Zacks Small-Cap Research

February 28, 2017
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Delmar Pharma (DMPI-NASDAQ)

DMPI: Zacks Company Report

DMPI: A New Phase II initiated, two new clinical trials to be initiated soon, Pipeline will be expanded to include NSCLC and ovarian cancer.

Current Price (02/27/17)	$4.63
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 2017.

Valuation is attractive now.

SUMMARY DATA

52-Week High	**$10.15**
52-Week Low	**$3.00**
One-Year Return (%)	**31.03**
Beta	**0.92**
Average Daily Volume (sh)	**29,029**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$48**
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	0.00 A	0.00 A	0.00 E	0.50 E	0.50 E
2018					2.00 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	-$0.18 A	-$0.15 A	-$0.16 E	-$0.36 E	-$0.88 E
2018					-$1.09 E

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

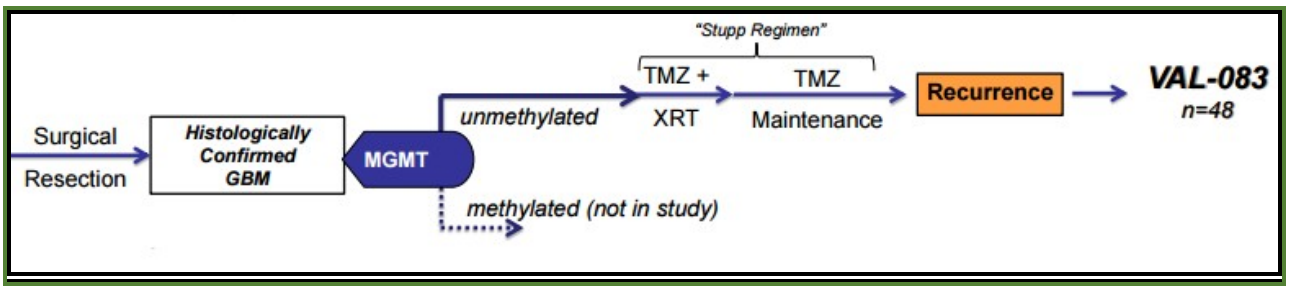
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WHAT'S NEW

DMPI Begins Dosing of Patients in Phase II Trial of VAL-083 for MGMT-unmethylated Recurrent Glioblastoma Multiforme

On Feb. 13, 2017, DMPI announced that it has commenced dosing patients in a **Phase II** clinical study of VAL-083 (dianhydrogalactitol) for MGMT-unmethylated Avastin®(bevacizumab)-naïve recurrent glioblastoma. The study is currently enrollin patients at the University of Texas MD Anderson Cancer Center.

- The single arm, biomarker-driven Phase II trial (NCT02717962) will test safety, tolerability and clinical efficacy of VAL-083 in **48 adult subjects** with MGMT-unmethylated GBM whose tumors have recurred following surgery and standard chemo-radiation with temozolomide.
- Patients will receive 40 mg/m^2 VAL-083 (IV) on days 1, 2, and 3 of a 21-day treatment-cycle, for up to twelve 21-day treatment cycles to determine if treatment with VAL-083 improves overall survival compared to historical controls.
- The lomustine arm of the recently published EORTC26101 trial will serve as the reference control;



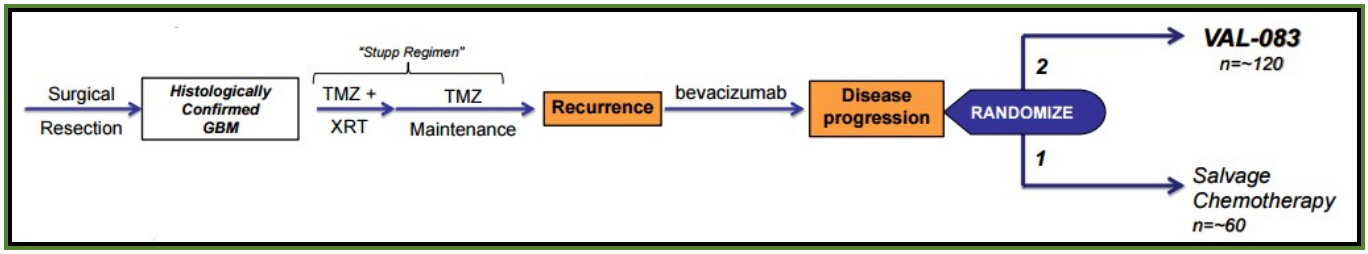
The majority of newly diagnosed GBM patients' tumors are characterized as MGMT-unmethylated, which is directly correlated with resistance to current standard front-line chemoradiation with temozolomide. VAL-083 is independent of MGMT expression and may provide a new therapeutic option for GBM patients whose tumors exhibit features making them resistant or unlikely to respond to currently available therapy.

Two New Clinical Trials with VAL-083 Will be Initiated Soon

A pivotal, randomized multi-center Phase III study measuring survival outcomes compared to a "physicians' choice" control for the treatment of bevacizumab-failed GBM

In late May 2016, DelMar announced the successful completion of an **End of Phase II meeting** with the FDA.

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.

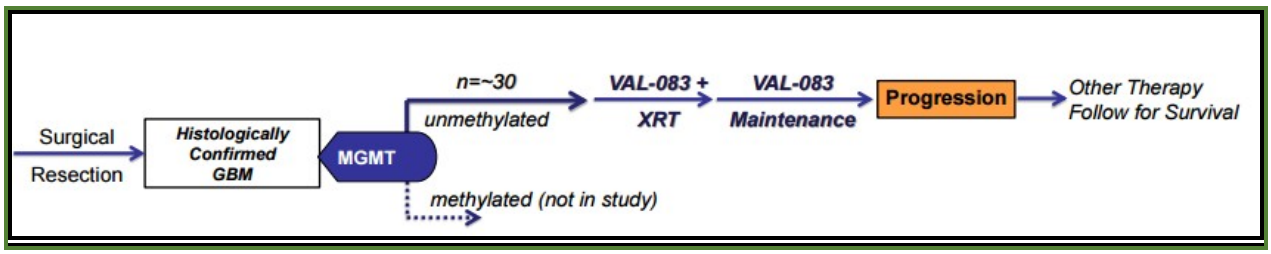


A summary of the proposed clinical trial design includes:

- Approximately 180 patients with histologically confirmed recurrent GBM who have failed both standard chemo-radiation and bevacizumab will be randomized in a 2:1 fashion to receive either VAL-083 or a commonly used salvage chemotherapy;
- The proposed study is projected to be enrolled at approximately 25 centers;
- The proposed primary endpoint is overall survival (OS);
- The proposed statistical design between the two arms of the study is 90% power, and is proposed to include an interim analysis at 50% events for futility with O'Brien-Fleming superiority boundary and non-binding, gamma (-5) futility boundary; and
- The estimated length of the proposed study is less than two years from initiation.

The proposed trial design is subject to feedback from the FDA and other regulatory authorities. DelMar plans to submit the protocol to the FDA **in coming weeks.**

An open label, single-arm, biomarker-driven, Phase II study of VAL-083 and radiation therapy patients in newly diagnosed MGMT-unmethylated GBM



- This single-arm trial will enroll up to 30 newly diagnosed (temozolomide-naïve) GBM patients to examine whether VAL-083 is active in patients with newly diagnosed GBM with MGMT-unmethylated compared to historical control;
- If successful, data from the trial will serve as a lead-in to a global randomized Phase II/III clinical trial of VAL-083 in newly diagnosed GBM patients with MGMT-unmethylated;
- Progression free survival (PFS) will serve as the primary endpoint to assess VAL-083 treatment activity;
- The study will also confirm the safety and tolerability of VAL-083 in combination with a standard-of-care radiation regimen; and
- The study will initially be enrolled at the Sun-Yat Sen University (Guangzhou, China) as a single center trial, but may be expanded to include additional centers.

This trial is being conducted in collaboration with **Guangxi Wuzhou** Pharmaceutical (Group) Co. Under the terms of the company's collaboration agreement Guangxi Wuzhou Pharmaceuticals is providing drug product and funding for the trial. The Sun-Yat Sen University Clinical Review Committee has approved the protocol and DelMar is completing the final remaining regulatory steps required for initiation of the trial and expects to begin enrollment in **1H2017.**

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.

Update on Fiscal Second Quarter Financials

R&D expenses for the fiscal second quarter ended December 31, 2016 were $1.12 million, compared to $0.79 million for the fiscal second quarter ended December 31, 2015.

SG&A expenses for the three month ended December 31, 2016 were $0.57 million, compared to $0.89 million for the same period of 2015.

For the three months ended December 31, 2016 the Company reported a net loss of $1.5 million ($0.13 per share), compared to a net loss of $2.6 million ($0.24 per share) for the three months ended December 31, 2015.

As of December 31, 2016, DelMar held $3.4 million in cash.

In early January 2017, DMPI announced an increase in funding of up to CDN$413,000 from the National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP) to support ongoing research with VAL-083.

This increased funding will support additional research into VAL-083's mechanism of action including validation of molecular targets responsible for the drug's activity against cancer, investigation of combination therapies and pivotal in vivo models in new indications.

We Continue to be Optimistic About DelMar's Prospect and Maintain our Valuation at $16.00 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 in 1H2017**. 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.

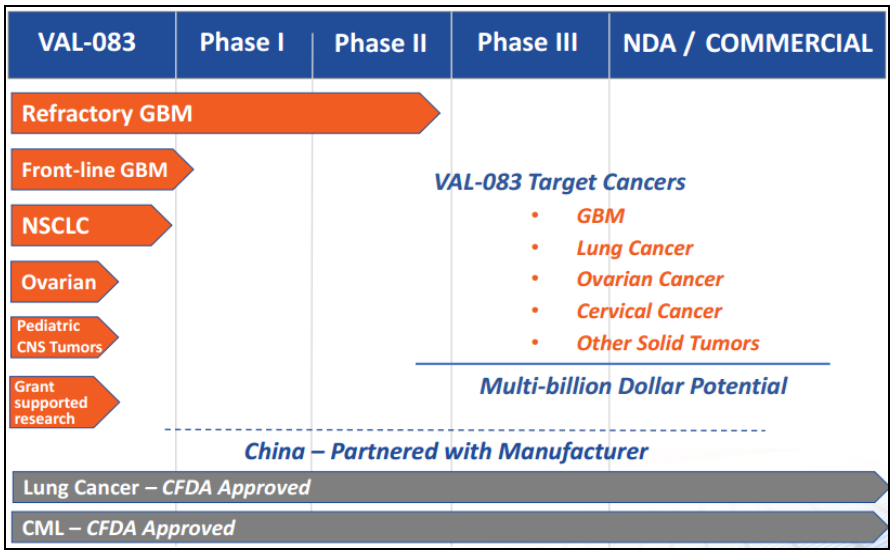
Currently, DMPI shares are trading at around $4.6 per share, which values the Company at about $48 million in market cap based on 11.3 million outstanding shares. This is a deep discount compared to its peers. We noticed that most small biotech companies of development stage are valued from $50 million 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 2017.

We estimate VAL-083 could be approved by the FDA in 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 $0.15 based on product sales of $35 million. EPS will grow to $1.11 in fiscal 2020 based on total product sales of $75 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 28% discount for 3 years. Our price target values DMPI at $180 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.



PROJECTED INCOME STATEMENT

	FY15	Sept	Dec	Mar	June	2016	Sept	Dec	Mar	June	2017	2018	2019	2020
$ in millions except per share data	FY	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	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	$0.50	$0.50	$2.00	$2.50	$3.50
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*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	$0.00	$35.00	$75.00
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*	*114.3%*
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$0.50**	**$2.00**	**$37.50**	**$78.50**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*300.0%*	*1775.0%*	*109.3%*
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	$5.25	$11.25
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$0.50**	**$2.00**	**$32.25**	**$67.25**
Gross Margin	-	-	-	-	-	-	-	-	-	-	*100.0%*	*100.0%*	*86.0%*	*85.7%*
R&D	$2.56	$0.60	$0.79	$0.79	$1.18	$3.36	$0.73	$1.12	$1.30	$4.50	$7.65	$7.50	$9.00	$12.00
% R&D	-	-	-	-	-	-	-	-	-	-	*1530.7%*	*375.0%*	*24.0%*	*15.3%*
SG&A	$2.17	$0.47	$0.89	$0.63	$0.86	$2.85	$1.32	$0.57	$0.75	$1.00	$3.64	$10.00	$20.00	$30.00
% SG&A	-	-	-	-	*#DIV/0!*	*#DIV/0!*	-	-	-	-	*727.6%*	*500.0%*	*53.3%*	*38.2%*
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	**($4.7)**	**($1.1)**	**($1.7)**	**($1.4)**	**($2.0)**	**($6.2)**	**($2.0)**	**($1.7)**	**($2.1)**	**($5.0)**	**($10.8)**	**($15.5)**	**$3.3**	**$25.3**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	*8.7%*	*32.2%*
Other Income (Net)	($0.1)	($0.5)	($1.0)	$0.3	($1.4)	($2.7)	($0.5)	$0.2	$0.0	$0.0	($0.3)	($0.8)	($0.8)	($0.8)
Pre-Tax Income	**($4.8)**	**($1.6)**	**($2.6)**	**($1.1)**	**($3.5)**	**($8.9)**	**($2.6)**	**($1.5)**	**($2.1)**	**($5.0)**	**($11.1)**	**($16.3)**	**$2.5**	**$24.5**
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%*	*20.4%*
Reported Net Income	**($4.8)**	**($1.6)**	**($2.6)**	**($1.1)**	**($3.5)**	**($8.9)**	**($2.6)**	**($1.5)**	**($2.1)**	**($5.0)**	**($11.1)**	**($16.3)**	**$2.5**	**$19.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*9.5*	*10.6*	*11.0*	*11.1*	*11.1*	*10.9*	*11.3*	*11.4*	*12.5*	*14.0*	*12.3*	*15.00*	*16.25*	*17.50*
Reported EPS	**($0.50)**	**($0.15)**	**($0.24)**	**($0.10)**	**($0.31)**	**($0.81)**	**($0.23)**	**($0.13)**	**($0.16)**	**($0.36)**	**($0.90)**	**($1.09)**	**$0.15**	**$1.11**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	$0.51	$0.54	$0.97	$0.00	$1.42	$2.93	$0.55	($0.21)	$0.00	$0.00	$0.34	$0.00	$0.00	$0.00
Non GAAP Net Income	**($4.3)**	**($1.1)**	**($1.7)**	**($1.1)**	**($2.0)**	**($5.9)**	**($2.0)**	**($1.7)**	**($2.1)**	**($5.0)**	**($10.8)**	**($16.3)**	**$2.5**	**$19.5**
Non GAAP EPS	**($0.45)**	**($0.10)**	**($0.15)**	**($0.10)**	**($0.18)**	**($0.54)**	**($0.18)**	**($0.15)**	**($0.16)**	**($0.36)**	**($0.88)**	**($1.09)**	**$0.15**	**$1.11**

Source: company filings and Zacks estimates

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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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