Marcum MicroCap Conference

Thursday, May 30, 2013 Grand Hyatt 109 E 42nd Street New York, NY 10017



# PHARMACEUTICALS Breakthrough Cancer Therapeutics

OTCQB: DMPI

JEFFREY BACHA, PRESIDENT & CEO

MAY 30, 2013





#### **Safe Harbor**

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. 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, including, our current reports on Form 8-K. We do not undertake to update these forward-looking statements made by us.



#### **OUR MISSION**

To benefit patients and create shareholder value by rapidly developing and commercializing well-validated anti-cancer therapies in high-impact orphan cancer indications where patients have failed modern therapy.



### **Value Proposition**

- Clinical and Commercial-stage pharmaceutical company
- Well-validated lead drug candidate
- Hold commercial rights to lead product in China
- Management has a history of successful exits
- Clinical team successfully developed Synribo®
- Streamlined clinical and global commercialization plan
- Strong financial position
- **❖** Public listing (OTCQB: DMPI)



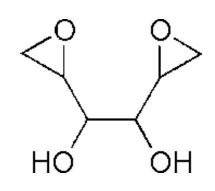
### **VAL-083**

Small molecule cancer therapy for refractory glioblastoma multiforme





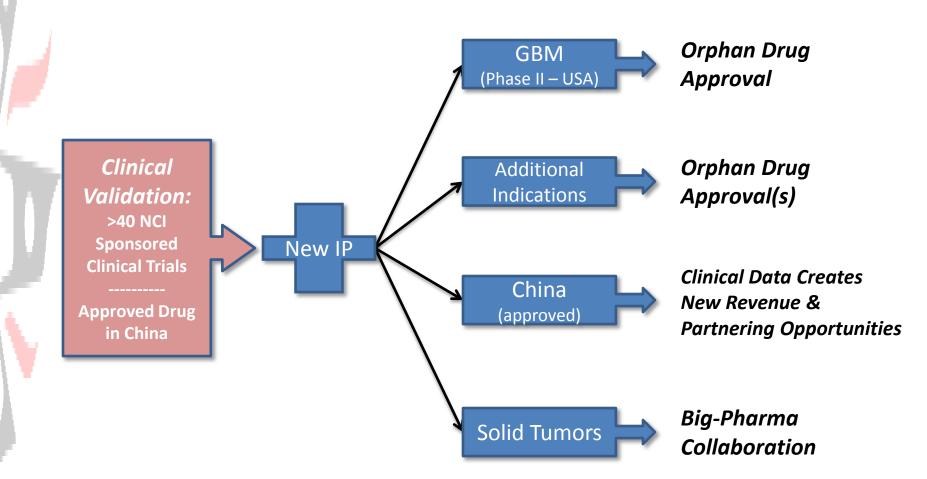
### VAL-083: DelMar's First Product Opportunity



- Currently undergoing Phase I/II clinical trial in patients with refractory glioblastoma multiforme (GBM)
- > Small-molecule chemotherapeutic
- Studied in previous human clinical studies at the National Cancer Institute (USA)
- > Favorable safety profile
- Well characterized mechanism of action
- Approved in China: Leukemia & Lung Cancer

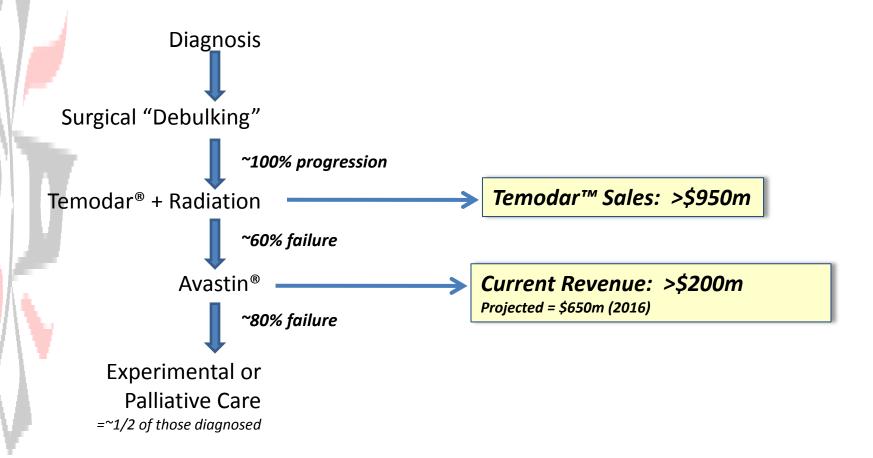


#### **VAL-083: Product Development Strategy**





### Glioblastoma Multiforme **Current Treatment Paradigm**







# Glioblastoma Multiforme The Problem

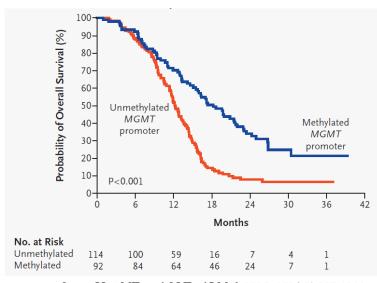
- Glioblastoma Multiforme (GBM): The most common and aggressive form of brain cancer
- Affects approx. 15,000 adults each year in USA
- Prognosis is very poor
  - **❖** Without Treatment = 4 ½ months
  - With Optimal Treatment = 15 months
- Resistance to standard chemotherapy is high
- Approximately half of patients tumors fail all other treatments
  - ❖ We know why!!!





# Glioblastoma Multiforme *The Problem: MGMT Drug Resistance*

- ➤ MGMT is a natural enzyme that causes resistance to Temodar™
- Highly correlated with patient response & survival
- Modern approaches such as vaccines & immunotherapies will not address this problem



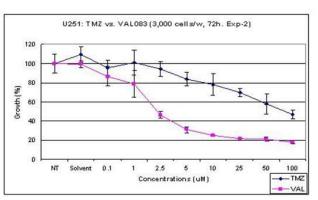
Source: Hegi ME et al. N Engl J Med. 2005; 352(10):997-1003.



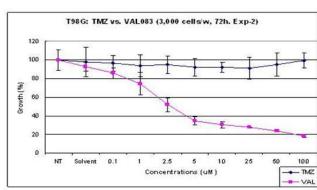
# Glioblastoma Multiforme (GBM) Potential Solution: VAL-083

- Novel small molecule drug candidate
- Data from National Cancer Institute demonstrates activity in GBM
- Works differently than other chemotherapies
- Not subject to MGMT resistance mechanism











### **Glioblastoma Multiforme (GBM)** VAL-083 Clinical Trial

- Phase I/II Study being conducted in USA
- Patients have failed Temodar® and Avastin®
- Goals of the Trial
  - Modernize Dosing Regimen
  - Confirm safety provile
  - Demonstrate ability to shrink or halt growth of tumors
- Initial Phase: Dose Modernization (20-30 patients)
- Leads to 80-100 patient registration trial
  - Open label design

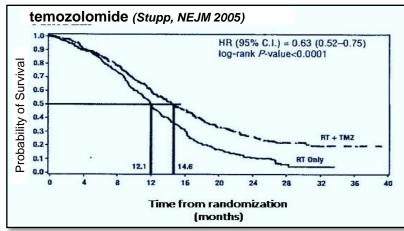


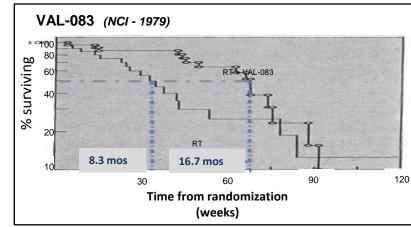


# VAL-083 Evidence of Clinical Efficacy in GBM

VAL-083 historical clinical data demonstrates comparable incremental survival benefit and overall survival comparable to today's standard of care

| Treatment of GBM                                    | temozolomide<br>(Phase III<br>Stupp 2005) | VAL-083<br>( Phase II<br>Eagan 1979) |
|---|---|--------------------------------------|
| Median Overall Survival<br>RT + Chemo               | 58 weeks                                  | 67 weeks                             |
| OS Benefit of adding Chemo: RT & Chemo vs. XRT Only | 2.5 months<br>(p<0.01)                    | 8.4 months (p=0.02)                  |
| Sample (n=)<br>Randomization                        | 573<br>1:1                                | 42<br>1:1                            |









### **Toxicity Comparison**

|                                | Temodar  | BCNU  | VAL-083         |
|--------------------------------|--|---|-----------------|
| Severe toxicity reported (>2%) | Hematologic*,<br>nausea, vomiting,<br>fatigue, asthenia,<br>neuropathy | Hematologic*,<br>pulmonary, nausea,<br>vomiting,<br>encephalopathy, renal | Hematologic*    |
| *DLT                           |  |   |                 |
| NADR                           | 21-28 days   | 21-35 days  | 18-21 days      |
| Recovery                       | Within 14 days   | 42-56 days  | Within 7-8 days |

As reported by BC Cancer Agency monograph (2010)

literature (1970s) & China commercial experience



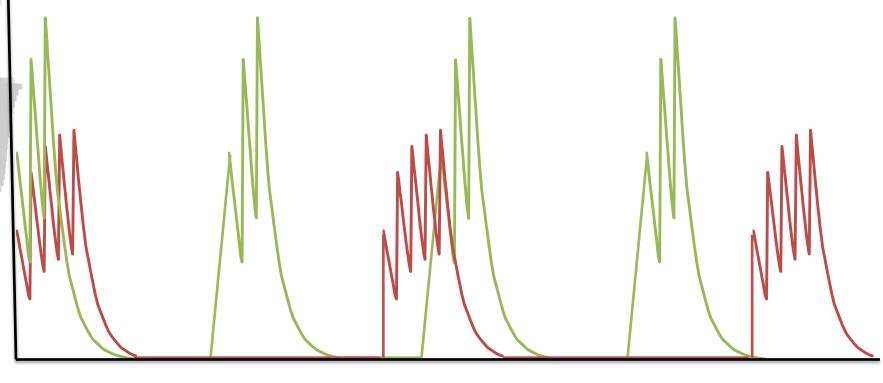


## **Illustrative Comparison of Dosing Regimen**

"Hit the tumor harder; more often"

DelMar Pharma "modernized" dosing regimen

NCI regimen from published efficacy studies



time



VAL-083 CSF Concentration

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### VAL-083 Dose-Escalation Study Illustration

Increasing dose NCI Dose (25 mg/m2)3 cohorts complete





# VAL-083 Phase I/II Clinical Trial Results to Date (AACR 2013)

- VAL-083 is safe and well tolerated at doses tested to date
- ➤ A portion (33%) of patients tumors were observed to shrink or stop growing following initiation of treatment
- Doses to date are lower than NCI-regimen
- Plasma exposure observed to increase in accordance with dose



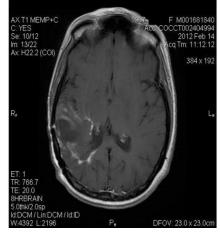
# VAL-083: Clinical Development in GBM Interim Results Presented at AACR (study ongoing)

# Patient Brainscans (MRI) impact on tumor following treatment with VAL-083

Before treatment with VAL-083 After treatment with VAL-083 Before treatment with VAL-083 After treatment with VAL-083









Patient #2

Patient #5

AACR2013 Poster Presentation



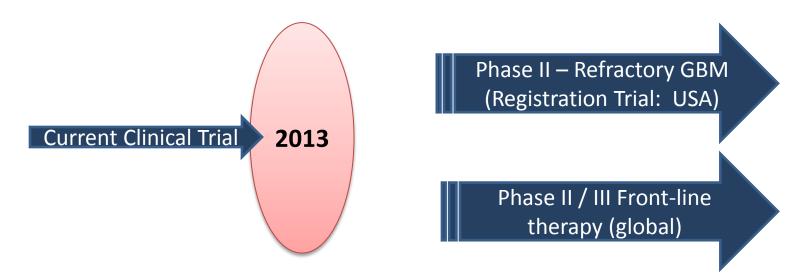
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### VAL-083: Clinical Development in GBM

Current Phase I/II Study → potentially position DelMar for advancement to registration trials



- Re-confirmed published activity against GBM
- ✓ Well defined registration trial
- Registration-ready commercial scale CMC
- New patents claims / Orphan drug protection





#### DelMar's Unique Partnership in China



Commercial and development partnership with Guangxi Wuzhou Pharmaceutical Group Co. Ltd.

- Provides DelMar with global rights to VAL-083, which is already approved as a cancer chemotherapy in China
- Near-term revenue opportunity for DelMar in high-growth international markets
- Guangxi Wuzhou Pharma will fund any clinical activities in China
- DelMar plans to partner China marketing rights to access an established sales force and generate royalty revenue







# VAL-083: China Opportunity

- Major potential market opportunity: Lung cancer = 1,000,000 new cases annually by 2025
- > Challenge: Current sales in China are minimal
  - Drug is not well positioned vis-à-vis standard of care in approved indications
- Solution: New data to promote sales
  - Near Term: Reposition for refractory therapy in approved indications
  - Longer Term: Expand market with new indications
- Seeking sales & marketing partnership to generate royalty revenue





#### **VAL-083** Intellectual Property:

**Orphan Drug Protection: Provides 7 – 10 years of** market exclusivity

- Granted in USA 2012
- Granted in Europe 2013

Filed Seven New Patent Applications since 2010





### **Leadership & Experience**



#### Jeffrey Bacha, BSc MBA: CEO & President

- > 20 years of experience in biotech and pharmaceuticals
- Founding CEO, Inimex Pharmaceuticals
- Senior Manager & Director, KPMG Health Ventures
- Emory Univ., School of Business
- UC San Diego, BioPhysics/PreMed



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

- Founder: Matix Pharmaceuticals (acquired by Chiron)
- Founder: Chemgenex (acquired by Cephalon)
- 30 years cancer drug discovery and development
- Harvard Medical School, Assistant Professor
- Stanford Univ. Med School, Research Associate
- NYU, PhD Radiation and Cancer Biology

DelMar PHARMACEUTICALS Development Team

Responsible for successful development & commercialization of more than 20 oncology products.





#### **Directors & Advisors**

**Bill Garner, MD,** Director, coFounder DelMar; CEO Invion Ltd. (ASX:IVX)

John K. Bell, CA Director, President of Onbelay Capital

Victor Levin, MD Prof. Emeritus MD Anderson Cancer Center (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** SFDA Oncology Advisory Panel (China FDA)

**Christine Charette** Former Biotech Analyst, BMO Nesbitt Burns

**Sol Barer, PhD** Founder, Celgene



#### **Track Record of Achievements**

- > Launched clinical trial in 2011
- > Awarded Orphan Drug Designation by USFDA & EMEA for VAL-083
- > Demonstrated clinical activity with lead drug candidate
- Awarded three research grants from National Research Council of Canada
- > Acquired exclusive commercial rights to VAL-083 in China
- > Filed seven new patents in 2011/12
- > Established a highly-experienced drug development team and advisors
- > Named to "Ready to Rocket" list in 2010/2012/2013
- > 2010 Winner: Discovery Parks Business Plan Competition
- ➤ Presented favorable interim data from clinical trials at leading cancer meetings 2012/2013



### DelMar's Anticipated Clinical Data Presentations from Glioblastoma Trial

| American Association of Cancer Research (AACR) | Data Presented 10-Apr/2013     |
|--|--------------------------------|
| American Society of Clinical Oncology (ASCO)   | Presentation 1-Jun/2013        |
| Society for NeuroOncology Annual Meeting (SNO) | Nov 21 – 24 (San Francisco CA) |





#### **CAPITALIZATION**

**Capital Raised to** Date:

\$13.6 million

**Shares Outstanding: 30.6 million** 

**Market** 

**Capitalization:** 

\$69 million

Ticker (OTCQB):

**DMPI** 

**Auditor:** 

**PricewaterhouseCoopers LLP** 





#### **DelMar Pharma Investment Thesis**

- Clinical-stage oncology company
- Proven drug candidate
- Streamlined commercialization plan
- Attractive valuation
- Highly experienced team
- ❖ OTCQB: DMPI





#### Thank You

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