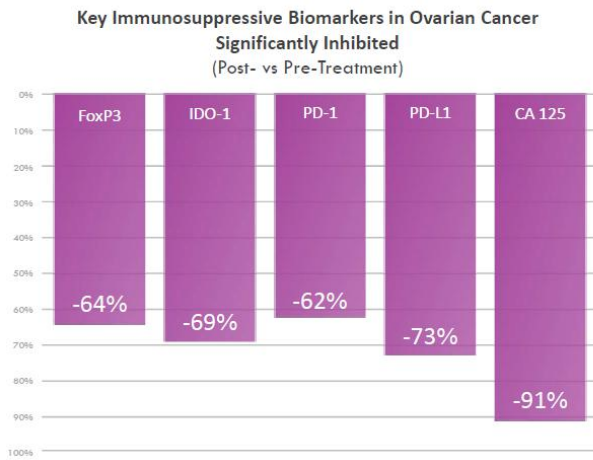
	Clinical Responses*	
	GEN-1	
	Low-Dose Cohorts 36 mg & 47 mg	High-Dose Cohorts 61 mg & 79 mg
Objective Tumor Response (CR/PR) RECIST 1.1	60%	100%
Interval Debulking Status R0 Resection Rate	40%	88%

Interferon- γ Expression in Ascites & Blood



OVATION I Study

Pro-immune Changes in Tumor Microenvironment



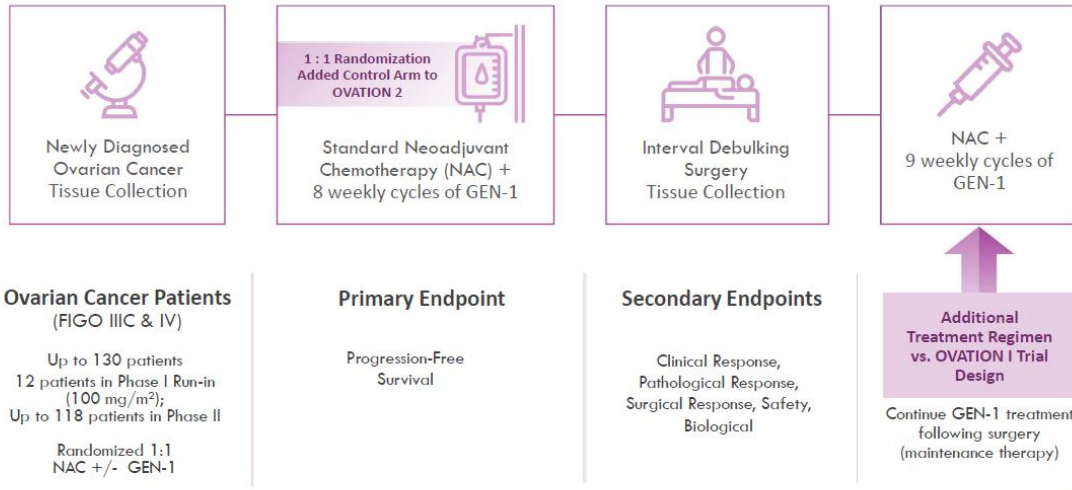
Density of immune biomarkers measured in tissue sections via immunocytochemical staining

Final CA125 measured in blood upon enrollment and at 5th GEN-1 treatment

Decrease in FOXP3 and IDO-1 not observed in previous NAC studies

GEN-1 OVATION 2 Ovarian Cancer Study

To Determine Efficacy and Biological Activity With NAC in Stage III/IV Patients



Ovarian Cancer Patients (FIGO IIIc & IV)

Up to 130 patients
 12 patients in Phase I Run-in
 (100 mg/m²);
 Up to 118 patients in Phase II
 Randomized 1:1
 NAC +/- GEN-1

Primary Endpoint

Progression-Free
 Survival

Secondary Endpoints

Clinical Response,
 Pathological Response,
 Surgical Response, Safety,
 Biological

Additional Treatment Regimen vs. OVATION 1 Trial Design

Continue GEN-1 treatment
 following surgery
 (maintenance therapy)

GEN-1 Summary



GEN-1 offers a novel way to harness the powerful immunological properties of IL-12;
The “Master Switch” to the body’s immune system



Five completed ovarian cancer trials demonstrate biologic and clinical activity;
Strong efficacy signals in Phase I; Mechanism of action confirmed

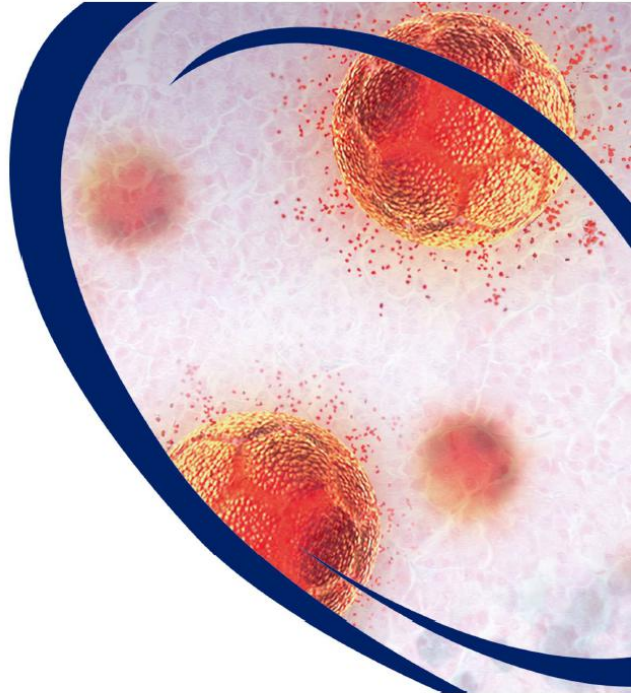


OVATION 2 offers new hope to a large segment of newly diagnosed advanced ovarian
cancer patient population



Completion of first phase of OVATION 2 on track for the 2nd half of 2019

Celsion
Financials



Financial Overview



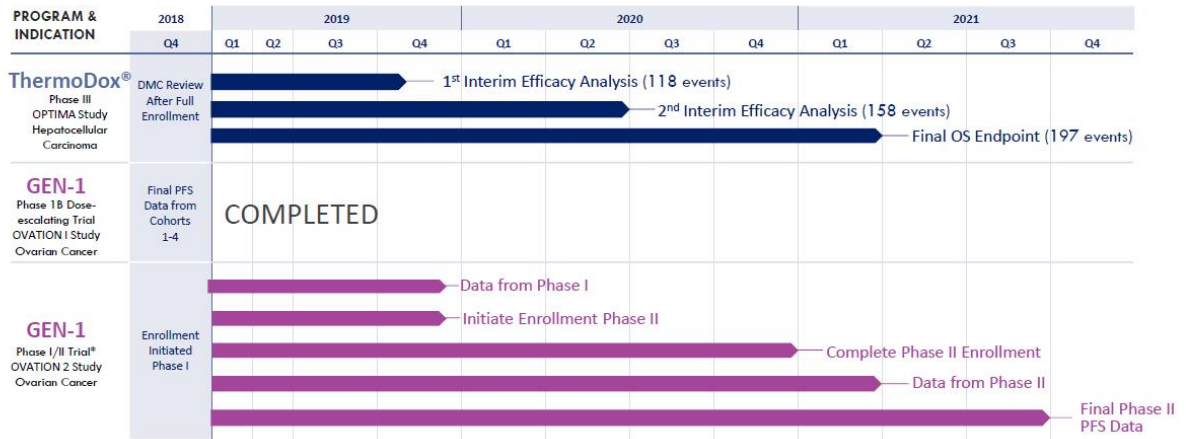
Cash & Investments at 9/30/2018	\$22.0 million
+ NOL sale by 12/31/2018	\$10.4 million
Total Cash & Investments	\$32.4 million
Estimated cash usage per month	\$1.5 million
Market Capitalization	~\$40 million



Common shares outstanding at 12/31/2018	18.7 million
+ Stock Options	3.2 million
+ Warrants*	1.6 million
Fully diluted shares outstanding	23.5 million
Average Daily Trading Volume	~100,000

Advanced Stage Clinical Development Programs

Milestone Events 2019-2021



Celsion Leadership Team



Michael H. Tardugno
Chairman, President and
Chief Executive Officer

Michael Tardugno's career has been focused exclusively in healthcare, with 40 years of experience in the pharmaceutical and medical device industries. Mr. Tardugno was appointed President and Chief Executive Officer of Celsion in January 2007, and was elected to the Chairman of the Board of Directors in October 2012. Prior to joining Celsion, Mr. Tardugno held senior executive positions with Mylan Laboratories, Bristol-Myers Squibb, Bausch & Lomb and Abbott Laboratories.



Nicholas Borys, MD
Executive Vice President and
Chief Medical Officer

Nicholas Borys joined Celsion in October 2007 as Vice President and Chief Medical Officer where he manages the clinical development programs for Celsion. Prior to joining Celsion, he held senior positions at Molecular Insight Pharmaceuticals, Cytogen Corporation, Anthra Pharmaceuticals, Amersham Healthcare and Hoffmann La-Roche.



Khurshheed Anwer, PhD, MBA
Executive Vice President and
Chief Scientific Officer

Khurshheed Anwer joined Celsion in June 2014 upon the acquisition of EGEN, Inc., where he was President and Chief Scientific Officer, a position he held since 2009. Prior to joining Celsion, Dr. Anwer was Director of Pre-Clinical Development at Valentis, Inc. From 1993 to 1999, he served in several positions at GeneMedicine, where he led several research projects in the area of nonviral gene therapy.



Jeffrey W. Church
Executive Vice President, CFO &
Corporate Secretary

Jeffrey Church joined Celsion in July 2010 as Vice President and Chief Financial Officer. He brings more than 35 years of experience in corporate finance, M&A, investor relations, and SEC reporting. Prior to joining Celsion, Mr. Church held senior financial executive positions with several private and public life science companies, including Alba Therapeutics, Novavax, GenVec and Meridian Medical Technologies.



Anthony Recupero
Vice President
Business Development

Anthony Recupero joined Celsion in 2018 and leads all business development activities. Dr. Recupero has nearly 20 years' leadership experience in senior business development and licensing roles at Adare Pharmaceuticals, Aptalis Pharma, Eurand, MaxCyte and Gene Logic with a background in multiple therapeutic areas, platforms and technologies including: cell based therapies, parenteral and oral drug delivery systems and monoclonal antibodies.





Corporate Information
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Lawrenceville, NJ 08648

P 609-896-9100
F 609-896-2200

www.celsion.com

NASDAQ: CLSN

