

Company Overview
August 2018

### Safe Harbor Statements

THIS PRESENTATION AND THE INFORMATION IN IT ARE PROVIDED IN CONFIDENCE, FOR THE SOLE PURPOSE OF EXPLORING BUSINESS OPPORTUNITIES BETWEEN ENZYCHEM LIFESCIENCES AND THE RECEIVING PARTY AND MAY NOT BE DISCLOSED TO ANY THIRD PARTY OR USED FOR ANY OTHER PURPOSE WITHOUT THE EXPRESS WRITTEN PERMISSION OF ENZYCHEM LIFESCIENCES.

ENZYCHEM LIFESCIENCES AND ITS EMPLOYEES WILL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, ANY LOSS OF PROFIT, LOSS OF USE, OR BUSINESS INTERRUPTION, BASED ON ANY CLAIMS UNDER THIS PRESENTATION.

THIS PRESENTATION AND THE INFORMATION IN IT MAY CONTAIN FORWARD-LOOKING STATEMENTS, THE ACHIEVEMENT OR SUCCESS OF WHICH INVOLVES RISKS, UNCERTAINTIES, AND ASSUMPTIONS. THE RISKS AND UNCERTAINTIES REFERRED TO INCLUDE – BUT ARE NOT LIMITED TO – RISKS AND UNCERTAINTIES ASSOCIATED WITH THE GENERAL ECONOMIC AND MARKET CONDITIONS, PERFORMANCE OF THE COMPANY, AND FUTURE CLINICAL STUDIES WITHOUT THIRD PARTY VERIFICATION. THE PREDICTION CONTAINS UNCERTAINTY IN NATURE AND THE ACTUAL FUTURE EVENT MAY VARY FROM THE PREDICTION PRODUCED IN THIS PRESENTATION.









## **INVESTMENT THESIS**

- Two rapidly growing businesses which generate substantial cash flow
  - API
  - Contrast Media
    - Total sales of \$26.1M in 2017 (\$16.1M in 2018 1H)
- Strong balance sheet/cash flow to support development of EC-18
- Building a pharmaceuticals business based upon a first-in-class, proprietary drug molecule platform (EC-18)
- EC-18 has the potential to be effective across a wide variety of indications
- Extensive IP portfolio for EC-18
- Spearheaded leadership team with expertise in drug development & regulatory affairs



### LEADERSHIP TEAM



Ki Young Sohn Chairman & CEO

- · Over 30 years of experience in the pharmaceutical and finance industry
- Former Chairman of Bridget Lifescience Corporation; Director at Samil PwC
- Author of 9 EC-18 scientific papers



**Hye Kyung Kim** Vice Chairman

- · Over 30 years of experience in health functional food
- CEO, Bridget Lifescience Corporation
- Former Vice Chair, KONEX Conference



Jae Yong Lee Vice President

- Over 30 years of experience in API industry and manufacturing
- · Former Director at Offi-Com and Adtech
- Former CEO, Hanseung C&S



Do Young Lee, PhD Chief Scientific Officer

- · 23 years of experience in New Drug Development
- Former Head of Translational Research, CrystalGenomics
- 2 successful NDA filings in Korea



Myung Hwan Kim, MD, PhD Chief Medical Officer

- Director, Center for Pancreatobiliary Diseases, AMC
- Professor, Division of Gastroenterology, University of Ulsan College of Medicine
- President, Asian-Oceanic Pancreatic Association



**DoHyun Cho, PhD**Chief Operating Officer

- Over 20 years of experience in healthcare
- Head of KHDI USA
- CEO, W Medical Strategy Group



Jeff Clark, MD, JD
Chief Licensing Officer, Director of IP

- Over 10 years of experience in IP and Patent Law
- Prior attorney at DLA Piper and Pepper Hamilton LLP
- Research Fellow, Cardiovascular Research Center, MGH
- Clinical Fellow, Molecular & Vascular Medicine, BIDMC



# Scientific Advisory Board



### Chair. Waun Ki Hong, MD, FACP, DMSc (Hon)

- · Head, MD Anderson Cancer Center
- President, American Association of Cancer Research
- Advisor, National Cancer Advisory Board
- Fellow, U.S. Academy
- · Scientific Advisor, NCI Board
- US FDA Oncologic Drug Advisory Committee



#### Jeff Crawford, MD

- · Professor, Duke University School of Medicine
- Lead Investigator of Clinical Trials for Neupogen
- Principal Investigator of Clinical Trials for Neulasta



#### Stephen Sonis, DMD, DMSc

- · Professor, Harvard School of Dental Medicine
- Senior Surgeon, the Dana-Farber Cancer Institute and Brigham and Women's Hospital
- In Chage of U.S. Phase II Clinical Trial of Oral Mucostis



#### David Grdina, PhD

- · Professor, the University of Chicago
- · Member of Reviewers Reserve, NIH
- Ad Hoc Member of Special Emphasis Panel, NCI



#### Larry Kwak, MD

- · Vice President, City of Hope Cancer Center
- · Director, Toni Stephenson Lymphoma Center
- Named one of TIME magazine's "100 Most Influential People" in 2010



### Jae Wha Kim, PhD

- Professor, University of Science and Technology (UST)
- · Principal Researcher, KRIBB
- Postdoctoral Fellow in Molecular Genetics & Microbiology, College of Medicine Univ. of Florida



#### Soon Kil Ahn, PhD

- · Dean & Professor, Incheon National University
- · Director, Insitutute for New Drug Development
- Former Executive Director, Chong Kun Dang Pharm



### Kyu Pyo Kim, MD, PhD

- Professor, Dept. Medical Oncology, Asan Medical Center
- Visiting Scholar, Cancer PK and PD Core Cancer Therapeutics Program, University of Pittsburgh
- · Researcher, KHIDI Ministry of Health Korea



#### Ronald Manning, PhD

- Over 10 years of specialized experience in MCM on ARS with BARDA, NIH, FDA and DOD
- Former Branch Chief, BARDA



### ENZYCHEM LIFESCIENCES TODAY

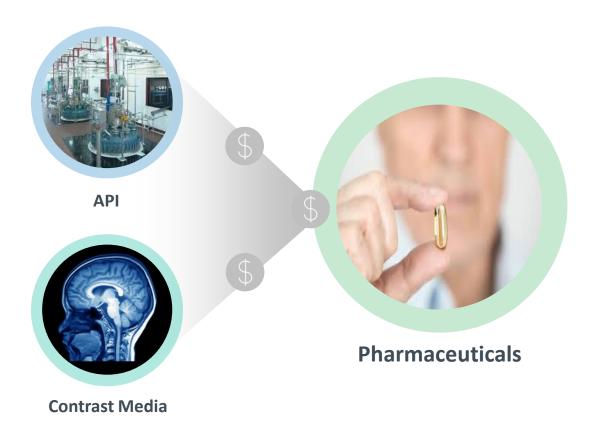
GLOBAL PROVIDER OF INNOVATIVE, BIOPHARMACEUTICAL SOLUTIONS



- KOSDAQ:183490 (Listed Feb 2018)
- Market cap: USD 706M
   (as of Aug 08, 2018)
- Forecast approximately 40% total sales growth in FY18
- Approximately 100
   employees in United

   States and South Korea

### CASH FLOW BUSINESSES TO FUND NEW DRUG DEVELOPMENT





# THREE OPERATING SEGMENTS EACH WITH UNIQUE GROWTH OPPORTUNITIES

**API** 

Stable Revenue Generating Business

Analgesics
Anti-coagulants
Expectorants
Anti-tuberculosis

\$25.4M FY17 REVENUE \$200M MARKET POTENTIAL **Contrast Media** 

Versatile Line of Contrast Imaging Products

MRI contrast agents CT scan contrast agents Low risk generic MRI contrast agents

\$0.7M FY17 REVENUE \$450M MARKET POTENTIAL **Pharmaceuticals** 

Proprietary EC-18 Platform Technology

Oncology Inflammatory Disease Pulmonary

\$14.9B GLOBAL MARKET POTENTIAL

DIVERSIFIED REVENUE BUSINESSES TO SUPPORT INVESTMENTS IN PHARMACEUTICALS



### LARGE-SCALE GMP MANUFACTURING FACILITIES



### First GMP Manufacturing Facility

- Production: Antibiotics (Cephalosporin)
- GMP Approval: April 2008 (Renewed in 2018)
- Building Area: 21,000 ft<sup>2</sup>
- Annual Production Capacity: 250 tons
- PMDA GMP Eligibility Approval (2015)

### **Second GMP Manufacturing Facility**

- Production: EC-18, Non-Cephalosporin API, contrast agents
- GMP Approval: January 2013 (Renewed in 2018)
- Building Area: 19,000 ft<sup>2</sup>
- Annual Production Capacity: 200 tons (EC-18 10 tons)
- EU GMP Approval Expected in 2018

### CONSTRUCTION OF THIRD MANUFACTURING FACILITY IN OSONG



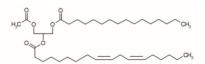


# EC-18 IMMUNE MODULATOR PLATFORM TECHNOLOGY

### EC-18 IMMUNE MODULATOR PLATFORM TECHNOLOGY

### A REVOLUTIONARY TECHNOLOGY ACTIVE IN MULTIPLE DISEASES

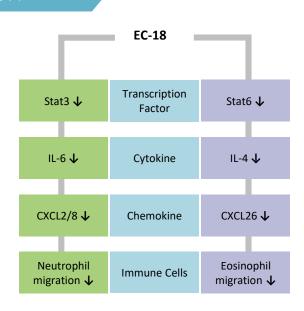
A new treatment modality for oncology, anti-inflammatory and pulmonary diseases



### NOVEL TECHNOLOGY WITH OVER 40+ YEARS RESEARCH

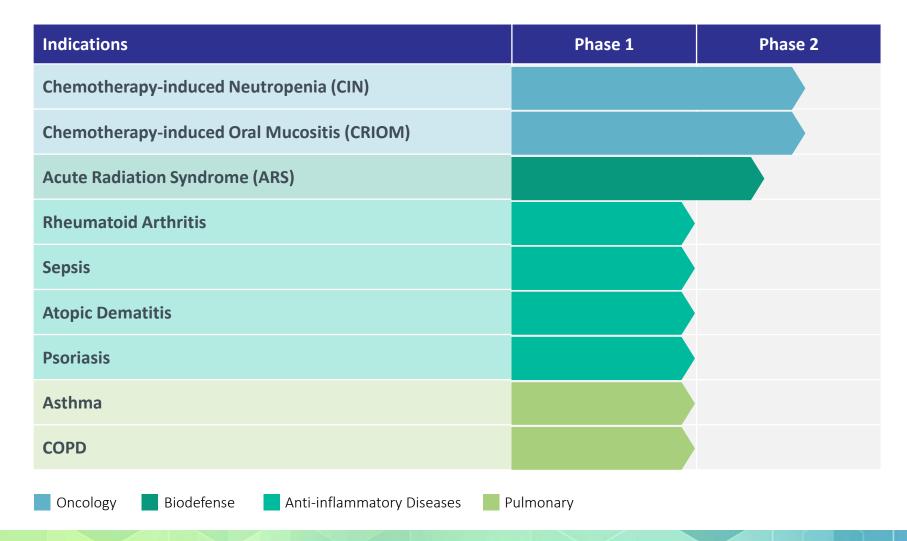
### EC-18 is a safe, oral, lipid-based, first-in-class, small molecule drug

- EC-18 is a synthetic monoacetyldiglyceride
- Modulates neutrophils and macrophages (innate immune system)
   with cytokines and chemokines; transcription factor STAT3 / STAT6
- Global Clinical Phase 2 Program in Chemotherapy Induced-Neutropenia, Chemoradiation-Induced Oral Mucositis (CRIOM)
- FDA Fast Track Designation in CRIOM
- FDA Orphan Drug Designation in Acute Radiation Syndrome (ARS)
- Potential for FDA Priority Review Voucher (PRV) in ARS





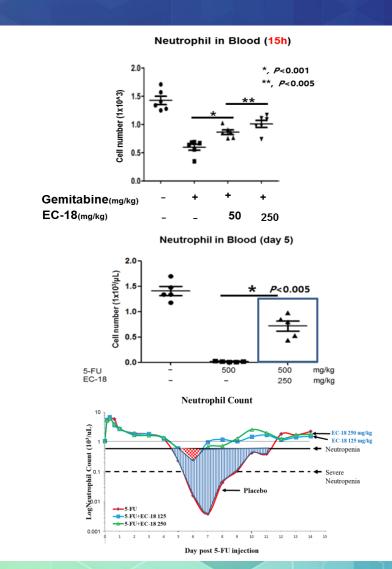
# EC-18 DEVELOPMENT PROGRAMS





# CHEMOTHERAPY-INDUCED NEUTROPENIA (CIN) PRECLINICAL EFFICACY DATA

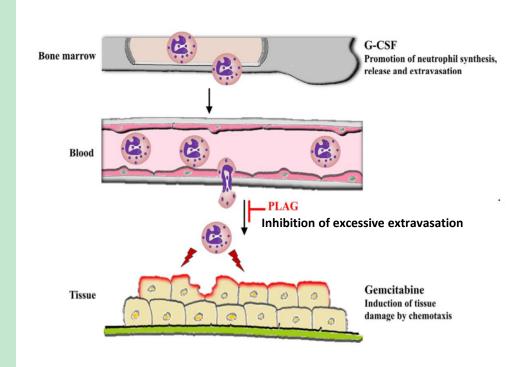
- Neutropenia is a common side-effect of chemotherapy and is associated with a higher risk of serious infections (below 500 cells/ul)
- Current treatment: Postpone/dose reduce chemotherapy or administer G-CSF
- Dose reductions may worsen outcomes, and G-CSF can cause various adverse events: injection-site discomfort, fever, malaise, and influenza-like symptoms
- Bone pain, the most common side effect, develops in 10-30% of patients receiving G-CSF





### MECHANISM OF ACTION - CIN

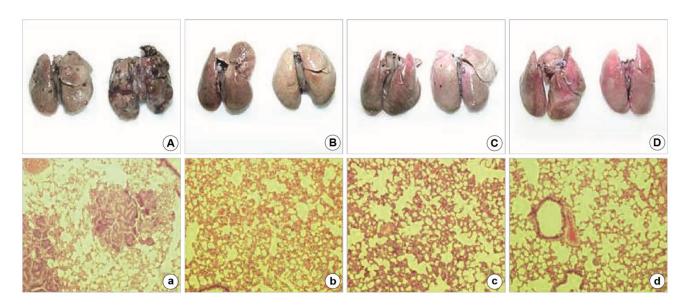
- Chemotherapy suppresses neutrophil production in bone marrow, decreases blood neutrophil content due to neutrophil leakage
- EC-18 (PLAG) regulates circulating neutrophils from exaggerated extravasation
- Gemcitabine-induced tissue damage triggers neutrophil extravasation and neutropenia
- EC-18 (PLAG) augments pegfilgrastim's therapeutic effect by inhibiting neutrophil transmigration through CXCL2/CXCL8 modulation





# EC-18 INHIBITS METASTASIS OF EXPERIMENTAL BILIARY CANCER CELLS

- EC-18 has potent anti-tumor activity in hematogenous metastatic biliary cancer cells, in vitro;
   stimulates activity of CD4+, CD8+ cells and macrophages
- Animals treated with EC-18 (50 mg/kg/day) showed no evidence of metastatic lesions throughout the experiment may have potential in the treatment of biliary cancer

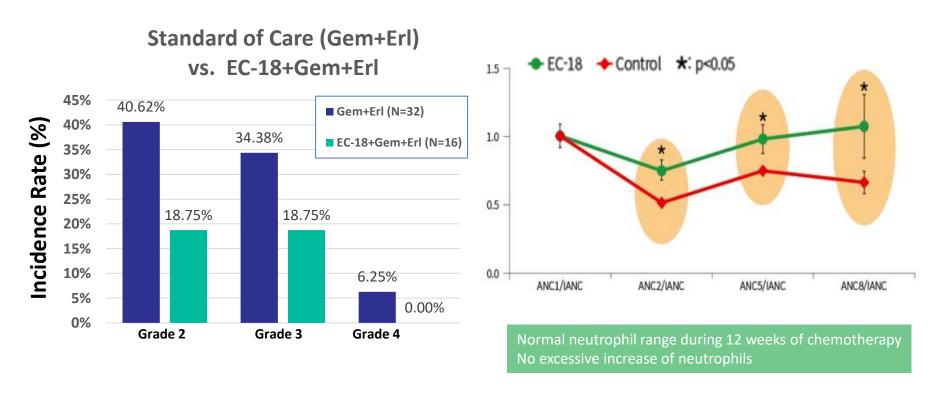


(A, a) Control hamsters, (B, b) hamsters treated with EC-18 10 mg/kg/day, (C, c) EC-18 25 mg/kg/day, (D, d) EC-18 50 mg/kg/day. Control group showed multiple metastatic lesions whereas, EC-18 10, 25, and 50 mg/kg/day treated group showed no evidence of the lesion.



# EC-18 REDUCES THE INCIDENCE OF CIN IN PANCREATIC CANCER PATIENTS IN PILOT STUDY

Study evaluated the effectiveness of EC-18 for the prevention of CIN in pancreatic cancer patients treated with gemcitabine-based chemotherapy



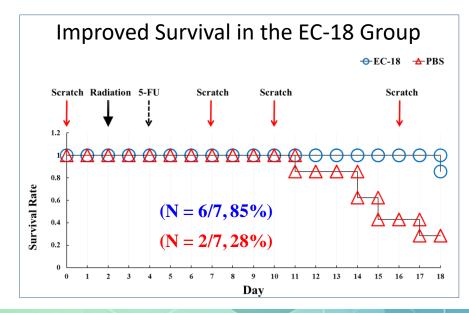
Total number of patients with Grade 2-4 neutropenia decreased 44.7% with addition of EC-18



# CHEMO-RADIATION INDUCED ORAL MUCOSITIS (CRIOM) PRECLINICAL EFFICACY

- No specific therapy for protection against mucositis is currently available for patients with solid tumors
- Study investigated the therapeutic effect of EC-18 (PLAG) in 5-FU-induced and chemoradiation oral mucositis animal models
- EC-18 was administered daily at 250 mg/kg/day
- EC-18 administration significantly reduced 5-FU/scratching-induced mucositis
- Histochemical staining data also revealed newly differentiated epidermis and blood vessels in the cheek pouches of EC-18-treated hamsters, indicative of recovery

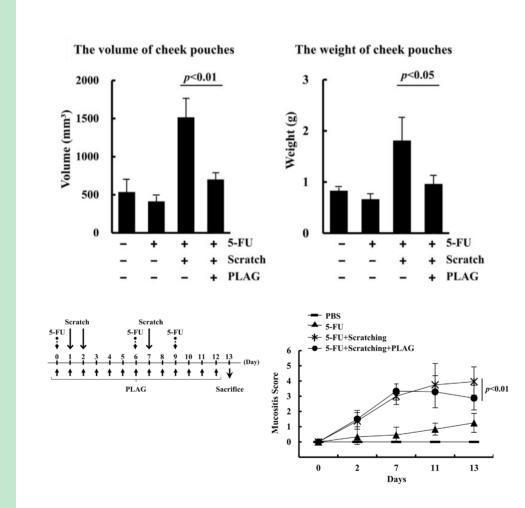






# EC-18 ENHANCES RECOVERY FROM 5-FU ORAL MUCOSITIS AND DRAMATICALLY REVERSED MUCOSITIS-ASSOCIATED WEIGHT LOSS

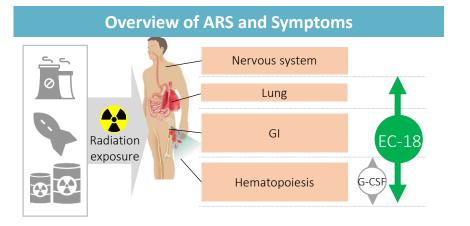
- Dramatic reversal of weight loss in EC-18 (PLAG) treated hamsters with mucositis was observed
- EG-18 administration had a significant effect in preventing weight loss associated with 5-FU/scratchinginduced mucositis
- By Day 13, hamsters in the 5-FU/scratching group exhibited a 15% decline in body weight compared to controls which lost only 5% body weight
- EC-18 enhances recovery from 5-FUinduced oral mucositis and could be a new treatment for the side effects of chemotherapy, such as mucositis and cachexia



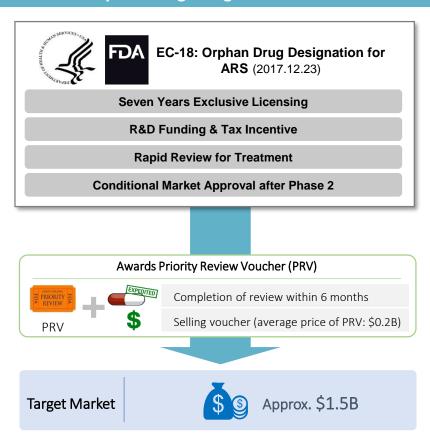


# ACUTE RADIATION SYNDROME (ARS)

# Mechanism of Action Radiation Blood Vessel Macrophage pSTAT3 ↑ Chemokine (CXCL2/8) ↑ Cytokine (IL-6, TNF, IL-1β) ↑ EC-18



### **Orphan Drug Designation for ARS**



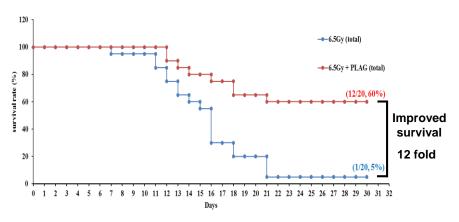


# ARS Animal Efficacy: Survival & Coagulopathy

### EC-18 showed efficacy in survival & coagulopathy in radiated mice

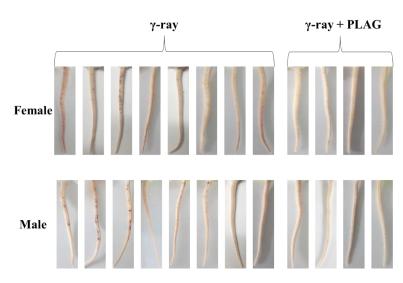
### ARS animal study using mice\_ Survival rate (for 30 days)

# Presence or absence of erythema or purpura (or severe bruising)



11 weeks Balb/c mice\_6.5 Gy γ-irradiation to whole body Each group: n= 20 (10 male & 10 female)

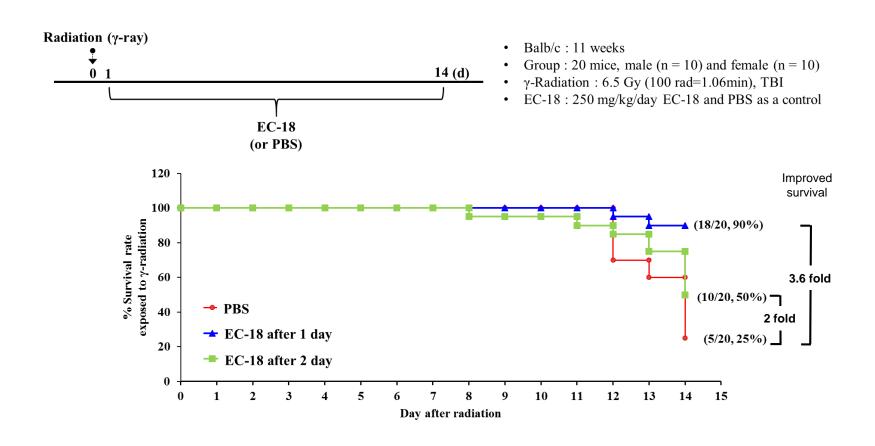
PLAG treatment: 250 mpk





# ARS Animal Efficacy: 24 or 48 Hour Delayed Treatment

### EC-18 also showed efficacy in survival in 24 or 48 hr delayed treatment model





### INDICATIONS IN DEVELOPMENT FOR EC-18

# CHEMOTHERAPY-INDUCED NEUTROPENIA (CIN)

- Common side-effect of chemotherapy, often requiring hospitalization
- > 1.5M patients per year in US
- Inpatient mortality rate of approximately 1 in 14 (7.2%)
- EC-18 is targeted for patients non-responsive to G-CSF, blood cancer patients and radiation therapy-treated patients
- Unique and differentiated MOA
- \$

\$3B Market Opportunity

# CHEMO-RADIATION INDUCED ORAL MUCOCITIS (CRIOM)

- Severe, diffuse mouth sores caused by chemotherapy or radiation treatment for cancer
- ~170K ulcerative patients/year in US
- Causes serious consequences for cancer patient treatment and survival
- No drug approved for CRIOM in patients with solid tumors
- High unmet medical needs
- FDA Fast Track Designation



\$2.6B Market Opportunity

# ACUTE RADIATION SYNDROME (ARS)

- Serious illness caused by high doses of radiation exposure, resulting in cellular degradation, multi-organ failure and death
- ~270K patients per case in city (with 2.0M population)
- EC-18 has efficacy in neutropenia, thrombocytopenia, oral mucositis, sepsis, pneumonia and skin damage, acute lung injury
- FDA Orphan Drug Designation



\$1.5B Market Opportunity



# OUR STRATEGY TO MAXIMIZE EC-18 OPPORTUNITY

### **Development Strategy**

- Target indications with high unmet medical need
- Near-term focus on advancing oncology indications
- Breakthrough FDA Status
- Co-development and technology licensing opportunities
- Pursue government procurement contracts in ARS

### **Intellectual Property**

- Strong IP portfolio
- 76 registered patents for new drug development
- 36 registered patents for API business
- 1 registered patent for contrast agents business
- 69 patent applications pending

### Regulatory

- Secured FDA Orphan Drug Designation in ARS
- Potential for Priority Review Voucher for ARS
- Secured FDA Fast Track Designation in CRIOM
- Potential FDA Breakthrough Therapy Designation in CIN





Financials

## FINANCIAL PERFORMANCE FY2014-2017

### **Total Sales Figures**







# FINANCIAL PERFORMANCE FY 2015-2018 1H

### Statement of Financial Position

(1,000 USD)

				(1,000 03D)
Criteria	2015	2016	2017	2018 1H
Current Asset	20,107	25,332	24,528	58,404
Non-current Asset	10,283	11,337	12,277	16,174
Total Asset	30,390	36,669	36,805	74,577
Current Liabilities	5,155	6,026	9,874	10,843
Non-current Liabilities	2,815	3,685	2,368	2,178
Total Liabilities	7,970	9,711	12,242	13,021
Capital	3,247	3,374	3,418	3,839
Capital Surplus	52,932	63,804	67,153	113,175
Accumulated Deficits	-33,759	-40,220	-46,008	-55,508
Total Equity	22,420	26,958	24,563	61,556

Sales: 2018 1H/2017 1H

\$16.1M/\$12.5M = **28% Growth** 

#### Income statement

(1,000 USD)

Criteria	2015	2016	2017	2018 1H
Total Sales	15,635	21,835	26,133	16,103
Cost of Goods Sold	13,280	18,242	21,971	14,163
Gross Margin	2,355	3,593	4,162	1,940
SG&A (including R&D)	9,239	9,819	9,542	10,876
Operating Income	-6,884	-6,226	-5,380	-8,936
Non Operating Expenses, Net	-4,864	-69	-252	-14
Income Before Income Taxes	-11,748	-6,295	-5,632	-8,950
Income Tax	33	36	34	112
Net Income	-11,781	-6,331	-5,666	-9,062

KOSDAQ IPO (2018.02.21): Capital Raised **\$44M** 



# **UPCOMING MILESTONES**



Initiate Phase 2 animal rule study for EC-18

in ARS in 4Q18



Results from Phase 2 EC-18 CIN & CRIOM study in 2H19



Market launch ARS product in 2H20 based on ODD



Market launch CRIOM product in 4Q20 based on FTD



## **INVESTMENT THESIS**

- Two rapidly growing businesses which generate substantial cash flow
  - API
  - Contrast Media
    - Total sales of \$26.1M in 2017 (\$16.1M in 2018 1H)
- Strong balance sheet/cash flow to support development of EC-18
- Building a pharmaceuticals business based upon a first-in-class, proprietary drug molecule platform (EC-18)
- EC-18 has the potential to be effective across a wide variety of indications
- Extensive IP portfolio for EC-18
- Spearheaded leadership team with expertise in drug development & regulatory affairs





