## UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

or

#### □ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

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	(I.R.S. Employer
incorporation or organization)	Identification No.)
Suite 720-999 West Broadway	
Vancouver, British Columbia, Canada	V5Z 1K5
(Address of principal executive offices)	(zip code)

<u>(604) 629-5989</u>

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes 🗹 No 🗆

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes 🗹 No 🗆

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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  $\Box$ Non-accelerated filer  $\Box$  (Do not check if smaller reporting company) Emerging growth company  $\Box$ 

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.  $\Box$ 

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes 🗆 No 🗹

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 21,601,475 shares of common stock are issued and outstanding as of November 8, 2017.

Accelerated filer  $\Box$ 

Smaller reporting company ☑

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Item 1. Financial Statements.

# **DelMar Pharmaceuticals, Inc.**

Consolidated Condensed Interim Financial Statements (Unaudited) For the three months ended September 30, 2017 (expressed in US dollars unless otherwise noted)

Consolidated Condensed Interim Balance Sheets (Unaudited)

(expressed in US dollars unless otherwise noted)

	Note	September 30, 2017 \$	June 30, 2017 \$
Assets			
Current assets			
Cash		13,156,485	6,586,014
Prepaid expenses and deposits		1,216,488	1,208,122
Taxes and other receivables		40,505	76,595
		14,413,478	7,870,731
Intangible assets - net		34,685	40,290
		14,448,163	7,911,021
Liabilities			
Current liabilities			
Accounts payable and accrued liabilities		1,438,182	1,182,312
Related party payables	4	86,567	88,957
Current portion of derivative liability	5	589	33,091
		1,525,338	1,304,360
Derivative liability	5	4,071	28,137
Stockholders' accumulated equity		1,529,409	1,332,497
Preferred stock			
Authorized			
5,000,000 shares, \$0.001 par value			
Issued and outstanding			
278,530 Series A shares at September 30, 2017 (June 30, 2017 – 278,530)	3,6	278,530	278,530
881,113 Series B shares at September 30, 2017 (June 30, 2017 – 881,113) 1 special voting share at September 30, 2017 (June 30, 2017 – 1)	6	6,146,880	6,146,880
Common stock			
Authorized			
50,000,000 shares, \$0.001 par value 22,559,235 issued at September 30, 2017 (June 30, 2017 – 14,509,633)	6	22.550	14,510
22,339,253 issued at September 50, $2017$ (June 50, $2017 - 14,509,055$ )	0	22,559	14,310
Additional paid-in capital	6	42,956,357	36,665,285
Warrants	6	7,321,844	4,570,574
Accumulated deficit		(43,828,594)	(41,118,433)
Accumulated other comprehensive income		21,178	21,178
		12,918,754	6,578,524
		14,448,163	7,911,021

Nature of operations, corporate history, and liquidity risk (note 1) Subsequent events (note 9)

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

Consolidated Condensed Interim Statement of Loss and Comprehensive Loss (Unaudited)

(expressed in US dollars unless otherwise noted)

		Three mont Septemb	
	Note	2017 \$	2016 \$
Expenses			
Research and development	6	1,934,643	732,729
General and administrative	6	744,621	1,316,639
		2,679,264	2,049,368
Other loss (income)			
Change in fair value of stock option and derivative liabilities	5,6	(56,568)	225,688
Foreign exchange loss		43,866	15,324
Interest income		(156)	(41)
		(12,858)	240,971
Net and comprehensive loss for the period		2,666,406	2,290,339
Computation of basic loss per share			
Net and comprehensive loss for the period		2,666,406	2,290,339
Series B Preferred stock dividend	6	41,666	307,298
		2,708,072	2,597,637
Basic and fully diluted loss per share		0.19	0.22
		0.18	0.23
Basic weighted average number of shares		15,292,781	11,301,989

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

Consolidated Condensed Interim Statement of Cash Flows (Unaudited)

(expressed in US dollars unless otherwise noted)

		Three mont Septemb	
		2017	2016
	Note	\$	\$
Cash flows from operating activities		· ·	
Loss for the period		(2,666,406)	(2,290,339)
Items not affecting cash			
Amortization of intangible assets		5,605	3,858
Change in fair value of stock option and derivative liabilities	5,6	(56,568)	225,688
Shares issued for services	6	-	564,000
Warrants issued for services	6	(1,481)	50,244
Stock option expense	6	64,870	31,818
Changes in non-cash working capital			
Taxes and other receivables		36,090	(19,969)
Prepaid expenses		(8,366)	(33,208)
Accounts payable and accrued liabilities		255,870	(178,161)
Related party payables	4	(2,390)	32,987
		(2,372,776)	(1,613,082)
Cash flows from financing activities			
Net proceeds from the issuance of shares and warrants	6	8,945,336	
Proceeds from the exercise of warrants	6	8,945,550	256,940
Series A preferred stock dividend	6	(2,089)	(2,089)
Series A preferred stock ulvidend	0	(2,089)	(2,089)
		8,943,247	254,851
		6,570,471	(1,358,231)
Increase (decrease) in cash		0,570,471	(1,556,251)
Cash - beginning of period		6,586,014	6,157,264
		12 156 495	4 700 022
Cash - end of period		13,156,485	4,799,033

# Supplementary information (note 8)

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

# 1 Nature of operations, corporate history, and liquidity risk

#### Nature of operations

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

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

#### **Corporate history**

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

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

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

## Liquidity risk

For the three months ended September 30, 2017, the Company reported a loss of \$2,666,406 and the Company had an accumulated deficit of \$43,828,594 at that date. As at September 30, 2017, the Company had cash on hand of \$13,156,485. During the three months ended September 30, 2017, the Company received \$8,945,336 in net proceeds from a registered direct offering. We believe, based on our current estimates, that we will be able to fund our operations beyond the next twelve months.

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

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

## 2 Significant accounting policies

#### **Basis of presentation**

The consolidated condensed interim financial statements of the Company have been prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP") and are presented in United States dollars. The functional currency of the Company and each of its subsidiaries is the United States dollar.

The accompanying consolidated condensed interim financial statements include the accounts of the Company and its wholly-owned subsidiaries, DelMar BC, Callco, and Exchangeco. All intercompany balances and transactions have been eliminated.

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

#### Unaudited interim financial data

The accompanying unaudited September 30, 2017 consolidated condensed interim balance sheet, the consolidated condensed interim statements of loss and comprehensive loss for the three months ended September 30, 2017 and 2016, and consolidated condensed cash flows for the three months ended September 30, 2017 and 2016, and the related interim information contained within the notes to the consolidated condensed interim financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission for interim financial information. Accordingly, they do not include all of the information and the notes required by U.S. GAAP for complete financial statements. These consolidated condensed interim financial statements should be read in conjunction with the audited financial statements of the Company as at June 30, 2017 included in our Form 10-K filed with the Securities and Exchange Commission on September 27, 2017. In the opinion of management, the unaudited consolidated condensed interim financial statements reflect all adjustments, consisting of normal and recurring adjustments, necessary for the fair statement of the Company's financial position at September 30, 2017 and results of its operations for the three months ended September 30, 2017 and 2016. The results for three months ended September 30, 2017 are not necessarily indicative of the results to be expected for the fiscal year ending June 30, 2018 or for any other future annual or interim period.

#### Use of estimates

The preparation of consolidated condensed interim financial statements in conformity with U.S. 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 liability, the valuation of equity instruments issued for services, and clinical trial accruals. There have been no changes to the methodology used in determining these estimates from the fiscal year ended June 30, 2017.

## Loss per share

Loss per share is calculated based on the weighted average number of common shares outstanding. For the three month period ended September 30, 2017 and 2016 diluted loss per share does not differ from basic loss per share since the effect of the Company's warrants and stock options are anti-dilutive. At September 30, 2017, potential common shares of 15,028,906 (2016 - 4,528,040) relating to warrants, 1,300,850 (2016 - 856,250) relating to stock options, and 2,202,792 (2016 - 2,255,605) relating to the Series B convertible preferred stock were excluded from the calculation of net loss per common share because their inclusion would be anti-dilutive.

#### **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.

Accounting Standards Update ("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 Nonpublic 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, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard. The adoption of this guidance is not expected to have a material impact on the consolidated, condensed financial statements.

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

The amendments in this update change existing guidance related to accounting for employee share-based payments affecting the income tax consequences of awards, classification of awards as equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual periods, with early adoption permitted. The Company has adopted this standard as of its September 30, 2017 quarter end.

#### ASU 2016-02 — Leases (Topic 842).

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

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

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

#### 3 Valent Technologies, LLC

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

For the three months ended September 30, 2017 and 2016 respectively, the Company recorded \$2,089 related to the dividend payable to Valent. The dividends have been recorded as a direct increase in accumulated deficit.

# 4 Related party transactions

Pursuant to employment and consulting agreements with the Company's officers the Company recognized a total of \$142,500 (2016 - \$120,000) in expenses for the three months ended September 30, 2017. Amounts owed to related parties are non-interest bearing and payable on demand.

The Company recognized \$52,500 (2016 - \$45,000) in directors' fees during the three months ended September 30, 2017.

As part of the Series B preferred stock dividend (note 6) the Company issued 1,511 (2016 - 1,511) shares of common stock to officers and directors of the Company and recognized \$1,269 (2016 - \$9,142) as a direct increase to accumulated deficit for the three months ended September 30, 2017.

The Company recorded \$2,089 (2016 - \$2,089) in dividends related to the Series A preferred stock issued to Valent (note 3) for the three months ended September 30, 2017.

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

# 5 Derivative liability

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

# 2013 Investor Warrants

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

As a result of the financing completed by the Company during the three months ended September 30, 2015 the exercise price of all of the 2013 Investor Warrants was reduced from \$3.20 to \$3.14. As a result of the financing completed by the Company during the three months ended September 30, 2017 the exercise price of the un-amended 2013 Investor Warrants was further reduced from \$3.14 to \$2.68. The change in exercise price did not result in a material change in the fair value of the derivative liability.



#### DelMar Pharmaceuticals, Inc. Notes to Consolidated Condensed Interim Financial Statements (Unaudited) September 30, 2017

(expressed in US dollars unless otherwise noted)

## 2013 Investor Warrant exercises

During the three months ended September 30, 2016, 42,907 of the 2013 Investor Warrants were exercised at an exercise price of \$3.14 per share. The Company received proceeds of \$134,900 from these exercises. The warrants that have been exercised were revalued at their respective exercise dates and then the reclassification to equity was recorded resulting in \$181,008 of the derivative liability being reclassified to equity.

There were no exercises of 2013 Investor Warrants during the three months ended September 30, 2017.

#### 2013 Investor Warrant amendments

During the year ended June 30, 2016, the Company entered into amendments (the "2013 Investor Warrant Amendments") with the holders of certain of the 2013 Investor Warrants to extend the expiration date to March 31, 2019 and remove the provision requiring an adjustment of the warrant exercise price in the event the Company sells common stock at a purchase price lower than the current warrant exercise price. During the three months ended September 30, 2016, 15,944 of the 2013 Investor Warrants were amended. The warrants that have been amended were revalued at their respective amendment dates and then the reclassification to equity was recorded resulting in \$53,006 of the derivative liability being reclassified to equity.

There were no amendments of the 2013 Investor Warrants during the three months ended September 30, 2017.

#### 2015 Agent Warrants

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

There were no exercises of the 2015 Agent Warrants during the three months ended September 30, 2017.

Notes to Consolidated Condensed Interim Financial Statements (Unaudited)

September 30, 2017

(expressed in US dollars unless otherwise noted)

The Company's derivative liability is summarized as follows:

		Three months ended September 30,	
	2017 \$	2016 \$	
Opening balance	61,228	693,700	
Change in fair value of warrants	(56,568)	140,594	
Reclassification to equity upon amendment of warrants	-	(53,006)	
Reclassification to equity upon exercise of warrants	-	(190,943)	
Closing balance	4,660	590,345	
Less current portion	(589)	-	
Long term portion	4,071	590,345	

The derivative liability consists of the following warrants:

	September	September 30, 2017	
	Number of warrants	\$	
2013 Investor Warrants	105,129	549	
Warrants issued for services	43,750	40	
2015 Agent Warrants	21,768	4,071	
Closing balance	170,647	4,660	
Less current portion	(148,879)	(589)	
Long-term portion	21,768	4,071	



Notes to Consolidated Condensed Interim Financial Statements (Unaudited) September 30, 2017

(expressed in US dollars unless otherwise noted)

# 6 Stockholders' equity

# Preferred stock

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

# Issued and outstanding

Special voting shares – at September 30, 2017 – 1 (June 30, 2017 – 1) Series A shares – at September 30, 2017 – 278,530 (June 30, 2017 – 278,530) Series B shares – at September 30, 2017 – 881,113 (June 30, 2017 – 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 2.5 shares of common stock equating to a conversion price of \$3.20 (the "Conversion Price") and will automatically convert to common stock at the earlier of 24 hours following regulatory approval of VAL-083 with a minimum closing bid price of \$8.00 or five years from the final closing date. The holders of the Series B Preferred Stock are entitled to an annual cumulative, in arrears, dividend at the rate of 9% payable quarterly. The 9% dividend accrues quarterly commencing on the date of issue and is payable quarterly on September 30, December 31, March 31, and June 30 of each year commencing on June 30, 2016. Dividends are payable solely by delivery of shares of common stock (the "PIK Shares"), 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.

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

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

Pursuant to the Series B Preferred Stock dividend, during the three months ended September 30, 2017, the Company issued 49,602 (2016 - 50,793) shares of common stock and recognized \$41,666 (2016 - \$307,298) as a direct increase in accumulated deficit.

A total of 881,113 (2016 - 902,238) shares of Series B Preferred Stock are outstanding as of September 30, 2017, such that a total of 2,202,792 (2016 - 2,255,605) shares of common stock are issuable upon conversion of the Series B Preferred Stock as at September 30, 2017. Converted shares are rounded up to the nearest whole share.

No shares of the Series B Preferred Stock were converted to common stock during the three months ended September 30, 2017 or 2016.

## DelMar Pharmaceuticals, Inc. Notes to Consolidated Condensed Interim Financial Statements (Unaudited) September 30, 2017

(expressed in US dollars unless otherwise noted)

## Series A Preferred Shares

Effective September 30, 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.

# **Common stock**

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

Issued and outstanding - September 30, 2017 - 22,559,235 (June 30, 2016 - 14,509,633)

	Shares of common stock outstanding	Common stock \$	Additional paid-in capital \$	Warrants \$	Accumulated deficit \$
Balance – June 30, 2017	14,509,633	14,510	36,665,285	4,570,574	(41,118,433)
Issuance of shares and warrants	8,000,000	8,000	6,184,585	2,752,751	-
Series B Preferred stock dividend	49,602	49	41,617	-	(41,666)
Stock option expense	-	-	64,870	-	-
Warrants issued for services	-	-	-	(1,481)	-
Series A Preferred cash dividend	-	-	-	-	(2,089)
Loss for the period	-	-	-	-	(2,666,406)
Balance – September 30, 2017	22,559,235	22,559	42,956,357	7,321,844	(43,828,594)

The issued and outstanding common shares at September 30, 2017 include 957,761 (June 30, 2017 - 982,761) shares of common stock on an as-exchanged basis with respect to the shares of Exchangeco that can be exchanged for shares of common stock of the Company.

## Three months ended September 30, 2017

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

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

In addition to the cash commission and other placement agent fees, the Company also incurred additional cash issue costs of \$254,664 resulting in net cash proceeds of \$8,945,336.

#### 2017 Omnibus Incentive Plan

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

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

#### **Performance Stock Unit grants**

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

Notes to Consolidated Condensed Interim Financial Statements (Unaudited)

September 30, 2017

(expressed in US dollars unless otherwise noted)

# Stock Options (granted under the Legacy Plan)

The following table sets forth the stock options outstanding under the Legacy Plan:

	Number of stock options outstanding	Weighted average exercise price \$
Balance – June 30, 2017	1,120,850	4.18
Granted	180,000	2.11
Balance – September 30, 2017	1,300,850	3.90

The following table summarizes stock options currently outstanding and exercisable at September 30, 2017 under the Legacy Plan:

Exercise price \$	Number Outstanding at September 30, 2017	Weighted average remaining contractual life (years)	Number exercisable at September 30, 2017
1.60	25,000	4.39	25,000
2.00	131,250	4.39	131,250
2.11	180,000	9.77	-
2.96	45,000	7.35	45,000
3.20	30,000	7.50	30,000
3.76	45,000	8.36	24,583
4.00	12,500	2.00	12,500
4.10	40,000	9.11	11,852
4.20	412,500	5.88	412,500
4.48	30,000	8.36	16,389
4.95	224,600	9.38	46,376
5.32	80,000	8.60	37,333
6.16	15,000	5.50	15,000
9.20	30,000	5.67	30,000
	1,300,850		837,783

Notes to Consolidated Condensed Interim Financial Statements (Unaudited)

September 30, 2017

(expressed in US dollars unless otherwise noted)

Included in the number of stock options outstanding are 25,000 stock options granted at an exercise price of CDN \$2.00. The exercise prices shown in the above table have been converted to \$1.60 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 revalued using a Black-Scholes pricing model using the following assumptions:

	September 30, 2017
Dividend rate	0%
Volatility	72.7% to 82.2%
Risk-free rate	1.5% to 1.8%
Term - years	1.3 to 3.0

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

		Three months ended September 30,	
	2017 \$	2016 \$	
Research and development General and administrative	(4,974)	30,715	
General and administrative	69,844	1,103	
	64,870	31,818	

All of the stock option expense for the periods ended September 30, 2017 and 2016 has been recognized as additional paid in capital. The aggregate intrinsic value of stock options outstanding at September 30, 2017 was \$nil (2016 - \$1,982,263) and the aggregate intrinsic value of stock options exercisable at September 30, 2017 was also \$nil (2016 - \$1,728,712). As of September 30, 2017, there was \$381,265 in unrecognized compensation expense that will be recognized over the next 2.75 years. No stock options granted under the Plan have been exercised to September 30, 2017. Upon the exercise of stock options new shares will be issued.

Notes to Consolidated Condensed Interim Financial Statements

(Unaudited) September 30, 2017

(expressed in US dollars unless otherwise noted)

A summary of status of the Company's unvested stock options under the Legacy Plan is presented below:

	Number of Options	Weighted average exercise price §	Weighted average grant date fair value \$
Unvested at June 30, 2017	318,033	4.81	2.57
Granted	180,000	2.11	1.13
Vested	(34,966)	4.78	2.58
Unvested at September 30, 2017	463,067	3.76	2.03

# Stock option liability

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

# Warrants

Certain of the Company's warrants have been recognized as a derivative liability (note 5). The following table summarizes changes in the Company's outstanding warrants as of September 30, 2017:

Description	Number
Balance – June 30, 2017	6,628,906
Issuance of 2018 Investor Warrants (i)	8,000,000
Issuance of 2018 Agent Warrants (ii)	400,000
Balance - September 30, 2017	15,028,906

i) The 2018 Investor Warrants are exercisable at \$1.25 per share until September 22, 2022.

ii) The 2018 Agent Warrants are exercisable at \$1.25 per share until September 20, 2022.



Notes to Consolidated Condensed Interim Financial Statements (Unaudited)

September 30, 2017

(expressed in US dollars unless otherwise noted)

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

		Exercise price	
Description	Number	\$	Expiry date
2017 In action	2.07(.024	2.50	A
2017 Investor	2,076,924		April 19, 2022
2013 Placement Agent	1,262,500	3.14	June 30, 2019
2018 Investor	8,000,000	1.25	September 22, 2022
2015 Investor	979,003	3.00	July 31, 2020
2013 Investor – Amended	778,504	3.14	March 31, 2019
2013 Investor – Un-amended (note 5)	105,129	2.68	January 25 to March 6, 2018
Dividend	812,502	5.00	January 24, 2018
Issued for services	265,000	3.00	March 1, 2020 to February 1, 2021
Issued for services	43,750	7.04	September 12, 2018
Issued for services	41,400	5.93	February 27, 2020
2018 Agent	400,000	1.25	September 20, 2022
2017 Agent	138,462	4.06	April 12, 2022
2016 Agent	103,964	4.00	May 12, 2021
2015 Agent	21,768	3.00	July 15, 2020
	15,028,906	2.25	

# 7 Financial instruments

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

- Level one inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level two inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals; and
- Level three unobservable inputs developed using estimates and assumptions, which are developed by the reporting entity and reflect those assumptions that a market participant would use.



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

The Company's financial instruments consist of cash and cash equivalents, other receivables, accounts payable, related party payables and derivative liability. The carrying values of cash and cash equivalents, other receivables, accounts payable and related party payables approximate their fair values due to the immediate or short-term maturity of these financial instruments.

#### Derivative liability

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

#### a) Fair value of derivative liability

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



Notes to Consolidated Condensed Interim Financial Statements (Unaudited) September 30, 2017

(expressed in US dollars unless otherwise noted)

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

	September 30, 201	17
Liability	Level 1 Level 2	Level 3
Derivative liability	<u> </u>	\$ 4,660
	June 30, 2017	
Liability	Level 1 Level 2	Level 3
Derivative liability	<u> </u>	\$ 61,228

# 8 Supplementary statement of cash flows information

	Three months ended September 30,	
	2017 2016	
	<u> </u>	\$
Reclassification of derivative liability to equity upon the exercise of warrants (note 5)	-	190,943
Reclassification of derivative liability to equity upon the amendment of warrants (note 5)	-	53,006
Reclassification of stock option liability to equity upon settlement (note 6)	-	260,969
Series B Preferred share common stock dividend (note 6)	41,666	307,298
Income taxes paid	-	-
Interest paid	-	-

# 9 Subsequent events

Subsequent to September 30, 2017, the Company granted 120,000 stock options to an officer and director of the Company. The options are exercisable at a price of \$0.87 until November 3, 2027. The options vest pro rata monthly over one year commencing December 3, 2017.

## Item 2. 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 the Company or any other person that the events or plans of the Company will be achieved. You should not unduly rely on these forward-looking statements, which speak only as of the date of this report. Except as may be required under applicable securities laws, we undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this report or to reflect the occurrence of unanticipated events.

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

# **Recent Highlights**

- We strengthened our management team by appointing Saiid Zarrabian as Interim Chief Executive Officer. Mr. Zarrabian's experience in overseeing the growth of multiple companies will augment DelMar's management as we continue to transition to a late-stage development company and seek additional opportunities to maximize shareholder value. Jeffrey Bacha will retain his position as President of the Company and a member of the Board and will also serve as the Company's Chief Operating Officer.
- During the quarter ended September 30, 2017, we initiated our pivotal STAR-3 clinical trial of VAL-083 in refractory glioblastoma multiforme ("GBM") and enrolled our first patient. The STAR-3 trial is designed to enroll 180 patients whose glioblastoma has recurred following standard of care treatment. There are currently no approved treatment options for these patients.
- In April and September 2017, we completed offerings of common stock and warrants for aggregate gross proceeds of approximately \$19 million. We intend to use the net proceeds of these offerings for our clinical trials and for general corporate purposes, which may include working capital, capital expenditures, research and development and other commercial expenditures. In addition, we may use the net proceeds from these offerings for acquisitions or investments in businesses, products or technologies that are complementary and accretive to our business.
- In September 2017, we initiated patient recruitment for an open label Phase 2 clinical trial of VAL-083 in newly diagnosed patients with MGMT-unmethylated GBM, which is being conducted with funding support through our collaboration with Guangxi Wuzhou Pharmaceutical (Group) Co. Ltd. This trial complements our ongoing open label Phase 2 clinical trial in patients with MGMT-unmethylated GBM whose tumors have recurred following treatment with temozolomide (bevacizumab naïve), which is being conducted in collaboration with the University of Texas MD Anderson Cancer Center.
- In September 2017, we received notice of allowance from the FDA for our Phase 1-2 VAL-083 REPROVe clinical trial in Ptresistant ovarian cancer. We will seek to initiate the REPROVe trial as soon as practicable, subject to negotiating acceptable clinical research agreements and budgets with clinical investigators and their institutions and obtaining IRB approvals.

- We presented promising research results supporting the potential of VAL-083 in the treatment of a range of cancers for patients whose tumors exhibit features that make them resistant to, or unlikely to respond to, currently available therapies. For example:
  - At the American Association for Cancer Research ("AACR")-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics we presented data suggesting the potential for synergy with treatments that depend on a cancer cell to be in the S-phase for activity. Such agents include topoisomerase inhibitors, commonly used in the treatment of brain cancer and other solid tumors, and PARP inhibitors, commonly used in the treatment of ovarian cancer;
  - At AACR's Special Conference: Addressing Critical Questions in Ovarian Cancer Research and Treatment we presented data demonstrating how VAL-083 targets the DNA of cancer cells in a mechanistically different fashion than platinum-based chemotherapeutic agents or PARP inhibitors, and how these differences position VAL-083 as a potential new therapeutic option in the treatment of ovarian cancer;
  - We presented data supporting the effectiveness of VAL-083 in the treatment of GBM at the annual meetings of the American Society for Clinical Oncology ("ASCO"), the American Association of Cancer Research ("AACR"), the World Federation of NeuroOncology Societies ("WFNOS"), the European Association for NeuroOncology, and the Society for NeuroOncology ("SNO"); and
  - We presented data supporting the activity of VAL-083 in treatment-resistant medulloblastoma both as a single agent and in combination with topoisomerase inhibitors at the SNO Pediatric Oncology Symposium and at the AACR Advances in Pediatric Research: From Mechanisms and Models to Treatment and Survivorship Conference.
- The US patent office granted DelMar a new patent covering improved analytical methods related to the manufacturing of the Company's lead compound, VAL-083. DelMar now holds eight issued US patents and eight issued patents outside the US. We have fourteen patent families in various stages of prosecution with over 100 patent filings in total.

# Overview

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

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



# VAL-083

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

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

We are currently studying VAL-083 in clinical trials for the treatment of GBM, the most common and aggressive form of brain cancer. We have also recently received notice of allowance from the FDA for an Investigational New Drug ("IND") to initiate clinical trials with VAL-083 in the treatment of ovarian cancer.

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

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

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

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

Based on published research and our own data, the cytotoxic functional groups and the mechanism of action of VAL-083 are 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 *in vitro* 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 trials. We believe that these historical clinical data and our own research support the development of VAL-083 as a potential new treatment for multiple cancers.



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

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

# Gliomas and Glioblastoma Multiforme ("GBM")

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

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

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

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

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

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

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

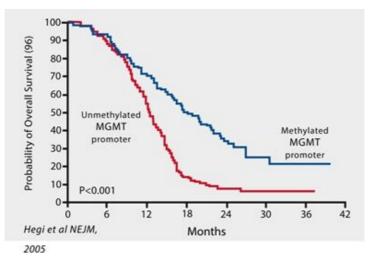
A majority of GBM patients' tumors are resistant to TMZ or nitrosourea therapy due to high expression of a naturally occurring enzyme called  $O^6$ -DNA methylguanine methyl-transferase ("MGMT") which repairs  $O^6$ -guanine lesions. MGMT repair in turn inhibits the activity of TMZ and nitrosoureas and allows a patient's GBM tumor to continue to grow despite treatment.



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

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





### VAL-083 in GBM

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

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

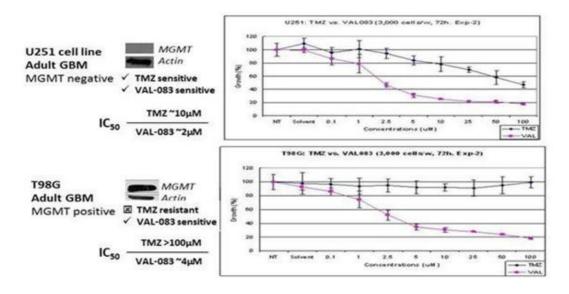
# A Summary of Published Data adapted from Separate Sources Comparing the Efficacy of VAL-083 and Other Therapies in the Treatment of GBM

	Comparat	Median Survival Benefit vs.	
Chemotherapy	py Radiation (XRT) Alone Radiation + Chemotherap		XRT alone
VAL-083			
(Eagan 1979)	8.4 months	16.8 months	8.4 months
Temozolomide (Temodar $^{\mathbb{R}}$ )			
(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

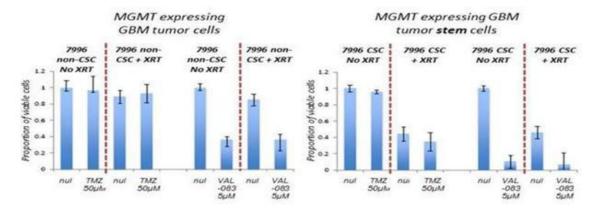
Our research, along with that of others, demonstrates that VAL-083's unique cytotoxic mechanism forms DNA cross-links at the N<sup>7</sup> position of guanine and retains cytotoxic activity independent of MGMT expression *in vitro*. This mechanism is distinct from that of temozolomide and nitrosoureas,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

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

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



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



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

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

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

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

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

The STAR-3 trial is designed to enroll up to 180 eligible patients that will be randomized at approximately 25 centers in the United States to receive either the investigational drug (VAL-083) or "investigator's choice salvage therapy" in a 2:1 fashion. Up to 120 eligible patients will be randomized to receive intravenous VAL-083 at 40 mg/m2 on days 1, 2, and 3 of a 21-day treatment cycle, for up to 12, 21-day treatment cycles or until they fulfill one of the criteria for study discontinuation, and up to 60 patients will be randomized to "investigator's choice" control, limited to temozolomide, lomustine, or carboplatin, until they fulfill one of the criteria for study discontinuation.

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

A detailed description of the STAR-3 trial can be found at clinicaltrials.gov, Identifier Number: NCT03149575.

# Phase 1 – 2 Clinical Trial Overview and Summary of Results

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

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

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

Patients received VAL-083 on days 1,2 and 3 on a 21-day treatment cycle. The Phase 1 portion of the study involved dose escalation cohorts until a maximum tolerated dose ("MTD") was established at 40mg/m<sup>2</sup>. 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, registrationdirected 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 DelMar's other planned clinical trials in related GBM populations, when assessing the New Drug Application ("NDA"). The FDA also noted that DelMar can rely on prior NCI studies and historical literature to support nonclinical data required for an NDA filing under 505(b)(2) which allows a sponsor to rely on already established safety and efficacy data in support of an NDA.

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

# Tumor Response and Outcomes

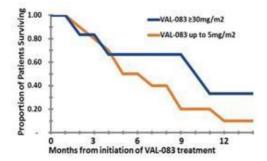
GBM patients in our Phase 1/2 clinical trial were not re-resected prior to treatment with VAL-083 and therefore had a growing recurrent GBM tumor at the time of enrollment. Patients were monitored for tumor response by MRI.

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

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

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

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



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

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

Reference	Post Avastin Salvage Therapy	Median Survival following Bevacizumab Failure
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 trial, we believe these outcomes support the potential of VAL-083 to offer meaningful clinical benefit to GBM patients who have failed bevacizumab, compared to currently available therapy.

## Safety and Tolerability

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

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

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



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

Hematologic parameter and CTCAE grade	dose	≤30 mg/n	$n^2$	40 mg/m	2 <sup>2</sup>	45 mg/m	2	50 mg/n	$n^2$
	<u>n =</u>	20		10 mg/m	<u> </u>	4	<u> </u>	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%
2 contop child	 G3	1	5%	-	0%	-	0%	3	43%
	G4	-	0%	-	0%	2	50%	-	0%
Neutropenia	≤G2	4	20%	-	0%	-	0%	-	0%
	G3	-	0%	-	0%	-	0%	3	43%
	G4	-	0%	-	0%	2	50%	1	14%
Thrombocytopenia	≤G2	9	45%	3	18%	-	0%	3	43%
· · · · · · · · · · · ·	G3	_	0%	_	0%	1	25%	3	43%
	G4	-	0%	1	6%	2	50%	1	14%
DLT Observed			nil		1		2		2

# Doses Achieved

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

Dosing Regimen & Study	Single Dose	Acute Regime	en (single cycle)	Comparative Cumulative Dose (@ 35 days)	Dose Intensity (dose per week)
NCI GBM historical regimen (Eagan etal) daily x 5 q 5wks (cycle = 35 days)	25 mg/m <sup>2</sup>	x5 days =	125 mg/m <sup>2</sup>	125 mg/m <sup>2</sup>	25 mg/m <sup>2</sup> /wk
DelMar VAL-083 optimized regimen daily x 3 q 3wks (cycle = 21 days)	40 mg/m <sup>2</sup>	x3 days =	120 mg/m <sup>2</sup>	240 mg/m <sup>2</sup>	40 mg/m <sup>2</sup> /wk

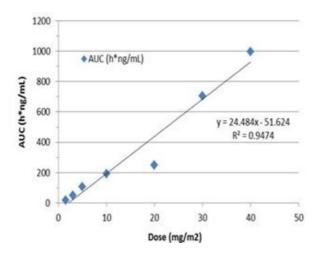
Daily x 5 q 5wks refers to a dosing regimen of once per day for five consecutive days every five weeks (35-day cycle); while daily x 3 q 3wks refers to a dosing regimen of once per day for three consecutive days every three weeks (21-day cycle).

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

# **Pharmacokinetics**

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

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



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

Based on observed and previously published pharmacokinetics, DelMar believes that therapeutic doses equal to, or above,  $20 \text{ mg/m}^2$  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.

#### MGMT & IDH1

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

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

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

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

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

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

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

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

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

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

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

# Phase 2 Trial in Newly Diagnosed MGMT-unmethylated GBM

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

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

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

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

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

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

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

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

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

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

A detailed description of this trial can be found at clinicaltrials.gov, Identifier Number: NCT03050736.

# **Ovarian Cancer**

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

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.

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



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

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

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

# Treatment Resistance to Pt-based Chemotherapy in Ovarian Cancer

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

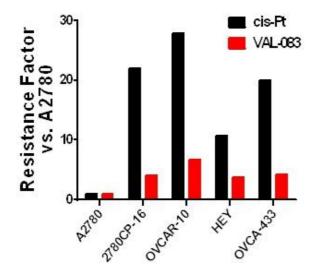
Pt-based chemotherapies function by causing extensive damage to a cancer cell's DNA. When a cell is ready to divide, cellular mechanisms assess potential DNA damage, and if severe damage is identified, the cell will halt the division process and may even be directed to self-destruct. Thus, chemotherapies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

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

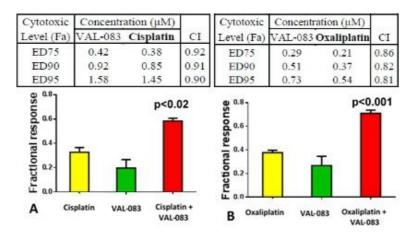
# VAL-083 in Ovarian Cancer

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

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



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



The combination of VAL-083 with either cisplatin (A) or oxaliplatin (B) in the human H460 (WT p53) NSCLC model demonstrated significant superadditivity ( $p\leq0.05$ ) 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.

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

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

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

## VAL-083 REPROVe Ovarian Cancer Trial

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

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

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

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

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

We will seek to initiate the REPROVe trial as soon as practicable, subject to negotiating acceptable clinical research agreements and budgets with clinical investigators and their institutions and obtaining IRB approvals.

A detailed description of the REPROVe trial can be found at clinicaltrials.gov, Identifier Number: NCT03281681.

## **Other Indications for VAL-083**

### VAL-083 in Lung Cancer

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

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

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

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

DelMar has developed new nonclinical data to support the utility of VAL-083 in the modern treatment of lung cancer. In an established murine xenograft model of NSCLC, the activity of VAL-083 was compared to standard platinum-based therapy with cisplatin against human NSCLC cell lines A549 (TKI-sensitive) and H1975 (TKI-resistant). In the study, VAL-083 demonstrated superior efficacy and safety in the treatment of TKI-susceptible (A549) tumors and in TKI-resistant (H1975) tumors.

Based on these data, we believe VAL-083's unique mechanism of action could make it a valuable drug of choice in NSCLC patients who are or become resistant to platinum-based chemotherapy and TKI therapy. In addition, VAL-083 readily crosses the blood brain barrier suggesting that it may be possible for VAL-083 to treat patients whose lung cancer has spread to the brain.

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

### 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 trial protocol into two separate studies: one focusing solely on refractory GBM and the other focusing on secondary brain cancers caused by other tumors that have spread to the brain.

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

### Pediatric Brain Tumors

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

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

## **Additional Indications for VAL-083**

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

## **Other Product Opportunities**

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



## **Corporate History**

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

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

## **Outstanding Securities**

As of November 9, 2017, the Company has 21,601,475 shares of common stock issued and outstanding, 957,761 shares of common stock issuable upon exchange of the Exchangeable Shares of Exchangeco (which entitle the holder to require Exchangeco to redeem (or, at the option of the Company or Callco, to have the Company or Callco purchase) the Exchangeable Shares, and upon such redemption or purchase to receive an equal number of shares of common stock of the Company) (the Exchangeable Shares are recognized on an as-exchanged for common stock basis for financial statement purposes), outstanding warrants to purchase 15,028,906 shares of common stock, 881,113 outstanding shares of Series B Preferred Stock that are convertible into 2,202,792 shares of common stock, and outstanding stock options to purchase 1,420,850 shares of common stock. 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 2.5 shares of common stock.

## **Related Parties**

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

Pursuant to employment and consulting agreements with the Company's officers the Company recognized a total of \$142,500 (2016 - \$120,000) in expenses for the three months ended September 30, 2017. Amounts owed to related parties are non-interest bearing and payable on demand.

The Company recognized \$52,500 (2016 - \$45,000) in directors' fees during the three months ended September 30, 2017.

As part of the Series B preferred stock dividend (note 6) the Company issued 1,511 (2016 - 1,511) shares of common stock to officers and directors of the Company and recognized 1,269 (2016 - 1,200) as a direct increase to accumulated deficit for the three months ended September 30, 2017.

The Company recorded \$2,089 (2016 - \$2,089) in dividends related to the Series A preferred stock issued to Valent (note 3) for the three months ended September 30, 2017.

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

## **Derivative Liability**

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

## 2013 Investor Warrants

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

As a result of the financing completed by the Company during the three months ended September 30, 2015 the exercise price of all of the 2013 Investor Warrants was reduced from \$3.20 to \$3.14. As a result of the financing completed by the Company during the three months ended September 30, 2017 the exercise price of the un-amended 2013 Investor Warrants was further reduced from \$3.14 to \$2.68. The change in exercise price did not result in a material change in the derivative liability.

## 2013 Investor Warrant exercises

During the three months ended September 30, 2016, 42,907 of the 2013 Investor Warrants were exercised at an exercise price of \$3.14 per share. The Company received proceeds of \$134,900 from these exercises. The warrants that have been exercised were revalued at their respective exercise dates and then the reclassification to equity was recorded resulting in \$181,008 of the derivative liability being reclassified to equity.

There were no exercises of 2013 Investor Warrants during the three months ended September 30, 2017.

## 2013 Investor Warrant amendments

During the year ended June 30, 2016, the Company entered into amendments (the "2013 Investor Warrant Amendments") with the holders of certain of the 2013 Investor Warrants to extend the expiration date to March 31, 2019 and remove the provision requiring an adjustment of the warrant exercise price in the event the Company sells common stock at a purchase price lower than the current warrant exercise price. During the three months ended September 30, 2016, 15,944 of the 2013 Investor Warrants were amended. The warrants that have been amended were revalued at their respective amendment dates and then the reclassification to equity was recorded resulting in \$53,006 of the derivative liability being reclassified to equity.

There were no amendments of the 2013 Investor Warrants during the three months ended September 30, 2017.

## **2015 Agent Warrants**

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

There were no exercises of the 2015 Agent Warrants during the three months ended September 30, 2017.



The Company's derivative liability is summarized as follows:

	Three months ended September 30,	
2017	2016	
\$	\$	
61,228	693,700	
(56,568)	140,594	
-	(53,006)	
<u> </u>	(190,943)	
4,660	590,943	
(589)	-	
4.071	590.943	
	Septembe 2017 \$ 61,228 (56,568) - 4,660	

The derivative liability consists of the following warrants:

	September	September 30, 2017	
	Number of warrants	\$	
2013 Investor Warrants	105,129	549	
Warrants issued for services	43,750	40	
2015 Agent Warrants	21,768	4,071	
Closing balance	170,647	4,660	
Less current portion	(148,879)	(589)	
Long-term portion	21,768	4,071	

# **Selected Quarterly Information**

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

Selected Balance Sheet Data

Working capital 12,888,140 6,566,3   Total assets 14,448,163 7,911,0		September 30, 2017 \$	June 30, 2017 \$
Total assets 14,448,163 7,911,0	Cash and cash equivalents	13,156,485	6,586,014
	Working capital	12,888,140	6,566,371
	Total assets	14,448,163	7,911,021
Derivative liability 4,660 61,2	Derivative liability	4,660	61,228
Total stockholders' equity 12,918,754 6,578,5	Total stockholders' equity	12,918,754	6,578,524



## Selected Statement of operations data

## For the three months ended:

	September 30, 2017 \$	September 30, 2016 \$
Research and development	1,934,643	732,729
General and administrative	744,621	1,316,639
Change in fair value of stock option and derivative liabilities	(56,568)	225,688
Foreign exchange loss	43,866	15,324
Interest income	(156)	(41)
Net and comprehensive loss for the period	2,666,406	2,290,339
Series B Preferred stock dividend	41,666	307,298
Net and comprehensive loss available to common stockholders	2,708,072	2,597,637
Basic weighted average number of shares outstanding	15,292,781	11,301,989
Basic and fully diluted loss per share	0.18	0.23

## Expenses net of share-based payments

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

## For the three months ended:

	September 30, 2017 \$	September 30, 2016 \$
Research and development	1,934,643	732,729
Share-based expenses included in research and development	4,974	(55,837)
Research and development net of non-cash	1,939,617	676,892
General and administrative	744,621	1,316,639
Share-based expenses included in general and administrative	(68,363)	(590,225)
General and administrative net of non-cash	676,258	726,414

## **Results of Operations**

# Comparison of the three months ended September 30, 2017 and September 30, 2016

	Three Months Ended			
	September 30, 2017 \$	September 30, 2016 \$	Change \$	Change %
Research and development	1,934,643	732,729	1,201,914	164
General and administrative	744,621	1,316,639	(572,018)	(43)
Change in fair value of stock option and derivative liabilities	(56,568)	225,688	(282,256)	(125)
Foreign exchange loss	43,866	15,324	28,542	186
Interest income	(156)	(41)	(115)	280
Net loss and comprehensive loss	2,666,406	2,290,339	376,067	



#### Research and Development

Research and development expenses increased to \$1,934,643 for the three months ended September 30, 2017 from \$732,729 for the three months ended September 30, 2016. The increase was largely attributable to an increase in clinical development costs with smaller impacts from an increase in intellectual property and preclinical research expenses. Partially offsetting these increases was a decrease in non-cash expenses during the three months ended September 30, 2017 non-cash expense related to stock option expense only while for the three months ended September 30, 2017 non-cash expense related to stock option expense of \$4,974 while non-cash expense for the three months ended September 30, 2017 was the result of a reversal of stock option expense of \$4,974 while non-cash expense for the three months ended September 30, 2016 was \$55,837. The change was due to a higher share price in the prior quarter compared to the current quarter resulting in a lower expense due to revaluation of unvested options.

Excluding the impact of non-cash expense, research and development expenses increased to \$1,939,617 during the current quarter from \$676,892 for the prior quarter. The increase in clinical costs for the three months ended September 30, 2017 compared to the three months ended September 30, 2016 was primarily due to manufacturing costs and initiation expenses for the commencement of enrollment for the Company's pivotal STAR-3 study. Also, during the current quarter, enrollment in the Company's Phase II GBM trial in unmethylated patients being conducted at the MD Anderson Cancer Center was ongoing while in the prior quarter, the study had not yet commenced. Intellectual property costs increased in the three months ended September 30, 2017 compared to the three months ended September 30, 2016 as the Company continued to expand and advance its patent portfolio. New patents filed in previous periods require on-going costs to advance those filings in the United States and in foreign jurisdictions. Patent costs can vary considerably depending on the filing of new patents, conversion of the provisional applications to PCT applications, foreign office actions, and actual filing costs. During the three months ended September 30, 2017 the Company announced the issuance of its eighth U.S. patent. Preclinical research increased primarily due to an increase in the ongoing mechanism of action research that the Company has undertaken in the current period.

## General and Administrative

General and administrative expenses were \$744,621 for the three months ended September 30, 2017 compared to \$1,316,639 for the three months ended September 30, 2016. The decrease was primarily due to a decrease in non-cash expenses in the current quarter compared to the prior quarter. In relation to general and administrative expenses during the three months ended September 30, 2017, the Company incurred non-cash expenses of \$68,363 relating to warrants issued for services and stock option expenses while during the three months ended September 30, 2016, the Company incurred non-cash expenses relating to shares and warrants issued for services, and stock option expense.

Excluding the impact of non-cash expenses, general and administrative expenses decreased in the three months ended September 30, 2017 to \$676,258 from \$726,414 for the three months ended September 30, 2016. Professional fees incurred during the three months ended September 30, 2017 relate to various matters including the preparation of the Company's 2017 Omnibus Incentive Plan, regulatory filings, and corporate governance matters. In the three months ended September 30, 2016 the costs were incurred related to preparing for the Company's uplisting of its common stock on the Nasdaq Stock Market as well as fees associated with one-time listing activities, and the filing of three registration statements with the SEC that were all declared effective in September 2016.

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

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

The Company recognized a gain of \$56,568 from the change in fair value of the derivative liability for the three months ended September 30, 2017 and a loss of \$225,688 for the three months ended September 30, 2016.

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

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

## Foreign Exchange

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

The Company recognized foreign exchange losses of \$43,866 and \$15,324 for the quarter ended September 30, 2017 and 2016, 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 three months ended September 30, 2017 and 2016 the Company recorded \$2,089 related to the dividend payable to Valent on the Series A preferred stock. The dividend has been recorded as a direct increase in accumulated deficit for both periods.

The Company issued 49,602 (2016 - 50,793) shares of common stock on September 30, 2017 as a dividend on the Series B Preferred stock and recognized \$41,666 (2016 - \$307,298) as a direct increase in accumulated deficit.

## Liquidity and Capital Resources

## Three months ended September 30, 2017 compared to the three months ended September 30, 2016

	September 30, 2017 \$	September 30, 2016 \$	Change \$	Change %
Cash flows from operating activities	(2,372,776)	(1,613,082)	(759,694)	47
Cash flows from financing activities	8,943,247	254,851	8,688,396	3,409

### **Operating** Activities

Net cash used in operating activities increased to \$2,372,776 for the three months ended September 30, 2017 from \$1,613,082 for the three months ended September 30, 2017 and 2016 the Company reported net losses of \$2,679,531 and \$2,290,339, respectively. During the three months ended September 30, 2017 the Company recorded a gain from the revaluation of the derivative and stock option liabilities of \$56,568 compared to a loss of \$225,688 for the three months ended September 30, 2016. Excluding the impact of changes in the fair value of the derivative and stock option liabilities, non-cash items relating to amortization, warrants issued for services, and stock option expense totaled \$68,994 for the three months ended September 30, 2017. Non-cash items relating to amortization, shares and warrants issued for services, and stock option expense totaled \$649,920 for the three months ended September 30, 2017 was cash from an increase in accounts payable and accrued liabilities of \$255,870. The most significant change in non-cash working capital for the three months ended September 30, 2017 was cash from an increase in accounts payable and accrued liabilities of \$255,870.

#### Financing Activities

During the three months ended September 30, 2017 the Company received \$8,945,336 in net proceeds from the completion of a registered direct offering by the Company of common stock and common stock purchase warrants. During the three months ended September 30, 2016 the Company received \$256,940 from the exercise of warrants.

In addition, the Company recorded \$2,089 related to the dividend payable to Valent during each of the three months ended September 30, 2017 and 2016 respectively.

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

## **Liquidity Risk**

(See note 1 to the consolidated condensed interim financial statements)

For the three months ended September 30, 2017, the Company reported a loss of \$2,666,406 and the Company had an accumulated deficit of \$43,828,594 at that date. As at September 30, 2017, the Company had cash on hand of \$13,156,485. During the three months ended September 30, 2017, the Company received \$8,945,336 in net proceeds from a registered direct offering. We believe, based on our current estimates, that we will be able to fund our operations beyond the next twelve months.

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

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

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

- the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;
- the costs associated with establishing manufacturing and commercialization capabilities;
- the costs of acquiring or investing in businesses, product candidates and technologies;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the effect of competing technological and market developments; and
- the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter.

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, debt financings or strategic collaborations. 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 the Company's significant accounting policies and the estimates derived there from is included in Note 2 to the Company's consolidated financial statements for the year ended June 30, 2017 contained in our Form 10-K filed with the SEC on September 27, 2017. While all of the significant accounting policies are important to the Company's consolidated financial statements, the following accounting policies and the estimates derived therefrom are critical:

- Warrants and shares issued for services
- Stock options
- Derivative liability
- Clinical trial accruals

#### Warrants and shares issued for services

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



#### Stock options

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

## Derivative liability

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

#### 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 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.

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

The Company does not have any off balance sheet arrangements.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not required for a smaller reporting company.

#### Item 4. Controls and Procedures.

#### **Disclosure Controls and Procedures**

Management, with the participation of the Chief Executive Officer and Chief Financial Officer, conducted an evaluation (as required by Rule 13a-15 under the Exchange Act) of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this report, due to the material weakness in internal control over financial reporting as discussed in the Company's Annual Report on Form 10-K for the year ended June 30, 2017, filed with the SEC on September 27, 2017.

#### Changes in internal controls

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# **PART II - OTHER INFORMATION**

## Item 1. Legal Proceedings.

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

## Item 1A. Risk Factors.

Not required for a smaller reporting company.

## Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the three months ended September 30, 2017, we issued 49,602 shares of common stock as dividends on our outstanding shares of Series B Preferred Stock.

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

## Item 3. Defaults Upon Senior Securities.

None.

## Item 4. Mine Safety Disclosures.

Not applicable.

# Item 5. Other Information.

None.

# Item 6. Exhibits.

No.	Description
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on
	<u>September 21, 2017)</u>
10.1	Form of Purchase Agreement, dated as of September 20, 2017 among DelMar Pharmaceuticals, Inc. and the purchasers
	thereunder (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on September
	<u>21, 2017)</u>
10.2	Engagement Letter, 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 on September 21, 2017)
31.1	Rule 13a-14(a)/ 15d-14(a) Certification of Chief Executive Officer*
31.2	Rule 13a-14(a)/ 15d-14(a) Certification of Chief Financial Officer*
32.1	Section 1350 Certification of Chief Executive Officer**
32.2	Section 1350 Certification of Chief Financial Officer**
EX-101.INS	XBRL INSTANCE DOCUMENT
EX-101.SCH	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT
EX-101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
EX-101.LAB	XBRL TAXONOMY EXTENSION LABELS LINKBASE
EX-101.PRE	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

\* Filed herewith

\*\*Furnished herewith



# SIGNATURES

Pursuant to the requirements 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.

Date: November 9, 2017

Date: November 9, 2017

# DelMar Pharmaceuticals, Inc.

By: /s/ Saiid Zarrabian

Saiid Zarrabian Interim Chief Executive Officer (Principal Executive Officer)

By: /s/ Scott Praill Scott Praill Chief Financial Officer (Principal Financial and Accounting Officer)

#### Certifications

I, Saiid Zarrabian, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q 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.

Date: November 9, 2017

/s/ Saiid Zarrabian Saiid Zarrabian Interim Chief Executive Officer (Principal Executive Officer) I, Scott Praill, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q 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.

Date: November 9, 2017

/s/ Scott Praill Scott Praill Chief Financial Officer (Principal Financial Officer)

## CERTIFICATION 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 Quarterly Report of DelMar Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Saiid Zarrabian, Interim Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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.

Dated: November 9, 2017

/s/ Saiid Zarrabian Saiid Zarrabian Interim Chief Executive Officer (Principal Executive Officer)

## CERTIFICATION 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 Quarterly Report of DelMar Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott Praill, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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.

Dated: November 9, 2017

/s/ Scott Praill Scott Praill Chief Financial Officer (Principal Financial Officer)