

DelMar Pharmaceuticals, Inc.  
Form 10-K  
September 27, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington D. C. 20549

**FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the year ended June 30, 2017

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from

Commission file number 001-37823

**DelMar Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

<b>Nevada</b>	<b>99-0360497</b>
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Suite 720-999 West Broadway

Vancouver, British Columbia, Canada V5Z 1K5

(Address of principal executive offices)

**(604) 629-5989**

(Issuer's telephone number)

**Securities registered pursuant to Section 12(b) of the Act:**

Title of Class: Common Stock, par value \$0.001

Name of exchange on which registered: The Nasdaq Capital Market

**Securities registered pursuant to Section 12(g) of the Act: None.**

Indicate by check mark whether the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act) Yes  No

As of December 30, 2016, the aggregate market value of the issued and outstanding common stock held by non-affiliates of the registrant, based upon the closing price of our common stock of \$3.19 was approximately \$30.2 million. For purposes of the above statement only, all directors, executive officers and 10% shareholders are assumed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

Number of shares of common stock outstanding as of September 27, 2017 was 21,551,872.

**DOCUMENTS INCORPORATED BY REFERENCE – None**



**FORM 10-K**

**FOR THE FISCAL YEAR ENDED JUNE 30, 2017**

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## **PART I**

### **Item 1. Business.**

#### **Background**

DelMar Pharmaceuticals, Inc. (the “Company”) is a clinical stage drug development company with a focus on the treatment of cancer. Our mission is to benefit patients and create shareholder value by developing and commercializing anti-cancer therapies for patients whose tumors exhibit features that make them resistant to, or unlikely to respond to, currently available therapies, particularly for orphan cancer indications where patients have failed, or are unlikely to respond to, modern therapy. Upon obtaining regulatory approval, we intend to commercialize VAL-083 for the treatment of orphan cancer indications such as refractory GBM. We may also seek collaborative development and commercialization partnerships to accelerate and expand the development of VAL-083 in newly diagnosed GBM and other non-orphan cancer indications.

Our lead product candidate, VAL-083, is a first-in-class DNA-targeting chemotherapeutic that demonstrated activity against a range of tumor types on prior Phase 1 and Phase 2 clinical trials sponsored by the US National Cancer Institute (“NCI”). Our research suggests that VAL-083’s mechanism of action is different than other agents targeting DNA that are widely used in the treatment of cancer such as temozolomide, nitrosoureas, platinum-based drugs, topoisomerase inhibitors and PARP inhibitors. NCI clinical research and data from our own clinical trials suggest that VAL-083 may be active against tumors that are resistant to other chemotherapies and may offer a superior safety profile to these other agents.

We have recently initiated a pivotal randomized Phase 3 clinical trial with VAL-083 for recurrent glioblastoma multiforme (“GBM”). The trial, entitled VAL-083 Phase 3 Study in Temozolomide-Avastin (bevacizumab) Recurrent GBM (“STAR-3”) will enroll approximately 180 patients at approximately 25 centers in the United States. Patients in the trial will have GBM that has recurred following surgery, chemo-radiation with temozolomide, and bevacizumab (Avastin™). The trial will compare the overall survival of these patients following treatment with VAL-083 versus standard-of-care chemotherapy. If successful, the results of this trial will position us to file a new drug application (“NDA”) for the approval of VAL-083 in the United States for the treatment of recurrent GBM. We anticipate that the trial will take approximately two years from first enrollment.

We have also initiated two open-label, bio-marker driven Phase 2 trials in MGMT-unmethylated GBM. MGMT is a DNA-repair enzyme that is associated with resistance to temozolomide, the current standard-of-care chemotherapy used in the treatment of GBM. Approximately two out of three GBM patients have MGMT-unmethylated tumors and

exhibit a high expression of MGMT, which is correlated with temozolomide treatment failure and poor patient outcomes. Our research demonstrates that VAL-083's anti-tumor activity is independent of MGMT expression. In these studies, we are using MGMT as a biomarker to identify patients for treatment with VAL-083. If successful, the result of these trials will position VAL-083 for advancement to pivotal clinical trials as a potential replacement for temozolomide in MGMT-unmethylated GBM. We anticipate presenting interim data from these trials at peer reviewed scientific meetings during calendar 2018.

We have received notice of allowance from the FDA for a Phase 1/2, Open-Label, Multicenter, Study of VAL-083 in Patients with **R**ecurrent **P**latinum **R**esistant **O**varian Cancer (“REPROVe”). Platinum-based chemotherapy is standard-of-care in the treatment of ovarian cancer. Nearly all ovarian cancer patients eventually become resistant to platinum (“Pt”) -based chemotherapy leading to treatment failure and poor patient outcomes. We have demonstrated that VAL-083 is active against Pt-resistant ovarian cancer *in vitro*. The Phase 1 portion of the REPROVe trial will enroll approximately 24 patients with Pt-resistant ovarian cancer to evaluate the overall response rate (“ORR”) following treatment with VAL-083. We plan to request a meeting with the FDA following completion of the Phase 1 portion of the REPROVe trial. If successful, data from this trial would lead to a confirmatory Phase 2 study of approximately 60 patients, which if successful, and subject to feedback from FDA may position us to potentially file an application for accelerated approval or to advance to a pivotal Phase 3 trial. We will seek to initiate the REPROVe trial as soon as practicable, subject to negotiating acceptable clinical research agreements and budgets with clinical investigators and their institutions and obtaining IRB approvals. We anticipate completing the Phase 1 portion of the VAL-083 REPROVe trial in approximately 18 months from the initiation of patient recruitment and we will present updates on the progress of the trial at peer reviewed scientific meetings.

In addition to our clinical development activities in the United States, we have entered into a collaboration with Guangxi Wuzhou Pharmaceutical Company, the only manufacturer presently licensed by the China Food and Drug Administration to produce VAL-083 for the China market. We have obtained certain exclusive commercial rights to VAL-083 in China where it is approved as a chemotherapy for the treatment of chronic myelogenous leukemia (“CML”) and lung cancer. This agreement potentially positions us to generate future royalty revenue through product sales or royalties for its approved indications in China while we seek global approval in new indications.

We have filed a broad portfolio of patent applications to protect our intellectual property. Our patent applications claim compositions and methods of use of VAL-083 and related compounds, synthetic methods, and quality controls for the manufacturing process of VAL-083. We believe that our portfolio of intellectual property rights provides a defensible market position for the commercialization of VAL-083. In addition, VAL-083 has been granted protection under the Orphan Drug Act by the FDA and the European Medicines Agency (“EMA”) for the treatment of glioma, including GBM. In 2016, the FDA also granted Orphan Drug protection to VAL-083 for the treatment of medulloblastoma and ovarian cancer.

Our drug discovery research focuses on identifying well-validated preclinical, clinical and commercial-stage compounds and establishing a scientific rationale for development in cancer indications for patients whose tumors exhibit features that make them resistant to, or unlikely to respond to, currently available therapies. Through our relationship with Valent Technologies, LLC (“Valent”), a company owned by Dr. Dennis Brown, our Chief Scientific Officer, we are able to utilize Valent’s proprietary ChemEstate bioinformatics tools to screen and identify potential candidates. Promising candidates are further researched through our network of consultants, academic centers, and contract research organizations. This approach allows us to identify and advance potential drug candidates without significant investment in “wet lab” infrastructure. Based on this strategy, we acquired the initial VAL-083 intellectual property and prototype drug product from Valent and advanced into Phase 2 and 3 clinical trials and have also identified additional drug candidates that we may have the opportunity to license or acquire in the future.

Our corporate development strategy is to advance our lead candidate into registration-directed clinical trials and then to consider licensing or acquiring additional product candidates in order to establish a product pipeline and position for long-term sustainability and growth of shareholder value. We believe the experience of our clinical development team will position us to efficiently develop drug candidates that we may acquire, or license in the future.

We plan to seek marketing partnerships to supplement our own commercialization efforts and potentially generate future royalty revenue.



## Recent Highlights

In April and September 2017, we completed offerings of common stock and warrants for aggregate gross proceeds of approximately \$19.0 million. We intend to use the net proceeds of these offerings for our clinical trials and for general corporate purposes, which may include working capital, capital expenditures, research and development and other commercial expenditures. In addition, we may use the net proceeds from these offerings for acquisitions or investments in businesses, products or technologies that are complementary to our business.

In July 2017, we initiated patient recruitment for the STAR-3 pivotal Phase 3 clinical trial of VAL-083 in refractory GBM and expect to enroll our first patient as soon as practicable.

In September 2017, we initiated patient recruitment for an open label Phase 2 clinical trial of VAL-083 in newly diagnosed patients MGMT-unmethylated GBM, which is being conducted with funding support through our collaboration with Guangxi Wuzhou Pharmaceutical (Group) Co. Ltd. This trial complements our ongoing open label Phase 2 clinical trial in patients with MGMT-unmethylated GBM whose tumors have recurred following treatment with temozolomide (bevacizumab naïve), which is being conducted in collaboration with the University of Texas MD Anderson Cancer Center.

In September 2017, we received notice of allowance from the FDA for our Phase 1-2 VAL-083 REPROVe clinical trial in Pt-resistant ovarian cancer. We will seek to initiate the REPROVe trial as soon as practicable, subject to negotiating acceptable clinical research agreements and budgets with clinical investigators and their institutions and obtaining IRB approvals.

We presented promising research results supporting the potential of VAL-083 in the treatment of a range of cancers for patients whose tumors exhibit features making them resistant to, or unlikely to respond to, currently available therapies. For example:

We presented data supporting the effectiveness of VAL-083 in the treatment of GBM at the annual meetings of the American Society for Clinical Oncology (“ASCO”), the American Association of Cancer Research (“AACR”), the World Federation of NeuroOncology Societies (“WFNOS”), the European Association for NeuroOncology and the Society for NeuroOncology (“SNO”);

We presented data supporting the effectiveness of VAL-083 in the treatment of lung cancer at the AACR Annual Meeting, the 17<sup>th</sup> World Congress on Lung Cancer and the AACR New Horizons in Cancer Research Conference;

We presented data supporting the activity of VAL-083 in treatment-resistant medulloblastoma both as a single agent and in combination with topoisomerase inhibitors at the SNO Pediatric Oncology Symposium and at the AACR Advances in Pediatric Research: From Mechanisms and Models to Treatment and Survivorship Conference; and

We presented data supporting the effectiveness of VAL-083 against chemotherapy-resistant ovarian cancers at the 11<sup>th</sup> Biennial Ovarian Cancer Research Symposium.

We continued to strengthen and expand our network of research collaborations with leading academic institutions including the announcement of a major sponsored research agreement with Duke University to evaluate VAL-083 as a front-line treatment for newly diagnosed patients with GBM.

We continued to strengthen our intellectual property portfolio. DelMar now holds eight issued US patents and eight issued patents outside of the US. We have fourteen patent families in various stages of prosecution, and over 100 patent filings in total.

We strengthened our Board of Directors and corporate governance with the addition of Saiid Zarrabian and the appointment of Dr. Erich Mohr as independent chairman.

### ***VAL-083***

Our product candidate VAL-083 is a “first-in-class” small molecule chemotherapeutic, which means that the molecular structure of VAL-083 is not an analogue or derivative of a product approved, or in development for the treatment of cancer. VAL-083 is a DNA-targeting agent that was originally discovered in the 1960’s. It was assessed in more than 40 NCI-sponsored Phase 1 and Phase 2 clinical trials as a treatment against various cancers including lung, brain, cervical, ovarian tumors and leukemia. Published preclinical 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 CML and lung cancer. VAL-083 has not been approved for any indications outside of China.

Our research demonstrates that the mechanism of action of VAL-083 is distinct from other DNA-targeting agents used in the treatment of cancer. VAL-083 exhibits its anti-cancer activity by forming DNA-cross links leading to DNA double strand breaks, cell-cycle arrest and cancer cell death. DNA-targeting agents are among the most widely used treatments for cancer. They exhibit anti-cancer effects by binding to DNA and interfering with normal processes within the cancer cell which prevents the cell from making the proteins needed to grow and survive. We have presented research at peer-reviewed scientific meetings demonstrating that VAL-083 is active in patient-derived tumor cell lines and cancer stem cells that are resistant to other chemotherapies. These data, combined with clinical activity demonstrated against various cancers in prior NCI-sponsored clinical trials gives us confidence that VAL-083 may offer an opportunity as a new treatment option for patients whose tumors are resistant to currently available chemotherapies.

We are currently studying VAL-083 in clinical trials for the treatment of GBM, the most common and aggressive form of brain cancer. We have also recently received notice of allowance from the FDA for an IND to initiate clinical trials with VAL-083 in the treatment of ovarian cancer. Upon obtaining regulatory approval, we intend to commercialize VAL-083 for the treatment of orphan cancer indications such as refractory GBM. We also plan to seek collaborative development and commercialization partnerships to accelerate and expand the development of VAL-083 in newly diagnosed GBM and other non-orphan cancer indications.

The FDA Office of Orphan Products Development (“OOPD”) has granted orphan drug designations to VAL-083 for the treatment of glioma, ovarian cancer and medulloblastoma. VAL-083 has also been granted an orphan drug designation for in the treatment of glioma in Europe. Orphan diseases are defined in the United States under the Rare Disease Act of 2002 as “any disease or condition that affects fewer than 200,000 persons in the United States”. The Orphan Drug Act of 1983 is a federal law that provides financial and other incentives including a seven-year period of market exclusivity in the United States to encourage the development of new treatments for orphan diseases.

### ***VAL-083 Mechanism of Action and the Opportunity in the Treatment of Cancer***

Chemotherapy forms the basis of treatment in nearly all cancers. We believe that VAL-083 may be effective in treating cancer patients whose tumors exhibit features that cause resistance to currently available chemotherapy or that have failed, or become resistant to, other chemotherapies.

Our research suggests that VAL-083 attacks cancer cells via a unique mechanism of action which is distinct from other chemotherapies used in the treatment of cancer. Our data indicate that VAL-083 forms interstrand crosslinks at the N<sup>7</sup> position of guanine on the DNA of cancer cells. Our data also indicate that this crosslink forms rapidly and is not easily repaired by the cancer cell resulting in cell-cycle arrest and lethal double-strand DNA breaks in cancer cells. VAL-083 readily crosses the blood brain barrier. Published preclinical and clinical research demonstrate that VAL-083 is absorbed more readily in tumor cells than in normal cells.

Based on published research and our own data, the cytotoxic functional groups and the mechanism of action of VAL-083 are understood to be functionally different from alkylating agents commonly used in the treatment of cancer. 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.

Our data also demonstrate that VAL-083's distinct mechanism may be able to overcome drug resistance against a range of cancers *in vitro*. For example, VAL-083 is active against MGMT-unmethylated GBM cells which are resistant to treatment with temozolomide and nitrosoureas. VAL-083 also retains a high level of activity in p53 mutated non-small cell lung cancer ("NSCLC"), ovarian cancer and medulloblastoma cell lines that are resistant to platinum-based chemotherapy.

Importantly, clinical activity against each of the tumors mentioned above was established in prior NCI-sponsored Phase 2 clinical trials. We believe that these historical clinical data and our own research support the development of VAL-083 as a potential new treatment for multiple cancers.

The main dose-limiting toxicity (“DLT”) related to the administration of VAL-083 in previous NCI-sponsored clinical studies and our own clinical trials is myelosuppression, particularly thrombocytopenia. Myelosuppression is the decrease in cells responsible for providing immunity, carrying oxygen, and causing normal blood clotting. Thrombocytopenia is a reduction in platelet counts, which assist in blood clotting. Myelosuppression and thrombocytopenia are common side effects of chemotherapy. There is no evidence of lung, liver or kidney toxicity even with prolonged treatment by VAL-083. Data from the Chinese market where the drug has been approved for more than 15 years supports the safety findings of the NCI studies.

Modern medicine allows for better management of myelosuppressive side effects. We believe this offers the potential opportunity to improve upon the drug’s already established efficacy profile by substantially increasing the dose of VAL-083 that can be safely administered to cancer patients.

### ***Gliomas and Glioblastoma Multiforme (“GBM”)***

Worldwide, there are an estimated 240,000 new cases of brain and central nervous system (“CNS”) tumors each year. Gliomas are a type of CNS tumor that arises from glial cells in the brain or spine. Glial cells are the cells surrounding nerves. Their primary function is to provide support and protection for neurons in the CNS.

GBM is the most common and the most lethal form of glioma. According to the World Health Organization, GBM occurs with an incidence of 3.17 per 100,000 person-years. Approximately 18,000 new cases of GBM are expected to be diagnosed in the United States and 26,000 in Europe during 2017.

GBM progresses quickly and patients’ conditions deteriorate rapidly progressing to death in less than two years for most patients. Common symptoms include headaches, seizures, nausea, weakness, paralysis and personality or cognitive changes such as loss of speech or difficulty in thinking clearly. The median survival in newly diagnosed patients with best available treatments is less than 15 months.

Standard treatment following diagnosis includes surgical resection to remove as much of the tumor as possible (“debulking”) followed by radiotherapy with concomitant and adjuvant chemotherapy with Temodar® (temozolomide “TMZ”). The outlook for GBM patients is generally poor, with a one-year survival rate of approximately 25% and a five-year survival rate of less than 3%.

Avastin® (bevacizumab, an anti-VEGF antibody) is approved as a single agent for patients with recurrent GBM following prior therapy in the US, Canada, Australia and Japan. Avastin® carries a “black-box warning” related to severe, sometimes fatal, side effects such as gastrointestinal perforations, wound healing complications and hemorrhage. There are no data demonstrating an improvement in disease-related symptoms or increased survival in refractory GBM with Avastin®.

TMZ and the nitrosoureas, including carmustine, lomustine, and nimustine, are alkylating agents that readily cross the blood-brain-barrier and are used in the treatment of CNS cancers, including GBM. Alkylating agents are among the oldest type of cancer chemotherapies in use today. Alkylating agents bind to DNA to cause damage to cancer cells. Their anti-tumor mechanism is via alkylation of DNA resulting in base-pair mismatch or strand-mediated crosslinks between base pairs. The DNA damage caused by alkylating agents mimics naturally occurring errors, resulting in apoptosis and tumor cell death.

The primary anti-cancer mechanism of TMZ and the nitrosoureas is to attack the tumor’s DNA via alkylation of the O<sup>6</sup>-position of the DNA base residue, guanine. TMZ treatment causes DNA damage mainly by methylation at the O<sup>6</sup>-position of guanine resulting in guanine-thymine base pair mismatches during replication. Nitrosoureas mediate their cytotoxic effect by methylation at the O<sup>6</sup>-position of guanine which produces a cross-link to cytosine residues resulting in double-strand DNA breaks during mitosis.

A majority of GBM patients’ tumors are resistant to TMZ or nitrosourea therapy due to high expression of a naturally occurring enzyme called O<sup>6</sup>-DNA methylguanine methyl-transferase (“MGMT”) which repairs O<sup>6</sup>-guanine lesions. MGMT repair in turn inhibits the activity of TMZ and nitrosoureas and allows a patients’ GBM tumor to continue to grow in spite of treatment.

Consistent with the importance of its repair activity, high expression of MGMT is strongly correlated with poor patient outcomes. Several clinical studies have established that MGMT is an important prognostic biomarker of response to TMZ and patient survival.

**Probability of GBM Patient Survival Correlated to Expression of MGMT Enzyme**

**(Unmethylated promoter = High MGMT Expression and Significantly Shorter Survival)**

***VAL-083 in GBM***

VAL-083 is first-in-class DNA targeting agent that readily crosses the blood-brain-barrier. Data from prior NCI-sponsored clinical trials with VAL-083 demonstrate activity against GBM and other central nervous system tumors. In general, historical NCI-sponsored trials demonstrate that tumor regression in brain cancer was achieved in 40% of patients treated and stabilization was achieved in an additional 20% to 30% of brain tumor patients following treatment with VAL-083.

VAL-083 demonstrated statistically significant improvement in the median survival of high grade glioma brain tumors, including GBM when combined with radiation versus radiation alone (p value = <0.05) with results similar, or superior to, other chemotherapies approved for the treatment of GBM.

**A Summary of Published Data adapted from Separate Sources Comparing the Efficacy of VAL-083 and Other Therapies in the Treatment of GBM**

Chemotherapy <b>VAL-083</b>	Comparative Therapy		Median Survival Benefit vs. <b>XRT alone</b>
	Radiation (XRT) Alone	Radiation + Chemotherapy	
<i>(Eagan 1979)</i>	<b>8.4 months</b>	16.8 months	8.4 months
Temozolomide (Temodar®)	12.1 months	14.6 months	2.5 months
<i>(Stupp 2005)</i>			
Lomustine (CCNU) <i>(Walker 1976)</i>	11.8 months	13 months	1.2 months
	10 months	12.5 months	2.5 months

Carmustine (BCNU)  
*(Reagan 1976)*  
Semustine (ACNU)  
*(Takakura 1986)*

12 months

14 months

2.0 months



Our research demonstrates that VAL-083's unique cytotoxic mechanism forms DNA cross-links at the N<sup>7</sup> position of guanine and retains cytotoxic activity independent of MGMT expression *in vitro*. This mechanism is distinct from that of temozolomide and nitrosoureas, which are DNA-targeting agents commonly used in the treatment of GBM. Of particular importance is in the treatment of GBM resistance to temozolomide, or nitrosoureas, due to activity of the repair enzyme MGMT, which results in chemoresistance in many GBM patients.

We have presented data demonstrating that VAL-083 is active independent of MGMT resistance in laboratory studies. VAL-083 has more potent activity against brain tumor cells in comparison to TMZ and overcomes resistance associated with MGMT, suggesting the potential to surpass the current standard-of-care in the treatment of GBM.

**A Summary of Our Data Demonstrating that VAL-083's Anti-Tumor Mechanism is Distinct from, and can Overcome, MGMT-Related Chemoresistance in the Treatment of GBM**

In addition, historical NCI clinical trial data and our own research support the activity of VAL-083 as a potentiator of radiotherapy. Radiotherapy in combination with temozolomide is the current standard of care in the treatment of GBM. Our research demonstrates that temozolomide and radiotherapy are ineffective against GBM cells exhibiting a high expression of MGMT, whereas VAL-083 potentiates the tumor-killing effect of radiation in these cells. Furthermore, the combination of VAL-083 and radiation has been demonstrated to be active against GBM cancer stem cells (CSCs) in vitro. CSCs are often resistant to chemotherapy and form the basis for tumor recurrence and metastasis. GBM CSCs display strong resistance to TMZ, even where MGMT expression is low. However, our data demonstrates that GBM CSCs are susceptible to VAL-083 independent of MGMT expression.

We believe that VAL-083's more potent activity against brain tumor cells in comparison to TMZ, the ability to overcome MGMT-mediated resistance, and activity against GBM cancer stem cells suggests the potential of VAL-083 to surpass the current standard-of-care in the treatment of GBM.

Based on our research demonstrating a novel anti-tumor mechanism and the historical clinical data demonstrating activity against GBM, we have initiated clinical trials in refractory GBM and in MGMT-unmethylated GBM. Our clinical trials in the United States are being conducted under investigational new drug ("IND") applications filed with the FDA. If successful, we believe data from these trials will support a potential paradigm shift in the treatment of GBM where VAL-083 could become the chemotherapy of choice in the treatment of the majority of GBM patients.

### **Clinical Trials of VAL-083 in Refractory GBM**

#### *Phase 3: VAL-083 STAR-3 GBM Trial*

The recently initiated VAL-083 STAR-3 GBM trial is an adaptive, randomized, controlled pivotal Phase 3 clinical trial in patients with refractory GBM. The trial is designed to assess the efficacy and safety of VAL-083 versus salvage therapy in GBM patients whose disease has progressed following prior treatment with temozolomide and bevacizumab. There is currently no approved standard-of-care therapy for these patients.

A total of up to 180 eligible patients will be randomized at approximately 25 centers in the United States to receive either the investigational drug (VAL-083) or "investigator's choice salvage therapy" in a 2:1 fashion. Up to 120 eligible patients will be randomized to receive intravenous VAL-083 at 40 mg/m<sup>2</sup> on days 1, 2, and 3 of a 21-day treatment

cycle, for up to 12 21-day treatment cycles or until they fulfill one of the criteria for study discontinuation.

Up to 60 patients will be randomized to “investigator’s choice” control, limited to temozolomide, lomustine, or carboplatin, until they fulfill one of the criteria for study discontinuation.

The primary endpoint of the STAR-3 trial is overall survival. The statistical design between the two arms of the study is 90% power, and includes an interim analysis at 50% of events for futility and superiority with O’Brien-Fleming boundary and non-binding, gamma (-5) futility boundary. We have based our assumptions for outcomes for the STAR-3 control arm on published literature. We are also undertaking a review of recent patient data to validate our control arm assumptions. In the event that this analysis suggests that a more conservative assumption is required, we may consider revising the trial design to maintain 90% power for the primary endpoint.

The study is estimated to complete in approximately two years from initiation. A detailed description of the STAR-3 trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov), Identifier Number: NCT03149575.

Phase 1 – 2 Clinical Trial Overview and Summary of Results

Forty-eight GBM patients were enrolled in our Phase 1/2 clinical trial at five centers: the Mayo Clinic in Rochester, Minnesota; the Brain Tumor Center at University of California, San Francisco; the Sarah Cannon Cancer Research Center in Nashville, Tennessee, Denver, Colorado; and the SCRI affiliate site at the Florida Cancer Specialist Research Institute in Sarasota, Florida.

The Phase 1/2 trial was an open-label, single arm dose-escalation study designed to evaluate the safety, tolerability, pharmacokinetics and anti-cancer activity of VAL-083 in patients with refractory GBM. The trial enrolled GBM patients whose disease has progressed following prior treatment with temozolomide and bevacizumab, unless either or both were contra-indicated.

The overall goal of our Phase 1/2 clinical trial was to determine a modernized dosing regimen for advancement into a pivotal registration-directed Phase 3 clinical trial.

Patients received VAL-083 on days 1,2 and 3 on a 21-day treatment cycle. The Phase 1 portion of the study involved dose escalation cohorts until a maximum tolerated dose (“MTD”) was established at 40mg/m<sup>2</sup> further 14-patient, Phase 2 expansion was then enrolled at the MTD to gather further safety data at our chosen therapeutic dose and to further explore the outcomes in this patient population.

In May 2016, we held an end of Phase 2 meeting with the FDA where design of a Phase 3, registration-directed clinical program for VAL-083 in refractory GBM was discussed. Based on the input we received from the FDA, the agency confirmed that it would consider the totality of data available, including data obtained from DelMar’s other planned clinical trials in related GBM populations, when assessing the New Drug Application (“NDA”). The FDA also noted that DelMar can rely on prior NCI studies and historical literature to support nonclinical data required for an NDA filing and that DelMar will have the option to file under a 505(b)(2) strategy which allows a sponsor to rely on already established safety and efficacy data in support of an NDA.

We reported updated results of our Phase 1/2 clinical trial at the 2016 ASCO annual meeting. In summary, these data are as follows:

Tumor Response and Outcomes

GBM patients in our Phase 1/2 clinical trial were not re-resected prior to treatment with VAL-083 and therefore had a growing recurrent GBM tumor at the time of enrollment. Patients were monitored for tumor response by MRI.

Consistent with un-resected refractory GBM, median progression free survival (“PFS”) was short at 1.2 months (range: 0.2 – 20.1 months). Five GBM patients treated with VAL-083 were reported to have stable disease as their best response following treatment; the remainder reported progressive disease.

Disease progression is typical in a refractory GBM population with non-resected tumors. However, we believe that slowed progression may provide meaningful clinical benefit in this patient population through prolonged overall survival and improved quality of life. According to published literature, GBM patients failing bevacizumab have a poor prognosis with expected survival under five months.

Ad-hoc subgroup analysis of the Phase 1 dose-escalation data indicated a dose response trend. Increased survival was observed following initiation of treatment in a high dose (30 and 40mg/m<sup>2</sup>, n=9) sub-group vs. a low dose (≤5mg/m<sup>2</sup>, n=6) sub-group with median survival of >9 months vs. 4.4 months for the high and low dose groups, respectively.

### Observed Survival Based on Phase 1 Sub-Group Analysis

An additional 14 patients were enrolled in an expansion cohort at the MTD (40mg/m<sup>2</sup>). Analysis of patients receiving an assumed therapeutic dose of VAL-083 (≥20mg/m<sup>2</sup>) demonstrated median survival of 8.35 months following bevacizumab failure. At the time of the analysis, more than half of patients receiving an assumed therapeutic dose survived more than six months following bevacizumab failure; more than 40% survived for nine months or are currently alive and more than 20% have survived for twelve months or more.

### ASCO 2016: VAL-083 compared to published literature

Reference	Post Avastin Salvage Therapy	Median Survival following Bevacizumab Failure
<b>Shih (2016)</b>	VAL-083	8.35 months
Rahman (2014)	nitrosourea	4.3 months
Mikkelsen (2011)	TMZ + irinotecan	4.5 months
Lu (2011)	dasatinib	2.6 months
Reardon (2011)	etoposide	4.7 months
Reardon (2011)	TMZ	2.9 months
Iwamoto (2009)	various	5.1 months

While recognizing these data are representative of a relatively small, non-controlled Phase 1/2 clinical trial, we believe these outcomes support the potential of VAL-083 to offer meaningful clinical benefit to GBM patients who have failed bevacizumab, compared to currently available therapy.

Safety and Tolerability

In the Phase 1 dose escalation regimen, no serious adverse events (“SAE”) related to VAL-083 were encountered at doses up to 40 mg/m<sup>2</sup>/day.

Increasing frequency of, and higher grade, hematologic toxicities were observed at doses above 40 mg/m<sup>2</sup>/day. Consistent with the published literature, the observed dose limiting toxicity for VAL-083 is primarily thrombocytopenia (low platelets). Observed platelet nadir occurred at approximately day 18, and recovery was rapid and spontaneous following treatment.

Based on Phase 1 observations, fourteen additional patients were enrolled in a Phase 2 expansion cohort at 40mg/m<sup>2</sup>, which was established as the MTD. Consistent with Phase 1, the dose of VAL-083 of 40 mg/m<sup>2</sup> on days 1, 2 and 3 of a 21-day cycle was generally well tolerated in Phase 2. At this dose, one subject previously treated with CCNU, a nitrosourea agent, reported severe (Grade 4) thrombocytopenia. As a result of this observation, the protocol inclusion criterion for platelet count was increased from 100,000/ $\mu$ L to 150,000/ $\mu$ L for patients receiving prior nitrosoureas within 12 weeks preceding enrollment. No other dose limiting toxicities were observed in Phase 2.

**VAL-083 Safety Observations From Phase 1/2 Clinical Trial**

Hematologic parameter and CTCAE grade	dose	≤30 mg/m <sup>2</sup>		40 mg/m <sup>2</sup>		45 mg/m <sup>2</sup>		50 mg/m <sup>2</sup>	
		n =							
Anemia	n =	20		17		4		7	
	≤G2	11	55 %	2	12 %	2	50 %	6	86 %
	G3	2	10 %	-	0 %	-	0 %	-	0 %
	G4	-	0 %	-	0 %	-	0 %	-	0 %
Leukopenia	≤G2	5	25 %	2	12 %	-	0 %	5	71 %
	G3	1	5 %	-	0 %	-	0 %	3	43 %
	G4	-	0 %	-	0 %	2	50 %	-	0 %
Neutropenia	≤G2	4	20 %	-	0 %	-	0 %	-	0 %
	G3	-	0 %	-	0 %	-	0 %	3	43 %
	G4	-	0 %	-	0 %	2	50 %	1	14 %
Thrombocytopenia	≤G2	9	45 %	3	18 %	-	0 %	3	43 %
	G3	-	0 %	-	0 %	1	25 %	3	43 %
	G4	-	0 %	1	6 %	2	50 %	1	14 %
DLT Observed			nil		1		2		2

Doses Achieved

We confirmed that we achieved doses of VAL-083 that are substantially higher than were utilized in the original published NCI-sponsored clinical trials. A summary in comparison to the NCI’s historical regimen is as follows:

Dosing Regimen & Study	Single Dose	Acute Regimen (single cycle)	Comparative Cumulative Dose (@ 35 days)	Dose Intensity (dose per week)
NCI GBM historical regimen (Eagan et al) daily x 5 q 5wks	25 mg/m <sup>2</sup>	x5 days = 125 mg/m <sup>2</sup>	125 mg/m <sup>2</sup>	25 mg/m <sup>2</sup> /wk



(cycle = 35 days)

DelMar VAL-083 optimized regimen daily x 40 mg/m<sup>2</sup> x3 days 120 240 mg/m<sup>2</sup> 40  
 3 q 3wks (cycle = 21 days) = mg/m<sup>2</sup> mg/m<sup>2</sup> mg/m<sup>2</sup>/wk

*Daily x 5 q 5wks refers to a dosing regimen of once per day for five consecutive days every five weeks (35-day cycle); while daily x 3 q 3wks refers to a dosing regimen of once per day for three consecutive days every three weeks (21-day cycle).*

Our optimized dosing regimen increases the amount of VAL-083 delivered to the CNS by 60% over historical regimens without increased toxicity. Thus, the DelMar regimen achieves both a higher maximum concentration and higher overall exposure, which we believe may increase the likelihood of successful treatment outcomes in glioblastoma and other brain tumors.

Pharmacokinetics

Pharmacokinetic (“PK”) analyses showed dose-dependent linear systemic exposure with a short (1-2h) plasma terminal half-life; average C<sub>max</sub> at 40 mg/m<sup>2</sup>/day was 781 ng/mL (5.3µM). The observed PK profile is comparable to published literature. Prior NCI-sponsored studies demonstrated that VAL-083 readily crosses the blood brain barrier and has a long (>20 hour) half-life in the central nervous system (“CNS”).

We believe that this PK profile is optimal for the treatment of brain tumors: A long CNS half-life is expected to maximize exposure of the drug in the brain increasing the likelihood of successful treatment outcomes, while a short plasma half-life is desirable to minimize systemic side effects.

**Observed pharmacokinetics from VAL-083 Phase 1 clinical trial dose vs. AUC**

Based on observed and previously published pharmacokinetics, DelMar believes that therapeutic doses equal to, or above, 20 mg/m<sup>2</sup> daily on days 1, 2 and 3 of a 21-day cycle should deliver sufficient levels of VAL-083 to brain tumors to achieve a therapeutic benefit.

MGMT & IDH1

High expression of MGMT and wild-type form of the enzyme isocitrate dehydrogenase (“IDH1”) have been previously shown to be diagnostic markers that correlate with resistance to currently available chemotherapies (e.g. temozolomide or nitrosourea) in the treatment of GBM and poor patient outcomes. Measurement of these biomarkers has become routine in clinical practice.

Notably, we have previously demonstrated that VAL-083’s anti-tumor mechanism is active independent from the MGMT status *in vitro*. While the science behind their importance in the disease pathway and their ultimate predictive value are still being explored, we believe we will ultimately be able to use such biomarkers in a prognostic fashion to select the patients most likely to respond to treatment as we expand the clinical development of VAL-083.

MGMT expression was characterized by PCR and/or ELISA for nineteen GBM patients enrolled in our Phase 1/2 study. IDH1 status was reported in eleven patients; both MGMT and IDH1 status were reported in four patients.

Biomarker	Observation in Phase 1/2 clinical trial
High MGMT (n=19)	84%
IDH-WT (n=11)	90%

Notably, all patients whose samples were tested for both markers were MGMT-unmethylated by PCR and wild-type IDH1, a phenotype that is correlated with particularly poor prognosis.

### **Clinical Trials of VAL-083 in MGMT-unmethylated GBM**

MGMT methylation status has been previously shown to be a diagnostic marker that correlates with patient outcomes and survival in GBM. GBM patients whose tumors are characterized as MGMT-unmethylated exhibit high expression of the DNA-repair enzyme MGMT. High MGMT levels have correlated resistance to currently available chemotherapies (e.g. temozolomide or nitrosourea) and significantly reduced survival. The development of new therapies for MGMT-unmethylated GBM is a significant unmet medical need.

Approximately two-thirds of newly diagnosed GBM patients have tumors assessed as MGMT-unmethylated. This represents a potential treatment population of approximately 12,000 patients in the United States and 18,000 patients in Europe annually.

Notably, we have previously demonstrated that VAL-083's anti-tumor mechanism is active independent from the MGMT status *in vitro*. This suggests the potential of VAL-083 as a replacement for currently available chemotherapies in MGMT-unmethylated GBM.

Measurement of MGMT methylation status has become routine in clinical practice. We can therefore utilize MGMT-methylation status to identify newly diagnosed GBM patients who are least likely to respond to temozolomide and instead treat them with VAL-083.

We have initiated two Phase 2 clinical trials to explore the potential of VAL-083 in the treatment of MGMT-unmethylated GBM. Expenditures related to our ongoing clinical trials in MGMT-unmethylated GBM are substantially supported through collaborations, which allows us to implement these protocols with minimal impact to our own working capital balance.

#### **Phase 2 Trial in Newly Diagnosed MGMT-unmethylated GBM**

In September 2017, we initiated a single arm, biomarker driven open-label Phase 2 study in newly diagnosed MGMT-unmethylated GBM patients at Sun Yat-sen University Cancer Center in Guangzhou, China. The trial is being conducted in the context of our 2012 collaboration agreement with Guangxi Wuzhou Pharmaceutical (Group) Co. Ltd. Under the terms of this agreement, Guangxi Wuzhou Pharmaceutical (Group) Co. Ltd. is responsible for funding VAL-083 clinical trials that we conduct in China.

In this study, VAL-083 will be combined with radiotherapy as a potential replacement for temozolomide in patients with high expression of MGMT. The main goal of the trial will be to confirm the safety of DelMar's optimized dosing regimen in combination with radiotherapy and to investigate outcomes of the combination of VAL-083 and radiotherapy in MGMT-unmethylated GBM patients.

Up to 30 newly diagnosed MGMT-unmethylated GBM patients will be enrolled in this trial. The primary efficacy endpoint is the determination of tumor response in patients measured by progression free survival. Assessments of safety and tolerability will be used to support further clinical development of VAL-083 in combination with radiotherapy. Pharmacokinetic assessments of VAL-083 in plasma and cerebral spinal fluid ("CSF") will be used to correlate drug exposure in the central nervous system with patient outcomes.

Outcomes following treatment with VAL-083 will be compared to MGMT-unmethylated patients in the RTOG0525 trial. We anticipate obtaining safety data from the trial within nine months and top-line outcomes data within 18 months from the commencement of patient enrollment.

Data from the trial will be used to establish a dosing regimen and trial design for advanced registration-directed clinical trials with VAL-083 in newly diagnosed MGMT-unmethylated GBM. If successful, data from the trial will strongly position VAL-083 as a potential replacement for current standard-of-care chemotherapy in the treatment of GBM.

*Phase 2 Study in Recurrent MGMT-unmethylated GBM in Collaboration with University of Texas MD Anderson Cancer Center*

In January 2017, we initiated a biomarker driven, open-label single-arm Phase 2 study in collaboration with the University of Texas with MD Anderson Cancer Center. This trial will enroll up to 48 MGMT-unmethylated GBM patients whose tumors have recurred following treatment with temozolomide. These patients will not have been treated with prior bevacizumab.

The primary endpoint of the trial is overall survival. Outcomes following treatment with VAL-083 will be compared to the outcome of MGMT-unmethylated patients who had been treated with lomustine (CCNU) following temozolomide failure in the recently published EORTC20601 trial.

Safety data from this trial will become part of the overall safety dossier to support future filings with the FDA and other regulatory agencies. A positive outcome will establish a strong position for VAL-083 in the treatment of MGMT-unmethylated GBM.

We anticipate presenting interim data from this trial at peer reviewed meetings during calendar 2018.

## **Ovarian Cancer**

Ovarian cancer is the fifth most common cancer in women and is the leading cause of death among women diagnosed with gynecological malignancies. In 2016, approximately 22,300 women in the US were diagnosed with ovarian cancer and 14,300 died from their disease. If detected early, ovarian cancer can often be cured with surgery. When detected early, up to 90% of patients are likely to survive for >5 years.

Unfortunately, the initial symptoms of ovarian cancer such as abdominal bloating, indigestion, pelvic pain or nausea are often attributed to symptoms caused by less a serious situation. Therefore, in most cases, ovarian cancer isn't diagnosed until it has progressed to an advanced stage when it is no longer possible to surgically remove all tumor tissue.

Without treatment, ovarian cancer spreads within the pelvic region and metastasizes to distant sites such as the lungs, liver, spleen and, rarely, the brain. When diagnosed at an advanced stage the 5-year survival rate is less than 40%. Women with ovarian cancer receive chemotherapy following surgery to treat residual disease.

Pt-based chemotherapy is the standard-of-care in the treatment of advanced ovarian cancer. Ovarian cancer patients whose tumors are sensitive to Pt-based chemotherapy have the most favorable outcome. Recently, the approval of PARP inhibitors in the treatment of ovarian cancer patients demonstrated improved outcomes, particularly patients whose tumors remain sensitive to Pt-based treatments.

Unfortunately, the development of resistance to Pt-based agents is nearly inevitable, leading to disease recurrence and increased mortality. Ultimately, most women with advanced ovarian cancer develop recurrent disease with progressively shorter disease-free intervals. Those whose tumors recur within 6 months of Pt-based therapy are considered Pt-resistant/refractory and have a very poor prognosis.

Currently, there are no high-efficacy therapeutic options for Pt-resistant ovarian tumors, leaving these cancer patients with a very poor prognosis. The response rate to second line therapy for Pt-resistant ovarian cancer patients is in the 10-15% range and overall survival is approximately 12-months. The development of new chemotherapies and targeted agents to overcome Pt resistance in ovarian cancer is a significant unmet medical need.

#### *Treatment Resistance to Pt-based Chemotherapy in Ovarian Cancer*

Pt-based chemotherapy is employed in the treatment of nearly 50% of all cancer patients. Treatment guidelines published by the National Comprehensive Cancer Network (“NCCN”) recommend Pt-based chemotherapy as a component of treatment against a range of solid tumors including but not limited to bladder, breast, cervical, colorectal, head-and-neck and testicular cancer. Pt-based chemotherapy is used to treat nearly all advanced-stage ovarian cancer patients.

Pt-based chemotherapies function by causing extensive damage to a cancer cell's DNA. When a cell is ready to divide, cellular mechanisms assess potential DNA damage, and if severe damage is identified, the cell will halt the division process and may even be directed to self-destruct. Thus, chemotherapies that target DNA are intended to be lethal to cancer cells, or at least prevent them from dividing to inhibit a tumor's growth.

Unfortunately, cancer cells are adept at overcoming DNA damage or employing mechanisms to repair damaged DNA. These factors limit the damage that DNA-damaging drugs can do or allow cancer cells to become resistant to chemotherapy. One of the most common obstacles to DNA-damaging chemotherapy is mutations to a gene called p53. Cellular processes governed by the p53 gene are critical in assessing DNA damage and determining if a cell should cease from dividing or self-destruct. When p53 does not function properly, cancer cells continue to divide despite the treatment with DNA-damaging chemotherapy, making these drugs ineffective and leading to treatment resistance. This occurs in nearly all cases of the most difficult ovarian cancer to treat – high grade serous ovarian cancer (HGSOC) – which accounts for up to 70% of ovarian cancer cases and approximately 90% of ovarian cancer deaths. P53 mutations are associated with resistance to Pt-based chemotherapy, which leads to treatment failure and increased mortality. Solving this problem is a major goal in the development of new treatments for ovarian cancer.

### **VAL-083 in Ovarian Cancer**

VAL-083 is a first-in-class, DNA-targeting agent that demonstrated activity in prior NCI-sponsored clinical trials. Activity against ovarian epithelial adenocarcinoma (“OEA”) and squamous cell carcinoma of the cervix (“SCC”) was reported in multiple studies. Importantly, NCI-researchers recommended VAL-083 for further advanced studies in the treatment of ovarian cancer.

We have presented data demonstrating that VAL-083's distinct mechanism of action allows activity in tumors that are resistant to other therapies. We have shown that cytotoxicity of VAL-083 against ovarian cancer is independent of sensitivity to cisplatin or p53 status *in vitro*. We have demonstrated that VAL-083 is active in Pt-resistant ovarian cells harboring a range of p53-mutations. Similar results were observed comparing activity of VAL-083, cisplatin and oxaliplatin in Pt-sensitive and -resistant non-small cell lung cancer (“NSCLC”) cell lines.

Our research has demonstrated that VAL-083 not only overcomes Pt resistance, but the combination of VAL-083 with Pt-based chemotherapy displays synergy in multiple models *in vitro* and *in vivo*. This further suggests a distinct mechanism of action and potential use as part of a VAL-083/Pt-combination therapy.





The combination of VAL-083 with either cisplatin (**A**) or oxaliplatin (**B**) in the human H460 (WT p53) NSCLC model demonstrated significant superadditivity ( $p \leq 0.05$ ) and/or synergism ( $CI < 1$ ) for both combinations. This cytotoxic effect of VAL-083 in combination with either platinum drug was observed also in A549 (WT p53) and H1975 (mutant p53) NSCLC cells, independently of p53 status (not shown). Data, where applicable, are shown as mean  $\pm$  SE; N=7.

While Pt-based chemotherapy is the standard treatment for ovarian cancer, PARP inhibitors have recently provided a new treatment option for a subset of patients with platinum-sensitive recurrent ovarian cancer. VAL-083 also demonstrates synergistic activity with the PARP inhibitor olaparib *in vitro*, suggesting VAL-083 may have utility in the treatment of ovarian cancer in combination with PARP inhibitors.

We believe that these data demonstrate the potential of VAL-083 to treat platinum-resistant ovarian cancers as a single-agent against platinum-resistant tumors in combination with platinum-based chemotherapeutic regimens or in combination with PARP inhibitors.

In April 2016, the FDA granted orphan drug designation for the use of VAL-083 in the treatment of ovarian cancer.

#### *VAL-083 REPROVe Ovarian Cancer Trial*

We have also recently received notice of allowance from the FDA of our IND for a Phase 1/2, Open-Label, Multicenter, Study of VAL-083 in Patients with **R**ecurrent **P**latinum **R**esistant **O**varian Cancer (REPROVe).

The Phase 1 portion of the trial will enroll approximately 24 patients with Pt-resistant ovarian cancer to evaluate the response to treatment with VAL-083.

Ovarian cancer patients enrolled in the trial will have been previously treated with at least two lines of Pt-based chemotherapy and up to two other cytotoxic regimens, whose cancer has recurred within 6 months of prior Pt-based chemotherapy.

The primary efficacy of the trial will be overall response rate (“ORR”) based on **Response Evaluation Criteria In Solid Tumors (RECIST)** criteria. RECIST is a set of published rules that define when tumors in cancer patients improve (“respond”), stay the same (“stabilize”), or worsen (“progress”) during treatment.

We plan to request a meeting with FDA following completion of the Phase 1 portion of the REPROVe trial. If successful, data from this trial would lead to a confirmatory Phase 2 study of approximately 60 patients, which if successful, and subject to feedback from the FDA may position us to potentially file an application for accelerated approval or to advance to a pivotal Phase 3 trial.

We will seek to initiate the REPROVe trial as soon as practicable, subject to negotiating acceptable clinical research agreements and budgets with clinical investigators and their institutions and obtaining IRB approvals. We anticipate completing the Phase 1 portion of the trial in approximately 18 months from the initiation of patient recruitment and presenting updates on the progress of this trial at peer reviewed meetings.

## Other Indications for VAL-083

### VAL-083 in Lung Cancer

Lung cancer is a leading cause of cancer death around the world and effective treatment for lung cancer remains a significant global unmet need despite advances in therapy. In general, prognosis for lung cancer patients remains poor, with a 5-year survival rate of less than 14% among males and less than 18% among females in most countries.

Incidence of lung cancer in the United States is approximately 59 per 100,000 with the majority (52:100,000) being NSCLC. World Health Organization projects that the incidence of lung cancer in China is expected to be approximately one million (1,000,000) new cases per year by 2025. Globally, the market for lung cancer treatment may exceed \$24 billion by 2033 according to a report published by Evaluate Pharma.

The activity of VAL-083 against solid tumors, including lung cancer, has been established in both preclinical and human clinical trials conducted by the NCI. VAL-083 is approved for the treatment of lung cancer in China; however, sales of VAL-083 in China have been limited by a lack of modern data, poor distribution, and preference for targeted therapies such as tyrosine kinase inhibitors (“TKIs”) in the modern era.

Non-small cell lung cancer (“NSCLC”) is the most common type of lung cancer. There are three common forms of NSCLC: adenocarcinomas are often found in an outer area of the lung; squamous cell carcinomas are usually found in the center of the lung next to an air tube (bronchus); and large cell carcinomas, which can occur in any part of the lung and tend to grow and spread faster than adenocarcinoma. NSCLC accounts for 85% of all lung cancer cases in the United States and approximately 90% of lung cancer cases diagnosed in China.

Recently approved immunotherapy drugs such as nivolumab (Opdivo®) and pembrolizumab (Keytruda®) have shown benefit in a subset of patients with recurrent NSCLC whose tumors exhibit immunogenic targets such as PD-L1. Many NSCLC patients’ tumors do not express immunotherapy targets at sufficient levels to trigger an immunotherapy treatment response and the development of resistance to immunotherapy has begun to emerge.

DelMar has developed new nonclinical data to support the utility of VAL-083 in the modern treatment of lung cancer. We have announced results of preclinical studies designed to evaluate the activity of VAL-083 in models of drug-resistant NSCLC in comparison to cisplatin. In an established murine xenograft model of NSCLC, the activity of VAL-083 was compared to standard platinum-based therapy with cisplatin against human NSCLC cell lines A549

(TKI-sensitive) and H1975 (TKI-resistant). In the study, VAL-083 demonstrated superior efficacy and safety in the treatment of TKI-susceptible (A549) tumors and in TKI-resistant (H1975) tumors.

Based on these data, we believe VAL-083's unique mechanism of action could make it a valuable drug of choice in NSCLC patients who are or become resistant to platinum-based chemotherapy and 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 lung cancer has spread to the brain.

We have developed a clinical trial protocol to explore the activity of VAL-083 in recurrent lung cancer. If successful, we believe data from this trial would support the potential to establish global partnerships and collaborations with larger pharmaceutical companies who have the resources and commercial infrastructure to effectively develop and commercialize VAL-083 as a treatment for NSCLC on a worldwide basis.

It is our current intention to conduct this trial with leading investigators in China under the terms of our collaboration with Guangxi Wuzhou Pharmaceutical Group Co. Ltd. ("Guangxi Wuzhou Pharmaceuticals"), which would allow us to enhance the potential value of VAL-083 without significantly increasing our own planned cash expenditures.

We determined, in consultation with Guangxi Wuzhou Pharmaceuticals, that initiation of a lung cancer trial should be delayed until our planned China-based trial in newly-diagnosed MGMT-unmethylated GBM had received regulatory approval. We received regulatory approval in July 2017 and in September 2017 we initiated this trial, and it is now our intention to work with Guangxi Wuzhou Pharmaceuticals to determine the appropriate strategy and timing for initiation of VAL-083 in clinical trials in lung cancer.

*Central Nervous System Metastases of Solid Tumors*

In June 2013, we split our Phase 1/2 clinical trial protocol into two separate studies: one focusing solely on refractory GBM and the other focusing on secondary brain cancers caused by other tumors that have spread to the brain. The successful management of systemic tumors by modern targeted therapies has led to increased incidence of mortality due to CNS metastases of lung cancer and other solid tumors.

Based on historical clinical activity and our own research, we believe that VAL-083 may be suitable for the treatment of patients with CNS metastases who currently have limited treatment options. Subject to the availability of financial and operating resources, we plan to develop a separate protocol for the continued exploration of VAL-083 in patients with secondary brain cancer caused by a solid tumor spreading to the brain.

*Pediatric Brain Tumors*

Tumors of the brain and spine make up approximately 20 percent of all childhood cancers and they are the second most common form of childhood cancer after leukemia.

The activity of VAL-083 against childhood and adolescent brain tumors has been established in both preclinical and human clinical trials conducted by the NCI. We have presented data indicating that VAL-083 offers potential therapeutic alternatives for the treatment of pediatric brain tumors including SHH-p53 mutated medulloblastoma. In March 2016, the FDA granted orphan drug designation for the use of VAL-083 in the treatment of medulloblastoma. Subject to the availability of resources, we intend to collaborate with leading academic researchers for the continued exploration of VAL-083 as a potential treatment of childhood brain tumors.

**Additional Indications for VAL-083**

In historical studies sponsored by the NCI in the United States, VAL-083 exhibited clinical activity against a range of tumor types including central nervous system tumors, solid tumors and hematologic malignancies. We have established new nonclinical data supporting the activity of VAL-083 in different types of cancer that are resistant to modern targeted therapies and we believe that the unique cytotoxic mechanism of VAL-083 may provide benefit to patients in a range of indications. We intend to continue to research these opportunities, and if appropriate, expand our clinical development efforts to include additional indications.

### **Other Product Opportunities**

Through our relationship with Valent Technologies, LLC (“Valent”), a company owned by Dr. Dennis Brown, our Chief Scientific Officer, we have identified additional drug candidates that we may have the opportunity to license or acquire in the future.

## VAL-083 Target Markets

DNA-targeting agents such as alkylating agents or platinum-based chemotherapy form the mainstay of chemotherapy treatments used in the treatment of cancers. Global sales of platinum-based chemotherapies reached nearly \$2.5 billion in 2011 and declined to \$600 million following the expiry of key patents. Alkylating agents such as temozolomide, bendamustine, nitrosoureas, and cyclophosphamide generated more than \$1.3 billion in sales in 2016 after reaching a peak of \$1.7 billion in 2014 (evaluate pharma).

*Fig X: Peak sales of selected DNA-targeting Agents*

Our lead product candidate, VAL-083, is a first-in-class DNA targeting agent with a novel mechanism of action. VAL-083's anti-cancer activity was established in a range of tumor types in prior NCI-sponsored clinical trials. Based on this novel mechanism, we have demonstrated that the anti-cancer activity is maintained against tumor cells that are resistant to other DNA-targeting agents. We believe this positions VAL-083 as a potential chemotherapy-of-choice for patients whose tumors are resistant to current standard-of-care chemotherapy in orphan and major cancer indications.

Our ongoing research and development activities are focused on indications where VAL-083 demonstrated promising activity in prior NCI-sponsored trials and where our research suggests an opportunity to address significant unmet medical needs due to the failure of existing treatments.

	2022
VAL-083 target markets	Estimated Global Sales
Glioblastoma multiforme (GBM)	\$ 1.5 B
Ovarian Cancer	\$ 4.6 B
Non-small cell lung cancer (NSCLC)	\$ 24.8 B
Source: Evaluate Pharma	

### Glioblastoma Multiforme



GBM is the most common and the most lethal form of glioma. According to the World Health Organization, GBM occurs with an incidence of 3.17 per 100,000 person-years. Approximately 18,000 new cases of GBM are expected to be diagnosed in the United States and 26,000 in Europe during 2017.

Newly diagnosed patients suffering from GBM are initially treated through invasive brain surgery, although disease progression following surgical resection is nearly 100%. Temozolomide (Temodar<sup>®</sup>) in combination with radiation is the front-line therapy for GBM following surgery. Global revenues of branded Temodar reached \$1.1 billion in 2009. Following patent expiry in 2013, global revenue for generic temozolomide exceeded \$400 million in 2014 even though most patients fail to gain long-term therapeutic benefits. Approximately 60% of GBM patients treated with Temodar<sup>®</sup> experience tumor progression within one year.

Bevacizumab (Avastin<sup>®</sup>) has been approved for the treatment of GBM in patients failing Temodar<sup>®</sup>. In clinical studies, only about 20% of patients failing Temodar<sup>®</sup> respond to Avastin<sup>®</sup> therapy and no improvement in median survival was reported. In spite of these low efficacy results, Avastin revenues for the treatment of GBM exceeded \$600 million in 2014.

The market for refractory (Avastin-failed) GBM is limited to those jurisdictions where Avastin is approved for the treatment of GBM. The United States, Canada, Australia, Japan and Switzerland represent the major markets where Avastin is used in the treatment of GBM. Based on our estimates, we believe that VAL-083 could generate sales for the treatment of refractory GBM in the \$100's of millions annually.

The market for MGMT-unmethylated GBM represents approximately two-thirds of all GBM patients worldwide. Based on our estimates, we believe that sales of VAL-083 for the treatment of MGMT-unmethylated GBM could exceed \$1 billion annually.

### Ovarian Cancer

According to Evaluate Pharma, the annual market for ovarian cancer therapies is projected to exceed \$4.6 billion in 2022. The American Cancer Society estimates that approximately 22,000 women will receive a new diagnosis of ovarian cancer and approximately 14,000 women will die from ovarian cancer in the United States each year. Ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system.

The potential of VAL-083 in the treatment of ovarian cancer has been established in prior NCI-sponsored clinical trials and by our recent research. The FDA has granted orphan drug status to VAL-083 as a potential treatment for ovarian cancer and we have recently received notice of allowance for our IND to initiate a Phase 1-2 clinical trial to investigate the safety and effectiveness of VAL-083 in patients with recurrent platinum resistant ovarian cancer (VAL-083 REPROVe trial).

Ovarian cancers are commonly treated with a platinum-based chemotherapy regimen. Initial tumor response rates are relatively high. However, the development of resistance to Pt-based chemotherapy in ovarian cancer patients is nearly inevitable. Our research suggests that VAL-083 may offer a potential treatment option for ovarian cancer patients who are resistant to platinum-based chemotherapy and as a potential combination therapy with other agents. We believe the profile of VAL-083 offers the potential to capture meaningful market share in the multi-billion ovarian cancer market.

### Lung Cancer

According to Evaluate Pharma, the annual market for lung cancer therapies is projected to reach nearly \$25 billion in 2022. Lung cancer is the most common cancer in the world with 1.8 million cases in 2012, representing 13% of all cancers according to a report published by the World Cancer Research Fund International. Lung cancer has a higher mortality rate than the next top three cancers combined and it is responsible for 1.6 million deaths annually, representing 19% of all cancer deaths. NSCLC represents approximately 90% of newly diagnosed lung cancers.

The potential of VAL-083 in the treatment of NSLSC has been established in both human clinical trials conducted by the NCI and by the drug's commercial approval in China. We believe the profile of VAL-083 offers the potential to capture meaningful market share in the multi-billion NSCLC market.

### **VAL-083 Manufacturing**

VAL-083 is a small-molecule chemotherapeutic. Chemical synthesis of the active pharmaceutical ingredient ("API") was initially established by the NCI. We have made improvements to this process and have obtained patents on these improvements. The current manufacturing process involves fewer than five synthetic steps.

VAL-083 drug product is a lyophilized (freeze-dried) formulation that is reconstituted for intravenous injection. We anticipate that overall cost of goods for an eventual commercial product will be similar to other injectable, small-molecule pharmaceuticals.

Supply of VAL-083 for our clinical trials to date has been provided through a collaboration with Guangxi Wuzhou Pharmaceutical (Group) Co. Ltd. Guangxi Wuzhou Pharma as a manufacturer has established a commercial-scale manufacturing process based on the North American process originally developed for the NCI that has been licensed by the Chinese FDA ("CFDA") for commercial supply of VAL-083 in China. We perform certain FDA-required release testing on drug product manufactured by Guangxi Wuzhou Pharma prior to use of drug product in our clinical trials.

We have also engaged third-party contract manufacturers with the capabilities to establish the processes, procedures and quality systems necessary to meet U.S., Canadian, E.U. and other international manufacturing requirements in accordance with Good Manufacturing Practice (“cGMP”) regulations. It is our intention to use these suppliers to support our Phase 3 clinical trials and commercial product production until such time as Guangxi Wuzhou Pharmaceuticals may receive certification by the USFDA.

DelMar has developed and patented certain intellectual property related to quality controls that are used in the release of VAL-083 for our clinical trials in the United States. This intellectual property is also required for product release under CFDA guidelines and we have granted access to our intellectual property for this purpose.

### **Research & Development Collaborations**

#### **Guangxi Wuzhou Pharmaceutical Company**

Pursuant to a memorandum of understanding and collaboration agreement, dated October 25, 2012, we have established a strategic collaboration with Guangxi Wuzhou Pharmaceutical Company (“Guangxi Wuzhou Pharmaceuticals”), a subsidiary of publicly traded Guangxi Wuzhou Zhongheng Group Co., Ltd. (SHG: 600252) (the “Guangxi Agreement”). VAL-083 is approved for the treatment of chronic myelogenous leukemia (“CML”) and lung cancer in China and Guangxi Wuzhou Pharmaceuticals is the only manufacturer licensed by the CFDA to produce the product for the China market. Through the Guangxi Agreement, we have been provided with exclusive access to drug product at the production price for our VAL-083 clinical trials in the United States and we have also secured certain commercial rights in China.

Pursuant to the Guangxi Agreement, we granted to Guangxi Wuzhou Pharmaceuticals a royalty-free license to certain of our intellectual property, as it relates to quality control and drug production methods for VAL-083, and we agreed that Guangxi Wuzhou Pharmaceuticals will be our exclusive supplier of VAL-083 for clinical trials and commercial sales, subject to Guangxi Wuzhou Pharmaceuticals obtaining and maintaining cGMP certification by the FDA, EMA or other applicable regulatory agencies, and Guangxi Wuzhou Pharmaceuticals being able to meet volumes ordered by us. In accordance with this agreement, we have contracted with established third-party suppliers for our Phase 3 clinical trials. We will continue to work with Guangxi Wuzhou Pharmaceuticals to achieve FDA compliance in order to potentially have them as our future supplier for global sales of VAL-083.

This Guangxi Agreement also provides us with certain exclusive commercial rights related to drug supply. Specifically, the Guangxi Agreement establishes an exclusive supply relationship between us and Guangxi Wuzhou Pharmaceuticals for the Chinese market and all markets outside China. Guangxi Wuzhou Pharmaceuticals agreed that

it may not sell VAL-083 for markets outside of China to any other purchaser other than us, provided that, during the first three years following regulatory clearance for marketing of VAL-083 in a particular country or region, we meet proposed sales volumes set by Guangxi Wuzhou Pharmaceuticals for the country or region. In addition, Guangxi Wuzhou Pharmaceuticals granted us a pre-emptive right in China (subject to our acceptance of proposed sales volume and prices) to purchase VAL-083 produced by Guangxi Wuzhou Pharmaceuticals.

Our collaboration with Guangxi Wuzhou Pharmaceuticals positions us with the potential to generate future revenue through product sales or royalties for its approved indications in China while we seek global approval in new indications.

Under the terms of the Guangxi Agreement, Guangxi Wuzhou Pharmaceuticals will provide funding support for clinical trials conducted in China and we are responsible for development and commercialization. We anticipate establishing sales channels in China through a third-party marketing partner in collaboration with Guangxi Wuzhou Pharmaceuticals in order to obtain sales or royalty revenue from China.

The term of the Guangxi Agreement (except as it relates to the exclusive rights in the China market) is indefinite, subject to termination upon written agreement of all parties, or if either party breaches any material term and fails to remedy such breach within 30 days of receipt of notice of the breach, or if any action to be taken thereunder is not agreed to by both parties, provided that such matter is referred to the chief executive officer of both parties, and they are unable to resolve such matter within 90 days. No payments have been made to date under the Guangxi Agreement.

### **Accurexa Collaboration**

We have entered into a collaboration agreement with Accurexa, Inc. (“Accurexa”). Accurexa is a biotechnology company focused on developing novel neurological therapies to be directly delivered to specific regions of the brain. Under the terms of the agreement, we and Accurexa will undertake collaborative research activities for the purpose of evaluating formulations of VAL-083 and one or more of temozolomide and BCNU (carmustine) for local delivery. Under the terms of the agreement, we will supply VAL-083 and Accurexa will conduct experiments related to the development and validation of a novel formulation for the combined local delivery of VAL-083 and temozolomide. We have been granted an exclusive right to license or acquire any product candidates and related intellectual property that results from research conducted under the agreement for further development and commercialization on an exclusive worldwide basis, or other terms that may be agreed upon between the parties. The initial financial commitment by us is not significant.

### **Duke University Collaboration**

In April 2017, we entered into a three-year collaboration with Duke University to evaluate VAL-083 as a front-line treatment for newly diagnosed patients with GBM. Under the terms of the collaboration, we will fund a series of preclinical studies to be conducted by Duke University’s Glioblastoma Drug Discovery Group to identify molecular characteristics of GBM tumors that are more likely to respond to VAL-083, and not the standard of care, temozolomide, as a front-line treatment or through combination therapies.

### **Patents and Proprietary Rights**

Our success will depend in part on our ability to protect our existing product candidate and the products we acquire or license by obtaining and maintaining a strong proprietary position. To develop and maintain our position, we intend to continue relying upon patent protection, orphan drug status, Hatch-Waxman exclusivity, trade secrets, know-how, continuing technological innovations and licensing opportunities.

We have filed patent applications claiming the use of, and improvements related to VAL-083. Our patent filings also include proposed treatment regimens, improvements to the manufacturing process, formulation and composition of the active pharmaceutical ingredient, and finished dosage forms of VAL-083. We are prosecuting our patent applications in the United States and other jurisdictions which we deem important for the potential commercial success of VAL-083.

Our patents and patent applications can be summarized in fourteen series as follows:

Series I is generally directed to synthesis of VAL-083.

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent No. 8,563,758	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol	2031
United States Patent No. 8,921,585	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol	2031
United States Patent No. 9,085,544	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol	2031
United States Patent No. 9,630,938	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol	2031
PCT Patent Application Serial No. PCT/US2011/048032	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol. National phase applications pending in various countries.	2031
PCT Patent Application Serial No. PCT/US2011/048032	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol: Patents granted in the following countries: Australia, China, Israel, Japan, Mexico, Singapore.	2031

Series II is generally directed to use of VAL-083 to treat a range of diseases and conditions, including but not limited to malignancies.

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent No. 9,066,918	Compositions And Methods To Improve The Therapeutic Benefit Of Suboptimally Administered Chemical Compounds Including Substituted Hexitols Such As Dianhydrogalactitol And Diacetyldianhydrogalactitol	2031
United States Patent Application Serial No. 14/753,911	Compositions And Methods To Improve The Therapeutic Benefit Of Suboptimally Administered Chemical Compounds Including Substituted Hexitols Such As Dianhydrogalactitol And Diacetyldianhydrogalactitol	
PCT Patent Application Serial No. PCT/US2011/048031	Compositions And Methods To Improve The Therapeutic Benefit Of Suboptimally Administered Chemical Compounds Including Substituted Hexitols Such As Dianhydrogalactitol And Diacetyldianhydrogalactitol. National phase applications pending in various countries.	2031

Series III is generally directed to analytical methods for VAL-083.

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent No. 9,759,698	Improved Analytical Methods For Analyzing And Determining Impurities In Dianhydrogalactitol	
United States Patent Application Serial No. 14/380,924	Improved Analytical Methods For Analyzing And Determining Impurities In Dianhydrogalactitol	
United States Patent No. 9,029,164	Improved Analytical Methods For Analyzing And Determining Impurities In Dianhydrogalactitol	2033
PCT Patent Application Serial No. PCT/IB2013/000793	Improved Analytical Methods For Analyzing And Determining Impurities In Dianhydrogalactitol. National phase applications pending in various countries.	2033
PCT Patent Application Serial No. PCT/IB2013/000793	Improved Analytical Methods For Analyzing And Determining Impurities In Dianhydrogalactitol granted in Australia	2033



<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
PCT Patent Application Serial No. PCT/US2014/066087	Improved Analytical Methods For Analyzing And Determining Impurities In Dianhydrogalactitol.	2034

Series IV is generally directed to the use of VAL-083 to treat GBM or medulloblastoma.

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent Application Serial No. 14/373,552	Use Of Substituted Hexitols Including Dianhydrogalactitol And Analogs To Treat Neoplastic Disease And Cancer Stem Cells Including Glioblastoma Multiforme And Medulloblastoma	
United States Patent No. 9,687,466	Use Of Substituted Hexitols Including Dianhydrogalactitol And Analogs To Treat Neoplastic Disease And Cancer Stem Cells Including Glioblastoma Multiforme And Medulloblastoma	2033
United States Patent Application Serial No. 15/617,756	Use Of Substituted Hexitols Including Dianhydrogalactitol And Analogs To Treat Neoplastic Disease And Cancer Stem Cells Including Glioblastoma Multiforme And Medulloblastoma	
PCT Patent Application Serial No. PCT/US2013/022505	Use Of Substituted Hexitols Including Dianhydrogalactitol And Analogs To Treat Neoplastic Disease And Cancer Stem Cells Including Glioblastoma Multiforme And Medulloblastoma. National phase applications pending in various countries.	2033

Series V is generally directed to the veterinary use of VAL-083.

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent Application Serial No. 14/400,271	Veterinary Use Of Dianhydrogalactitol, Diacetyldianhydrogalactitol, And Dibromodulcitol To Treat Malignancies	

Series VI is generally directed to the use of VAL-083 to treat tyrosine-kinase-inhibitor-resistant malignancies.

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent Application Serial No. 14/409,909	Methods For Treating Tyrosine-Kinase-Inhibitor-Resistant Malignancies In Patients With Genetic Polymorphisms Or Ahi1 Dysregulations Or Mutations Employing Dianhydrogalactitol, Diacetyldianhydrogalactitol, Dibromodulcitol, Or Analogs Or Derivatives Thereof	
		2033

PCT Patent Application  
Serial No.  
PCT/US2013/047320

Methods For Treating Tyrosine-Kinase-Inhibitor-Resistant Malignancies In Patients With Genetic Polymorphisms Or Ahi1 Dysregulations Or Mutations Employing Dianhydrogalactitol, Diacetyldianhydrogalactitol, Dibromodulcitol, Or Analogs Or Derivatives Thereof. National phase applications pending in various countries.

Series VII is generally directed to the use of VAL-083 to treat recurrent malignant glioma and progressive secondary brain tumor.

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent Application Serial No. 14/682,226	Use Of Dianhydrogalactitol And Analogs And Derivatives Thereof To Treat Recurrent Malignant Glioma Or Progressive Secondary Brain Tumor	
PCT Application Serial No. PCT/US2014/040461	Use Of Dianhydrogalactitol And Analogs And Derivatives Thereof To Treat Recurrent Malignant Glioma Or Progressive Secondary Brain Tumor. National phase applications pending in various countries.	2034

Series VIII is generally directed to the use of VAL-083 to treat non-small-cell lung cancer.

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent Application Serial No. 14/710,240	Use of Dianhydrogalactitol and Analogs or Derivatives Thereof in Combination With Platinum-Containing Antineoplastic Agents to Treat Non Small-Cell Carcinoma of the Lung and Brain Metastases	
PCT Patent Application Serial No. PCT/US2015/024462	Use of Dianhydrogalactitol and Analogs or Derivatives Thereof to Treat Non-Small Cell Carcinoma of the Lung and Ovarian Cancer. National phase applications pending in various countries.	2035
PCT Patent Application Serial No. PCT/US2016/032120	Combination of Analogs or Derivatives of Dianhydrogalactitol with Platinum-Containing Antineoplastic Agents to Treat Cancer.	2035

Series IX is generally directed to the use of VAL-083 and radiation to treat NSCLC and GBM.

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent Application Serial No. 15/525,933	Dianhydrogalactitol Together with Radiation to Treat Non-Small-Cell Carcinoma of the Lung and Glioblastoma Multiforme.	
PCT Patent Application Serial No. PCT/US2015/059814	Dianhydrogalactitol Together with Radiation to Treat Non-Small-Cell Carcinoma of the Lung and Glioblastoma Multiforme	2035

Series X is generally directed to the use of VAL-083 in NSCLC and ovarian carcinoma by induction of DNA damage and stalling of cell cycle:

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
PCT Patent Application Serial No. PCT/IB2016/001436	Use of Dianhydrogalactitol or Derivatives and Analogs Thereof for Treatment of Non-Small-Cell Lung Carcinoma, Glioblastoma, and Ovarian Carcinoma by Induction of DNA Damage and Stalling of Cell Cycle.	2036

Series XI is generally directed to the use of VAL-083 in the treatment of pediatric CNS malignancies:

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
United States Patent Application Serial No. 15/624,200	Use of Dianhydrogalactitol or Derivatives and Analogs Thereof for Treatment of Pediatric Central Nervous System Malignancies.	
PCT Patent Application Serial No. PCT/US2016/058661	Use of Dianhydrogalactitol or Derivatives and Analogs Thereof for Treatment of Pediatric Central Nervous System Malignancies.	2036

Series XII is generally directed to the analysis and resolution of VAL-083 preparations:

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
PCT Patent Application Serial No. PCT/US2016/063362	Methods for analysis and Resolution of Preparations of Dianhydrogalactitol and Derivatives and Analogs Thereof.	2036

Series XIII-XIV –Provisional U.S. patent applications

<b>Patent or Patent Application No.</b>	<b>Title</b>	<b>Expiry</b>
	Two provisional U.S. patent applications have been filed	

One of the inventors listed in our Series IX applications is an employee of the University of California, San Francisco. If a patent issues from a patent application in this series with a claim that the University of California employee conceived of, in whole or in part, then the Regents of the University of California will share ownership of any such patent with us. Our research agreements with the University of California address this issue by providing the Company with an exclusive option, for a limited period of time, to negotiate a royalty-bearing exclusive license for commercialization of the invention covered by that patent.

In addition to patent protection, we may also seek orphan drug status whenever it is available. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for a period of seven years in the U.S. and Canada, and 10 years in the E.U. Orphan drug designation does not prevent competitors from developing or marketing different drugs for the same indication or the same drug for a different clinical indication.

In February 2012, the FDA granted orphan drug status to VAL-083 for the treatment of glioma. In January 2013, the EMA also granted orphan drug protection to VAL-083 for the treatment of glioma. In the spring of 2016, the FDA Office of Orphan Products Development granted orphan drug designations to VAL-083 for the treatment of ovarian cancer and medulloblastoma.

In addition to our patents and orphan drug protection, we intend to rely on the Hatch-Waxman Amendments for five years of data exclusivity for VAL-083. Under the Hatch-Waxman Amendments, newly approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. These amendments provide five-year data exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active ingredient. The Hatch-Waxman Amendments prohibit the approval of an abbreviated new drug application, also known as an ANDA or generic drug application, during the five-year exclusive period if no patent is listed. If there is a patent listed and the ANDA applicant certifies that the NDA holder's listed patent for the product is invalid or will not be infringed, the ANDA can be submitted four years after NDA approval. Protection under the Hatch-Waxman Amendments will not prevent the filing or approval of another full NDA; however, the applicant would be required to conduct its own pre-clinical studies and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Amendments also provide three years of data exclusivity for the approval of NDAs with new clinical trials for previously approved drugs and supplemental NDAs, for example, for new indications, dosages or strengths of an existing drug, if new clinical investigations were conducted by or on behalf of the sponsor and were essential to the approval of the application. This three-year exclusivity covers only the new changes associated with the supplemental NDA and does not prohibit the FDA from approving ANDAs for drugs containing the original active ingredient.

We also rely on trade secret protection for our confidential and proprietary information. We believe that the substantial costs and resources required to develop technological innovations, such as the manufacturing processes associated with VAL-083, will help us to protect the competitive advantage of our product candidate.

The protection of intellectual property rights in China (where our clinical product candidate, VAL-083, is manufactured pursuant to a collaboration agreement with the only manufacturer presently licensed by the CFDA to produce the product for the China market, and where VAL-03 is approved for the treatment of CML and lung cancer) is relatively weak compared to the United States, which may negatively affect our ability to generate revenue from VAL-083 in China.

Our policy is to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees and consultants, the agreements provide that all inventions conceived by the individual shall be our exclusive property.

## **Government Regulation and Product Approval**

Regulation by governmental authorities in the U.S. and other countries is a significant factor, affecting the cost and time of our research and product development activities, and will be a significant factor in the manufacture and marketing of any approved products. Our product candidates will require regulatory approval by governmental agencies prior to commercialization. In particular, our products are subject to rigorous preclinical and clinical testing and other approval requirements by the FDA and similar regulatory authorities in other countries. Various statutes and regulations also govern or influence the manufacturing, safety, reporting, labeling, transport and storage, record keeping and marketing of our products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, the necessary regulatory approvals could harm our business.

The regulatory requirements relating to the testing, manufacturing and marketing of our products may change from time to time and this may impact our ability to conduct clinical trials and the ability of independent investigators to conduct their own research with support from us.

The clinical development, manufacturing and marketing of our products are subject to regulation by various authorities in the U.S., the E.U. and other countries, including, in the U.S., the FDA, in Canada, Health Canada, and, in the E.U., the EMA. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act in the U.S. and numerous directives, regulations, local laws and guidelines in Canada and the E.U. govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. Product development and approval within these regulatory frameworks takes a number of years and involves the expenditure of substantial resources.

Regulatory approval will be required in all the major markets in which we seek to develop our products. At a minimum, approval requires the generation and evaluation of data relating to the quality, safety, and efficacy of an investigational product for its proposed use. The specific types of data required and the regulations relating to this data will differ depending on the territory, the drug involved, the proposed indication and the stage of development.

In general, new chemical entities are tested in animals until adequate evidence of safety is established to support the proposed clinical study protocol designs. Clinical trials for new products are typically conducted in three sequential phases that may overlap. In Phase 1, the initial introduction of the pharmaceutical into either healthy human volunteers or patients with the disease (20 to 50 subjects), the emphasis is on testing for safety (adverse effects), dosage tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase 2 involves studies in a limited patient population (50 to 200 patients) to determine the initial efficacy of the pharmaceutical for specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse side effects and safety risks. Once a compound shows preliminary evidence of some effectiveness and is found to have an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to more fully evaluate clinical outcomes in a larger patient population in adequate and well-controlled studies designed to yield statistically sufficient clinical data to demonstrate efficacy and safety.

In the U.S., specific preclinical data, manufacturing and chemical data, as described above, need to be submitted to the FDA as part of an IND application, which, unless the FDA objects, will become effective 30 days following receipt by the FDA. Phase 1 studies in human volunteers may commence only after the application becomes effective. Prior regulatory approval for human healthy volunteer studies is also required in member states of the E.U. Currently, in each member state of the E.U., following successful completion of Phase 1 studies, data are submitted in summarized format to the applicable regulatory authority in the member state in respect of applications for the conduct of later Phase 2 studies. The regulatory authorities in the E.U. typically have between one and three months in which to raise any objections to the proposed study, and they often have the right to extend this review period at their discretion. In the U.S., following completion of Phase 1 studies, further submissions to regulatory authorities are necessary in relation to Phase 2 and III studies to update the existing IND. Authorities may require additional data before allowing the studies to commence and could demand that the studies be discontinued at any time if there are significant safety issues. In addition to the regulatory review, studies involving human subjects must be approved by an independent body. The exact composition and responsibilities of this body will differ from country to country. In the U.S., for example, each study will be conducted under the auspices of an independent institutional review board (IRB) at each institution at which the study is conducted. The IRB considers among other things, the design of the study, ethical factors, the privacy of protected health information as defined under the Health Insurance Portability and Accountability Act, the safety of the human subjects and the possible liability risk for the institution. Equivalent rules to protect subjects' rights and welfare apply in each member state of the E.U. where one or more independent ethics committees, which typically operate similarly to an IRB, will review the ethics of conducting the proposed research. Other regulatory authorities around the rest of the world have slightly differing requirements involving both the execution of clinical trials and the import/export of pharmaceutical products. It is our responsibility to ensure we conduct our business in accordance with the regulations of each relevant territory.



In order to gain marketing approval, we must submit a dossier to the relevant authority for review, which is known in the U.S. as a new drug application (NDA) and in the E.U. as a marketing authorization application (MAA). The format is usually specific and laid out by each authority, although in general it will include information on the quality of the chemistry, manufacturing and pharmaceutical aspects of the product as well as the nonclinical and clinical data. Once the submitted NDA is accepted for filing by the FDA, it undertakes the review process that currently takes on average 10 months, unless an expedited priority review is granted which takes six months to complete. Approval can take several months to several years, if multiple 10-month review cycles are needed before final approval is obtained, if at all.

The approval process can be affected by a number of factors. The NDA may require additional preclinical, manufacturing data or clinical trials which may be requested at the end of the 10-month NDA review cycle, thereby delaying approval until additional data are submitted and may involve substantial unbudgeted costs.

In addition to obtaining approval for each product, in many cases each drug manufacturing facility must be approved. The regulatory authorities usually will conduct an inspection of relevant manufacturing facilities, and review manufacturing procedures, operating systems and personnel qualifications. Further inspections may occur over the life of the product. An inspection of the clinical investigation sites by a competent authority may be required as part of the regulatory approval procedure. As a condition of marketing approval, the regulatory agency may require post-marketing surveillance to monitor for adverse effects or other additional studies as deemed appropriate. After approval for the initial indication, further clinical studies may be necessary to gain approval for any additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product.

The FDA offers a number of regulatory mechanisms that provide expedited or accelerated approval procedures for selected drugs in the indications on which we are focusing our efforts. These include accelerated approval under Subpart H of the agency's NDA approval regulations, fast track drug development procedures, breakthrough drug designation and priority review. At this time, we have not determined whether any of these approval procedures will apply to our current drug candidate.

By leveraging existing preclinical and clinical safety and efficacy data, we seek to build upon an existing knowledge base to accelerate our research. In addition, through our focus on end-stage population which has no current treatment options, regulatory approval for commercialization may sometimes be achieved in an accelerated manner. Accelerated approval by the FDA in this category may be granted on objective response rates and duration of responses rather than demonstration of survival benefit. As a result, trials of drugs to treat end-stage refractory cancer indications have historically involved fewer patients and generally have been faster to complete than trials of drugs for other indications. We are aware that the FDA and other similar agencies are regularly reviewing the use of objective endpoints for commercial approval and that policy changes may impact the size of trials required for approval, timelines and expenditures significantly.

The U.S., E.U. and other jurisdictions may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which, in the U.S., is generally a disease or condition that affects no more than 200,000 individuals. In the E.U., orphan drug designation can be granted if: the disease is life threatening or chronically debilitating and affects no more than 50 in 100,000 persons in the E.U.; without incentive, it is unlikely that the drug would generate sufficient return to justify the necessary investment; and no satisfactory method of treatment for the condition exists or, if it does, the new drug will provide a significant benefit to those affected by the condition. If a product that has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for a period of seven years in the U.S. and 10 years in the E.U. Orphan drug designation does not prevent competitors from developing or marketing different drugs for the same indication or the same drug for different indications. Orphan drug designation must be requested before submitting an NDA or MAA. After orphan drug designation is granted, the identity of the therapeutic agent and its potential orphan use are publicly disclosed. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. However, this designation provides an exemption from marketing and authorization fees charged to NDA sponsors under the

Prescription Drug User Fee Act (PDUFA Fees).

We are also subject to numerous environmental and safety laws and regulations, including those governing the use and disposal of hazardous materials. The cost of compliance with and any violation of these regulations could have a material adverse effect on our business and results of operations. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, accidental contamination or injury from these materials may occur. Compliance with laws and regulations relating to the protection of the environment has not had a material effect on our capital expenditures or our competitive position. However, we are not able to predict the extent of government regulation, and the cost and effect thereof on our competitive position, which might result from any legislative or administrative action pertaining to environmental or safety matters.

### **Competition**

The development and commercialization of new drugs is highly competitive and we may face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions worldwide.

Various products currently are marketed for the treatment of the cancers that we are targeting with VAL-083, or may target with future product candidates, and a number of companies are developing new treatments. Companies also developing products for GBM include but are not limited to Celgene Corp., Celldex Therapeutics, Northwest Biotherapeutics, Inc., Immunocellular Therapeutics Ltd., and many major pharmaceutical companies. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and create value in patient therapy.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than products that we may develop. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

We expect that our ability to compete effectively will depend upon our ability to:

successfully and rapidly complete adequate and well-controlled clinical trials that demonstrate statistically significant safety and efficacy and to obtain all requisite regulatory approvals in a cost-effective manner;

maintain a proprietary position for our manufacturing processes and other technology;

produce our products in accordance with United States FDA and international regulatory guidelines;

attract and retain key personnel; and

build or access an adequate sales and marketing infrastructure for any approved products.

Failure to do one or more of these activities could have an adverse effect on our business, financial condition or results of operations.

## **Corporate History**

The Company is a Nevada corporation formed on June 24, 2009 under the name Berry Only Inc. On January 25, 2013, the Company entered into and closed an exchange agreement (the “Exchange Agreement”), with Del Mar Pharmaceuticals (BC) Ltd. (“DelMar (BC)”), 0959454 B.C. Ltd. (“Callco”), and 0959456 B.C. Ltd. (“Exchangeco”) and the security holders of DelMar (BC). Upon completion of the Exchange Agreement, DelMar (BC) became a wholly-owned subsidiary of the Company (the “Reverse Acquisition”).

DelMar Pharmaceuticals, Inc. is the parent company of DelMar (BC), a British Columbia, Canada corporation incorporated on April 6, 2010, which is a clinical stage company with a focus on the development of drugs for the treatment of cancer. The Company is also the parent company to Callco and Exchangeco which are British Columbia, Canada corporations. Callco and Exchangeco were formed to facilitate the Reverse Acquisition.

On May 20, 2016, the Company effected a 1-for-4 reverse split of its common stock. All share amounts in this report give effect to the reverse split unless otherwise indicated.

## **Research and Development**

During the years ended June 30, 2017 and 2016, we recognized \$5,003,640 and \$3,360,878, respectively in research and development expenses.

## Employees

We have four full-time employees and retain the services of approximately 15 persons on an independent contractor/consultant and contract-employment basis. As such, we currently operate in a “virtual” corporate structure in order to minimize fixed personnel costs. Over time, we plan to establish a base of full time employees and corporate infrastructure.

## Item 1A. Risk Factors

**An investment in the Company’s common stock involves a high degree of risk. In determining whether to purchase the Company’s common stock, an investor should carefully consider all of the material risks described below, together with the other information contained in this report before making a decision to purchase the Company’s securities. An investor should only purchase the Company’s securities if he or she can afford to suffer the loss of his or her entire investment.**

### Risks Related to Our Business

*Our independently audited June 30, 2017 consolidated financial statements contain liquidity risk disclosure.*

Our audited financial statements for the fiscal year ended June 30, 2017, include an explanatory paragraph regarding our liquidity risk. For the year ended June 30, 2017, the Company reported a loss of \$8,081,764 and the Company had an accumulated deficit of \$41,118,433 at that date. As at June 30, 2017, the Company had cash on hand of \$6,586,014. The Company does not have the prospect of achieving revenues in the near future and the Company will require additional funding for its clinical trials, to maintain its research and development projects and for general operations. There is a great degree of uncertainty with respect to the expenses the Company will incur in executing its business plan. In addition, the Company has not begun to commercialize or generate revenues from its product candidate.

Consequently, management is pursuing various financing alternatives to fund the Company’s operations so it can continue as a going concern in the medium to longer term. During the year ended June 30, 2017, the Company received \$7,932,107 in net proceeds from a public offering financing and \$545,026 in proceeds from the exercise of share purchase warrants. Subsequent to June 30, 2017, the Company completed a registered direct offering of an aggregate of 8,000,000 shares of common stock and warrants to purchase an aggregate of 8,000,000 shares of

common stock at a price of \$1.25 per share and related warrant for net proceeds of approximately \$9 million. We believe, based on our current estimates, that we will be able to fund our operations beyond the next twelve months.

There is no assurance that our cost estimates will prove to be accurate or that unforeseen events, problems or delays will not occur with respect thereto. The ability of the Company to meet its obligations and continue the research and development of its product candidate is dependent on its ability to continue to raise adequate financing. There can be no assurance that such financing will be available to the Company in the amount required at any time or for any period or, if available, that it can be obtained on terms satisfactory to the Company. The Company may tailor its drug candidate development program based on the amount of funding the Company raises.

***We have a limited operating history and a history of operating losses, and expect to incur significant additional operating losses.***

We are an early stage company and there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We expect to incur substantial additional net expenses over the next several years as our research, development and commercial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the preclinical and clinical development of our product candidate; obtaining necessary regulatory approvals from the FDA and international regulatory agencies; successful manufacturing, sales and marketing arrangements; and raising sufficient funds to finance our activities. If we are unsuccessful at some or all of these undertakings, our business, prospects and results of operations may be materially adversely affected.

***We will need to raise additional capital, which may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to technologies or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings and/or license and development agreements with collaboration partners. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, then-existing stockholders' interests may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely their rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

If we raise funds through collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Our inability to obtain additional financing could adversely affect our ability to meet our obligations under our planned clinical trials and could negatively impact the timing of our clinical results.***

Our ability to meet our obligations and continue the research and development of our product candidate is dependent on our ability to continue to raise adequate financing. We may not be successful in obtaining such additional financing in the amount required at any time, or for any period, or, if available, that it can be obtained on terms satisfactory to us. In the event that we are unable to obtain such additional financing, we may be unable to meet our obligations under our planned clinical trials and we may have to tailor our drug candidate development programs based on the amount of funding we raise which could negatively impact the timing of our clinical results.

***If we are unable to effectively implement or maintain a system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.***

Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that fiscal



year. Management determined that as of June 30, 2017, our disclosure controls and procedures and internal control over financial reporting were not effective due to a material weakness in our internal control over financial reporting related to our limited number of employees in our accounting department and inadequate segregation of duties over authorization, review and recording of transactions. Any failure to implement new or improved controls necessary to remedy the material weakness described above, or difficulties encountered in the implementation or operation of these controls, could harm our operations, decrease the reliability of our financial reporting, and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

***We are an early-stage company and may never achieve commercialization of our candidate products or profitability.***

We are at an early stage of development and commercialization of our technologies and product candidate. We have not yet begun to market any products and, accordingly, have not begun or generate revenues from the commercialization of our product. Our product will require significant additional clinical testing and investment prior to commercialization. A commitment of substantial resources by ourselves and, potentially, our partners to conduct time-consuming research and clinical trials will be required if we are to complete the development of our product candidate. There can be no assurance that our product candidate will meet applicable regulatory standards, obtain required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs or be successfully marketed. Our product candidate is not expected to be commercially available for several years, if at all.

*We are currently focused on the development of a single product candidate.*

Our product development efforts are currently focused on a single product, VAL-083, for which we are researching multiple indications. If VAL-083 fails to achieve clinical endpoints or exhibits unanticipated toxicity or if a superior product is developed by a competitor, our prospects for obtaining regulatory approval and commercialization may be negatively impacted. In the long-term, we hope to establish a pipeline of product candidates, and we have identified additional product candidates that we may be able to acquire or license in the future. However, at this time we do not have any formal agreements granting us any rights to such additional product candidates.

*Even if we are able to commercialize any product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.*

The commercial success of our current or future product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidate will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities (such as Medicare and Medicaid), private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish and maintain pricing sufficient to realize a meaningful return on our investment.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize VAL-083 or any other product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the

United States and elsewhere. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidate profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable non-U.S. regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***We are dependent on obtaining certain patents and protecting our proprietary rights.***

Our success will depend, in part, on our ability to obtain patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties or having third parties circumvent our rights. We have filed and are actively pursuing patent applications for our products. The patent positions of biotechnology, biopharmaceutical and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. Thus, there can be no assurance that any of our patent applications will result in the issuance of patents, that we will develop additional proprietary products that are patentable, that any patents issued to us or those that already have been issued will provide us with any competitive advantages or will not be challenged by any third parties, that the patents of others will not impede our ability to do business or that third parties will not be able to circumvent our patents. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of our products not under patent protection, or, if patents are issued to us, design around the patented products we developed or will develop.

We may be required to obtain licenses from third parties to avoid infringing patents or other proprietary rights. No assurance can be given that any licenses required under any such patents or proprietary rights would be made available, if at all, on terms we find acceptable. If we do not obtain such licenses, we could encounter delays in the introduction of products or could find that the development, manufacture or sale of products requiring such licenses could be prohibited.

A number of pharmaceutical, biopharmaceutical and biotechnology companies and research and academic institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to or affect our business. Some of these technologies, applications or patents may conflict with our technologies or patent applications. Such conflict could limit the scope of the patents, if any, that we may be able to obtain or result in the denial of our patent applications. In addition, if patents that cover our activities are issued to other companies, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost or be able to develop or obtain alternative technology. If we do not obtain such licenses, we could encounter delays in the introduction of products, or could find that the development, manufacture or sale of products requiring such licenses could be prohibited. In addition, we could incur substantial costs in defending ourselves in suits brought against us on

patents it might infringe or in filing suits against others to have such patents declared invalid.

Patent applications in the U.S. are maintained in secrecy and not published if either: i) the application is a provisional application or, ii) the application is filed and we request no publication, and certify that the invention disclosed “has not and will not” be the subject of a published foreign application. Otherwise, U.S. applications or foreign counterparts, if any, publish 18 months after the priority application has been filed. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we or any licensor were the first creator of inventions covered by pending patent applications or that we or such licensor was the first to file patent applications for such inventions. Moreover, we might have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost to us, even if the eventual outcome were favorable to us. There can be no assurance that our patents, if issued, would be held valid or enforceable by a court or that a competitor’s technology or product would be found to infringe such patents.

Moreover, we may be subject to third-party preissuance submissions of prior art to the USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate, or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In addition, the protection of intellectual property rights in China (where our clinical product candidate, VAL-083, is manufactured pursuant to a collaboration agreement with the only manufacturer presently licensed by the China Food and Drug Administration to produce the product for the China market, and where VAL-083 is approved for the treatment of CML and lung cancer) is relatively weak compared to the United States, which may negatively affect our ability to generate royalty revenue from sales of VAL-083 in China.

Much of our know-how and technology may not be patentable. To protect our rights, we require employees, consultants, advisors and collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Further, our business may be adversely affected by competitors who independently develop competing technologies, especially if we obtain no, or only narrow, patent protection.

***Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. The Leahy-Smith Act includes provisions that affect the way patent applications are prosecuted and affect patent litigation. The United States Patent and Trademark Office, or PTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act. However, many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if

any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

*We may be unable to protect our patents and proprietary rights.*

Our future success will depend to a significant extent on our ability to:

obtain and keep patent protection for our products and technologies on an international basis;

enforce our patents to prevent others from using our inventions;

maintain and prevent others from using our trade secrets; and

operate and commercialize products without infringing on the patents or proprietary rights of others.

We can provide no assurance that our patent rights will afford any competitive advantages and these rights may be challenged or circumvented by third parties. Further, patents may not be issued on any of our pending patent applications in the U.S. or abroad. Because of the extensive time required for development, testing and regulatory review of a product candidate, it is possible that before a product candidate can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing or eliminating any advantage of the patent.

If we sue others for infringing our patents, a court may determine that such patents are invalid or unenforceable. Even if the validity of our patent rights is upheld by a court, a court may not prevent the alleged infringement of our patent rights on the grounds that such activity is not covered by our patent claims.

In addition, third parties may sue us for infringing their patents. In the event of a successful claim of infringement against us, we may be required to:

defend litigation or administrative proceedings;

pay substantial damages;

stop using our technologies and methods;

stop certain research and development efforts;

develop non-infringing products or methods; and

obtain one or more licenses from third parties.

If required, we can provide no assurance that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in development, manufacture and commercialization of our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we infringe third-party rights, will be costly, time consuming, and may distract management from other important tasks.



As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in research areas which are similar to those areas in which they were involved at their former employers, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs and be a distraction to management and which may have a material adverse effect on us, even if we are successful in defending such claims.

***We are subject to various government regulations.***

The manufacture and sale of human therapeutic and diagnostic products in the U.S., Canada and foreign jurisdictions are governed by a variety of statutes and regulations. These laws require approval of manufacturing facilities, controlled research and testing of products and government review and approval of a submission containing manufacturing, preclinical and clinical data in order to obtain marketing approval based on establishing the safety and efficacy of the product for each use sought, including adherence to current cGMP during production and storage, and control of marketing activities, including advertising and labeling.

VAL-083 and any other products we may develop will require significant development, preclinical and clinical testing and investment of substantial funds prior to its commercialization. The process of obtaining required approvals can be costly and time-consuming, and there can be no assurance that we will successfully develop any future products that will prove to be safe and effective in clinical trials or receive applicable regulatory approvals. Markets other than the U.S. and Canada have similar restrictions. Potential investors and shareholders should be aware of the risks, problems, delays, expenses and difficulties which we may encounter in view of the extensive regulatory environment which controls our business.

***We may request priority review for our product candidate in the future. The FDA may not grant priority review for our product candidate. Moreover, even if the FDA designated such product for priority review, that designation may not lead to a faster regulatory review or approval process and, in any event, would not assure FDA approval.***

We may be eligible for priority review designation for our product candidate if the FDA determines such product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Thus, while the FDA has granted priority review to other oncology disease products, our product candidate, should we determine to seek priority review, may not receive similar designation. Moreover, even if our product candidate is designated for priority review, such a designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within an accelerated timeline or thereafter.

***We believe we may in some instances be able to secure approval from the FDA or comparable non-U.S. regulatory authorities to use accelerated development pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.***

We anticipate that we may seek an accelerated approval pathway for our product candidate. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such accelerated approval. There can also be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a New Drug Application (“NDA”), for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback that we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., breakthrough therapy designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other non-U.S. authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for any of our product candidates that we determine to seek accelerated approval for would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

***We have conducted, and may in the future conduct, clinical trials for certain of our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.***

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any of our clinical trials that we determine to conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of the product candidate.

In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;

administrative burdens of conducting clinical trials under multiple foreign regulatory schema;

foreign exchange fluctuations; and

diminished protection of intellectual property in some countries.

***If our clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA and comparable non-U.S. regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidate.***

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable non-U.S. regulatory authorities, such as the EMA, impose similar restrictions. We may never receive such approvals. We must complete extensive preclinical development and

clinical trials to demonstrate the safety and efficacy of our product candidate in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable non-U.S. regulatory authorities for any product candidate.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if (1) we are required to conduct additional clinical trials or other testing of our product candidate beyond the trials and testing that we contemplate, (2) we are unable to successfully complete clinical trials of our product candidate or other testing, (3) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or (4) there are unacceptable safety concerns associated with our product candidate, we, in addition to incurring additional costs, may:

be delayed in obtaining marketing approval for our product candidates;

not obtain marketing approval at all;

obtain approval for indications or patient populations that are not as broad as we intended or desired;

obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;

be subject to additional post-marketing testing or other requirements; or

be required to remove the product from the market after obtaining marketing approval.

***If we experience any of a number of possible unforeseen events in connection with clinical trials of our product candidates, potential marketing approval or commercialization of our product candidates could be delayed or prevented.***

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent marketing approval of our product candidate, including:

clinical trials of our product candidate may produce unfavorable or inconclusive results;

we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

the number of patients required for clinical trials of our product candidate may be larger than we anticipate, patient enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

data safety monitoring committees may recommend suspension, termination or a clinical hold for various reasons, including concerns about patient safety;

regulators or IRBs may suspend or terminate the trial or impose a clinical hold for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;

patients with serious, life-threatening diseases included in our clinical trials may die or suffer other adverse medical events for reasons that may not be related to our product candidate;

participating patients may be subject to unacceptable health risks;

patients may not complete clinical trials due to safety issues, side effects, or other reasons;

changes in regulatory requirements and guidance may occur, which require us to amend clinical trial protocols to reflect these changes;

our third-party contractors, including those manufacturing our product candidate or components or ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their

contractual obligations to us in a timely manner or at all;

regulators or institutional review boards, or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

patients who enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;

we may have to suspend or terminate clinical trials of our product candidate for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of a product candidate;

regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their respective standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar drug or drug candidate;

the FDA or comparable non-U.S. regulatory authorities may disagree with our clinical trial design or our interpretation of data from preclinical studies and clinical trials;

the FDA or comparable non-U.S. regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;

the supply or quality of raw materials or manufactured product candidate or other materials necessary to conduct clinical trials of our product candidate may be insufficient, inadequate, delayed, or not available at an acceptable cost, or we may experience interruptions in supply; and

the approval policies or regulations of the FDA or comparable non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Product development costs for us will increase if we experience delays in testing or pursuing marketing approvals and we may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidate. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidate or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidate and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of marketing approval of our product candidate.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, we may not achieve our clinical development on our anticipated timeline, or at all, and our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for VAL-083 or any other product candidate if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:



the size and nature of the patient population;

the severity of the disease under investigation;

the proximity of patients to clinical sites;

the eligibility criteria for the trial;

the design of the clinical trial;

efforts to facilitate timely enrollment;

competing clinical trials; and

clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidate, delay or halt the development of and approval processes for our product candidate and jeopardize our ability to achieve our clinical development timeline and goals, including the dates by which we will commence, complete and receive results from clinical trials. Enrollment delays may also delay or jeopardize our ability to commence sales and generate revenues from our product candidate. Any of the foregoing could cause the value of the Company to decline and limit our ability to obtain additional financing, if needed.

***Positive results in previous clinical trials of VAL-083 may not be replicated in future clinical trials, which could result in development delays or a failure to obtain marketing approval.***

Positive results in previous clinical studies of VAL-083 may not be predictive of similar results in future clinical trials. Also, interim results during a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed preclinical studies and clinical trials for VAL-083 may not be predictive of the results we may obtain in later stage trials. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA or EMA, or other regulatory agency, approval for their products.

***FDA approval of VAL-083 or future product candidates may be denied.***

There can be no assurance that the FDA will ultimately approve our NDA. The FDA may deny approval of VAL-083 for many reasons, including:

we may be unable to demonstrate to the satisfaction of the FDA that our products are safe and effective for its intended uses;

the FDA may disagree with our interpretation of data from the clinical trials;

we may be unable to demonstrate that any clinical or other benefits our products outweigh any safety or other perceived risks; or

we may not be able to successfully address any other issues raised by the FDA.

If VAL-083 fails to receive FDA approval, our business and prospects will be materially adversely impacted.

***We expect to rely on orphan drug status to develop and commercialize our product candidate, but our orphan drug designations may not confer marketing exclusivity or other expected commercial benefits as anticipated.***

Market exclusivity afforded by orphan drug designation is generally offered as an incentive to drug developers to invest in developing and commercializing products for unique diseases that impact a limited number of patients. The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Qualification to maintain orphan drug status is generally monitored by the regulatory authorities during the orphan drug exclusivity period, currently seven years from the date of approval in the United States.

We have been granted orphan drug designation in the United States for GBM, ovarian cancer, and medulloblastoma, and in Europe for GBM. We expect to rely on orphan drug exclusivity for our product candidate. It is possible that the incidence and prevalence numbers for GBM could change. Should the incidence and prevalence of GBM patients materially increase, it is possible that the orphan drug designation, and related market exclusivity, in the United States could be lost. Further, while we have been granted this orphan designation, the FDA can still approve different drugs for use in treating the same indication or disease, which would create a more competitive market for us and our revenues will be diminished.

Further, it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to the orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product.

***If the market opportunities for our product candidate are smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Because the target patient populations of our product candidate are small, we must be able to successfully identify patients and capture a significant market share to achieve and maintain profitability.***

We focus our research and product development on treatments for orphan cancer indications. Our projections of both the number of people who have failed other therapies or have limited medical options, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Additionally, because our target patient populations are small, we will be required to capture a significant market share to achieve and maintain profitability.

***We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our products.***

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be

subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects or even death as a result of participating in our clinical trials.

*We may not receive regulatory approvals for our product candidate or there may be a delay in obtaining such approvals.*

Our product and our ongoing development activities are subject to regulation by regulatory authorities in the countries in which we or our collaborators and distributors wish to test, manufacture or market our products. For instance, the FDA will regulate the product in the U.S. and equivalent authorities, such as the EMA, will regulate in Europe. Regulatory approval by these authorities will be subject to the evaluation of data relating to the quality, efficacy and safety of the product for its proposed use, and there can be no assurance that the regulatory authorities will find our data sufficient to support product approval of VAL-083 or any future product candidates.

The time required to obtain regulatory approval varies between countries. The FDA is required to facilitate the development and expedite the review of drugs and biologics that are intended for the treatment of a serious or life-threatening disease or condition and which demonstrate the potential to address unmet medical needs for the condition. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy that may be potentially better than available therapy. Under the fast track program, the sponsor of a new drug or biologic candidate may request the FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 days after receipt of the sponsor's request. In the U.S., for products without "Fast Track" status, it can take over eighteen (18) months after submission of an application for product approval to receive the FDA's decision. Even with Fast Track status, FDA review and decision can take over twelve (12) months. At present, we do not have Fast Track status for VAL-083.

Different regulators may impose their own requirements and may refuse to grant, or may require additional data before granting, an approval, notwithstanding that regulatory approval may have been granted by other regulators. Regulatory approval may be delayed, limited or denied for a number of reasons, including insufficient clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements as well as case load at the regulatory agency at the time.

***We may fail to comply with regulatory requirements.***

Our success will be dependent upon our ability, and our collaborative partners' abilities, to maintain compliance with regulatory requirements, including cGMP, and safety reporting obligations. The failure to comply with applicable regulatory requirements can result in, among other things, fines, injunctions, civil penalties, total or partial suspension of regulatory approvals, refusal to approve pending applications, recalls or seizures of products, operating and production restrictions and criminal prosecutions.

***Even if our product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for the product candidate may be smaller than we estimate.***

We have never commercialized a product. Even if VAL-083 or any other product candidate is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of our product candidate may require significant resources and may not be successful. If our product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of VAL-083 or any other product candidate, if approved for commercial sale, will depend on a number of factors, including:

the efficacy and safety of the product;

the potential advantages of the product compared to alternative treatments;

the prevalence and severity of any side effects;

the clinical indications for which the product is approved;

whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;

limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;

our ability to offer the product for sale at competitive prices;

our ability to establish and maintain pricing sufficient to realize a meaningful return on our investment;

the product's convenience and ease of administration compared to alternative treatments;

the willingness of the target patient population to try, and of physicians to prescribe, the product;

the strength of sales, marketing and distribution support;

the approval of other new products for the same indications;

changes in the standard of care for the targeted indications for the product;

the timing of market introduction of our approved products as well as competitive products and other therapies;

availability and amount of reimbursement from government payors, managed care plans and other third-party payors;

adverse publicity about the product or favorable publicity about competitive products; and

potential product liability claims.

The potential market opportunities for our product candidate are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidate could be smaller than our estimates of the potential market opportunities.

***If our product candidate receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.***

Clinical trials of our product candidate are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side



effects. If, following approval of our product candidate, we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

regulatory authorities may withdraw their approval of the drug or seize the drug;

we may be required to recall the drug or change the way the drug is administered;

additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;

we may be subject to fines, injunctions or the imposition of civil or criminal penalties;

regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;

we may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;

we could be sued and held liable for harm caused to patients;

the drug may become less competitive; and

our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

***Any product candidate for which we obtain marketing approval, along with the manufacturing processes, qualification testing, post-approval clinical data, labeling and promotional activities for such product, will be subject to continual and additional requirements of the FDA and other regulatory authorities.***

These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, good manufacturing practices, or GMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. Even if marketing approval of our product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling.

In addition, later discovery of previously unknown problems with our products, manufacturing processes, or failure to comply with regulatory requirements, may lead to various adverse results, including:

restrictions on such products, manufacturers or manufacturing processes;

restrictions on the labeling or marketing of a product;

restrictions on product distribution or use;

requirements to conduct post-marketing  
clinical trials;

requirements to institute a risk evaluation mitigation strategy, or REMS, to monitor safety of the product post-approval;

warning letters issued by the FDA or other regulatory authorities;

withdrawal of the products from the market;

refusal to approve pending applications or supplements to approved applications that we submit;

recall of products, fines, restitution or disgorgement of profits or revenue;

suspension, revocation or withdrawal of marketing approvals;

refusal to permit the import or export of our products; and

injunctions or the imposition of civil or criminal penalties.

***If we are unable to establish sales, marketing and distribution capabilities or enter into acceptable sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidates that we develop, if and when those product candidates are approved.***

We do not have a sales, marketing or distribution infrastructure and have limited experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization, outsource these functions to third parties, or license our product candidates to others. If approved, we may seek to license VAL-083 to a large pharmaceutical company with greater resources and experience than us. We may not be able license the VAL-083 on reasonable terms, if at all. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. We expect that we will commence the development of these capabilities prior to receiving approval of our product candidate. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. Such a delay may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to our product candidate, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently.

We expect to seek one or more strategic partners for commercialization of our product candidate outside the United States. As a result of entering into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales and marketing capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidate.

***We face substantial competition from other pharmaceutical and biotechnology companies and our operating results may suffer if we fail to compete effectively.***

The development and commercialization of new drug products is highly competitive. We expect that we will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to VAL-083 and any other product candidates that we may seek to develop or commercialize in the future. Specifically, due to the large unmet medical need, global demographics and relatively attractive reimbursement dynamics, the oncology market is fiercely competitive and there are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, have fewer or more tolerable side effects or are less costly than any product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

All of the top ten global pharmaceutical companies and many of the mid-size pharmaceutical companies have a strong research and development and commercial presence in oncology. Smaller companies also focus on oncology, including companies such as ARIAD Pharmaceuticals, Inc., Agios Pharmaceuticals, Inc., BIND Therapeutics, Inc., Clovis Oncology, Inc., Endocyte, Inc., Epizyme, Inc., ImmunoGen, Inc., Incyte Corporation, Infinity Pharmaceuticals, Inc., MacroGenics, Inc., Merrimack Pharmaceuticals, Inc., OncoMed Pharmaceuticals, Inc., Onconova Therapeutics, Inc., Pharmacyclics, Inc., Puma Biotechnology, Inc., Seattle Genetics, Inc. and TESARO, Inc.

Several companies are marketing and developing oncology immunotherapy products. Companies with approved marketed oncology products for GBM are Merck (Temodar<sup>®</sup>) and Genentech (Avastin<sup>®</sup>). Companies with oncology immunotherapy product candidates in clinical development include Northwest Biotherapeutics (DCVax-L), Celldex Therapeutics (Rindopepimut (CDX-110)) and ImmunoCellular Therapeutics (ICT-107).

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products before we are able to obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our existing and potential future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***If we are unable to or delayed in obtaining state regulatory licenses for the distribution of our product, we would not be able to sell our product candidate.***

The majority of states require manufacturer and/or wholesaler licenses for the sale and distribution of drugs into that state. The application process is complicated, time consuming and requires dedicated personnel or a third-party to oversee and manage. If we are delayed in obtaining these state licenses, or denied the licenses, even with FDA approval, we would not be able to sell or ship product into that state which would adversely affect our sales and revenues.

***We rely on key personnel and, if we are unable to retain or motivate key personnel or hire qualified personnel, we may not be able to grow effectively.***

We are dependent on certain members of our management, scientific and drug development staff and consultants, the loss of services of one or more of whom could materially adversely affect us.

We currently have four full-time employees, and retain the services of approximately 15 persons on an independent contractor/consultant and contract-employment basis. Our ability to manage growth effectively will require us to continue to implement and improve our management systems and to recruit and train new employees. Although we have done so in the past and expect to do so in the future, there can be no assurance that we will be able to successfully attract and retain skilled and experienced personnel.

Our success depends in large part upon our ability to attract and retain highly qualified personnel. We compete in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain personnel, which would be very costly.

*We may be subject to foreign exchange fluctuation.*

Our functional and reporting currency is the United States dollar. We maintain bank accounts in United States and Canadian dollars. A portion of our expenditures are in foreign currencies, most notably in Canadian dollars, and therefore we are subject to foreign currency fluctuations, which may, from time to time, impact our financial position and results. We may enter into hedging arrangements under specific circumstances, typically through the use of forward or futures currency contracts, to minimize the impact of increases in the value of the Canadian dollar. In order to minimize our exposure to foreign exchange fluctuations we may hold sufficient Canadian dollars to cover our expected Canadian dollar expenditures.

***Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop.***

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidate despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we commercially sell any product that we may develop. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidate. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for our product candidate or products that we may develop;

injury to our reputation and significant negative media attention;

withdrawal of clinical trial participants;

significant costs to defend resulting litigation;

substantial monetary awards to trial participants or patients;

loss of revenue;

reduced resources of our management to pursue our business strategy; and

the inability to commercialize any products that we may develop.

Although we maintain general liability insurance, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if and when we begin selling any product candidate that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product



candidate, which could adversely affect our business, financial condition, results of operations and prospects.

### **Risks Related to Our Dependence on Third Parties**

***We rely on third parties to conduct clinical trials for our product candidate. Any failure by a third-party to meet its obligations with respect to the clinical development of our product candidate may delay or impair our ability to obtain regulatory approval for our product candidate.***

We rely on academic institutions and private oncology centers to conduct our clinical trials. Our reliance on third parties to conduct clinical trials could, depending on the actions of such third parties, jeopardize the validity of the clinical data generated and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities.

Such clinical trial arrangements provide us with information rights with respect to the clinical data, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the clinical trials. If investigators or institutions breach their obligations with respect to the clinical trials of our product candidate, or if the data proves to be inadequate, then our ability to design and conduct any future clinical trials may be adversely affected.

***We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We currently rely on third-party clinical research organizations, or CROs, to conduct our clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. Our agreements with these third parties generally allow the third-party to terminate the agreement at any time. If we are required to enter into alternative arrangements because of any such termination the introduction of our product candidates to market could be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we design our clinical trials and will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidate or commercialization of our products, producing additional losses and depriving us of potential product revenue.

***We may seek to enter into collaborations with third parties for the development and commercialization of our product candidate. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our product candidate.***

We may seek third-party collaborators for development and commercialization of our product candidate. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, non-profit organizations, government agencies, and biotechnology companies. We are currently party to a limited number of such arrangements and have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidate. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidate currently pose, and will continue to pose, the following risks to us:

collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

collaborators may not pursue development and commercialization of our product candidate or may elect not to continue or renew development or commercialization programs based on preclinical or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidate if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidate or that result in costly litigation or arbitration that diverts management attention and resources; and

collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of our product candidate in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

***If we are not able to establish collaborations, we may have to alter our development and commercialization plans.***

Our drug development programs and the potential commercialization of our product candidate will require substantial additional cash to fund expenses. We may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidate.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical studies or clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate

and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of our product candidate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or bring it to market and generate product revenue.

***We currently manufacture our clinical supplies at a single location. Any disruption at this facility could adversely affect our business and results of operations.***

We have engaged a single manufacturer to produce active pharmaceutical ingredient and drug product for our STAR-3 Phase 3 clinical trial. In addition, we rely on our manufacturing partner, Guangxi Wuzhou Pharmaceuticals (Group) Co. Ltd., for the manufacture of clinical supply of VAL-083 for our preclinical and Phase 2 clinical studies. If our manufacturer's facility were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to replace our clinical supply. In such event, we would be forced to rely entirely on other third-party contract manufacturers for an indefinite period of time. We have established a relationship with a back-up manufacturer, which has produced quantities of the active pharmaceutical ingredient contained in VAL-083. However, at this time no drug product has been manufactured by a third-party back-up manufacturer. Any disruptions or delays by our third-party manufacturers or Guangxi Wuzhou Pharmaceuticals or their failure to meet regulatory compliance could impair our ability to develop VAL-083, which would adversely affect our business and results of operations.

We rely on these third-party manufacturers to provide drug product supply for our Phase 3 clinical trial. There is no assurance that such a supplier will be able to meet our needs from a technical, timing, or cost-effective manner. Our failure to enter into appropriate agreements with such a third-party manufacturer would delay the initiation of our pivotal Phase 3 clinical trial.

*We may become subject to liabilities related to risks inherent in working with hazardous materials.*

Our discovery and development processes involve the controlled use of hazardous and radioactive materials. We are subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources. We are not specifically insured with respect to this liability. Although we believe that we are in compliance in all material respects with applicable environmental laws and regulations and currently do not expect to make material capital expenditures for environmental control facilities in the near-term, there can be no assurance that we will not be required to incur significant costs to comply with environmental laws and regulations in the future, or that our operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

### **Risks Related to Our Common Stock**

*The market price of our common stock is, and is likely to continue to be, highly volatile and subject to wide fluctuations.*

The market price of our common stock is highly volatile and could be subject to wide fluctuations in response to a number of factors that are beyond our control, including:

variations in our quarterly operating results;

announcements that our revenue or income are below analysts' expectations;

general economic slowdowns;

sales of large blocks of our common stock; and

announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments.

***Because we became public by means of a reverse acquisition, we may not be able to attract, or maintain, the attention of brokerage firms.***

Because we became public through a “reverse acquisition”, securities analysts of brokerage firms may not provide or continue to provide coverage of us since there is little incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any follow-on offerings on behalf of the Company in the future.

***Voting power of our shareholders is highly concentrated by insiders.***

Our officers, directors, and 5% shareholders control, either directly or indirectly, a substantial portion of our voting securities. Therefore, our management may significantly affect the outcome of all corporate actions and decisions for an indefinite period of time including election of directors, amendment of charter documents and approval of mergers and other significant corporate transactions.

***We do not intend to pay dividends on our common stock for the foreseeable future.***

We have paid no dividends on our common stock to date and we do not anticipate paying any dividends to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of the business, we currently anticipate that any earnings will be retained to finance our future expansion and for the implementation of our business plan. Investors should take note of the fact that a lack of a dividend can further affect the market value of our common stock, and could significantly affect the value of any investment in the Company.

***Our articles of incorporation allow for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.***

Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors has the authority to issue up to 5,000,000 shares of our preferred stock (of which 1 share has been designated Special Voting Preferred Stock and is issued and outstanding, 278,530 shares have been designated Series A Preferred Stock and are issued and outstanding, and 1,000,000 shares have been designated as Series B Preferred Stock, of which 881,113 shares are issued and outstanding) without further stockholder approval. As a result, our Board of Directors could authorize the issuance of additional series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders. Although we have no present intention to issue any additional shares of preferred stock or to create any additional series of preferred stock, we may issue such shares in the future.

***Our issuance of common stock upon exercise of warrants or options, exchange of Exchangeable Shares, or conversion of Series B Preferred Stock may depress the price of our common stock.***



As of September 27, 2017, the Company has 21,551,872 shares of common stock issued and outstanding, 957,761 shares of common stock issuable upon exchange of the Exchangeable Shares of Exchangeco (which entitle the holder to require Exchangeco to redeem (or, at the option of the Company or Callco, to have the Company or Callco purchase) the Exchangeable Shares, and upon such redemption or purchase to receive an equal number of shares of common stock of the Company) (the Exchangeable Shares are recognized on an as-exchanged for common stock basis for financial statement purposes), outstanding warrants to purchase 15,028,906 shares of common stock, outstanding Series B convertible preferred shares that are convertible into 2,202,792 shares of common stock, and outstanding options to purchase 1,300,850 shares of common stock. All Exchangeable Shares, warrants, and options are convertible or exercisable into one share of common stock. Each share of Series B preferred stock is convertible into 2.5 shares of common stock. The issuance of shares of common stock upon exercise of outstanding warrants or options or exchange of Exchangeable Shares could result in substantial dilution to our stockholders, which may have a negative effect on the price of our common stock.

## **FORWARD-LOOKING STATEMENTS**

Statements in this Annual Report on Form 10-K may be “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors, including those described above under “Risk Factors,” and under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this report and in other documents which we file with the Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to our ability to raise any financing which we may require for our operations, competition, government regulations and requirements, pricing and development difficulties, our ability to make acquisitions and successfully integrate those acquisitions with our business, as well as general industry and market conditions and growth rates, and general economic conditions. Any forward-looking statements speak only as of the date on which they are made, and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of this report, except as may be required under applicable securities laws.

### **Item 1B. Unresolved Staff Comments.**

Not required for a smaller reporting company.

### **Item 2. Properties.**

Our corporate headquarters are located at Suite 720-999 West Broadway, Vancouver, British Columbia, Canada, V5Z 1K5. Our clinical operations are managed at 3475 Edison Way, Suite R, Menlo Park, California, 94025. Our current monthly base rent for our corporate headquarters is \$4,508 (CDN \$5,850) under a one-year lease which will expire in June 2018. In addition, Valent, which is owned by Dr. Dennis Brown, our Chief Scientific Officer, leases facilities in California and we have access to such facilities pursuant to an informal unwritten arrangement with Valent. Our leased premises, academic relationships, and access to the Valent facility are sufficient to meet the immediate needs of our business, research and operations.

### **Item 3. Legal Proceedings.**

There are no legal proceedings to which the Company is party or any of its property is the subject.

**Item 4. Mine Safety Disclosures.**

Not applicable.

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**PART II****Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

Our common stock is listed on The Nasdaq Capital Market, under the symbol “DMPI” effective July 12, 2016. Previously, the Company’s common stock was quoted on the OTCQX, and prior to that, on the OTCQB.

The following table contains information about the range of high and low sale prices for our common stock for each quarter during the last two fiscal years. The source of these high and low sales prices was the Nasdaq Capital Market and the OTC.QX.

Calendar Quarter	High Sales Price	Low Sales Price
2015 Third Quarter	\$3.48	\$1.72
2015 Fourth Quarter	\$6.12	\$2.84
2016 First Quarter	\$4.52	\$3.00
2016 Second Quarter	\$10.87	\$3.52
2016 Third Quarter	\$9.9	\$5.52
2016 Fourth Quarter	\$6.10	\$3.00
2017 First Quarter	\$5.39	\$2.88
2017 Second Quarter	\$4.45	\$1.66

As of September 22, 2017, there were approximately 243 holders of record of the Company’s common stock.

**Dividends**

The Company has never declared or paid any cash dividends on its common stock. The Company currently intends to retain future earnings, if any, to finance the expansion of its business. As a result, the Company does not anticipate paying any cash dividends in the foreseeable future.

**Sales of Unregistered Securities**

During the three months ended June 30, 2017, we issued 15,625 shares of common stock upon conversion of 6,250 shares of Series B Preferred Stock and 49,602 shares of common stock as dividends on our outstanding shares of Series B Preferred Stock.

In connection with the foregoing, the Company relied upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering.

**Issuer Purchases of Equity Securities**

None.

**Item 6. Selected Financial Data.**

Not required for a smaller reporting company.

## **Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

This Management’s Discussion and Analysis (“MD&A”) contains “forward-looking statements”, within the meaning of the Private Securities Litigation Reform Act of 1995, which represent our projections, estimates, expectations or beliefs concerning, among other things, financial items that relate to management’s future plans or objectives or to our future economic and financial performance. In some cases, you can identify these statements by terminology such as “may”, “should”, “plans”, “believe”, “will”, “anticipate”, “estimate”, “expect” “project”, or “intend”, including their opposites or similar or expressions. You should be aware that these statements are projections or estimates as to future events and are subject to a number of factors that may tend to influence the accuracy of the statements. These forward-looking statements should not be regarded as a representation by the Company or any other person that the events or plans of the Company will be achieved. You should not unduly rely on these forward-looking statements, which speak only as of the date of this report. Except as may be required under applicable securities laws, we undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this report or to reflect the occurrence of unanticipated events.

You should review the factors and risks we describe under “Risk Factors” in this report on Form 10-K for the year ended June 30, 2017 and in the Company’s other filings with the Securities and Exchange Commission, available at [www.sec.gov](http://www.sec.gov). Actual results may differ materially from any forward-looking statement.

### **Corporate History**

We are a Nevada corporation formed on June 24, 2009 under the name Berry Only, Inc (“Berry”). Prior to a reverse acquisition undertaken on January 25, 2013 Berry did not have any significant assets or operations. The Company is the parent company of Del Mar Pharmaceuticals (BC) Ltd. (“DelMar (BC)”), a British Columbia, Canada corporation incorporated on April 6, 2010, that is focused on the development of drugs for the treatment of cancer. The Company is also the parent company to 0959454 B.C. Ltd., a British Columbia corporation (“Callco”), and 0959456 B.C. Ltd., a British Columbia corporation (“Exchangeco”). Callco and Exchangeco were formed to facilitate the reverse acquisition.

References to the Company, “we”, “us”, and “our” refer to the Company and its wholly-owned subsidiaries, DelMar (BC), Callco and Exchangeco. References to “Berry” refer to the Company prior to the reverse acquisition.

### **Reverse Stock Split**

Effective May 20, 2016, the Company effected a 1-for-4 reverse split of its common stock. All common shares, warrants, stock options, conversion ratios, and per share information in this report and the consolidated financial statements and management discussion and analysis give retroactive effect to this 1-for-4 reverse stock split. The Company's authorized and issued preferred stock was not affected by the split. However, the conversion price for the conversion of the Company's Series B preferred stock into common stock was adjusted as a result of the reverse stock split.

### **Registered Direct Financing**

Subsequent to June 30, 2017 the Company completed a registered direct offering (the "2018 Registered Offering") of an aggregate of 8,000,000 shares of common stock and 8,000,000 warrants to purchase an additional 8,000,000 shares of common stock at a price of \$1.25 per share and related warrant for gross proceeds of \$10.0 million. The warrants have an exercise price of \$1.25 per share, are immediately exercisable and have a term of exercise of five years.

The Company engaged a placement agent for the 2018 Registered Offering. Under the Company's engagement agreement with the placement agent, the Company paid \$800,000 in cash commission and other fees to the placement agent and issued warrants to purchase 400,000 shares of common stock to the placement agent (the "2018 Agent Warrants"). The 2018 Agent Warrants are exercisable at a per share price of \$1.25 and have a term of exercise of five years.

In addition to the cash commission and other placement agent fees, the Company also incurred additional cash issue costs of approximately \$235,000 resulting in net cash proceeds of approximately \$9.0 million.

## **Outstanding Securities**

As of September 27, 2017, the Company has 21,551,872 shares of common stock issued and outstanding, 957,761 shares of common stock issuable upon exchange of the Exchangeable Shares of Exchangeco (which entitle the holder to require Exchangeco to redeem (or, at the option of the Company or Callco, to have the Company or Callco purchase) the Exchangeable Shares, and upon such redemption or purchase to receive an equal number of shares of common stock of the Company) (the Exchangeable Shares are recognized on an as-exchanged for common stock basis for financial statement purposes), outstanding warrants to purchase 15,028,906 shares of common stock, 881,113 outstanding shares of Series B Preferred Stock that are convertible into 2,202,792 shares of common stock, and outstanding options to purchase 1,300,850 shares of common stock. All Exchangeable Shares, warrants, and options are convertible or exercisable into one share of common stock. Each Series B convertible preferred share is convertible into 2.5 shares of common stock.

## **Related Parties**

The Company acquired its initial patents and technology rights from Valent Technologies, LLC, (“Valent”), an entity owned by Dr. Dennis Brown, the Company’s Chief Scientific Officer and Director. As a result, Valent is a related party to the Company.

### Related party transactions during the years ended June 30, 2017 and 2016

Pursuant to employment and consulting agreements with the Company’s officers the Company recognized a total of \$856,250 (2016 - \$480,000) in compensation expense for the year ended June 30, 2017. Amounts owed to related parties are non-interest bearing and payable on demand.

The Company recognized \$169,500 (2016 – \$167,083) in directors’ fees during the year ended June 30, 2017. In addition, during the year ended June 30, 2016, upon the resignation of one of the Company’s directors, the Company and the director entered into a lock-up agreement limiting the director’s ability to sell shares. The Company paid \$45,000 in consideration pursuant to the lock-up agreement.

As part of the Series B preferred stock dividend the Company issued 6,044 (2016 – 1,028) shares of common stock to officers and directors of the Company and recognized \$23,767 (2016 - \$3,278) as a direct increase to the accumulated deficit.



The Company recorded \$8,356 (2016 - \$8,356) in dividends related to the Series A preferred stock issued to Valent for the year ended June 30, 2017.

During the year ended June 30, 2017 Valent exercised 125,000 (2016 – 0) common stock purchase warrants at \$1.54 per share (CA \$2.00) for total proceeds of \$192,075 (2016 – 0).

During the year ended June 30, 2017 the Company granted 224,600 (2016 – 0) stock options to officers of the Company at an exercise price of \$4.95. The stock options vest pro rata on a monthly basis over 36 months and expire on February 17, 2027.

#### Employment and consulting contracts

On February 9, 2017, the Company entered into an employment agreement with Jeffrey Bacha, the Company's president and chief executive officer. Pursuant to the employment agreement, Mr. Bacha will continue to serve as the Company's president and chief executive officer for an indefinite period until termination of the employment agreement in accordance with its terms. The Company will pay Mr. Bacha an annual base salary of \$250,000 (which may be adjusted on an annual basis in the discretion of the board of directors) and Mr. Bacha will also be eligible to participate in any bonus plan and long term incentive plan established by the Company for senior executives. The employment agreement may be terminated by the Company with or without cause (as defined therein). In the event the Company terminates the employment agreement without cause, the Company will be required to pay Mr. Bacha, any accrued and unpaid base salary, plus an amount equal to 12 months of Mr. Bacha's base salary plus one additional month's base salary for each completed year of service, up to 18 months' base salary.

On February 9, 2017, the Company entered into an employment agreement with Scott Prail, the Company's chief financial officer. Pursuant to the employment agreement, Mr. Prail will continue to serve as the Company's chief financial officer for an indefinite period until termination of the employment agreement in accordance with its terms. The Company will pay Mr. Prail an annual base salary of \$200,000 (which may be adjusted on an annual basis in the discretion of the board of directors) and Mr. Prail will also be eligible to participate in any bonus plan and long term incentive plan established by the Company for senior executives. The employment agreement may be terminated by the Company with or without cause (as defined therein). In the event the Company terminates the employment agreement without cause, the Company will be required to pay Mr. Prail, any accrued and unpaid base salary, plus an amount equal to 12 months of Mr. Prail's base salary plus one additional month's base salary for each completed year of service, up to 18 months' base salary.

On February 9, 2017, the Company entered into an amendment to a consulting agreement with Dr. Dennis Brown, the Company's chief scientific officer. Pursuant to the amendment, Dr. Brown will continue to serve as the Company's chief scientific officer until December 31, 2017, which period may be extended in accordance with the terms of the agreement. The Company will pay Dr. Brown an annual consulting fee of \$200,000 during 2017. The Company may also pay to Dr. Brown a bonus and incentive compensation as determined at the discretion of the board of directors.

#### 2017 Omnibus Incentive Plan

On July 7, 2017, and subject to approval by the Company's stockholders, the Company's board of directors approved adoption of the Company's 2017 Omnibus Equity Incentive Plan (the "2017 Plan"). The board of directors also approved a form of Performance Stock Unit Award Agreement to be used in connection with grants of performance stock units ("PSUs") under the 2017 Plan.

Under the 2017 Plan, 3,487,785 shares of Company common stock are reserved for issuance, less the number of shares of common stock subject to grants of stock options made, or that may be made, under the Del Mar Pharmaceuticals (BC) Ltd. 2013 Amended and Restated Stock Option Plan (the "Legacy Plan"). If all shares available under the Legacy Plan were used, there would remain 1,730,906 shares available for issuance under the 2017 Plan. The number of shares of Company common stock available for issuance under the 2017 Plan will automatically increase as needed such that the number of shares of common stock available for issuance with respect to awards at any time under the 2017 Plan is thirteen percent (13%) of the Company's fully diluted shares of common stock (less the number of shares of common stock subject to outstanding awards granted under the 2017 Plan and options granted under the Legacy Plan). The maximum number of shares of the Company's common stock with respect to which any one participant (other than an outside director) may be granted stock options or stock appreciation rights during any calendar year is 500,000 shares. The maximum number of shares of common stock that may be subject to awards to outside directors, in the aggregate, during any calendar year is 1,500,000. No award will be granted under the 2017 Plan on or after July 7, 2027, but awards granted prior to that date may extend beyond that date.

Performance Stock Unit grants

Subject to approval by the Company's stockholders of the 2017 Plan, the Company's board of directors granted a total of 1,000,000 PSUs under the 2017 Plan to the Company's independent directors. In total, the awards represent the right to receive an aggregate of 1,000,000 shares of the Company's common stock upon vesting of the PSU based on targets approved by the Company's board of directors related to the Company's fully diluted market capitalization. The PSUs will vest in full upon the later of one year from the grant date and the Company achieving a fully diluted market capitalization of at least \$500 million for five consecutive business days. The PSUs expire on July 7, 2022.

Stock option grants

Subsequent to June 30, 2017, the Company granted a total of 180,000 stock options to the Company's independent directors. The stock options are exercisable at a price of \$2.11 and have a term of 10 years. They vest as to one-third on June 30, 2018 and 15,000 on a quarterly basis commencing September 30, 2018.

## **Derivative Liability**

The Company has issued common stock purchase warrants. Based on the terms of certain of these warrants the Company determined that the warrants were a derivative liability which is recognized at fair value at the date of the transaction and remeasured at fair value each reporting period with the changes in fair value recorded in the consolidated statement of loss and comprehensive loss.

### ***2013 Investor Warrants***

During the quarter ended March 31, 2013 the Company issued an aggregate of 3,281,250 units at a purchase price of \$3.20 per unit, for aggregate gross proceeds of \$10,500,000. Each unit consisted of one share of common stock and one five-year warrant (the "2013 Investor Warrants") to purchase one share of common stock at an initial exercise price of \$3.20. The exercise price of the 2013 Investor Warrants is subject to adjustment in the event that the Company issues common stock at a price lower than the exercise price, subject to certain exceptions. The 2013 Investor Warrants are redeemable by the Company at a price of \$0.004 per 2013 Investor Warrant at any time subject to the conditions that (i) the Company's common stock has traded for twenty (20) consecutive trading days with a closing price of at least \$6.40 per share with an average trading volume of 50,000 shares per day, and (ii) the underlying shares of common stock are registered for resale.

As a result of the financing completed by the Company during the year ended June 30, 2016 the exercise price of the 2013 Investor Warrants was reduced from \$3.20 to \$3.144.

*Year ended June 30, 2016*

### **2013 Investor Warrant exercises**

During the year ended June 30, 2016, 144,500 of the 2013 Investor Warrants were exercised for cash at an exercise price of \$3.144 per share. The Company received proceeds of \$454,308 from these exercises. The warrants that have been exercised were revalued at their exercise date and then the reclassification to equity was recorded resulting in \$285,895 of the derivative liability being reclassified to equity.

2013 Investor Warrant amendments

During the year ended June 30, 2016, the Company entered into amendments (the “2013 Investor Warrant Amendments”) with the holders of certain of the 2013 Investor Warrants. Pursuant to the 2013 Investor Warrant Amendments, 767,560 of the 2013 Investor Warrants were amended to extend the expiration date to March 31, 2019 and remove the provision requiring an adjustment of the exercise price in the event the Company sells common stock at a purchase price lower than the current warrant exercise price. As a result of the 2013 Investor Warrant Amendments, the Company has recognized a loss of \$31,491 and has reclassified \$1,319,480 from the derivative liability to equity. The 2013 Investor Warrants were revalued to the date of the amendment and were then reclassified to equity.

*Year ended June 30, 2017*

2013 Investor Warrant exercises

During the year ended June 30, 2017, 60,095 of the 2013 Investor Warrants were exercised at an exercise price of \$3.144 per share. Also, 5,000 of the previously amended 2013 Investor Warrants were exercised. The Company received proceeds of \$204,659 from these exercises. The warrants that have been exercised were revalued at their respective exercise dates and then the reclassification to equity was recorded resulting in \$238,474 of the derivative liability being reclassified to equity.

2013 Investor Warrant amendments

During the year ended June 30, 2017, pursuant to the 2013 Investor Warrant Amendments, 15,944 of the 2013 Investor Warrants were amended. As a result, the Company has reclassified \$53,006 from the derivative liability to equity. The 2013 Investor Warrants were revalued to their respective amendment dates and were then reclassified to equity.

### ***2013 Placement Agent Warrants***

On December 30, 2015, the Company entered into amendments (the “2013 Placement Agent Warrant Amendments”) with the holders of warrants the Company issued to the placement agent for the financing completed during the quarter ended March 31, 2013 (the “2013 Placement Agent Warrants”). Pursuant to the 2013 Placement Agent Warrant Amendments, 1,262,500 of the 2013 Placement Agent Warrants were amended to extend the expiration date to June 30, 2019 and remove the provision requiring an adjustment of the exercise price in the event the Company issues common stock at a price lower than the current warrant exercise price. As a result of the 2013 Placement Agent Warrant Amendments, for the year ended June 30, 2016 the Company has recognized a loss of \$242,400 and has reclassified \$2,277,550 from the derivative liability to equity. The 2013 Placement Agent Warrants were revalued to the date of the amendment and were then reclassified to equity.

### ***2015 Agent Warrants***

As part of the Company’s financing completed during the year ended June 30, 2016, the Company issued warrants to purchase 23,477 shares of common stock to certain placement agents (“2015 Agent Warrants”) and recognized them as a derivative liability of \$29,594 at the time of issuance. The 2015 Agent Warrants are exercisable at a per share price equal to \$3.00 until July 15, 2020. During the year ended June 30, 2017, 680 (2016 – 0) of the 2015 Agent Warrants were exercised for cash proceeds of \$2,040 and 1,000 (2016 – 31) of the 2015 Agent Warrants were exercised on a cashless basis for 594 (2016 – 21) shares of common stock. The total reclassification to equity subsequent to revaluation at the respective exercise dates was \$9,935 (2016 - \$133).

### ***Warrants issued for services***

In prior periods, the Company has issued 75,000 warrants for services that have been treated as a derivative liability. During the year ended June 30, 2016, 31,250 of these warrants were exercised on a cashless basis for 9,383 shares of common stock and the reclassification to equity of \$76,406. There were no exercises of these warrants during the year ended June 30, 2017.

The Company’s derivative liability is summarized as follows:

Years ended  
**June 30,    June 30,**

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	<b>2017</b>	<b>2016</b>
	<b>\$</b>	<b>\$</b>
Opening balance	693,700	2,364,381
Change in fair value of warrants	(331,057)	1,963,733
Change in fair value due to change in warrant terms	-	295,456
Reclassification to equity upon amendment of warrants	(53,006 )	(3,597,030)
Issuance of 2015 Agent Warrants	-	29,594
Reclassification to equity upon exercise of warrants	(248,409)	(362,434 )
Closing balance	61,228	693,700
Less current portion	(33,091 )	-
Long term portion	28,137	693,700

The derivative liability consists of the following warrants as at June 30, 2017 and 2016:

	Year ended June 30, 2017	
	Number of warrants	\$
2013 Investor Warrants	105,129	33,091
Warrants issued for services	43,750	4,468
2015 Agent Warrants	21,768	23,669
Closing balance	170,647	61,228
Less current portion	(105,129)	(33,091)
Long-term portion	65,518	28,137

	Year ended June 30, 2016	
	Number of warrants	\$
2013 Investor Warrants	181,156	503,796
Warrants issued for services	43,750	103,906
2015 Agent Warrants	23,448	85,998
	248,354	693,700

### **Selected Annual Information**

The financial information reported herein has been prepared in accordance with accounting principles generally accepted in the United States. The Company's functional currency at June 30, 2017 is the US\$. The following tables represent selected financial information for the Company for the periods presented.

#### *Selected Balance Sheet Data*



	<b>June 30,</b>	<b>June 30,</b>
	<b>2017</b>	<b>2016</b>
	<b>\$</b>	<b>\$</b>
Cash and cash equivalents	6,586,014	6,157,264
Working capital	6,566,371	5,692,336
Total assets	7,911,021	6,355,799
Derivative liability	61,228	693,700
Total stockholders' equity	6,578,524	4,858,778

*Selected Statement of operations data***For the years ended:**

	June 30, 2017 \$	June 30, 2016 \$
Research and development	5,003,640	3,360,878
General and administrative	3,317,189	2,853,140
Change in fair value of stock option and derivative liabilities	(245,963 )	2,341,660
Change in fair value of derivative liability due to change in warrant terms	-	295,456
Foreign exchange loss	7,355	13,838
Interest income	(457 )	(108 )
Net and comprehensive loss for the period	8,081,764	8,864,864
Series B Preferred stock dividend	790,454	238,326
Net and comprehensive loss available to common stockholders	8,872,218	9,103,190
Basic weighted average number of shares outstanding	12,047,079	10,948,481
Basic loss per share	0.74	0.83

**Expenses net of share-based payments**

The following table discloses research and development, and general and administrative expenses net of share-based payment expenses.

**For the years ended:**

	<b>June 30,</b> <b>2017</b> <b>\$</b>	<b>June 30,</b> <b>2016</b> <b>\$</b>
Research and development	5,003,640	3,360,878
Share-based expenses included in research and development	(102,828 )	(528,977 )
Research and development net of non-cash	4,900,812	2,831,901

General and administrative	3,317,189	2,853,140
Share-based expenses included in general and administrative	(667,521 )	(659,957 )
General and administrative net of non-cash	2,649,668	2,193,183

**Comparison of the years ended June 30, 2017 and June 30, 2016**

	Years ended		Change	Change %
	June 30, 2017	June 30, 2016		
	\$	\$	\$	
Research and development	5,003,640	3,360,878	1,642,762	49
General and administrative	3,317,189	2,853,140	464,049	16
Change in fair value of stock option and derivative liabilities	(245,963 )	2,341,660	(2,587,623)	(1,105 )
Change in fair value of derivative liability due to change in warrant terms	-	295,456	(295,456 )	(100 )
Foreign exchange loss	7,355	13,838	(6,483 )	(47 )
Interest income	(457 )	(108 )	(349 )	323
Net loss	8,081,764	8,864,864	(783,100 )	

*Research and Development*

Research and development expenses increased to \$5,003,640 for the year ended June 30, 2017 from \$3,360,878 for the year ended June 30, 2016. The increase was largely attributable to an increase in clinical and preclinical research, intellectual property, and personnel, partially offset by a reduction in non-cash expenses during the year ended June 30, 2017 compared to the year ended June 30, 2016. Excluding the impact of non-cash expense, research and development expenses increased to \$4,900,812 during the current year from \$2,831,901 for the prior year. For both the year ended June 30, 2017 and 2016 non-cash expenses related to warrants issued for services and stock option expense. The decrease in non-cash expenses for the year ended June 30, 2017 compared to the year ended June 30, 2016 was due to a decrease in recognition in warrants issued for services in the current period.

The increase in clinical costs for the year ended June 30, 2017 compared to the year ended June 30, 2016 was primarily due to protocol development, manufacturing costs, and preparation for the commencement of enrollment for the Company's pivotal STAR-3 study. Intellectual property costs increased in the year ended June 30, 2017 compared to the year ended June 30, 2016 as the Company continued to expand and advance its patent portfolio. New patents filed in previous periods require on-going costs to advance those filings in the United States and in foreign jurisdictions. Patent costs can vary considerably depending on the filing of new patents, conversion of the provisional applications to PCT applications, foreign office actions, and actual filing costs. Preclinical research increased primarily due to an increase in the ongoing mechanism of action research that the Company has undertaken in the current period as well as its collaboration with Duke University. Personnel costs increased in the year ended June 30, 2017 compared to the year ended June 30, 2016 due to an increase in compensation for research and management staff.

*General and Administrative*

General and administrative expenses were \$3,317,189 for the year ended June 30, 2017 compared to \$2,853,140 for the year ended June 30, 2016. The increase was primarily due to an increase in professional fees, office and sundry, personnel costs, and non-cash expenses partially offset by a decrease in travel. In relation to general and administrative expenses during the year ended June 30, 2017, the Company incurred non-cash expenses of \$667,521 related to shares and warrants issued for services and stock option expense while during the year ended June 30, 2016 the Company incurred non-cash expenses of \$659,957 relating to shares and warrants issued for services and stock option expense. The increase in the current period was due to timing of the issuance of shares for services.

Excluding the impact of non-cash expenses, general and administrative expenses increased in the year ended June 30, 2017 to \$2,649,668 from \$2,193,183 for the year ended June 30, 2016. Professional fees increased during the year ended June 30, 2017 compared to the year ended June 30, 2016 due to costs related to preparing for the Company's uplisting of its common stock on the Nasdaq Stock Market as well as fees associated with one-time listing activities

and filing three registration statements that were all declared effective in September 2016. In addition, business development and partnering activities are higher in the current period than in the prior period. Office and sundry costs have increased in part due to the initial fees to list our common stock on the Nasdaq Stock Market. Additional increases in office and sundry costs relate to expenses to maintain our digital communications channels for a full year in 2017 compared to a shorter period in 2016. Personnel costs have increased in the year ended June 30, 2017 compared to the year ended June 30, 2016 due to an increase in compensation for management staff. Travel decreased in the current period compared to the prior period as in the prior period the Company completed two financings compared to one in the current period.

*Change in fair value of stock option and derivative liabilities*

Based on the terms of certain warrants issued by the Company, the Company determined that the warrants were a derivative liability which is recognized at fair value at the date of the transaction and re-measured at fair value every reporting period with gains or losses on the changes in fair value recorded in the consolidated statement of loss and comprehensive loss. The balances recognized during the years ended June 30, 2017 and 2016 were primarily due to changes in the Company's common stock price between the date the warrants were last valued on June 30, 2016 and 2015 respectively which are the previous valuation dates for the years ended June 30, 2017 and 2016.

The Company recognized a gain of \$245,963 from the change in fair value of the stock option and derivative liabilities for the year ended June 30, 2017. Certain of the Company's stock options have been issued in CA\$. Of these, a portion have been classified as a stock option liability which is revalued at each reporting date. During the year ended June 30, 2017, the Company recognized a revaluation loss of \$85,094 relating to the revaluation of these stock options. During the year ended June 30, 2017, the Company amended 43,750 of these stock options held by five optionees such that the exercise price of the options was adjusted to be denominated in US\$. No other terms of the stock options were amended. As a result of the amendment, \$260,969 was reclassified to equity during the year ended June 30, 2017.

For the year ended June 30, 2016 the Company recognized a loss of \$1,963,733 due to the change in fair value of the derivative liability. In addition, the Company recognized a loss due to a change in warrant terms of \$295,456 which resulted from the change in fair value of the 2013 Investor Warrants and the 2013 Placement Agent Warrants upon their respective amendments. During the year ended June 30, 2016, the Company also recognized a loss of \$377,927 relating to the revaluation of stock options. On June 30, 2016, the Company amended 87,500 of these stock options held by three optionees such that the exercise price of the options was adjusted to be denominated in US\$. No other terms of the stock options were amended. As a result of the amendments, \$351,750 was reclassified to equity at June 30, 2016.

Changes in the Company's common stock price can result in significant volatility in the Company's reported net loss due to its impact on the fair value of the derivative liability. As a result of revaluation gains and losses, the Company expects that its reported net income or loss will continue to fluctuate significantly.

#### Out-of-period adjustment

The consolidated statement of operations and comprehensive loss for the year ended June 30, 2016 includes a \$100,868 out-of-period adjustment related to remeasuring of the stock option liability that arose during the year ended June 30, 2015. This adjustment increased the stock based compensation expense and the corresponding stock option liability by \$100,868. The impact of these adjustments to the year ended June 30, 2016 is not material.

#### *Foreign Exchange Gain*

The Company's functional currency at June 30, 2017 is the US\$ but the Company incurs a portion of its expenses in CA\$. The foreign exchange gains and losses are reported in other loss (income) in the consolidated condensed interim statement of loss and comprehensive loss.

The Company recognized a foreign exchange loss of \$7,355 for the year ended June 30, 2017 compared to a loss of \$13,838 for the year ended June 30, 2016. The change was due to changes in the exchange rate between the CA\$ and the US\$ and to varying levels of CA\$ cash and accounts payable.

#### *Preferred Share Dividends*

For each of the years ended June 30, 2017 and 2016 the Company recorded \$8,356 related to the dividend payable to Valent on the Series A preferred stock. The dividend has been recorded as a direct increase in accumulated deficit for both periods.

The Company issued 200,446 (2016 – 30,360) shares of common stock during the year ended June 30, 2017 as a stock dividend on the Series B Preferred stock and recognized \$790,454 (2016 - \$238,326) as a direct increase in accumulated deficit.

## Liquidity and Capital Resources

### Year ended June 30, 2017 compared to the year ended June 30, 2016

	<b>June 30,</b>	<b>June 30,</b>	<b>Change</b>	<b>Change</b>
	<b>2017</b>	<b>2016</b>	<b>\$</b>	<b>%</b>
	<b>\$</b>	<b>\$</b>		
Cash flows from operating activities	(8,019,071)	(5,145,814)	(2,873,257)	56
Cash flows from investing activities	(20,956 )	(16,762 )	(4,194 )	25
Cash flows from financing activities	8,468,777	9,565,407	(1,096,630)	(11 )

### *Operating Activities*

Net cash used in operating activities increased to \$8,019,071 for the year ended June 30, 2017 from \$5,145,814 for the year ended June 30, 2016. During the year ended June 30, 2017 and 2016 the Company reported net losses of \$8,081,764 and \$8,864,864 respectively. The Company recognized a gain of \$245,963 from the revaluation of the derivative and stock option liabilities for the year ended June 30, 2017 compared to a loss of \$2,341,660 for the year ended June 30, 2016. Excluding the impact of changes in the fair value of the derivative and stock option liabilities, non-cash items relating to amortization, warrants and shares issued for services, and stock option expense totaled \$787,032 for the year ended June 30, 2017. Non-cash items relating to the loss due to amortization, changes in warrant terms, warrants and shares issued for services and stock option expense totaled \$1,494,678 for the year ended June 30, 2016. The largest changes in non-cash working capital for the year ended June 30, 2017 were from a decrease due to payment of prepaid expenses and deposits of \$1,063,991, an increase in accounts payable and accrued liabilities of \$598,310, a decrease due to taxes and other receivables of \$58,208, and an increase in related party payables of \$45,513. The largest changes in non-cash working capital for the year ended June 30, 2016 were from a reduction of accounts payable and accrued liabilities of \$178,263, a reduction of related party payables of \$47,376, and from a decrease in prepaid expenses of \$100,907.

During the last quarter of the year ended June 30, 2017, the Company prepared for the commencement of its Phase III clinical trial. In relation to the start of this trial, the Company has paid deposits that will be credited against future study costs and experienced an increase in accounts payable at June 30, 2017 compared to June 30, 2016.

### *Investing Activities*

During the year ended June 30, 2017, the Company incurred \$20,956 (2016 - \$16,762) in cash costs for the development of its web site.

### *Financing Activities*

During the year ended June 30, 2017, the Company received \$7,932,107 in net proceeds from a public offering of its common stock and common stock purchase warrants. During the year ended June 30, 2016 the Company received net proceeds of \$6,540,821 from the issuance of Series B preferred shares and \$2,453,633 in net proceeds from the completion of a public offering of common stock and common stock purchase warrants. Including deferred costs recorded by the Company at June 30, 2015, the total net cash proceeds of the public offering were \$1,903,514.



During the year ended June 30, 2017 and 2016 the Company received cash proceeds of \$545,026 and \$579,309 respectively from the exercise of warrants. In addition, the Company recorded \$8,356 related to the Series A Preferred stock dividend payable to Valent during each of the years ended June 30, 2017 and 2016.

## **Operating Capital and Capital Expenditure Requirements**

### **Liquidity risk**

For the year ended June 30, 2017, the Company reported a loss of \$8,081,764 and the Company had an accumulated deficit of \$41,118,433 at that date. As at June 30, 2017, the Company had cash on hand of \$6,586,014. During the year ended June 30, 2017, the Company received \$7,932,107 in net proceeds from a public offering financing and \$545,026 in proceeds from the exercise of share purchase warrants. Subsequent to June 30, 2017, the Company completed a registered direct offering of an aggregate of 8,000,000 shares of common stock and warrants to purchase an aggregate of 8,000,000 shares of common stock at a price of \$1.25 per share and related warrant for net proceeds of approximately \$9 million. We believe, based on our current estimates, that we will be able to fund our operations beyond the next twelve months.

The Company does not have the prospect of achieving revenues in the near future and the Company will require additional funding for its clinical trials, to maintain its research and development projects, and for general operations. There is a great degree of uncertainty with respect to the expenses the Company will incur in executing its business plan.

Consequently, management is pursuing various financing alternatives to fund the Company's operations so it can continue as a going concern in the medium to longer term.

There is no assurance that our cost estimates will prove to be accurate or that unforeseen events, problems or delays will not occur with respect thereto. The ability of the Company to meet its obligations and continue the research and development of its product candidate is dependent on its ability to continue to raise adequate financing. There can be no assurance that such financing will be available to the Company in the amount required at any time or for any period or, if available, that it can be obtained on terms satisfactory to the Company. The Company may tailor its drug candidate development program based on the amount of funding the Company raises.

Our future funding requirements will depend on many factors, including but not limited to:

the rate of progress and costs of our clinical trials, preclinical studies and other discovery and research and development activities;

the costs associated with establishing manufacturing and commercialization capabilities;

the costs of acquiring or investing in businesses, product candidates and technologies;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the costs and timing of seeking and obtaining FDA and other regulatory approvals;

the effect of competing technological and market developments; and

the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter.

### **Critical Accounting Policies**

The preparation of financial statements, in conformity with generally accepted accounting principles in the United States, requires companies to establish accounting policies and to make estimates that affect both the amount and timing of the recording of assets, liabilities, revenues and expenses. Some of these estimates require judgments about matters that are inherently uncertain and therefore actual results may differ from those estimates.

A detailed presentation of all of the Company's significant accounting policies and the estimates derived there from is included in Note 2 to the Company's consolidated financial statements for the year ended June 30, 2017 contained in this Form 10-K. While all of the significant accounting policies are important to the Company's consolidated financial statements, the following accounting policies and the estimates derived therefrom have been identified as being critical:

Warrants and shares issued for services

Stock options

Derivative liability

Warrants and shares issued for services

Periodically, the Company has issued equity instruments for services provided by employees and nonemployees. The equity instruments are valued at the fair value of the instrument granted.

### Stock options

The Company accounts for these awards under ASC 718, “Compensation - Stock Compensation” (“ASC 718”). ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on the date of grant and recognition of compensation over the requisite service period for awards expected to vest. Compensation expense for unvested options to non-employees is revalued at each period end and is being amortized over the vesting period of the options. The determination of grant-date fair value for stock option awards is estimated using the Black-Scholes model, which includes variables such as the expected volatility of the Company’s share price, the anticipated exercise behavior of its grantee, interest rates, and dividend yields. These variables are projected based on the Company’s historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for non-cash expenses. Such value is recognized as expense over the requisite service period, net of estimated forfeitures, using the straight-line attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. The Company considers many factors when estimating expected forfeitures, including type of awards granted, employee class, and historical experience. Actual results and future estimates may differ substantially from current estimates.

### Derivative liability

The Company accounts for certain warrants under the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company’s own stock, on the understanding that in compliance with applicable securities laws, the warrants require the issuance of securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. The Company classifies warrants in its balance sheet as a derivative liability which is fair valued at each reporting period subsequent to the initial issuance. As quoted prices for the derivative liability are not available, the Company uses a simulated probability valuation model to value the warrants. Determining the appropriate fair-value model and calculating the fair value of warrants requires considerable judgment. Any change in the estimates used may cause the value to be higher or lower than that reported. The estimated volatility of the Company’s common stock at the date of issuance, and at each subsequent reporting period, is based on the historical volatility of similar life sciences companies. The risk-free interest rate is based on rates published by the government for bonds with a maturity similar to the expected remaining life of the warrants at the valuation date. The expected life of the warrants is assumed to be equivalent to their remaining contractual term.

### **Off-Balance Sheet Arrangements**

The Company does not have any off-balance sheet arrangements.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Not required for a smaller reporting company.

**Item 8. Financial Statements.**

DelMar Pharmaceuticals, Inc.

Consolidated Financial Statements

**June 30, 2017**

(in US dollars unless otherwise noted)

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of DelMar Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of DelMar Pharmaceuticals, Inc. (the “Company”) as of June 30, 2017, and the related consolidated statements of operations and comprehensive loss, changes in stockholders’ accumulated equity (deficit) and cash flows for the year ended June 30, 2017. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company’s internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of DelMar Pharmaceuticals, Inc. at June 30, 2017, and the consolidated results of its operations and its cash flows for the year ended June 30, 2017, in conformity with U.S. generally accepted accounting principles.

Vancouver, Canada /s/ ERNST & YOUNG LLP  
September 27, 2017 Chartered Professional Accountants

Report of Independent Registered Public Accounting Firm

To the Stockholders of DelMar Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of DelMar Pharmaceuticals, Inc. and its subsidiaries as of June 30, 2016 and the related consolidated statements of operations and comprehensive loss, changes in stockholders' accumulated equity (deficit) and cash flows for the year ended June 30, 2016. Management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. Our audit of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall consolidated financial statement presentation. We were not engaged to perform an audit of the company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of DelMar Pharmaceuticals Inc. and its subsidiaries as of June 30, 2016 and the results of their operations and their cash flows for the year ended June 30, 2016 in conformity with accounting principles generally accepted in the United States of America.

*signed "PricewaterhouseCoopers LLP"*

**Chartered Professional Accountants**



Vancouver, British Columbia

September 12, 2016

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**DelMar Pharmaceuticals, Inc.**

## Consolidated Balance Sheet

(in US dollars unless otherwise noted)

	Note	June 30, 2017 \$	June 30, 2016 \$
<b>Assets</b>			
<b>Current assets</b>			
Cash		6,586,014	6,157,264
Prepaid expenses and deposits	8	1,208,122	144,131
Taxes and other receivables		76,595	18,387
		7,870,731	6,319,782
Intangible assets - net		40,290	36,017
		7,911,021	6,355,799
<b>Liabilities</b>			
<b>Current liabilities</b>			
Accounts payable and accrued liabilities		1,182,312	584,002
Related party payables	6	88,957	43,444
Current portion of derivative liability	4	33,091	-
		1,304,360	627,446
Stock option liability	5	-	175,875
Derivative liability	4	28,137	693,700
		1,332,497	1,497,021
<b>Stockholders' accumulated equity</b>			
<b>Preferred stock</b>			
Authorized			
5,000,000 shares, \$0.001 par value			
Issued and outstanding			
278,530 Series A shares at June 30, 2017 (June 30, 2016 – 278,530)	3,5	278,530	278,530
881,113 Series B shares at June 30, 2017 (June 30, 2016 – 902,238)	5	6,146,880	6,294,255
1 special voting share at June 30, 2017 (June 30, 2016 – 1)		-	-

Common stock			
Authorized			
50,000,000 shares, \$0.001 par value			
14,509,633 issued at June 30, 2017 (June 30, 2016 – 11,187,023)	5	14,510	11,187
Additional paid-in capital	5	36,665,285	28,833,105
Warrants	5	4,570,574	1,658,382
Accumulated deficit		(41,118,433)	(32,237,859)
Accumulated other comprehensive income		21,178	21,178
		6,578,524	4,858,778
		7,911,021	6,355,799

**Liquidity risk, nature of operations, and corporate history** (note 1)

**Subsequent events** (note 11)

The accompanying notes are an integral part of these consolidated financial statements.

**DelMar Pharmaceuticals, Inc.**

## Consolidated Statement of Operations and Comprehensive Loss

(in US dollars unless otherwise noted)

	Note	Year ended June 30, 2017 \$	Year ended June 30, 2016 \$
Expenses			
Research and development	6	5,003,640	3,360,878
General and administrative	6	3,317,189	2,853,140
		8,320,829	6,214,018
Other loss (income)			
Change in fair value of stock option and derivative liabilities	4,5	(245,963 )	2,341,660
Change in fair value of derivative liability due to change in warrant terms	4,5	-	295,456
Foreign exchange loss		7,355	13,838
Interest income		(457 )	(108 )
		(239,065 )	2,650,846
Net and comprehensive loss for the year		8,081,764	8,864,864
Computation of basic loss per share			
Net and comprehensive loss for the year		8,081,764	8,864,864
Series B Preferred stock dividend	5	790,454	238,326
		8,872,218	9,103,190
Basic and fully diluted loss per share		0.74	0.83
Basic weighted average number of shares		12,047,079	10,948,481

The accompanying notes are an integral part of these consolidated financial statements.

**DelMar Pharmaceuticals, Inc.**

## Consolidated Statement of Changes in Stockholders' Accumulated Equity (Deficit)

(in US dollars unless otherwise noted)

	Number of shares	Common stock \$	Additional paid-in capital \$	Accumulated other comprehensive income \$	Preferred stock \$	Warrants \$ \$\$	Accumulated deficit \$	Stockholders' equity (deficiency) \$
Balance - June 30, 2015	9,864,175	9,864	17,392,800	21,178	278,530	89,432	(18,613,294)	(821,490 )
Issuance of shares and warrants - net of issue costs	1,069,417	1,069	1,201,662	-	-	671,189	-	1,873,920
Issuance of Series B Preferred Shares – net of issue costs	-	-	4,513,019	-	6,294,255	246,566	(4,513,019 )	6,540,821
Shares issued for services	27,500	28	146,872	-	-	-	-	146,900
Warrants issued for services	-	-	-	-	-	677,445	-	677,445
Reclassification of stock option liability	-	-	381,497	-	-	-	-	381,497
Warrants exercised for cash	186,167	186	891,266	-	-	(26,250 )	-	865,202
Cashless exercise of warrants	9,404	9	76,530	-	-	-	-	76,539
Amendment of warrants (note 4)	-	-	3,597,032	-	-	-	-	3,597,032
Stock option expense	-	-	394,132	-	-	-	-	394,132

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Series A preferred cash dividend (note 3)	-	-	-	-	-	-	(8,356 )	(8,356 )
Series B preferred stock dividend	30,360	31	238,295	-	-	-	(238,326 )	-
Loss for the period	-	-	-	-	-	-	(8,864,864 )	(8,864,864 )
Balance - June 30, 2016	11,187,023	11,187	28,833,105	21,178	6,572,785	1,658,382	(32,237,859 )	4,858,778
Issuance of shares and warrants - net of issue costs	2,769,232	2,769	4,978,601	-	-	2,950,737	-	7,932,107
Shares issued for services	60,000	60	563,940	-	-	-	-	564,000
Warrants issued for services	-	-	-	-	-	81,602	-	81,602
Reclassification of stock option liability	-	-	260,969	-	-	-	-	260,969
Warrants exercised for cash (note 4)	239,525	240	908,183	-	-	(120,147 )	-	788,276
Cashless exercise of warrants	594	1	5,158	-	-	-	-	5,159
Amendment of warrants (note 4)	-	-	53,006	-	-	-	-	53,006
Stock option expense	-	-	124,747	-	-	-	-	124,747
Conversion of Series B preferred stock to common stock	52,813	53	147,322	-	(147,375 )	-	-	-
Series A preferred cash dividend (note 3)	-	-	-	-	-	-	(8,356 )	(8,356 )
Series B preferred stock dividend	200,446	200	790,254	-	-	-	(790,454 )	-
Loss for the period	-	-	-	-	-	-	(8,081,764 )	(8,081,764 )

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Balance - June 30, 2017	14,509,633	14,510	36,665,285	21,178	6,425,410	4,570,574	(41,118,433)	6,578,524
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The accompanying notes are an integral part of these consolidated financial statements.

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**DelMar Pharmaceuticals, Inc.**

## Consolidated Statement of Cash Flows

(in US dollars unless otherwise noted)

		Years ended June 30,	
		2017	2016
	Note	\$	\$
Cash flows from operating activities			
Loss for the period		(8,081,764)	(8,864,864)
Items not affecting cash			
Amortization of intangible assets		16,683	10,288
Change in fair value of stock option and derivative liabilities	4,5	(245,963 )	2,341,660
Change in fair value of derivative liability due change in warrant terms	4,5	-	295,456
Shares issued for services	5	564,000	146,900
Warrants issued for services	5	81,602	647,902
Stock option expense	5	124,747	394,132
Changes in non-cash working capital			
Prepaid expenses and deposits	8	(1,063,991)	100,907
Taxes and other receivables		(58,208 )	7,444
Accounts payable and accrued liabilities		598,310	(178,263 )
Related party payables	6	45,513	(47,376 )
		(8,019,071)	(5,145,814)
Cash flows from investing activities			
Intangible assets - website development costs		(20,956 )	(16,762 )
		(20,956 )	(16,762 )
Cash flows from financing activities			
Net proceeds from the issuance of shares and warrants	5	7,932,107	2,453,633
Net proceeds from the issuance of Series B Preferred Stock	5	-	6,540,821
Proceeds from the exercise of warrants	5	545,026	579,309
Series A preferred stock dividend	5	(8,356 )	(8,356 )
		8,468,777	9,565,407
Increase in cash and cash equivalents		428,750	4,402,831
Cash – beginning of year		6,157,264	1,754,433
Cash – end of year		6,586,014	6,157,264



**Supplementary information (note 9)**

The accompanying notes are an integral part of these consolidated financial statements.

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**DelMar Pharmaceuticals, Inc.**

Notes to Consolidated Financial Statements

June 30, 2017

(in US dollars unless otherwise noted)

**1 Liquidity risk, nature of operations, and corporate history**

**Liquidity risk**

For the year ended June 30, 2017, DelMar Pharmaceuticals, Inc. (the “Company”) reported a loss of \$8,081,764 and the Company had an accumulated deficit of \$41,118,433 at that date. As at June 30, 2017, the Company had cash on hand of \$6,586,014. During the year ended June 30, 2017, the Company received \$7,932,107 in net proceeds from a public offering financing and \$545,026 in proceeds from the exercise of share purchase warrants (note 5). Subsequent to June 30, 2017, the Company completed a registered direct offering of an aggregate of 8,000,000 shares of common stock and warrants to purchase an aggregate of 8,000,000 shares of common stock at a price of \$1.25 per share and related warrant for net proceeds of approximately \$9 million (note 11). We believe, based on our current estimates, that we will be able to fund our operations beyond the next twelve months.

The Company does not have the prospect of achieving revenues in the near future and the Company will require additional funding for its clinical trials, to maintain its research and development projects, and for general operations. There is a great degree of uncertainty with respect to the expenses the Company will incur in executing its business plan. Consequently, management is pursuing various financing alternatives to fund the Company’s operations so it can continue as a going concern in the medium to longer term.

There is no assurance that our cost estimates will prove to be accurate or that unforeseen events, problems or delays will not occur with respect thereto. The ability of the Company to meet its obligations and continue the research and development of its product candidate is dependent on its ability to continue to raise adequate financing. There can be no assurance that such financing will be available to the Company in the amount required at any time or for any period or, if available, that it can be obtained on terms satisfactory to the Company. The Company may tailor its drug candidate development program based on the amount of funding the Company raises.

## **Nature of operations**

The Company is a clinical stage drug development company with a focus on the treatment of cancer. We are conducting clinical trials in the United States with our product candidate, VAL-083, as a potential new treatment for glioblastoma multiforme, the most common and aggressive form of brain cancer. We have also acquired certain exclusive commercial rights to VAL-083 in China where it is approved as a chemotherapy for the treatment of chronic myelogenous leukemia and lung cancer. In order to accelerate our development timelines, we leverage existing clinical and commercial data from a wide range of sources. We plan to seek marketing partnerships in order to potentially generate future royalty revenue.

The address of the Company's administrative offices is Suite 720 - 999 West Broadway, Vancouver, British Columbia, V5Z 1K5 with clinical operations located at 3485 Edison Way, Suite R, Menlo Park, California, 94025.

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**DelMar Pharmaceuticals, Inc.**

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**Corporate history**

The Company is a Nevada corporation formed on June 24, 2009 under the name Berry Only, Inc. On January 25, 2013 (the “Reverse Acquisition Closing Date”), the Company entered into and closed an exchange agreement (the “Exchange Agreement”), with Del Mar Pharmaceuticals (BC) Ltd. (“DelMar (BC)”), 0959454 B.C. Ltd. (“Callco”), and 0959456 B.C. Ltd. (“Exchangeco”) and the security holders of DelMar (BC). Upon completion of the Exchange Agreement, DelMar (BC) became a wholly-owned subsidiary of the Company (the “Reverse Acquisition”).

DelMar Pharmaceuticals, Inc. is the parent company of DelMar (BC), a British Columbia, Canada corporation incorporated on April 6, 2010, which is a clinical stage company with a focus on the development of drugs for the treatment of cancer. The Company is also the parent company to Callco and Exchangeco which are British Columbia, Canada corporations. Callco and Exchangeco were formed to facilitate the Reverse Acquisition.

References to the Company refer to the Company and its wholly-owned subsidiaries, DelMar (BC), Callco and Exchangeco.

**2 Significant accounting policies**

**Reverse Stock Split**

On May 16, 2016, the Company filed a Certificate of Change with the Secretary of State of Nevada that effected a 1-for-4 (1:4) reverse stock split of its common stock, par value \$0.001 per share. The reverse split became effective on May 20, 2016. Pursuant to the Certificate of Change, the Company’s authorized common stock was decreased in the same proportion as the split resulting in a decrease from 200,000,000 authorized shares of common stock to

50,000,000 shares authorized. The par value of its common stock was unchanged at \$0.001 per share, post-split. All common shares, warrants, stock options, conversion ratios, and per share information in these consolidated financial statements give retroactive effect to the 1-for-4 reverse stock split. The Company's authorized and issued preferred stock was not affected by the split.

### **Basis of presentation**

The consolidated financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles ("US GAAP") and are presented in United States dollars. The Company's functional currency is the United States dollar.

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below and have been consistently applied to all periods presented.

### **Consolidation**

The consolidated financial statements include the accounts of Del Mar (BC), Callco, and Exchangeco as at and for the years ended June 30, 2017 and 2016. Inter-company balances and transactions have been eliminated on consolidation.

**DelMar Pharmaceuticals, Inc.**

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**Use of estimates**

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions about future events that affect the reported amounts of assets, liabilities, expenses, contingent assets and contingent liabilities as at the end or during the reporting period. Actual results could significantly differ from those estimates. Significant areas requiring management to make estimates include the derivative liability, the valuation of equity instruments issued for services, and clinical trial accruals. Further details of the nature of these assumptions and conditions may be found in the relevant notes to these consolidated financial statements.

**Cash and cash equivalents**

Cash is held at recognized Canadian and United States financial institutions. Interest earned is recognized in the consolidated statement of operations and comprehensive loss.

**Foreign currency translation**

The functional currency of the Company at June 30, 2017 is the United States dollar. Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign-currency denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange losses or gains in the consolidated statement of operations and comprehensive loss. Non-monetary assets and liabilities are translated at historical exchange rates. Expenses are translated at average exchange rates during the period. Exchange gains and losses are included in consolidated statement of operations and comprehensive loss for the period.

## **Current and deferred income taxes**

The Company follows the liability method of accounting for income taxes. Under this method, current income taxes are recognized for the estimated income taxes payable for the current period. Income taxes are accounted for using the asset and liability method of accounting. Deferred income taxes are recognized for the future income tax consequences attributable to differences between the carrying values of assets and liabilities and their respective income tax bases and for loss carry-forwards. Deferred income tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the periods in which temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax laws or rates is included in earnings in the period that includes the enactment date. When realization of deferred income tax assets does not meet the more-likely-than-not criterion for recognition, a valuation allowance is provided.

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**DelMar Pharmaceuticals, Inc.**

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**Financial instruments**

The Company has financial instruments that are measured at fair value. To determine the fair value, we use the fair value hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use to value an asset or liability and are developed based on market data obtained from independent sources. Unobservable inputs are inputs based on assumptions about the factors market participants would use to value an asset or liability. The three levels of inputs that may be used to measure fair value are as follows:

Level one - inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level two - inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals; and

Level three - unobservable inputs developed using estimates and assumptions, which are developed by the reporting entity and reflect those assumptions that a market participant would use.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. Changes in the observability of valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

The Company's financial instruments consist of cash and cash equivalents, taxes and other receivables, accounts payable and accrued liabilities, related party payables and derivative liability. The carrying values of cash and cash equivalents, taxes and other receivables, accounts payable and accrued liabilities and related party payables



approximate their fair values due to the immediate or short-term maturity of these financial instruments.

Derivative liability

The Company accounts for certain warrants under the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the warrants require the issuance of securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. The Company classifies these warrants on its balance sheet as a derivative liability which is fair valued at each reporting period subsequent to the initial issuance. The Company has used a simulated probability valuation model to value the warrants. Determining the appropriate fair-value model and calculating the fair value of warrants requires considerable judgment. Any change in the estimates (specifically probabilities) used may cause the value to be higher or lower than that reported. The estimated volatility of the Company's common stock at the date of issuance, and at each subsequent reporting period, is based on the historical volatility of similar life sciences companies. The risk-free interest rate is based on rates published by the government for bonds with a maturity similar to the expected remaining life of the warrants at the valuation date. The expected life of the warrants is assumed to be equivalent to their remaining contractual term.

**DelMar Pharmaceuticals, Inc.**

## Notes to Consolidated Financial Statements

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## a) Fair value of derivative liability

The derivative is not traded in an active market and the fair value is determined using valuation techniques. The Company uses judgment to select a variety of methods to make assumptions that are based on specific management plans and market conditions at the end of each reporting period. The Company uses a fair value estimate to determine the fair value of the derivative liability. The carrying value of the derivative liability would be higher or lower as management estimates around specific probabilities change. The estimates may be significantly different from those recorded in the consolidated financial statements because of the use of judgment and the inherent uncertainty in estimating the fair value of these instruments that are not quoted in an active market. All changes in the fair value are recorded in the consolidated statement of operations and comprehensive loss each reporting period. This is considered to be a Level 3 financial instrument as volatility is considered a Level 3 input.

The Company has the following liabilities under the fair value hierarchy:

Liability	June 30, 2017		
	Level 1	Level 2	Level 3
Derivative liability	-	-	61,228

Liability	June 30, 2016		
	Level 1	Level 2	Level 3
Derivative liability	-	-	693,700

*Out- of- period adjustment*

The consolidated statement of operations and comprehensive loss for the year ended June 30, 2016 includes a \$100,868 out-of-period adjustment related to the remeasuring of the stock option liability that arose during the year ended June 30, 2015. This adjustment increased the stock based compensation expense and the corresponding stock option liability by \$100,868. The impact of these adjustments for the year ended June 30, 2016 and prior periods is not material.

## **Intangible assets**

### *Website development costs*

Website development costs are stated at cost less accumulated amortization. The Company capitalizes website development costs associated with graphics design and development of the website application and infrastructure. Costs related to planning, content input, and website operations are expensed as incurred. The Company amortizes website development costs on a straight-line basis over three years. At June 30, 2017 total capitalized cost was \$67,261 (2016 - \$46,305) and the Company has recognized \$16,683 and \$10,288 respectively, in amortization expense during the years ended June 30, 2017 and 2016.

### *Patents*

Expenditures associated with the filing, or maintenance of patents, licensing or technology agreements are expensed as incurred. Costs previously recognized as an expense are not recognized as an asset in subsequent periods. Once the technology has achieved commercialization, patent costs will be deferred and amortized over the remaining life of the related patent.

**DelMar Pharmaceuticals, Inc.**

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**Research and development costs (including clinical trial expenses and accruals)**

Research and development expenses include payroll, employee benefits, stock-based compensation expense, and other headcount-related expenses associated with research and development. Research and development expenses also include third-party development and clinical trial expenses noted below. Such costs related to research and development are included in research and development expense until the point that technological feasibility is reached, which for our drug candidate, is generally shortly before the drug is approved by the relevant food and drug administration. Once technological feasibility is reached, such costs will be capitalized and amortized to cost of revenue over the estimated life of the product.

Clinical trial expenses are a component of research and development costs and include fees paid to contract research organizations, investigators and other service providers who conduct specific research for development activities on behalf of the Company. The amount of clinical trial expenses recognized in a period related to service agreements is based on estimates of the work performed on an accrual basis. These estimates are based on patient enrollment, services provided and goods delivered, contractual terms and experience with similar contracts. The Company monitors these factors by maintaining regular communication with the service providers. Differences between actual expenses and estimated expenses recorded are adjusted for in the period in which they become known. Prepaid expenses or accrued liabilities are adjusted if payments to service providers differ from estimates of the amount of service completed in a given period.

Research and development costs are expensed in the period incurred. As at June 30, 2017 and 2016, all research and development costs have been expensed.

**Shares for services**

The Company has issued equity instruments for services provided by employees and non-employees. The equity instruments are valued at the fair value of the instrument granted.

### **Stock options**

The Company accounts for these awards under Accounting Standards Codification (“ASC”) 718, “Compensation - Stock Compensation” (“ASC 718”). ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on the date of grant and recognition of compensation over the requisite service period for awards expected to vest. Compensation expense for unvested options to non-employees is revalued at each period end and is being amortized over the vesting period of the options. The determination of grant-date fair value for stock option awards is estimated using the Black-Scholes model, which includes variables such as the expected volatility of the Company’s share price, the anticipated exercise behavior of its grantee, interest rates, and dividend yields. These variables are projected based on the Company’s historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments. Such value is recognized as expense over the requisite service period, net of estimated forfeitures, using the accelerated attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. The Company considers many factors when estimating expected forfeitures, including type of awards granted, employee class, and historical experience. Actual results and future estimates may differ substantially from current estimates.

**DelMar Pharmaceuticals, Inc.**

Notes to Consolidated Financial Statements

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**Comprehensive income**

In accordance with ASC 220, “Comprehensive Income” (“ASC 220”), all components of comprehensive income, including net loss, are reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and other comprehensive (income) loss, including foreign currency translation adjustments, are reported, net of any related tax effect, to arrive at comprehensive income. No taxes were recorded on items of other comprehensive income.

**Loss per share**

Income or loss per share is calculated based on the weighted average number of common shares outstanding. For the years ended June 30, 2017 and 2016 diluted loss per share does not differ from basic loss per share since the effect of the Company’s warrants, stock options, and convertible preferred shares are anti-dilutive. As at June 30, 2017, potential common shares of 7,749,756 (2016 – 5,468,876) related to outstanding warrants and stock options and 2,202,792 (2016 – 2,255,595) relating to outstanding Series B convertible preferred shares were excluded from the calculation of net loss per common share because their inclusion would be anti-dilutive.

**Segment information**

The Company identifies its operating segments based on business activities, management responsibility and geographical location. The Company operates within a single operating segment being the research and development of cancer indications, and operates primarily in one geographic area, being North America. The Company is conducting one clinical trial in China but the planned expenses to be incurred over the course of the study are not expected to be significant. All of the Company’s assets are located in either Canada or the United States.

## Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

*ASU 2016-09, Compensation—Stock Compensation (Topic 718): “Improvements to Employee Share-Based Payment Accounting”.*

The amendments in this update change existing guidance related to accounting for employee share-based payments affecting the income tax consequences of awards, classification of awards as equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual periods, with early adoption permitted. The Company is currently evaluating the potential impact of the adoption of this standard.

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*ASU 2016-02, "Leases" (Topic 842).*

The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the consolidated balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the consolidated income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the potential impact of the adoption of this standard.

*ASU No. 2016-01, "Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities".*

The updated guidance enhances the reporting model for financial instruments, and requires entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, and the separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (i.e., securities or loans and receivables) on the balance sheet or the accompanying notes to the financial statements. The guidance is effective for annual and interim reporting periods beginning after December 15, 2017. The Company is currently assessing this standard for its impact on future reporting periods.

*ASU 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern".*

The objective of the guidance is to require management to explicitly assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with each annual and



interim period, management will assess if there is substantial doubt about an entity's ability to continue as a going concern within one year after the issuance date of an entity's financial statements. The new standard defines substantial doubt and provides examples of indicators thereof. The definition of substantial doubt incorporates a likelihood threshold of "probable" similar to the current use of that term in U.S. GAAP for loss contingencies. The new standard will be effective for all entities in the first annual period ending after December 15, 2016 (December 31, 2016 for calendar year-end entities). The Company adopted this standard as of its December 31, 2016 quarter-end.

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**DelMar Pharmaceuticals, Inc.**

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**3 Valent Technologies LLC agreements**

On September 12, 2010, the Company entered into a Patent Assignment Agreement (the “Valent Assignment Agreement”) with Valent Technologies, LLC (“Valent”) pursuant to which Valent transferred to the Company all its right, title and interest in and to the patents for VAL-083 owned by Valent. The Company now owns all rights and title to VAL-083 and is responsible for the drug’s further development and commercialization. In accordance with the terms of the Valent Assignment Agreement, Valent is entitled to receive a future royalty on all revenues derived from the development and commercialization of VAL-083. In the event that the Company terminates the agreement, the Company may be entitled to receive royalties from Valent’s subsequent development of VAL-083 depending on the development milestones the Company has achieved prior to the termination of the Valent Assignment Agreement.

On September 30, 2014, the Company entered into an exchange agreement (the “Valent Exchange Agreement”) with Valent and DelMar (BC). Pursuant to the Valent Exchange Agreement, Valent exchanged its loan payable in the outstanding amount of \$278,530 (including aggregate accrued interest to September 30, 2014 of \$28,530), issued to Valent by DelMar (BC), for 278,530 shares of the Company’s Series A Preferred Stock. The Series A Preferred Stock has a stated value of \$1.00 per share (the “Series A Stated Value”) and is not convertible into common stock. The holder of the Series A Preferred Stock is entitled to dividends at the rate of 3% of the Series A Stated Value per year, payable quarterly in arrears.

For the years ended June 30, 2017 and 2016 respectively, the Company recorded \$8,356 related to the dividend payable to Valent. The dividends have been recorded as a direct increase in accumulated deficit.

One of the Company’s officers and directors is a principal of Valent and as result Valent is a related party to the Company (note 6).

**4 Derivative liability**

The Company has issued common stock purchase warrants. Based on the terms of certain of these warrants the Company determined that the warrants were a derivative liability which is recognized at fair value at the date of the transaction and remeasured at fair value each reporting period with the changes in fair value recorded in the consolidated statement of operations and comprehensive loss.

***2013 Investor Warrants***

During the quarter ended March 31, 2013 the Company issued an aggregate of 3,281,250 units at a purchase price of \$3.20 per unit, for aggregate gross proceeds of \$10,500,000. Each unit consisted of one share of common stock and one five-year warrant (the "2013 Investor Warrants") to purchase one share of common stock at an initial exercise price of \$3.20. The exercise price of the 2013 Investor Warrants is subject to adjustment in the event that the Company issues common stock at a price lower than the exercise price, subject to certain exceptions. The 2013 Investor Warrants are redeemable by the Company at a price of \$0.004 per 2013 Investor Warrant at any time subject to the conditions that (i) the Company's common stock has traded for twenty (20) consecutive trading days with a closing price of at least \$6.40 per share with an average trading volume of 50,000 shares per day, and (ii) the underlying shares of common stock are registered for resale.

**DelMar Pharmaceuticals, Inc.**

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As a result of the financing completed by the Company during the year ended June 30, 2016 (note 5) the exercise price of the 2013 Investor Warrants was reduced from \$3.20 to \$3.144 resulting in the recognition of a loss of \$8,098.

*Year ended June 30, 2016*

2013 Investor Warrant exercises

During the year ended June 30, 2016, 144,500 of the 2013 Investor Warrants were exercised for cash at an exercise price of \$3.144 per share. The Company received proceeds of \$454,308 from these exercises. The warrants that have been exercised were revalued at their exercise date and then the reclassification to equity was recorded resulting in \$285,895 of the derivative liability being reclassified to equity.

2013 Investor Warrant amendments

During the year ended June 30, 2016, the Company entered into amendments (the “2013 Investor Warrant Amendments”) with the holders of certain of the 2013 Investor Warrants. Pursuant to the 2013 Investor Warrant Amendments, 767,560 of the 2013 Investor Warrants were amended to extend the expiration date to March 31, 2019 and remove the provision requiring an adjustment of the exercise price in the event the Company sells common stock at a purchase price lower than the current warrant exercise price. As a result of the 2013 Investor Warrant Amendments, the Company has recognized a loss of \$31,491 and has reclassified \$1,319,480 from the derivative liability to equity. The 2013 Investor Warrants were revalued to the date of the amendment and were then reclassified to equity.

*Year ended June 30, 2017*

2013 Investor Warrant exercises

During the year ended June 30, 2017, 60,095 of the 2013 Investor Warrants were exercised at an exercise price of \$3.144 per share. Also, 5,000 of the previously amended 2013 Investor Warrants were exercised. The Company received proceeds of \$204,659 from these exercises. The warrants that have been exercised were revalued at their respective exercise dates and then the reclassification to equity was recorded resulting in \$238,474 of the derivative liability being reclassified to equity.

2013 Investor Warrant amendments

During the year ended June 30, 2017 pursuant to the 2013 Investor Warrant Amendments, 15,944 of the 2013 Investor Warrants were amended. As a result, the Company has reclassified \$53,006 from the derivative liability to equity. The 2013 Investor Warrants were revalued to their respective amendment dates and were then reclassified to equity.

***2013 Placement Agent Warrants***

On December 30, 2015, the Company entered into amendments (the “2013 Placement Agent Warrant Amendments”) with the holders of warrants the Company issued to the placement agent for the financing completed during the quarter ended March 31, 2013 (the “2013 Placement Agent Warrants”). Pursuant to the 2013 Placement Agent Warrant Amendments, 1,262,500 of the 2013 Placement Agent Warrants were amended to extend the expiration date to June 30, 2019 and remove the provision requiring an adjustment of the exercise price in the event the Company issues common stock at a price lower than the current warrant exercise price. As a result of the 2013 Placement Agent Warrant Amendments, for the year ended June 30, 2016 the Company has recognized a loss of \$242,400 and has reclassified \$2,277,550 from the derivative liability to equity. The 2013 Placement Agent Warrants were revalued to the date of the amendment and were then reclassified to equity.

**DelMar Pharmaceuticals, Inc.**

## Notes to Consolidated Financial Statements

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***2015 Agent Warrants***

As part of the Company's financing completed during the year ended June 30, 2016 (note 5), the Company issued warrants to purchase 23,477 shares of common stock to certain placement agents ("2015 Agent Warrants") and recognized them as a derivative liability of \$29,594 at the time of issuance. The 2015 Agent Warrants are exercisable at a per share price equal to \$3.00 until July 15, 2020. During the year ended June 30, 2017, 680 (2016 – 0) of the 2015 Agent Warrants were exercised for cash proceeds of \$2,040 and 1,000 (2016 – 31) of the 2015 Agent Warrants were exercised on a cashless basis for 594 (2016 – 21) shares of common stock. The total reclassification to equity subsequent to revaluation at the respective exercise dates was \$9,935 (2016 – \$133).

***Warrants issued for services***

In prior periods, the Company has issued 75,000 warrants for services that have been treated as a derivative liability. During the year ended June 30, 2016, 31,250 of these warrants were exercised on a cashless basis for 9,383 shares of common stock and the reclassification to equity of \$76,406. There were no exercises of these warrants during the year ended June 30, 2017.

The Company's derivative liability is summarized as follows:

	Years ended June 30,	
	2017	2016
	\$	\$
Opening balance	693,700	2,364,381

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Change in fair value of warrants	(331,057)	1,963,733
Change in fair value due to change in warrant terms	-	295,456
Reclassification to equity upon amendment of warrants	(53,006 )	(3,597,030)
Issuance of 2015 Agent Warrants	-	29,594
Reclassification to equity upon exercise of warrants	(248,409)	(362,434 )
Closing balance	61,228	693,700
Less current portion	(33,091 )	-
Long-term portion	28,137	693,700

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**DelMar Pharmaceuticals, Inc.**

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The derivative liability consists of the following warrants as at June 30, 2017 and 2016:

	Year ended June 30, 2017	
	Number of	\$
	warrants	
2013 Investor Warrants	105,129	33,091
Warrants issued for services	43,750	4,468
2015 Agent Warrants	21,768	23,669
Closing balance	170,647	61,228
Less current portion	(105,129)	(33,091)
Long-term portion	65,518	28,137

	Year ended June 30, 2016	
	Number of	\$
	warrants	
2013 Investor Warrants	181,156	503,796
Warrants issued for services	43,750	103,906
2015 Agent Warrants	23,448	85,998
	248,354	693,700

**5 Stockholders' equity (deficiency)**



Preferred stock

Authorized

5,000,000 preferred shares, \$0.001 par value

Issued and outstanding

Special voting shares – at June 30, 2017 and 2016 – 1

Series A shares – at June 30, 2017 – 278,530 (June 30, 2016 – 278,530)

Series B shares – at June 30, 2017 – 881,113 (June 30, 2016 – 902,238)

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**DelMar Pharmaceuticals, Inc.**

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Series B Preferred Shares

During the year ended June 30, 2016, the Company issued an aggregate of 902,238 shares of Series B Preferred Stock at a purchase price of at \$8.00 per share. Each share of Series B Preferred Stock is convertible into 2.5 shares of common stock equating to a conversion price of \$3.20 (the “Conversion Price”) and will automatically convert to common stock at the earlier of 24 hours following regulatory approval of VAL-083 with a minimum closing bid price of \$8.00 or five years from the final closing date. The holders of the Series B Preferred Stock are entitled to an annual cumulative, in arrears, dividend at the rate of 9% payable quarterly. The 9% dividend accrues quarterly commencing on the date of issue and is payable quarterly on June 30, September 30, December 31, and March 31 of each year commencing on June 30, 2016. Dividends are payable solely by delivery of shares of common stock, in an amount for each holder equal to the aggregate dividend payable to such holder with respect to the shares of Series B Preferred Stock held by such holder divided by the Conversion Price. The Series B Preferred Stock does not contain any repricing features. Each share of Series B Preferred Stock entitles its holder to vote with the common stock on an as-converted basis.

In addition, the Company and the holders entered into a royalty agreement, pursuant to which the Company will pay the holders of the Series B Preferred Stock, in aggregate, a low, single-digit royalty based on their pro rata ownership of the Series B Preferred Stock on products sold directly by the Company or sold pursuant to a licensing or partnering arrangement (the “Royalty Agreement”).

Upon conversion of a holder’s Series B Preferred Stock to common stock, such holder shall no longer receive ongoing royalty payments under the Royalty Agreement but will be entitled to receive any residual royalty payments that have vested. Rights to the royalties shall vest during the first three years following the applicable closing date, in equal thirds to holders of the Series B Preferred Stock on each of the three vesting dates, upon which vesting dates such royalty amounts shall become vested royalties.

Pursuant to the Series B Preferred Stock dividend, during the year ended June 30, 2017, the Company issued 200,446 (2016 – 30,360) shares of common stock and recognized \$790,454 (2016 – \$238,326) as a direct increase in accumulated deficit. During the year ended June 30, 2017, a total of 21,125 (2016 – 0) shares of Series B Preferred Stock were converted for an aggregate 52,813 (2016 – 0) shares of common stock.

#### Series A Preferred Shares

Effective December 31, 2014 pursuant to the Company's Valent Exchange Agreement (note 3), the Company filed a Certificate of Designation of Series A Preferred Stock (the "Series A Certificate of Designation") with the Secretary of State of Nevada. Pursuant to the Series A Certificate of Designation, the Company designated 278,530 shares of preferred stock as Series A Preferred Stock. The shares of Series A Preferred Stock have a stated value of \$1.00 per share (the "Series A Stated Value") and are not convertible into common stock. The holder of the Series A Preferred Stock is entitled to dividends at the rate of 3% of the Series A Stated Value per year, payable quarterly in arrears. Upon any liquidation of the Company, the holder of the Series A Preferred Stock will be entitled to be paid, out of any assets of the Company available for distribution to stockholders, the Series A Stated Value of the shares of Series A Preferred Stock held by such holder, plus any accrued but unpaid dividends thereon, prior to any payments being made with respect to the common stock.

#### Special voting shares

In connection with the Exchange Agreement (note 1), on the Reverse Acquisition Closing Date, the Company, Calco, Exchangeco and Computershare Trust Company of Canada (the "Trustee") entered into a voting and exchange trust agreement (the "Trust Agreement"). Pursuant to the Trust Agreement, Company issued one share of Special Voting Preferred Stock (the "Special Voting Share") to the Trustee, and the parties created a trust for the Trustee to hold the Special Voting Share for the benefit of the holders of the shares of Exchangeco acquired as part of the Reverse Acquisition (the "Exchangeable Shares") (other than the Company and any affiliated companies) (the "Beneficiaries"). Pursuant to the Trust Agreement, the Beneficiaries will have voting rights in the Company equivalent to what they would have had they received shares of common stock in the same amount as the Exchangeable Shares held by the Beneficiaries.

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In connection with the Exchange Agreement and the Trust Agreement, on January 17, 2013, the Company filed a certificate of designation of Special Voting Preferred Stock (the “Special Voting Certificate of Designation”) with the Secretary of State of Nevada. Pursuant to the Special Voting Certificate of Designation, one share of the Company’s blank check preferred stock was designated as Special Voting Preferred Stock. The Special Voting Preferred Stock votes as a single class with the common stock and is entitled to a number of votes equal to the number of Exchangeable Shares of Exchangeco outstanding as of the applicable record date (i) that are not owned by the Company or any affiliated companies and (ii) as to which the holder has received voting instructions from the holders of such Exchangeable Shares in accordance with the Trust Agreement.

The Special Voting Preferred Stock is not entitled to receive any dividends or to receive any assets of the Company upon any liquidation, and is not convertible into common stock of the Company.

The voting rights of the Special Voting Preferred Stock will terminate pursuant to and in accordance with the Trust Agreement. The Special Voting Preferred Stock will be automatically cancelled at such time as the share of Special Voting Preferred Stock has no votes attached to it.

**Common stock**

Authorized

50,000,000 common shares, \$0.001 par value

Issued and outstanding at June 30, 2017 – 14,509,633 (2016 – 11,187,023). The issued and outstanding common shares at June 30, 2017 include 982,761 (2016 – 1,014,011) shares of common stock on an as-exchanged basis with respect to the Exchangeable Shares.

Public offering financings

*Year ended June 30, 2017*

On April 12, 2017 the Company completed a registered public offering (the “2017 Public Offering”) of an aggregate of 2,769,232 shares of common stock and warrants to purchase an additional 2,076,924 shares of common stock at a price of \$3.25 per share and related warrant for gross proceeds of approximately \$9.0 million. The related warrants have an exercise price of \$3.50 per share, are immediately exercisable, and have a term of exercise of five years (the “2017 Investor Warrants”).

The Company engaged a placement agent for the 2017 Public Offering. Under the Company’s engagement agreement with the placement agent, the Company agreed to pay up to an 8% cash commission and issue warrants to purchase shares of common stock (the “2017 Agent Warrants”) up to the number of shares of common stock equal to 5% of the aggregate number of shares issued in the 2017 Public Offering. Pursuant to the placement agent agreement the Company issued 138,462 2017 Agent Warrants. The 2017 Agent Warrants are exercisable at a per share price equal to \$4.06 and have a term of exercise of five years.

In addition to the cash commission the Company also incurred additional cash issue costs of \$347,897 resulting in net cash proceeds of \$7,932,107. The 2017 Agent Warrants have been recognized as non-cash issue costs of \$424,401. Including the fair value of the 2017 Agent Warrants, total issue costs were \$1,492,298.

**DelMar Pharmaceuticals, Inc.**

Notes to Consolidated Financial Statements

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(in US dollars unless otherwise noted)

*Year ended June 30, 2016*

On July 15, 2015 the Company's Registration Statement on Form S-1 relating to a public offering by the Company of common stock and common stock purchase warrants (the "2015 Public Offering") was declared effective by the Securities and Exchange Commission. Pursuant to the 2015 Public Offering, the Company issued 1,069,417 shares of common stock at \$2.40 per share and 1,069,417 warrants (the "2015 Investor Warrants") to purchase shares of common stock at \$0.001 per warrant for total gross proceeds of \$2,566,660. The 2015 Investor Warrants are exercisable at \$3.00 per share for a period of five years until they expire on July 31, 2020.

The Company engaged certain placement agents for the sale of a portion of the shares and 2015 Investor Warrants. Under the Company's engagement agreements with these placement agents, the Company agreed to pay up to a 7% cash commission and issue warrants to purchase shares of common stock (the "2015 Agent Warrants") up to the number of shares of our common stock equal to 5% of the aggregate number of shares sold in the 2015 Public Offering by such placement agents. Pursuant to the placement agent agreements the Company paid a total cash commission of \$80,575 and issued 23,477 2015 Agent Warrants (note 4). The 2015 Agent Warrants are exercisable at a per share price equal to \$3.00 during the five-year period commencing six months from the effective date of the 2015 Public Offering, which period shall not extend further than five years from the effective date of the 2015 Public Offering. Therefore, all 2015 Agent Warrants expire on July 15, 2020.

In addition to the cash commission of \$80,575 the Company also incurred additional cash issue and closing costs of \$582,511 (including costs deferred at June 30, 2015 of \$550,119) resulting in net cash proceeds of \$1,903,514. The 2015 Agent Warrants have been recognized as non-cash issue costs of \$29,594.

Shares issued for services

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During the year ended June 30, 2017, the Company issued 60,000 (2016 – 27,500) shares of common stock for services resulting in the recognition of \$564,000 (2016 – \$146,900) in expense. All of the shares issued for services for the years ended June 30, 2017 and 2016 have been recognized as general and administrative expense.

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**DelMar Pharmaceuticals, Inc.**

## Notes to Consolidated Financial Statements

June 30, 2017

(in US dollars unless otherwise noted)

**Stock options**

The Company's Board of Directors has approved and adopted a stock option plan (the "Legacy Plan"). Under the Legacy Plan, the number of common shares that will be reserved for issuance to officers, directors, employees and consultants under the Legacy Plan will not exceed 7.5% of the share capital of the Company on a fully diluted basis. The requisite service period of the options ranges from six months to three years and also has a range of six months to three years contractual term.

The following table sets forth the options outstanding under the Legacy Plan as of June 30, 2017:

	Number of stock options outstanding	Weighted average exercise price
Balance – June 30, 2015	898,750	3.76
Granted	177,500	3.96
Cancelled	(12,500 )	4.20
Forfeited	(207,500 )	4.02
Balance – June 30, 2016	856,250	3.77
Granted	264,600	4.82
Balance – June 30, 2017	1,120,850	4.18



**DelMar Pharmaceuticals, Inc.**

## Notes to Consolidated Financial Statements

June 30, 2017

(in US dollars unless otherwise noted)

The following table summarizes stock options currently outstanding and exercisable at June 30, 2017:

Exercise price \$	Number Outstanding at June 30, 2017	Weighted average remaining contractual life (years)	Number exercisable at June 30, 2017
1.54	25,000	4.64	25,000
2.00	131,250	4.64	131,250
2.96	45,000	7.60	45,000
3.20	30,000	7.75	30,000
3.76	45,000	8.61	20,833
4.00	12,500	2.25	12,500
4.10	40,000	9.36	8,519
4.20	412,500	6.13	412,500
4.48	30,000	8.61	13,889
4.95	224,600	9.63	27,659
5.32	80,000	8.85	30,667
6.16	15,000	5.75	15,000
9.20	30,000	5.92	30,000
	1,120,850		802,817

Included in the number of stock options outstanding are 25,000 stock options granted at an exercise price of CA \$2.00. The exercise prices for these stock options shown in the above table have been converted to US \$1.54 using the period ending closing exchange rate. Certain stock options have been granted to non-employees and will be revalued at each reporting date until they have fully vested.

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The stock options have been valued using a Black-Scholes pricing model using the following assumptions:

	June 30, 2017		June 30, 2016	
Dividend rate	0	%	0	%
Volatility	77.5% to 88.7	%	84% to 118	%
Risk-free rate	1.00% to 1.74	%	1.00	%
Term – years	3.0		0.5 to 3.0	

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**DelMar Pharmaceuticals, Inc.**

## Notes to Consolidated Financial Statements

June 30, 2017

(in US dollars unless otherwise noted)

The Company has recognized the following amounts as stock-based compensation expense for the periods noted:

	Years ended June 30,	
	2017	2016
	\$	\$
Research and development	77,706	263,509
General and administrative	47,041	130,623
	124,747	394,132

Of the total stock option expense of \$124,747 (2016 – \$394,132) for the years ended June 30, 2017 and 2016, all of it has been recognized as additional paid in capital. The aggregate intrinsic value of stock options outstanding at June 30, 2017 was \$56,783 (2016 – \$3,486,910) and the aggregate intrinsic value of stock options exercisable at June 30, 2017 was \$56,783 (2016 – \$2,941,031). As at June 30, 2017 there was \$334,518 in unrecognized compensation expense that will be recognized over the next 2.67 years. No stock options granted under the Plan have been exercised to June 30, 2017. Upon the exercise of stock options new shares will be issued.

A summary of the status of the Company's unvested stock options as at June 30, 2017 under all plans is presented below:

Number of options	Weighted average exercise price \$	Weighted average grant date fair value \$
-------------------------	------------------------------------------------	-------------------------------------------------------

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Unvested at June 30, 2015	180,590	3.80	1.64
Granted	177,500	3.96	2.24
Vested	(147,293)	3.71	2.09
Forfeited	(65,093 )	3.67	0.91
Cancelled	(4,688 )	4.20	2.28
Unvested at June 30, 2016	141,016	3.17	1.73
Granted	264,600	4.82	2.61
Vested	(87,583 )	4.68	2.48
Unvested at June 30, 2017	318,033	4.81	2.57

The aggregate intrinsic value of unvested stock options at June 30, 2017 was \$0 (2016 – \$547,279). The unvested stock options have a remaining weighted average contractual term of 9.35 (2016 – 9.51) years.

**DelMar Pharmaceuticals, Inc.**

## Notes to Consolidated Financial Statements

June 30, 2017

(in US dollars unless otherwise noted)

Stock option liability

Certain of the Company's stock options have been issued in CA\$. Of these, a portion have been classified as a stock option liability which is revalued at each reporting date. During the year ended June 30, 2017, the Company amended 43,750 (2016 – 87,500) of these stock options held by five (2016 – three) optionees such that the exercise price of the options was adjusted to be denominated in US\$. No other terms of the stock options were amended. As a result of the amendment, the Company recognized \$85,094 (2016 – \$377,927) in stock option liability expense and \$260,969 (2016 – \$351,750) was reclassified to equity during the year ended June 30, 2017.

**Warrants**

	Number of warrants	Amount \$
Balance – June 30, 2015	125,000	89,432
Issuance of 2015 Investor Warrants (i)	1,069,417	671,189
Exercise of 2015 Investor Warrants (i)	(41,667 )	(26,250 )
Issuance of 2016 Agent Warrants (ii)	103,963	246,566
Warrants issued for services (iii)	265,000	677,445
Balance – June 30, 2016	1,521,713	1,658,382
Issuance of 2017 Investor Warrants (iv)	2,076,924	2,526,336
Issuance of 2017 Agent Warrants (iv)	138,462	424,401
Exercise of Valent warrants (v)	(125,000 )	(89,432 )
Exercise of 2015 Investor Warrants (i)	(48,750 )	(30,715 )
Warrants issued for services (iii)	41,400	81,602

Balance - June 30, 2017                      3,604,749    4,570,574

The 2015 Investor Warrants are exercisable at a price of \$3.00. The warrants expire on July 31, 2020. During the year ended June 30, 2017, 48,750 (2016 – 41,667) warrants were exercised for proceeds of \$146,250 (2016 – \$125,001).

ii) As part of its Series B Preferred Stock financing the Company issued to the placement agent for this financing warrants (the “2016 Agent Warrants”) which are exercisable at a price of \$4.00 until May 12, 2021.

iii) During the year ended June 30, 2017, the Company issued 41,400 (2016 – 265,000) warrants for services at an exercise price of \$5.93 (2016 – \$3.00). The warrants expire at the various dates noted in the table.

iv) As part of the financing completed by the Company in April 2017, the Company issued the 2017 Investor Warrants and the 2017 Agent Warrants. The 2017 Investor Warrants are exercisable at \$3.50 until April 19, 2022 and the 2017 Agent Warrants are exercisable at \$4.06 until April 12, 2022.

v) The Valent warrants were exercised at \$1.54 (CA\$2.00) for proceeds of \$192,075.

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**DelMar Pharmaceuticals, Inc.**  
Notes to Consolidated Financial Statements  
June 30, 2017

(in US dollars unless otherwise noted)

Certain of the Company's warrants have been recognized as a derivative liability (note 4).

The following table summarizes the changes in the Company's outstanding warrants as of June 30, 2017:

Description	Number
Balance – June 30, 2016	4,612,627
Issuance of 2017 Investor Warrants	2,076,924
Issuance of 2017 Agent Warrants	138,462
Exercise of 2013 Investor Warrants	(65,077 )
Exercise of Valent warrants	(125,000 )
Exercise of 2015 Investor Warrants	(48,750 )
Exercise of 2015 Agent Warrants	(1,680 )
Issuance of warrants issued for services	41,400
Balance – June 30, 2017	6,628,906

The following table summarizes the Company's outstanding warrants as of June 30, 2017:

Description	Number	Exercise price \$	Expiry date
2017 Investor	2,076,924	3.50	April 19, 2022
2013 Placement Agent	1,262,500	3.14	June 30, 2019
2015 Investor	979,003	3.00	July 31, 2020
2013 Investor – Amended	778,504	3.14	March 31, 2019
2013 Investor – Unamended	105,129	3.14	January 25 to March 6, 2018
Dividend	812,502	5.00	January 24, 2018
Issued for services	265,000	3.00	March 1, 2020 to February 1, 2021
Issued for services	43,750	7.04	September 12, 2018
Issued for services	41,400	5.93	February 27, 2020
2017 Agent	138,462	4.06	April 12, 2022
2016 Agent	103,964	4.00	May 12, 2021
2015 Agent	21,768	3.00	July 15, 2020
	6,628,906	3.53	

#### **6 Related party transactions**

Pursuant to employment and consulting agreements with the Company's officers the Company recognized a total of \$856,250 (2016 – \$480,000) in compensation expense for the year ended June 30, 2017. Amounts owed to related parties are non-interest bearing and payable on demand.



**DelMar Pharmaceuticals, Inc.**

Notes to Consolidated Financial Statements

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The Company recognized \$169,500 (2016 – \$167,083) in directors' fees during the year ended June 30, 2017. In addition, during the year ended June 30, 2016, upon the resignation of one of the Company's directors, the Company and the director entered into a lock-up agreement limiting the director's ability to sell shares. The Company paid \$45,000 in consideration pursuant to the lock up agreement.

As part of the Series B preferred stock dividend (note 5) the Company issued 6,044 (2016 – 1,028) shares of common stock to officers and directors of the Company and recognized \$23,767 (2016 – \$3,278) as a direct increase to the accumulated deficit.

The Company recorded \$8,356 (2016 – \$8,356) in dividends related to the Series A preferred stock issued to Valent (note 3) for the year ended June 30, 2017.

During the year ended June 30, 2017 Valent (note 5) exercised 125,000 (2016 – 0) common stock purchase warrants at \$1.54 per share (CA \$2.00) for total proceeds of \$192,075 (2016 – 0).

During the year ended June 30, 2017 the Company granted 224,600 (2016 – 0) stock options to officers of the Company at an exercise price of \$4.95. The stock options vest pro rata on a monthly basis over 36 months and expire on February 17, 2027 (note 5).

**7 Current and deferred income taxes**

The Company has the following non-capital losses available to reduce taxable income of future years:

Expiry date \$

2029	59,064
2030	936,786
2031	1,014,530

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2033	3,658,407
2034	5,016,448
2035	4,334,239
2036	5,483,466
2037	5,249,468

In addition, the Company has non-refundable Federal investment tax credits of \$207,080 that expire between 2029 and 2037 and non-refundable British Columbia investment tax credits of \$112,448 that expire between 2019 and 2027.

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**DelMar Pharmaceuticals, Inc.**

Notes to Consolidated Financial Statements

June 30, 2017

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Significant components of the Company's deferred tax assets and tax liabilities are shown below:

	June 30, 2017	June 30, 2016
	\$	\$
Deferred tax assets:		
Non-capital losses carried forward	7,340,286	4,997,819
Capital losses carried forward	17,925	-
Financing costs	5,512	7,448
Scientific research and development	350,435	233,773
Scientific research and development - ITC	319,528	-
	8,033,686	5,239,040
Deferred tax liabilities:		
Scientific research and development – ITC	(53,841 )	-
	7,979,845	5,239,040
Valuation allowance	(7,979,845)	(5,239,040)
Net deferred tax assets	-	-

The income tax benefit of these tax attributes has not been recorded in these consolidated financial statements because of the uncertainty of their recovery.

The Company's effective income tax rate differs from the statutory income tax rate of 34% (2016 – 34%).

The differences arise from the following items:

	June 30, 2017	June 30, 2016
	\$	\$
Tax recovery at statutory income tax rates	(2,747,800)	(2,885,559)

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Permanent differences	(15,342 )	1,119,908
Effect of rate differentials between jurisdictions	464,938	257,900
Other	(62,962 )	34,116
Change in valuation allowance	2,361,166	1,473,635

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**DelMar Pharmaceuticals, Inc.**

Notes to Consolidated Financial Statements

June 30, 2017

(in US dollars unless otherwise noted)

**8 Commitments and contingencies**

The Company has the following obligations over the next five fiscal year ending June 30, 2018:

	2018
	\$
Clinical development	1,523,873
Office lease	54,096
	1,577,969

**Clinical development**

The Company has entered into contracts for drug manufacturing and clinical study management related to its Phase III clinical trial. Pursuant to the commitment for clinical trial management, the Company has paid a total of \$1,019,883 in deposits related to study initiation. The total of \$1,019,883 is included in the consolidated balance sheet at June 30, 2017 in the prepaid expenses and deposits balance of \$1,208,122. These deposits are available to be applied against invoices received from the contract research organization.

**Office lease**

The Company currently rents its offices pursuant to a one-year lease that commenced on July 1, 2017 at a rate of \$4,508 (CA\$5,850) per month. During the year ended June 30, 2017, the Company recorded \$35,908 as rent expense (2016 - \$36,610).

**9 Supplementary statement of cash flows information**

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	Year ended June 30, 2017	Year ended June 30, 2016
Series B Preferred Stock common stock dividend (note 5)	790,454	238,326
Non-cash issue costs (note 5)	424,401	-
Reclassification of derivative liability to equity upon the exercise of warrants (note 4)	248,409	362,434
Reclassification of derivative liability to equity upon the amendment of warrants (note 4)	53,006	3,597,030
Reclassification of stock option liability to equity upon settlement (note 5)	260,969	381,497
Conversion of Series B Preferred stock to common stock (note 5)	147,375	-
Non-cash website development costs	-	29,543
Income taxes paid	-	-
Interest paid	-	-

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**DelMar Pharmaceuticals, Inc.**

Notes to Consolidated Financial Statements

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**10 Financial risk management**

**Market risk**

Market risk is the risk that changes in market prices, such as foreign exchange rates, interest rates and equity prices will affect the Company's income or valuation of its financial instruments.

The Company is exposed to financial risk related to fluctuation of foreign exchange rates. Foreign currency risk is limited to the portion of the Company's business transactions denominated in currencies other than the United States dollar, primarily general and administrative expenses incurred in Canadian dollars. The Company believes that the results of operations, financial position and cash flows would be affected by a sudden change in foreign exchange rates, but would not impair or enhance its ability to pay its Canadian dollar accounts payable. The Company manages foreign exchange risk by converting its US\$ to CA\$ as needed. The Company maintains the majority of its cash in US\$. As at June 30, 2017, Canadian dollar denominated accounts payable and accrued liabilities exposure in US\$ totaled \$126,618.

a) Foreign exchange risk

Foreign exchange risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. If foreign exchange rates were to fluctuate within +/-10% of the closing rate at year-end, the maximum exposure is \$12,662.

Balances in foreign currencies at June 30, 2017 and 2016 are as follows:

June 30,	June 30,
2017	2016
balances	balances
CA\$	CA\$

Trade payables	164,226	94,443
Cash	39,251	61,918

b)Interest rate risk

The Company is subject to interest rate risk on its cash and believes that the results of operations, financial position and cash flows would not be significantly affected by a sudden change in market interest rates relative to the investment interest rates due to the short-term nature of the investments. As at June 30, 2017, cash held in Canadian dollar accounts or short-term investments were \$30,262. The Company's cash balance currently earns interest at standard bank rates. If interest rates were to fluctuate within +/-10% of the closing rate at year end the impact of the Company's interest bearing accounts will be not be significant.

The only financial instruments that expose the Company to interest rate risk are its cash and cash equivalents.

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**DelMar Pharmaceuticals, Inc.**  
 Notes to Consolidated Financial Statements  
 June 30, 2017

(in US dollars unless otherwise noted)

**Liquidity risk**

Liquidity risk is the risk that the Company will encounter difficulty in raising funds to meet cash flow requirements associated with financial instruments. The Company continues to manage its liquidity risk based on the outflows experienced for the period ended June 30, 2017 and is undertaking efforts to conserve cash resources wherever possible. The maximum exposure of the Company's liquidity risk is \$1,271,269 as at June 30, 2017 (note 1).

**Credit risk**

Credit risk arises from cash and cash equivalents, deposits with banks and financial institutions, as well as outstanding receivables. The Company limits its exposure to credit risk, with respect to cash and cash equivalents, by placing them with high quality credit financial institutions. The Company's cash equivalents consist primarily of operating funds with commercial banks. Of the amounts with financial institutions on deposit, the following table summarizes the amounts at risk should the financial institutions with which the deposits are held cease trading:

The maximum exposure of the Company's credit risk is \$76,595 at June 30, 2017.

Cash and cash equivalents	Insured amount	Non-insured amount
\$	\$	\$
6,586,014	140,254	6,445,760

**Concentration of credit risk**

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents.

The Company places its cash and cash equivalents in accredited financial institutions and therefore the Company's management believes these funds are subject to minimal credit risk. The Company has no significant off-balance sheet concentrations of credit risk such as foreign currency exchange contracts, option contracts or other hedging arrangements.

## **11 Subsequent events**

### **Registered direct financing**

Subsequent to June 30, 2017 the Company completed a registered direct offering (the "2018 Registered Offering") of an aggregate of 8,000,000 shares of common stock and 8,000,000 warrants to purchase an additional 8,000,000 shares of common stock at a price of \$1.25 per share and related warrant for gross proceeds of \$10.0 million. The warrants have an exercise price of \$1.25 per share, are immediately exercisable and have a term of exercise of five years.

The Company engaged a placement agent for the 2018 Registered Offering. Under the Company's engagement agreement with the placement agent, the Company paid \$800,000 in cash commission and other fees to the placement agent and issued warrants to purchase 400,000 shares of common stock to the placement agent (the "2018 Agent Warrants"). The 2018 Agent Warrants are exercisable at a per share price of \$1.25 and have a term of exercise of five years.

In addition to the cash commission and other placement agent fees, the Company also incurred additional cash issue costs of approximately \$235,000 resulting in net cash proceeds of approximately \$9.0 million.

The unamended 2013 Investor Warrants contain provisions that result in an adjustment of the exercise price of these warrants in the event the Company sells common stock at a price lower than the current exercise price of the unamended 2013 Investor Warrants. As a result of the registered direct financing, the 105,129 unamended 2013 Investor Warrants will have their exercise price adjusted.

**DelMar Pharmaceuticals, Inc.**

Notes to Consolidated Financial Statements

June 30, 2017

(in US dollars unless otherwise noted)

**2017 Omnibus Incentive Plan**

Subsequent to June 30, 2017, and subject to approval by the Company's stockholders, the Company's board of directors approved adoption of the Company's 2017 Omnibus Equity Incentive Plan (the "2017 Plan"). The board of directors also approved a form of Performance Stock Unit Award Agreement to be used in connection with grants of performance stock units ("PSUs") under the 2017 Plan.

Under the 2017 Plan, 3,487,785 shares of Company common stock are reserved for issuance, less the number of shares of common stock subject to grants of stock options made, or that may be made, under the Del Mar Pharmaceuticals (BC) Ltd. 2013 Amended and Restated Stock Option Plan (the "Legacy Plan"). If all shares available under the Legacy Plan were used, there would remain 1,730,906 shares available for issuance under the 2017 Plan. The number of shares of Company common stock available for issuance under the 2017 Plan will automatically increase as needed such that the number of shares of common stock available for issuance with respect to awards at any time under the 2017 Plan is thirteen percent (13%) of the Company's fully diluted shares of common stock (less the number of shares of common stock subject to outstanding awards granted under the 2017 Plan and options granted under the Legacy Plan). The maximum number of shares of Company common stock with respect to which any one participant (other than an outside director) may be granted stock options or stock appreciation rights during any calendar year is 500,000 shares. The maximum number of shares of common stock that may be subject to awards to outside directors, in the aggregate, during any calendar year is 1,500,000. No award will be granted under the 2017 Plan on or after July 7, 2027, but awards granted prior to that date may extend beyond that date.

**Performance Stock Unit grants**

Subject to approval by the Company's stockholders of the 2017 Plan, the Company's board of directors granted a total of 1,000,000 PSUs under the 2017 Plan to the Company's independent directors. In total, the awards represent the right to receive an aggregate of 1,000,000 shares of the Company's common stock upon vesting of the PSU based on targets approved by the Company's board of directors related to the Company's fully diluted market capitalization. The PSUs will vest in full upon the later of one year from the grant date and the Company achieving a fully diluted market capitalization of at least \$500 million for five consecutive business days. The PSUs expire on July 7, 2022.

**Stock option grants**

Subsequent to June 30, 2017, a total of 180,000 stock options were granted to the Company's independent directors. The stock options are exercisable at a price of \$2.11 and have a term of 10 years. They vest as to one-third on June 30, 2018 and 15,000 on a quarterly basis commencing September 30, 2018.

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**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. Controls and Procedures.**

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017. Based on that evaluation, and as a result of the material weakness described below, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of June 30, 2017.

Internal Control Over Financial Reporting

*Management's Annual Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally

accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon that evaluation, our management concluded that our internal control over financial reporting was not effective as of June 30, 2017 because of a material weakness in our internal control over financial reporting related to an inadequate segregation of duties over authorization, review and recording of transactions. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented or detected and corrected on a timely basis. Despite the existence of this material weakness, we believe the financial information presented herein is materially correct and in accordance with generally accepted accounting principles in the United States.

### **Remediation Plan for the Material Weakness**

Management has been actively engaged in developing remediation plans to address the above material weakness. The remediation efforts in process or expected to be implemented include the following:

Management has engaged an external consulting firm to assist with our internal accounting functions.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report is not subject to attestation by our registered public accounting firm because we are not an accelerated filer under the Exchange Act.

### *Changes in Control Over Financial Reporting*

As previously reported, for the fiscal years ended June 30, 2015 and 2016, management identified a material weakness related to the accounting, presentation, and disclosure of non-routine financial instrument transactions. As part of our remediation plan, beginning in November 2015, management engaged an industry expert to assist with the identification and assessment of non-routine, financial instrument related transactions and re-designing controls to identify, research, evaluate and review the appropriate accounting related to non-routine complex transactions and technical accounting and other equity transactions. As a result of these remediation steps, management believes that the aforementioned material weakness has been remediated.

In addition, as part of its remediation plan to address the company's material weakness related to its inadequate segregation of duties, management has engaged an external consulting firm to assist with our internal accounting functions.

**Item 9B. Other Information.**

None.

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**PART III****Item 10. Directors, Executive Officers and Corporate Governance.**

Below are the names and certain information regarding the Company's executive officers and directors.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Erich Mohr, PhD R. Psych.	62	Chairman of the Board
Jeffrey Bacha, BSc, MBA	49	President, Chief Executive Officer and Director
Dennis Brown, PhD	67	Chief Scientific Officer and Director
Scott Prail, CPA	51	Chief Financial Officer
John K. Bell, FCPA, CPA,	69	Director
Lynda Cranston, BScN, MScN, ICD.D	69	Director
Robert J. Toth, Jr., MBA	54	Director
Saiid Zarrabian	65	Director

**Dr. Erich Mohr, Ph.D., R. Psych.**, has served as the independent chairman of the Company since July 7, 2017 and as independent director since March 31, 2015. Dr. Mohr has nearly two decades of biotechnology experience in executive leadership roles as co-founder, chief scientific officer, chief executive officer and board member. Dr. Mohr has overseen and participated in dozens of clinical development programs and regulatory advisory panels. He is currently Chairman, Chief Executive Officer and Founder of MedGenesis Therapeutix Inc., a privately-held biopharmaceutical company committed to developing and commercializing innovative therapeutics to provide life-enhancing treatments to patients with serious neurologic diseases. Formerly, he was Chairman and Chief Executive Officer of CroMedica Global Inc., which merged with PRA International in 2002 to form one of the major contract research organizations in the world. In addition to his industry experience, Dr. Mohr has over 30 years of experience in experimental therapeutics of CNS disorders including eight years at the University of Ottawa, ultimately as a Professor of Medicine (Neurology) and Psychology. Dr. Mohr is the author of over 150 publications, books, book chapters and abstracts. Currently, he is the Chair of the Board of Governors of the University of Victoria, British Columbia, having previously served as a member and as Vice Chair. He earned his Masters of Science and Ph.D. in Neuropsychology at the University of Victoria, British Columbia, and his Bachelors of Arts in Psychology and dual Bachelors of Science in Chemistry and Biology from the University of the Pacific in Stockton, California. Dr. Mohr's scientific and business executive knowledge and experience qualify him to serve on our Board of Directors.

**Jeffrey Bacha, BSc, MBA** has been chief executive officer and President of the Company since January 25, 2013, and director of the Company since February 11, 2013. Mr. Bacha is one of our founders and has been President, Chief Executive Officer and director of DelMar (BC) since inception. 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. From July 2006 to August 2009, Mr. Bacha was Executive Vice President Corporate Affairs and Chief Operating Officer at Clera, Inc. From March 2005 to July 2006 Mr. Bacha was Consultant and held various positions at Clera Inc., Urogen Holdings Inc. and XBiotech, Inc. From 1999 through 2004, Mr. Bacha served as President & CEO of Inimex Pharmaceuticals, a venture-capital funded drug discovery and development company and is a former Senior Manager and Director of KPMG Health Ventures. Mr. Bacha holds an MBA from the Goizueta Business School at Emory University and a degree in BioPhysics from the University of California, San Diego. Mr. Bacha's experience as one of our founders and Chief Executive Officer qualifies him to serve on our Board of Directors.

**Dr. Dennis Brown, PhD**, has been chief scientific officer of the Company since January 25, 2013 and director of the Company since February 11, 2013. Dr. Brown is one of our founders and has served as Chief Scientific Officer and director of DelMar (BC) since inception. Dr. Brown has more than thirty 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. 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 of about 34 issued U.S. patents and applications, many with foreign counterparts. Dr. Brown's scientific knowledge and experience qualifies him to serve on our Board of Directors.

**Scott Prail, CPA, BSc.** has been chief financial officer of the Company since January 29, 2013 and previously served as a consultant to DelMar (BC). Since 2004, Mr. Prail has been an independent consultant providing accounting and administrative services to companies in the resource industry. Mr. Prail served as CFO of Strata Oil & Gas, Inc. from June 2007 to September 2008. From November 1999 to October 2003 Mr. Prail was Director of Finance at Inflazyme Pharmaceuticals Inc. Mr. Prail completed his articling at Price Waterhouse (now PricewaterhouseCoopers LLP) and obtained his Chartered Professional Accountant designation in 1996. Mr. Prail obtained his Certified Public Accountant (Illinois) designation in 2001. Mr. Prail received a Financial Management Diploma (Honors), from British Columbia Institute of Technology in 1993, and a Bachelor of Science from Simon Fraser University in 1989.

**John K. Bell, FCPA, FCA, ICD.D** has served as a director of the Company since February 11, 2013. John K. Bell is Chairman of Onbelay Capital Inc., a Canadian based private equity company with principal investments in Telematics and auto parts manufacturing (for past 5 years). Prior to that, from 1996 to 2005, Mr. Bell was CEO and owner of Polymer Technologies Inc., an automotive parts manufacturer. Prior to that, from 1977 to 1995, Mr. Bell was founder and owner of Shred-Tech Limited a global manufacturer and supplier of industrial shredders and mobile document shredders. Mr. Bell served as interim CEO and director of ATS Automation Tooling Systems (TSX-ATA) in 2007. Mr. Bell is a director of Strongco Corporation (TSX-SQP), Canopy Growth Corp..(TSX-V-CGC), and the Royal Canadian Mint (TSX-MNT). Mr. Bell is the past National secretary and board member of The Crohns and Colitis Foundation of Canada. Mr. Bell is also the past Chairman of Waterloo Regional Police, Cambridge Memorial Hospital, Canada's Technology Triangle accelerator network and The Region of Waterloo prosperity counsel. Mr. Bell is a graduate of Western University Ivey School of Business, a Fellow of the institute of Chartered Accountants of Ontario, a graduate of the Institute of Directors Program of Canada and the owner's president program at Harvard and International marketing program at Oxford. Mr. Bell's financial and executive business experience qualifies him to serve on our Board of Directors.

**Lynda Cranston BScN, MScN, ICD.D** has served as a director of the Company since February 5, 2015 and serves as the Chair of our Governance and Compensation Committee. Mrs. Cranston recently retired from the healthcare

industry where she had been a CEO for over 20 years. Her last appointment prior to her retirement was as the first CEO of the Provincial Health Services Authority (2002 to 2013). Prior to this appointment Mrs. Cranston had been the first CEO of the Canadian Blood Services in Ottawa, ON (1998-2001). Before moving to Ottawa, Mrs. Cranston, as the CEO of BC Women's Hospital and Healthcare Centre had merged the organization with the BC Children's Hospital and the Sunny Hill Health Centre for Children to become the Children's and Women's Healthcare Centre of BC. Following the merger Mrs. Cranston became the first CEO. Mrs. Cranston also sits on the national board of the Gastrointestinal Society as its chair. In 2013, Mrs. Cranston was identified as a member of Diversity 50 by the Canadian Board Diversity Council as being one of Canada's most board ready candidates. Mrs. Cranston was awarded the Board Chair Award of Excellence by the HealthCare Leaders' Association of British Columbia in 2008. In 2007, she was inducted into Canada's Most Powerful Women Top 100 Hall of Fame after having been identified in '04,'05 & '06 as one of Canada's Most Powerful Women Top 100. Mrs. Cranston is a recipient of the YWCA Women of Distinction Award, the 125th Anniversary of the Confederation of Canada Commemorative Medal for community contributions, and the Queen's Golden Jubilee Medal for contribution to Canada and community. Ms. Cranston's healthcare industry and executive knowledge and experience qualify her to serve on our Board of Directors.

**Robert J. Toth, Jr., MBA** has served as a director of the Company since August 20, 2013. Since 2005, Mr. Toth has primarily been managing his personal investment portfolio. From 2004-2005, Mr. Toth served as a consulting analyst to Narragansett Asset Management, a New York-based healthcare-focused hedge fund, where he advised the firm on biotechnology investments. From 2001-2003, he was the Senior Portfolio Manager for San Francisco-based EGM Capital's Medical Technology hedge fund, where he was responsible for managing and maintaining a dedicated medical technology portfolio. Mr. Toth began his Wall Street career in 1996 as an Equity Research Associate for Vector Securities International, a healthcare-focused brokerage firm. From 1997-1999 he served as Senior Biotechnology Analyst. He joined Prudential Securities as Senior Vice President and Biotechnology Analyst where he served from 1999-2001 following Prudential's acquisition of Vector. His responsibilities included the analysis of commercial, clinical and scientific fundamentals of oncology and genomics-based biotechnology companies on behalf of institutional investors. Mr. Toth was named to the Wall Street Journal's Allstar List for stock picking in 1999. Mr. Toth received an MBA from the University of Washington and Bachelor of Science degrees in Biological Sciences and Biochemistry from California Polytechnic State University, San Luis Obispo. Mr. Toth's financial and biotechnology industry knowledge and experience qualify him to serve on our Board of Directors.

**Saiid Zarrabian** has served as a director of the Company since July 7, 2017. Since October 2016 Mr. Zarrabian has served as an advisor to Redline Capital Partners, S.A., a Luxemburg based investment firm. From 2012 to 2014 he served as Chairman and member of the Board of La Jolla Pharmaceutical Company during which time the company's transition from an OTC listed company to a NASDAQ listed company. From 2012 to 2013 he served as president of the Protein Production Division of Intrexon Corporation, a synthetic biology company. He has also previously served as CEO & member of the Board of Cynlect, Inc., a stem cell processing and visualization Instrumentation company until its sale in 2012, as president and COO of Senomyx, Inc., a company focused on discovery and commercialization of new flavor ingredients, as COO of Pharmacoepia, Inc., a former publicly-traded provider of combinatorial chemistry discovery services and compounds, where he also served as president & COO of its MSI Division. In addition, Mr. Zarrabian has served on numerous private and public company boards, including at Immune Therapeutics, Inc., Exemplar Pharma, LLC, Ambit Biosciences Corporation, eMolecules, Inc., and Penwest Pharmaceuticals CO. His other experience includes COO at Molecular Simulations, COO of Symbolics, Inc., and as R&D Director at Computervision, Inc. Mr. Zarrabian's scientific and business executive knowledge and experience qualify him to serve on our Board of Directors.

The Company's chief executive and chief financial officers are full-time employees and devote 100% of their business time to us. Dr. Brown, our chief scientific officer, devotes approximately 80% of his business time to us. See "Executive Compensation".

Our directors are appointed for a one-year term to hold office until the next annual general meeting of our shareholders or until removed from office in accordance with our bylaws and the provisions of the Nevada Revised Statutes.

Our officers are appointed by our board of directors and serve at its pleasure.

### **Involvement in Certain Legal Proceedings**

To our knowledge, our directors and executive officers have not been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);  
  
being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of
3. competent jurisdiction, permanently or temporarily enjoining him from or otherwise limiting his involvement in any type of business, securities or banking activities or to be associated with any person practicing in banking or securities activities;

being found by a court of competent jurisdiction in a civil action, the SEC or the Commodity Futures Trading Commission to have violated a Federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

being subject of, or a party to, any Federal or state judicial or administrative order, judgment decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any Federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

being subject of or party to any sanction or order, not subsequently reversed, suspended, or vacated, of any self-regulatory organization, any registered entity or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

### **Board Committees**

The Board of Directors has formed an Audit Committee, which currently consists of John K. Bell, Chair, Robert Toth, and Saiid Zarrabian, all of whom are independent (as that term is defined under the Nasdaq Marketplace Rules) and financially literate (as such qualification is interpreted by the Board of Directors in its business judgment). We are relying upon the exemption in section 6.1 of Canadian National Instrument 52-110 – Audit Committees from Parts 3 and 5 thereof. In addition, our Board has determined that Mr. Bell qualifies as an audit committee financial expert within the meaning of SEC regulations and The NASDAQ Marketplace Rules.

The Board of Directors has also formed a Corporate Governance and Compensation Committee which consists of Lynda Cranston, Chair, Saiid Zarrabian, Erich Mohr, and Robert Toth. The Corporate Governance and Compensation Committee assists the Board of Directors in fulfilling its oversight responsibilities relating to (i) corporate governance practices and policies and (ii) compensation matters, including compensation of the directors and senior management of the Company and the administration of compensation plans of the Company.

### **Nomination of Directors**

The Board of Directors assesses potential candidates to fill perceived needs on the Board of Directors for required skills, expertise, independence and other factors. The Company's independent directors also perform the functions of the Nominations Committee.

### **Orientation and Continuing Education**

New members of the Board of Directors are provided with sufficient information to ensure that they are familiarized with the Company and the policies and mandates of the Board of Directors. Members of the Board of Directors are encouraged to communicate with management, legal counsel and, where applicable, auditors and technical consultants of the Company to keep themselves current with industry developments and applicable legal, accounting and regulatory changes.

### **Board Leadership Structure and Role in Risk Oversight**

Dr. Erich Mohr serves as the chairman of the Board of Directors. Jeffrey Bacha serves as our chief executive officer. We have not adopted a policy on whether the Chief Executive Officer and Chairman positions should be separate.

Our Board of Directors is primarily responsible for overseeing our risk management processes. The Board of Directors receives and reviews periodic reports from management, auditors, legal counsel, and others, as considered appropriate regarding the Company's assessment of risks. The Board of Directors focuses on the most significant risks facing the Company and the Company's general risk management strategy, and also ensures that risks undertaken by the Company are consistent with the board's appetite for risk. While the Board of Directors oversees the Company's risk management, management is responsible for day-to-day risk management processes. We believe this division of responsibilities is the most effective approach for addressing the risks facing the Company and that our board leadership structure supports this approach.



## **Code of Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. The Board of Directors is committed to a high standard of corporate governance practices and, through its oversight role, encourages and promotes a culture of ethical business conduct. Our code of ethics is available on our website at [delmarpharma.com](http://delmarpharma.com).

## **Assessments**

The Board of Directors assesses, on an ongoing basis, its overall performance and that of its committees in order to determine whether they are performing effectively. The Board of Directors also assesses, on an ongoing basis, the effectiveness and contribution of each director of the Company, having regard to the competencies and skills each director is expected to bring to the Board of Directors.

## **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who own more than 10% of the issued and outstanding shares of our common stock to file reports of initial ownership of common stock and other equity securities and subsequent changes in that ownership with the SEC. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. To our knowledge, during the fiscal year ended June 30, 2017, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with.

## **Item 11. Executive Compensation.**

The Board of Directors has formed a Corporate Governance and Compensation Committee which reviews and approves management compensation. The Corporate Governance and Compensation Committee is responsible for approving management compensation, including salaries, bonuses, and equity compensation. The Company seeks to provide competitive compensation arrangements that attract and retain key talent necessary to achieve the business objectives of the Company.

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The following table sets forth all compensation paid in respect of the Company's principal executive officers and those individuals who received compensation in excess of \$100,000 per year for the years ended June 30, 2017 and 2016.

Name and Principal Position	Period	Salary (US\$)	Bonus Awards (US\$)	Option Awards (US\$)(3)	Total (US\$)
Jeffrey Bacha, President and CEO	Year Ended June 30, 2017	(1) 305,000	56,250	249,257	610,507
	Year Ended June 30, 2016	180,000	-	-	180,000
Dennis Brown, Chief Scientific Officer	Year Ended June 30, 2017	175,000	40,000	249,257	464,257
	Year Ended June 30, 2016	150,000	-	-	150,000
Scott Praill, Chief Financial Officer	Year Ended June 30, 2017	(2) 240,000	40,000	99,596	379,596
	Year Ended June 30, 2016	150,000	-	-	150,000

(1) Per employment agreement dated February 9, 2017, base salary is \$250,000 per year. Upon signing the employment contract, a payment of \$55,000 was made.

(2) Per employment agreement dated February 9, 2017, base salary is \$200,000. Upon signing the employment agreement, a payment of \$40,000 was made.

(3) Stock options were granted on February 17, 2017. The options have an exercise price of \$4.95 and have a ten-year term. The grant date fair value was calculated using the Black Scholes valuation model with the following assumptions: dividend rate – 0%; volatility – 82.6%, risk-free rate – 1.74%; and a term of three years.

On February 9, 2017, the Company entered into an employment agreement with Jeffrey Bacha, the Company's president and chief executive officer. Pursuant to the employment agreement, Mr. Bacha will continue to serve as the Company's president and chief executive officer for an indefinite period until termination of the employment agreement in accordance with its terms. The Company will pay Mr. Bacha an annual base salary of \$250,000 (which may be adjusted on an annual basis in the discretion of the board of directors) and Mr. Bacha will also be eligible to participate in any bonus plan and long-term incentive plan established by the Company for senior executives. The employment agreement may be terminated by the Company with or without cause (as defined therein). In the event the Company terminates the employment agreement without cause, the Company will be required to pay Mr. Bacha, any accrued and unpaid base salary, plus an amount equal to 12 months of Mr. Bacha's base salary plus one additional month's base salary for each completed year of service, up to 18 months' base salary. Under a previous consulting agreement between DelMar (BC) and Mr. Bacha, Mr. Bacha was compensated \$15,000 on a monthly basis.

On February 9, 2017, the Company entered into an employment agreement with Scott Prail, the Company's chief financial officer. Pursuant to the employment agreement, Mr. Prail will continue to serve as the Company's chief financial officer for an indefinite period until termination of the employment agreement in accordance with its terms. The Company will pay Mr. Prail an annual base salary of \$200,000 (which may be adjusted on an annual basis in the discretion of the board of directors) and Mr. Prail will also be eligible to participate in any bonus plan and long-term incentive plan established by the Company for senior executives. The employment agreement may be terminated by the Company with or without cause (as defined therein). In the event the Company terminates the employment agreement without cause, the Company will be required to pay Mr. Prail, any accrued and unpaid base salary, plus an amount equal to 12 months of Mr. Prail's base salary plus one additional month's base salary for each completed year of service, up to 18 months' base salary. Under a previous consulting agreement between DelMar (BC) and Mr. Prail, Mr. Prail was compensated \$12,500 on a monthly basis.

On February 9, 2017, the Company entered into an amendment to a consulting agreement with Dr. Dennis Brown, the Company's chief scientific officer. Pursuant to the amendment, Dr. Brown will continue to serve as the Company's chief scientific officer until December 31, 2017, which period may be extended in accordance with the terms of the agreement. The Company will pay Dr. Brown an annual consulting fee of \$200,000 during 2017. The Company may also pay to Dr. Brown a bonus and incentive compensation as determined at the discretion of the board of directors. Pursuant to a consultant agreement effective January 1, 2015, the Company was compensating Dr. Brown at USD \$12,500 on a monthly basis.

Dr. Brown devotes approximately 80% of his business time to us. The consulting agreement with Dr. Brown, does not specify the amount of time Dr. Brown is required to devote to us, but does require that Dr. Brown provide us with the full benefit of his knowledge, expertise and ingenuity, and prohibits Dr. Brown from engaging in any business, enterprise or activity contrary to or that would detract from our business.

#### **Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth outstanding equity awards to our named executive officers as of June 30, 2017.

Name	Option awards		Equity incentive plan awards:		
	Number of securities underlying unexercised options (#)	Number of securities underlying unexercised options (#)	number of securities underlying unexercised options (#)	Option exercise price (US\$)	Option expiration date
Jeffrey Bacha	37,500	-	-	2.00 (1)	Feb 1, 2022
	87,500	-	-	4.20	Aug 15, 2023
	11,527	82,073	-	4.95	Feb 17, 2027
Dennis Brown	37,500	-	-	2.00 (1)	Feb 1, 2022
	87,500	-	-	4.20	Aug 15, 2023
	11,527	82,073	-	4.95	Feb 17, 2027
Scott Prail	12,500	-	-	2.00 (1)	Feb 1, 2022
	87,500	-	-	4.20	Aug 15, 2023
	4,606	32,794	-	4.95	Feb 17, 2027

(1) Original exercise price was CDN \$2.00. Price was amended to USD \$2.00 on June 30, 2016. All other terms of the option grants remain unchanged.

## Director Compensation

Director compensation is intended to provide an appropriate level of remuneration considering the responsibilities, time requirements and accountability of the Directors.

The following table sets forth director compensation for the fiscal year ended June 30, 2017 (excluding compensation to the Company's executive officers set forth in the summary compensation table above) paid by the Company.

Name	Fees Earned or Paid in Cash (\$)(1)	Stock Awards (\$)(3)	Option Awards (\$)(2)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
John K. Bell	45,500	-	-	-	-	-	45,500
Robert J. Toth, Jr.	40,500	-	-	-	-	-	40,500
Lynda Cranston	43,000	-	-	-	-	-	43,000
Erich Mohr	40,500	-	-	-	-	-	40,500
Saiid Zarrabian (4)	-	-	-	-	-	-	-

(1) Effective July 1, 2017, directors will be paid a \$35,000 annual retainer, an additional \$5,000 annual retainer for chairing a committee, and the chairman of the Board will be paid an additional annual retainer of \$25,000.

(2) On July 7, 2017, each independent director was granted 36,000 stock options at an exercise price of \$2.11. The options have a ten-year term and vest as to one-third on June 30, 2018 and 3,000 on a quarterly basis commencing September 30, 2018.

(3) On July 7, 2017, subject to approval by the Company's stockholders of the 2017 Plan, the Company's board of directors granted a total of 1,000,000 PSUs under the 2017 Plan to the Company's independent directors. Each award represents the right to receive an aggregate of 1,000,000 shares of the Company's common stock upon vesting of the PSU based on targets approved by the Company's board of directors related to the Company's fully diluted market capitalization. The PSUs will vest in full upon the Company achieving a fully diluted market capitalization of at least \$500 million for five consecutive business days. The PSUs expire on July 7, 2022.

(4) Mr. Zarrabian was appointed to the Board of Director on July 7, 2017.

## Risk Management

The Company does not believe risks arising from its compensation policies and practices for its employees are reasonably likely to have a material adverse effect on the Company.

## Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information, as of September 27, 2017, with respect to the beneficial ownership of the outstanding common stock by (i) any holder of more than five (5%) percent; (ii) each of the Company's executive officers and directors; and (iii) the Company's directors and executive officers as a group. Except as otherwise indicated, each of the stockholders listed below has sole voting and investment power over the shares beneficially owned.

Name of Beneficial Owner (1)	Common Stock Beneficially Owned		Percentage of Common Stock (2)	
Directors and Officers:				
Jeffrey Bacha	1,093,120	(3)	4.2	%
Dennis Brown	1,062,327	(4)	4.9	%
Scott Prail	187,226	(5)	*	
John K. Bell	129,737	(6)	*	
Robert J. Toth, Jr.	44,471	(7)	*	
Lynda Cranston	35,540	(8)	*	
Erich Mohr	60,076	(9)	*	
Saiid Zarrabian	0	(10)	*	
All officers and directors as a group (8 persons)	2,612,497		11.2	%
Beneficial owners of more than 5%:				
Valent Technologies LLC	537,500	(11)	2.5	%
Franklin Resources, Inc.	1,884,615	(12)	8.4	%
Charles B. Johnson	1,884,615	(12)	8.4	%
Rupert H. Johnson, Jr.	1,884,615	(12)	8.4	%
Franklin Advisers, Inc.	1,884,615	(12)	8.4	%

\* Less than 1%

(1) Except as otherwise indicated, the address of each beneficial owner is c/o DelMar Pharmaceuticals, Inc., Suite 720 - 999 West Broadway, Vancouver, British Columbia, Canada V5Z 1K5.

Applicable percentage ownership is based on 21,551,872 shares of common stock outstanding as of September 27, 2017, together with securities exercisable or convertible into shares of common stock within 60 days of September 27, 2017 for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC and (2) generally includes voting or investment power with respect to securities. Shares of common stock that are currently exercisable or exercisable within 60 days of September 27, 2017 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage of ownership of such person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Includes 868,386 shares issuable upon exchange of Exchangeable Shares (including 158,750 shares held in trust), (3) 148,400 shares issuable upon exercise of vested stock options, 15,000 shares issuable upon exercise of warrants, and 7,813 shares issuable upon the conversion of Series B Preferred Stock.

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Includes 537,500 shares held by Valent, 148,400 shares issuable upon exercise of vested stock options, 21,250  
(4) shares issuable upon exercise of warrants held by Dr. Brown, and 7,500 shares issuable upon the conversion of Series B Preferred Stock.

Includes 110,696 shares issuable upon exercise of vested stock options, 25,000 shares issuable upon exchange of  
(5) Exchangeable Shares, 12,500 shares issuable upon exercise of warrants and 9,375 shares upon the conversion of Series B Preferred Stock.

Includes 74,737 shares owned by Onbelay Capital, Inc., 12,500 shares issuable upon exercise of warrants held by  
(6) Onbelay Capital, Inc., 30,000 shares issuable upon exercise of vested stock options, and 12,500 shares issuable upon the conversion of Series B Preferred Stock held by Onbelay Capital, Inc.

(7) Includes 30,000 shares issuable upon exercise of vested stock options and 3,250 shares issuable upon the conversion of Series B Preferred Stock

(8) Includes 30,000 shares issuable upon exercise of vested options and 3,125 shares issuable upon the conversion of Series B Preferred Stock.

(9) Includes 30,000 shares issuable upon exercise of vested stock options and 23,438 shares issuable upon the conversion of Series B Preferred Stock.

(10) Mr. Zarrabian was appointed to the Board of Directors on July 7, 2017

(11) Valent is owned by Dennis Brown, the Company's Chief Scientific Officer.

Based on Schedule 13G filed with the SEC on May 10, 2017. Includes 807,962 shares issuable upon the exercise of warrants. The address of the shareholder is One Franklin Parkway, San Mateo, CA 94403-1906. Charles B. Johnson and Rupert H. Johnson, Jr. (the “Principal Shareholders”) each own in excess of 10% of the outstanding common stock of Franklin Resources, Inc. (“FRI”) and are the principal stockholders of FRI. FRI and the Principal Shareholders may be deemed to be, for purposes of Rule 13d-3 under the Securities Act, the beneficial owners of (12) securities held by persons and entities for whom or for which FRI subsidiaries provide investment management services. The number of shares that may be deemed to be beneficially owned and the percentage of the class of which such shares are a part are reported in Items 9 and 11 of the cover pages of the Schedule 13G for FRI and each of the Principal Shareholders. FRI, the Principal Shareholders and each of the Investment Management Subsidiaries (as defined in the Schedule 13G) disclaim any pecuniary interest in any of such securities. See the Schedule 13G filed on May 10, 2017 for more information.

### Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth the aggregate information of our equity compensation plans in effect as of June 30, 2017:

Plan	Number of securities to be issued upon exercise of outstanding options and rights	Weighted-average price of outstanding options and rights	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)</b>
Equity compensation plans approved by security holders	-	-	-
Equity compensation plans not approved by security holders – Amended and Restated 2003 Employee Stock Option Plan	1,120,850	4.02	713,814
Totals	1,120,850	4.02	713,814

#### 2017 Omnibus Incentive Plan

On July 7, 2017, and subject to approval by the Company’s stockholders, the Company’s board of directors approved adoption of the Company’s 2017 Omnibus Equity Incentive Plan (the “2017 Plan”). The board of directors also approved



a form of Performance Stock Unit Award Agreement to be used in connection with grants of performance stock units (“PSUs”) under the 2017 Plan.

Under the 2017 Plan, 3,487,785 shares of Company common stock are reserved for issuance, less the number of shares of common stock subject to grants of stock options made, or that may be made, under the Del Mar Pharmaceuticals (BC) Ltd. 2013 Amended and Restated Stock Option Plan (the “Legacy Plan”). If all shares available under the Legacy Plan were used, there would remain 1,730,906 shares available for issuance under the 2017 Plan. The number of shares of Company common stock available for issuance under the 2017 Plan will automatically increase as needed such that the number of shares of common stock available for issuance with respect to awards at any time under the 2017 Plan is thirteen percent (13%) of the Company’s fully diluted shares of common stock (less the number of shares of common stock subject to outstanding awards granted under the 2017 Plan and options granted under the Legacy Plan). No award will be granted under the 2017 Plan on or after July 7, 2027, but awards granted prior to that date may extend beyond that date.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

#### **Certain Relationships and Related Transactions**

On September 12, 2010, DelMar (BC) entered into a Patent Assignment Agreement (the “Assignment”) with Valent Technologies LLC pursuant to which Valent assigned to DelMar (BC) its rights to patent applications and the prototype drug product related to VAL-083. In accordance with the Assignment the consideration paid by DelMar (BC) was \$250,000 to acquire the prototype drug product. In accordance with the terms of the Assignment, Valent is entitled to receive a future royalty (in the single digits) on certain revenues derived from the development and commercialization of VAL-083. In the event that DelMar (BC) terminates the agreement, DelMar (BC) may be entitled to receive royalties from Valent’s subsequent development of VAL-083 depending on the development milestones DelMar (BC) has achieved prior to the termination of the Assignment. The Assignment has a term (on a country-by-country basis), of the later of ten years or until patent rights covered by the Assignment no longer exist, subject to earlier termination in the event DelMar (BC) breaches its payment obligations and fails to remedy such breach within 60 days, or if either party materially breaches any of its obligations and does not cure such breach within 30 days after receipt of notice thereof.

Pursuant to a loan agreement dated February 3, 2011, between DelMar (BC) and Valent, Valent loaned DelMar \$250,000 for the purchase of the prototype drug product under the Assignment. The loan is unsecured, bears interest at 3% per year, and is payable on demand. Effective September 30, 2014, the Company entered into and closed an agreement with Valent to exchange its loan, including accrued interest to September 30, 2014, with Valent for 278,530 shares of preferred stock of the Company. The preferred stock has an annual 3% dividend.

In addition, under the terms of the Assignment, DelMar (BC) issued to Valent warrants to acquire 125,000 common shares at an exercise price of CDN \$2.00 per share upon the completion of the financing transaction that closed in February 2012.

Valent, which is owned by Dr. Dennis Brown, our Chief Scientific Officer, leases facilities in California and we have access to such facilities pursuant to an informal unwritten arrangement with Valent.

Included in accounts payable at June 30, 2017 is a net aggregate amount of \$88,957 owed to the Company's officers and directors for fees and expenses. The Company pays related party payables incurred for fees and expenses under normal commercial terms.

#### **Director Independence**

John K. Bell, Robert J. Toth, Jr., Lynda Cranston, Saiid Zarrabian, and Erich Mohr are independent as that term is defined under the Nasdaq Marketplace Rules.

#### **Item 14. Principal Accounting Fees and Services.**

On October 7, 2016, Ernst & Young LLP ("E&Y"), Chartered Professional Accountants, were appointed as the Company's new auditors.

PricewaterhouseCoopers LLP ("PwC"), Chartered Professional Accountants, were the Company's auditors until October 4, 2016.

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The following is a summary of fees paid by the Company for professional services rendered by E&Y for the year ended June 30, 2017 and PwC for the year ended June 30, 2016.

	Year Ended June 30, 2017	<b>Year Ended June 30, 2016</b>
Audit fees	\$112,000	\$115,000
Audit related fees	\$20,125	\$16,000
Tax fees	\$-	\$-
All other fees	\$-	\$-
Total fees	\$132,125	\$131,000

*Audit fees.* Audit fees represent fees for professional services performed by E&Y and PwC for the audit of our annual financial statements and the review of our quarterly financial statements, as well as services that are normally provided in connection with statutory and regulatory filings or engagements.

*Audit-related fees.* Audit-related fees represent fees for assurance and related services performed by E&Y and PwC that are reasonably related to the performance of the audit or review of our financial statements.

*Tax Fees.* Neither E&Y nor PwC performed any tax compliance services for us during the years ended June 30, 2017 or 2016.

*All other fees.* Neither E&Y nor PwC received any other fees from us for the years ended June 30, 2017 or 2016.

In accordance with applicable laws, rules and regulations, our audit committee charter and pre-approval policies established by the audit committee require that the audit committee review in advance and pre-approve all audit and permitted non-audit fees for services provided to us by our independent registered public accounting firm. The services performed by, and the fees to be paid to E&Y and PwC, in 2017 and 2016 were approved by the audit committee.

## PART IV

### Item 15. Exhibits.

- 2.1 Exchange Agreement, dated January 25, 2013, among the Company, Exchangeco, Callco, DelMar (BC) and securityholders of DelMar (BC) (incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed with the SEC on January 31, 2013)
- 3.1 Articles of Incorporation of the Company (incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-1 filed with the SEC on August 17, 2010)
- 3.2 Articles of Merger of the Company (incorporated by reference to Exhibit 3.1(b) of the Company's Current Report on Form 8-K filed with the SEC on January 23, 2013)
- 3.3 Certificate of Designation of Special Voting Preferred Stock of the Company (incorporated by reference to Exhibit 3.1(a) of the Company's Current Report on Form 8-K filed with the SEC on January 23, 2013)
- 3.4 Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-1 filed with the SEC on August 17, 2010)
- 3.5 Amendment to Bylaws of the Company (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on February 14, 2013)
- 3.6 Certificate of Designation of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014)
- 3.7 Certificate of Amendment to Articles of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on January 7, 2013)
- 3.8 Certificate of Change (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on May 20, 2016)
- 3.9 Certificate of Designation of Series B Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on May 5, 2016)
- 4.1 Specimen Common Stock Certificate, \$.001 par value (incorporated by reference to Exhibit 4 of the Company's Registration Statement on Form 8-A filed with the SEC on September 14, 2012)
- 4.2 Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1/A filed with the SEC on July 9, 2015)
- 4.3 Form of Investor Warrant (incorporated by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K filed with the SEC on January 31, 2013)
- 4.4

Form of Dividend Warrant (incorporated by reference to Exhibit 10.7 of the Company's Current Report on Form 8-K filed with the SEC on January 31, 2013)

- 4.5 Form of Election to Exercise Warrants (incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed with the SEC on June 9, 2014)
- 4.6 Form of Investor Warrant Amendment (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on November 6, 2014)
- 4.7 Form of Dividend Warrant Amendment (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on November 6, 2014)
- 4.8 Form of Placement Agent Warrant Amendment (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 31, 2015)
- 4.9 Form of Placement Agent Warrant (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on May 5, 2016)
- 4.10 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2017)
- 4.11 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2017)

- 10.1 Form of Placement Agent Agreement (incorporated by reference to Exhibit 1.1 of the Company's Registration Statement on Form S-1/A filed with the SEC on July 15, 2015)
- 10.2 Intercompany Funding Agreement, dated January 25, 2013, between the Company and Exchangeco (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on January 31, 2013)
- 10.3 Support Agreement, dated January 25, 2013, among the Company, Exchangeco and Callco (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on January 31, 2013)
- 10.4 Voting and Exchange Trust Agreement, dated January 25, 2013, among the Company, Callco, Exchangeco, and the Trustee (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on January 31, 2013)
- 10.5† Memorandum of Understanding and Collaboration Agreement between Guangxi Wuzhou Pharmaceutical (Group) Co. Ltd. and DelMar (BC) (incorporated by reference to Exhibit 10.8 of the Company's Current Report on Form 8-K filed with the SEC on January 31, 2013)
- 10.6† Patent Assignment Agreement, dated September 12, 2010, between DelMar (BC) and Valent (incorporated by reference to Exhibit 10.9 of the Company's Current Report on Form 8-K/A filed with the SEC on March 14, 2013)
- 10.7 Amendment, dated January 21, 2013, to Patent Assignment Agreement, dated September 12, 2010, between DelMar (BC) and Valent (incorporated by reference to Exhibit 10.10 of the Company's Current Report on Form 8-K/A filed with the SEC on March 14, 2013)
- 10.8 Form of Exchange Agreement (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on January 7, 2015)
- 10.9 Consulting Agreement, effective January 1, 2015 between DelMar (BC) and Jeffrey Bacha (incorporated by reference to Exhibit 10.16 of the Company's Registration Statement on Form S-1 filed with the SEC on April 10, 2015)
- 10.10 Consulting Agreement, effective January 1, 2015 between DelMar (BC) and Dennis Brown (incorporated by reference to Exhibit 10.17 of the Company's Registration Statement on Form S-1 filed with the SEC on April 10, 2015)
- 10.11 Consulting Agreement, effective January 1, 2015 between DelMar (BC) and Scott Prail (incorporated by reference to Exhibit 10.18 of the Company's Registration Statement on Form S-1 filed with the SEC on April 10, 2015)
- 10.12 Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on May 5, 2016)
- 10.13 Form of Royalty Agreement (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on May 5, 2016)

- 10.14 Form of Securities Purchase Agreement, dated April 12, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2017)
- 10.15 Engagement Letter Agreement, dated January 24, 2017 between DelMar Pharmaceuticals, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2017)
- 10.16 Amendment No. 1 to letter agreement between DelMar Pharmaceuticals, Inc. H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2017)
- 10.17 Amendment No. 2 to letter agreement between DelMar Pharmaceuticals, Inc. H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2017)
- 10.18 Employment agreement among Delmar Pharmaceuticals Inc., Delmar Pharmaceuticals (BC) Ltd. and Jeffrey Bacha (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on February 10, 2017)
- 10.19 Employment agreement among Delmar Pharmaceuticals Inc., Delmar Pharmaceuticals (BC) Ltd. and Scott Praill (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed with the SEC on February 10, 2017)
- 10.20 Amendment to consulting agreement between Delmar Pharmaceuticals (BC) Ltd. and Dennis Brown (incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed with the SEC on February 10, 2017)

- 10.21 2017 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed with the SEC on July 12, 2017)
- 10.22 Form of Performance Share Unit Award Agreement (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed with the SEC on July 12, 2017)
- 10.23 Engagement Letter Agreement, dated September 17, 2017 between DelMar Pharmaceuticals, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2017)
- 10.24 Form of Securities Purchase Agreement, dated September 20, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2017)
- 16.1 Letter from PricewaterhouseCoopers LLP (incorporated by reference to Exhibit 16.1 of the Company's Current Report on Form 8-K filed with the SEC on October 7, 2016)
- 21.1 Subsidiaries (incorporated by reference to Exhibit 21 of the Company's Registration Statement on Form S-1 filed with the SEC on June 14, 2013)
- 23.1 Consent of Ernst & Young LLP\*
- 23.2 Consent of PricewaterhouseCoopers LLP\*
- 31.1 Certification of principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 \*
- 31.2 Certification of principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 \*
- 32.1 Certification of principal executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  
\*\*
- 32.2 Certification of principal financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  
\*\*
- 99.1 Audit Committee Charter (incorporated by reference to Exhibit 10.21 of the Company's Annual Report on Form 10-K filed with the SEC on September 3, 2015)

EX-101.INS XBRL Instance Document \*  
EX-101.SCH XBRL Taxonomy Extension Schema Document \*  
EX-101.CAL XBRL Taxonomy Extension Calculation Linkbase \*  
EX-101.DEF XBRL Taxonomy Extension Definition Linkbase \*  
EX-101.LAB XBRL Taxonomy Extension Labels Linkbase \*  
EX-101.PRE XBRL Taxonomy Extension Presentation Linkbase \*

† Confidential treatment is requested for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Exchange Act. In accordance with Rule 24b-2, these confidential portions have been omitted from this exhibit and



filed separately with the Commission.

\* Filed herewith

\*\* Furnished herewith

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## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**DELMAR  
PHARMACEUTICALS, INC.**

Dated: September 27, 2017 By: /s/ Jeffrey Bacha  
Name: Jeffrey Bacha  
Title: Chief Executive Officer  
(principal executive officer)

Dated: September 27, 2017 By: /s/ Scott Praille  
Name: Scott Praille  
Title: Chief Financial Officer  
(principal financial and accounting officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<i>SIGNATURE</i>	<i>TITLE</i>	<i>DATE</i>
/s/ Jeffrey Bacha Jeffrey Bacha	Chief Executive Officer, Director (principal executive officer)	September 27, 2017
/s/ Scott Praille Scott Praille	Chief Financial Officer (principal financial and accounting officer)	September 27, 2017
/s/ Dennis Brown Dennis Brown	Director	September 27, 2017
/s/ John K. Bell John K. Bell	Director	September 27, 2017
/s/ Robert J. Toth, Jr. Robert J. Toth	Director	September 27, 2017
/s/ Lynda Cranston	Director	September 27, 2017

Lynda Cranston

/s/ Saiid Zarrabian     Director  
Saiid Zarrabian

September 27, 2017

/s/ Erich Mohr     Director  
Erich Mohr

September 27, 2017