Zacks Small-Cap Research

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Delmar Pharma (DMPI-OTCQB)

DMPI: Ready to advance VAL-083 to pivotal Phase II/III trial for the treatment of glioblastoma in 1H2015, pipeline will be expanded to include NSCLC– Outperform

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	11/26/2013
Current Price (02/20/15)	$0.73
Twelve- Month Target Price	**$4.50**

OUTLOOK

DMPI is a clinical/commercial stage drug development 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. The company is on track to initiate registration directed trial of VAL-083 for brain cancer 1H 2015. Valuation is attractive now. We maintain an Outperform rating on its shares.

SUMMARY DATA

52-Week High	**$1.54**
52-Week Low	**$0.64**
One-Year Return (%)	**-13.33**
Beta	**0.00**
Average Daily Volume (sh)	**25,992**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$29**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**5.7**
Insider Ownership (%)	**38.5**
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)
2014	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2015	0.00 A	0.00 E	0.00 E	0.00 E	0.00 E
2016					0.50 E
2017					1.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.03 A	-$0.06 A	-$0.05 A	-$0.03 A	-$0.16 A
2015	-$0.04 A	-$0.03 A	-$0.06 E	-$0.06 E	-$0.18 E
2016					-$0.24 E
2017					-$0.26 E

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

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WHAT'S NEW

- **DMPI ready to advance VAL-083 into Phase II/III registrational study for glioblastoma in 1H15;**
- **Pipeline will be expanded to include NSCLC;**
- **Conservative cash burn;**
- **Valuation attractive, and maintain Outperform rating;**

DMPI Ready to Move VAL-083 to Pivotal Trial for GBM

Recently, DelMar management held a conference call outlining its clinical development plan with regard to its lead cancer drug candidate **VAL-083**.

During the conference call, CEO Jeff Bacha reviewed and updated data from the ongoing **Phase I/II**, open label single arm study in patients with recurrent GBM and the company expects to advance VAL-083 to pivotal **Phase II/III** trial for the treatment of refractory GBM in **1H2015**.

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 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. Approximately **30 patients** have been enrolled in the Phase I portion of the study.

Update on Clinical Data

The updated Phase I/II data were presented at the 19th Annual Society for Neuro-Oncology Meeting held November 13-16, 2014 in Miami.

Data to date have demonstrated that VAL-083 is safe and well tolerated at doses up to 40mg/m^2. No drug-related serious adverse events or dose limiting toxicities (DLTs) have been detected and a maximum tolerated dose (MTD) has not been reached at doses up to 40 mg/m^2. DelMar is currently studying a dose of 50mg/m^2 in this clinical trial.

Historical studies sponsored by the NCI achieved promising results in newly diagnosed and recurrent GBM using a dosing regimen of 25 mg/m^2/day for 5 days every five weeks. Historically, dose limiting hematologic toxic effects were noted on white blood cell (WBC) and platelet counts.

The DelMar dosing regimen uses a cycle of treatment on the first three days of every three weeks. The hypothesis is that this regimen along with improvement in management of myelosuppression in the modern era would allow for more aggressive dosing and potentially improved patient outcomes.

DMPI GBM Phase I/II Trial Results to Date:

Successfully & Safely Dosing Higher than NCI in Clinical Trials

Society for Neuro-Oncology Annual Meeting (Nov 2014)

DOSE & STUDY	Single Dose	Acute Regimen (single cycle)		Comparative Dose (@ 35 days)	Dose Density (dose per week)	Status
NCI GBM (Eagan) daily x 5 q 5wks *(cycle = 35 days)*	25 mg/m^2	X 5 d =	125 mg/m^2	125 mg/m^2	25mg/m^2/wk	Historical Regimen ***MYELOSUPPRESSION REPORTED***
DelMar VAL-083 daily x 3 q 3wks *(cycle = 21 days)*	30 mg/m^2	X 3 d =	90 mg/m^2	180 mg/m^2	30mg/m^2/wk	No DLT
	40 mg/m^2		120 mg/m^2	240 mg/m^2	40mg/m^2/wk	No DLT
	50 mg/m^2		150 mg/m^2	300 mg/m^2	50mg/m^2/wk	***Ongoing DLT Observed***
	60 mg/m^2		180 mg/m^2	360 mg/m^2	60mg/m^2/wk	planned

Three patients exhibiting a response (stable disease or partial response) reported improved clinical signs with a maximum response of 28 cycles (84 weeks) prior to discontinuing due to adverse events unrelated to the study.

Cohort 50mg/m^2 has been fully enrolled (3 patients) and first DLT has been observed signaling the trial is nearing end of dose escalation. The company plans to enroll 3 additional patients at 50mg/m^2. If any experience DLT, then 40mg/m^2 will be DLT. If none experience DLT, then trial will advance to 60mg/m^2 dose. If continued strong trend toward DLT is observed, then 50mg/m^2 will be confirmed as DLT.

Our **key takeaways** from the clinical data presentation:

- DelMar has achieved significantly higher doses compared to NCI regimen without encountering dose limiting toxicity;
- Hints of cytotoxicity suggest that VAL-083 is nearing MTD;
- Calculated drug concentrations in tissue suggest VAL-083 is achieving active drug levels at the tumor;

A Registration Directed Phase II Trial and a Phase II/III to Begin in 2015

Based on the positive interim data, DelMar plans to initiate a **registration directed Phase II trial** in **refractory GBM in 1H2015**. Based on historical development of other products in GBM, it's possible that DelMar may be able to obtain FDA approval to commercialize VAL-083 to treat patients who have failed other therapies from an open-label Phase II registration-directed clinical trial, which will save significant costs of a large Phase III clinical trial. It's also possible that the FDA may grant fast-track, accelerated approval and/or priority review status to VAL-083, which will enable DelMar to begin filing for commercial approval during the clinical trial process.

Based on historical precedent with the FDA, the **Phase II registration directed trial** are expected to mirror the Avastin approval study in that indication. Under this scenario, the Phase II trial would be:

- Single-arm; open label design;
- Primary endpoints: overall survival, radiographic response;
- Secondary endpoints: quality of life, safety and tolerability;
- N = 80-100 patients;
- Minimum response rate = 20%;
- Enrollment: Patients with recurrent GBM who have failed or are ineligible for both Temodar® and Avastin® (i.e. the same population as in the current trial);

The recent failure of **Avastin** in the front line treatment of GBM has highlighted the need for new therapies in newly diagnosed patients, particularly those with unmethylated MGMT promoter regions who do not respond to standard of care with **temozolomide**.

DelMar would plan to advance modernized dosing regimen into a **Phase II/III trial** in **newly diagnosed patients** with unmethylated MGMT promoter in parallel with the refractory GBM registration trial (i.e. in 2015). The Company has begun designing this trial with KOLs.

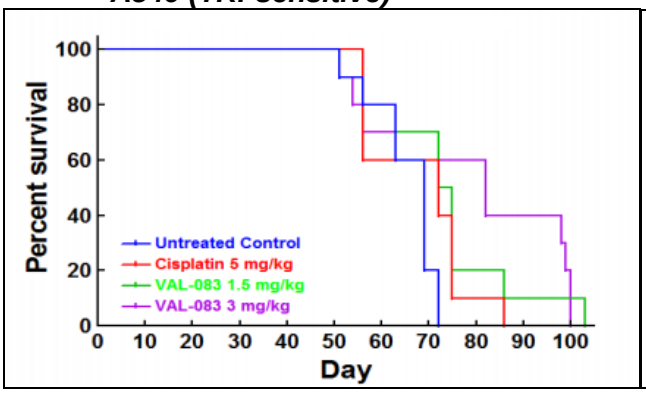
- Randomized groups: Temodar vs. VAL-083;
- Primary endpoints: overall survival;
- Secondary endpoints: PFS6 & radiographic response;
- N = 500 – 600 patients (with interim endpoint at ~10% enrollment);

We estimate data from the registration trial in refractory GBM will be available in mid-2016 and an NDA will be filed in late 2016 or early 2017. The FDA approval will occur in late 2017 or early 2018.

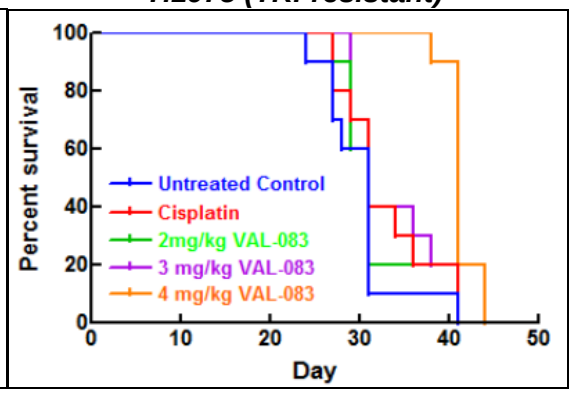
Pipeline Will be Expanded to NSCLC

DMPI presented promising new data supporting VAL-083 activity in non-small cell lung cancer at the AACR's New Horizons in Cancer Research Meeting. The data 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)



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

Conservative Cash Burn

As of December 31, 2014, DMPI held $4.0 million in cash and cash equivalents.

In July, 2014, Del Mar was awarded a non-refundable financial contribution of up to CDN$194,000 from the National Research Council of Canada's Industrial Research Assistance Program (NRC-IRAP). This funding represents the fourth contribution that DelMar has received from NRC-IRAP, bringing the total to CDN$327,000 in financial support to date.

The fund will be used to support continued non-clinical research aimed at providing competitive differentiation for VAL-083 as a new medicine in the treatment of glioblastoma and other cancers, including non-small cell lung cancer.

DelMar received gross proceeds of $2.4 million from the exercise of warrants at $0.65 per warrant that closed on June 6 and an additional $0.5 million in gross proceeds from exercise of these warrants under the tender offer which closed on August 8.

According to management, cash burn rate is less than $1 million/quarter, which is very conservative inour view. Current cash will be sufficient to fund current operations through the end of 2015.

Valuation Very Attractive

We maintain our Outperform rating on DelMar shares and reiterate our 12-month price target of $4.50 per share. Our call is 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 II** trial of VAL-083 for **recurring GBM** and a **Phase II/III** trial for **first line GBM** in 1H15. This will be a significant milestone for the Company which will position the Company in a late stage development.

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 $0.75 per share, which values the Company at about $29 million in market cap based on 39 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 II trial in 1H 2015.

We estimate VAL-083 could be approved by the FDA in calendar 2017 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 $0.06 based on product sales of $35 million. EPS will grow to $0.35 in fiscal 2020 based on total product sales of $70 million.

Based on our financial model and the Company's fundamentals, we have a price target of $4.50 per share for DMPI. We think a P/E ratio of 38x is appropriate for DMPI considering its growth in the next few years. Based on this P/E multiple, we come up with our price target of $4.50 per share using 25% discount for 5 years. Our price target values DMPI at $176 million in market cap, which we think is still conservative compared to its peers.

But risk is 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 bar on both clinical and regulatory hurdle in the US is higher. We remind investors that risks associated with drug development are high.

Another concern we have is that DMPI has a limited pipeline. Right now, VAL-083 is the Company's only clinical-stage candidate. While DelMar has early-stage second-generation analogues from the VAL-083 chemistry platform and has access to additional clinical-stage product candidates through its relationship with Valent Technologies LLC, no other clinical stage candidates currently in the DelMar portfolio. If VAL-083 fails, the value of the Company will be negatively impacted significantly.

PROJECTED INCOME STATEMENT

_	Sept	Dec	Mar	June	FY14	Sept	Dec	Mar	June	FY15	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	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	$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	$1.00	$2.00	$2.50	$3.50
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*100.0%*	*100.0%*	*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	$0.00	$7.50	$35.00	$70.00
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*366.7%*	*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**	**$1.00**	**$9.50**	**$37.50**	**$73.50**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*100.0%*	*850.0%*	*294.7%*	*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	$0.00	$0.75	$3.50	$7.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$1.00**	**$8.75**	**$34.00**	**$66.50**
Gross Margin	-	-	-	-	-	-	-	-			*100.0%*	*100.0%*	*92.1%*	*90.7%*	*90.5%*
R&D	$0.56	$0.57	$0.62	$0.37	$2.12	$0.67	$0.61	$1.00	$1.20	$3.48	$5.00	$7.00	$7.50	$9.00	$12.00
% R&D	-	-	-	-	-	-	-	-	-	-	*1000.0%*	*700.0%*	*78.9%*	*24.0%*	*16.3%*
SG&A	$0.74	$0.64	$0.97	$0.79	$3.13	$0.45	$0.66	$1.05	$1.10	$3.25	$6.00	$7.50	$15.00	$20.00	$25.00
% SG&A	-	-	-	-	-	-	-	-	-	-	*1200.0%*	*750.0%*	*157.9%*	*53.3%*	*34.0%*
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	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**($1.3)**	**($1.2)**	**($1.6)**	**($1.2)**	**($5.3)**	**($1.1)**	**($1.3)**	**($2.1)**	**($2.3)**	**($6.7)**	**($10.5)**	**($13.5)**	**($13.8)**	**$5.0**	**$29.5**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	*13.3%*	*40.1%*
Other Income (Net)	$8.1	$0.3	($1.6)	$0.0	$6.9	($0.2)	$0.2	($0.2)	($0.2)	($0.4)	($0.8)	($0.8)	($0.8)	($0.8)	($0.8)
Pre-Tax Income	**$6.8**	**($0.9)**	**($3.2)**	**($1.1)**	**$1.6**	**($1.3)**	**($1.1)**	**($2.3)**	**($2.5)**	**($7.1)**	**($11.3)**	**($14.3)**	**($14.6)**	**$4.2**	**$28.7**
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	$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%*	*0.0%*	*17.4%*
Reported Net Income	**$6.8**	**($0.9)**	**($3.2)**	**($1.1)**	**$1.6**	**($1.3)**	**($1.1)**	**($2.3)**	**($2.5)**	**($7.1)**	**($11.3)**	**($14.3)**	**($14.6)**	**$4.2**	**$23.7**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*41.7*	*21.7*	*31.7*	*32.5*	*31.9*	*36.5*	*37.8*	*40.0*	*45.0*	*39.8*	*48.0*	*55.0*	*60.00*	*65.00*	*70.00*
Reported EPS	**$0.16**	**($0.04)**	**($0.10)**	**($0.03)**	**$0.05**	**($0.04)**	**($0.03)**	**($0.06)**	**($0.06)**	**($0.18)**	**($0.24)**	**($0.26)**	**($0.24)**	**$0.06**	**$0.34**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	($8.09)	($0.34)	$1.61	$0.00	($6.82)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$1.00
Non GAAP Net Income	**($1.3)**	**($1.2)**	**($1.6)**	**($1.1)**	**($5.2)**	**($1.3)**	**($1.1)**	**($2.3)**	**($2.5)**	**($7.1)**	**($11.3)**	**($14.3)**	**($14.6)**	**$4.2**	**$24.7**
Non GAAP EPS	**($0.03)**	**($0.06)**	**($0.05)**	**($0.03)**	**($0.16)**	**($0.04)**	**($0.03)**	**($0.06)**	**($0.06)**	**($0.18)**	**($0.24)**	**($0.26)**	**($0.24)**	**$0.06**	**$0.35**

Source: company filings and Zacks estimates

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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