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111 North Canal Street, Chicago, IL 60606

# **Delmar Pharma**

(DMPI-OTCQB)

DMPI: Clinical/commercial stage biopharmaceutical company with strong balance sheet, but pipeline is weak – initiating with Neutral

Current Recommendation	Neutral
Prior Recommendation	N/A
Date of Last Change	06/20/2013
Current Price (07/01/13)	\$2.10
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. We are also comfortable with the Company's balance sheet which will last through 1Q2015.

Although price could double in the next 12 months, risk is also high at this time due to the early stage development of VAL-083. Although VAL-083 is a platform, it is the only clinical stage candidate and no other candidates are close to human clinical trials.

# **SUMMARY DATA**

52-Week High 52-Week Low One-Year Return (%) Beta Average Daily Volume (sh)	\$2.20 \$2.00 N/A N/A 11,000	N/A N/A Med-Drugs N/A					
Shares Outstanding (mil) Market Capitalization (\$mil) Short Interest Ratio (days) Institutional Ownership (%) Insider Ownership (%)	31 \$66 N/A 5.7 38.5	ZACK Reven (in million		Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec) 0.00 A
Annual Cash Dividend Dividend Yield (%)	\$0.00 0.00	2013 2014 2015	0.00 A	0.00 E	0.00 E	0.00 E	0.00 E 0.50 E 1.00 E
5-Yr. Historical Growth Rates Sales (%) Earnings Per Share (%) Dividend (%)	N/A N/A N/A	(EPS is	ngs per Sh operating earn Q1 (Mar)		n recurring iter <b>Q3</b> (Sep)	ms) <b>Q4</b> (Dec)	Year (Dec)
P/E using TTM EPS P/E using 2013 Estimate P/E using 2014 Estimate	N/A N/A N/A	2012 2013 2014 2015	-\$0.06 A	-\$0.06 E	-\$0.06 E	-\$0.06 E	-\$0.18 A -\$0.25 E -\$0.21 E -\$0.23 E
Zacks Rank	N/A	Zacks	Projected E	PS Growth	Rate - Next	5 Years %	N/A

#### **KEY POINTS**

- We are initiating coverage of DelMar Pharma (DMPI) with a Neutral rating. Our 12-month price target is \$4.50 per share.
- ➤ DelMar is a clinical/commercial stage biopharmaceutical company focused on the development and commercialization of cancer drugs. The development strategy of the Company is to rapidly develop and commercialize well-validated anti-cancer therapies in high-impact orphan cancer indications where patients have failed modern therapy.
- Based on this development strategy, DMPI has identified and is developing VAL-083 for the treatment of glioblastoma multiforme (GBM). VAL-083 is the Company's lead drug candidate currently in Phase I/II clinical trial for recurring GBM. Both FDA and EMEA granted orphan drug status for VAL-083 for the treatment of glioma, including GBM.
- VAL-083 is a well validated drug candidate with efficacy and safety profile established by NCI and published literature. Historical data have shown that VAL-083 has been efficacious and safe for the treatment of a variety of cancer indications including brain cancer, leukemia, lung cancer, and ovarian cancer.
- VAL-083 has been approved in China for the treatment of chronic myelogenous leukemia (**CML**) and **lung cancer**. DelMar has a strategic collaboration with Guangxi Wuzhou Pharma of China for the development of VAL-083 for other indications. The Company has acquired exclusive commercial rights to VAL-083 in China and is seeking a partner with strong oncology sales force in China for the commercialization of VAL-083, which would generate near term royalty revenue for the Company as early as in late 2013.
- DelMar is developing VAL-083 in the US for the treatment of refractory GBM. Currently, VAL-083 is in a Phase I/II clinical trial. The Company has reported positive interim results from the ongoing Phase I/II trial. Based on the efficacy data and safety profile, the Company plans to initiate a registration directed **Phase II** trial for recurring GBM and **Phase II/III** trials for newly diagnosed GBM following successful completion of the current dose modernization clinical study.
- Market potential is huge for VAL-083. The unique mechanism of action of VAL-083 differentiates it from other alkylating agents, such as Temodar, current market leader for the treatment of GBM. VAL-083 has the potential to overcome the resistance issue of Temodar or other alkylating agents, which will help the drug to capture a significant market share when approved. VAL-083 has the potential of being a blockbuster for the Company.
- DelMar has a relatively strong balance sheet. As of March 31, 2013, the Company had \$7.5 million in cash, which could last though the first quarter of 2015. Current cash will accelerate the development of VAL-083.
- Although our price target represents an over 100% return, we remind investors that risk is also high at this point. Both clinical and regulatory hurdles are high for VAL-083 since the drug candidate is still in early stage of development. Limited pipeline is also concern. Although VAL-083 is a platform, it is the Company's only clinical stage candidate. If it fails, the impact on the value of the Company will be significant.

#### **OVERVIEW**

DelMar Pharmaceuticals, Inc. (DMPI) is a clinical and commercial stage drug development company with a focus on the **treatment of cancer**.

DelMar's lead product candidate is **VAL-083**, which represents a "first in class" small-molecule chemotherapeutic. The molecular structure of VAL-083 is not an analog or derivative of other small molecule chemotherapeutics approved for the treatment of cancer. VAL-083 has been assessed in multiple clinical studies sponsored by the National Cancer Institute (NCI) in the United States as a treatment against various cancers including lung, brain, cervical, ovarian tumors and leukemia. Published pre-clinical and clinical data suggest that VAL-083 may be active against a range of tumor types. VAL-083 is approved as a cancer chemotherapeutic **in China** for the treatment of chronic myelogenous leukemia (**CML**) and **lung cancer**, but has not been approved for any indications outside of China.

VAL-083 was originally discovered in the 1960's. DelMar has a broad portfolio of new patent applications to protect its intellectual property. Patent applications claim compositions and methods related to the use of VAL-083, related and next generation compounds as well as methods of synthesis and quality controls for the manufacturing process of VAL-083.

In October 2011, DelMar initiated **Phase I/II** clinical trials with VAL-083 as a potential new treatment for glioblastoma multiforme (**GBM**), the most common and aggressive form of brain cancer. The Phase I/II trial is currently recruiting patients at two clinical sites in the US.

Data from the Phase I/II trial support the safety of VAL-083 and activity against recurrent GBM. VAL-083 maintains activity in tumors resistant to the current front-line GBM therapy, Temodar ® and has demonstrated benefit in patients who have failed second line therapy, Avastin ®.

In addition to clinical development activities in the United States, DelMar has obtained exclusive commercial rights to VAL-083 **in China**. DMPI plans to seek marketing partnerships in China in order to generate royalty revenue while the Company seeks global approval in new indications.

DelMar Pharmaceuticals, Inc. is the parent company of Del Mar Pharmaceuticals (BC) Ltd., a British Columbia, Canada Corporation incorporated in April, 2010, In January 2013, Del Mar (BC) completed a reverse acquisition with Berry Only Inc., a Nevada corporation formed on June 24, 2009. Prior to the reverse acquisition, Berry did not have any significant assets or operations.

DMPI's executive offices are located in Vancouver, British Columbia, Canada. Its clinical operations are managed at Menlo Park, California.

### **INVESTMENT THESIS**

#### The ChemState Bioinformatics Technology

DelMar's drug discovery research focuses on identifying well-validated clinical and commercial-stage compounds and establishing a scientific rationale for development in **modern orphan drug indications**. Through its relationship with **Valent Technologies**, **LLC**, a company owned by Delmar's chief scientific officer Dr. Dennis Brown, the Company is able to utilize Valent's proprietary **ChemState**™ **bioinformatics** tools, which are used to screen and identify potential candidates.

Promising candidates are further researched through the Company's network of expert consultants and contract research organizations. This approach allows DelMar to rapidly identify and advance potential drug candidates without significant investment in "wet lab" infrastructure. Based on this strategy, DelMar

acquired initial **VAL-083** intellectual property and prototype drug product from Valent and have identified multiple additional drug candidates that the Company may have the opportunity to license or acquire in the future to expand the DelMar Pharma drug development pipeline.

# GBM: First Target Market for VAL-083

**VAL-083** represents a "first-in-class" small-molecule chemotherapeutic, which means that the molecular structure of VAL-083 is not an analogue or derivative of other small molecule chemotherapeutics approved for the treatment of cancer.

VAL-083 has been assessed in multiple NCI-sponsored clinical studies in various cancers including lung, brain, cervical, ovarian tumors and leukemia. The results for brain cancer were most compelling. VAL-083 has been assessed as chemotherapy in the treatment of newly diagnosed and recurrent brain tumors. 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% - 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 vs. radiation alone.

**Temozolomide (Temodar, TMZ)** is a front-line therapy for the treatment of GBM, however, it is often ineffective due to drug inactivation by O<sup>6</sup>-methylguanine-DNA methyltransferase (**MGMT**).

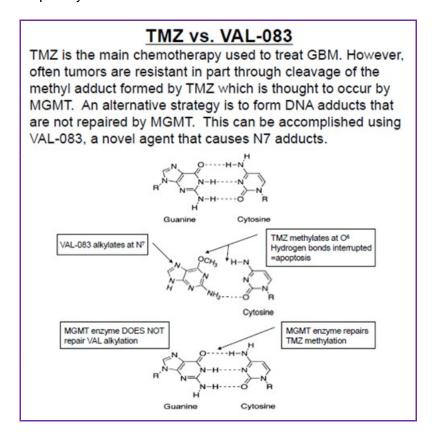
The mechanism of action of VAL-083 is understood to be a **bi-functional alkylating agent**. Alkylating agents are a commonly used class of chemotherapy drugs. They work by binding to DNA and interfering with normal DNA replication processes within the cancer cell, which prevents the cell from making the proteins needed to grow and survive. After exposure to alkylating agents, the cancer cell becomes dysfunctional and dies. There are a number of alkylating agents on the market that are used by physicians to treat different types of cancer.

Based on published research, the functional groups associated with the mechanism of action of VAL-083 are understood to be **functionally different** from commonly used alkylating agents, including **Temodar.** VAL-083 has previously demonstrated activity in cell-lines that are resistant to other types of chemotherapy. No evidence of cross-resistance has been reported in published clinical studies. Based

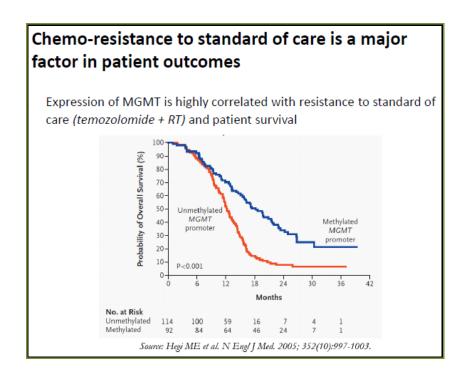
on the presumed alkylating functionality of VAL-083, published literature suggests that DNA repair mechanisms associated with the leading brain cancer therapies, including **Temodar** and **nitrosourea** resistance may not confer resistance to VAL-083. Therefore, VAL-083 may be effective in treating tumors that have failed or become resistant to other chemotherapies.

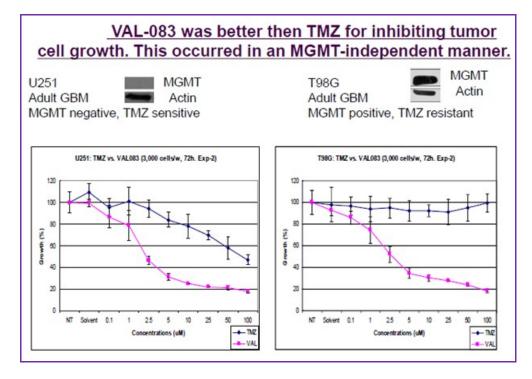
VAL-083 is a novel alkylating agent that creates N<sup>7</sup> cross-links on DNA. The ultimate effect of VAL-083 is to inhibit DNA replication, which will consequently result in cell apoptosis. The alkylation site of VAL-083 is different from those led by other alkylating chemotherapeutic agents, such as temozolomide (TMZ), which creates O<sup>6</sup> methylation on DNA.

TMZ causes a DNA lesion by creating O<sup>6</sup> methylation on DNA. The drug, however, often becomes ineffective due to DNA repair by MGMT in tumor cells.



DelMar has presented new research at peer-reviewed scientific meetings demonstrating that VAL-083 is active in some patients, patient-derived tumor cell lines and cancer stem cells that are resistant to other chemotherapies. Of particular importance is resistance to Temodar ® due to activity of the repair enzyme known as **MGMT**, which results in resistance to front-line therapy in many GBM patients. At AACR in 2012, DelMar presented data demonstrating that VAL-083 is active independent of MGMT resistance in laboratory studies.





VAL-083 readily crosses the blood brain barrier where it maintains a long half-life in comparison to the plasma. Published preclinical and clinical research demonstrates that VAL-083 is selective for brain tumor tissue.

VAL-083 has been granted **Orphan Drug Status** by both the FDA and European Medicines Agency (EMEA) for the treatment of glioma. As an orphan drug for glioma, VAL-083 will enjoy market exclusivity for seven years in the US and ten years in the EU following market approval.

# Historical Pre-Clinical and Clinical Data of VAL-083 for GBM

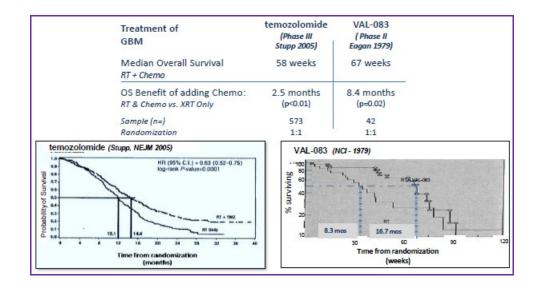
VAL-083 was originally discovered in the 1960's.

**Previous preclinical studies** showed that VAL-083 had cytotoxic activity in a wide range of cell lines, including sarcomas, melanomas, GBM, and lung cancer. VAL-083 was also found active in cyclophosphamide, nitrosourea (BCNU) and phenylanine mustard resistance cell lines. No evidence of cross-resistance has been reported in published clinical studies.

VAL-083 also inhibited the growth of cancer stem cells by 80-100% in neurosphere self-renewal assays. Conversely, there was minimal effect on normal human neural stem cells. VAL-083 has better *in vitro* efficacy than TMZ against brain tumor cells, can overcome resistance associated with MGMT, and targets brain tumor CSCs demonstrating that it has the potential to surpass the standard-of-care.

VAL-083 has been assessed in multiple **NCI-sponsored clinical studies** in various cancers including lung, brain, cervical, ovarian tumors and leukemia. However, further research was not pursued in the United States due to an increased focus by the NCI on targeted therapies during the era.

Among the clinical studies conducted by the NCI, results for **glioblastoma** are of particular interest, because those results were compelling compared to Temodar, current standard of care. Overall, VAL-083 has demonstrated objective response rates of 44% and a median survival of up to 67 weeks in glioblastoma clinical studies and has proven to be synergistic with radiation and other chemotherapies.



In separate historical clinical trials, **combination** of VAL-083 and radiation therapy showed a median survival benefit comparable or superior to that of Temodar plus radiation. Other chemotherapeutics, such as Lomustine (CCNU), Carmustine (BCNU) and Nimustine (ACNU), are less frequently used for the treatment of glioblastoma due to no apparent survival benefits. Lomustine is an akylating nitrosourea compound, and Carmustine is a mustard gas-related  $\beta$ -chloro-nitrosourea agent. Nimustine is also a nitrosourea alkylating agent. In 2009, Roche's Avastin was approved by the FDA for the treatment of recurring GBM based on its 20% response rate. Avastin showed no survival benefit in recurrent GBM. Data presented at ASCO 2013 confirmed that Avastin therapy in newly diagnosed GBM patients demonstrated no survival benefit in the front-line setting.

Chemotherapy	Comparative II	Radiation +	Median Survival Benefit
.,	Radiation	Chemotherapy	vs. XRT
Temodar™	12.1 months	2.5 months	
VAL-083	8.3 months	8.0 months	
Reported Radiation + Ch	GBM		
Carmustine™ (BCNU)	40-50		
Lormustine™ (CCNU)	52 w		
Nimustine™ (ACNU)	35 w		
Avastin™	No reported be		

VAL-083 also showed a favorable safety profile. The main dose-limiting toxicity related to the administration of VAL-083 in previous NCI-sponsored clinical studies was **myelosuppression**. Bone marrow suppression is a common side effect of chemotherapy. There is no evidence of lung, liver or kidney toxicity even with prolonged treatment by VAL-083. Commercial data from the Chinese market where the drug has been approved for more than 15 years supports the safety findings of the NCI studies.

Please remember the dose-limiting toxicity of VAL-083 was established prior to the development of medicines now available to manage myelosuppression. Various types of medications and other forms of therapy are now available for management of myelosuppressive side effects. This offers the potential of increasing the dose of VAL-083 in the modern patient population thereby providing a potential opportunity to improve the drug's already established efficacy profile.

Toxicity Comparison										
	Temodar	BCNU	VAL-083							
Severe toxicity reported (>2%)	Hematologic*, nausea, vomiting, fatigue, asthenia, neuropathy	Hematologic*, pulmonary, nausea, vomiting, 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										

# Current Phase I/II Clinical Trial of VAL-083 for GBM

Based on historical data and the Company's own research, DelMar initiated a **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.

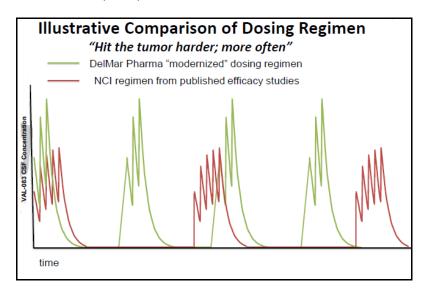
The primary outcome measures in the dose-modernization portion of the clinical trial will be the determination of maximum tolerated dose (MTD). The determination of MTD will be based on analysis of tolerance data from the first cycle of therapy in each dose group.

**Secondary outcome measures** include tumor response in patients with recurrent malignant glioma or progressive secondary brain tumor and pharmacokinetics. Response to therapy and disease progression will be evaluated by magnetic resonance imaging (MRI) prior to each treatment cycle.

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 (or other selected optimum dosing regimen) in a registration directed **Phase II** clinical trial. Up to 30 patients will be enrolled in the Phase I study.

DelMar also changed the dosing regimen with VAL-083 for its clinical trials. The modernized dosing regimen optimizes VAL-083's pharmacokinetics.

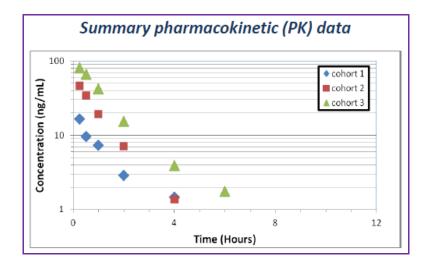
The NCI regimen is 25 mg/m² for 5 days every 5-6 weeks. Del Mar Pharma modernized the regimen for the goal to increase individual doses while reducing the number of days per treatment from 5 to 3 and the time interval between treatments from 5-6 weeks to 3 weeks. At planned doses, DelMar's modified regimen leads to more frequent and higher VAL-083 peak concentration in the CSF and thus higher drug intensity and possibly better efficacy. The intensity will be determined in the ongoing Phase I/II study when the maximum tolerated dose (MTD) is found.



In April 2012, the Company presented preliminary data of the Phase I/II trial at the American Association of Cancer Research (AACR) annual meeting. Following are the key findings:

- VAL-083 is well tolerated to date with no drug-related SAEs;
- Maximum tolerated dose has not been reached after completion of cohort 1 to 3. Dose escalation is in progress;

- There is one partial response, maintained over 15 cycles;
- 33.3% (3/9) of patients having failed prior therapy show stable disease or tumor regression in response to VAL-083 treatment;
- The PK analysis shows dose-dependent increase in exposure with a short 1-2 h half-life and a Cmax of <100 ng/mL;



On June 1, 2013 at the American Society of Clinical Oncology (ASCO) Annual Meeting, DelMar presented additional clinical data from the ongoing Phase I/II clinical trial with VAL-083. Three cohorts of patients have been enrolled so far, testing VAL-083 at 1.5mg/m<sup>2</sup>; 3.0mg/m<sup>2</sup> and 5.0mg/m<sup>2</sup>.

Highlights of the ASCO data presentation include:

- VAL-083 therapy is well tolerated in glioblastoma multiforme (GBM) and secondary progressive brain tumor patients with no drug-related serious adverse events at doses studied to date.
- At doses in cohorts 1-3, 25% (2/8) of GBM patients and 17% (1/6) of secondary-progressive brain cancer patients showed stable disease or tumor regression in response to VAL-083 treatment at the doses tested to date. These patients had failed prior therapy. The doses tested in these cohorts were well below those used in historical clinical studies.
- Cohort 3 was expanded to gather additional data on central nervous system (CNS) metastatic patients at the 5mg/m² dose level.
- Maximum tolerated dose (MTD) has not been reached after completion of cohort three. Continued dose escalation is planned.
- There is one patient response, maintained over 15 cycles;
- Pharmacokinetic analysis shows dose-dependent increase in plasma exposure following doses of VAL-083.

Tumor Type	n	Prior Therapy	DLT	SAE	Tumor Response
GBM	8	Surgery/XRT/TMZ/ BEV	None	None (n=6) Not related to study drug (n=2)*	Overall = 25% PR (1); SD (1)
CNS met	6**	Standard of care***	None	None (n=5) Not related to study drug (n=1)	Overall = 17% SD (1)

As part of the ASCO presentation, the Company also announced plans to split the protocol into two separate studies: one focusing solely on **refractory glioblastoma** and the other focusing on **metastatic brain cancers**. Due to prior chemotherapy and radiation therapy, patients with secondary brain tumors are likely more prone to myelosuppression and may have a different MTD than patients with GBM. The strategy of splitting the trial into two separate studies will enable the Company to focus on accelerating the development of VAL-083 as a potential new treatment for glioblastoma while appropriately exploring the potential of the drug to treat patients with solid tumors that have spread to the brain. Cancers known to frequently metastasize to the brain where historical data from the National Cancer Institute supports the anti-tumor activity of VAL-083 include lung, breast and melanoma.

The Phase I portion of the trial will be completed by the end of 2013. The Company anticipates presenting additional data at upcoming scientific and financial meetings during 2013.

# Future Development Plan for VAL-083

DelMar is seeking to complete the dose-escalation portion of the Phase I/II study in advance of the Society for NeuroOncology meeting this year (Nov 2013 in SF), which will position the Company to advance modernized dosing regimen into a **registration directed Phase II trial** in **refractory GBM** in early 2014.

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: PFS6 & Radiographic response
- Secondary endpoints: overall survival;
- 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);

In the front line, DelMar anticipates a Phase II/III design in **newly diagnosed GBM** patients with unmethylated MGMT, which would leverage an existing companion diagnostic to identify patients with high-expression of MGMT who are unlikely to respond to Temodar® therapy.

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 early 2014). 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);

# Huge Market Potential for VAL-083

**Glioblastoma multiforme** (GBM), also called glioblastoma, is the most common and most aggressive type of primary brain tumor and accounts for approximately 50% to 60% of all primary brain tumors.

According to National Cancer Institute (NCI) data, the peak incidence occurs between the ages of 45 and 70 years. In the United States, the age-adjusted brain tumor incidence rate was 6.5 per 100,000 men and women per year. The age-adjusted death rate was 4.3 per 100,000 men and women per year. It is estimated that 23,130 men and women (12,770 men and 10,360 women) will be diagnosed with and 14,080 men and women will die of **cancer of the brain and other nervous system** in 2013 in the US. Worldwide, approximately 238,000 new cases of brain and other CNS tumors were diagnosed in the year 2008, with an estimated mortality of 128,000.

Glioblastomas are among the most aggressively malignant human neoplasms. The median survival time from the time of diagnosis without any treatment is usually less than 1 year. Despite multimodality treatment consisting of open craniotomy with surgical resection of as much of the tumor as possible, followed by radiotherapy, chemoradiotherapy, Avastin, and symptomatic care with corticosteroids, median survival is about 14 months. The overall 5-year survival is less than 10% with the standard of care today. Increasing age (> 60 years of age) carries a worse prognostic risk. Death is usually due to cerebral edema or increased intracranial pressure.

Glioblastoma remains one of the most difficult tumors to treat due to several complicating factors:

- The tumor cells are very resistant to conventional therapies;
- The brain is susceptible to damage due to conventional therapy;
- The brain has a very limited capacity to repair itself;
- Many drugs cannot cross the blood-brain barrier to act on the tumor;
- Resistance develops over time for some drugs including Temodar;
- Many drugs do not target cancer stem cells (CSC) which are responsible for relapse of glioblastoma;

**Surgery** is the first stage of treatment of glioblastoma. It is used to take a section for a pathological diagnosis, to relieve some of the symptoms of a large mass pressing against the brain, to remove the tumor mass prior to treatment with radiotherapy and chemotherapy, and to attempt to prolong survival.

After surgery, **radiotherapy** in combination with Chemotherapy is the mainstay of treatment for glioblastoma. A pivotal clinical trial carried out in the early 1970s showed that GBM patients who received radiation had a median survival more than double those who did not receive radiation therapy. Subsequent clinical research has attempted to build on the backbone of surgery followed by radiation. A combination of radiotherapy and chemotherapy has generally exhibited a benefit in comparison to radiotherapy alone.

Chemotherapy (including targeted therapy) is a third method to treat glioblastoma. Although the addition of chemotherapy to radiation improves survival in many cancer types, this is not the case for most cases of glioblastoma. Most studies showed little or no benefit from the addition of chemotherapy to radiation for glioblastoma patients. However, currently, two chemotherapeutic agents (including one targeted therapy) approved by the FDA are frequently used for the treatment of glioblastoma in combination with radiation therapy. They are **Temodar** (temozolomide) from Merck/Schering Plough for newly diagnosed GBM and **Avastin** from Roche for recurred GBM. Temodar in combination with radiotherapy demonstrated a survival benefit vs. radiotherapy alone while Avastin following temodar failure demonstrated an ability to slow tumor progression in approximately 1 in 5 patients, although there was no overall survival benefit.

A large clinical trial of 573 newly diagnosed GBM patients randomized to standard radiation versus radiation plus temozolomide chemotherapy showed that the group receiving temozolomide survived a median of 14.6 months as opposed to 12.1 months for the group receiving radiation alone. This treatment regime is currently considered standard of care for glioblastoma and has a 26% survival at two years.

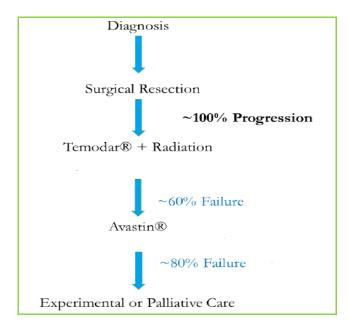
Temozolomide is a front-line therapy for the treatment of GBM, however, it is often ineffective due to drug inactivation by O<sup>6</sup>-methylguanine-DNA methyltransferase **(MGMT)**.

The US FDA recently approved **Avastin** (bevacizumab) to treat patients with **recurred glioblastoma** (but not newly diagnosed GBM) after standard therapy based on the results of 2 studies that showed Avastin reduced tumor size in some glioblastoma patients. In the first study, the efficacy of Avastin was demonstrated by an objective response rate of 25.9%. Median duration of response was 4.2 months. In the second study, the efficacy of Avastin was supported by an objective response rate of 19.6%. Median duration of response was 3.9 months.

Other less frequently used chemotherapeutics for the treatment of glioblastoma include Bristol Myers Squibb's **Carmustine** injection, and CeeNu capsules (**Lomustine**), and Eisai's **Carmustine wafer**.

	Median Survival		
Chemotherapy	Radiation alone	Radiation + Chemo	Median Survival Benefit vs XRT
Temodar	12.1 months	14.6 months (56 weeks)	2.5 months
Avastin		N/A	N/A
Lomustine		52 weeks	N/A
Carmustine		40-50 weeks	N/A
Semustine		35 weeks	N/A

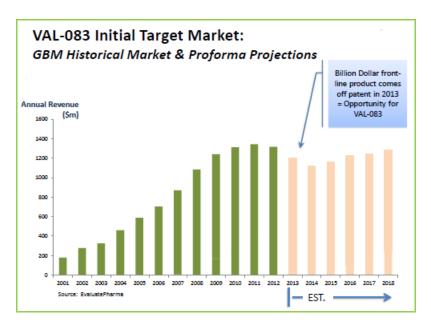
Temodar in combination with radiation is the **front-line therapy** for GBM following surgery. However, approximately 60% of GBM patients treated with Temodar experience tumor progression within one year. As a second line treatment of GBM in patients failing Temodar, Avastin only demonstrated 20%-26% response rate in clinical studies. Therefore, approximately 48% of patients who are diagnosed with GBM will fail both front-line therapy and Avastin.



Recently at ASCO 2013, Roche reported that **Avastin** failed to prolong survival when added to chemoradiation therapy for **newly diagnosed glioblastoma**. Those who received Avastin in the late-stage study of 637 previously untreated patients also experienced more side effects, such as low platelet counts, blood clots and elevated blood pressure.

Clearly, there is an unmet medical need for the treatment of glioblastoma. All these have highlighted the need for new therapies in both newly diagnosed and recurring GBM patients.

The glioblastoma market is a multibillion dollar business. Worldwide sales of **Temodar** reached \$1 billion in 2009. The patent of Temodar will expire in August 2013. **VAL-083** has a differentiated mechanism of action for the treatment of glioblastoma, which will help VAL-083 capture a significant share of the glioblastoma market when it reaches the market. Also, unlike Temodar which only targets newly diagnosed patients and Avastin which only targets recurring patients, VAL-083 targets **both newly diagnosed** and **recurring glioblastoma** patients, which will help drive revenue growth more dramatically if approved.



The market potential is even greater if we consider that VAL-083 can also target other cancer indications, such as lung cancer, breast cancer, ovarian cancer and leukemia. If DelMar only develops VAL-083 for lung cancer and GBM to be conservative, the potential market size for those two indications is huge.

#### Partnership In China Will Provide Near-Term Royalty Revenue Opportunity

DelMar also obtained exclusive commercial rights to VAL-083 in China. In October 2012, the Company entered into a strategic collaboration agreement with Guangxi Wuzhou Pharmaceutical Company, a subsidiary of publicly traded Zhongheng Group Co., Ltd (SHG 600252) for the development of VAL-083, known as "**DAG for Injection**" in China. Wuzhou is the only manufacturer presently licensed by the China Food and Drug Administration (CFDA) to produce VAL-083 for the China market.

This agreement provides DelMar with exclusive commercial rights, which position the Company to generate near-term revenue through product sales or royalties for its approved indications in China. The Company anticipates entering into a marketing partnership which will provide ongoing funding, sales or royalties commencing in late 2013.

The collaboration **expands the previous exclusive supply relationship** between DelMar and Guangxi Wuzhou Pharmaceutical to include the Chinese market and all markets outside China. The companies will work together to insure the product specifications meet global standards in order to accelerate international development and regulatory approval. Wuzhou Pharmaceutical will be the exclusive supplier of DAG for Injection and DelMar will be responsible for development and commercialization. DAG for Injection is approved by the CFDA as a cancer chemotherapy for the treatment of Chronic Myelogenous Leukemia **(CML)** and **lung cancer**. Guangxi Wuzhou Pharmaceutical is licensed by CFDA to manufacture and sell VAL-083 in China for these indications. So far, sales of DAG for Injection have been minimal since the drug is not well positioned vis-à-vis standard of care in approved indications. Use

of DAG in the modern era has been limited by a preference for targeted therapies such as tyrosine kinase inhibitors (TKIs).

The two companies plan to develop new clinical and non-clinical data in collaboration with leading cancer researchers to demonstrate the utility of VAL-083 in the treatment of CML and lung cancer, particularly for patients who do not respond to, or cannot access, modern treatments such as tyrosine kinase inhibitors. The data, if favorable, will allow the **repositioning** of VAL-083 in the China market, and eventually global markets, for the treatment of hematologic cancers and solid tumors. Longer term, the two companies plan to expand the China market with new indications such as GBM.

The collaboration may lead to **global development of VAL-083 for leukemia and lung cancer**. The activity of VAL-083 against CML and lung cancer was studied extensively by the NCI. VAL-083 demonstrated activity against CML and NSCLC (non-small cell lung cancer) in laboratory and animal studies. VAL-083 was also investigated in a number of clinical trials in the United States and Europe during the 1970s both as a stand-alone therapy and in combination with other chemotherapeutic regimens for leukemia and lung cancer.

We believe that VAL-083's unique bi-functional alkylating mechanism of action could make it a valuable drug of choice in CML and NSCLC patients who are or become resistant to TKI therapy. In addition, VAL-083 readily crosses the blood brain barrier suggesting that it may be possible for VAL-083 to treat patients whose cancer has spread to the brain.

Since current sales of VAL-083 in China have been minimal, DelMar is seeking to collaborate with a **new company** having an established, medical-affairs driven, oncology sales force in China. Currently, pharmaceutical industry in China is transitioning from pure generics to research based development. It is our belief that physician education, combined with new data and KOL support will enable the repositioning and growth of the VAL-083 in China. Guangxi Wuzhou Pharmaceuticals does not have an oncology sales infrastructure.

DelMar will either sub-license its exclusive commercial rights in return for a royalty or take a mark-up on the transfer pricing as an intermediary. Final structure will be driven by the desire of the marketing partner. The Company is in discussions with a number of parties with the goal of solidifying the partnership before year end.

### Balance Sheet is Relatively Strong

On March 7, 2013, DelMar completed a \$10.5 million private placement.

Each unit consists of one share of common stock and one common stock purchase warrant. The maximum offering in the Private Placement consisted of 9,375,000 units for gross proceeds of \$7.5 million. In addition, the warrants associated with the private placement may provide up to an additional \$10.5 million in funding to support drug development activities. The placement agent has been granted an over-allotment option. The overallotment option was increased to 3,750,000 units for additional gross proceeds of \$3.0 million to accommodate investor interest. The overallotment option has been exercised in full in conjunction with this closing. Net proceeds from this offering were approximately \$8.6 million.

These funds will accelerate the advancement of the ongoing VAL-083 clinical trials for refractory glioblastoma.

As of March 31, 2013, the Company has cash and cash equivalents of \$7.5 million and a working capital balance of \$6.8 million. Current cash could last through the first quarter of 2015.

## Experienced Management Team

Jeffrey Bacha, B.Sc., MBA, President & CEO/cofounder

Mr. Bacha is a seasoned executive leader with nearly twenty years of life sciences experience in the areas of operations, strategy and finance. His background includes successful public and private company building from both a start-up and turn around perspective; establishing and leading thriving management and technical teams; and raising capital in both the public and private markets. Mr. Bacha serves as a Director of Sernova Corp. (TSX-V: SVA), was the founding CEO of Inimex Pharmaceuticals Inc. and co-founder of XBiotech and Urigen Holdings Inc. He has also held positions as Exec. VP Corporate Affairs & Chief Operating Officer at Clera Inc., VP Corporate Development at Inflazyme Pharmaceuticals Ltd. (TSE: IZP) and Senior Manager & Director at KPMG Health Ventures . In 2003, Mr. Bacha was recognized as a "Top 40 under 40" executive by Business in Vancouver magazine and is active in the community through volunteerism with the Leukemia & Lymphoma Society's Team in Training program and as Chairman of the Board for Covenant House Vancouver, an organization dedicated to assisting at-risk and homeless youth to re-enter society . He received his MBA (honors) from the Goizueta Business School at Emory University and a B.Sc. in BioPhysics/Premed from the University of California. San Diego.

### Dennis M. Brown, Ph.D., Chief Scientific Officer/cofounder & Director

Dr. Brown has more than twenty years of drug discovery and development experience. He has served as Chairman of Mountain View Pharmaceutical's Board of Directors since 2000 and is the President of Valent Technologies, LLC. In 1999 he founded ChemGenex Therapeutics, which merged with a publicly traded Australian company in 2004 to become ChemGenex Pharmaceuticals (ASX: CXS/NASDAQ: CXSP), of which he served as President and a Director until 2009. He was previously a co-founder of Matrix Pharmaceutical, Inc., where he served as Vice President (VP) of Scientific Affairs from 1985-1995 and as VP, Discovery Research, from 1995-1999. He also previously served as an Assistant Professor of Radiology at Harvard University Medical School and as a Research Associate in Radiology at Stanford University Medical School. He received his B.A. in Biology and Chemistry (1971), M.S. in Cell Biology (1975) and Ph.D. in Radiation and Cancer Biology (1979), all from New York University. Dr. Brown is an inventor on about 34 issued US patents and applications, many with foreign counterparts.

## Scott Praill, CA, Chief Financial Officer

Mr. Praill has been Chief Financial Officer of the Company since January 2013 and previously served as a consultant to the Company. Since 2004, Mr. Praill has been an independent consultant providing accounting and administrative services to companies in the resource industry. Mr. Praill served as CFO of Strata Oil & Gas, Inc. from June 2007 to September 2008. From November 1999 to October 2003 Mr. Praill was Director of Finance at Inflazyme Pharmaceuticals Inc. Mr. Praill completed his articling at Price Waterhouse (now PricewaterhouseCoopers LLP) and obtained his Chartered Accountant designation in 1996. Mr. Praill obtained his Certified Public Accountant (Illinois) designation in 2001. Mr. Praill received a Financial Management Diploma (Honors), from the British Columbia Institute of Technology in 1993, and a Bachelor of Science from Simon Fraser University in 1989.

### **VALUATION**

We are initiating coverage of Del Mar Pharmaceuticals (DMPI) with a Neutral rating. Our 12-month price target is \$4.50.

DMPI is a clinical and commercial stage biopharmaceutical company focused on the development and commercialization of oncology drugs. The Company's only and key 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 2014. 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 as early as in late 2013, which is a derisking 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 \$2 per share, which values the Company at about \$62 million in market cap based on 31 million outstanding shares. It looks like this is a discount compared to its peers. We noticed that most small biotech companies of development stage are valued from \$50 million to \$500 million 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 early 2014.

We estimate VAL-083 could be approved by the FDA in 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 2018 with an EPS of \$0.06 based on product sales of \$35 million. EPS will grow to \$0.35 in 2019 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 \$140 million in market cap, which we think is appropriate and fare 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, especially for early stage of drug candidates. VAL-083 is only in Phase I clinical trial, and both clinical and regulatory hurdles are significant at this point.

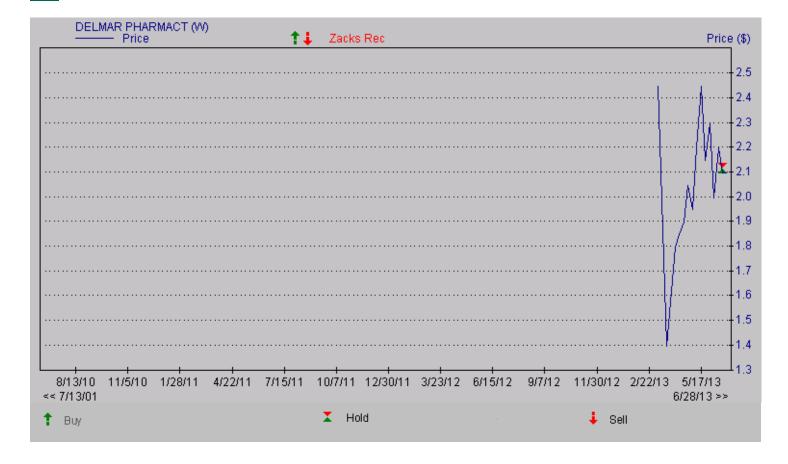
Another concern we have is that DMPI has a limited pipeline. Right now, VAL-083 is the Company's only clinical-stage candidate. While DelMar has early-stage second-generation analogues from the VAL-083 chemistry platform and access to additional clinical-stage product candidates through its relationship 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

_	2010	2011	2012			2013			2014	2015	2016	2017	2018	2019
\$ in millions except per share data	FY	FY	FY	Q1	Q2	Q3	Q4	FYE	FYE	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
Royalty	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.50	\$1.00	\$1.50	\$2.00	\$2.50	\$3.50
YOY Growth	-	-	-	-	-	-	-	-	-	100.0%	50.0%	33.3%	25.0%	40.0%
Product Sales YOY Growth	\$0.00	\$0.00	\$0.00	\$0.00 -	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	<b>\$</b> 0.00	<b>\$7.50</b>	\$35.00 366.7%	\$70.00 100.0%
Total Revenues	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.50	\$1.00	\$1.50	\$9.50	\$37.50	\$73.50
YOY Growth		-	-	-	-	-	-	-	-	100.0%	50.0%	533.3%	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	\$0.75	\$3.50	\$7.00
Gross Income	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.50	\$1.00	\$1.50	\$8.75	\$34.00	\$66.50
Gross Margin	-	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	92.1%	90.7%	90.5%
R&D	\$0.04	\$1.05	\$1.55	\$0.63	\$0.65	\$0.70	\$0.85	\$2.83	\$3.50	\$5.00	\$7.00	\$7.50	\$9.00	\$12.00
% R&D	φ0.0 <del>4</del>	\$1.00 -	φ1.33 -	φυ.os -	φυ. <del>0</del> 3	φ0.70 -	φυ.oo	φ2.03 -	700.0%	500.0%	φ1.00 466.7%	78.9%	<b>д9.00</b> 24.0%	φ12.00 16.3%
SG&A	\$0.07	\$0.24	\$1.15	\$0.92	\$0.93	\$0.95	\$1.00	\$3.80	\$4.50	\$6.00	\$7.50	\$15.00	\$20.00	\$25.00
% SG&A	-	-	-	-	-	-	-	-	900.0%	600.0%	500.0%	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
% Other	-	-		-					0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Operating Income	(\$0.11)	(\$1.3)	(\$2.7)	(\$1.6)	(\$1.6)	(\$1.7)	(\$1.9)	(\$6.6)	(\$7.5)	(\$10.0)	(\$13.0)	(\$13.8)	\$5.0	\$29.5
Operating Margin Other Income (Net)	\$0.0	(\$0.0)	\$0.3	(\$5.9)	(\$0.2)	(\$0.2)	(\$0.2)	(\$6.5)	(\$0.8)	(\$0.8)	(\$0.8)	(\$0.8)	13.3% (\$0.8)	40.1% (\$0.8)
Pre-Tax Income	(\$0.11)	(\$1.3)	(\$2.4)	(\$7.4)	(\$1.8)	(\$1.9)	(\$2.1)	(\$13.1)	(\$8.3)	(\$10.8)	(\$13.8)	(\$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	\$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%	45.0 17.4%
Reported Net Income	(\$0.11)	(\$1.3)	(\$2.4)	(\$7.4)	(\$1.8)	(\$1.9)	(\$2.1)	(\$13.1)	(\$8.3)	(\$10.8)	(\$13.8)	(\$14.6)	\$4.2	\$23.7
YOY Growth	-	-	-	-	-	-	-	- '	-	-	-	-	-	-
Net Margin	- 6.1	- 8.5	- 13.2	- 24.3	30.6	- 31.0	32.0	29.5	40.0	- 48.0	- 55.0	60.00	- 65.00	- 70.00
Weighted avg. Shares Out	(\$0.02)												\$0.06	\$0.34
Reported EPS  YOY Growth	(\$0.02)	(\$0.16)	(\$0.18)	(\$0.30)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.44)	(\$0.21)	(\$0.23)	(\$0.25)	(\$0.24)	<b>\$0.00</b>	<b>\$0.34</b>
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One time charge	\$0.00	\$0.00	\$0.00	\$5.85	\$0.00	\$0.00	\$0.00	\$5.85	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$1.00
Non GAAP Net Income	(\$0.11)	(\$1.3)	(\$2.4)	(\$1.6)	(\$1.8)	(\$1.9)	(\$2.1)	(\$7.2)	(\$8.3)	(\$10.8)	(\$13.8)	(\$14.6)	\$4.2	\$24.7
Non GAAP EPS	(\$0.02)	(\$0.16)	(\$0.18)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.25)	(\$0.21)	(\$0.23)	(\$0.25)	(\$0.24)	\$0.06	\$0.35

Source: company filings and Zacks estimates

# HISTORICAL ZACKS RECOMMENDATIONS



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