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 fiscal year ended June 30, 2019
or

☐ 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)

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

12707 High Bluff Dr., Suite 200
San Diego, CA, 92130
(Address of principal executive offices) (Zip Code)

(858) 350-4364
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	DMPI	The Nasdaq Capital Market

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

Indicate by check mark if 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 website, 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 such files). ☑ Yes ☐ No

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 Act) ☐ Yes ☑ No

As of December 31, 2018, 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 $3.42 was approximately $8.4 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 6, 2019 was 11,388,483.

DOCUMENTS INCORPORATED BY REFERENCE – None

FORM 10-K

FOR THE FISCAL YEAR ENDED JUNE 30, 2019
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PART I

Item 1. Business.

Background

DelMar Pharmaceuticals, Inc. (the "Company," "we," "us," or "our") is a clinical stage, biopharmaceutical company focused on the development and commercialization of new cancer therapies. Our mission is to benefit patients by developing and commercializing anti-cancer therapies for patients whose solid tumors exhibit features that make them resistant to, or unlikely to respond to, currently available therapies, with particular focus on orphan cancer indications.

As of June 30, 2019, we have spent approximately $40.5 million of shareholder capital in developing VAL-083, a novel, validated, DNA-targeting agent, for the treatment of drug-resistant solid tumors such as glioblastoma multiforme ("GBM") and potentially other solid tumors, including ovarian cancer, non-small cell lung cancer ("NSCLC"), and diffuse intrinsic pontine glioma ("DIPG"). VAL-083 is a first-in-class, small-molecule, DNA-targeting chemotherapeutic that has demonstrated activity against a range of tumor types in prior Phase 1 and Phase 2 clinical studies sponsored by the US National Cancer Institute ("NCI"). As part of our business strategy, we leverage and build upon these prior NCI investments and data from more than 40 NCI- Phase 1 and Phase 2 clinical studies, which includes an estimated 1,000 patient safety database, added to our own research to identify and target unmet medical needs in modern cancer care. DNA-targeting agents are among the most successful and widely used treatments for cancer. Their efficacy is based on the ability to bind with a cancer cell's DNA and interfere with the process of protein production required for growth and survival of cancer cells. "First-in-class" means that VAL-083 embodies a unique molecular structure which is not an analogue or derivative of any approved product, or product under development, for the treatment of cancer.

Prior studies of VAL-083 have shown increased median overall survival benefits versus radiation alone, validating the tumor affecting properties of VAL-083. Our recent research has highlighted the opportunities afforded by VAL-083's unique mechanism of action and its potential to address unmet medical needs in a well-defined and acknowledged biomarker selected population within the larger GBM population. We are thus focusing our initial development efforts on patients whose tumors exhibit biological features that make them resistant to, or unlikely to respond to, currently available therapies as identified by National Comprehensive Cancer Network ("NCCN"). For example, our research demonstrating VAL-083's activity in GBM independent of the O6-methyl guanine methyltransferase ("MGMT") methylation status allows us to focus patient selection based on this important biomarker and thus improve the probability of success in our current and future clinical studies.

We are currently conducting two open-label, biomarker driven Phase 2 studies in MGMT-unmethylated GBM. MGMT is a DNA-repair enzyme that is associated with resistance to temozolomide ("TMZ"), the current standard-of-care chemotherapy used in the treatment of GBM. Greater than 60% of GBM patients have MGMT-unmethylated tumors and exhibit a high expression of MGMT, which is correlated with TMZ treatment failure and poor patient outcomes as indicated in the NCCN guidelines for GBM treatment published in September, 2017. Our research demonstrates that VAL-083's anti-tumor activity is independent of MGMT expression. In our current Phase 2 studies we are using MGMT as a biomarker to identify patients for treatment with VAL-083 in three distinct GBM patient populations:

- First-line in combination with radiation
- As adjuvant therapy immediately following chemoradiation and initial TMZ treatment, and
- In the recurrent treatment setting.

If successful, the results of these studies could position VAL-083 for advancement to pivotal clinical studies as a potential replacement for TMZ in MGMT-unmethylated GBM. As both of our clinical studies are open label studies, we anticipate presenting data from these studies at peer reviewed scientific meetings during the latter part of calendar year 2019 as well as during the first half of calendar year 2020.

With respect to our STAR-3, Phase 3 study, we have finalized the decision to discontinue this clinical study due to patient enrollment rates, potential ability to measure positive results in a study that did not pre-select a biomarker identified patient population, and potential risk of success assessment. As importantly, terminating the study has allowed us to focus on more rapid enrollment of GBM patients in our two biomarker-driven Phase 2 studies.

With the US Food and Drug Administration ("FDA") approval for our investigational new drug application ("IND"), we have future plans for a phase 1/2, open-label, multicenter study of VAL-083 in patients with **Re**current **P**latinum **R**esistant **Ov**arian Cancer ("REPROVe"). Platinum-based chemotherapy is the 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.* However, based on ongoing evaluation and input from our ovarian cancer advisory board, we are reassessing the development of VAL-083 for the treatment of ovarian cancer. We are in the process of evaluating the best path forward in ovarian cancer and are evaluating strategic options, including the potential combination of VAL-083 with PARP inhibitors. At the American Association for Cancer Research ("AACR") Annual Meeting in 2018 we presented preclinical data showing that VAL-083 can synergize PARP inhibitors in both a BRACA-proficient and -deficient setting.

In addition to our clinical development activities in the United States, pursuant to our collaboration with Guangxi Wuzhou Pharmaceutical (Group) Co. Ltd. ("Guangxi Wuzhou Pharmaceutical Company"), we have provided Guangxi Wuzhou Pharmaceutical Company certain 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. Guangxi Wuzhou Pharmaceutical Company is the only manufacturer presently licensed by the China Food and Drug Administration ("CFDA") to produce the product for the China market.

We have a broad patent portfolio to protect our intellectual property. Our patent applications claim composition of matter 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 gliomas, including GBM. The FDA has also granted Orphan Drug protection to VAL-083 for the treatment of medulloblastoma and ovarian cancer.

Our corporate development strategy is to advance VAL-083 on an indication-by-indication basis, and then to consider out-licensing our products when they have matured enough to warrant proper licensing valuations. In addition to VAL-083's applicability to multiple solid tumor indications, we are also constantly evaluating licensing, or acquiring additional product candidates, in order to establish a product pipeline and to position us for long-term sustainability and growth of shareholder value. We believe the experience of our clinical development team will position us to efficiently develop possible drug candidates that we may acquire, or license, in the future.

We intend to continue to evaluate options for our strategic direction. These options may include raising additional capital, the acquisition of another company and/or complementary assets, our sale, or another type of strategic partnership.

Recent Highlights

- As of September 1, 2019, we relocated our headquarters from Vancouver, British Columbia to San Diego, California. The Vancouver office will remain open as an administrative office.

- On August 16, 2019, we closed on the sale of (i) 4,895,000 shares of our common stock, par value $0.001 per share, (ii) pre-funded warrants to purchase an aggregate of 2,655,000 shares of common stock and (iii) common warrants to purchase an aggregate of 7,762,500 shares of common stock, including 800,000 shares of common stock and warrants to purchase an aggregate of 1,012,500 shares of common stock sold pursuant to a partial exercise by the underwriters of the underwriters' option to purchase additional securities. Each share of common stock or pre-funded warrant, as applicable, was sold together with a common warrant to purchase one share of common stock at a combined effective price to the public of $1.00 per share and accompanying common warrant.

  We believe the net proceeds from this offering of approximately $6.7 million will be sufficient to complete full enrollment in all three patient groups of our two ongoing Phase 2 clinical studies for our drug development candidate, VAL-083, expected to occur by the fourth quarter of calendar year 2020.

- As of August 1, 2019, we provided an update on the first 20 patients enrolled in our ongoing Phase 2 clinical study investigating the first-line treatment of VAL-083 in combination with radiation therapy in newly-diagnosed, MGMT-unmethylated GBM. The study, which is being conducted at the Sun Yat-sen University Cancer Center ("SYSUCC") is designed to enroll up to 30 patients to determine whether first-line therapy with VAL-083 treatment improves progression free survival ("PFS"). The current standard of care is first-line TMZ with radiation.

  As of August 1, 2019, of the first 20 enrolled patients, 17 have received at least their first assessment (two patients have not been enrolled long enough to receive their first assessment and one patient died before their first assessment). "Best Overall Response" for these patients per Investigator Assessment were:

- Nine have been assessed as having achieved a complete response (CR) (9/17, or 53%)

- Seven have been assessed with stable disease (SD), (7/17, or 41%); and

- One has been assessed as disease progression (PD) (1/17, or 6%).

  As of August 1, 2019, of the 20 patients enrolled, 17 (85%) have received their two-month (post-third cycle) MRI and investigator assessment, 13 (65%) have received their five-month MRI and investigator assessment, and seven (35%) have received their eight-month MRI and investigator assessment. Two patients (10%) have not been on the study long enough to reach their first assessment, and one patient (5%) died before their first assessment. Importantly, 16 of the 20 patients enrolled (80%) were still alive as of the data cut-off date.

- On July 24, 2019 we announced the enrollment of the first patient in the adjuvant (pre-temozolomide maintenance) arm of our Phase 2, open label study of VAL-083 in MGMT-unmethylated GBM being conducted at the University of Texas MD Anderson Cancer Center ("MDACC"). The MDACC Institutional Review Board ("IRB") had previously approved the addition of up to 24 patients in the pre-TMZ maintenance setting (i.e. the adjuvant setting). The up to 24 newly-diagnosed patients will have undergone surgery and chemoradiation with TMZ but will now receive VAL-083 in place of standard of care TMZ for adjuvant therapy.

- As of July 24, 2019, we have enrolled 56 of the planned up to 83 patients in the recurrent arm of our Phase 2, open-label clinical study of VAL-083 in bevacizumab (Avastin®)-naïve, recurrent GBM ("rGBM") patients with MGMT-unmethylated status. This study is being conducted at MDACC and is designed to determine the impact of VAL-083 treatment on overall survival compared to historical reference control. We previously announced that the MDACC IRB had approved the addition of up to 35 patients to our rGBM study at a dose of 30 mg/m^2. As previously disclosed, we had lowered the dose in this study from 40 mg/m^2 to 30 mg/m^2 to improve tolerance in this patient population and thereby to potentially increase overall exposure to VAL-083 by increasing the number of cycles of drug patients are able to receive. Upon completion of the initial 48 patients in this study, 13 will have had the 30 mg/m^2 dose and 35 will have had the 40 mg/m^2. Therefore, potentially adding an additional 35 patients at 30 mg/m^2 would result in a total of 48 patients receiving the 30 mg/m^2 dose.

- On June 26, 2019, we amended our articles of incorporation, as amended, to increase the number of authorized shares of common stock from 7,000,000 to 95,000,000 shares.

- On June 3, 2019, we entered into a securities purchase agreement for the issuance and sale of an aggregate of 1,170,000 shares of common stock in a registered direct offering (the "RD Offering") and warrants to purchase 760,500 shares of common stock in a concurrent private placement, at a combined purchase price of $3.10 per share and related warrant. The warrants have an exercise price of $3.10 per share, are immediately exercisable, and have a term of exercise of five years. The closing of the issuance and sale of these securities was consummated on June 5, 2019. The net proceeds from the offering, after deducting offering expenses and placement agent fees and expenses payable by us, were approximately $3.2 million.

- On May 22, 2019, the Nasdaq Staff notified us that we did not meet the stockholders' equity requirements as of March 31, 2019. We submitted a plan to regain compliance with The Nasdaq Capital Market on May 29, 2019. On June 13, 2019, the Nasdaq Hearings Panel issued a decision granting our request for continued listing, subject to the condition that on or before October 15, 2019, we shall have issued public disclosure on Form 8-K that we have met the stockholders' equity requirement and have demonstrated compliance with all other requirements for continued listing. On September 6, 2019, the Nasdaq Hearings Panel confirmed that, as a result of our recent financing, we have regained compliance with the Nasdaq stockholders' equity requirements. Accordingly, the Nasdaq Hearing Panel has determined to continue the listing of our securities on Nasdaq and closed the matter.

- On May 20, 2019 we announced the expansion of our Scientific Advisory Board ("SAB") with the addition of the following neuro-oncologists:

    - Dr. David Reardon, clinical director of the Center for Neuro-Oncology at the Dana-Farber Cancer Institute and a Professor of Medicine at the Harvard Medical School

    - Dr. Timothy Cloughesy, professor of neurology at the David Geffen School of Medicine at the University of California, Los Angeles and a member of the UCLA Brain Research Institute and Jonsson Comprehensive Cancer Center

    - Dr. Nicholas Butowski, a neuro-oncologist practicing at UCSF Medical Center in San Francisco, CA, and director of translational research in neuro-oncology and a researcher at the Brain Tumor Center

- On April 4, 2019, we announced the formation of an SAB. Its inaugural members are Drs. Napoleone Ferrara and John de Groot. Dr. John de Groot, Chairman, ad interim of the Department of Neuro-Oncology at the MD Anderson Cancer Center is an expert in glioma biology and angiogenesis which is the key area of clinical development for VAL-083. Dr. Ferrara is a world-renowned molecular biologist whose pioneering work on the identification of VEGF, a signal protein produced by cells that stimulates the formation of blood vessels, led to the development of Genentech Inc.'s Avastin® for the treatment of certain types of cancer, including ovarian cancer and GBM. Dr. Ferrara is also a member of our Board of Directors and he will serve as the SAB's Chairman. The SAB will work closely with our management team to optimize the development of VAL-083.

Underwritten Offering

On August 16, 2019, we closed on the sale of (i) 4,895,000 shares of our common stock, par value $0.001 per share (the "Common Stock"), (ii) pre-funded warrants ("PFW") to purchase an aggregate of 2,655,000 shares of Common Stock and (iii) common warrants to purchase an aggregate of 7,762,500 shares of Common Stock, including 800,000 shares of Common Stock and warrants to purchase an aggregate of 1,012,500 shares of Common Stock sold pursuant to a partial exercise by the underwriters of the underwriters' option to purchase additional securities, in our previously announced underwritten public offering (the "Offering"). Each share of Common Stock or pre-funded warrant, as applicable, was sold together with a common warrant to purchase one share of Common Stock at a combined effective price to the public of $1.00 per share and accompanying common warrant.

The net proceeds from the Offering, including from the partial exercise of the underwriters' option to purchase additional securities, were approximately $6.7 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. We intend to use the net proceeds from the Offering for our clinical studies 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 the Offering for investments in businesses, products or technologies that are complementary to our business.

We granted the underwriters a 45-day option, ending September 28, 2019, to purchase up to an additional 1,012,500 shares of Common Stock and/or common warrants to purchase up to 1,012,500 shares of Common Stock, at the public offering price less discounts and commissions. On August 15, 2019, the underwriters partially exercised this option by purchasing 800,000 shares of Common Stock and common warrants to purchase an aggregate of 1,012,500 shares of Common Stock.

The common stock purchase warrants are exercisable at $1.00 per share and the PFW are exercisable at $0.01 per share until their expiry on August 16, 2024. We also issued 377,500 warrants to the underwriters of the Offering. The underwriter warrants are exercisable at $1.15 per share commencing 180 days from August 16, 2019 until their expiry on August 16, 2022.

Subject to certain ownership limitations, the warrants are exercisable commencing on the issuance date at an exercise price equal to $1.00 per share of common stock, subject to adjustments as provided under the terms of the warrants.

Each pre-funded warrant is exercisable for one share of our common stock (subject to adjustment as provided for therein) at any time at the option of the holder until such pre-funded warrant is exercised in full, provided that the holder will be prohibited from exercising pre-funded warrants for shares of our common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

Registered Direct Offering and Private Placement

On June 3, 2019, we entered into a securities purchase agreement for the issuance and sale of an aggregate of 1,170,000 shares of common stock in a registered direct offering (the "RD Offering") and, in a concurrent private placement, warrants to purchase 760,500 shares of common stock at a combined purchase price of $3.10 per share and related warrant. The warrants have an exercise price of $3.10 per share, are immediately exercisable and have a term of exercise of five years. The closing of the issuance and sale of these securities was consummated on June 5, 2019. The gross proceeds from the offering, prior to deducting offering expenses and placement agent fees and expenses payable by us, were $3.6 million.

Subject to certain ownership limitations, the warrants are exercisable commencing on the issuance date at an exercise price equal to $3.10 per share of common stock, subject to adjustments as provided under the terms of the warrants.

China Clinical Study Update

In August, 2019, we provided an update on the first 20 patients enrolled in our ongoing Phase 2 clinical study investigating the first-line treatment of VAL-083 in combination with radiation therapy in newly-diagnosed, MGMT-unmethylated GBM. The study, which is being conducted at the Sun Yat-sen University Cancer Center ("SYSUCC") is designed to enroll up to 30 patients to determine whether first-line therapy with VAL-083 treatment improves progression free survival ("PFS"). The current standard of care is first-line temozolomide ("TMZ") with radiation.

As of August 1, 2019, of the first 20 enrolled patients, 17 have received at least their first assessment (two patients have not been enrolled long enough to receive their first assessment and one patient died before their first assessment). "Best Overall Response" for these patients per Investigator Assessment were:

- Nine have been assessed as having achieved a complete response (CR) (9/17, or 53%)
- Seven have been assessed with stable disease (SD), (7/17, or 41%); and
- One has been assessed as disease progression (PD) (1/17, or 6%).

Of the 20 patients enrolled, 17 (85%) have received their two-month (post-third cycle) MRI and investigator assessment, 13 (65%) have received their five-month MRI and investigator assessment, and seven (35%) have received their eight-month MRI and investigator assessment. Two patients (10%) have not been on the study long enough to reach their first assessment, and one patient (5%) died before their first assessment. Importantly, 16 of the 20 patients enrolled (80%) were still alive as of the data cut-off date.

Clinical Updates Presented at 2019 American Society of Clinical Oncology

On May 31, 2019, we provided clinical study updates from our ongoing first-line and recurrent studies in patients with MGMT-unmethylated GBM at a Key Opinion Leader ("KOL") presentation during the 2019 American Society of Clinical Oncology ("ASCO") annual meeting in Chicago, IL.

At the KOL presentation, we provided an update on the ongoing Phase 2 clinical study investigating the front-line treatment of VAL-083 with radiation therapy in newly diagnosed MGMT-unmethylated GBM. This study is being conducted at SYSUCC in Guangzhou, China in collaboration with Guangxi Wuzhou Pharmaceutical Company. The study is designed to enroll up to 30 patients to determine if first-line therapy with VAL-083 treatment, in lieu of first-line temozolomide, improves PFS.

As of May 17, 2019, eighteen patients have been enrolled in the study. Of these patients, fifteen have received their post-cycle 3 MRI and investigator assessment, and ten have received their post-cycle 7 MRI and investigator assessment. Two patients have not been on the study long enough to reach their first assessment, and one patient died before their first assessment. Assessments are based on the study investigator's clinical and radiologic assessment, according to the RANO criteria. For the fifteen patients who have received at least one assessment, eight patients were assessed with a "Best Overall Response" of "Complete Response" (8/15, 53.3% CR) and seven patients were assessed with a "Best Overall Response" of "Stable Disease" (7/15, 46.7% SD). Fourteen of the eighteen patients were still alive at the data cut-off date.

We also provided an update on the ongoing recurrent arm of the Phase 2 clinical study of VAL-083 in patients with MGMT-unmethylated, Bevacizumab-naïve recurrent GBM. This study is being conducted in collaboration with MDACC. This biomarker-driven study (testing for MGMT methylation status) has been amended to enroll up to 83 patients (35 with a starting dose of 40 mg/m^2; 48 with a starting dose of 30 mg/m^2) to determine the potential of VAL-083 treatment to improve overall survival compared to historical reference control of 7.2 months with lomustine.

- As of May 5, 2019, 51 patients have been enrolled, 35 patients at a starting dose of 40 mg/m^2, and 16 patients at a starting dose of 30 mg/m^2.
- For the 47 patients who have been on study long enough to be assessed at the post-cycle 2 MRI:
    - 9/35 (25.7%) patients initially receiving 40 mg/m^2 exhibited "Stable Disease" per investigator assessment at the end of cycle 2
    - 4/12 (33.3%) patients initially receiving 30 mg/m^2 exhibited "Stable Disease" per investigator assessment at the end of cycle 2

Additionally, the study protocol has been amended to include enrollment of up to 24 newly-diagnosed GBM patients who have completed chemoradiation treatment with TMZ and received no subsequent TMZ maintenance therapy but will receive VAL-083 instead (the adjuvant arm). The adjuvant arm of the study has been included to explore whether earlier intervention with VAL-083 instead of TMZ maintenance therapy offers clinical benefit and extends the time to recurrence as compared to TMZ maintenance therapy.

Consistent with prior studies, myelosuppression (primarily thrombocytopenia and neutropenia) is the most common adverse event in both ongoing clinical studies.

VAL-083 Clinical Studies

We are currently developing VAL-083, a novel DNA-targeting agent for the treatment of GBM and potentially other solid tumors, including ovarian cancer. Our recent research has highlighted the opportunities afforded by VAL-083's unique mechanism of action and its potential to address unmet medical needs by focusing our development efforts on patients whose tumors exhibit biological features that make them resistant to, or unlikely to respond to, currently available therapies. For example, our research demonstrating VAL-083's activity in GBM is independent of the MGMT methylation status allows us to focus patient selection based on this important biomarker.

The evaluation of MGMT promotor methylation status has increasingly become common practice in the diagnostic assessment of GBM. In September 2017, the National Comprehensive Cancer Network ("NCCN") updated guidelines for the standard treatment of GBM based on MGMT methylation status. We believe these recently published guidelines provide for enhanced opportunities for us to capitalize on VAL-083's unique mechanism of action by utilizing MGMT methylation as a biomarker to optimize patient selection for our novel DNA-targeting agent to target the majority of GBM patients who are diagnosed with MGMT-unmethylated tumors.

Our current priority is to leverage this research and VAL-083's unique mechanism of action to efficiently advance our drug candidate for the most promising indications, including:

- MGMT-unmethylated GBM, currently comprising two ongoing separate Phase 2 clinical studies for:
    - GBM patients in two study arms at MDACC:

- as adjuvant therapy immediately following chemoradiation; and
- in Avastin®-naïve rGBM patients;

o Newly diagnosed GBM patients (ongoing study at SYSUCC); and

- Potential future indications include ovarian cancer, NSCLC, and other solid tumor indications.

MGMT-unmethylated GBM

GBM is the most common and the most lethal form of glioma. According to the Central Brain Tumor Registry of the United States, GBM occurs with an incidence of 3.20 per 100,000 person-years. Approximately 13,000 new cases of GBM were diagnosed in the United States and 16,000 in Europe during 2017. Within the GBM patient population, approximately two-thirds of patients are unmethylated with respect to their MGMT status.

Measurement of MGMT (O6-methyl guanine methyltransferase) methylation status has become routine in clinical practice as a biomarker that correlates with resistance to the standard-of-care chemotherapy with temozolomide (Temodar® "TMZ"), and patient outcomes in GBM. Greater than 60% of GBM patients' tumors are characterized as "MGMT-unmethylated" and exhibit a high expression of MGMT, a naturally occurring DNA-repair enzyme, the activity of which nullifies the chemotherapeutic activity of TMZ. The development of new therapies for MGMT-unmethylated GBM is a significant unmet medical need. Importantly, the most recent update to NCCN guidelines states that the treatment benefit of TMZ is likely to be lower in GBM patients with an unmethylated MGMT promoter, and therefore, allows for withholding of TMZ in the treatment of newly diagnosed GBM patients with MGMT-unmethylated tumors due to lack of efficacy.

We have demonstrated that VAL-083's anti-tumor mechanism is active independent from the MGMT status*in vitro*. We believe this suggests the potential of VAL-083 as a replacement for the current standard-of-care chemotherapy, temozolomide, in MGMT-unmethylated GBM. We are therefore utilizing MGMT-methylation status to identify GBM patients who are unlikely to respond to temozolomide and instead treat them with VAL-083.

We believe that our research, in the context of the recent amendment to NCCN guidelines, highlights this unmet need and the opportunity for VAL-083 as a potential new standard-of-care in the treatment of MGMT-unmethylated GBM.

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

In February 2017, we initiated a biomarker driven, open-label, single-arm Phase 2 study in collaboration with MDACC. This biomarker-driven study (testing for MGMT methylation status) has been amended to enroll up to 83 patients (35 with a starting dose of 40 mg/m^2; 48 with a starting dose of 30 mg/m^2) to determine the potential of VAL-083 treatment to improve overall survival in GBM patients whose tumors have recurred following treatment with temozolomide. These patients will not have been treated previously with Avastin®. In addition, this study has been amended to include 24 patients in the adjuvant patient population. The GBM patients in the adjuvant arm of the study will have had treatment with TMZ in combination with radiation but rather than then being treated with additional cycles of TMZ, these patients will begin treatment with VAL-083.

Recurrent Study Arm

As of July 24, 2019, 56 patients had been enrolled in the recurrent arm of this Phase 2 study. The original starting dose of 40 mg/m^2 of VAL-083 on days 1, 2 and 3, of a 21-day cycle, which was based on the results from our previous Phase 1/2 safety study of VAL-083 in patients with recurrent glioma (clinicaltrials.gov identifier: NCT01478178), has continued to demonstrate myelosuppression as the principal side effect of VAL-083, as per prior clinical experience. The safety profile has been well within the existing safety monitoring guidelines described in the present study protocol. However, in consultation with the principal investigator at MDACC, we have amended the protocol for this clinical study to modify the starting dose of VAL-083 to 30 mg/m^2 on days 1, 2 and 3, of a 21-day cycle for this specific population previously treated with temozolomide. This modification may improve tolerance in this patient population and thereby potentially increase overall exposure to VAL-083 by increasing the number of cycles of drug patients may be able to receive. We have modified the patient screening platelet count, from 100,000/µL to 125,000/µL, for the same reasons.

The historical comparison survival data for the recurrent arm of the study is lomustine based on a median overall survival of 7.2 months in unmethylated patients. Safety data from this study will become part of the overall safety dossier to support future filings with the FDA and other regulatory agencies.

On May 31, 2019, we provided a clinical study update on the recurrent study arm of our MDACC clinical study at a KOL presentation during the 2019 ASCO annual meeting in Chicago, IL.

- As of May 5, 2019, 51 patients have been enrolled, 35 patients at a starting dose of 40 mg/m^2, and 16 patients at a starting dose of 30 mg/m^2.
- For the 47 patients who have been on study long enough to be assessed at the post-cycle 2 MRI:
    - 9/35 (25.7%) patients initially receiving 40 mg/m^2 exhibited "Stable Disease" per investigator assessment at the end of cycle 2
    - 4/12 (33.3%) patients initially receiving 30 mg/m^2 exhibited "Stable Disease" per investigator assessment at the end of cycle 2

It is important for this GBM patient population, which has been heavily pre-treated with temozolomide, to be able to be treated with multiple cycles of VAL-083 without significant hematological toxicities. We believe the modified dose of VAL-083, in addition to the change in patient eligibility platelet counts, should help provide for enhanced patient safety. We believe a positive outcome from this study can establish a position for VAL-083 in the treatment of MGMT-unmethylated rGBM.

A detailed description of this study can be found at clinicatrials.gov, Identifier Number: NCT02717962.

Adjuvant Study Arm

On July 24, 2019, we announced the enrollment of the first patient in the adjuvant arm of the Phase 2 study being conducted at MDACC.

As noted above, patients in the recurrent arm of the MDACC clinical study have been heavily pre-treated with temozolomide. Based on published data from our MDACC and SYSUCC clinical studies, we believe there is a significant opportunity to treat GBM patients in the pre-temozolomide maintenance stage (i.e., adjuvant). At the AACR's annual meeting in April 2019, we reported that myelosuppression (thrombocytopenia and neutropenia) is the most common adverse event associated with VAL-083. The higher potential for myelosuppression with the 40 mg/m^2/day of VAL-083 in this study appears to be correlated with the number of cycles of prior TMZ maintenance therapy (> 5 cycles). These patients will have had an initial cycle of TMZ following radiation but will not have yet started subsequent cycles of TMZ (i.e. maintenance stage TMZ patients). The MDACC IRB has approved the addition of up to 24 patients to the adjuvant setting. These patients will have had an initial cycle of temozolomide following radiation but will not have yet started subsequent cycles of TMZ (i.e. maintenance stage TMZ patients). The comparison survival data for this study is survival data from Tanguturi et al (2017 Nero-Oncology) for MGMT-unmethylated patients of 6.9 months.

Phase 2 Study 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 SYSUCC in Guangzhou, China. The study is being conducted under our collaboration agreement with Guangxi Wuzhou Pharmaceutical Company.

In this Phase 2 study, VAL-083 is being combined with radiotherapy as a potential replacement for standard-of-care chemoradiation with temozolomide in patients with MGMT-unmethylated GBM. One goal of the study will be to confirm the safety of the three-day VAL-083 dosing regimen in combination with radiotherapy and to investigate outcomes of the combination of VAL-083 and radiotherapy in MGMT-unmethylated GBM patients.

We plan to enroll up to 30 newly-diagnosed, MGMT-unmethylated GBM patients in this study. The efficacy endpoints of the study include tumor response, as assessed by the Response Assessment in NeuroOncology ("RANO"), and progression-free survival ("PFS"), progression-free survival at six months ("PFS6"), and overall survival ("OS"), compared to historical results in the target population. The study is being conducted in two parts: (1) Dose-confirmation: VAL-083 in cohorts (20, 30 and 40 mg/m^2/day IV daily x 3 every 21 days) to assess safety and activity when administered concurrently with x-ray therapy ("XRT") to confirm the maximum tolerated dose ("MTD"), and (2) Expansion: VAL-083 will be studied in up to 20 additional patients at the target dose, as determined by the dose-confirmation part of the study, administered concurrently with XRT. 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.

Dose confirming cohorts studying 20, 30, and 40 mg/m^2/day x three every 21 days have been completed. Based on the dose confirmation phase of the study, we have selected 30 mg/m^2 for combination with irradiation for the treatment of newly-diagnosed MGMT-unmethylated GBM patients.

As of August 1, 2019, of the first 20 enrolled patients, 17 have received at least their first assessment (two patients have not been enrolled long enough to receive their first assessment and one patient died before their first assessment). "Best Overall Response" for these patients per Investigator Assessment were:

- Nine have been assessed as having achieved a complete response (CR) (9/17, or 53%)
- Seven have been assessed with stable disease (SD), (7/17, or 41%); and
- One has been assessed as disease progression (PD) (1/17, or 6%).

Of the 20 patients enrolled, 17 (85%) have received their two-month (post-third cycle) MRI and investigator assessment, 13 (65%) have received their five-month MRI and investigator assessment, and seven (35%) have received their eight-month MRI and investigator assessment. Two patients (10%) have not been on the study long enough to reach their first assessment, and one patient (5%) died before their first assessment. Importantly, 16 of the 20 patients enrolled (80%) were still alive as of the data cut-off date.

Through our research, and that of the NCI, we have previously demonstrated that VAL-083 crosses the blood brain barrier. New preliminary data from the SYSUCC study indicate that the concentration of VAL-083 is generally higher in CSF than in plasma at two hours post-infusion.

Concentration of VAL-083 — Two Hours Post Dose

Dose (mg/m^2)	n	Mean Concentrations (ng/mL)		Conc. Ratio @ 2 hours
		Plasma (2 hours post dose)	CSF (2 hours post dose)	CSF/Plasma
20	1	110	154	1.40
30	3	97	134	1.41
40	3	170	190	1.13

By comparison, temozolomide is typically 80% lower in the CSF than the plasma (Schreck et al. 2018, Oncology (Williston Park)). The reason this is important is that accumulation of VAL-083 in the CSF further validates that VAL-083 crosses the blood-brain-barrier and demonstrates that therapeutic drug concentrations in the CSF are achievable for extended periods of time.

Ovarian Cancer

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

In September 2017, we filed an IND for the use of VAL-083 in ovarian cancer, along with a protocol for a Phase 1/2, open-label, multicenter, study of VAL-083 in patients with **Re**current **P**latinum **R**esistant **Ov**arian Cancer (the REPROVe study).

The FDA has allowed this study to begin enrolling patients, but based on ongoing evaluation and input from our ovarian advisory board, we are reassessing the ovarian cancer program. We are in the process of evaluating the best path forward in ovarian cancer and are looking at various strategic options including combination with PARP inhibitors.

Fast Track Designation

In December 2017, the FDA granted Fast Track designation for VAL-083 in rGBM.

Fast Track designation is designed to expedite the review of drugs that show promise in treating life-threatening diseases and address unmet medical needs, with the goal of getting new treatments to patients earlier. Fast Track designation provides sponsors with an opportunity for increased frequency for communication with the FDA to ensure an optimal development plan and to collect appropriate data needed to support drug approval. Additional benefits of the Fast Track designation may include an Accelerated Approval, a Priority Review, and a Rolling Review. Accelerated Approval is granted to drugs that demonstrate an effect on a surrogate, or intermediate endpoints, reasonably likely to predict clinical benefit. Priority Review shortens the FDA review process for a new drug from ten months to six months and is appropriate for drugs that demonstrate significant improvements in both safety and efficacy of an existing therapy. Rolling Review provides a drug company the opportunity to submit completed sections of its New Drug Application ("NDA") for review by the FDA. Typically, NDA reviews do not commence until the drug company has submitted the entire application to the FDA. Through the Fast Track designation, the FDA attempts to ensure that questions raised during the drug development process are resolved quickly, often leading to earlier approval and increased access for patients.

Current Treatments for Gliomas and Glioblastoma Multiforme

Gliomas are a type of Central Nervous System ("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.

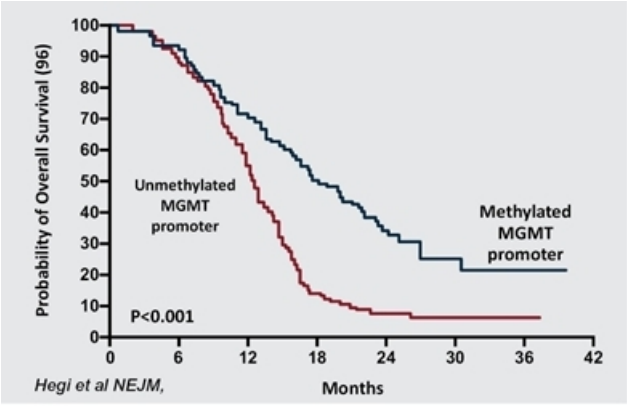
GBM is the most common and the most lethal form of glioma. According to the Central Brain Tumor Registry of The United States, GBM occurs with an incidence of 3.20 per 100,000 person-years. Approximately 13,000 new cases of GBM were diagnosed in the United States and 16,000 in Europe during 2017.

Common symptoms of GBM include headaches, seizures, nausea, weakness, paralysis and personality or cognitive changes such as loss of speech or difficulty in thinking clearly. GBM progresses quickly and patients' conditions deteriorate rapidly progressing to death. The outlook for GBM patients is generally poor. The overall median survival in newly diagnosed GBM patients with best available treatments is less than 15 months, and two-year and five-year survival rates are approximately 30% and 10%, respectively. Median overall survival in newly-diagnosed, unmethylated GBM patients is 12.2 months.

In September 2017, the National Comprehensive Cancer Network ("NCCN"), updated treatment guidelines for GBM. The recommended treatment regimen for GBM includes surgical resection to remove as much of the tumor as possible ("debulking") followed by radiotherapy with concomitant and adjuvant chemotherapy with temozolomide with or without tumor treating fields ("TTF"). GBM patients whose tumors exhibit an unmethylated promotor for the gene encoding the DNA repair enzyme MGMT, a biomarker correlated with resistance to temozolomide, may be treated with radiation alone following surgery.

Patients with an unmethylated MGMT promotor have high levels of MGMT, a naturally-occurring DNA repair enzyme that repairs tumor-fighting lesions induced by TMZ thus allowing a patient's tumor to continue to grow despite treatment which leads to poor outcomes. Measurement of MGMT methylation status has become routine in clinical practice as biomarker that correlates with response to TMZ and patient outcomes in GBM.

Probability of GBM Patient Survival Correlated to Expression of MGMT Enzyme
(Unmethylated promoter = High MGMT Expression and Significantly Shorter Survival)



TTF (Optune®) is a non-invasive technique for adults with GBM. TTF uses alternating electrical fields to disrupt tumor cell division, or cause cell death, thereby preventing the tumor from growing or spreading as quickly. A clinical study reported that GBM patients treated with TTF combined with TMZ experienced longer survival than those treated with TMZ alone.

The majority of GBM patients' tumors recur within 6 – 12 months of initial treatment. Experimental therapy through clinical studies is recommended under NCCN guidelines for eligible patients. NCCN guidelines also recommend treatment with systemic chemotherapy, such as lomustine ("CCNU"). For patients who are eligible for additional surgical debulking, local chemotherapy with carmustine ("BCNU") wafers may be employed. CCNU and BCNU target the same DNA-site as TMZ and are also subject to MGMT-related resistance.

Avastin (Avastin®, an anti-VEGF antibody) recently received full approval in the US, Canada, Australia, and Japan as a single agent for patients with recurrent GBM following prior therapy. Avastin carries an FDA "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 for GBM patients treated with Avastin.

Recurrent GBM patients, especially those whose tumors progress following treatment with Avastin, have limited or no treatment options and a very poor prognosis. According to published literature, the median survival for GBM patients whose tumors progress following Avastin is less than five months.

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 tumors exhibiting biological features that cause resistance to currently available chemotherapy, particularly for patients who have failed, or become resistant to, other treatment regimens.

Based on published research and our own data, the cytotoxic functional groups, and the mechanism of action of VAL-083 are 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 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 inter-strand crosslinks at the N^7 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.

In vitro, our data also demonstrate that VAL-083's distinct mechanism may be able to overcome drug resistance against a range of cancers. 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 studies. We believe that these historical clinical data and our own research support the development of VAL-083 as a potential new treatment for multiple types of cancer.

The main dose-limiting toxicity ("DLT") related to the administration of VAL-083 in previous NCI-sponsored clinical studies and our own clinical studies is myelosuppression, particularly thrombocytopenia. Myelosuppression, including thrombocytopenia, is a common side effect of chemotherapy. 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. 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.

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.

VAL-083 Historical Data

VAL-083 is first-in-class DNA targeting agent that readily crosses the blood-brain-barrier. Data from prior NCI-sponsored clinical studies with VAL-083 demonstrate activity against GBM and other CNS tumors. In general, historical NCI-sponsored studies 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. In these studies, 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 ($p < 0.05$) with results similar, or superior to, other chemotherapies approved for the treatment of GBM.

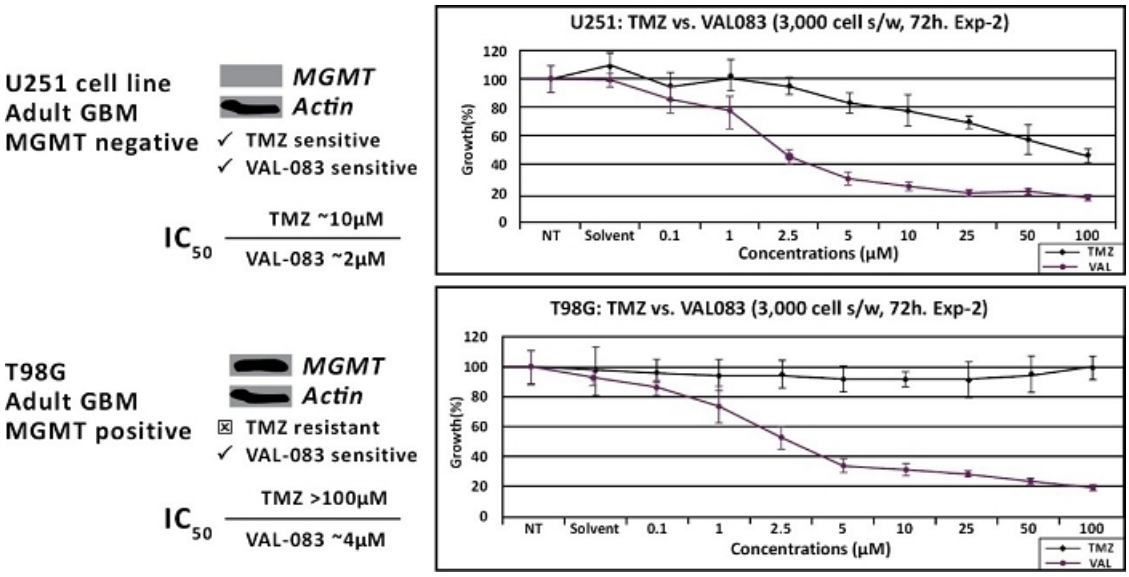
A Summary of Published Data adapted from Separate Sources Comparing the Efficacy of VAL-083 and Other Therapies in the Treatment of GBM

Chemotherapy	Comparative Therapy		Median Survival Benefit vs. XRT alone
	Radiation (XRT) Alone	Radiation + Chemotherapy	
VAL-083 (Eagan 1979)	**8.4 months**	**16.8 months**	**8.4 months**
Temozolomide (Temodar®) (Stupp 2005)	12.1 months	14.6 months	2.5 months
Lomustine (CCNU) *(Walker 1976)*	11.8 months	13 months	1.2 months
Carmustine (BCNU) *(Reagan 1976)*	10 months	12.5 months	2.5 months
Semustine (ACNU) *(Takakura 1986)*	12 months	14 months	2.0 months

VAL-083 is Active Independent of MGMT

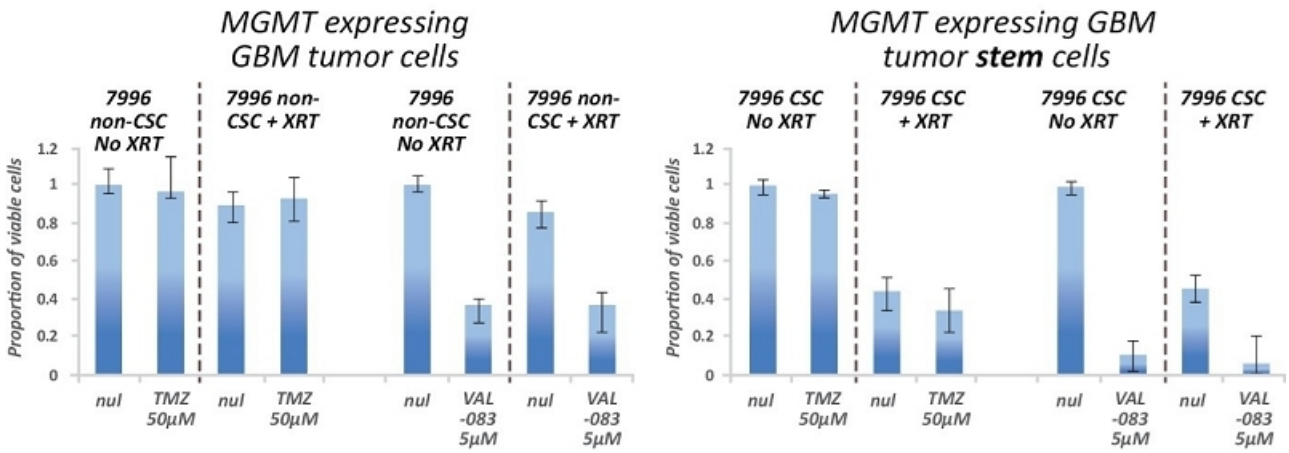
We have presented data at several peer reviewed meetings demonstrating that VAL-083 is active independent of MGMT resistance in GBM cell lines and other CNS tumor cells. Our research, along with that of others, demonstrates that VAL-083's unique cytotoxic mechanism forms DNA cross-links at the N^7 position of guanine and retains cytotoxic activity independent of MGMT expression *in vitro*. Our studies demonstrate that 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 Chemo resistance in the Treatment of GBM



In addition, historical NCI clinical study 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 newly diagnosed 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 independent of MGMT expression. 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.

A Summary of Our Data Demonstrating that VAL-083 Maintains Activity in Both Temozolomide-resistant GBM Cell Lines and Matched Cancer Stem Cells and Potentiates Radiotherapy



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

Phase 1 – 2 Clinical Study Overview and Summary of Results

In an open-label, single arm dose-escalation study designed to evaluate the safety, tolerability, pharmacokinetics, and anti-cancer activity of VAL-083, we enrolled forty-eight GBM patients whose disease progressed following prior treatment with temozolomide and Avastin. The study was conducted at five centers in the United States: 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 and Denver, Colorado; and the SCRI affiliate site at the Florida Cancer Specialist Research Institute in Sarasota, Florida.

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^2. A 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 in which we discussed with the FDA the design of a Phase 3, registration-directed clinical program for VAL-083 in refractory GBM. 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 our other planned clinical studies in related GBM populations, when assessing the NDA. The FDA also noted that we may be able to rely on prior NCI studies and historical literature to support nonclinical data required for an NDA filing under a 505(b)(2) strategy which allows a sponsor to rely on already established safety and efficacy data in support of an NDA.

In summary, the data from our previous Phase 1/2 study are as follows:

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^2/day.

Increasing frequency of, and higher grade, hematologic toxicities were observed at doses above 40 mg/m^2/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^2 which was established as the MTD. Consistent with Phase 1, the dose of VAL-083 of 40 mg/m^2 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/µL to 150,000/µL for patients receiving prior nitrosoureas within 12 weeks preceding enrollment. No other dose limiting toxicities were observed.

VAL-083 Safety Observations from Phase 1/2 Clinical Study

Hematologic parameter and CTCAE grade	**dose**	**≤30 mg/m^2**		**40 mg/m^2**		**45 mg/m^2**		**50 mg/m^2**	
	n =	20		17		4		7	
Anemia	≤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

Based the results of our Phase 1/2 study, we confirmed that we achieved doses of VAL-083 that are higher than were utilized in the original published NCI-sponsored clinical studies. 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 (cycle = 35 days)	25 mg/m^2	x5 days = 125 mg/m^2	125 mg/m^2	25 mg/m^2/wk.
DelMar VAL-083 achieved regimen daily x 3 q 3wks (cycle = 21 days)	40 mg/m^2	x 3 days = 120 mg/m^2	240 mg/m^2	40 mg/m^2/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 achieved dosing regimen increased the amount of VAL-083 delivered to the CNS over historical regimens without increased toxicity. Thus, our regimen achieved 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.

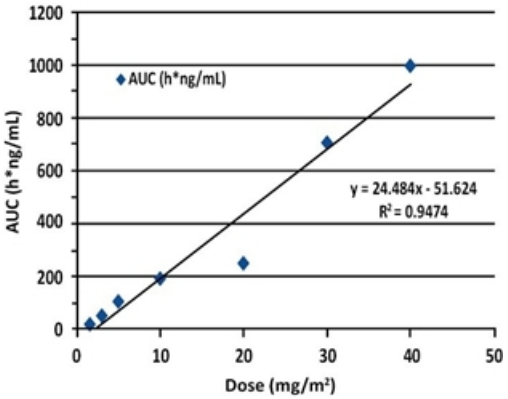
Based on our ongoing Phase 2 study at MDACC, we believe that the safety profile of the 40 mg/m^2 is within the existing safety monitoring guidelines described in the present study protocol. However, in consultation with the principal investigator at MDACC, we have amended the protocol for the study to modify the starting dose of VAL-083 to 30 mg/m^2 on days 1, 2 and 3, of a 21-day cycle for this specific study population which has been previously treated with temozolomide. We believe this modification may improve tolerance in this patient population and maximize overall exposure to VAL-083 thereby increasing the number of cycles of drug patients are able to receive. The 30 mg/m^2 dosing regimen is 20% over the historical regimen.

Pharmacokinetics

Pharmacokinetic ("PK") analyses showed dose-dependent linear systemic exposure with a short (1-2h) plasma terminal half-life; average Cmax at 40 mg/m^2/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 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 study dose vs. AUC



Based on observed and previously published pharmacokinetics, we believe that therapeutic doses equal to, or above, 20 mg/m^2 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. We are currently using a dose of 30 mg/m^2 daily on days 1, 2 and 3 of a 21-day cycle in our two Phase 2 studies that are currently ongoing.

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*. 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.

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

Tumor Response and Outcomes

GBM patients in our Phase 1/2 clinical study 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 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 Avastin have a poor prognosis with expected survival under five months.

Analysis of twenty-two patients receiving an assumed therapeutic dose of VAL-083 ($\geq$20mg/m^2) demonstrated median survival of 8.35 months following Avastin failure.

VAL-083 compared to published literature

Reference	Post Avastin Salvage Therapy	Median Survival following Avastin Failure
Shih (2016)	**VAL-083**	**8.35 months**
Rahman (2014)	nitrosourea	4.3 months
Mikkelson (2011)	TMZ + irinotecan	4.5 months
Lu (2011)	dasatinib	2.6 months
Reardon (2011)	etoposide	4.7 months
Reardon (2011)	TMZ	2.9 months
Iwomoto (2009)	various	5.1 months

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

VAL-083 Historical Data and Our Research in 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.

Without treatment, ovarian cancer spreads within the pelvic region and metastasizes to distant sites such as the lungs, liver, spleen and, rarely, the brain. The initial symptoms of ovarian cancer such as abdominal bloating, indigestion, pelvic pain, or nausea are often attributed to symptoms caused by a less serious condition. Therefore, in most cases, ovarian cancer is not diagnosed until it has progressed to an advanced stage when it is no longer possible to surgically remove all tumor tissue.

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.

VAL-083's activity against ovarian epithelial adenocarcinoma ("OEA") and squamous cell carcinoma of the cervix ("SCC") was reported in prior NCI-sponsored clinical studies. Importantly, NCI-researchers recommended VAL-083 for further advanced studies in the treatment of ovarian cancer.

Pt-based chemotherapy is employed in the treatment of nearly 50% of all cancer patients and is employed in the treatment regimen of nearly all advanced-stage ovarian cancer patients. 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.

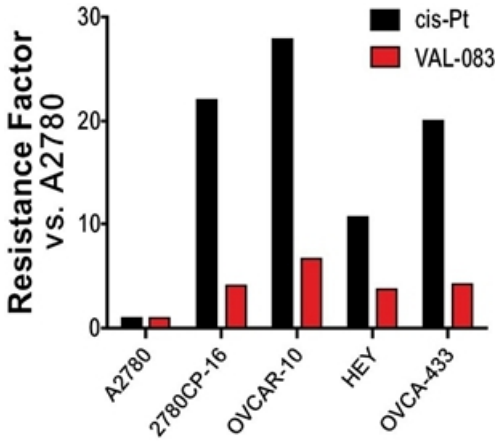
Pt-based chemotherapies function by causing extensive damage to a cancer cell's DNA. Cancer cells are adept at overcoming DNA damage or employing mechanisms to repair DNA damage induced by Pt-based chemotherapy. One of the most common obstacles to DNA-damaging chemotherapy is mutations to a gene called 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.

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.

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.

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.

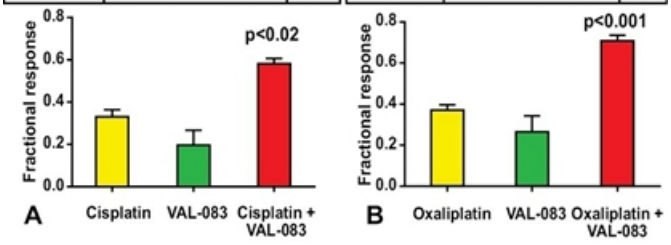
Our research has demonstrated that VAL-083 not only overcomes Pt resistance, but the combination of VAL-083 with Pt-based chemotherapy displays synergy in multiple models *in vitro* and *in vivo.* This further suggests a distinct mechanism of action and potential use as part of a VAL-083/Pt-combination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



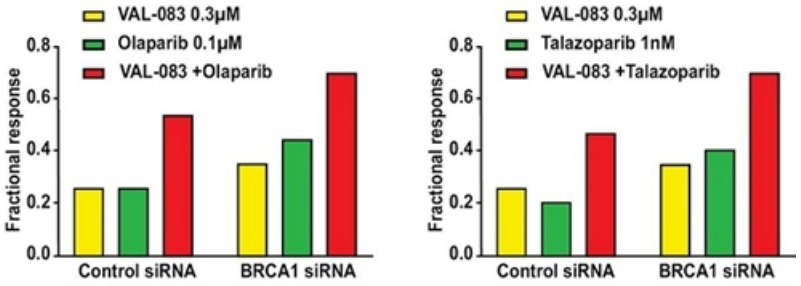
The combination of VAL-083 with either cisplatin **(A)** or oxaliplatin **(B)** in the human H460 (WT p53) NSCLC model demonstrated significant super additivity ($p \leq 0.05$) and/or synergism (CI<1) for both combinations. This cytotoxic effect of VAL-083 in combination with either platinum drug was 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 ± SE; N=7.

Cytotoxic Level (Fa)	Concentration (μM) VAL-083	**Cisplatin**	CI
ED75	0.42	0.38	0.92
ED90	0.92	0.85	0.91
ED95	1.58	1.45	0.90

Cytotoxic Level (Fa)	Concentration (μM) VAL-083	**Oxaliplatin**	CI
ED75	0.29	0.21	0.86
ED90	0.51	0.37	0.82
ED95	0.73	0.54	0.81



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 certain PARP inhibitors, including olaparib (Lynparza) and talazoparib *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.

Other Indications for VAL-083 — Potential Future Opportunities

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. Incidence of lung cancer in the United States is approximately 47 per 100,000 with the majority (85%) being NSCLC, the most common type of lung cancer. 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 studies conducted by the NCI. DelMar has developed new nonclinical data to support the utility of VAL-083 in the modern treatment of lung cancer. 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.

Central Nervous System Metastases of Solid Tumors

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. In June 2013, we split our Phase 1/2 clinical study 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.

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 studies 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.

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. For example, TMZ had peak annual sales of $1.1 billion in 2010, while bendamustine, had peak annual sales of $0.8 billion in 2014.

Our 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 studies. 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 studies and where our research suggests an opportunity to address significant unmet medical needs due to the failure of existing treatments.

VAL-083 target markets		2024 Estimated Global Sales
Glioblastoma multiforme (GBM)	*$*	*1.5B*
Ovarian Cancer	*$*	*4.2B*
Non-small cell lung cancer (NSCLC)	*$*	*32.6B*

Source: Evaluate Pharma

Glioblastoma Multiforme

GBM is the most common and the most lethal form of glioma. According to the Central Brain Tumor Registry of The United States, GBM occurs with an incidence of 3.20 per 100,000 person-years. Approximately 13,000 new cases of GBM were diagnosed in the United States and 16,000 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®) in combination with radiation is the front-line therapy for GBM following surgery. Global revenues of branded Temodar reached $1.1 billion in 2010. Approximately 60% of GBM patients treated with Temodar® experience tumor progression within one year. Median overall survival in newly-diagnosed, unmethylated GBM patients is 12.2 months.

Bevacizumab (Avastin®) has been approved for the treatment of GBM in patients failing Temodar®. In clinical studies, approximately 20% of patients failing Temodar® respond to Avastin® therapy and no improvement in median survival was reported.

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.

Ovarian Cancer

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 studies 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 study to investigate the safety and effectiveness of VAL-083 in patients with recurrent platinum resistant ovarian cancer (VAL-083 REPROVe study).

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

Lung cancer is the most common cancer in the world with 1.8 million cases in 2012, representing 13% of all cancers. According to the American Lung Association, lung cancer is the leading cancer killer in both men and women in the U.S. During 2018, an estimated 234,030 new cases of lung cancer were expected to be diagnosed.

The potential of VAL-083 in the treatment of NSLSC has been established in both human clinical studies 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.

Until recently, supply of VAL-083 for our clinical studies has been provided through our collaboration with Guangxi Wuzhou Pharmaceutical Company. Guangxi Wuzhou Pharmaceutical Company 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 CFDA for commercial supply of VAL-083 in China. However, to-date, they have not achieved the quality of systems necessary to meet FDA manufacturing standards.

To address the need to meet FDA standards, we have 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. We have now received drug supply manufactured under full cGMP conditions. We intend to use this drug supply for all future clinical studies.

We have developed and patented certain intellectual property related to quality controls that are used in the release of VAL-083 for our clinical studies 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, 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 Pharmaceutical Company is the only manufacturer licensed by the CFDA to produce the product for the China market. Through the Guangxi Agreement, we have been provided drug product at the production price for our VAL-083 clinical studies in the United States and China and we have also secured certain commercial rights in China.

Pursuant to the Guangxi Agreement, we granted to Guangxi Wuzhou Pharmaceutical Company 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 Pharmaceutical Company will be our exclusive supplier of VAL-083 for clinical studies and commercial sales, subject to Guangxi Wuzhou Pharmaceutical Company obtaining and maintaining cGMP certification by the FDA, EMA or other applicable regulatory agencies, and Guangxi Wuzhou Pharmaceutical Company being able to meet volumes ordered by us. We will continue to work with Guangxi Wuzhou Pharmaceutical Company to achieve US 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 Pharmaceutical Company for the Chinese market and all markets outside China. Guangxi Wuzhou Pharmaceutical Company 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 Pharmaceutical Company for the country or region. In addition, Guangxi Wuzhou Pharmaceutical Company 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 Pharmaceutical Company.

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.

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.

Patent or Patent Application No.	Title	Expiry
United States Patent No. 8,563,758	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol	
United States Patent No. 8,921,585	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol	
United States Patent No. 9,085,544	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol	
United States Patent No. 9,630,938	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol	
PCT Patent Application Serial No. PCT/US2011/048032	Method Of Synthesis Of Substituted Hexitols Such As Dianhydrogalactitol. National phase applications pending and granted in various countries.	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.

Patent or Patent Application No.	Title	Expiry
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	
United States Patent No. 9,901,563	Compositions And Methods To Improve The Therapeutic Benefit Of Suboptimally Administered Chemical Compounds Including Substituted Hexitols Such As Dianhydrogalactitol And Diacetyldianhydrogalactitol	

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

Patent or Patent Application No.	Title	Expiry
United States Patent No. 9,759,698	Improved Analytical Methods For Analyzing And Determining Impurities In Dianhydrogalactitol	
United States Patent No. 10,145,824	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	
PCT Patent Application Serial No. PCT/IB2013/000793	Improved Analytical Methods For Analyzing And Determining Impurities In Dianhydrogalactitol. National phase applications pending and granted in various countries.	2033

Patent or Patent Application No.	Title	Expiry
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.

Patent or Patent Application No.	Title	Expiry
United States Patent Application Serial No. 16/242,752	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	
United States Patent No. 10,201,521	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.

Patent or Patent Application No.	Title	Expiry
United States Patent No. 9,814,693	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.

Patent or Patent Application No.	Title	Expiry
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	
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.	2033

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

Patent or Patent Application No.	Title	Expiry
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 and granted in various countries.	2034

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

Patent or Patent Application No.	Title	Expiry
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

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

Patent or Patent Application No.	Title	Expiry
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. National phase applications pending in various countries.	2035

- Series X is generally directed to the use of VAL-083 in NSCLC and ovarian cancer:

Patent or Patent Application No.	Title	Expiry
United States Patent Application Serial No. 15/759,104	Use of Dianhydrogalactitol And Derivatives Thereof in the Treatment of Glioblastoma, Lung Cancer and Ovarian Cancer.	

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

Patent or Patent Application No.	Title	Expiry
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.	
United States Patent Application Serial No. 15/771,631	Use of Dianhydrogalactitol or Derivatives and Analogs Thereof for Treatment of Pediatric Central Nervous System Malignancies.	

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

Patent or Patent Application No.	Title	Expiry
United States Patent Application Serial No. 15/778,546	Methods for analysis and Resolution of Preparations of Dianhydrogalactitol and Derivatives and Analogs Thereof.	
PCT Patent Application Serial No. PCT/US2016/063362	Methods for analysis and Resolution of Preparations of Dianhydrogalactitol and Derivatives and Analogs Thereof. National phase applications pending in various countries.	2036

- Series XIII is generally directed to combinations:

Patent or Patent Application No.	Title	Expiry
PCT Patent Application Serial No. PCT/US2018/030391	Use of Dianhydrogalactitol and Analogs and Derivatives in Combination VEGF inhibitors to Treat Cancer	2038

Patent or Patent Application No.	Title	Expiry
PCT Patent Application Serial No. PCT/US2018/020314	Use of Dianhydrogalactitol and Analogs and Derivatives in Combination with a P53 Modulator or a PARP Inhibitor	2038

- Series XIV is generally directed to DIPG:

Patent or Patent Application No.	Title	Expiry
PCT Patent Application Serial No. PCT/IB2018/001357	Dianhydrogalactitol for the Treatment of Diffuse Intrinsic Pontine Gliomas	2038

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 us 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.

VAL-083 has been granted protection under the Orphan Drug Act by the FDA and the European Medicines Agency for the treatment of gliomas, including GBM. The FDA has also granted Orphan Drug protection to VAL-083 for the treatment of medulloblastoma and ovarian cancer.

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 studies to demonstrate safety and effectiveness. The Hatch-Waxman Amendments also provide three years of data exclusivity for the approval of NDAs with new clinical studies 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 studies 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 studies 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 studies 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 3 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 studies 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 studies 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, studies of drugs to treat end-stage refractory cancer indications have historically involved fewer patients and generally have been faster to complete than studies 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 studies 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 Act (PDUFA Fees).

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies, and after approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements, including cGMPs. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;

- reporting on advertisements and promotional labeling;
- drug sampling and distribution requirements; and
- complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals as well as consumers, including to industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution and disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approvals, refusal to approve pending applications, and criminal prosecution resulting in fines and incarceration. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Sales of our product candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any drug candidates that we develop will be made on a payor-by-payor basis. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of our product candidates, once approved, and have a material adverse effect on our sales, results of operations and financial condition.

Because of our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors, we will also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we will conduct our business, including our clinical research, proposed sales, marketing and educational programs. Failure to comply with these laws, where applicable, can result in the imposition of significant civil penalties, criminal penalties, or both. The U.S. laws that may affect our ability to operate, among others, include: the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; certain state laws governing the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs; federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

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 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®) and Genentech (Avastin ®). Companies with oncology immunotherapy product candidates in clinical development include, but are not limited to, 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 studies, 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 study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

- successfully and rapidly complete adequate and well-controlled clinical studies 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 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

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

DelMar Pharmaceuticals, Inc. is the parent company of Del Mar (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. We are 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, we effected a 1-for-4 reverse split of our common stock. All share amounts in this report give effect to the reverse split unless otherwise indicated.

On May 8, 2019, we effected a one-for-ten reverse stock split (the "Reverse Stock Split") of our issued and outstanding and authorized common stock. All per share amounts and number of shares of common stock in this report on Form 10-K reflect the Reverse Stock Split. The Reverse Stock Split does not affect the our authorized preferred stock of 5,000,000 shares; except that, pursuant to the terms of the Certificate of Designations of Series B Convertible Preferred Stock for the issued and outstanding shares of our Series B Convertible Preferred Stock, par value $0.001 per share (the "Series B Preferred Stock"), the conversion price at which shares of Series B Preferred Stock may be converted into shares of common stock will be proportionately adjusted to reflect the Reverse Stock Split.

On June 26, 2019, we amended our articles of incorporation, as amended, to increase the number of authorized shares of common stock from 7,000,000 to 95,000,000 shares.

Research and Development

During the years ended June 30, 2019 and 2018, we recognized $3,662,056 and $7,132,952, respectively, in research and development expenses.

Employees

We have two 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.

Available Information

We maintain an internet website at www.delmarpharma.com. We do not incorporate the information on our website into this report and you should not consider it part of this report.

Item 1A. Risk Factors

An investment in our common stock involves a high degree of risk. In determining whether to purchase our 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 our securities. An investor should only purchase our securities if he or she can afford to suffer the loss of his or her entire investment.

Risks Related to Our Business

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. As of June 30, 2019, we had cash and cash equivalents of $3,718,758. Taking into consideration the net proceeds from the financing we closed on August 16, 2019 of approximately $6.7 million we expect to fund our operations into the fourth quarter of calendar 2020. We will also need to raise additional capital to fund our operations. 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 affect 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.

In addition, we have retained Oppenheimer & Co. Inc. as a financial advisor to assist us in our evaluation of a broad range of strategic alternatives to enhance stockholder value, including additional capital raising transactions, an acquisition, merger, business combination, licensing and/or other strategic transaction involving us. There is no assurance that the review of strategic alternatives will result in us changing our business plan, pursuing any particular transaction, or, if we pursue any such transaction, that it will be completed. We do not expect to make further public comment regarding the strategic review until our Board of Directors has approved a specific transaction or otherwise deems disclosure of significant developments is appropriate.

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 studies 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 studies 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. In addition, we could be required to cease our operations.

Our exploration and pursuit of strategic alternatives may not be successful.

In September 2018, we announced that we had retained Oppenheimer & Co. Inc. as a financial advisor to assist us in our evaluation of a broad range of strategic alternatives. Potential strategic alternatives that may be explored or evaluated as part of this process include the potential for capital raising transactions, an acquisition, merger, business combination, licensing and/or other strategic transaction involving us. Despite devoting efforts to identify and evaluate potential strategic transactions, the process may not result in any definitive offer to consummate a strategic transaction, or, if we receive such a definitive offer, the terms may not be as favorable as anticipated or may not result in the execution or approval of a definitive agreement. Even if we enter into a definitive agreement, we may not be successful in completing a transaction or, if we complete such a transaction, it may not enhance stockholder value or deliver expected benefits.

If we fail to maintain compliance with the requirements of The Nasdaq Capital Market LLC ("Nasdaq") for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is listed for trading on The Nasdaq Capital Market.

As previously disclosed, on June 28, 2018, the Staff of the Listing Qualifications Department of The Nasdaq Stock Market (the "Nasdaq Staff") notified us that it did not comply with the minimum $1.00 per share bid price requirement for continued listing, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"), and we were therefore granted 180 calendar days, through December 26, 2018, to regain compliance. On December 27, 2018, the Nasdaq Staff notified us that we had not regained compliance with the Bid Price Requirement, that our stockholders' equity as reported in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 did not qualify us for an additional 180 calendar day extension period for compliance and that we would therefore be subject to delisting unless we requested a hearing before a Nasdaq Hearings Panel. Accordingly, we requested a hearing, which was held on January 31, 2019, at which we presented our plan of compliance. On February 4, 2019, the Nasdaq Hearings Panel issued a decision granting our request for continued listing of our common stock on The Nasdaq Capital Market pursuant to an extension through June 25, 2019, subject to the condition that we shall have demonstrated a closing bid price of $1.00 per share or more for a minimum of ten consecutive business days by June 25, 2019. As a result of our previously disclosed one-for-ten reverse stock split effected on May 8, 2019, on May 23, 2019, we received written notice from Nasdaq that we have regained compliance with the Bid Price Requirement. However, our common stock has recently traded below the Bid Price Requirement, and we may be subject to an additional notice from Nasdaq if we do not satisfy the Bid Price Requirement.

Notwithstanding, there can be no assurance that we will be able to maintain compliance, and if we are unable to maintain compliance with the continued listing requirements, including the Bid Price Requirement, our securities may be delisted from Nasdaq, which could reduce the liquidity of our common stock materially and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock may no longer be recognized as a "covered security" and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock.

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, 2019 and in past periods, our disclosure controls and procedures and internal control over financial reporting were not effective due to material weaknesses 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, as well as the financial reporting of such transactions. Any failure to implement new or improved controls necessary to remedy the material weaknesses 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 studies 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 of 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 CFDA to manufacture VAL-083 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.

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 studies 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 studies 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 studies for certain of our product candidates at sites outside the United States, and the FDA may not accept data from studies conducted in such locations.

We have conducted and may in the future choose to conduct one or more of our clinical studies outside the United States. Although the FDA may accept data from clinical studies conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study 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 studies 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 studies are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from studies conducted outside of the United States. If the FDA does not accept the data from any of our clinical studies that we determine to conduct outside the United States, it would likely result in the need for additional studies, which would be costly and time-consuming and delay or permanently halt our development of the product candidate.

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

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical studies;
- administrative burdens of conducting clinical studies under multiple foreign regulatory schema;
- foreign exchange fluctuations; and
- diminished protection of intellectual property in some countries.

If our clinical studies 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 studies 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 studies or other testing of our product candidate beyond the studies and testing that we contemplate, (2) we are unable to successfully complete clinical studies of our product candidate or other testing, (3) the results of these studies 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 studies 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 studies that could delay or prevent marketing approval of our product candidate, including:

- clinical studies of our product candidate may produce unfavorable or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of patients required for clinical studies of our product candidate may be larger than we anticipate, patient enrollment in these clinical studies may be slower than we anticipate or participants may drop out of these clinical studies 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 study 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 studies 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 studies due to safety issues, side effects, or other reasons;
- changes in regulatory requirements and guidance may occur, which require us to amend clinical study protocols to reflect these changes;
- our third-party contractors, including those manufacturing our product candidate or components or ingredients thereof or conducting clinical studies 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 study or conduct a clinical study at a prospective study site;
- we may experience delays in reaching or fail to reach agreement on acceptable clinical study contracts or clinical study protocols with prospective study sites;
- patients who enroll in a clinical study may misrepresent their eligibility to do so or may otherwise not comply with the clinical study protocol, resulting in the need to drop the patients from the clinical study, increase the needed enrollment size for the clinical study or extend the clinical study's duration;
- we may have to suspend or terminate clinical studies 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 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 FDA or comparable non-U.S. regulatory authorities may disagree with our clinical study design or our interpretation of data from preclinical studies and clinical studies;
- the supply or quality of raw materials or manufactured product candidate or other materials necessary to conduct clinical studies 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 studies and prepare for possible commercialization of our product candidate. We do not know whether any preclinical tests or clinical studies will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical study 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 study 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 studies, 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 studies 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 studies. Patient enrollment is a significant factor in the timing of clinical studies, 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 study;
- the design of the clinical study;
- efforts to facilitate timely enrollment;
- competing clinical studies; 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 studies could result in significant delays or may require us to abandon one or more clinical studies altogether. Enrollment delays in our clinical studies 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 studies. 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 our value to decline and limit our ability to obtain additional financing, if needed.

Positive results in previous clinical studies of VAL-083 may not be replicated in future clinical studies, 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 studies. Also, interim results during a clinical study do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical studies even after achieving promising results in early-stage development. Accordingly, the results from the completed preclinical studies and clinical studies for VAL-083 may not be predictive of the results we may obtain in later stage studies. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies. 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 studies 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 studies;
- 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 studies due to unexpected side effects or other safety risks that could preclude approval of our products.

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

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical studies 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 studies.

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.

In December 2017, the FDA granted Fast Track designation for VAL-083 in rGBM.

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 studies of our product candidate are conducted in carefully defined subsets of patients who have agreed to enter into clinical studies. Consequently, it is possible that our clinical studies 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 studies;
- 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®) and Genentech (Avastin ®). Companies with oncology immunotherapy product candidates in clinical development include, but are not limited to, 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 studies, 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 study sites and patient registration for clinical studies, 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 two 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 study 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 study participants;
- significant costs to defend resulting litigation;
- substantial monetary awards to study 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 studies 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 studies. Our reliance on third parties to conduct clinical studies 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 study 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 studies. If investigators or institutions breach their obligations with respect to the clinical studies of our product candidate, or if the data proves to be inadequate, then our ability to design and conduct any future clinical studies may be adversely affected.

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

We currently rely on third-party clinical research organizations, or CROs, to conduct our clinical studies. 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 studies. 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 studies and will remain responsible for ensuring that each of our clinical studies are conducted in accordance with the general investigational plan and protocols for the study. 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 studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of study 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 studies and post the results of completed clinical studies 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 studies 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 studies. 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 study 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 studies, provide insufficient funding for a clinical study program, stop a clinical study or abandon a product candidate, repeat or conduct new clinical studies 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 studies, 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 GMP active pharmaceutical ingredient and a single manufacturer to produce drug product for our clinical studies. In addition, we have relied on our manufacturing partner, Guangxi Wuzhou Pharmaceutical Company, for the manufacture of clinical supply of VAL-083 for our preclinical and Phase 2 clinical studies to-date. 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 do not currently have established relationships with any back-up manufacturers. 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 Pharmaceutical Company 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 clinical studies. 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, or halt, our clinical studies.

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 us in the future.

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 us.

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 648,613 shares are issued and outstanding, as of September 6, 2019) 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, Performance Share Units, or options, exchange of Exchangeable Shares, or conversion of Series B Preferred Stock may depress the price of our common stock.

As of September 6, 2019, we had 11,388,483 shares of common stock issued and outstanding, 7,813 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 us or Callco, to have us or Callco purchase) the Exchangeable Shares, and upon such redemption or purchase to receive an equal number of shares of our common stock) (the Exchangeable Shares are recognized on an as-exchanged for common stock basis for financial statement purposes), outstanding warrants to purchase 9,683,596 shares of common stock, outstanding Series B convertible preferred shares that are convertible into 162,177 shares of common stock and outstanding options to purchase 1,329,199 shares of common stock (of which 549,199 options are subject to stockholder approval of the increase in the number of shares authorized for issuance under our 2017 Omnibus Equity Incentive Plan (the "2017 Plan"), as amended, at the next annual meeting of stockholders). 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 0.25 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 currently located at 12707 High Bluff Dr., Suite 200, San Diego CA, 92130. We recently relocated our headquarters from Suite 720-999 West Broadway, Vancouver, British Columbia, Canada which will remain open as an administrative office. Our clinical operations are managed at 3475 Edison Way, Suite R, Menlo Park, California, 94025. Our current monthly base rent for our Vancouver office is $2,844 (CDN $3,725) on a month-to-month basis. In addition, Valent Technologies, LLC ("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 we are a party or any of our property is the subject.

Item 4. Mine Safety Disclosures.

Not applicable.

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, our common stock was quoted on the OTC.QX, and prior to that, on the OTCQB.

As of August 30, 2019, there were approximately 314 holders of record of our common stock.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future.

Sales of Unregistered Securities

During the three months ended June 30, 2019, we issued 3,841 shares of common stock as dividends on our outstanding shares of Series B Preferred Stock, 1,175 shares of common stock in relation to services received by us, and 1,250 common shares upon the conversion of Exchangeco shares.

In connection with the foregoing, we 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 phrases 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 us or any other person that our events or plans 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, 2019 and in our other filings with the Securities and Exchange Commission, available at www.sec.gov. Actual results may differ materially from any forward-looking statement.

References to "we", "us", and "our", refer to DelMar Pharmaceuticals, Inc. and our wholly-owned subsidiaries, Del Mar (BC), Callco and Exchangeco.

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. We are the parent company of Del Mar Pharmaceuticals (BC) Ltd. ("Del Mar (BC)"), a British Columbia, Canada corporation incorporated on April 6, 2010, that is focused on the development of drugs for the treatment of cancer. We are 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.

Effective September 1, 2019, we moved our corporate head office from Vancouver, British Columbia, Canada, to San Diego, California. The Vancouver office will remain open as an administrative office.

Outstanding Securities

As of September 6, 2019, we had 11,388,483 shares of common stock issued and outstanding, 7,813 shares of common stock issuable upon exchange of the Exchangeable Shares of Exchangeco (which entitle the holder to require Exchangeco to redeem (or, at our option or Callco's, to have us or Callco purchase) the Exchangeable Shares, and upon such redemption or purchase to receive an equal number of shares of our common stock) (the Exchangeable Shares are recognized on an as-exchanged for common stock basis for financial statement purposes), outstanding warrants to purchase 9,683,596 shares of common stock, 648,613 outstanding shares of Series B Preferred Stock that are convertible into 162,177 shares of common stock, and outstanding stock options to purchase 1,329,199 shares of common stock (of which 549,199 options are subject to stockholder approval of the increase in the number of shares authorized for issuance under the 2017 Plan at the next annual meeting of stockholders). All Exchangeable Shares, warrants, and stock options are convertible, or exercisable into, one share of common stock. Each Series B convertible preferred share is convertible into 0.25 shares of common stock.

On May 8, 2019, we effected a one-for-ten reverse stock split (the "Reverse Stock Split") of our issued and outstanding and authorized common stock. All per share amounts and number of shares of common stock in the MD&A and consolidated financial statements reflect the Reverse Stock Split. The Reverse Stock Split does not affect the our authorized preferred stock of 5,000,000 shares; except that, pursuant to the terms of the Certificate of Designations of Series B Convertible Preferred Stock for the issued and outstanding shares of our Series B Convertible Preferred Stock, par value $0.001 per share, the conversion price at which shares of Series B Preferred Stock may be converted into shares of common stock will be proportionately adjusted to reflect the Reverse Stock Split.

On June 26, 2019, we amended our articles of incorporation, as amended, to increase the number of authorized shares of common stock from 7,000,000 to 95,000,000 shares.

Related Parties

We acquired our initial patents and technology rights from Valent, an entity owned by Dr. Dennis Brown, our Chief Scientific Officer. As a result, Valent is a related party to us.

During the year ended June 30, 2018, we recognized a total expense of $311,683 relating to the settlement agreement with our former President and Chief Operating Officer. Amounts owed to officers and directors, including to our former President and Chief Operating Officer, have been aggregated and not shown separately, and are non-interest bearing and payable on demand.

Selected Annual Information

The financial information reported herein has been prepared in accordance with accounting principles generally accepted in the United States. Our functional currency at June 30, 2019 and June 30, 2018 is the US$. The following tables represent selected financial information for us for the periods presented.

Selected Balance Sheet data

	June 30, 2019 $	June 30, 2018 $
Cash and cash equivalents	3,718,758	5,971,995
Working capital	1,955,468	5,407,929
Total assets	4,037,255	7,074,855
Total stockholders' equity	1,967,530	5,435,223

Selected Statement of operations data

For the years ended:

	June 30, 2019 $	June 30, 2018 $
Research and development	3,662,056	7,132,952
General and administrative	4,736,440	4,041,711
Change in fair value of derivative liabilities	(433,503)	(60,111)
Derivative liability issue costs	126,186	-
Foreign exchange loss	17,746	57,003
Interest income	(60,704)	(33,243)
Net and comprehensive loss for the year	8,048,221	11,138,312
Series B Preferred stock dividend	80,431	176,236
Net and comprehensive loss available to common stockholders	8,128,652	11,314,548
Basic weighted average number of shares	2,574,692	2,086,142
Basic and fully diluted loss per share	3.16	5.42

Expenses net of non-cash, share-based compensation expense - non-GAAP

The following table discloses research and development, and general and administrative expenses net of non-cash, share-based compensation payment expense. The disclosure has been provided to reconcile the total operational expenses on a GAAP basis and the non-GAAP operational expenses net of non-cash stock-based compensation in order to provide an estimate of cash used in research and development, and general and administrative expense. Management uses the cash basis of expenses for forecasting and budget purposes to determine the allocation of resources and to plan for future financing opportunities.

For the years ended:

	June 30, 2019 $	June 30, 2018 $
Research and development - GAAP	3,662,056	7,132,952
Less: non-cash share-based compensation expense	(88,445)	(149,452)
Research and development net of non-cash share-based, compensation expense- Non-GAAP	3,573,611	6,983,500
General and administrative - GAAP	4,736,440	4,041,711
Less: non-cash share-based compensation expense	(901,218)	(596,079)
General and administrative net of non-cash share-based, compensation expense – Non-GAAP	3,835,222	3,445,632

Results of Operations

Comparison of the years ended June 30, 2019 and June 30, 2018

	Years ended			
	June 30, 2019 $	June 30, 2018 $	Change $	Change %
Research and development	3,662,056	7,132,952	(3,470,896)	(49)
General and administrative	4,736,440	4,041,711	694,729	17
Change in fair value of derivative liabilities	(433,503)	(60,111)	(373,392)	621
Derivative liability issue costs	126,186	-	126,186	100
Foreign exchange loss	17,746	57,003	(39,257)	(69)
Interest income	(60,704)	(33,243)	(27,461)	83
Net loss and comprehensive loss	8,048,221	11,138,312	(3,090,091)	

Research and Development

Research and development expenses decreased to $3,662,056 for the year ended June 30, 2019 from $7,132,952 for the year ended June 30, 2018. The decrease was largely attributable to a decrease in clinical development costs due to the termination of the STAR-3 study, personnel, preclinical research, intellectual property and travel expenses during the year ended June 30, 2019 compared to the year ended June 30, 2018. For the years ended June 30, 2019 and 2018 we incurred non-cash share-based compensation expense of $88,445 and $149,452, respectively, related to stock option expense and shares issued for services. During the year ended June 30, 2018, we entered into a separation agreement with our former President and Chief Operating Officer that required the accelerated vesting of certain stock options. The research and development portion of the expense of the accelerated vesting was recognized during the year ended June 30, 2018 resulting in a higher non-cash share-based compensation expense for the year ended June 30, 2018 compared to the year ended June 30, 2019.

Excluding the impact of non-cash share-based compensation expense, research and development expenses decreased to $3,573,611 during the current year from $6,983,500 for the prior year. The decrease in clinical development costs for the year ended June 30, 2019 compared to the year ended June 30, 2018 was primarily due to the termination of our STAR-3, Phase 3 study which was announced in February 2018. During the year ended June 30, 2018, we incurred significant study start-up costs in relation to the STAR-3 study. In addition, clinical development costs were higher in the prior year compared to the current year due to the timing of certain manufacturing activities for the production of GMP material and related stability studies. Clinical development costs can vary significantly due to the timing of patient enrollment, how a patient reacts to treatment, and the number of treatment cycles a patient receives.

Personnel costs decreased during the year ended June 30, 2019 compared to the year ended June 30, 2018 primarily due to amounts recognized in the prior year pursuant to the settlement agreement with our former President and Chief Operating Officer. Preclinical research decreased largely due to a decrease in the ongoing mechanism of action research that we have undertaken in the prior year. Intellectual property costs decreased in the year ended June 30, 2019 compared to the year ended June 30, 2018 as we have refined our patent portfolio by focusing on our most important patent claims in the most important 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. Travel costs have decreased in the year ended June 30, 2019 compared to the year ended June 30, 2018 as we have focused on reducing all travel expenses.

General and Administrative

General and administrative expenses were $4,736,440 for the year ended June 30, 2019 compared to $4,041,711 for the year ended June 30, 2018. The increase was largely due to higher non-cash share-based compensation expense and cash expenses related to personnel, professional fees, and office and sundry expenses partially offset by lower travel costs in the current year compared to the prior year. In relation to general and administrative expenses during the years ended June 30, 2019 and June 30, 2018, we incurred non-cash share-based compensation expense of $901,218 and $596,079, respectively, relating to performance share units, warrants issued for services, and stock options.

Excluding the impact of non-cash share-based compensation expense, general and administrative expenses increased in the year ended June 30, 2019 to $3,835,222 from $3,445,632 for the year ended June 30, 2018. Personnel costs increased during the year ended June 30, 2019 compared to the year ended June 30, 2018 primarily due to the appointment of our new President and Chief Executive Officer in May 2018. The increase in professional fees related primarily to our proposed rights offering. We filed a registration statement in connection with a proposed rights offering (the “Rights Offering”), which registration statement was last amended on June 10, 2019. Due to management’s assessment that market conditions were not conducive to an offering that would be in the best interests of our stockholders, we terminated the Rights Offering on June 27, 2019 and withdrew the related registration statement and post-effective amendment thereto that were previously filed with the Securities and Exchange Commission. As a result, the professional fees related to the Rights Offering of $555,664 were expensed in the quarter ended June 30, 2019. Office and sundry expenses increased in the year ended June 30, 2019 compared to the year ended June 30, 2018 due to higher costs for proxy mailout and solicitation for our 2019 annual meeting of stockholders compared to our 2018 annual meeting of stockholders. Additionally, the cost of certain insurance has increased in the current year compared to the prior year. Partially offsetting these items are lower travel costs in the year ended June 30, 2019 compared to the year ended June 30, 2018 as we have focused on reducing all travel expenses.

Change in fair value of derivative liability

Based on the terms of certain warrants issued by us, we have 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, 2019 and 2018 were primarily due to changes in our common stock price between the date the respective warrants were previously valued and the respective reporting dates of June 30, 2019 and 2018.

We recognized gains of $433,503 and $60,111 from the change in fair value of the derivative liability for the years ended June 30, 2019 and 2018, respectively. During the year ended June 30, 2019 the we completed a registered direct offering (“RD Offering”) of shares of common stock and warrants to purchase shares of common stock. The exercise price of the warrants issued in the RD Offering is subject to adjustment in the event that we issue common stock at a price lower than the exercise price, subject to certain exceptions, prior to June 28, 2019. As a result, we accounted for these warrants as a derivative liability. The change in fair value of the RD Offering warrants from the date of issue until June 28, 2019 of $432,386 has been recorded in the consolidated statement of operations and comprehensive loss for the year ended June 30, 2019. Upon expiry of the repricing feature on June 28, 2019, the fair value of the derivative liability at that time of $492,884 was reclassified to equity.

Foreign Exchange

Our functional currency at June 30, 2019 and June 30, 2018 was the US$ but we incur a portion of our expenses in CA$. The foreign exchange gains and losses are reported in other loss (income) in the consolidated statement of loss and comprehensive loss. We have recognized foreign exchange losses of $17,746 and $57,003 for the years ended June 30, 2019 and 2018, respectively. The losses were due to changes in the exchange rate between the CA$ and the US$ and to varying levels of CA$ cash and accounts payable.

Preferred Share Dividends

For each of the years ended June 30, 2019 and 2018 we recorded $8,356 related to the cash 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.

During the year ended June 30, 2019, we issued 18,271 (2018 – 19,841) shares of common stock as a dividend on the Series B Preferred stock and recognized $80,431 (2018 - $176,236) as a direct increase in accumulated deficit.

Liquidity and Capital Resources

Years ended June 30, 2019 compared to the years ended June 30, 2018

	June 30, 2019 $	June 30, 2018 $	Change $	Change %
Cash flows from operating activities	(6,327,425)	(9,850,850)	3,523,425	(36)
Cash flows from investing activities	-	(12,649)	12,649	(100)
Cash flows from financing activities	4,074,188	9,249,480	(5,175,292)	(56)

Operating Activities

Net cash used in operating activities decreased to $6,327,425 for the year ended June 30, 2019 from $9,850,850 for the year ended June 30, 2018. During the years ended June 30, 2019 and 2018, we reported net losses of $8,048,221 and $11,138,312, respectively. During the year ended June 30, 2019, we recorded a gain from the revaluation of the derivative liabilities of $433,503 compared to a gain of $60,111 for the year ended June 30, 2018. Excluding the impact of changes in the fair value of the derivative liabilities and non-cash derivative issue costs of $13,495, non-cash items relating to amortization of intangible assets, shares and warrants issued for services, stock option expense, and performance stock unit expense totaled $1,006,011 and $770,059, respectively, for the years ended June 30, 2019 and 2018.

The most significant change in non-cash working capital for the year ended June 30, 2019 was an increase in cash from a decrease in prepaid expenses and deposits of $754,682 due to a partial refund of our clinical study deposit related to our now-terminated STAR-3 Phase 3 study. The other significant change in non-cash working capital in the current year was an increase in cash from an increase in accounts payable and accrued liabilities of $202,000 and increase in related party payable of $164,779. The most significant changes in non-cash working capital for the years ended June 30, 2018 was cash from an increase of accounts payable and accrued liabilities of $295,774 and cash from a decrease in prepaid expense and deposits of $173,192.

Investing activities

There were no cash flows from investing activities during the year ended June 30, 2019. During the year ended June 30, 2018, we incurred $12,649 in relation to the development of our website.

Financing Activities

During the year ended June 30, 2019, we received $3,362,379 in net proceeds from the completion of a registered direct offering by us of common stock and common stock purchase warrants, and $726,165 in net proceeds from the exercise of warrants pursuant to the Warrant Exercise Agreements. During the year ended June 30, 2018, we received $8,945,336 in net proceeds from the completion of a registered direct offering by us of common stock and common stock purchase warrants, and $312,500 from the exercise of common stock purchase warrants for cash. In addition, we recorded $8,356 related to the dividend payable to Valent on our Series A Preferred stock during each of the years ended June 30, 2019 and 2018, respectively.

Capital Expenditure Requirements

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

- the rate of progress and cost of our clinical studies, 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;
- the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter; and.
- the impact of public entity operations.

In September 2018, we announced that we had engaged Oppenheimer & Co. Inc. as our strategic advisor to help manage the exploration and evaluation of a wide range of strategic opportunities. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, or strategic collaborations. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our shares of capital stock. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights. Economic conditions may affect the availability of funds and activity in equity markets. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or make changes to our operating plan. In addition, we may have to seek a partner for one or more of our product candidate programs at an earlier stage of development, which would lower the economic value of those programs to us.

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 our significant accounting policies and the estimates derived therefrom is included in Note 2 to our consolidated financial statements for the year ended June 30, 2019 contained elsewhere in this report on Form 10-K. While all of the significant accounting policies are important to our consolidated financial statements, the following accounting policies and the estimates derived therefrom are critical:

- Warrants and shares issued for services
- Stock options
- Performance stock units
- Derivative liabilities
- Clinical trial accruals

Warrants and shares issued for services

We have 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

We account 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 our share price, the anticipated exercise behavior of its grantee, interest rates, and dividend yields. These variables are projected based on our 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 actual forfeitures, using the accelerated attribution method. We recognize forfeitures as they occur. 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.

Performance stock units

We also account for performance stock units (PSU's) under 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. As vesting of the PSU's is based on a number of factors, the determination of the grant-date fair value for PSU's has been estimated using a Monte Carlo simulation approach which includes variables such as the expected volatility of our share price and interest rates to generate potential future outcomes. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for the PSUs. Such value is recognized as expense over the derived service period using the accelerated attribution method. The estimation of PSUs 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.

Derivative liabilities

We account 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. We classify these warrants on our balance sheet as a derivative liability which is fair valued at each reporting period subsequent to the initial issuance. We have used a Black-Scholes Option Pricing Model (based on a closed-form model that uses a fixed equation) to estimate the fair value of the share warrants. Determining the appropriate fair-value model and calculating the fair value of warrants requires considerable judgment. Any change in the estimates (specifically probabilities and volatility) used may cause the value to be higher or lower than that reported. The estimated volatility of our common stock at the date of issuance, and at each subsequent reporting period, is based on our historical volatility. 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.

Clinical trial accruals

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 our behalf. 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. We monitor 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.

Off-Balance Sheet Arrangements

We do 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, 2019
(in US dollars unless otherwise noted)

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of DelMar Pharmaceuticals, Inc. (the "Company") as of June 30, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2019 and 2018, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the US federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting 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 audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.
Vancouver, Canada
September 9, 2019

DelMar Pharmaceuticals, Inc.
Consolidated Balance Sheets

(in US dollars unless otherwise noted)

	Note	June 30, 2019 $	June 30, 2018 $
Assets			
Current assets			
Cash and cash equivalents		3,718,758	5,971,995
Prepaid expenses and deposits	8	280,248	1,034,930
Interest, taxes and other receivables		26,187	39,519
		4,025,193	7,046,444
Intangible assets - net		12,062	28,411
		4,037,255	7,074,855
Liabilities			
Current liabilities			
Accounts payable and accrued liabilities		1,744,517	1,478,086
Related party payables	6	325,208	160,429
		2,069,725	1,638,515
Derivative liabilities	4	-	1,117
		2,069,725	1,639,632
Stockholders' equity			
Preferred stock			
Authorized			
5,000,000 shares, $0.001 par value			
Issued and outstanding			
278,530 Series A shares at June 30, 2019 (June 30, 2018 – 278,530)	3,5	278,530	278,530
673,613 Series B shares at June 30, 2019 (June 30, 2018 – 881,113)	5	4,699,304	6,146,880
1 special voting share at June 30, 2019 (June 30, 2018 – 1)	5	-	-
Common stock			
Authorized			
95,000,000 shares (June 30, 2018 – 7,000,000), $0.001 par value			
3,839,358 issued at June 30, 2019 (June 30, 2018 – 2,296,667)	5	3,839	2,297
Additional paid-in capital	5	50,954,741	43,198,193
Warrants	5	6,588,283	8,229,482
Accumulated deficit		(60,578,345)	(52,441,337)
Accumulated other comprehensive income		21,178	21,178
		1,967,530	5,435,223
		4,037,255	7,074,855

Liquidity risk, nature of operations, and corporate history (note 1)
Subsequent events (note 11)

The accompanying notes are an integral part of theseconsolidated financial statements.

DelMar Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss

(in US dollars unless otherwise noted)

	Note	Year ended June 30, 2019 $	Year ended June 30, 2018 $
Expenses			
Research and development	6	3,662,056	7,132,952
General and administrative	6	4,736,440	4,041,711
		8,398,496	11,174,663
Other loss (income)			
Change in fair value of derivative liabilities	4,5	(433,503)	(60,111)
Derivative liability issue costs	4	126,186	-
Foreign exchange loss		17,746	57,003
Interest income		(60,704)	(33,243)
		(350,275)	(36,351)
Net and comprehensive loss for the year		8,048,221	11,138,312
Computation of basic loss per share			
Net and comprehensive loss for the year		8,048,221	11,138,312
Series B Preferred stock dividend	5	80,431	176,236
		8,128,652	11,314,548
Basic and fully diluted loss per share		3.16	5.42
Basic weighted average number of shares		2,574,692	2,086,142

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

DelMar Pharmaceuticals, Inc.
Consolidated Statements of Changes in Stockholders' Equity

(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 $
Balance - June 30, 2017	1,450,963	1,451	36,678,344	21,178	6,425,410	4,570,574	(41,118,433)	6,578,524
Issuance of shares and warrants - net of issue costs	800,000	800	5,371,693	-	-	3,572,843	-	8,945,336
Shares issued for services	863	1	8,581	-	-	-	-	8,582
Warrants issued for services	-	-	-	-	-	192,400	-	192,400
Warrants exercised for cash	25,000	25	418,810	-	-	(106,335)	-	312,500
Stock option expense	-	-	495,925	-	-	-	-	495,925
Performance stock unit expense	-	-	48,624	-	-	-	-	48,624
Series A preferred cash dividend	-	-	-	-	-	-	(8,356)	(8,356)
Series B preferred stock dividend	19,841	20	176,216	-	-	-	(176,236)	-
Loss for the year	-	-	-	-	-	-	(11,138,312)	(11,138,312)
,								
Balance - June 30, 2018	2,296,667	2,297	43,198,193	21,178	6,425,410	8,229,482	(52,441,337)	5,435,223
Issuance of shares and warrants - net of issue costs	1,170,000	1,170	2,332,102	-	-	52,899	-	2,386,171
Exercise and exchange of warrants	296,667	297	2,930,565	-	-	(2,210,697)	-	720,165
Conversion of Series B preferred stock to common stock	51,876	52	1,447,524	-	(1,447,576)	-	-	-
Reclassification of derivative liability to equity	-	-	-	-	-	492,884	-	492,884
Shares issued for services	3,444	3	13,774	-	-	-	-	13,777
Warrants issued for services	-	-	-	-	-	23,715	-	23,715
Shares issued on reverse stock split	2,433	2	-	-	-	-	-	2
Stock option expense	-	-	426,029	-	-	-	-	426,029
Performance stock unit expense	-	-	526,141	-	-	-	-	526,141
Series A preferred cash dividend	-	-	-	-	-	-	(8,356)	(8,356)
Series B preferred stock dividend	18,271	18	80,413	-	-	-	(80,431)	-
Loss for the year	-	-	-	-	-	-	(8,048,221)	(8,048,221)
Balance - June 30, 2019	3,839,358	3,839	50,954,741	21,178	4,977,834	6,588,283	(60,578,345)	1,967,530

The accompanying notes are an integral part of theseconsolidated financial statements.

DelMar Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

(in US dollars unless otherwise noted)

	Note	Years ended June 30, 2019 $	2018 $
Cash flows from operating activities			
Loss for the year		(8,048,221)	(11,138,312)
Items not affecting cash			
Non-cash derivative issue costs		13,495	-
Amortization of intangible assets		16,349	24,528
Change in fair value of derivative liabilities	4,5	(433,503)	(60,111)
Shares issued for services	5	13,777	8,582
Warrants issued for services	5	23,715	192,400
Stock option expense	5	426,029	495,925
Performance stock unit expense	5	526,141	48,624
Changes in non-cash working capital			
Prepaid expenses and deposits	8	754,682	173,192
Interest, taxes and other receivables		13,332	37,076
Accounts payable and accrued liabilities		202,000	295,774
Related party payables	6	164,779	71,472
		(6,327,425)	(9,850,850)
Cash flows from investing activities			
Intangible assets - website development costs		-	(12,649)
		-	(12,649)
Cash flows from financing activities			
Net proceeds from the issuance of shares and warrants	5	3,362,379	8,945,336
Net proceeds from the exercise and exchange of warrants	5	720,165	312,500
Series A preferred stock dividend	5	(8,356)	(8,356)
		4,074,188	9,249,480
Decrease in cash and cash equivalents		(2,253,237)	(614,019)
Cash and cash equivalents – beginning of year		5,971,995	6,586,014
Cash and cash equivalents – end of year		3,718,758	5,971,995
Supplementary information (note 9)			

The accompanying notes are an integral part of theseconsolidated financial statements.

(in US dollars unless otherwise noted)

1 Liquidity risk, nature of operations, and corporate history

Liquidity risk

These consolidated financial statements have been prepared on a going concern basis which assumes that DelMar Pharmaceuticals, Inc. (the "Company") will continue its operations for the foreseeable future and contemplates the realization of assets and the settlement of liabilities in the normal course of business.

For the year ended June 30, 2019, the Company reported a loss of $8,048,221, and a negative cash flow from operations of $6,327,425. The Company had an accumulated deficit of $60,578,345 as of June 30, 2019. As of June 30, 2019, the Company has cash and cash equivalents on hand of $3,718,758. The Company is in the development stage and has not generated any revenues to-date. The Company does not have the prospect of achieving revenues until such time that its product candidate is commercialized, or partnered, which may not ever occur. In the future, the Company will require additional funding to maintain its clinical trials, research and development projects, and for general operations. The Company may tailor its drug candidate development program based on the amount of funding the Company is able to raise in the future.

These circumstances had indicated substantial doubt existed about the Company's ability to continue as a going concern. Subsequent to June 30, 2019, the Company completed an underwritten public offering for net proceeds of approximately $6.7 million (note 11). The Company believes, based on its current estimates, that it will be able to fund its operations beyond the next twelve months from the date these consolidated financial statements are issued. As a result, substantial doubt about the Company's ability to continue as a going concern has been alleviated.

These financial statements do not give effect to any adjustments to the amounts and classification of assets and liabilities that may be necessary should the Company be unable to continue as a going concern. Such adjustments could be material.

Nature of operations

The Company is a clinical stage drug development company with a focus on the treatment of cancer that is conducting clinical trials in the United States and China with our product candidate, VAL-083, as a potential new treatment for glioblastoma multiforme, the most common and aggressive form of brain cancer. The Company has acquired certain 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 the Company's development timelines, the Company leverages existing clinical and commercial data from a wide range of sources. The Company may seek marketing partnerships in order to potentially generate future royalty revenue.

The address of the Company's headquarters is Suite 200 - 12707 High Bluff Dr., San Diego, California, 92130, it has an administrative office located at Suite 720 - 999 West Broadway, Vancouver, British Columbia, V5Z 1K5, with clinical operations located at 3485 Edison Way, Suite R, Menlo Park, California, 94025.

(in US dollars unless otherwise noted)

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. ("Del Mar (BC)"), 0959454 B.C. Ltd. ("Callco"), and 0959456 B.C. Ltd. ("Exchangeco") and the security holders of Del Mar (BC). Upon completion of the Exchange Agreement, Del Mar (BC) became a wholly-owned subsidiary of the Company (the "Reverse Acquisition").

DelMar Pharmaceuticals, Inc. is the parent company of Del Mar (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, Del Mar (BC), Callco and Exchangeco.

2 Significant accounting policies

Reverse Stock Split

On May 7, 2019, the Company filed a Certificate of Change with the Secretary of State of Nevada that effected a 1-for-10 (1:10) reverse stock split of its common stock, par value $0.001 per share, which became effective on May 8, 2019. 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 70,000,000 authorized shares of common stock to 7,000,000 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-10 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 years presented.

Consolidation

The consolidated financial statements of the Company include the accounts of Del Mar (BC), Callco, and Exchangeco as at and for the years ended June 30, 2019 and 2018. Intercompany balances and transactions have been eliminated on consolidation.

(in US dollars unless otherwise noted)

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 of, or during, the reporting period. Actual results could significantly differ from those estimates. Significant areas requiring management to make estimates include the derivative liabilities, 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 and cash equivalents consist of cash and highly liquid investments with original maturities from the purchase date of three months or less that can be readily convertible into known amounts of cash. Cash and cash equivalents are 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, 2019 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.

(in US dollars unless otherwise noted)

Financial instruments

The Company has financial instruments that are measured at fair value. To determine the fair value, the Company uses 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 liabilities. 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 liabilities

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, or contain a repricing feature under certain conditions. 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 Black-Scholes Option Pricing Model (based on a closed-form model that uses a fixed equation) to estimate the fair value of the share warrants. Determining the appropriate fair-value model and calculating the fair value of warrants requires considerable judgment. Any change in the estimates (specifically probabilities and volatility) 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 the Company. 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.

(in US dollars unless otherwise noted)

a) Fair value of derivative liabilities

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 liabilities. The carrying value of the derivative liabilities would be higher, or lower, as management estimates around specific probabilities change. The estimates may be significantly different from those amounts ultimately 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:

	June 30, 2019		
Liability	**Level 1**	**Level 2**	**Level 3**
Derivative liabilities	-	-	-

	June 30, 2018		
Liability	**Level 1**	**Level 2**	**Level 3**
Derivative liabilities	-	-	1,117

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, 2019, the total capitalized cost was $79,910 (2018 - $79,910) and the Company has recognized $16,349 and $24,528, respectively, in amortization expense during the years ended June 30, 2019 and 2018.

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 Company has achieved regulatory approval patent costs will be deferred and amortized over the remaining life of the related patent.

(in US dollars unless otherwise noted)

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 the Company's 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, 2019 and 2018, 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 actual forfeitures, using the accelerated attribution method. The Company recognizes forfeitures as they occur. 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.

(in US dollars unless otherwise noted)

Performance stock units

The Company also accounts for performance stock units (PSU's) under 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 expense over the requisite service period for awards expected to vest. As vesting of the PSU's is based on a number of factors, the determination of the grant-date fair value for PSU's has been estimated using a Monte Carlo simulation approach which includes variables such as the expected volatility of the Company's share price and interest rates to generate potential future outcomes. 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 the PSUs. Such value is recognized as expense over the derived service period using the accelerated attribution method. The estimation of PSUs 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.

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, 2019 and 2018 diluted loss per share does not differ from basic loss per share since the effect of the Company's warrants, stock options, performance stock units, and convertible preferred shares is anti-dilutive. As at June 30, 2019, potential common shares of 1,831,779 (2018 – 1,690,810) related to outstanding warrants and stock options, nil (2018 – 120,000) relating to performance stock units, and 168,427 (2018 – 220,279) 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 ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date.

(in US dollars unless otherwise noted)

Recently adopted

Accounting Standards Board ("ASU") 2017-09 — Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting

The amendments in this update provide guidance about which changes to the terms, or conditions of a stock-based payment award, require an entity to apply modification accounting in Topic 718. The amendments in ASU 2017-09 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for (1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The adoption of ASU 2017-09 did not have a material impact on the Company's results of operations or financial position.

ASU 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 reporting periods beginning after December 15, 2017. The adoption of ASU 2016-01 did not have a material impact on the Company's results of operations or financial position.

Not yet adopted

ASU 2017-11 — I. Accounting for Certain Financial Instruments with Down Round Features, II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Non-public Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception

The amendments in this update are intended to reduce the complexity associated with the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, a down round feature would no longer cause a freestanding equity-linked financial instrument (or an embedded conversion option) to be accounted for as a derivative liability at fair value with changes in fair value recognized in current earnings. In addition, the indefinite deferral of certain provisions of Topic 480 have been re-characterized to a scope exception. The re-characterization has no accounting effect. ASU 2017-11 is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company issued certain share purchase warrants in the quarter ended June 30, 2019 that contained a down round feature. The Company has accounted for these warrants as a derivative liability and has recognized $432,386 as a change in the fair value of the derivative liability in the consolidated statement of operations and comprehensive loss for the year ended June 30, 2019. In addition, $126,186 has been recognized as derivative issue costs. Upon expiry of the down round feature on June 28, 2019, $492,884 was reclassified from derivative liability to additional paid in capital. Had the Company adopted ASU 2017-11 for the year ended June 30, 2019, these warrants would not have been accounted for as a derivative liability.

(in US dollars unless otherwise noted)

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 adoption of ASU 2016-02 is not expected to have a material impact on the Company's results of operations or financial position.

ASU 2018-07 — Stock Compensation (Topic 718) Improvements to Nonemployee Shares-based Payment Accounting

The amendments in this update are intended to the reduce cost and complexity and to improve financial reporting for share-based payments issued to nonemployees. The ASU expands the scope of Topic 718, Compensation —Stock Compensation, which currently only includes share-based payments issued to employees, to also include share-based payments issued to nonemployees for goods and services. The existing guidance on nonemployee share-based payments is significantly different from current guidance for employee share-based payments. This ASU expands the scope of the employee share-based payments guidance to include share-based payments issued to nonemployees. By doing so, the FASB improves the accounting of nonemployee share-based payments issued to acquire goods and services used in its own operations. The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The adoption of ASU 2018-07 is not expected to have a material impact on the Company's results of operations or financial position.

3 Valent Technologies LLC agreements

One of the Company's officers is a principal of Valent Technologies, LLC ("Valent") and as result Valent is a related party to the Company.

On September 12, 2010, the Company entered into a Patent Assignment Agreement (the "Valent Assignment Agreement") with 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 Del Mar (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 Del Mar (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, 2019 and 2018 respectively, the Company recorded $8,356 related to the dividend paid to Valent. The dividends have been recorded as a direct increase in accumulated deficit.

(in US dollars unless otherwise noted)

4 Derivative liabilities

The Company has issued common stock purchase warrants. Based on the terms of certain of these warrants the Company determined that the warrants were derivative liabilities which are 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.

2019 Investor Warrants

As part of the Company's registered direct offering completed June 5, 2019 (note 5) the Company issued 760,500 share purchase warrants exercisable at a price of $3.10 until June 5, 2024 (the "2019 Investor Warrants"). The exercise price of the 2019 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, prior to June 28, 2019. As a result, upon issuance on June 5, 2019, the Company has accounted for the 2019 Investor Warrants as a derivative liability. The change in fair value of the 2019 Investor Warrants from the date of issue until June 28, 2019 has been recorded in the consolidated statement of operations and comprehensive loss for the year ended June 30, 2019. Upon expiry of the repricing feature on June 28, 2019, the fair value of the derivative liability at that time of $492,884 was reclassified to equity.

2013 Investor Warrants

During the quarter ended March 31, 2013 the Company issued an aggregate of 328,125 units at a purchase price of $32.00 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 $32.00. The exercise price of the 2013 Investor Warrants was subject to adjustment in the event that the Company issued common stock at a price lower than the exercise price, subject to certain exceptions. The 2013 Investor Warrants expired on March 31, 2019.

2015 Agent Warrants

As part of the Company's financing completed in a prior period, the Company issued warrants to purchase 2,180 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 $30.00 until July 15, 2020.

(in US dollars unless otherwise noted)

The Company's derivative liabilities are summarized as follows:

	Years ended June 30,	
	2019	**2018**
	$	**$**
Opening balance	1,117	61,228
Issuance of 2019 Investor Warrants	925,270	-
Change in fair value of warrants	(433,503)	(60,111)
Reclassification of 2019 Investor Warrants to equity	492,884	-
Closing balance	-	1,117
Less current portion	-	-
Long-term portion	-	1,117

The derivative liabilities consist of the following warrants as at June 30, 2019 and 2018:

	Year ended June 30, 2019	
	Number of warrants	**$**
2015 Agent warrants	2,180	-
Closing balance	2,180	-
Less current portion	-	-
Long-term portion	2,180	-

	Year ended June 30, 2018	
	Number of warrants	**$**
Warrants issued for services	4,375	-
2015 Agent warrants	2,180	1,117
Closing balance	6,555	1,117
Less current portion	-	-
Long-term portion	6,555	1,117

(in US dollars unless otherwise noted)

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, 2019 and 2018 – 1
Series A shares – at June 30, 2019 – 278,530 (June 30, 2018 – 278,530)
Series B shares – at June 30, 2019 – 673,613 (June 30, 2018 – 881,113)

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 0.25 shares of common stock equating to a conversion price of $32.00 (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 $80.00 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.

(in US dollars unless otherwise noted)

Pursuant to the Series B Preferred Stock dividend, during the year ended June 30, 2019, the Company issued 18,271 (2018 – 19,841) shares of common stock and recognized $80,431 (2018 – $176,236) as a direct increase in accumulated deficit. During the year ended June 30, 2019, a total of 207,500 (2018 – 0) shares of Series B Preferred Stock were converted for an aggregate 51,876 (2018 – 0) shares of common stock.

A total of 673,613 (2018 – 881,113) shares of Series B Preferred Stock are outstanding as of June 30, 2019, such that a total of 168,427 (2018 – 220,279) shares of common stock are issuable upon conversion of the Series B Preferred Stock as at June 30, 2019. Converted shares are rounded up to the nearest whole share.

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, Callco, 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.

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.

(in US dollars unless otherwise noted)

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
95,000,000 as at June 30, 2019 (2018 - 7,000,000) common shares, $0.001 par value

The issued and outstanding common shares at June 30, 2019 of 3,839,358 (2018 – 2,296,667) include 7,813 (2018 – 91,276) shares of common stock on an as-exchanged basis with respect to the Exchangeable Shares.

On May 8, 2019, pursuant to the Company effecting a 1-for-10 (1:10) reverse stock split of its common stock, the Company issued 2,433 additional shares of common stock due to the rounding up of fractional common shares to the nearest whole share (note 2).

On June 26, 2019, the Company amended its articles of incorporation, as amended, to increase the number of authorized shares of common stock from 7,000,000 to 95,000,000 shares.

Public offering financings

Year ended June 30, 2019

On June 5, 2019 the Company completed a registered direct offering (the "2019 Registered Offering") of an aggregate of 1,170,000 shares of common stock and warrants to purchase an additional 760,500 shares of common stock at a price of $3.10 per share and related warrant for gross proceeds of $3.6 million. The warrants have an exercise price of $3.10 per share, are immediately exercisable and have a term of exercise of five years (the "2019 Investor Warrants").

The Company engaged a placement agent for the 2019 Registered Offering. Under the Company's engagement agreement with the placement agent, the Company paid $290,160 in cash commission and other fees to the placement agent and issued warrants to purchase 46,800 shares of common stock to the placement agent (the "2019 Agent Warrants"). Commencing December 3, 2019, the 2019 Agent Warrants are exercisable at $3.875 per share until June 3, 2024.

In addition to the cash commission and other placement agent fees, the Company also incurred additional cash issue costs of $151,585 resulting in net cash proceeds of $3,185,255.

Year ended June 30, 2018

On September 22, 2017 the Company completed a registered direct offering (the "2018 Registered Offering") of an aggregate of 800,000 shares of common stock and warrants to purchase an additional 800,000 shares of common stock at a price of $12.50 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 "2018 Investor Warrants").

(in US dollars unless otherwise noted)

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 40,000 shares of common stock to the placement agent (the "2018 Agent Warrants"). The 2018 Agent Warrants are exercisable at a per share price of $12.50 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 $254,664 resulting in net cash proceeds of $8,945,336.

Shares issued for services

During the year ended June 30, 2019, the Company issued 3,444 (2018 – 863) shares of common stock for services resulting in the recognition of $13,777 (2018 – $8,582) in expense. All of the shares issued for services for the years ended June 30, 2019 and 2018 have been recognized as research and development expense.

2017 Omnibus Incentive Plan

As approved by the Company's stockholders at the annual meeting of stockholders held on April 11, 2018, on July 7, 2017, as amended on February 1, 2018, 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, 780,000 shares of Company common stock are reserved for issuance, less the number of shares of common stock issued under the Del Mar (BC) 2013 Amended and Restated Stock Option Plan (the "Legacy Plan") or that are subject to grants of stock options made, or that may be made, under the Legacy Plan. A total of 165,485 shares of common stock have been issued under the Legacy Plan and/or are subject to outstanding stock options granted under the Legacy Plan, and a total of 122,698 shares of common stock have been issued under the 2017 Plan and/or are subject to outstanding stock options granted under the 2017 Plan leaving a potential 491,817 shares of common stock available for issuance under the 2017 Plan if all such options under the Legacy Plan were exercised and no new grants are made under the Legacy Plan.

In relation to the Company's rights offering that was terminated by the Company on June 26, 2019, the Company's board of directors temporarily reduced the number of shares of common stock that could be issued under the Company's 2017 Plan to 14,217 shares of common stock meaning that as of June 30, 2019, rather than the full number of 491,817, only 14,217 shares of common stock were available for issuance under the 2017 Plan. Subsequent to June 30, 2019, the reserve under the 2017 Plan was increased by the board of directors back to a potential 491,817 shares of common stock available for issuance under the 2017 Plan if all such options under the Legacy Plan were exercised and no new grants are made under the Legacy Plan.

The maximum number of shares of Company common stock with respect to which any one participant may be granted awards during any calendar year is 8% of the Company's fully diluted shares of common stock on the date of grant (excluding the number of shares of common stock issued under the 2017 Plan and/or the Legacy Plan or subject to outstanding awards granted under the 2017 Plan and/or 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.

(in US dollars unless otherwise noted)

Performance stock units

The Company's board of directors granted PSUs under the 2017 Plan to the Company's directors. The awards represent the right to receive 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 vest at various fully diluted market capitalization levels with full vesting occurring 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. On April 30, 2019 the Company's directors all agreed to the cancellation of all PSU's. In relation to the PSU cancellation, the Company has recognized the full amount of the expense of the PSU's in the fourth quarter of fiscal 2019.

The following table sets forth the PSUs outstanding under the 2017 Plan as of June 30, 2019:

	Number of PSUs outstanding
Balance – June 30, 2017	-
Granted	140,000
Forfeited	(20,000)
Balance – June 30, 2018	120,000
Cancelled	(120,000)
Balance – June 30, 2019	-

The Company has recognized $526,141 (including accelerated expense recognition due to the cancellation of the PSU's of $322,877) (2018 - $48,624) in expense related to the PSUs during the year ended June 30, 2019 with all of it being recognized as general and administrative expense. There was no unrecognized PSU expense at June 30, 2019 (2018 - $526,140).

The PSUs have been valued using the following assumptions:

	June 30, 2019
Dividend rate	0%
Volatility	79.0 to 82.5%
Risk-free rate	2.56% to 2.71%
Term – years	1.67 to 3.24

(in US dollars unless otherwise noted)

Stock options

The following table sets forth the aggregate stock options outstanding under all plans as of June 30, 2019:

	Number of stock options outstanding	Weighted average exercise price
Balance – June 30, 2017	112,085	41.81
Granted	152,698	11.35
Forfeited	(2,100)	21.10
Balance – June 30, 2018	262,683	24.27
Granted	30,000	6.10
Expired	(4,500)	28.37
Balance – June 30, 2019	288,183	22.31

(in US dollars unless otherwise noted)

The following table summarizes stock options currently outstanding and exercisable under all plans at June 30, 2019:

Exercise price $	Number Outstanding at June 30, 2019	Weighted average remaining contractual life (years)	Number exercisable at June 30, 2019
6.10	30,000	9.36	13,610
7.00	5,451	8.98	1,817
8.70	12,000	8.34	12,000
9.83	83,647	8.89	30,206
10.60	3,600	8.79	1,500
11.70	30,000	3.66	30,000
15.27	2,500	2.92	2,500
20.00	13,125	2.27	13,125
21.10	14,400	8.02	8,400
29.60	4,500	5.60	4,500
37.60	4,500	6.61	4,500
40.00	1,250	0.25	1,250
41.00	4,000	7.36	3,486
42.00	41,250	3.56	41,250
44.80	3,000	6.61	3,000
49.50	22,460	5.07	19,549
53.20	8,000	6.85	8,000
61.60	1,500	3.75	1,500
92.00	3,000	3.92	3,000
	288,183		203,193

Included in the number of stock options outstanding are 2,500 stock options granted at an exercise price of CA $20.00. The exercise prices for these stock options shown in the above table have been converted to US $15.27 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.

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

	June 30, 2019	June 30, 2018
Dividend rate	0%	0%
Volatility	70.6% to 101.5%	72.4 to 87.1%
Risk-free rate	1.62% to 3.17%	1.49% to 2.86%
Term – years	0.1 to 3.0	0.6 to 3.03

(in US dollars unless otherwise noted)

The Company has recognized the following amounts as stock option expense for the periods noted:

	Years ended June 30,	
	2019	**2018**
	$	**$**
Research and development	74,667	140,870
General and administrative	351,362	355,055
	426,029	495,925

All of the stock option expense for the years ended June 30, 2019 and 2018 has been recognized as additional paid in capital. The aggregate intrinsic value of stock options outstanding at June 30, 2019 and 2018 was $0 and the aggregate intrinsic value of stock options exercisable at June 30, 2019 and 2018 was also $0. As at June 30, 2019 there was $164,329 in unrecognized compensation expense that will be recognized over the next 2.4 years. No stock options granted under the Plan have been exercised to June 30, 2019. Upon the exercise of stock options new shares will be issued.

A summary of status of the Company's unvested stock options as at June 30, 2019 under all plans is presented below:

	Number of options	**Weighted average exercise price $**	**Weighted average grant date fair value $**
Unvested at June 30, 2017	31,803	48.09	25.74
Granted	152,698	11.35	6.01
Vested	(44,241)	27.81	15.02
Forfeited	(2,100)	21.10	11.32
Unvested at June 30, 2018	138,160	14.39	7.63
Granted	30,000	6.10	2.56
Vested	(83,170)	14.51	7.65
Unvested at June 30, 2019	84,990	11.35	5.82

The aggregate intrinsic value of unvested stock options at June 30, 2019 and 2018 was $0. The unvested stock options have a remaining weighted average contractual term of 8.78 (2018 – 8.81) years.

Stock option modifications

During the year ended June 30, 2018, certain stock options were modified pursuant to a separation agreement with the Company's former President and Chief Operating Officer. A total of 6,670 options had their vesting accelerated such that they became fully vested on December 22, 2018, resulting in additional stock option expense of $93,777. In addition, a total of 21,860 options were modified such that their remaining exercise period was increased from one year to three years, resulting in additional stock option expense of $28,561.

Also, during the year ended June 30, 2018, certain stock options were modified pursuant to the resignation of the Company's former Chairman. A total of 1,500 options had their vesting accelerated such that they became fully vested on June 2, 2019, resulting in additional stock option expense of $679. In addition, a total of 4,500 (including the 1,500 whose vesting was accelerated) options were modified such that their remaining exercise period was increased from 90 days to one year, resulting in additional stock option expense of $2,182.

(in US dollars unless otherwise noted)

Warrants

	Number of warrants	Amount $
Balance – June 30, 2017	**360,475**	**4,570,574**
Issuance of 2018 Investor and 2018 Agent Warrants (i)	840,000	3,572,843
Exercise of 2018 Investor Warrants (i)	(25,000)	(106,335)
Warrants issued for services (ii)	42,000	192,400
Balance – June 30, 2018	**1,217,475**	**8,229,482**
Exercise and exchange of 2018 Investor Warrants (iii)	(495,000)	(2,210,697)
Issuance of 2019 Investor Warrants (note 4)	760,500	492,884
Issuance of 2019 Agent Warrants (iv)	46,800	52,899
Warrants issued for services (ii)	14,000	23,715
Balance – June 30, 2019	**1,543,775**	**6,588,283**

i) As part of the financing completed by the Company on September 22, 2017, the Company issued the 2018 Investor Warrants and the 2018 Agent Warrants. The 2018 Investor Warrants are exercisable at $12.50 until September 22, 2022 and the 2018 Agent Warrants are exercisable at $12.50 until September 20, 2022.

ii) Warrants issued for services are exercisable at various prices and expire at the various dates noted in the table below.

iii) On November 25, 2018, the Company entered into Warrant Exercise and Exchange Agreements (the "Warrant Exercise Agreements") with certain holders (the "Exercising Holders") of the 2018 Investor Warrants. Pursuant to the Warrant Exercise Agreements, in order to induce the Exercising Holders to exercise the 2018 Investor Warrants for cash, the Company agreed to reduce the exercise price from $12.50 to $4.00 per share. Pursuant to the Warrant Exercise Agreements, the Exercising Holders exercised their 2018 Investor Warrants with respect to an aggregate of 197,500 shares of common stock underlying such 2018 Investor Warrants (the "Exercised Shares"). The Company received net proceeds of $720,165, comprising aggregate gross proceeds of $790,000 net of expenses of $69,835, from the exercise of the 2018 Investor Warrants.

In addition, in order to further induce the Exercising Holders to exercise the 2018 Investor Warrants, the Warrant Exercise Agreements also provided for the issuance of one share of common stock to the Exercising Holders in exchange for every three shares of common stock underlying the 2018 Investor Warrants held by the Exercising Holders that are not being exercised for cash pursuant to the Warrant Exercise Agreements, if any. On November 26, 2018, the Company issued an aggregate of 99,167 shares of common stock in exchange for 297,500 2018 Investor Warrants.

iv) As part of the financing completed by the Company on June 5, 2019, the Company issued the 2019 Agent Warrants. Commencing December 3, 2019, the 2019 Agent Warrants are exercisable at $3.875 until June 3, 2024.

(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 for the year ended June 30, 2019:

Description	**Number**
Balance – June 30, 2018	**1,428,128**
Issuance of 2019 Investor Warrants	760,500
Issuance of 2019 Agent Warrants	46,800
Exercise of 2018 Investor Warrants for cash	(197,500)
Cashless exchange of 2018 Investor Warrants	(297,500)
Warrants issued for services	14,000
Expiry of warrants	(210,832)
Balance – June 30, 2019	**1,543,596**

The following table summarizes the Company's outstanding warrants as of June 30, 2019:

Description	**Number**	**Exercise price $**	**Expiry date**
2019 Investor	760,500	3.10	June 5, 2024
2018 Investor	280,000	12.50	September 22, 2022
2017 Investor	207,721	35.00	April 19, 2022
2015 Investor	97,905	30.00	July 31, 2020
Issued for services	26,500	30.00	July 1, 2020 to February 1, 2021
Issued for services	6,000	17.80	January 25, 2023
Issued for services	33,600	11.70	February 27, 2023
Issued for services	12,000	9.00	September 15, 2023
Issued for services	4,140	59.30	February 27, 2020
Issued for services	2,000	9.00	October 11, 2021
2019 Agent	46,800	3.875	June 3, 2024
2018 Agent	40,000	12.50	September 20, 2022
2017 Agent	13,848	40.60	April 12, 2022
2016 Agent	10,402	40.00	May 12, 2021
2015 Agent	2,180	30.00	July 15, 2020
	1,543,596	12.60	

(in US dollars unless otherwise noted)

6 Related party transactions

During the year ended June 30, 2018, the Company recognized a total expense of $311,683 relating to the settlement agreement with the Company's former President and Chief Operating Officer. Amounts owed to officers and directors, including to the Company's former President and Chief Operating Officer, have been aggregated and not shown separately, and are non-interest bearing and payable on demand.

7 Current and deferred income taxes

For the years ended June 30, 2019, and 2018, the Company did not record a provision for income taxes due to a full valuation allowance against our deferred tax assets.

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

	June 30, 2019 $	June 30, 2018 $
Deferred tax assets:		
Non-capital losses carried forward	10,823,529	9,416,047
Capital losses carried forward	17,925	17,925
Financing costs	-	5,512
Scientific research and development	534,398	396,758
Scientific research and development - ITC	484,135	354,411
	11,859,987	10,190,653
Deferred tax liabilities:		
Scientific research and development – ITC	(81,386)	(61,230)
	11,778,601	10,129,423
Valuation allowance	(11,778,601)	(10,129,423)
Net future 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 21% (2018 – 21%).

The differences arise from the following items:

	June 30, 2019 $	June 30, 2018 $
Tax recovery at statutory income tax rates	(1,690,126)	(3,063,036)
Permanent differences	(527,532)	290,722
Effect of rate differentials between jurisdictions	(429,531)	76,364
Impact of changes in income tax rates	-	138,516
Scientific research and development – ITC	(39,807)	(354,411)
Other	106,320	75,422
Change in valuation allowance	2,580,676	2,836,423
	-	-

(in US dollars unless otherwise noted)

As of June 30, 2019, the Company had combined US and Canadian net operating loss carry forwards of $43.2 million (2018 – 34.7 million) that begin expiring in 2029. In addition, the Company has non-refundable Canadian federal investment tax credits of $303,969 (2018 - $226,778) that expire between 2029 and 2039 and non-refundable British Columbia investment tax credits of $166,000 (2018 – 127,633) that expire between 2019 and 2029. The Company also has Canadian scientific research and development tax credits of $2.0 million (2018 – 1.5 million) that do not expire.

The Tax Cuts and Jobs Act ("2018 Tax Act") was enacted in December 2018. The 2018 Tax Act, among other things, reduces the U.S. federal corporate tax rate from 35% to 21%, effective January 1, 2019, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign earnings. The Company revalued our deferred tax assets as of June 30, 2018 based on a U.S. federal tax rate of 21%, which resulted in a reduction to our deferred tax assets of $138,516 fully offset by a reduction to the valuation allowance. The Company is not required to pay a one-time transition tax on earnings of our foreign subsidiary as the foreign subsidiary has an accumulated deficit.

8 Commitments and contingencies

The Company has the following obligations over the next five fiscal years ending June 30, 2024:

Clinical development

The Company has entered into contracts for drug manufacturing and clinical study management and safety related to its Phase II clinical trials for a total of $659,343. Pursuant to the commitment for clinical trial management, the Company has paid a total of $142,568 in deposits related to study initiation and certain study costs. These deposits are available to be applied against invoices received from the contract research organization but have not been netted against the Company's commitments for the fiscal year ended June 30, 2020.

Office lease

The Company currently rents its offices on a month-to-month basis at a rate of $2,844 (CA$3,725) per month. During the year ended June 30, 2019, the Company recorded $52,926 as rent expense (2018 - $58,434).

9 Supplementary statement of cash flows information

	Year ended June 30, 2019	Year ended June 30, 2018
Series B Preferred Stock common stock dividend (note 5)	80,431	176,236
Non-cash issue costs (note 5)	52,899	148,087
Issue costs in accounts payable (note 5)	64,432	-
Reclassification of derivative liability to equity (note 4)	492,884	-
Conversion of Series B Preferred Stock to common stock (note 5)	1,447,576	-
Income taxes paid	-	-
Interest paid	-	-

(in US dollars unless otherwise noted)

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 Sates 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$. As at June 30, 2019, Canadian dollar denominated accounts payable and accrued liabilities exposure in US$ totaled $178,327.

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 $13,865.

Balances in foreign currencies at June 30, 2019 and 2018 are as follows:

	June 30, 2019 balances CA$	June 30, 2018 balances CA$
Trade payables	201,279	79,858
Cash	24,248	41,459
Interest, taxes, and other receivables	26,099	14,618

b) Interest rate risk

The Company is subject to interest rate risk on its cash and cash equivalents 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, 2019, cash and cash equivalents held by the Company were $3,718,758. 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 due to the current low market interest rates.

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

(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, 2019 and is undertaking efforts to conserve cash resources wherever possible. The maximum exposure of the Company's liquidity risk is $2,069,725 as at June 30, 2019.

Credit risk

Credit risk arises from cash and cash equivalents, deposits with banks, financial institutions, and contractors 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 $26,187 at June 30, 2019 relating to interest, taxes, and other receivables. The credit risk related to uninsured cash and cash equivalents balances is $3,718,758 at June 30, 2019.

	Cash and cash equivalents $	Insured amount $	Non-insured amount $
	3,718,758	75,158	3,643,600

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.

(in US dollars unless otherwise noted)

11 Subsequent events

Underwritten public offering

On August 16, 2019, the Company closed on the sale of (i) 4,895,000 shares of its common stock, par value $0.001 per share (the "Common Stock"), (ii) pre-funded warrants ("PFW") to purchase an aggregate of 2,655,000 shares of Common Stock and (iii) common warrants to purchase an aggregate of 7,762,500 shares of Common Stock ("2020 Investor Warrants"), including 800,000 shares of Common Stock and 2020 Investor Warrants to purchase an aggregate of 1,012,500 shares of Common Stock sold pursuant to a partial exercise by the underwriters of the underwriters' option to purchase additional securities, in the Company's underwritten public offering (the "Offering"). Each share of Common Stock or PFW, as applicable, was sold together with a 2020 Investor Warrant to purchase one share of Common Stock at a combined effective price to the public of $1.00 per share of Common Stock and accompanying 2020 Investor Warrant.

The net proceeds from the Offering, including from the partial exercise of the underwriters' option to purchase additional securities, were approximately $6.7 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

The 2020 Investor Warrants are exercisable at $1.00 per share and the PFW are exercisable at $0.01 per share until their expiries on August 16, 2024. The Company also issued 377,500 warrants to the underwriters of the Offering. The underwriter warrants are exercisable at $1.15 per share commencing February 10, 2020 until their expiry on August 14, 2022.

The Company granted the underwriters a 45-day option, ending September 28, 2019, to purchase up to an additional 1,012,500 shares of Common Stock and/or 2020 Investor Warrants to purchase up to 1,012,500 shares of Common Stock, at the public offering price less discounts and commissions. On August 15, 2019, the underwriters partially exercised this option by purchasing 800,000 shares of Common Stock and 2020 Investor Warrants to purchase an aggregate of 1,012,500 shares of Common Stock.

Subsequent to the closing of the Offering, all of the 2,655,000 PFW were exercised at $0.01 per PFW for proceeds of $26,550.

2017 Plan changes and stock option grants

Subsequent to June 30, 2019, and subject to approval by the Company's stockholders, the Company's board of directors approved an increase in the number of shares of common stock available to be issued under the 2017 Plan by 1,500,000. The increase brings the total number of shares available under the 2017 Plan to 2,280,000. As of June 30, 2019, the available number of shares of common stock under the 2017 Plan was 491,817.

The Company also granted 1,041,016 stock options to officers and directors of the Company. Of this total, 491,817 were granted under the existing 2017 Plan limit and 549,199 will be exercisable subject to approval by the Company's stockholders of the share increase. All stock options have an exercise price of $0.61and expire on September 5, 2029. Of the 1,041,016 stock options granted, 375,000 vest pro rata monthly over one year from the date of grant and 666,016 vest as to one-sixth on the six month anniversary of the grant date with the remaining five-sixths vesting pro rate monthly over 30 months commencing on the seven month anniversary of the grant date.

Share issuances

Subsequent to June 30, 2019, we have issued 688 shares for services and 25,000 shares of Series B Preferred stock were converted into 6,250 shares of common stock.

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, 2019. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, for the reasons set forth below, our disclosure controls and procedures were not effective as of June 30, 2019.

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 our 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 of the 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 the evaluation, our management concluded that our internal control over financial reporting was not effective as of June 30, 2019 because of material weaknesses in our internal control over financial reporting. A material weakness is a control deficiency or combination of deficiencies in internal control, 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. Our management concluded that we have a material weakness in the design and operating effectiveness of our internal controls over financial reporting because of inadequate segregation of duties over authorization, review and recording of transactions, as well as the financial reporting of such transactions.

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 and further enhance our internal controls which has increased the number of personnel involved in financial reporting.

- Over the course of the fiscal year ended June 30, 2019, we have continued to integrate personnel from our external consulting firm into our systems of internal controls in the following areas:
    - Preparation and review of accounting and financial documents; and
    - Payment processing procedures.

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.

While the implementation of improved controls and procedures has strengthened our internal control framework and disclosure controls, we continue to believe we have a material weakness related to the lack of sufficient segregation of duties.

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

During the year ended June 30, 2019, we continued to integrate the external accounting firm into the financial reporting and internal control systems and controls.

As we continue to evaluate and work to improve our internal control over financial reporting, we may determine to take additional measures to address the material weakness or determine to supplement or modify certain of the remediation measures described above.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Below are the names and certain information regarding our executive officers and directors.

Name	Age	Position
Robert E. Hoffman	53	Chairman of the Board
Saiid Zarrabian	67	President, Chief Executive Officer and Director
Dennis Brown, PhD	70	Chief Scientific Officer
Scott Praill, CPA	53	Chief Financial Officer
John K. Bell, FCPA, CPA	72	Director
Lynda Cranston, BScN, MScN, ICD.D	72	Director
Napoleone Ferrara, MD	63	Director
Robert J. Toth, Jr., MBA	56	Director

Robert E. Hoffman has served as our director since April 11, 2018 and as our Chairman since June 2, 2018. He has served as a member of Kura Oncology, Inc.'s Board of Directors since March 2015. Mr. Hoffman has served as Senior Vice President and Chief Financial Officer of Heron Therapeutics, Inc., a publicly-held pharmaceutical company since April 2017. Prior to joining Heron Therapeutics, Inc., Mr. Hoffman served as Executive Vice President and Chief Financial Officer of Innovus Pharmaceuticals, Inc., a publicly-held pharmaceutical company, from September 2016 to April 2017. From July 2015 to September 2016, Mr. Hoffman served as Chief Financial Officer of AnaptysBio, Inc., a publicly-held biotechnology company. From June 2012 to July 2015, Mr. Hoffman served as the Senior Vice President, Finance and Chief Financial Officer of Arena Pharmaceuticals, Inc., or Arena, a publicly-held biopharmaceutical company. From August 2011 to June 2012 and previously from December 2005 to March 2011, he served as Arena's Vice President, Finance and Chief Financial Officer and in a number of various roles of increasing responsibility from 1997 to December 2005. From March 2011 to August 2011, Mr. Hoffman served as Chief Financial Officer for Polaris Group, a biopharmaceutical drug company. Mr. Hoffman formerly served as a member of the Board of Directors of CombiMatrix Corporation, a molecular diagnostics company, and MabVax Therapeutics Holdings, Inc., a biopharmaceutical company. Mr. Hoffman serves as a member of the Financial Accounting Standards Board's Small Business Advisory Committee and the steering committee of the Association of Bioscience Financial Officers. Mr. Hoffman formerly served as a director and President, of the San Diego Chapter of Financial Executives International. Mr. Hoffman holds a B.B.A. from St. Bonaventure University, and is licensed as a C.P.A. (inactive) in the State of California. Mr. Hoffman's financial and executive business experience qualifies him to serve on our Board of Directors.

Saiid Zarrabian has served as our director since July 7, 2017, Chief Executive Officer since November 3, 2017, and President since January 1, 2018. From 2014 to 2015 he operated a private personal business. Since October 2016, Mr. Zarrabian has served as an advisor to Redline Capital Partners, S.A., a Luxembourg 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 transitioned 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 and member of the Board of Cyntellect, 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, and as COO of Pharmacopeia, 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 business executive knowledge and experience qualify him to serve on our Board of Directors.

Dennis Brown, PhD, has been our chief scientific officer since January 25, 2013. He also served as our director from February 11, 2013 to April 11, 2018. Dr. Brown is one of our founders and has served as Chief Scientific Officer and director of Del Mar (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 many issued U.S. patents and applications, many with foreign counterparts.

Scott Praill, CPA, BSc. has been our chief financial officer since January 29, 2013 and previously served as a consultant to Del Mar (BC). From 2004 to 2012 Mr. Praill was an independent consultant providing accounting and administrative services to companies in the resource industry. Mr. Praill served as CFO of Strata Oil & Gas, Inc. from June 2007 to September 2008. From November 1999 to October 2003 Mr. Praill was Director of Finance at Inflazyme Pharmaceuticals Inc. Mr. Praill completed his articling at Price Waterhouse (now PricewaterhouseCoopers LLP) and obtained his Chartered Professional Accountant designation in 1996. Mr. Praill obtained his Certified Public Accountant (Illinois) designation in 2001. Mr. Praill 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 our director since February 11, 2013 and serves as the Chair of the Audit Committee. Mr. Bell is Chairman of Onbelay Capital Inc., a Canadian based private equity company. 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-WEED), 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 our director since February 5, 2015 and serves as the Chair of our Nominating and Corporate Governance Committee. Mrs. Cranston comes to the Board with over 20 years of experience at the CEO level in healthcare. She is presently Chair of the British Columbia Rapid Transit Company. She previously was, from 2014 to 2016, the National Chair of the Gastrointestinal Association of Canada. In 2013 she retired from the healthcare industry and her last appointment prior to her retirement was as the first CEO of the British Columbia Provincial Health Services Authority (2002 to 2013). From 1998-2001, Mrs. Cranston had been the first CEO of the Canadian Blood Services in Ottawa, ON. Before moving to Ottawa, Mrs. Cranston, as the CEO of B.C. 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. 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. Mrs. Cranston is a graduate of the University of Ottawa and the University of Western Ontario. Mrs. Cranston's healthcare industry and executive knowledge and experience qualify her to serve on our Board of Directors.

Napoleone Ferrara, MD, has served as our director since June 22, 2018. Since January 2013 he has served as a professor of pathology and since July 2014 as an adjunct professor of ophthalmology and pharmacology at the University of California, San Diego. Previously, Dr. Ferrara held increasingly senior positions at Genentech, Inc., over a 24-year period, including fellow, staff scientist and senior scientist. He is a pioneer in the study of angiogenesis biology and identification of its regulators. Dr. Ferrara's lab is responsible for discovering the isolation and cDNA cloning of VEGF and demonstrated that VEGF was a major mediator of tumor angiogenesis leading to the development of Avastin® (bevacizumab). Additionally, his lab's studies led to the clinical development of an anti-VEGF antibody fragment, Lucentis® (ranibizumab), as a highly effective therapy preventing vision loss in intraocular neovascular disorders. Dr. Ferrara has been the recipient of over 60 awards/honors, given more than 300 presentations, authored over 70 patents, and written more than 300 articles, reviews/editorials and published book chapters. He received his fellowship training and postdoctoral research from the University of California, San Francisco, his M.D. (cum laude) and residency training from the University of Catania Medical School, and his Maturita' Classica from Liceo Classico Mario Cutelli. Dr. Ferrara's scientific knowledge and experience qualify him to serve on our Board of Directors.

Robert J. Toth, Jr., MBA has served as our director since August 20, 2013 and serves as Chair of our Compensation Committee. 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 quality him to serve on our Board of Directors.

Our chief executive and chief financial officers are full-time employees and devote 100% of their business time to us. Our 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.

See “Executive Compensation”.

Our directors are appointed for a one-year term to hold office until the next annual general meeting of our stockholders 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);

3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of 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;

4. 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;

5. 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

6. 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 E. Hoffman, and Robert Toth, 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 Nominating and Corporate Governance Committee which consists of Lynda Cranston, Chair, John Bell, and Napoleone Ferrara. The Nominating and Corporate Governance Committee assists the Board of Directors in fulfilling its oversight responsibilities relating to corporate governance practices and policies.

In addition, the Board of Directors has formed a Compensation Committee which consists of Robert Toth, Chair, Napoleone Ferrara, and Robert E. Hoffman. The Compensation Committee assists the Board of Directors in fulfilling its oversight responsibilities relating to compensation matters, including compensation of the directors and our senior management and the administration of our compensation plans.

Nomination of Directors

The Nominating and Corporate Governance Committee of 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 Nominating and Corporate Governance Committee consists of independent directors only.

Orientation and Continuing Education

New members of the Board of Directors are provided with sufficient information to ensure that they are familiarized with us, our policies, and the mandates of the Board of Directors. Members of the Board of Directors are encouraged to communicate with management, legal counsel and, where applicable, our auditors and technical consultants to keep themselves current with industry developments and applicable legal, accounting and regulatory changes.

Board Leadership Structure and Role in Risk Oversight

Robert E. Hoffman serves as the chairman of our Board of Directors. Saiid Zarrabian serves as our Chief Executive Officer and President. We have not adopted a formal policy on whether the Chief Executive Officer and Chairman positions should be separated.

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 our assessment of risks. The Board of Directors focuses on the most significant risks facing us and our general risk management strategy, and also ensures that risks undertaken by us are consistent with the board's appetite for risk. While the Board of Directors oversees our risk management, management is responsible for the day-to-day risk management processes. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board leadership structure supports this approach.

Code of Ethics

We have adopted a Code of Ethics and Business Conduct that applies to all of our executive officers, financial and accounting officers, our directors, our financial managers and all of our employees. 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. A copy of our Code of Ethics and Business Conduct is posted under the "Investors" tab under Corporate Governance on our website, which is located at www.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 of our directors, having regard to the competencies and skills each director is expected to bring to the Board of Directors.

Item 11. Executive Compensation.

The Board of Directors has formed a Compensation Committee which reviews and approves management compensation. The Compensation Committee is responsible for approving management compensation, including salaries, bonuses, and equity compensation. We seek to provide competitive compensation arrangements that attract and retain key talent necessary to achieve our business objectives.

The following table presents information regarding the total compensation awarded to, earned by, or paid to our Chief Executive Officer and the two most highly-compensated executive officers (other than the Chief Executive Officer) who were serving as executive officers as of June 30, 2019 and June 30, 2018 for services rendered in all capacities to us for the years ended June 30, 2019 and June 30, 2018. These individuals are our Named Executive Officers for 2019.

Name and Principal Position	Period	Salary (US$)	Bonus Awards (US$)	Equity Awards (US$))	Total (US$)
Saiid Zarrabian,	Year Ended				
President and CEO	June 30, 2019	470,000(1)	165,665	—	635,665
	Year Ended June 30, 2018	237,412	85,631	615,992	939,035
Jeffrey Bacha,	Year Ended				
Former President and CEO	June 30, 2019	—	—	—	—
	Year Ended June 30, 2018	537,579(2)	—	122,338	659,917
Dennis Brown, PhD,	Year Ended				
Chief Scientific Officer	June 30, 2019	200,000(3)	—	—	200,000
	Year Ended June 30, 2018	200,000	—	—	200,000
Scott Praill,	Year Ended				
Chief Financial Officer	June 30, 2019	220,000(4)	52,250	30,627	302,877
	Year Ended June 30, 2018	200,000	10,000	—	210,000

(1) On July 7, 2017, Mr. Zarrabian was elected to the Board of Directors. Upon his appointment Mr. Zarrabian was granted 3,600 stock options that are exercisable at $21.10 until July 7, 2027 for total compensation expense of $40,752. Effective April 11, 2018, he was also issued 20,000 PSUs for total compensation expense of $98,428. The PSUs were cancelled effective April 30, 2019. For serving as an independent director from July 7, 2017 until November 3, 2017 he was paid $8,750.

On November 3, 2017, Mr. Zarrabian was appointed interim chief executive officer and on January 1, 2018 he was also appointed interim president. On November 3, 2017 we entered into an agreement with Mr. Zarrabian pursuant to which he will receive an annualized fee of $280,000 and be eligible to receive a bonus targeted up to 30% of the $280,000 annual fee which may be adjusted by the Board based on his individual performance and our performance as a whole, with such performance targets to be established by the Board. Upon execution of the agreement, we paid Mr. Zarrabian an advance of $45,000 of the annual fee. With the $45,000 advance, Mr. Zarrabian purchased shares of our common stock on the market. For the period from November 3, 2017 to May 20, 2018 we paid Mr. Zarrabian a total of $243,510 under the consulting agreement which includes the $45,000 advance, $130,134 in consulting fees, and $68,376 in bonus. Upon his appointment as interim chief executive officer he was granted 12,000 stock options that are exercisable at $8.70 until November 3, 2027 for total compensation expense of $53,567.

On May 21, 2018, we entered into an employment agreement with Mr. Zarrabian pursuant to which Mr. Zarrabian was appointed as our permanent president and chief executive officer. Under the Agreement, Mr. Zarrabian will receive an annual base salary of $470,000 and will be eligible to receive a fiscal year target bonus of up to 50% of base salary (which may be adjusted by the Board to up to 60% of base salary based on overachievement of bonus targets or other performance criteria). Any bonus earned for a fiscal year will be payable in cash, but the Board may pay up to 50% of the bonus, as well as any bonus in excess of 50% of base salary, in the form of stock options granted under our 2017 Omnibus Equity Incentive Plan (or any successor plan). The bonus for our fiscal year ended June 30, 2019 will be based on the period from the effective date of the agreement (May 21, 2018) through June 30, 2019. Mr. Zarrabian's bonus for our fiscal year ended June 30, 2019 is to be determined. The employment agreement may be terminated by us with or without cause (as defined therein). In the event we terminate the employment agreement without cause, we will be required to pay Mr. Zarrabian continued payment of his base salary for 12 months, a prorated bonus for the year of termination based on performance through the date of termination, an additional six months of vesting credit for any outstanding options, and continued health coverage during the severance period. In the event that an involuntary termination occurs during a period beginning sixty days before a definitive corporate transaction agreement is entered into that would result in a change in control, or within twelve months following a change in control, the severance period will increase to eighteen months' severance, Mr. Zarrabian will receive 100% of his target bonus, and his options will be fully vested. During the period from May 21, 2018 to June 30, 2018 Mr. Zarrabian was paid $53,528 under the employment agreement. We have also recorded a pro-rated bonus of $17,255. Upon his appointment as full-time president and chief executive officer Mr. Zarrabian was granted 83,647 stock options that are exercisable at $9.825 until May 21, 2028 for total compensation expense of $423,245.

(2) On February 9, 2017, we entered into an employment agreement with Jeffrey Bacha, our former president and chief executive officer. We paid Mr. Bacha an annual base salary of $250,000 and Mr. Bacha will also be eligible to participate in any bonus plan and long-term incentive plan established by us for senior executives. On December 22, 2017, we entered into a settlement agreement with Mr. Bacha pursuant to which, effective January 1, 2018, he would no longer serve as our officer. In addition, Mr. Bacha did not stand for re-election to the Board of Directors at our 2018 annual meeting of stockholders held on April 11, 2018. Pursuant to the terms of the settlement agreement and consistent with the terms of the employment agreement between Mr. Bacha and us dated February 9, 2017, as amended, Mr. Bacha was entitled to (i) accrued and unpaid base salary through January 1, 2018, (ii) payment for his accrued and unused vacation through January 1, 2018, (iii) severance in an amount equal to 13 months of Mr. Bacha's base salary, or $270,833, (iv) payment in an amount equal to 12 months' of coverage under our benefits plans, or $9,600 and (v) reimbursement for any properly incurred business expenses submitted with appropriate documentation in accordance with our expense reimbursement policies through December 31, 2017. In addition, all of Mr. Bacha's unvested stock options were deemed vested as of January 1, 2018 and will remain exercisable for three years and any unexercised options will expire on December 31, 2020. In addition, effective January 1, 2018, Mr. Bacha will provide consulting services to us through April 30, 2018 for a consulting fee of $20,833 per month and subsequent to April 30, 2018 on an hourly basis. The separation agreement and the employment agreement contain customary post-termination restrictive covenants in favor of us including confidentiality, non-competition and non-solicitation covenants. As a result of modifying Mr. Bacha's stock options, a total of $122,338 has been recognized.

(3) On January 1, 2015, we entered into a consulting agreement with Dr. Dennis Brown, our chief scientific officer. Subsequent to this agreement, it has been amended and is now renewed on an annual basis. Under the most recent renewal, Dr. Brown will continue to serve as our chief scientific officer until December 31, 2019, which period may be extended in accordance with the terms of the agreement. We will pay Dr. Brown an annual consulting fee of $200,000 during calendar year 2019. We may also pay to Dr. Brown a bonus and incentive compensation as determined at the discretion of the Board of Directors. 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.

(4) On February 9, 2017, we entered into an employment agreement with Scott Praill, our chief financial officer. Pursuant to the employment agreement, Mr. Praill will continue to serve as our chief financial officer for an indefinite period until termination of the employment agreement in accordance with its terms. We will pay Mr. Praill 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. Praill will also be eligible to participate in any bonus plan and long-term incentive plan established by us for senior executives. Mr. Praill's bonus for our fiscal year ended June 30, 2019 is to be determined. The employment agreement may be terminated by us with or without cause (as defined therein). In the event we terminate the employment agreement without cause, we will be required to pay Mr. Praill, any accrued and unpaid base salary, plus an amount equal to 12 months of Mr. Praill's base salary plus one additional month's base salary for each completed year of service, up to 18 months' base salary. On November 8, 2018, Mr. Praill was granted 10,000 stock options that are exercisable at $6.099 until November 8, 2028 for total compensation expense of $30,627.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth outstanding equity awards to our named executive officers as of June 30, 2019, reflecting our one-for-ten reverse stock split occurring on May 8, 2019.

	Option awards					Stock awards	
Name	**Number of securities underlying unexercised options (#) Exercisable**	**Number of securities underlying unexercised options (#) un-exercisable**	**Equity incentive plan awards: number of securities underlying unexercised unearned options (#)**	**Option exercise price (US$)**	**Option expiration date**	**Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)**	**Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)**
Saiid Zarrabian	2,100(1)	1,500	—	21.10	July 7, 2027	—	—
	12,000(2)	—	—	8.70	Nov 3, 2027		
	30,206(3)	53,441	—	9.825	May 21, 2028		
Jeffrey Bacha	3,750	—	—	20.00(5)	Dec 31, 2020	—	—
	8,750	—	—	42.00	Dec 31, 2020		
	9,360	—	—	49.50	Dec 31, 2020		
Dennis Brown, PhD	3,750	—	—	20.00(5)	Feb 1, 2022	—	—
	8,750	—	—	42.00	Aug 15, 2023		
	7,280(4)	2,080	—	49.50	Feb 17, 2027		
Scott Praill	1,250	—	—	20.00(5)	Feb 1, 2022	—	—
	8,750	—	—	42.00	Aug 15, 2023		
	2,909(4)	831	—	49.50	Feb 17, 2027		
	1,944(6)	8,056	—	6.099	November 8, 2028		

(1) Stock options vest as to 1,200 on June 30, 2018, and 300 options vest each three months thereafter starting September 30, 2018.

(2) Stock options vest pro rata monthly until full vesting on November 3, 2018.

(3) Stock options vest as to 1/6th on November 21, 2018 with the remaining shares vesting in equal monthly installments over a period of 30 months commencing on December 21, 2018.

(4) Stock options vest pro rata monthly until fully vesting on February 17, 2020.

(5) Original exercise price was CDN $20.00. Price was amended to USD $20.00 on June 30, 2016. All other terms of the option grants remain unchanged.

(6) Stock options vest as to 1/6th on May 8, 2019 with the remaining shares vesting in equal monthly installments over a period of 30 months commencing on June 8, 2019.

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, 2019 (excluding compensation to our executive officers set forth in the summary compensation table above) paid by us, reflecting our one-for-ten reverse stock split occurring on May 8, 2019.

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 ($)
Robert E. Hoffman	60,000	—	10,235	—	—	—	70,235
John K. Bell	40,000	—	10,235	—	—	—	50,235
Lynda Cranston	40,000	—	10,235	—	—	—	50,235
Napoleone Ferrara, MD	35,000	—	10,235	—	—	—	45,235
Robert J, Toth, Jr.	40,000	—	10,235	—	—	—	50,235

(1) For our fiscal year ended June 30, 2019, our directors were paid a $35,000 annual retainer, an additional $5,000 annual retainer for chairing a committee, and the chairman of the board was paid an additional annual retainer of $25,000.

(2) On November 8, 2018, independent directors were granted 4,000 stock options at an exercise price of $6.099. The options have a ten-year term and vest pro rata over one year from the date of grant.

(3) On April 30, 2019, the 20,000 Performance Stock Units issued under the 2017 Plan in fiscal 2018 to each of our independent directors were cancelled.

Risk Management

We do not believe risks arising from its compensation policies and practices for its employees are reasonably likely to have a material adverse effect on us.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information, as of September 6, 2019, with respect to the beneficial ownership of the outstanding common stock, reflecting our one-for-ten reverse stock split occurring on May 8, 2019, by (i) any holder of more than five (5%) percent; (ii) each of our executive officers and directors; and (iii) our 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	Percentage of Common Stock[2]
Directors and Officers:		
Saiid Zarrabian	60,290[3]	*
Dennis Brown, PhD	90,888[4]	*
Scott Praill	25,955[5]	*
Robert E. Hoffman	5,466[6]	*
John K. Bell	21,567[7]	*
Robert J. Toth, Jr.	10,873[8]	*
Lynda Cranston	9,979[9]	*
Napoleone Ferrara, MD	5,938[10]	*
Jeffrey Bacha	104,063[11]	*
All officers and directors as a group (9 persons)	335,019	2.93%

* 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.

(2) Applicable percentage ownership is based on 10,913,483 shares of common stock outstanding as of September 6, 2019, together with securities exercisable or convertible into shares of common stock within 60 days of September 6, 2019 for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC and 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 6, 2019 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.

(3) Includes 54,200 shares issuable upon the exercise of vested stock options.

(4) Includes 53,750 shares held by Valent Technologies, LLC, 20,820 shares issuable upon exercise of vested stock options, 2,125 shares issuable upon exercise of warrants held by Dr. Brown, and 750 shares issuable upon the conversion of Series B Preferred Stock.

(5) Includes 16,381 shares issuable upon exercise of vested stock options, 1,250 shares issuable upon exercise of warrants and 938 shares upon the conversion of Series B Preferred Stock.

(6) Includes 5,466 shares issuable upon exercise of vested stock options.

(7) Includes 9,701 shares owned by Onbelay Capital, Inc., 1,250 shares issuable upon exercise of warrants held by Onbelay Capital, Inc., 9,366 shares issuable upon exercise of vested stock options, and 1,250 shares issuable upon the conversion of Series B Preferred Stock held by Onbelay Capital, Inc.

(8) Includes 9,366 shares issuable upon exercise of vested stock options and 325 shares issuable upon the conversion of Series B Preferred Stock.

(9) Includes 9,366 shares issuable upon exercise of vested options and 313 shares issuable upon the conversion of Series B Preferred Stock.

(10) Includes 5,938 shares issuable upon exercise of vested stock options.

(11) Includes 625 shares issuable upon the exchange of Exchangeable Shares held in trust, 21,860 shares issuable upon exercise of vested stock options, and 1,500 shares issuable upon exercise of warrants.

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, 2019:

Plan	Number of securities to be issued upon exercise of outstanding options and rights	Weighted-average exercise price of outstanding options and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column
Equity compensation plans approved by security holders (1)	122,698	$ 8.81	491,817
Equity compensation plans not approved by security holders – Del Mar (BC) 2013 Amended and Restated Stock Option Plan	165,485	$ 32.32	-
Totals	288,183	$ 22.31	491,817

(1) As approved by our stockholders at the annual meeting of stockholders held on April 11, 2018, on July 7, 2017, as amended on February 1, 2018, our Board of Directors approved adoption of our 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, 780,000 shares of our common stock are reserved for issuance, less the number of shares of common stock issued under the Del Mar (BC) 2013 Amended and Restated Stock Option Plan (the "Legacy Plan") or that are subject to grants of stock options made, or that may be made, under the Legacy Plan. A total of 122,698 shares of common stock, net of forfeitures, have been issued under the Legacy Plan and/or are subject to outstanding stock options granted under the Legacy Plan, and a total of 165,485 shares of common stock have been issued under the 2017 Plan and/or are subject to outstanding stock options granted under the 2017 Plan leaving a potential 491,817 shares of common stock available for issuance under the 2017 Plan if all such options under the Legacy Plan were exercised and no new grants are made under the Legacy Plan. The maximum number of shares of our common stock with respect to which any one participant may be granted awards during any calendar year is 8% of our fully diluted shares of common stock on the date of grant (excluding the number of shares of common stock issued under the 2017 Plan and/or the Legacy Plan or subject to outstanding awards granted under the 2017 Plan and/or 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, Del Mar (BC) entered into a Patent Assignment Agreement (the "Assignment") with Valent Technologies LLC pursuant to which Valent assigned to Del Mar (BC) its rights to patent applications and the prototype drug product related to VAL-083. In accordance with the Assignment the consideration paid by Del Mar (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 Del Mar (BC) terminates the agreement, Del Mar (BC) may be entitled to receive royalties from Valent's subsequent development of VAL-083 depending on the development milestones Del Mar (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 Del Mar (BC) breaches its payment obligations and fails to remedy such breach within 60 days, or if either party materially beaches 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 Del Mar (BC) and Valent, Valent loaned Del Mar $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, we 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 our preferred stock. The preferred stock has an annual 3% dividend.

One of our, Dr. Dennis Brown, is a principal of Valent and as result Valent is a related party to us.

Director Independence

John K. Bell, Robert J. Toth, Jr., Lynda Cranston, Robert E. Hoffman, and Napoleone Ferrara, MD 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 our new auditors.

PricewaterhouseCoopers LLP ("PwC"), Chartered Professional Accountants, were our auditors until October 4, 2016.

The following is a summary of fees paid by us for professional services rendered by E&Y for the years ended June 30, 2019 and June 30, 2018.

	Year Ended June 30, 2019	Year Ended June 30, 2018
Audit fees	$ 132,800	$ 137,800
Audit related fees	$ 182,800	$ 22,000
Tax fees	$ -	$ -
All other fees	$ -	$ -
Total fees	$ 315,600	$ 159,800

Audit fees. Audit fees represent fees for professional services performed by E&Y 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 that are reasonably related to the performance of the audit or review of our financial statements.

Tax Fees. E&Y has not performed any tax compliance services for us during the years ended June 30, 2019 or 2018.

All other fees. E&Y did not receive any other fees from us for the years ended June 30, 2019 or 2018.

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, in 2019 and 2018 were approved by the audit committee.

PART IV

Item 15. Exhibits.

2.1	Exchange Agreement, dated January 25, 2013, among the Company, Exchangeco, Callco, Del Mar (BC) and securityholders of Del Mar (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)
3.10	The Certificate of Amendment to the Articles of Incorporation, as amended, of DelMar Pharmaceuticals Inc., dated April 11, 2018 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2018)
3.11	Certificate of Correction to the Company's articles of incorporation, filed with the Secretary of State of the State of Nevada on April 17, 2019 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on April 17, 2019)
3.12	Certificate of Change of DelMar Pharmaceuticals, Inc., dated May 7, 2019 and effective May 8, 2019 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on May 8, 2019)
3.13	Certificate of Amendment to the Articles of Incorporation, as amended, of DelMar Pharmaceuticals Inc., dated June 26, 2019 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on June 28, 2019)

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)
4.12	Form of Warrant Certificate (incorporated by reference to Exhibit 4.1 of Amendment No. 1 to the Company's Current Report on Form 8-K/A filed with the SEC on August 15, 2019)
4.13	Form of Pre-Funded Warrant Certificate (incorporated by reference to Exhibit 4.2 of Amendment No. 1 to the Company's Current Report on Form 8-K/A filed with the SEC on August 15, 2019)
4.14	Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.3 of Amendment No. 1 to the Company's Current Report on Form 8-K/A filed with the SEC on August 15, 2019)
4.15	Form of Warrant Agency Agreement (incorporated by reference to Exhibit 4.4 of Amendment No. 1 to the Company's Current Report on Form 8-K/A filed with the SEC on August 15, 2019)
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 Del Mar (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 Del Mar (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 Del Mar (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 Del Mar (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 Del Mar (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 Del Mar (BC) and Scott Praill (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 (As Amended and Restated Effective as of February 1, 2018) (incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q filed with the SEC on February 14, 2018)
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)
10.25	Settlement Agreement, dated January 1, 2018, between Delmar Pharmaceuticals, Inc. and Jeffrey Bacha (incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed with the SEC on February 14, 2018
10.26	Agreement, effective as of November 3, 2017 between the Company and Mr. Zarrabian (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on November 8, 2017
10.27	Employment agreement, effective as of May 21, 2018 between the Company and Mr. Zarrabian (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on May 22, 2018, 2017
10.28	Placement Agency Agreement, dated June 3, 2019, among the Company, Maxim Group LLC and Dawson James Securities, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on June 3, 2019)
10.29	Form of Purchase Agreement, dated as of June 3, 2019 among the Company and the purchasers thereunder (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on June 3, 2019)
10.30	Underwriting Agreement, dated as of August 14, 2019, among the Company, Maxim Group LLC and Dawson James Securities, Inc. (incorporated by reference to Exhibit 1.1 of Amendment No. 1 to the Company's Current Report on Form 8-K/A filed with the SEC on August 15, 2019)
10.31	Form of Leak-Out Agreement, dated as of August 14, 2019, among the Company and the signatories thereto (incorporated by reference to Exhibit 10.1 of Amendment No. 1 to the Company's Current Report on Form 8-K filed with the SEC on August 15, 2019)
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*
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 **
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

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 9, 2019

By: /s/ Saiid Zarrabian
Name: Saiid Zarrabian
Title: Chief Executive Officer
(principal executive officer)

Dated: September 9, 2019

By: /s/ Scott Praill
Name: Scott Praill
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.

SIGNATURE	*TITLE*	*DATE*
/s/ Saiid Zarrabian Saiid Zarrabian	Chief Executive Officer, Director (principal executive officer)	September 9, 2019
/s/ Scott Praill Scott Praill	Chief Financial Officer (principal financial and accounting officer)	September 9, 2019
/s/ Dennis Brown Dennis Brown	Chief Scientific Officer	September 9, 2019
/s/ John K. Bell John K. Bell	Director	September 9, 2019
/s/ Robert J. Toth Robert J. Toth	Director	September 9, 2019
/s/ Lynda Cranston Lynda Cranston	Director	September 9, 2019
/s/ Robert E. Hoffman Robert E. Hoffman	Director	September 9, 2019
/s/ Napoleone Ferrara Napoleone Ferrara	Director	September 9, 2019

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-213600) of DelMar Pharmaceuticals, Inc. and in the related prospectus,

(2) Registration Statement (Form S-3 No. 333-213601) of DelMar Pharmaceuticals, Inc. and in the related prospectus, and

(3) Registration Statement (Form S-3 No. 333-229020) of DelMar Pharmaceuticals, Inc. and in the related prospectus;

of our report dated September 9, 2019, with respect to the consolidated financial statements of DelMar Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of DelMar Pharmaceuticals, Inc. for the year ended June 30, 2019.

Vancouver, Canada,
September 9, 2019

/s/ Ernst & Young LLP
Chartered Professional Accountants

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Saiid Zarrabian, certify that:

1. I have reviewed this Annual Report on Form 10-K of DelMar Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: September 9, 2019

By: /s/ Saiid Zarrabian
Saiid Zarrabian
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Scott Praill, certify that:

1. I have reviewed this Annual Report on Form 10-K of DelMar Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: September 9, 2019

By: /s/ Scott Praill
Scott Praill
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of DelMar Pharmaceuticals, Inc. (the "Company") on Form 10-K for the fiscal year ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Saiid Zarrabian, Chief Executive Officer of the Company, certify to my knowledge and in my capacity, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 9, 2019

By: /s/ Saiid Zarrabian
Saiid Zarrabian
Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of DelMar Pharmaceuticals, Inc. (the "Company") on Form 10-K for the fiscal ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott Praill, Chief Financial Officer of the Company, certify to my knowledge and in my capacity, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 9, 2019

By: /s/ Scott Praill
Scott Praill
Chief Financial Officer