

DelMar Pharmaceuticals Reports First Quarter Fiscal Year 2016 Financial Results and Provides Corporate Update

- Management to host business update conference call and webcast on Monday, November 23, 2015 at 4:30 p.m. ET / 1:30 p.m. PT -

VANCOUVER, British Columbia and MENLO PARK, Calif., Nov. 17, 2015 /PRNewswire/ - DelMar Pharmaceuticals, Inc. (OTCQX: 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 first quarter of the 2016 fiscal year ending September 30, 2015. The Company also provided a recap of recent corporate and clinical program highlights and an overview of expected near-term milestones.



DelMar will host a conference call and live webcast for investors, analysts and other interested parties on Monday, November 23rd at 4:30 p.m. ET / 1:30 p.m. PT. During the call, management will provide a business update and discuss DelMar's <u>data presentation at the Society for Neuro-Oncology ("SNO") Annual meeting</u>, which will be held November 19-22, 2015, at the Marriott Riverfront Hotel in San Antonio, Texas.

"We have made tremendous progress in executing our clinical development strategy with VAL-083 in refractory glioblastoma multiforme ("GBM") and identifying additional value drivers through non-clinical research that position us to expand our clinical development efforts into non-small cell lung cancer ("NSCLC") and other solid tumors. We have completed full enrollment of the Phase II expansion cohort in our refractory GBM clinical trial. The results of this study will be the basis for advancing VAL-083 into the planned registration-directed Phase II/III trial in refractory GBM," stated Jeffrey Bacha, president and CEO of DelMar Pharmaceuticals.

"Our clinical development expansion strategy for VAL-083 is proceeding as planned, and we expect to initiate new clinical studies in newly diagnosed GBM and NSCLC patients in the near future," added Mr. Bacha. "Our research collaborations continue to explore the mechanism of VAL-083 and these efforts have unlocked further opportunities for VAL-083 to address unmet medical needs by providing improved treatment options for patients with

other tumor types, including ovarian cancer and difficult to treat sub-types of malignant pediatric brain tumors."

RECENT CORPORATE HIGHLIGHTS

- We reported the completion of enrollment in the 14-patient expansion cohort of our Phase II clinical study of VAL-083 in patients with refractory GBM. In addition, we confirmed 40mg/m² as the maximum tolerated dose ("MTD") for advancement into registration-directed clinical trials. This optimized dosing regimen delivers substantially higher doses compared to previous clinical trials conducted by the National Cancer Institutes ("NCI") in the United States. We believe that such higher doses may enhance the potential of VAL-083 to impact a patient's tumor as well as to improve patient outcomes:
- We reported the observation of a <u>promising dose-response trend in the Phase I portion of the clinical trial</u>. A subset analysis of patients in dose cohorts receiving ≥30mg/m² had a median survival of approximately nine (9) months vs. approximately five (5) months in dose cohorts receiving <10mg/m²;
- We reported additional non-clinical data supporting the favorable differentiation of VAL-083 versus standard of care in the treatment of GBM, non-small cell lung cancer and other solid tumors. We believe these data support the potential of VAL-083 to address the modern unmet medical needs in the treatment of a range of cancers, especially where other therapies have failed or are predicted to give sub-optimal outcomes;
- We announced that the <u>Mayo Clinic Cancer Center in Rochester</u>, <u>Minnesota</u> and the <u>Sarah Cannon Cancer Research Center at HealthOne</u>, <u>Denver</u>, <u>Colorado</u> have had been added as new clinical trial sites in our ongoing, multicenter Phase I/II clinical trial study of VAL-083 in patients with refractory GBM. We now have five clinical sites involved in our study;
- At the American Association for Cancer Research ("AACR") Advances in Pediatric Research: From Mechanisms and Models to Treatment and Survivorship, we presented data indicating that <u>VAL-083 offers potential therapeutic alternatives in</u> <u>difficult-to-treat pediatric brain tumors</u>;
- At AACR's Advances in Ovarian Cancer Research: Exploiting Vulnerabilities
 Conference, we presented data supporting the <u>effectiveness of VAL-083 against</u>
 <u>cisplatin-resistant ovarian cancers and raised the potential for VAL-083 as a treatment</u>
 <u>for ovarian cancer as a single-agent against platinum-resistant tumors or in</u>
 <u>combination with platinum-based chemotherapeutic regimens</u>;
- We announced we have <u>launched a suite of online corporate communication channels</u>
 to maintain ongoing and direct communication with shareholders and other interested
 parties. The Company hosts official digital portals on social medial channels including
 <u>Twitter</u>, <u>LinkedIn</u>, <u>Facebook</u>, <u>Google+</u> and <u>The Chairman's Blog</u>; and
- We accessed additional capital to support our drug development and research programs through a registered stock offering for gross proceeds of \$2.6 million

"I am extremely pleased with our significant achievements in recent months. DelMar is well positioned for major developments as VAL-083 advances toward registration-directed studies for refractory GBM and into clinical trials for new indications. We anticipate that the VAL-083 program will continue to produce key data during the remainder of 2015 and throughout 2016," concluded Mr. Bacha.

EXPECTED NEAR-TERM MILESTONES

- Present updated safety and efficacy data from the Phase II clinical trial in patients with refractory GBM at the Society for Neuro-Oncology Annual Meeting;
- Initiate registration-directed Phase II/III clinical trials for VAL-083 as a new treatment option for refractory GBM in 2016;
- Initiate new clinical trials, including front-line GBM and NSCLC;
- Continue to pursue non-clinical research with VAL-083 as a potential treatment option for chemo-resistant cancers:
- Establish collaboration discussions with leading investigators to advance VAL-083 into clinical studies as a potential treatment for children suffering from recurrent medulloblastoma or high grade gliomas;
- Maximize the value of the VAL083 pipeline through potential partnering opportunities;
- Continue to actively communicate DelMar's progress to the investment and medical communities through presentations at peer-reviewed scientific meetings;
- Continue to build the Company's intellectual property portfolio; and
- Continue to implement strategies to enable DelMar to meet qualifications to list its shares on a national stock exchange.

CONFERENCE CALL DETAILS

DelMar plans to host a conference call on Monday, November 23, 2015, at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time, to discuss quarterly results and the Company's presentation at the Society for Neuro-Oncology annual meeting. 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 (844) 303-8663 (toll-free) with Conference ID 81768802. 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, and will be archived for 30 days.

SUMMARY OF FINANCIAL RESULTS FOR THE FIRST QUARTER OF FISCAL YEAR 2016 ENDED SEPTEMBER 30, 2015

For the three months ended September 30, 2015 the Company reported a net loss of \$1,621,388, or a net loss per share of \$0.04, compared to a net loss of \$1,516,736, or a net loss per share of \$0.04 for the three months ended September 30, 2014. In connection with the preparation of the Company's financial statements for the three months ended September 30, 2015, and following discussion with a third party accounting consultant, it was determined that the certain common stock purchase warrants issued by the Company for placement agents' services on March 6, 2013 (the "Placement Agent Warrants") should have been originally accounted for as a derivative liability in our audited financial statements. We determined that this was a material adjustment and as a result we have restated our audited June 30, 2015 and 2014 annual financial statements to report the impacts of the accounting error retroactive to March 2013.

"We strive to maintain the utmost integrity in all aspects of our business. Importantly, the reclassification of the Placement Agent Warrants does not affect our working capital or our operations as we seek to build shareholder value by implementing DelMar's business plan," stated Mr. Bacha. "The fundamentals of our business, including developing our portfolio of clinical and non-clinical data supporting the potential of VAL-083 to address modern unmet medical needs in the treatment of cancer and the solid experience base of our development team, remain strong."

During the three months ended September 30, 2015 the Company completed a public offering of its shares and warrants for gross proceeds of \$2.6 million.

Based on management's current projections, the Company has enough capital to fund its operations into the third quarter of 2016.

FINANCIAL SUMMARY

The following represents selected financial information as of September 30, 2015. 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, 2015 \$	June 30, 2015 \$
		(as restated)
Cash and cash equivalents		
	2,804,096	1,754,433
Working capital		
	2,619,924	1,722,336
Total Assets		
	3,031,461	2,575,421
Derivative liability		
	2,954,986	2,364,381
Total stockholders' deficit		
rotal otoottiolasio aciiok	(514,507)	(821,490)
Selected Statement of Operations Data		
For the Three months Ended:		
	September 30,	September 30,
	2015 \$	2014 \$
	Ψ	(as restated)
Research and development	603,845	671,627
General and administrative	474,025	445,000
Change in fair value of derivative liability Change in fair value of derivative liability due to change in warrant	539,446	562,969
terms	21,565	(167,190)
Foreign exchange loss (gain)	(17,473)	2,391
Interest expense	-	2,091
Interest income	(20)	(152)

Net loss from operations	1,621,388	1,516,736
Basic weighted average number of shares outstanding	42,481,875	36,451,014
Basic loss per share	0.04	0.04

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 is approved in China for the treatment of chronic myelogenous leukemia (CML) and lung cancer, and has received orphan drug designation in Europe and the U.S. for the treatment of malignant gliomas.

DelMar has demonstrated that VAL-083's anti-tumor activity is unaffected by the expression of MGMT, a DNA repair enzyme that is implicated in chemotherapy resistance and poor outcomes in GBM patients following standard front-line treatment with Temodar[®] (temozolomide).

DelMar recently announced the completion of enrollment in a Phase II clinical trial of VAL-083 in refractory GBM. Patients have been enrolled at five clinical centers in the United States: Mayo Clinic (Rochester, MN); UCSF (San Francisco, CA) and three centers associated with the Sarah Cannon Cancer Research Institute (Nashville, TN, Sarasota, FL and Denver, CO).

In the Phase I dose-escalation portion of the study, VAL-083 was well tolerated at doses up to $40 \, \text{mg/m}^2$ using a regimen of daily x 3 every 21 days. Adverse events were typically mild to moderate; no treatment-related serious adverse events reported at doses up to $40 \, \text{mg/m}^2$. Dose limiting toxicity (DLT) defined by thrombocytopenia (low platelet counts) was observed in two of six (33%) of patients at $50 \, \text{mg/m}^2$. Generally, DLT-related symptoms resolved rapidly and spontaneously without concomitant treatment, although one patient who presented with hemorrhoids received a platelet transfusion as a precautionary measure.

Sub-group analysis of data from the Phase I dose-escalation portion of the study suggested a dose-dependent and clinically meaningful survival benefit following treatment with VAL-083 in GBM patients whose tumors had progressed following standard treatment with temozolomide, radiotherapy, bevacizumab and a range of salvage therapies.

Patients in a low dose (</=5mg/m²) sub-group had a median survival of approximately five (5) months versus median survival of approximately nine (9) months for patients in the therapeutic dose (30mg/m² & 40mg/m²) sub-group following initiation of VAL-083 treatment. DelMar reported increased survival at 6, 9 and 12 months following initiation of treatment with VAL-083 in the therapeutic dose sub-group compared to the low dose sub-group.

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/; (604) 629-5989. Connect with the Company on Twitter, LinkedIn, Facebook, and Google+. Investor Relations Counsel: Amato & Partners LLC.

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.

Logo - https://photos.prnewswire.com/prnh/20150909/265198LOGO

To view the original version on PR Newswire, visithttp://www.prnewswire.com/news-releases/delmar-pharmaceuticals-reports-first-quarter-fiscal-year-2016-financial-results-and-provides-corporate-update-300179852.html

SOURCE DelMar Pharmaceuticals, Inc.