

## INSTITUTIONAL RESEARCH

# **Biotechnology** COMPANY UPDATE

Member FINRA/SIPC

March 1, 2018

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## **DelMar Pharmaceuticals (Nasdaq/DMPI)**

**BUY** 

Refocusing on VAL-083 in rGBM

DelMar is a biopharmaceutical company focused on the development and commercialization of new cancer therapies

### **Investment Highlights**

- 1) DelMar has recently revised the development strategy for its lead VAL-083 product candidate, focusing now on recurrent MGMT-unmethylated glioblastoma (GBM) using VAL-083 as a single agent. MGMT methylation status has become routine in GBM treatment clinical practice as a biomarker which correlates with resistance to the standard-of-care chemotherapy with temozolomide (Temodar) and patient outcomes. DelMar plans to use this biomarker to allow the Company to optimize patient selection for treatment with its lead drug candidate, VAL-083, in an ongoing Phase 2 trial at MD Anderson Cancer Center. This Phase 2 trial was initiated about one year ago, and is designed to enroll up to 48 patients, with 17 patients enrolled to date. A recent amendment (September 2017) to the National Comprehensive Cancer Network guidelines for the standard treatment of GBM based on MGMT methylation status is expected to provide higher visibility and more opportunity for VAL-083's unique mechanism of action.
- 2) DelMar is also making progress on its other pipeline programs, most notably with the first patient dosing of its open label Phase 2 clinical trial of VAL-083 combined with chemotherapy in newly diagnosed patients with MGMT-unmethylated GBM, which is being conducted at Sun Yat-sen University Cancer Center in Guangzhou, China with partner Guangxi Wuzhou. DelMar also recently provided an update on its Phase 1/2 trial using VAL-083 as a single agent in platinum-resistant Ovarian Cancer. The Company now anticipates that its REPROVe trial, which is designed to enroll up to 24 patients to assess the overall response rate vs. historical control group, will open for patient enrollment in the first half of this year. The IND for VAL-083 as a potential treatment in platinum-resistant Ovarian Cancer was allowed by the FDA in September 2017; DelMar is investigating additional applications for this drug in oncology through pre-clinical studies. Finally, the recent FDA full approval of Genentech's Avastin (bevacizumab) for recurrent GBM has led

Price Target	\$6.60
Current Price	\$1.15

Estimates	F2016A	F2017A	F2018E
Revenues(\$000s)	\$0	\$0	\$0
1Q September	0	0	0 A
2Q December	0	0	0 A
3Q March	0	0	
4Q June	0	0	
EPS (diluted)	(\$0.81)	(\$0.74)	(\$0.55)
1Q September	(0.15)	(0.23)	(0.18) A
2Q December	(0.24)	(0.13)	(0.14) A
3Q March	(0.10)	(0.18)	
4Q June	(0.32)	(0.09)	

EBITDA/Share	(\$0.46)	(\$0.61)	(\$0.50)
EV/EBITDA (x)	N/A	N/A	N/A
Stock Data			
52-Week Range		\$0	0.78-\$5.20
Shares Outstanding (mil.)			22.0
Market Capitalization (mil.)			\$25.3
Enterprise Value (mil.)			\$14.7
Debt to Capital (12/17)			3.8%
Book Value/Share (12/17)			\$0.45
Price/Book			2.5 x
Average Trading Volume (3-Month)			966,500
Insider Ownership			10.0%
Institutional Ownership			15.1%
Short interest (Millions)			1.2
Dividend / Yield			\$0.00/0.0%
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Price target and ratings changes over the past 3 yrs: Updated - August 8, 2017 - Buy - Price Target \$6.60



DelMar to put its Phase 3 STAR-3 pivotal trial on hold for up to twelve months in order to re-evaluate the Company's ability to find suitable patients – DelMar will continue to provide treatment for patients already enrolled in STAR-3 but will not recruit further patients for the study for a while. DelMar also recently announced the appointment of Dr. Saiid Zarrabian as interim President and CEO; his prior experience includes positions with La Jolla Pharmaceuticals, Intrexon and Cyntellect.

3) The Company recently reported financial results for their Q2/18 quarter (ending December), including a net loss of \$3.2 million or (\$0.14) per share compared with a net loss of \$1.5 million or (\$0.13) per share in the prior year period. The increased net loss this year was due to higher R&D expenses, to \$2.1 million this year from \$1.1 million a year ago, and higher general and administrative costs, to \$1.0 million from \$570,000 last year, due to increased R&D activity related to one Phase 3 and 2 Phase 2 trials ongoing with VAL-083. Operating cash burn came in at \$4.5 million for DelMar for the first six months of the 2018 fiscal year, up from \$3.1 million in the prior year period, and at the end of December the Company had \$11.0 million in cash on hand. DelMar management estimates that the Company currently has adequate funding to last until the second quarter of calendar 2019. We estimate that DelMar will post a net loss of \$12.1 million, or (\$0.55) per share in fiscal 2018E ending June, based on steady or slightly decreased expense levels for the second half of this fiscal year.

#### **Conclusion/Stock Valuation**

We are maintaining our BUY rating and \$6.60 Price Target on DelMar Pharmaceuticals shares, based on recent net positive clinical progress and on valuation metrics for our eight-member comparable group of similar-stage oncology stocks (particularly targeting brain cancer), which include CytRx (CYTR, Not Rated), ImmunoCellular Therapeutics (IMUC, Not Rated), Inspyr Therapeutics (NSPX, Not Rated), Medicenna Therapeutics (MDNA, Not Rated), Merrimack Pharmaceuticals (MACK, Not Rated), Northwest Biotherapeutics (NWBO, Not Rated), Tocagen (TOCA, Not Rated), and Vascular Biologics (VBLT, Not Rated).

#### **Risk Factors**

In addition to normal economic and market risk factors that impact most equities and the common risks shared by DelMar with other companies in the industry, we believe an investment in DMPI involves the following risks:

- **Reliance on key management** At present, DMPI relies on several key members of its management team who either founded the Company or have been in key executive positions for an extended period of time. Should one or more of these key executives leave the Company, DMPI could find it difficult to replace their long-standing knowledge of operations and industry expertise.
- **Reliance on partnerships** To date, DMPI has signed a number of development partnerships for its pharmaceutical technologies and products. Thus, in the future certain factors related to product commercialization and new product development may be determined by third parties and out of the control of Company management.
- **Limited stock liquidity** Trading volume in DMPI stock is comparatively light and these shares have a relatively limited history of trading on major US stock exchanges compared with other healthcare stocks. As such, news regarding DMPI, its target market, partners and/or competitors could lead to significant volatility in the stock price.
- Competitive Markets The Company and its partners compete in its target pharmaceutical product markets with a number of companies, many of which are considerably larger than the Company. There



can be no assurance that the Company and its partners will be able to successfully compete and launch new products into these competitive markets in the future.

- **FDA and regulatory risks** DMPI and its partners are subject to regulatory review for its ongoing research and development activities, principally the US Food and Drug Administration's application processes. In addition, the quality assurance and manufacture of the Company's pharmaceutical products are subject to ongoing oversight and regulation, and any negative correspondence from the FDA or other regulatory agencies could have an adverse effect on the ongoing operations of the Company.
- Lack of historic profitability DMPI has not achieved operating profitability on a quarterly basis for several years, and according to our forecasts may not be expected to do so in the near future. Although the Company maintains adequate cash reserves at the present time, there can be no assurance the Company will not need to raise additional working capital in the future should operating losses continue.
- Need to defend patents and other intellectual property DMPI currently holds a number of US and International patents on its product develop candidates and related technologies, some of which expire in the near future. The Company may be required to defend its patents in the US and overseas in the future, and there can be no assurance these defenses will be successful.



Robert M. Wasserman

#### DelMar Pharmaceuticals, Inc. Consolidated Statements of Income (In 000s, except per share data)

FYE June	2015	<u>2016</u>	<u>1Q17</u>	<u>2Q17</u>	3Q17	<u>4Q17</u>	<u>2017</u>	2018E	2019E
		1	<u>September</u>	<u>December</u>	<u>March</u>	<u>June</u>			
			60	**	**	**	ا مه	60	<b>\$5,000</b>
Revenue	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$5,000
Operating Expenses									
Research and development	2,556	3,361	733	1,121	1,086	2,064	5,004	8,500	6,000
General and administrative	2,169	2,853	1,317	571	698	731	3,317	4,000	4,500
Other operating expenses	0	0	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	0	<u>0</u>	<u>0</u>
Total operating expenses	4,725	6,214	2,049	<u>1,692</u>	1,784	2,795	8,321	12,500	10,500
Income (loss) from operations	(\$4,725)	(\$6,214)	(\$2,049)	(\$1,692)	(\$1,784)	(\$2,795)	(\$8,321)	(\$12,500)	(\$5,500)
Other loss (income)	<u>377</u>	(2,651)	(241)	<u>370</u>	(84)	<u>194</u>	239	<u>400</u>	(100)
Net income (loss) before taxes	(\$4,348)	(\$8,865)	(\$2,290)	(\$1,322)	(\$1,868)	(\$2,601)	(\$8,082)	(\$12,100)	(\$5,600)
Series B preferred stock dividend	0	<u>0</u>	(307)	(160)	(210)	1,467	<u>790</u>	<u>0</u>	<u>0</u>
Net income (loss) to common	(\$4,348)	(\$8,865)	(\$2,598)	(\$1,482)	(\$2,078)	(\$1,134)	(\$8,872)	(\$12,100)	(\$5,600)
Basic income per share	<u>(\$0.46)</u>	<u>(\$0.81)</u>	(\$0.23)	<u>(\$0.13)</u>	<u>(\$0.18)</u>	<u>(\$0.09)</u>	<u>(\$0.74)</u>	<u>(\$0.55)</u>	(\$0.25)
Diluted income per share	<u>(\$0.46)</u>	(\$0.81)	(\$0.23)	<u>(\$0.13)</u>	<u>(\$0.18)</u>	<u>(\$0.09)</u>	<u>(\$0.74)</u>	<u>(\$0.55)</u>	(\$0.25)
Basic shares outstanding	9,517	10.948	11,302	11,424	11,574	12,047	12,047	22,000	22,500
Diluted shares outstanding	9,517	10,948	11,302	11,424	11,574	12,047	12,047	22,000	22,500
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Key ratios:									
Revenue growth	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
G &A/revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
R&D/revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Deprec, amort & non-cash comp.	(32)	3,840	875	(430)	360	(17)	788	1,000	1,200
Cash Flow/share	(\$0.46)	(\$0.46)	(\$0.13)	(\$0.15)	(\$0.13)	(\$0.22)	(\$0.67)	(\$0.50)	(\$0.20)
EBITDA/share	(\$0.46)	(\$0.46)	(\$0.13)	(\$0.15)	(\$0.13)	(\$0.22)	(\$0.61)	(\$0.50)	(\$0.20)

	Balance Sh	<u>eets</u>				
	(\$000s)					
Assets:	6/30/17	12/31/17		Quarterly Ear	rnings Compa	<u>risons</u>
Current Assets				<u>September</u>	<u>December</u>	March
Cash and equivalents	\$6,586	\$11,022	Revenues	(in \$Mill)		
Taxes and other receivables	77	25	2015			
Prepaid expenses and other current assets	1,208	1,141	2016	0	0	
Total current	7,871	12,187	2017	0	0	
Intangibles and other long-term assets	<u>40</u>	<u>29</u>	2018E	0	0	
Total Assets	\$7,911	\$12,216				
			Earnings p	er Share (diluted)		
Liabilities:			2015			
Current liabilities			2016	(\$0.15)	(\$0.24)	(\$0.
Accounts payable and accrued liabilities	\$1,182	\$1,829	2017	(\$0.23)	(\$0.13)	(\$0.
Related party payables	89	398	2018E	(\$0.18)	(\$0.14)	
Current portion of derivative liability	<u>33</u>	<u>0</u>				
Total current	1,304	2,227				
Stock option liability						
Derivative liability	<u>28</u>	<u>5</u>				
Total liabilities	1,332	2,232				
Stockholders' equity	6.579	9.984				
TOTAL LIAB & EQ	\$7,911	\$12,216				

Source: Dawson James Securities, Inc. estimates; Company documents

**March** 

0

0

(\$0.10)

(\$0.18)

<u>Total</u>

0 0

0

(\$0.46)

(\$0.81)

(\$0.74) (\$0.55)

<u>June</u>

0 0

(\$0.32)

(\$0.09)



#### **Important Disclosures:**

#### **Price Chart:**



<u>Price target and ratings changes over the past 3 years:</u> Updated – Buy – August 8, 2017 – Price Target \$6.60

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- 2) Neutral: the analyst believes the price of the stock is fairly valued for the next 12-18 months:
- 3) **Sel**I: the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

	Company Co	verage	Investment Banking		
<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals	
Market Outperform (Buy)	15	88%	5	33%	
Market Perform (Neutral)	2	12%	0	0%	
Market Underperform (Sell)	0	0%	0	0%	
Total	17	100%	5	29%	

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