

November 14, 2016



# **DelMar Pharmaceuticals Announces First Quarter Fiscal Year 2017 Financial Results and Corporate Update**

**- Company will host a business update conference call and webcast on Tuesday, November 15, 2016 at 4:30 PM EST -**

**The Company also highlights recent corporate and clinical achievements and provides an overview of expected near-term milestones.**

VANCOUVER, British Columbia and MENLO PARK, Calif., Nov. 14, 2016 /PRNewswire/ - [DelMar Pharmaceuticals, Inc.](#) (NASDAQ: DMPI) ("DelMar" and the "Company"), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, today announced its financial results for the quarter ending September 30, 2016, the first quarter of the Company's 2017 fiscal year. DelMar executive management will host a business update conference call and live webcast for investors, analysts and other interested parties on Tuesday, November 15, 2016 at 4:30 pm EST.



"Looking back, 2016 has been a transformational year for our Company," stated Jeffrey Bacha, DelMar's Chairman and chief executive officer. Our goals this year included listing our company's shares on a national exchange, successfully completing our initial Phase I/II clinical trial in refractory GBM, preparing for a pivotal Phase III clinical trial and expanding our research efforts with VAL-083 into new indications."

## **RECENT CORPORATE HIGHLIGHTS**

- DelMar raised gross proceeds of approximately \$7.2 million in a private placement and our common stock began trading on the Nasdaq Capital Markets under the symbol "DMPI";
- DelMar confirmed that the Institutional Review Board ("IRB") at the University of Texas MD Anderson Cancer Center ("MD Anderson") approved our planned Phase

- II clinical study with VAL-083 in patients with GBM at first recurrence/progression;
- DelMar reported promising data from our Phase I/II clinical trial of VAL-083 in refractory GBM at the American Society of Clinical Oncology ("ASCO") annual meeting; supporting the potential for an improved survival benefit for bevacizumab-failed GBM patients treated with VAL-083 in comparison to current salvage chemotherapy;
  - DelMar announced the successful completion of an 'End of Phase II' meeting with the FDA and confirmed plans to advance VAL-083 into a pivotal Phase III clinical trial for GBM patients whose tumors have progressed following treatment with bevacizumab;
  - DelMar entered into a collaborative research agreement with Accurexa, Inc. to explore local delivery of VAL-083 as a potential combination therapy for the treatment of brain tumors;
  - DelMar continued to report promising research results supporting the potential of VAL-083 in new indications:
    - Presented data supporting the effectiveness of VAL-083 against chemotherapy-resistant ovarian cancers, including data suggesting the potential for treatment synergy of VAL-083 combined with Astra Zeneca's PARP inhibitor, Lynparza™ (olaparib), at the 11<sup>th</sup> Biennial Ovarian Cancer Research Symposium;
    - Presented new research results demonstrating that VAL-083 exhibits a distinct mode of action compared to other chemotherapies used in the treatment of newly diagnosed GBM patients at the European Association of Neuro-Oncology annual meeting;
    - Presented new non-clinical data supporting the differentiation of VAL-083 in the treatment of lung cancer in comparison to platinum and tyrosine kinase inhibitor treatments at the AACR New Horizons in Cancer Research meeting;
    - Presented data indicating that VAL-083 offers potential therapeutic alternatives in difficult-to-treat pediatric brain tumors at the AACR – Advances in Pediatric Research: From Mechanisms and Models to Treatment and Survivorship Conference.
  - DelMar continued to strengthen its intellectual property portfolio. DelMar now holds six issued US patents and seven issued patents outside of the US representing thirteen patent families in various stages of prosecution, and over 100 patent filings in total.

"We were very pleased with the outcome of our End-of-Phase II meeting and the guidance provided by the FDA," said Mr. Bacha. "The DelMar clinical team and our advisors have been developing a Phase III study protocol that would provide strong statistical power, enroll fewer than 200 patients, and is designed to reach its final endpoint in two years or less. We plan to submit the protocol to the FDA in the coming weeks, and subject to the FDA's continued guidance and availability of funding, anticipate initiating a registration-directed Phase III study as soon as practicable."

DelMar is also pleased to confirm the accomplishment of critical steps toward initiating new clinical trials designed to position VAL-083 as an alternative to temozolomide in newly diagnosed GBM for patients whose tumors exhibit a high expression of MGMT, the DNA repair enzyme linked to failure of standard front-line chemotherapy and poor patient

outcomes:

- The MD Anderson IRB has approved the protocol of the Company's planned Phase II Study of VAL-083 in patients with MGMT-unmethylated, bevacizumab-naive recurrent glioblastoma. DelMar anticipates completing study initiation activities and commencing the dosing of patients in the coming weeks.
- The Company is also completing the final remaining steps required for initiation of an international clinical trial in newly diagnosed GBM patients with high expression of MGMT.

"Importantly, these two new Phase II trials are largely supported through our collaborators, so their initiation will not materially impact our near-term cash expenditures," stated Mr. Bacha. "Our current working capital will support DelMar's operations for at least the next twelve months and, while our planned Phase III clinical trial will require additional financing, we have the opportunity to expand our clinical research efforts in GBM and to continue advancing our research into new indications without an immediate need to raise additional funds."

## **EXPECTED NEAR-TERM MILESTONES**

- Commence treating patients at MD Anderson with VAL-083 in a Phase II clinical study of GBM patients with high expression of MGMT at first recurrence/progression;
- Submit a Phase III protocol to the FDA proposing a pivotal, multi-center, randomized clinical trial of VAL-083 in GBM patients who have failed both standard chemotherapy and bevacizumab;
- Initiate a Phase II clinical trial in China in newly-diagnosed GBM patients as an alternative to temozolomide in patients with high expression of MGMT;
- Expand DelMar's clinical research with VAL-083 in new solid tumor indications, subject to financial resources;
- Present our research results at international peer-reviewed scientific meetings;
- Continue to pursue pre-clinical research that further differentiates VAL-083 from established chemotherapeutic regimens, and to identify opportunities for combination therapy;
- Maximize the value of the VAL-083 pipeline through collaborations with industry leaders in attractive oncology markets; and
- Continue to build our intellectual property portfolio.

## **CONFERENCE CALL DETAILS**

DelMar plans to host a conference call to discuss quarterly results and provide a corporate update on Tuesday, November 15, 2016, at 4:30 p.m. Eastern Time. For both "listen-only" participants and those who wish to take part in the question and answer portion of the call, the telephone Dial-in Number is **800-895-0198** (toll free) with Conference ID **DELMAR**.

Listeners can also attend the call via [webcast](#). A link to the webcast and slides will be available on the [IR Calendar](#) of the [Investors section](#) of the Company's website at [www.delmarpharma.com](http://www.delmarpharma.com) and will be archived for 30 days.

## SUMMARY OF FINANCIAL RESULTS FOR THE FIRST QUARTER OF FISCAL YEAR 2017 ENDED SEPTEMBER 30, 2016

For the three months ended September 30, 2016 the Company reported a net loss of \$2,290,339, or a net loss per share of \$0.23, compared to a net loss of \$1,621,388, or a net loss per share of \$0.15 for the three months ended September 30, 2015.

### FINANCIAL SUMMARY

The following represents selected financial information as of September 30, 2016. The Company's financial information has been prepared in accordance with U.S. GAAP and this selected information should be read in conjunction with DelMar's consolidated financial statements and management's discussion and analysis ("MD&A"), as filed.

DelMar's financial statements as filed with the U.S. Securities Exchange Commission can be viewed on the company's website at: <http://ir.delmarpharma.com/all-sec-filings>.

#### Selected Balance Sheet Data

	September 30, 2016 \$	June 30, 2016 \$
	<u>                    </u>	<u>                    </u>
Cash and cash equivalents	4,799,033	6,157,264
Working capital	4,532,456	5,692,336
Total assets	5,046,887	6,355,799
Derivative liability	590,345	693,700
Total stockholders' equity	3,974,270	4,858,778

#### Selected Statement of Operations Data

For the Three Months Ended:

	September 30, 2016 \$	September 30, 2015 \$
	<u>                    </u>	<u>                    </u>
Research and development	732,729	603,845
General and administrative	1,316,639	474,025
Change in fair value of derivative liability	225,688	539,446
Change in fair value of derivative liability due to change in warrant terms	-	21,565
Foreign exchange loss (gain)	15,324	(17,473)
Interest income	(41)	(20)
Net and comprehensive loss	<u>2,290,339</u>	<u>1,621,388</u>
<b>Computation of basic loss per share</b>		
Net and comprehensive loss	2,290,339	1,621,388
Series B Preferred stock dividend	<u>307,298</u>	<u>-</u>
Net and comprehensive loss available to common stockholders	2,597,637	1,621,388

Basic weighted average number of shares outstanding	11,301,989	10,620,469
	0.23	0.15
Basic loss per share		

## About VAL-083

VAL-083 is a "first-in-class," small-molecule chemotherapeutic. In more than 40 Phase I and II clinical studies sponsored by the U.S. National Cancer Institute, VAL-083 demonstrated clinical activity against a range of cancers including lung, brain, cervical, ovarian tumors and leukemia both as a single-agent and in combination with other treatments.

VAL-083 has received an orphan drug designation in Europe for the treatment of malignant gliomas and the U.S. FDA Office of Orphan Products has granted an orphan designation to VAL-083 for the treatment of glioma, medulloblastoma and ovarian cancer.

The Company has completed a successful end of Phase II meeting with the US FDA and plans to advance VAL-083 into a pivotal clinical trial for GBM patients following bevacizumab failure. DelMar presented data from its Phase I/II clinical trial in refractory GBM at the 2016 American Association of Clinical Oncology ("ASCO") Annual meeting demonstrating that the median survival of 22 patients receiving an assumed therapeutic dose of VAL-083 ( $\geq 20\text{mg}/\text{m}^2$ ) was 8.35 months following Avastin™ (bevacizumab) failure compared to published literature where survival of approximately two to five months has been reported.

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

In addition to the pivotal trial, DelMar also plans to initiate two separate Phase II clinical trials in earlier-stage GBM patients.

- In collaboration with the [University of Texas MD Anderson Cancer Center](#): A non-comparative, biomarker-driven, Phase II study to determine if treatment of MGMT-unmethylated recurrent GBM with VAL-083 or CCNU improves overall survival at 9 months, compared to historical control in bevacizumab naïve patients. (clinicaltrials.gov identifier: NCT02717962)
- In collaboration with [Sun-Yat Sen University](#) and Guangxi Wuzhou Pharmaceutical (Group) Co.: A single arm Phase II clinical trial to confirm the tolerability of DelMar's dosing regimen in combination with radiotherapy (XRT) and to explore the activity of VAL-083 in newly diagnosed MGMT-unmethylated GBM patients whose tumors are known to express high levels of MGMT.

DelMar believes that data from these clinical trials, if successful, will form the basis of a

new paradigm in the treatment for all GBM patients who fail, or whose tumors exhibit features that make them unlikely to respond to currently available chemotherapy.

In addition to its clinical research in GBM, DelMar believes that its research supports a unique mechanism of action for VAL-083 and that these data support the potential of VAL-083 as a new chemotherapy that may offer improved outcomes in the treatment of GBM and other solid tumors in patients whose tumors have failed or exhibit features that make them resistant to or unlikely to respond to current standard-of-care chemotherapy.

The company and its collaborators from the University of Texas MD Anderson Cancer Center recently presented data at the 11<sup>th</sup> Biennial Ovarian Cancer Research Symposium demonstrating that VAL-083 was able to overcome cisplatin-resistance in ovarian cancer cell lines with known p53 mutations and displays synergy with both cisplatin and AstraZeneca's PARP inhibitor Olaparib™ against ovarian cancer *in vitro*.

Further details can be found at <http://www.delmarpharma.com/scientific-publications.html>.

### **About DelMar Pharmaceuticals, Inc.**

DelMar Pharmaceuticals, Inc. was founded to develop and commercialize new cancer therapies in indications where patients are failing or have become intolerable to modern targeted or biologic treatments. The Company's lead drug in development, VAL-083, is currently undergoing clinical trials in the U.S. as a potential treatment for refractory glioblastoma multiforme. VAL-083 has been extensively studied by U.S. National Cancer Institute, and is currently approved for the treatment of chronic myelogenous leukemia and lung cancer in China. Published pre-clinical and clinical data suggest that VAL-083 may be active against a range of tumor types via a novel mechanism of action that could provide improved treatment options for patients.

For further information, please visit <http://delmarpharma.com/>; or contact DelMar Pharmaceuticals Investor Relations: [ir@delmarpharma.com](mailto:ir@delmarpharma.com) / (604) 629-5989. Connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#), and [Google+](#).

### *Safe Harbor Statement*

*Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology; the availability of substantial additional funding for the Company to continue its operations and to conduct research and development, clinical studies and future product commercialization; and, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in our filings with the SEC, including, our current reports on Form 8-K.*

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