# **Company Update**

September 2016



**Breakthrough Cancer Therapeutics** 

NASDAQ: DMPI

## **Forward-Looking Statements**

Any statements contained in this presentation that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995 and Canadian securities laws. Any forward-looking statements contained herein or made in the course of the presentation are based on current expectations, but are subject to a number of risks and uncertainties. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology; the availability of substantial additional funding for the Company to continue its operations and to conduct research and development, clinical studies and future product commercialization; and, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in our filings with the SEC and the British Columbia Securities Commission, including our current reports on Form 8-K's, Form 10-Q's and most recent Form 10-K. We do not undertake to update these forward-looking statements made by us.



# Recent Highlights: Spring & Summer 2016

- NASDAQ Listing
- Presented abstracts at AACR and ASCO Annual Meetings
- Completed successful 'End of Phase 2' meeting with US FDA for VAL-083 in refractory GBM
- US FDA expanded orphan designation for VAL-083 to include medulloblastoma and ovarian cancer
- MD Anderson collaboration for first-recurrence of GBM
- \$7.2 million private placement
- Accurexa collaboration to develop novel local delivery of combination chemotherapy



# 2016: A Transitional Year

## 2015

- Single "early-stage" clinical trial
- OTC listed

## 2016

- NASDAQ Listing
- Becoming a "late-stage" clinical company
  - Advancing VAL-083 into Phase III clinical trials

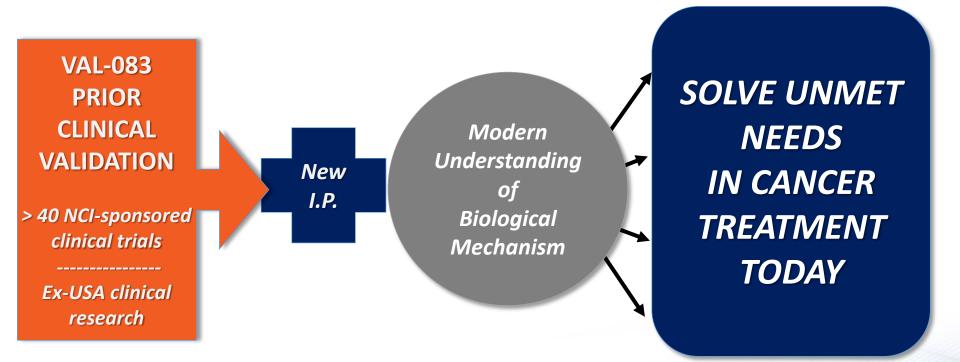
## • Expanding our product development portfolio

- Moving VAL-083 toward "up-front" in GBM
  - MDACC collaboration in first recurrence of GBM
  - International study in newly diagnosed GBM
- Expanding beyond CNS tumors: NSCLC, Ovarian
- Accurexa Collaboration for Combination Chemotherapy



VAL-083: DelMar's Initial Product Candidate Leveraging Historical Clinical Data with Modern Science

## Reduce Cost, Risk & Time in Drug Discovery & Development





# VAL-083: DelMar's Initial Product Candidate

- First-in-class small molecule chemotherapy
- Readily crosses blood-brain-barrier
- >40 NCI-sponsored clinical trials demonstrate clinical activity against multiple tumor types
  - CNS, Solid & Hematologic Tumors
- Safety database: >1000 patients
  - Safety & toxicity
  - Pharmacokinetics
- Novel mechanism
  - DNA interstrand cross-links at N7-position of guanine leading to S-phase arrest and apoptosis



 $C_{6}H_{10}O_{4}$ 

ΟН

MW=146

## VAL-083 Targeting Unmet Medical Needs in Cancer

## **Data supports VAL-083 for multiple cancer indications**





### Large Market Opportunities:

2014 world -wide revenues

Non-small cell lung cancer	\$6.8 B
Glioma	\$1.0 B
Ovarian cancer	>\$500 M
Pediatric medulloblastoma	orphan
Source: Evaluate Pharma	





# Alkylating Agents in GBM

	TMZ	BCNU/CCNU/ACNU	VAL-083
Cytotoxic Target	O6-Guanine	O6-Guanine	N7-G
DNA damage	Base mismatch Single strand break	Interstrand crosslinks (G-C), double strand break	Interstrand crosslinks (G-G), double-strand break
Cell cycle arrest	G2/M	G2/M	S/G2
ATR-Chk1	activated	activated	Not activated
ATM-Chk2	activated	activated	activated
MGMT	dependent	dependent	independent
MMR	dependent	independent	research ongoing
p53	dependent	dependent	Less dependent
Cross blood-brain barrier?	yes	yes	yes



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# Alkylating Agents in GBM

	TMZ	BCNU/CCNU/ACNU	VAL-083	
Cytotoxic Target	O6-Guanine O6-Guanine		N7-G	
DNA damage	Base mismatch Single strand break	Interstrand crosslinks (G-C),	Interstrand crosslinks (G-G),	
Cell c    VAL-083's Unique Mechanism of Action compared to other chemotherapies used in GBM provides      ATR-(    opportunities				
• Overcome resistance to current therapy				
• Combination therapy approaches				
p53	dependent	dependent	Less dependent	
Cross blood-brain barrier?	yes	yes	yes	



## A Novel Combination Therapy for Brain Cancer

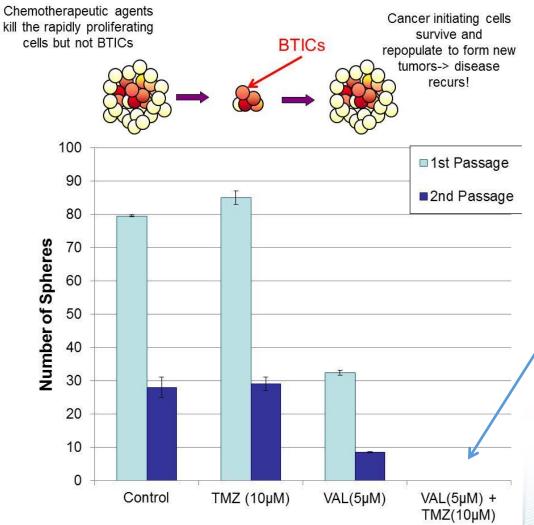




- Collaboration announced Sept. 7, 2016
- Developing implantable wafer based on Accurexa's ACX-31 delivery platform containing VAL-083 plus temozolomide and/or BCNU
- Combination will hit <u>two</u> distinct cytotoxic DNA alkylation targets: O6 and N7 of guanine while minimizing systemic toxicity
- Potential synergy against cancer stem cells already established
- DelMar retains right to license or acquire products for further development and commercialization



## VAL-083 + Temozolomide: Potential Activity Against Cancer Stem Cells



AACR 2012: SF188 brain-tumor initiating cells in a self-renewal assay. VAL-083 is active where temozolomide is not, but the combination was particularly striking



## A Novel Combination Therapy for Brain Cancer



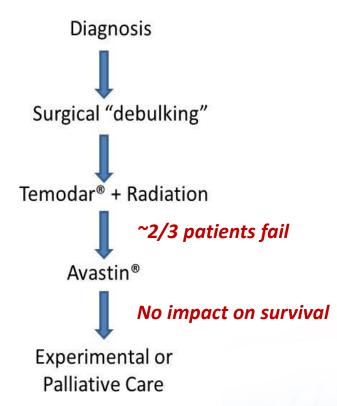


- Leverages Accurexa's experience with temozolomide + BCNU combination product
  - Accurexa announced successful pre-IND meeting with FDA in August 2016
  - Dr Bob Langer & Henry Brem (Gliadel<sup>™</sup>) serve as advisors
- Leverages DelMar's research regarding VAL-083 mechanism of action
  - Activity against MGMT(+) GBM and BTICs
- Provides DelMar with a potential exciting product opportunity with minimal near-term financial commitment
- Expect pre-clinical proof-of-concept in 6 9 months



VAL-083 Overcoming Chemo-resistance: A Paradigm Shift in the Treatment of GBM

## Current GBM Treatment Paradigm: Median Survival <15 months





VAL-083 Overcoming Chemo-resistance: A Paradigm Shift in the Treatment of GBM

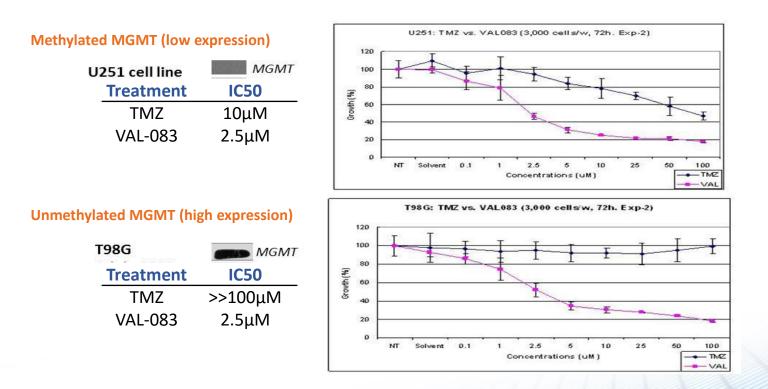
**New Paradigm Vision** for GBM Diagnosis Surgical "debulking" MGMT Assessment 2/3 1/3 **Temodar**<sup>®</sup> **VAL-083** Radiotherapy Radiotherapy **VAL-083** plus ... potential for Immunotherapy, Anti-VEGF, EFT

- VAL-083 Addresses MGMT-mediated resistance: <u>A Major Unmet Need</u>
  - VAL-083 is active independent of MGMTresistance
  - 2/3 of newly diagnosed GBM patients are resistant to Temodar<sup>®</sup> or nitrosoureas due to high-expression of MGMT
  - MGMT is a biomarker for patient selection
  - Prior NCI-sponsored trials demonstrate clinical activity against GBM



VAL-083 Overcoming Chemoresistance: A Paradigm Shift in the Treatment of GBM

• VAL-083: Active independent of MGMT resistance mechanism Historical NCI-sponsored clinical data demonstrates activity in GBM





VAL-083 Post Avastin Refractory GBM Phase I/II Clinical Trial



Phase I/II: Safety Study of VAL-083 in Patients With Recurrent Malignant Glioma

Patients have failed Temodar<sup>®</sup> (temozolomide) and Avastin<sup>®</sup> (bevacizumab)

ClinicalTrials.gov Identifier: NCT01478178

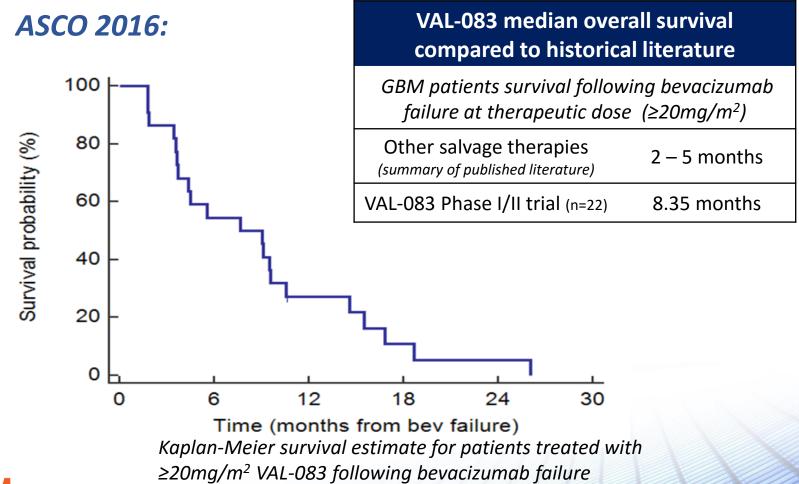


Summary of FDA End of Phase II Meeting (June 2016)

- Confirmed dosing regimen suitable for advancement to registration-directed trials
- Single Pivotal Phase III sufficient to support NDA
- DelMar may leverage historical nonclinical and clinical data to support NDA filing under 505(b)2



# VAL-083 Post Avastin Refractory GBM Phase I/II Clinical Trial





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# VAL-083: Implementing a Paradigm Shift in the Treatment of GBM

## 2016 Next Steps:

**1.** Advance to pivotal phase III trial in post-Avastin refractory GBM

## **STATUS: Trial Design Under Discussion with Advisors**

- Likely adaptive design
- VAL-083 vs. physicians' choice salvage therapy
- Under 200 patients



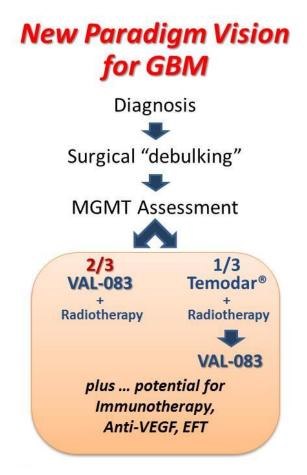
# VAL-083: Implementing a Paradigm Shift in the Treatment of GBM

## 2016 Next Steps:

- 2. Initiate two <u>new</u> Phase II clinical trials in GBM patients with high MGMT expression using DelMar dosing regimen
  - Newly Diagnosed in collaboration with Guangxi Wuzhou Pharma STATUS:
    - ✓ Clinical Research Committee and Ethics Committee have approved protocol
    - $\checkmark$  Finalizing contract with CRO & preparing for Site Initiation
  - First Recurrence in collaboration with MD Anderson Cancer Center STATUS:
    - ✓ Clinical Research Committee and MDACC IRB have approved protocol
      ✓ Preparing for Site Initiation



# VAL-083's First Opportunity: GBM



# VAL-083's distinct anti-cancer mechanism

- Would create a new survival paradigm for the first time in decades
- Unlocks potential to overcome chemo-resistance and surpass standard of care
- Lays the foundation for global development to address >\$1 billion market opportunity as chemotherapy of choice in the treatment of GBM



## **Building Our Pipeline:**

DelMar Research & NCI Data Support Broad Oncology Opportunities

## VAL-083: Differentiation from Standard-of-Care Platinum-based Chemotherapy

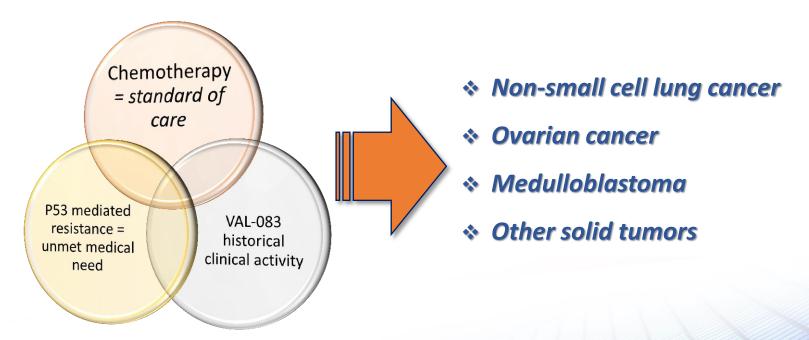
- Distinct cytotoxic mechanism targeting N7-position of guanine via DNA crosslinks
- > More potent vs. platinum-based chemotherapy on an equimolar basis *in vivo*
- Synergy with platinum-based chemotherapy
  - ✓ VAL-083 not dependent on p53 activation for cytotoxic activity *in vitro*
  - ✓ No evidence of over-lapping toxicity *in vivo*
- Active against both platinum-resistant and TKI-resistant NSCLC strains in vitro and in vivo



# Building Our Pipeline:DelMar Research & NCI Data Support Broad Oncology Opportunities

## VAL-083:

# Commercial opportunity to address unmet medical needs





# Expanding Our Clinical Portfolio: VAL-083 in NSCLC

- Lung cancer is the leading cause of cancer death world-wide
- Non-small cell lung cancer (NSCLC)
  - ✓ Current drugs represent >\$6 billion in world wide annual sales
  - ✓ Overall 5 year NSCLC survival rate: 15%
  - ✓ CNS metastases a leading cause of NSCLC mortality
- Existing and new data support potential of VAL-083 in NSCLC
- VAL-083 is approved in China for the treatment of lung cancer
- Phase IV NSCLC trial to be initiated in 2016
  - Funded via DelMar collaboration with Chinese manufacturer
  - Study Goals:
    - Provide biomarker-driven guidance to treating physicians under existing approval in China
    - Phase II proof-of-concept to support global development in biomarker circumscribed subsets of NSCLC where there is unmet medial need
- Global partnering opportunity



# Building Our Pipeline: VAL-083 in Ovarian Cancer & Pediatric Brain Cancer

## DelMar research and historical clinical data support potential of VAL-083 in Ovarian Cancer and Medulloblastoma

### **Ovarian Cancer**

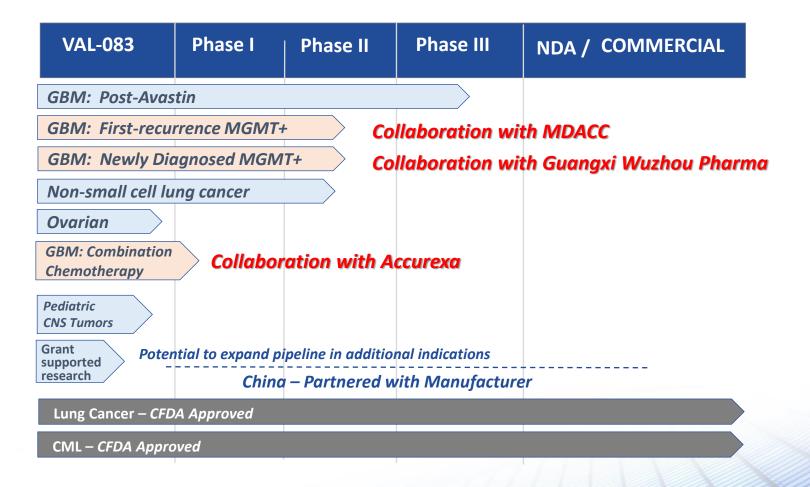
- USFDA Granted Orphan Designation, April 2016
- Ranks 5<sup>th</sup> in female cancer deaths world-wide
- 75% of patients relapse with treatment-resistant tumors
- Median survival in platinum-resistant recurrent ovarian: 6 9 months

## Medulloblastoma

- FDA Granted Orphan Designation, March 2016
- Most common pediatric brain tumor
- Recurrent tumors with p53 mutation have no treatment and poor prognosis



## DelMar Pharma 2016: A Transformational Year





# Growing Patent Portfolio: Robust Intellectual Property Protection

- Thirteen separate patent families with multiple patents
  - Claims include use, manufacturing, analytical, mechanism and composition claims
- Six US patents and seven international patents issued to date
  - Patent protection into 2036 in USA
- More than 100 patent filings + 4 provisional applications pending on a global basis
- VAL-083 granted orphan drug designation in US & EU
  - Seven years market exclusivity after approval in US
  - 10 years market exclusivity after approval in Europe



# **Financial Snapshot**

- \$7.2 million private placement Q2/2016
- Current capital funds operations thru end of 2017
- Near-term filing of June 30, 2016 10K

Common Shares	Pro-forma 31-Mar/2016	
common shares	Post 1:4 reverse split	
DMPI Shares	10.0 m	
ExchangeCo	<u>1.0 m</u>	
Total Outstanding	11.0 m	
Other securities (as converted to common)		
Preferred Shares	2.2 m	
Warrants	4.7 m	
Options	<u>0.9 m</u>	
Fully Diluted	18.8 m	



## **Management and Advisors**

#### Management

#### Jeffrey Bacha, BSc MBA: Chairman & C.E.O.

- 20 years biopharma experience
- Founding CEO, Inimex Pharmaceuticals
- Senior Manager & Director, KPMG Health Ventures

#### Dennis Brown, PhD: Chief Scientific Officer

- Founder Matrix Pharmaceuticals Chemgenex Pharmaceuticals (both acquired)
- Academic Appointments: Harvard & Stanford

#### **Richard Schwartz, MD: Chief Medical Officer**

- Oncology Clinical Research Bayer AG
- Stanford University School of Medicine

#### Scott Praill, CPA: Chief Financial Officer

- Experienced Public Company CFO
- PricewaterhouseCoopers LLP

#### **Board of Directors**

#### Jeffrey Bacha - Chairman

#### **Dennis Brown, PhD**

John Bell, CPA – Audit Committee Chair

• President, Onbelay Capital

#### Lynda Cranston, MScN ICD.D – Comp. & Gov. Committee Chair

Healthcare Executive

#### Erich Mohr, PhD, R. Psych

• Chair, Medgenesis Therapeutix

#### Rob Toth, MBA

• Former Analyst, Prudential Healthcare

#### **Advisors**

Victor Levin, MD – Prof. Emeritus MDACC (neuro-oncology) Susan Chang, MD - Chair, NeuroOncology Department UCSF James Perry, MD - Chair, Canadian Brain Tumor Consortium Howard Burris, MD - Director, Sarah Cannon Cancer Research Institute Bill Bodell, PhD - Prof. Emeritus UC Berkley (DNA Damage & Repair) Dan Zhang, MD - CFDA Oncology Advisory Panel (China FDA) Christine Charette - Former Biotech Analyst, BMO Nesbitt Burns Sol Barer, PhD - Founder, Celgene



## **Actionable Milestones**

#### **Clinical Research**

- Refractory GBM
- Front-line GBM
- First Recurrence in GBM
- Non-small cell lung cancer

#### **Pre-clinical Research**

- Ovarian Cancer
- Medulloblastoma
- VAL-083 Combination Chemotherapy

#### **Conference Attendance**

- Sept 11 13
- Sept 12 13
- Sept 20 22
- Oct 12 16
- Nov 17 20



#### **Pivotal Phase III**

- New Phase II clinical trial: Collaboration with Guangxi wuzhou
- New Phase II clinical trial: Collaboration with MDACC
- New Phase II clinical trial planned

Ongoing research to define clinical strategies; Anticipated presentations at peer-reviewed conferences

Collaboration with Accurexa to Establish Proof of Concept

HC Wainwright / Rodman Renshaw 11<sup>th</sup> Annual Biennial Ovarian Cancer Research Symposium Aegis Capital Growth Conference European Association of Neuro-Oncology (EANO) Society for Neuro-Oncology Annual Meeting (SNO)

# DelMar Pharmaceuticals, Inc. Investment Opportunity

## ✓ VAL-083

"First-in-class" small molecule chemotherapy

- Unique anti-cancer mechanism overcomes chemo-resistance
- NCI demonstrated clinical activity across a range of cancers
- Promising interim outcomes data in refractory GBM clinical trial
  - Advancing to "late-stage" clinical development in 2016
- Pipeline expansion opportunities in high value oncology markets
- Robust IP protection from newly issued patents
- Orphan drug designation in USA and EU
- ✓ Transformational Near-term Catalysts
- ✓ Solid Financial Position
- Experienced Team with History of Success



## NASDAQ:DMPI

### **Corporate Headquarters**

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## **Clinical Operations**

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## www.delmarpharma.com





**Breakthrough Cancer Therapeutics**