Zacks Small-Cap Research

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Delmar Pharma (DMPI-NASDAQ)

DMPI: Zacks Company Report

DMPI: Pipeline will be expanded to include NSCLC and ovarian cancer while ready to advance VAL-083 to pivotal Phase III trial in 2016,

Current Price (09/15/16)	$6.95
Valuation	**$16.00**

OUTLOOK

DMPI is a clinical/commercial stage biopharmaceutical company with a focus on oncology. We are impressed with the efficacy data and safety profile of its lead drug candidate VAL-083 for brain cancer.

DMPI recently reported positive VAL-083 Phase I/II clinical data for brain cancer and preclinical data for lung cancer and ovarian cancer. The company is on track to initiate registration directed trial of VAL-083 for brain cancer in 2016.

Valuation is attractive now.

SUMMARY DATA

52-Week High	**$10.15**
52-Week Low	**$1.72**
One-Year Return (%)	**250.47**
Beta	**0.80**
Average Daily Volume (sh)	**28,264**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$75**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**N/A**
Industry	**Med-Drugs**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2015	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2016	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2017					0.50 E
2018					7.00 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.15 A	-$0.11 A	-$0.03 A	-$0.12 A	-$0.08 A
2016	-$0.10 A	-$0.15 A	-$0.10 A	-$0.18 A	-$0.54 E
2017					-$1.08 E
2018					-$1.14 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

DelMar and Accurexa to Collaborate in the Development of a Combination Chemotherapy for the Local Treatment of Brain Cancer

On Sept. 7, 2016, DelMar and Accurexa announced a **collaboration** to develop a novel formulation for the **local delivery** of combination chemotherapy for the treatment of brain cancer and other solid tumors.

Under the terms of the collaboration agreement DelMar will supply VAL-083 (dianhydrogalactitol) to be formulated within Accurexa's proprietary **ACX-31** implantable polymer wafer to locally deliver VAL-083 in combination with temozolomide and/or BCNU for the treatment of brain cancer. DelMar has been granted an exclusive option to license or acquire and commercialize product candidates and intellectual property resulting from the research.

Working together with Accurexa will allow DelMar to explore a promising new product opportunity that is complementary to the company's existing portfolio of systemic drug development programs established around VAL-083 without significant cash outlay or impact on the company's near-term cash burn rate.

DelMar and Accurexa believe that combining VAL-083 with temozolomide and/or BCNU within Accurexa's proprietary drug delivery system may provide treatment advantages while limiting systemic toxicity.

The two companies will seek to establish a **novel formulation** which incorporates VAL-083 into the ACX-31 polymer wafer and to establish non-clinical proof of concept regarding the proposed advantages of the combination therapy. DelMar will supply Accurexa with VAL-083 and the companies will share certain limited costs associated with the research. DelMar has been granted an exclusive option to license or acquire and commercialize product candidates and intellectual property resulting from the research for a defined period after the completion of the research. DelMar's option to negotiate a license or acquire the technology includes any and all results, research materials, related information and product candidates, including without limitation ACX-31 and related intellectual property and all rights thereto on an exclusive world-wide basis or other such terms as the parties may agree, in order to further develop and commercialize products based on the research project.

Since both companies have already made significant investments into the IP, mechanism of action and formulation of VAL-083 and ACX-31, respectively. Therefore, developing a combined formulation is not expected to require significant cash expenditures. This collaboration is a highly cost-effective approach to expand DelMar's product development portfolio.

Balance Sheet Boosted by Recent Financing

As of June 30, 2016, DelMar held $6.2 million in cash.

In May 2016, DelMar announced a closing of a private placement of Preferred Shares for gross proceeds of $6.1 million, and the restructuring of 2,095,238 warrants. These steps enable DelMar to substantially improve its balance sheet, remove a significant portion of the derivative liability from its balance sheet.

DelMar has made a great deal of progress in the development of its lead product candidate, VAL-083. These new funds will allow the company to maintain the momentum it has established in this program through 2017.

We Set our new Valuation at $16.00 per share Post Reverse Split and Uplisting on NASDAQ

On July 11, DelMar announced the approval from the Nasdaq Stock Market LLC for the listing of its common stock on the NASDAQ Capital Market. The company's common stock began trading on the NASDAQ Capital Market at the opening of trading on July 12, 2016 under the ticker symbol DMPI.

In preparation for the uplisting, the company did a 1-for-4 reverse stock split of its authorized, issued and outstanding common stock in May 2016.

The NASDAQ uplisting marks a major corporate milestone for the Company. The uplisting will position the company to broaden its shareholder base, increase appeal to institutional investors, provide improved liquidity and ultimately contribute to increasing shareholder value.

As a result of the uplisting and the reverse split, we adjusted our valuation to $16.00 per share from previous $4.00 per share.

We continue to be bullish on the DelMar story based on recent clinical progress the company has made and attractive valuation of the company shares.

DMPI is a clinical and commercial stage biopharmaceutical company focused on the development and commercialization of oncology drugs. The Company's lead drug candidate VAL-083 is currently in a **Phase I/II** trial for the treatment of recurring GBM.

Previous multiple clinical studies conducted by NCI have demonstrated that VAL-083 is safe and efficacious for the treatment of GBM. Interim data from the Company's Phase I/II trial confirmed the efficacy and safety profile of VAL-083 in GBM patients. Based on the data currently available, DMPI intends to initiate a registration directed **Phase III** trial of VAL-083 for **recurring GBM** as quickly as possible, and possibly **in late 2016**. This will be a significant milestone for DelMar which will position the Company as a late stage development company.

DelMar also plans to expand its pipeline by initiating clinical trials of VAL-083 for lung cancer and ovarian cancer.

VAL-083 has been approved in China for leukemia and lung cancer and DMPI has acquired its commercial rights in China market. Delmar is seeking to enter into a marketing partnership that could generate upfront fees, milestones and royalty revenue for DMPI, which is a de-risking event for the Company.

VAL-083 is a first-in-class alkylating agent with a different mechanism of action from that of **Temodar**, current market leader for GBM. The unique MOA of VAL-083 overcomes the resistance problem for Temodar.

Currently, DMPI shares are trading at around $7.5 per share, which values the Company at about $75 million in market cap based on 10 million outstanding shares. This is a deep discount compared to its peers. We noticed that most small biotech companies of development stage are valued from $50 million to $1 billion depending on how advanced the pipeline is and which indications the company is targeting. DMPI's lead drug candidate VAL-083 is in a Phase I/II clinical trial and will enter a registration directed Phase III trial in 2016.

We estimate VAL-083 could be approved by the FDA in late 2018 or early 2019 for recurring GBM. The broad application of VAL-083, including first line, second line and third line treatment of GBM, and other cancers, means a great market potential for VAL-083, which could be a blockbuster for DelMar. We estimate DMPI will be profitable in fiscal 2019 with an EPS of $0.24 based on product sales of $35 million. EPS will grow to $1.27 in fiscal 2020 based on total product sales of $70 million.

Based on our financial model and the Company's fundamentals, we have a valuation at $16.00 per share for DMPI. We think a P/E ratio of 30x is appropriate for DMPI considering its growth in the next few years. Based on this P/E multiple, we come up with our valuation of $16.00 per share using 25% discount for 4 years. Our price target values DMPI at $160 million in market cap, which we think is still conservative compared to its peers.

But risk is still high at this point for DMPI. Although VAL-083 has been approved in China for marketing, its indications are leukemia and lung cancer, different from the current indication of GBM under development in the US. The bars on both clinical and regulatory hurdle in the US are higher. We remind investors that risks associated with drug development are high. But generally speaking, DMPI is a name with a favorable risk/reward profile for investors with a high risk tolerance and longtime investment horizon.

A Registration Directed Phase III Trial to Begin in 2016

In late May, DelMar announced the successful completion of an **End of Phase II meeting** with the FDA.

DelMar's advanced development program for VAL-083 will feature a single randomized **Phase III study** measuring survival outcomes compared to a "physicians' choice" control, which, if successful, would serve as the basis for a New Drug Application (NDA) submission for VAL-083. The control arm will consist of a limited number of salvage chemotherapies currently utilized in the treatment of Avastin-failed GBM. The final pivotal trial design will be confirmed with the FDA following further discussions with the Company's clinical advisors.

The FDA confirmed that it will consider the totality of data available, including data obtained from DelMar's other planned clinical trials in related GBM populations, when assessing the NDA. The FDA also noted that DelMar can rely on prior US National Cancer Institutes (NCI) studies and historical literature to support non-clinical data required for an NDA filing and that DelMar will have the option to file under a **505(b)(2) strategy**, which allows a sponsor to rely on already established safety and efficacy data in support an NDA.

The company plans to initiate the study as quickly as possible. We estimate **it could happen in late 2016.**

The registration directed Phase II/III trial for the refractory GBM will take about 9 to 12 months. We estimate data from this will be available in 2H17 and an NDA will be filed in 2H17 or early 2018. The FDA approval will occur in late 2018 or early 2019.

In addition to the proposed Phase III clinical trial, DelMar plans to conduct two additional **Phase II** studies in separate GBM populations:

- In collaboration with the University of Texas MD Anderson Cancer Center, DelMar plans to conduct a randomized **Phase II** clinical trial of VAL-083 versus CCNU in bevacizumab-naïve MGMT-unmethylated GBM patients at first recurrence/progression to confirm the tolerability of DelMar's dosing regimen and assess outcomes in recurrent bevacizumab-naïve GBM patients whose tumors are known to express high levels of MGMT (NCT02717962); and
- In collaboration with Sun Yat-Sen University and Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd, DelMar plans to conduct a single arm **Phase II** clinical trial to confirm the tolerability of DelMar's dosing regimen in combination with radiotherapy (XRT) and to explore the activity of VAL-083 in newly diagnosed MGMT-unmethylated GBM patients whose tumors are known to express high levels of MGMT.

Update on Ongoing Phase I/II Refractory GBM Clinical Trial with VAL-083

On June 4, 2016, DelMar presented updated data from its ongoing Phase I/II clinical trial in refractory glioblastoma multiforme (GBM) with its lead anti-cancer product candidate, VAL-083 (dianhydrogalactitol) at the American Society of Clinical Oncology's (ASCO) Annual Meeting.

Background of the Phase I/II clinical trial

DelMar initiated the **Phase I/II** clinical trial of VAL-083 for the treatment of **refractory glioblastoma multiforme (GBM)** or **progressive secondary brain tumor** in October 2011. The Phase I/II study is an open-label, single arm dose-escalation study designed to evaluate the safety, tolerability, pharmacokinetics and anti-tumor activity of VAL-083 in patients with histologically confirmed initial diagnosis of primary WHO Grade IV malignant glioma (GBM), now recurrent. Patients with prior low-grade glioma or anaplastic glioma are eligible if histologic assessment demonstrates transformation to GBM. Patients must have been previously treated for GBM with surgery, and/or radiation, if appropriate, and must have failed both Bevacizumab (Avastin) and temozolomide (Temodar), unless either or both are contra-indicated. Patients with brain tumors that have developed due to CNS metastases were eligible for the DelMar clinical trial at early doses.

The primary outcome measures in the dose-modernization portion of the clinical trial will be the determination of maximum tolerated dose (MTD). **Secondary outcome** measures include tumor response in patients and pharmacokinetics.

An initial phase of the Phase I/II study will involve dose escalation cohorts until a maximum tolerated dose (MTD) is established in the context of modern care. Once the modernized dosing regimen has been established, additional patients will be enrolled at the MTD in a registration directed **Phase II** clinical trial.

The study was designed for patients to receive VAL-083 on days 1, 2, and 3 of a 21-day cycle. Tumor response is assessed according to RANO criteria prior to every other 21-day treatment cycle and patients exhibiting stable disease or tumor regression remained on VAL-083. Determination of MTD is based on 3+3 design.

The Phase II Expansion Study

In the Phase I dose-escalation portion of the study, VAL-083 was well tolerated at doses up to 40mg/m^2 using a regimen of daily x 3 every 21 days. The 40 mg/m^2/d dose exhibited a favorable safety profile, with a trend toward improved survival versus lower doses. Following determination of the maximum tolerated dose (MTD) at 40 mg/m^2/d, a 14-patient Phase II expansion cohort was rapidly enrolled at a dose of 40 mg/m^2/d on day 1, 2, 3 of a 21-day cycle.

DelMar commenced enrollment in the **14-patient expansion** cohort for the trial in GBM near the end of the **second quarter of 2015**. The purpose of the expansion cohort is to gain additional information about the safety and efficacy of VAL-083 at a 40mg/m^2 dose prior to advancement into registration-directed Phase II/III clinical trials.

On October 21, 2015, DelMar announced the full enrollment of the Phase II expansion cohort.

To further explore the therapeutic window of VAL-083, DelMar also enrolled three (3) patients an interim dose of 45mg/m^2. Patients enrolled in this clinical trial have failed both front-line therapy with temozolomide and second-line Avastin and, in most cases, one or more salvage therapies.

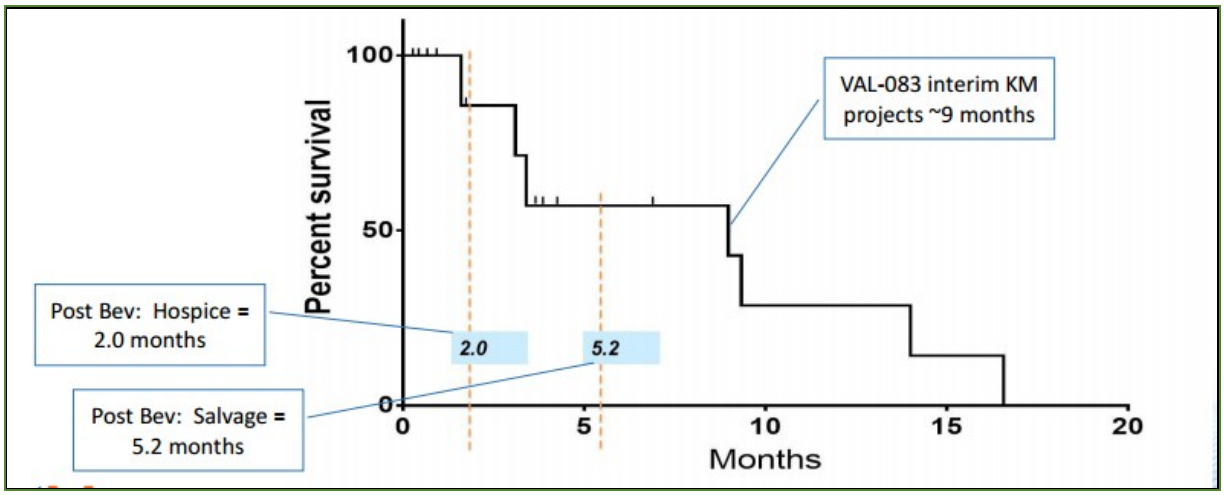
Updated data were presented at the 20th Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology being held November 19 - 22, 2015, in San Antonio, Texas. Here are the summary of the updated data:

- The 14th and final patient to be enrolled in the Phase II expansion cohort initiated treatment on October 14, 2015, and all patients enrolled in the Phase II expansion cohort have received at least one cycle of treatment to date.

- Safety observations in the Phase II expansion cohort to date are consistent with the Phase I dose-escalation cohort. Generally, observed myelosuppression is mild (Grade 1), with the exception of one patient.

    - One subject previously treated with CCNU developed Grade 4 thrombocytopenia suggesting patients with prior nitrosourea treatment who may exhibit higher susceptibility to thrombocytopenia. The inclusion criteria were modified to account for this observation.

- To date, 20 GBM patients failing standard front-line therapy and bevacizumab have been treated with an assumed well-tolerated therapeutic dose of VAL-083 (30mg/m^2 /d & 40mg/m^2 /d). A Kaplan Meyer survival estimate based on interim analysis of patients enrolled in the Phase II expansion cohort is consistent with observations made in the Phase I dose-escalation portion of the study. Preliminary analysis suggests a potentially meaningful survival benefit in this population following treatment with VAL-083 at doses ≥30 mg/m^2 /d in comparison to published reports for the same population



In 2009, Iwamoto reported a median overall survival of 2.0 months after failing bevacizumab for patients receiving only hospice care, and 5.2 months after failing bevacizumab for patients receiving further salvage therapy. The observed median survival to date following treatment with VAL-083 is **9.2 months**.

Multiple historical NCI-sponsored clinical studies of VAL-083 demonstrated that, in general, tumor regression in brain cancer was achieved following therapy in greater than 40% of patients treated and stabilization was achieved in an additional 20% to 30%. In published clinical studies VAL-083 has previously been shown to have a statistically significant impact on median survival in high grade glioma brain tumors when combined with radiation versus radiation alone with results similar or superior to other chemotherapies approved for use in GBM.

Chemotherapy	Comparative Therapy Survival		Median Survival Benefit vs. XRT
	Radiation	Radiation + Chemotherapy	
Temodar™	12.1 months	58 weeks (14.6 months)	2.5 months
VAL-083	8.3 months	67 weeks (16.7 months)	8.0 months

Reported Radiation + Chemo Survival w/ other chemotherapeutic agents in GBM

Carmustine™ (BCNU)	40-50 weeks
Lormustine™ (CCNU)	52 weeks
Nimustine™ (ACNU)	35 weeks
Avastin™	No reported benefit to survival

We think the interim survival data from the Phase II expansion cohort is highly promising. We are especially impressed with the safety profile of VAL-083 at the dose of 40 mg/m^2/d and the projected greater than 9-month median survival. Taken together with historical and recently demonstrated clinical activity, these results suggest that VAL-083's distinct anti-cancer mechanism has the potential to overcome chemo-resistance and surpass the standard of care in the treatment of GBM.

Updated Data Presented at ASCO 2016

DelMar presented updated data at 2016 AACR. In summary, DelMar presented that:

- VAL-083 attacks cancer cells via a unique mechanism of action which is distinct from other chemotherapies used in the treatment of GBM. Specifically, VAL-083 is active independent of MGMT, a DNA repair enzyme which is highly expressed in approximately 2/3 of GBM patients and correlated with resistance to temozolomide, the current front-line chemotherapy in the treatment of GBM. Of patients tested in the DelMar trial, 84% exhibited high MGMT.
- Median survival of 22 patients receiving an assumed therapeutic dose of VAL-083 (≥20mg/m^2) was **8.35 months**, suggesting that VAL-083 may offer improved survival for GBM patients following bevacizumab (Avastin) failure in comparison to currently available salvage therapy. Median survival for VAL-083 treated patients following bevacizumab failure compared with published literature demonstrating survival of approximately three to five months with common salvage therapy regimens.

VAL-083 compared to published literature

Reference	Post Avastin Salvage Therapy	Median Survival from Bevacizumab Failure
Rahman *(2014)*	nitrosourea	4.3 months
Mikkelson *(2011)*	TMZ + irinotecan	4.5 months
Lu *(2011)*	dasatinib	2.6 months
Reardon *(2011)*	etoposide	4.7 months
Reardon *(2011)*	TMZ	2.9 months
Iwomoto *(2009)*	various	5.1 months
DelMar Trial	***VAL-083***	**8.35 months**

- A dose of 40 mg/m^2/day VAL-083 administered on the first three days of every three-week cycle is well tolerated in refractory GBM patients and has been selected for study in subsequent clinical trials.

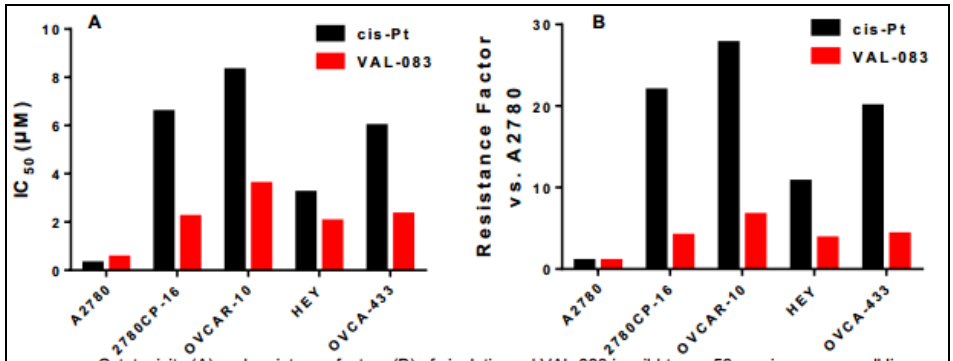
DelMar Expands VAL-083 Development Program to Ovarian Cancer

In early September 2015, DelMar announced that it will expand its pipeline by conducting clinical trial of VAL-083 for the treatment of **ovarian cancer**.

In October 2015, the company presented **preclinical data** from its recent research of VAL-083 as a potential new treatment for ovarian cancer at the American Association for Cancer Research (AACR) Advances in Ovarian Cancer Research: Exploiting Vulnerabilities Conference being held October 17-20, 2015 in Orlando, FL.

The presentation is entitled, "*A Comparison of the Mechanisms and Cytotoxic Activity of Dianhydrogalactitol (VAL-083) to Cisplatin in Ovarian Tumor Models Harboring Wild-type and Mutant p53"*

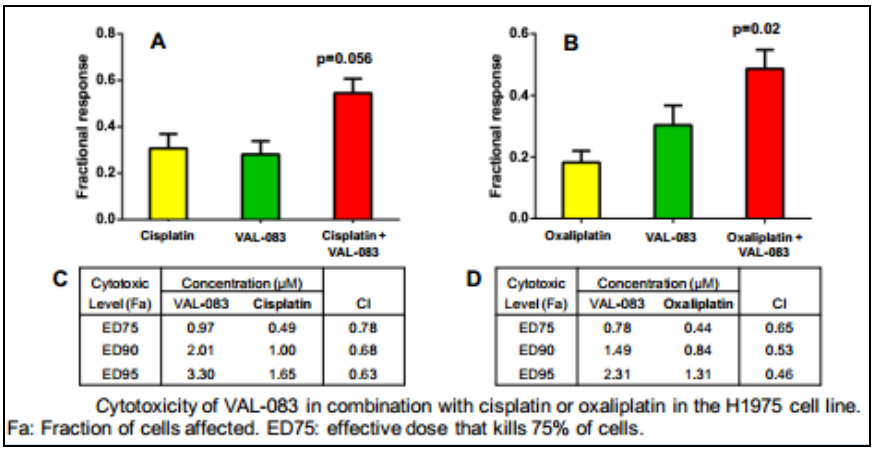
The activity of VAL-083 was examined in five ovarian cancer cell lines: including one cisplatin-sensitive (A2780), and four cisplatin-resistant (2780CP-16, OVCAR-10, Hey and OVCA-433) tumors *in vitro*. The relative tumor-killing effect (IC_{50}) was compared in cisplatin-sensitive versus cisplatin-resistant cell-lines. VAL-083 maintained significantly greater cytotoxic activity in comparison to cisplatin. These results demonstrate a lack of significant cross-resistance between cisplatin and VAL-083, further suggesting distinct modes of action for VAL-083.



Cytotoxicity (A) and resistance factors (B) of cisplatin and VAL-083 in wild-type p53 ovarian cancer cell lines.
Resistance Factor is calculated the ratio of IC_{50} in the resistant cell line to the IC_{50} in A2780.

Data presented also suggested that the cytotoxic a mechanism of VAL-083 that is much less dependent on, or independent of, p53. In cisplatin-resistant (2780CP-16) ovarian cancer cells, only VAL-083 caused significant activation of p53 and p21, and induced greater Ser-15 and Ser-20 phosphorylation of p53, all of which are hallmarks of cytotoxic DNA damage. This further supports the conclusion of distinct modes of action for VAL-083 versus platinum-based chemotherapy and activity against platinum-resistant cancer phenotypes.

The combination of VAL-083 with either cisplatin or oxaliplatin in the human H1975 model demonstrated significant super-additivity ($p \leq 0.05$) and synergy (CI<1). These results suggest non-overlapping mechanism of action between the platinum drugs and VAL-083, and support the potential for synergistic benefit for a combination of VAL-083 and platinum-based therapies in the treatment of cisplatin resistant cancers.



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Cytotoxic Level (Fa)	Concentration (µM) VAL-083	Cisplatin	CI
ED75	0.97	0.49	0.78
ED90	2.01	1.00	0.68
ED95	3.30	1.65	0.63

D

Cytotoxic Level (Fa)	Concentration (µM) VAL-083	Oxaliplatin	CI
ED75	0.78	0.44	0.65
ED90	1.49	0.84	0.53
ED95	2.31	1.31	0.46

Cytotoxicity of VAL-083 in combination with cisplatin or oxaliplatin in the H1975 cell line.
Fa: Fraction of cells affected. ED75: effective dose that kills 75% of cells.

These data have been developed in collaboration with researchers at MD Anderson Cancer Center.

On September 13, 2016, DelMar and its collaborators from the University of Texas MD Anderson Cancer Center presented new data in a research poster entitled "Activity of dianhydrogalactitol (VAL-083) in ovarian tumor models, sensitive or resistant to cisplatin" at the 11th Biennial Ovarian Cancer Research Symposium.

In summary,

- VAL-083 demonstrated cytotoxic activity against all ovarian cancer cell lines tested and is substantially less dependent on wild-type p53 for cytotoxic activity.
- VAL-083 was able to circumvent 70-85% of cisplatin-resistance in an ovarian cancer cell line panel with several known p53 mutations and displays synergy with cisplatin in p53 mutant cell line H1975.

- VAL-083 demonstrated synergy with AstraZeneca's PARP inhibitor Olaparib™ in ovarian cancer cell line A2780.
- The potency of VAL-083 activity was increased when HR was impaired in A2870 cells with BRCA1 knockdown, demonstrating that VAL-083 induced DNA-lesions are repaired via HR.

These data further support the potential of VAL-083 as a new treatment for ovarian cancer.

A New Phase II Trial of VAL-083 for GBM to be Initiated by MD Anderson

On Jan. 13, 2016, DelMar announced that it has entered into a collaboration with MD Anderson Cancer Center to accelerate the clinical development of VAL-083 for the treatment of glioblastoma multiforme (GBM).

As part of the collaboration, MD Anderson will initiate a **new Phase II** clinical study with VAL-083 in patients with GBM at first recurrence/progression, **prior to Avastin**™ (bevacizumab) exposure. Patients eligible for the study will have recurrent GBM characterized by a high expression of MGMT, the DNA repair enzyme implicated in drug-resistance and poor patient outcomes following current front-line chemotherapy. MGMT promoter methylation status will be used as a validated biomarker for enrollment and tumors must exhibit an unmethylated MGMT promoter for patients to be eligible for the trial.

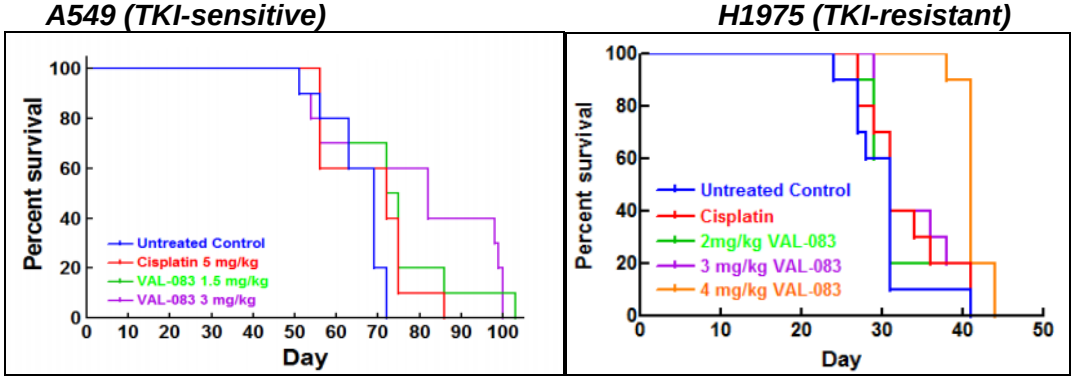
Pipeline will also be Expanded to NSCLC

Preclinical Data Support Development of VAL-083 for NSCLC

Recently, DMPI presented promising preclinical data supporting VAL-083 activity in non-small cell lung cancer at the AACR's New Horizons in Cancer Research Meeting, at the AACR annual meeting and at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.

The data presented at the AACR New Horizons meeting showed that VAL-083 is superior to **cisplatin** in both *in vivo* tumor models that are sensitive and resistant to tyrosine kinase inhibitors (TKI) and has synergistic effect in combination with cisplatin. The data suggests important clinical and market potential of VAL-083 in **NSCLC**.

A549 (TKI-sensitive) ***H1975 (TKI-resistant)***



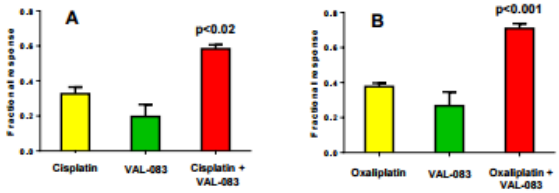
The data presented at the AACR annual meeting demonstrated that VAL-083's mechanism is distinct from platinum-based chemotherapy, the current standard of care for NSCLC. VAL-083 retains its high level of anti-cancer activity in p53 mutated NSCLC cell lines compared to cisplatin or oxaliplatin.

In addition, the combination of VAL-083 with either cisplatin or oxaliplatin demonstrated superadditivity/synergy against NSCLC cell lines, including those resistant to tyrosine kinase inhibitors. These results support the potential benefit of a VAL-083/platinum combination therapy in newly diagnosed NSCLC patients.

Combination of VAL-083 with cisplatin or oxaliplatin in H460, A549 and H1975 NSCLC

The combination of VAL-083 with either cisplatin or oxaliplatin in the human NSCLC models demonstrated significant superadditivity ($p \leq 0.05$) and/or synergism ($CI < 1$) for both combinations. Significantly, this cytotoxic effect of VAL-083 in combination with either platinum drug was observed in both TKI-resistant (H1975 and H460) and TKI-sensitive (A549) NSCLC cells. These results suggest non-overlapping mechanism of action between the platinum drugs and VAL-083, and support the potential for synergistic benefit for a combination of VAL-083 and platinum-based therapies in the treatment of lung cancer.

Human H460 NSCLC cell line

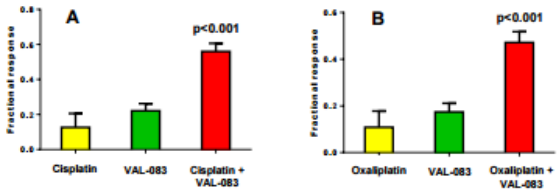


Cytotoxic Level (Fa)	Concentration (μM) VAL-083	Cisplatin	CI
ED75	0.42	0.38	0.92
ED90	0.92	0.85	0.91
ED95	1.58	1.45	0.90

Cytotoxic Level (Fa)	Concentration (μM) VAL-083	Oxaliplatin	CI
ED75	0.29	0.21	0.86
ED90	0.51	0.37	0.82
ED95	0.73	0.54	0.81

Figure 4. The cytotoxic effect of VAL-083 in combination with cisplatin (**A**) or oxaliplatin (**B**) on H460 cells. The table provides CI values for the Fa shown and achieved at indicated drug concentrations. Data, where applicable, are shown as Mean +/- SE, N=4.

Human A549 NSCLC cell line

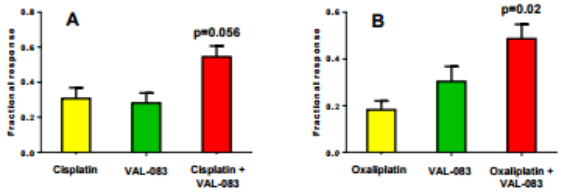


Cytotoxic Level (Fa)	Concentration (μM) VAL-083	Cisplatin	CI
ED75	1.79	0.67	0.87
ED90	3.09	1.16	0.82
ED95	4.48	1.68	0.79

Cytotoxic Level (Fa)	Concentration (μM) VAL-083	Oxaliplatin	CI
ED75	1.55	0.46	0.91
ED90	2.26	0.68	0.78
ED95	2.92	0.88	0.71

Figure 5. The cytotoxic effect of VAL-083 in combination with cisplatin (**A**) or oxaliplatin (**B**) on A549 cells. The table provides CI values for the Fa shown and achieved at indicated drug concentrations. Data, where applicable, are shown as Mean +/- SE, N=7.

Human H1975 NSCLC cell line



Cytotoxic Level (Fa)	Concentration (μM) VAL-083	Cisplatin	CI
ED75	0.97	0.49	0.78
ED90	2.01	1.00	0.68
ED95	3.30	1.65	0.63

Cytotoxic Level (Fa)	Concentration (μM) VAL-083	Oxaliplatin	CI
ED75	0.78	0.44	0.65
ED90	1.49	0.84	0.53
ED95	2.31	1.31	0.46

Figure 6. The cytotoxic effect of VAL-083 in combination with cisplatin (**A**) or oxaliplatin (**B**) on H1975 cells. The table provides CI values for the Fa shown and achieved at indicated drug concentrations. Data, where applicable, are shown as Mean +/- SE, N=4.

These data provide support for the potential of VAL-083 as a viable treatment option for NSCLC patients failing platinum-based therapy.

At 2016 AACR meeting, MD Anderson researchers presented new **in vitro** data from their studies with VAL-083 indicating that:

- VAL-083 induces apoptosis independent of p53 status, and appears to have a distinct mode of action from platinum-based chemotherapies widely used in the treatment of NSCLC and ovarian cancer;
- VAL-083 demonstrated ability to circumvent cisplatin-resistance in all ovarian cell lines tested;
- VAL-083 was active against NSCLC tumors harboring T790M, p53 and/or KRAS mutations, known to confer resistance to currently available therapies; and
- VAL-083 demonstrated super-additivity or synergy in combination with platinum-based chemotherapy.

These results support VAL-083 as a viable treatment option for refractory NSCLC and ovarian cancer patients failing platinum-based therapy as well as the potential benefit of a VAL-083-platinum combination.

Clinical Development Plan for NSCLC Revealed

On Sept 8, DMPI presented the VAL-083 NSCLC clinical development plan in a poster entitled,"Post-Market Clinical Trial of Dianhydrogalactitol in the Treatment of Relapsed or Refractory Non-Small Cell Lung Cancer" at the 16th World Conference on Lung Cancer in Denver, Colorado.

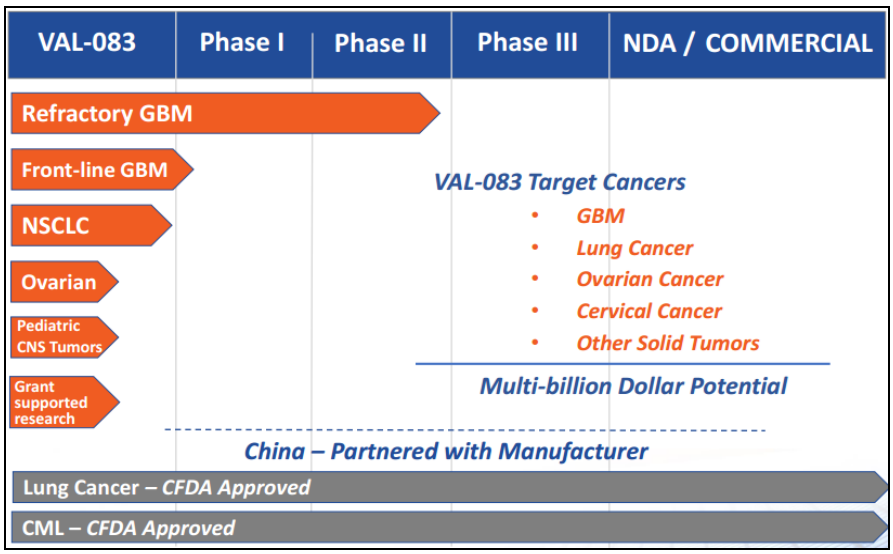
This is an open label post-market **Phase IV** study of VAL-083 in treatment of NSCLC patients who have failed standard platinum doublet therapy. Up to 20 patients will be enrolled into the study. Study patients

will receive VAL-083 intravenous (IV) dose of 40 mg/day for five consecutive days, with 1-2 weeks' rest, for two courses, followed by maintenance therapy 40 mg/day IV for five consecutive days every 28 days. Patients will continue to receive treatment until withdrawal criteria are met or the patient receives up to 12 cycles of therapy, whichever comes first.

The primary endpoint is the assessment of disease control rate, defined as objective response rate, including complete (CR), partial (PR) response rates, and stable disease (SD). Secondary endpoints will include evaluation of progression free survival (PFS) and overall survival (OS). Results will provide guidance to treating physicians under the context of VAL-083's current approval in China and clinical proof-of-concept to support DelMar's global development of VAL-083 as a potential new treatment for NSCLC.

The study will be considered complete when the last patient either experiences disease progression or an intolerable toxicity, or withdraws from the study. The study is anticipated to take approximately **1-2 years.**

VAL-083 is already approved in China for NSCLC. New clinical data will support sales growth in China and achieve royalty revenue to DelMar through sales partnership. The company is positioning VAL-083 for global development in lung cancer.



PROJECTED INCOME STATEMENT

_	Sept	Dec	Mar	June	FY15	Sept	Dec	Mar	June	2016	2017	2018	2019	2020
$ in millions except per share data	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	FY	FYE	FYE	FYE	FYE
Milestone	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Royalty	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.50	$2.00	$2.50	$3.50
YOY Growth	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*	*300.0%*	*25.0%*	*40.0%*
Product Sales	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00	$35.00	$70.00
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*600.0%*	*100.0%*
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$7.00**	**$37.50**	**$73.50**
YOY Growth	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*	*1300.0%*	*435.7%*	*96.0%*
CoGS	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.75	$5.25	$10.50
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$6.25**	**$32.25**	**$63.00**
Gross Margin	-	-	-	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*100.0%*	*89.3%*	*86.0%*	*85.7%*
R&D	$0.67	$0.61	$0.64	$0.63	$2.56	$0.60	$0.79	$0.79	$1.18	$3.36	$7.00	$7.50	$9.00	$12.00
% R&D	-	-	-	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*1400.0%*	*107.1%*	*24.0%*	*16.3%*
SG&A	$0.45	$0.66	$0.50	$0.57	$2.17	$0.47	$0.89	$0.63	$0.86	$2.85	$7.50	$15.00	$18.50	$24.00
% SG&A	-	-	-	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*1500.0%*	*214.3%*	*49.3%*	*32.7%*
Others	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**($1.1)**	**($1.3)**	**($1.1)**	**($1.2)**	**($4.7)**	**($1.1)**	**($1.7)**	**($1.4)**	**($2.0)**	**($6.2)**	**($14.0)**	**($16.3)**	**$4.8**	**$27.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	*12.7%*	*36.7%*
Other Income (Net)	($0.2)	$0.2	($0.5)	$0.4	($0.1)	($0.5)	($1.0)	$0.3	($1.4)	($2.7)	($0.8)	($0.8)	($0.8)	($0.8)
Pre-Tax Income	**($1.3)**	**($1.1)**	**($1.6)**	**($0.7)**	**($4.8)**	**($1.6)**	**($2.6)**	**($1.1)**	**($3.5)**	**($8.9)**	**($14.8)**	**($17.1)**	**$4.0**	**$26.2**
Net Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$5.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*19.1%*
Reported Net Income	**($1.3)**	**($1.1)**	**($1.6)**	**($0.7)**	**($4.8)**	**($1.6)**	**($2.6)**	**($1.1)**	**($3.5)**	**($8.9)**	**($14.8)**	**($17.1)**	**$4.0**	**$21.2**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*9.1*	*9.4*	*9.7*	*9.8*	*9.5*	*10.6*	*11.0*	*11.1*	*11.1*	*10.9*	*13.8*	*15.00*	*16.25*	*17.50*
Reported EPS	**($0.15)**	**($0.11)**	**($0.17)**	**($0.08)**	**($0.50)**	**($0.15)**	**($0.24)**	**($0.10)**	**($0.31)**	**($0.81)**	**($1.08)**	**($1.14)**	**$0.24**	**$1.21**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	$0.00	$0.00	$0.51	$0.00	$0.51	$0.54	$0.97	$0.00	$1.42	$2.93	$0.00	$0.00	$0.00	$1.00
Non GAAP Net Income	**($1.3)**	**($1.1)**	**($1.1)**	**($0.7)**	**($4.3)**	**($1.1)**	**($1.7)**	**($1.1)**	**($2.0)**	**($5.9)**	**($14.8)**	**($17.1)**	**$4.0**	**$22.2**
Non GAAP EPS	**($0.15)**	**($0.11)**	**($0.12)**	**($0.08)**	**($0.45)**	**($0.10)**	**($0.15)**	**($0.10)**	**($0.18)**	**($0.54)**	**($1.08)**	**($1.14)**	**$0.24**	**$1.27**

Source: company filings and Zacks estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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