# 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 June 30, 2019

OR

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

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

Commission file number 000-50626

# CYCLACEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

200 Connell Drive, Suite 1500 Berkeley Heights, New Jersey (Address of principal executive offices) **91-1707622** (I.R.S. Employer Identification No.)

**07922** (Zip Code)

Registrant's telephone number, including area code: (908) 517-7330

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

	Trading	Name of each exchange on which
Title of each class	Symbol(s)	registered
Common Stock, par value \$0.001 per share	CYCC	The Nasdaq Stock Market LLC
Preferred Stock, \$0.001 par value	CYCCP	The Nasdaq Stock Market LLC

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  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  $\boxtimes$  No  $\square$ 

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

 Large accelerated filer □
 Accelerated filer □

 Non-accelerated filer ⊠
 Smaller reporting filer ⊠

 Emerging growth company □

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter):

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.

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

As of August 9, 2019 there were 17,199,974 shares of the registrant's common stock outstanding.

# CYCLACEL PHARMACEUTICALS, INC.

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# PART I. FINANCIAL INFORMATION

## **Item 1. Financial Statements**

## CYCLACEL PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS

## (In \$000s, except share, per share, and liquidation preference amounts) (Unaudited)

	Dec	cember 31, 2018	J	June 30, 2019
ASSETS				
Current assets:				
Cash and cash equivalents	\$	17,504	\$	15,159
Prepaid expenses and other current assets		2,283		2,991
Total current assets		19,787		18,150
Property and equipment, net Property and equipment, net		36		29
Property and equipment, net Right-of-use lease asset		-		1,285
Total assets	\$	19,823	\$	19,464
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:	*		*	
Accounts payable	\$	2,719	\$	1,106
Accrued and other current liabilities		1,732		1,394
Total current liabilities		4,451		2,500
Lease liability		-		1,233
Other liabilities		100		-
Total liabilities		4,551		3,733
Stockholders' equity:				
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2018 and June 30, 2019; 6% Convertible Exchangeable preferred stock; 335,273 shares issued and outstanding at December 31, 2018 and June 30, 2019. Aggregate preference in liquidation of \$4,006,512 as of December 31, 2018 and June 30, 2019.		-		-
Series A convertible preferred stock, \$0.001 par value; 264 shares issued and outstanding at December 31, 2018 and June 30, 2019.		-		
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2018 and June 30, 2019;				
12,497,447 and 17,199,974 shares issued and outstanding at December 31, 2018 and June 30, 2019.		12		17
Additional paid-in capital		365,817		369,944
Accumulated other comprehensive loss		(760)		(808)
Accumulated deficit		(349,797)		(353,422)
Total stockholders' equity		15,272		15,731
Total liabilities and stockholders' equity	\$	19,823	\$	19,464

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

## CYCLACEL PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

## (In \$000s, except share and per share amounts) (Unaudited)

	Three Months Ended June 30,			Six Mont June	 ded
	 2018		2019	 2018	2019
Revenues:					
Total revenues	 -		-	 -	 -
Operating expenses:					
Research and development	1,182		1,153	1,980	2,165
General and administrative	1,283		1,184	2,647	2,376
Total operating expenses	 2,465		2,337	 4,627	 4,541
Operating loss	 (2,465)		(2,337)	 (4,627)	 (4,541)
Other income (expense):					
Foreign exchange gains (losses)	(39)		21	(43)	36
Interest income	84		56	153	135
Other income, net	 66		170	632	170
Total other income (expense), net	 111		247	742	 341
Loss before taxes	 (2,354)		(2,090)	 (3,885)	 (4,200)
Income tax benefit	502		307	684	575
Net loss	 (1,852)		(1,783)	 (3,201)	 (3,625)
Dividend on convertible exchangeable preferred shares	(50)		(50)	(101)	(101)
Net loss applicable to common shareholders	\$ (1,902)	\$	(1,833)	\$ (3,302)	\$ (3,726)
Basic and diluted earnings per common share:	 				
Net loss per share - basic and diluted	\$ (0.16)	\$	(0.11)	\$ (0.28)	\$ (0.24)
Weighted average common shares outstanding	11,997,447		17,199,974	11,997,447	15,428,962

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

# CYCLACEL PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

# (In \$000s) (Unaudited)

	Three Months Ended June 30,			Six Mont June	-		
	 2018		2019	 2018		2019	
Net loss	\$ (1,852)	\$	(1,783)	\$ (3,201)	\$	(3,625)	
Translation adjustment	9,624		4,453	3,296		556	
Unrealized foreign exchange gain on intercompany loans	(9,577)		(4,480)	(3,301)		(603)	
Comprehensive loss	\$ (1,805)	\$	(1,810)	\$ (3,206)	\$	(3,672)	

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

# CYCLACEL PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

## (In thousands, except share amounts) (Unaudited)

	Preferre	ed Stock	Common	Stock	Additional Paid-in	Accumulated Other Comprehensiv	e A	ccumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss		Deficit	Equity
Balances at December 31, 2017	335,537	<del>\$</del> -	11,997,447	\$ 12	\$ 365,057	\$ (794	<b>1)</b> \$	(342,509)	21,766
Issue of common stock on									
At Market Issuance sales									
agreement	-	-	-	-	-		-	-	-
Stock-based compensation	-	-	-	-	79		-	-	79
Preferred stock dividends	-	-	-	-	(50)		-	-	(50)
Unrealized foreign exchange on									
intercompany loans	-	-	-	-	-	6,27		-	6,276
Translation adjustment	-	-	-	-	-	(6,328	3)	-	(6,328)
Loss for the period	-		-	-	-			(1,348)	(1,348)
Balances at March 31, 2018	335,537	\$-	11,997,447	\$ 12	\$ 365,086	\$ (84)	5)\$	(343,857)	20,395
Issue of common stock on									
At Market Issuance sales									
agreement	-	-	-	-	-		-	-	-
Stock-based compensation	-	-	-	-	87		-	-	87
Preferred stock dividends	-	-	-	-	(50)		-	-	(50)
Unrealized foreign exchange on									
intercompany loans	-	-	-	-	-	(9,578		-	(9,578)
Translation adjustment	-	-	-	-	-	9,623	3	-	9,623
Loss for the period	-		-		-			(1,853)	(1,853)
Balances at June 30, 2018	335,537	<del>\$</del> -	11,997,447	\$ 12	\$ 365,123	<b>\$ (80</b> )	<u>l) </u>	(345,710)	\$ 18,624
Balances at December 31, 2018	335,537	\$-	12,497,447	\$ 12	\$ 365,817	\$ (76	) \$	(349,797)	15,272
Issue of common stock on									
At Market Issuance sales									
agreement	-	-	4,702,527	5	4,106		-	-	4,111
Stock-based compensation	-	-	-	-	85		-	-	85
Preferred stock dividends	-	-	-	-	(50)		-	-	(50)
Unrealized foreign exchange on									
intercompany loans	-	-	-	-	-	\$ 3,87		-	3,876
Translation adjustment	-	-	-	-	-	\$ (3,89)	7)	-	(3,897)
Loss for the period	-	-	-	-	-		-	(1,842)	(1,842)
Balances at March 31, 2019	335,537	\$ -	17,199,974	\$ 17	\$ 369,958	\$ (78)	l) \$	(351,639)	17,555
Issue of common stock on									
At Market Issuance sales									
agreement	-	-	-	-	(56)		-	-	(56)
Stock-based compensation	-	-	-	-	92		-	-	92
Preferred stock dividends	-	-	-	-	(50)		-	-	(50)
Unrealized foreign exchange on									
intercompany loans	-	-	-	-	-	(4,48)		-	(4,480)
Translation adjustment	-	-	-	-	-	4,453	3	-	4,453
Loss for the period		-	-		-		-	(1,783)	(1,783)
Balances at June 30, 2019	335,537	\$ -	17,199,974	<u>\$ 17</u>	\$ 369,944	\$ (80)	3) \$	(353,422)	\$ 15,731

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

## CYCLACEL PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

## (In \$000s) (Unaudited)

		ths Ended e 30,
	2018	2019
Operating activities:	¢ (2.201)	ф (D. СОБ)
Net loss	\$ (3,201)	\$ (3,625)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	15	10
Gain on disposal of property and equipment	-	(29)
Stock-based compensation	167	178
Changes in lease liability	-	(52)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(860)	(749)
Accounts payable and other current liabilities	(63)	(2,052)
Net cash used in operating activities	(3,942)	(6,319)
Investing activities:		
Purchase of property, plant and equipment	(31)	(3)
Proceeds from sale of property and equipment		29
Net cash provided by (used in) investing activities	(31)	26
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	-	4,056
Payment of preferred stock dividend	(101)	(101)
Net cash provided by (used in) financing activities	(101)	3,955
	(101)	
Effect of exchange rate changes on cash and cash equivalents	(12)	(7)
Net (decrease) in cash and cash equivalents	(4,086)	(2,345)
Cash and cash equivalents, beginning of period	23,910	17,504
Cash and cash equivalents, end of period	\$ 19,824	\$ 15,159
Supplemental cash flow information:		
Cash received during the period for:	150	105
Interest	153	135
Taxes	-	-
Non cash financing activities:		
Accrual of preferred stock dividends	50	50

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

## CYCLACEL PHARMACEUTICALS, INC. NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Company Overview

#### Nature of Operations

Cyclacel Pharmaceuticals, Inc. ("Cyclacel" or "the Company") is a clinical-stage biopharmaceutical company using cell cycle control, transcriptional regulation and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases. Cyclacel is a pioneer company in the field of cell cycle biology with a vision to improve patient healthcare by translating cancer biology into medicines.

As of June 30, 2019, substantially all efforts of the Company to date have been devoted to performing research and development, conducting clinical trials, developing and acquiring intellectual property, raising capital and recruiting and training personnel.

## 2. Summary of Significant Accounting Policies

#### **Basis of Presentation**

The consolidated balance sheet as of June 30, 2019, the consolidated statements of operations, comprehensive loss, and stockholders' equity for the three and six months ended June 30, 2019 and 2018 and the consolidated statements of cash flows for the six months ended June 30, 2019 and 2018, and all related disclosures contained in the accompanying notes, are unaudited. The consolidated balance sheet as of December 31, 2018 is derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the Securities and Exchange Commission ("SEC"). The consolidated financial statements are presented on the basis of accounting principles that are generally accepted in the United States ("GAAP") for interim financial information and in accordance with the rules and regulations of the SEC. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States for a complete set of financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments necessary to present fairly the consolidated balance sheet as of June 30, 2019, and the results of operations and, comprehensive loss for the three and six months ended June 30, 2019, and cash flows for the six months ended June 30, 2019 have been made. The interim results for the three and six months ended June 30, 2019, and cash flows for the six months ended financial statements and the accompanying notes for the year ended December 31, 2018 that are included in the Company's Annual Report on Form 10-K filed with the SEC.

## **Going Concern**

Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern for a period of at least one year from the date the financial statements are issued. The Company expects that its cash of \$15.2 million as of June 30, 2019 will be sufficient to fund its operating expenses and capital expenditure requirements through the end of 2020.

This evaluation is based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued, including:

- a. The Company's current financial condition, including its sources of liquidity;
- b. The Company's conditional and unconditional obligations due or anticipated within one year;
- c. The funds necessary to maintain the Company's operations considering its current financial condition, obligations, and other expected cash flows; and
- d. Other conditions and events, when considered in conjunction with the above, that may adversely affect the Company's ability to meet its obligations.

The future viability of the Company beyond the end of 2020 is dependent on its ability to raise additional capital to finance its operations. The Company does not currently have sufficient funds to complete development and commercialization of any of its drug candidates. Additional funding may not be available to the Company on favorable terms, or at all. If the Company is not able to secure additional funding when needed, it may have to delay, reduce the scope of or eliminate one or more of its clinical trials or research and development programs or make changes to its operating plan. In addition, it may have to partner one or more of its product candidate programs at an earlier stage of development, which would lower the economic value of those programs to the Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.



## Accounting standards adopted in the period

On January 1, 2019, the Company adopted the guidance on accounting for leases ("ASC 842") in Accounting Standards Update No, 2016-02, *Leases*, as amended by subsequent updates issued in 2018 and 2019. The guidance requires that lessees recognize both a lease liability, which is a lessee's obligation to make lease payments arising from a lease measured on a discounted basis, and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term at the commencement date.

The Company has elected the package of practical expedients permitted in ASC 842. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC 842, (b) whether classification of the operating leases would be different in accordance with ASC 842, or (c) whether any unamortized initial direct costs would have met the definition of initial direct costs in ASC 842 at lease commencement. In addition, the Company has elected an accounting policy to not allocate payments made under the lease agreement between lease and non-lease components.

The Company transitioned to the new guidance at the adoption date by recognizing a lease liability of \$1.5 million for the present value of the remaining minimum rental payments, as defined under prior accounting rules, and a corresponding right-of-use asset. In addition, the Company reclassified an existing deferred rent obligation of \$120,000 created under prior accounting rules against the opening right-of-use asset. Because the Company adopted the new leasing guidance on a cumulative catch-up basis effective January 1, 2019, the Company has not recast prior period financial statements for the effects of this new standard. Accordingly, the Company's financial condition as of December 31, 2018 and June 30, 2019 may not be comparable.

#### **Recently Issued Accounting Pronouncements**

In August 2018, the FASB issued ASU 2018-15, "Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract." ASU 2018-15 requires implementation costs incurred by customers in cloud computing arrangements to be deferred over the noncancellable term of the cloud computing arrangements plus any optional renewal periods (1) that are reasonably certain to be exercised by the customer or (2) for which exercise of the renewal option is controlled by the cloud service provider. The effective date of this pronouncement is for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, and early adoption is permitted. The standard can be adopted either using the prospective or retrospective transition approach. The Company is currently evaluating the impact of this pronouncement on the Company's consolidated financial statements and disclosures.

#### Fair Value of Financial Instruments

Financial instruments consist of cash equivalents, accounts payable and accrued liabilities. The carrying amounts of cash equivalents, accounts payable and accrued liabilities approximate their respective fair values due to the nature of the accounts, notably their short maturities.

#### **Comprehensive Income (Loss)**

All components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments, are reported, net of any related tax effect, to arrive at comprehensive income (loss). No taxes were recorded on items of other comprehensive income (loss). There were no reclassifications out of other comprehensive income (loss) during the three months and six months ended June 30, 2018 and 2019.

## **Revenue recognition**

With effect from January 1, 2018, the Company recognizes revenue using the five step-model provided in ASC 606, *Revenue from Contracts with Customers* ("ASC 606"):

- (1) identify the contract with a customer;
- (2) identify the performance obligations in the contract;
- (3) determine the transaction price;
- (4) allocate the transaction price to the performance obligations in the contract; and
- (5) recognize revenue when, or as, the Company satisfies a performance obligation.

The transaction price includes fixed payments and an estimate of variable consideration, including milestone payments. The Company determines the variable consideration to be included in the transaction price by estimating the most likely amount that will be received and then applies a constraint to reduce the consideration to the amount which is probable of being received. When applying the constraint, the Company considers:

- Whether achievement of a development milestone is highly susceptible to factors outside the entity's influence, such as milestones involving the judgment or actions of third parties, including regulatory bodies;
- Whether the uncertainty about the achievement of the milestone is not expected to be resolved for a long period of time;
- Whether the Company can reasonably predict that a milestone will be achieved based on previous experience; and.
- The complexity and inherent uncertainty underlying the achievement of the milestone.

The transaction price is allocated to each performance obligation based on the relative selling price of each performance obligation. The best estimate of the selling price is determined after considering all reasonably available information, including market data and conditions, entity-specific factors such as the cost structure of the deliverable and internal profit and pricing objectives.

The revenue allocated to each performance obligation is recognized as or when the Company satisfies the performance obligation.

The Company recognizes a contract asset, when the value of satisfied (or part satisfied) performance obligations is in excess of the payment due to the Company, and deferred revenue when the amount of unconditional consideration is in excess of the value of satisfied (or part satisfied) performance obligations. Once a right to receive consideration is unconditional, that amount is presented as a receivable.

With effect from January 1, 2018, grant revenue, if new grants are obtained, will be presented as a reduction against the related research and development expenses.

#### Leases

Effective from January 1, 2019, the Company accounts for lease contracts in accordance with ASC 842. As of June 30, 2019, all of the Company's leases are classified as operating leases.

The Company recognizes an asset for the right to use an underlying leased asset for the lease term and records lease liabilities based on the present value of the Company's obligation to make lease payments under the lease. As the Company's leases do not indicate an implicit rate, the Company uses a best estimate of its incremental borrowing rate to discount the future lease payments. The Company estimates its incremental borrowing rate based on observable information about risk-free interest rates that are the same tenure as the lease term, adjusted for various factors, including the effects of assumed collateral, the nature of how the risk-free loan is repaid (e.g., amortizing versus bullet), and the Company's credit risk.

The Company evaluates options included in its lease agreements to extend or terminate the lease. The Company will reflect the effects of exercising those options in the lease term when it is reasonably certain that the Company will exercise that option. In assessing whether it is reasonably certain that the Company will exercise an option, the Company considers factors such as:

- The lease payments due in any optional period;
- Penalties for failure to exercise (or not exercise) the option;
- Market factors, such as the availability of similar assets and current rental rates for such assets;
- The nature of the underlying leased asset and its importance to the Company's operations; and
- The remaining useful lives of any related leasehold improvements.

Lease expense for lease payments is recognized on a straight-line basis over the lease term. Variable lease payments, if any, are recognized in the period when the obligation to make those payments is incurred. Lease incentives received prior to lease commencement are recorded as a reduction in the right-of-use asset. Fixed lease incentives received after lease commencement reduce both the lease liability and the right-of-use asset.

The Company has elected an accounting policy to account for the lease and non-lease components as a single lease component.

#### 3. Revenue

Revenue recognized in the three and six months ended June 30, 2018 and 2019 was \$nil.

The aggregate transaction price that is allocated to performance obligations that are unsatisfied (or partially unsatisfied) as of June 30, 2019 was \$nil.

#### 4. Net Loss per Common Share

The Company calculates net loss per common share in accordance with ASC 260 "Earnings Per Share" ("ASC 260"). Basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period.

The following potentially dilutive securities have not been included in the computation of diluted net loss per share for the three and six months ended June 30, 2018 and 2019, as the result would be anti-dilutive:

	June 30, 2018	June 30, 2019
Stock options	796,856	2,342,268
Convertible preferred stock	1,698	1,698
Series A preferred stock	132,000	132,000
Common stock warrants	7,490,500	7,490,500
Total shares excluded from calculation	8,421,054	9,966,466

## 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in \$000s):

	Dece	December 31,		ıne 30,
		2018	2019	
Research and development tax credit receivable	\$	1,148	\$	1,710
Prepayments and VAT receivable		899		1,045
Other current assets		236		236
	\$	2,283	\$	2,991

Included in other current assets at June 30, 2019 is \$170,000 of receivables. This relates to royalty payments receivable under a December 2005 Asset Purchase Agreement, or APA, whereby Xcyte Therapies, Inc., or Xcyte (a business acquired by the Company in March 2006) sold certain assets and intellectual property to ThermoFisher Scientific Company, or TSC (formerly Invitrogen Corporation) through the APA and other related agreements. The assets and technology were not part of the Company's product development plan following the transaction between Xcyte and Cyclacel in March 2006. Accordingly, the company recognized \$170,000 of other income related to this transaction during the six months ended June 30, 2019.

## 6. Accrued and Other Liabilities

Accrued and other current liabilities consisted of the following (in \$000s):

	December 31, 2018	J	June 30, 2019
Accrued research and development	\$ 1,110	\$	1,005
Accrued legal and professional fees	259		182
Other current liabilities	363		207
	\$ 1,732	\$	1,394

## 7. Leases

The Company has a single lease related to its facility in Dundee, Scotland.

## As of and for the six months ended June 30, 2019

The Company recognized operating lease expense of \$156,329. Cash payments made during the three months ended June 30, 2019 totaled \$245,222 and were presented as cash outflows from operating activities. The remaining lease term is approximately 6.3 years as of June 30, 2019. The discount rate used by the Company in determining the lease liability was 12%.

Remaining lease payments under the lease are:

2019	\$ 160,032
2019 2020	320,065
2021	320,065
2022	320,065
2023	320,065
Thereafter	560,113
	\$ 2,000,405

## As of and for the twelve months ended December 31, 2018

Prior to January 1, 2019, the Company accounted for its Dundee facility lease under ASC 840, *Leases*. Rent expense, which includes lease payments related to the Company's research and development facilities and corporate headquarters and other rent related expenses, was \$0.5 and \$0.4 million for each of the years ended December 31, 2017 and 2018, respectively.

The following is a summary of the Company's future contractual obligations and commitments relating to its facilities leases as at December 31, 2018 (in thousands):

	Oper Lea Oblig	ise
2019	\$	321
2020		321
2021		321
2022		321
2023		321
thereafter		581
Total future minimum lease obligations	\$	2,186

## 8. Stock Based Compensation

ASC 718 requires compensation expense associated with share-based awards to be recognized over the requisite service period, which for the Company is the period between the grant date and the date the award vests or becomes exercisable. Most of the awards granted by the Company (and still outstanding) vest ratably over one to four years. The Company recognizes all share-based awards under the straight-line attribution method, assuming that all granted awards will vest. Forfeitures are recognized in the periods when they occur.

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the three and six months ended June 30, 2018 and 2019 as shown in the following table (in \$000s):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2	018	2	2019	2	2018		2019
General and administrative	\$	63	\$	57	\$	122	\$	112
Research and development		23		35		45		66
Stock-based compensation costs before income taxes	\$	86	\$	92	\$	167	\$	178

## 2018 Plan

In May 2018, the Company's stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"), under which Cyclacel may make equity incentive grants to its officers, employees, directors and consultants. The 2018 Plan replaces the 2015 Equity Incentive Plan (the "2015 Plan").

The 2018 Plan allows for the issuance of up to 1,500,000 shares of the Company's common stock pursuant to various types of award grants, including stock options and restricted stock units. In addition, the 2018 Plan allows up to 709,889 additional shares to be issued if awards outstanding under the 2018 Plan are cancelled or expire on or after the date of the Company's 2018 annual meeting of stockholders.

As of June 30, 2019, the Company has reserved 152,083 shares of the Company's common stock under the 2018 Plan, including shares that were available under the 2015 Plan and carried forward to the 2018 Plan. Stock option awards granted under the Company's equity incentive plans have a maximum life of 10 years and generally vest over a one to four-year period from the date of grant.

There were 1,550,270 options granted during the six months ended June 30, 2019. These options had a grant date fair value ranging between \$0.52-\$0.61 per option.

There were 306,304 options granted during the year ended December 31, 2018. These options had grant date fair values ranging between \$1.17-\$1.29 per option. Of these options, approximately 174,272 are performance based and will vest upon the fulfillment of certain clinical objectives. The Company determined that the satisfaction of one criterion, the commencement of the HEM study by December 31, 2018, occurred as of December 31, 2018, but that the other vesting criteria related to these awards were not probable as of December 31, 2018. As such, the Company recognized compensation cost for these grants under the expectation that 25% of these awards (the portion associated with the HEM study) will vest.

There were no stock options exercised during each of the six months ended June 30, 2018 and 2019, respectively. The Company does not expect to be able to benefit from the deduction for stock option exercises that may occur because the company has tax loss carryforwards from prior periods that would be expected to offset any potential taxable income.

## **Outstanding Options**

A summary of the share option activity and related information is as follows:

	Number of Options Outstanding	A E	Veighted Average Exercise 2 Per Share	Weighted Average Remaining Contractual Term (Years)	In	gregate ttrinsic ıe (\$000)
Options outstanding at December 31, 2018	831,611	\$	6.68	8.13	\$	
Granted	1,550,270	\$	0.71			
Cancelled/forfeited	(39,613)	\$	2.76			
Options outstanding at June 30, 2019	2,342,268	\$	2.80	8.90	\$	
Unvested at June 30, 2019	(1,827,156)	\$	1.25	9.15	\$	
Vested and exercisable at June 30, 2019	515,112	\$	8,28	8.02	\$	



The fair value of the stock options granted is calculated using the Black-Scholes option-pricing model as prescribed by ASC 718 using the following assumptions:

	Year ended December 31, 2018	Six months ended June 30, 2019
Expected term (years)	6	5 - 6
Risk free interest rate	2.730% - 2.855%	2.105 - 2.610%
Volatility	105% - 107%	103 - 110%
Expected dividend yield over expected term	0.00%	0.00%
Resulting weighted average grant date fair value	\$1.25	\$0.52 - \$0.61

#### 9. Stockholders Equity

#### October 2018 At Market Issuance

On October 4, 2018, the Company entered into a Common Stock Sales Agreement, or the Sales Agreement, with H.C. Wainwright & Co., LLC, or Wainwright, as sales agent, pursuant to which Wainwright was authorized to sell shares of common stock, par value \$0.001 per share, having an aggregate offering price of up to \$5,000,000, by any method that is deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Shares sold under the Sales Agreement were offered and sold pursuant to the Company's previously filed and effective Registration Statement on Form S-3 and a prospectus supplement and accompanying base prospectus. The Company paid Wainwright a commission of 3.0% of the gross sales price per share sold. The Sales Agreement was concluded during the first quarter of 2019, during which the Company sold a further 4,702,527 shares for gross proceeds of approximately \$4.3 million. Aggregate net proceeds to the Company were approximately \$4.7 million, after deducting commissions and other expenses.

#### **Warrants**

As of June 30, 2019, there were 7,490,500 warrants outstanding, each with an exercise price of \$2.00. All such warrants were issued in connection with the July 2017 underwritten public offering and are immediately exercisable. The warrants expire in 2024. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser, 9.99%) of the shares of our Common Stock then outstanding after giving effect to such exercise.

The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Company's common stock. The warrant holders must pay the exercise price in cash upon exercise of the warrants, unless such warrant holders are utilizing the cashless exercise provision of the warrants. On the expiration date, unexercised warrants will automatically be exercised via the "cashless" exercise provision.

Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

There was no exercise of warrants during the three and six months ended June 30, 2019.

## Series A Preferred Stock

8,872 shares of the Company's Series A Preferred Stock were issued in the July 2017 underwritten public offering. During the year ended December 31, 2017, 8,608 shares of the Series A Preferred Stock were converted into 4,304,000 shares of common stock. As of June 30, 2019, 264 shares of the Series A Preferred Stock remain issued and outstanding.

Each share of Series A Preferred Stock is convertible at any time at the option of the holder thereof, into a number of shares of common stock determined by dividing \$1,000 by the initial conversion price of \$2.00 per share, subject to a 4.99% blocker provision, or, upon election by a holder prior to the issuance of shares of Series A Preferred Stock, 9.99%, and is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. The 264 shares of Series A Preferred Stock issued and outstanding at June 30, 2019, are convertible into 132,000 shares of common stock.

In the event of a liquidation, the holders of shares of the Series A Preferred Stock shall be permitted to participate on an as-converted-to-commonstock basis in any distribution of assets of the Company. The Company shall not pay any dividends on shares of common stock (other than dividends in the form of common stock) unless and until such time as dividends on each share of Series A Preferred Stock are paid on an as-converted basis. There is no restriction on the Company's ability to repurchase shares of Series A Preferred Stock while there is any arrearage in the payment of dividends on such shares, and there are no sinking fund provisions applicable to the Series A Preferred Stock.

Subject to certain conditions, at any time following the issuance of the Series A Preferred Stock, the Company has the right to cause each holder of the Series A Preferred Stock to convert all or part of such holder's Series A Preferred Stock in the event that (i) the volume weighted average price of our common stock for 30 consecutive trading days (the "Measurement Period") exceeds 300% of the initial conversion price of the Series A Preferred Stock (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the daily trading volume on each Trading Day during such Measurement Period exceeds \$500,000 per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company. The right to cause each holder of the Series A Preferred Stock to convert all or part of such holder's Series A Preferred Stock shall be exercised ratably among the holders of the then outstanding preferred stock.

The Series A Preferred Stock has no maturity date, will carry the same dividend rights as the common stock, and with certain exceptions, contains no voting rights. In the event of any liquidation or dissolution of the Company, the Series A Preferred Stock ranks senior to the common stock in the distribution of assets, to the extent legally available for distribution.

#### 6% Convertible Exchangeable Preferred Stock

As of June 30, 2019, there were 335,273 shares of the Company's 6% Convertible Exchangeable Preferred Stock ("6% Preferred Stock") issued and outstanding at an issue price of \$10.00 per share. Dividends on the 6% Preferred Stock are cumulative from the date of original issuance at the annual rate of 6% of the liquidation preference of the 6% Preferred Stock, payable quarterly on the first day of February, May, August and November, commencing February 1, 2005. Any dividends must be declared by the Company's Board and must come from funds that are legally available for dividend payments. The 6% Preferred Stock has a liquidation preference of \$10.00 per share, plus accrued and unpaid dividends.

The Company may automatically convert the 6% Preferred Stock into common stock if the per share closing price of the Company's common stock has exceeded \$2,961, which is 150% of the conversion price of the 6% Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

The 6% Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

The Company may, at its option, redeem the 6% Preferred Stock in whole or in part, out of funds legally available at the redemption price of \$10.00 per share.

The 6% Preferred Stock is exchangeable, in whole but not in part, at the option of the Company on any dividend payment date beginning on November 1, 2005 (the "Exchange Date") for the Company's 6% Convertible Subordinated Debentures ("Debentures") at the rate of \$10.00 principal amount of Debentures for each share of 6% Preferred Stock. The Debentures, if issued, will mature 25 years after the Exchange Date and have terms substantially similar to those of the 6% Preferred Stock. No such exchanges have taken place to date.

## 10. Subsequent Events

On May 29, 2019, the Board of Directors declared a quarterly cash dividend in the amount of \$0.15 per share on the Company's Preferred Stock. The cash dividend was paid on August 1, 2019 to the holders of record of the Preferred Stock as of the close of business on July 12, 2019.

On July 9, 2019, the Company received a written notice from The Nasdaq Stock Market LLC ("Nasdaq") that the Company has been granted an additional 180 calendar days, or until January 6, 2020, to regain compliance with the minimum \$1.00 bid price per share requirement of the Listing Rules of Nasdaq (the "Written Notice"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company had an initial period of 180 calendar days, or until July 8, 2019, to regain compliance with the minimum closing bid price requirement. The Company did not regain compliance with the minimum closing bid price requirement. The Company did not regain compliance with the minimum closing bid price requirement by July 8, 2019. The Company was previously notified by Nasdaq that it might be afforded a second 180 calendar period to regain compliance with the minimum closing bid price requirement under certain circumstances if the Company notified Nasdaq of its intent to cure the deficiency. As a result, the Company applied for an extension of the cure period, as permitted under the notification. In order to cure the deficiency, the Company indicated that, to the extent necessary, it planned to effect a reverse stock split in order to regain compliance with the minimum closing bid price requirement.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including, without limitation, Management's Discussion and Analysis of Financial Condition and Results of Operations, contains "forward-looking statements" within the meaning of Section 27A of the Securities Exchange Act of 1933 as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We intend that the forward-looking statements be covered by the safe harbor for forward-looking statements in the Exchange Act. The forward-looking information is based on various factors and was derived using numerous assumptions. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. These forward-looking statements are usually accompanied by words such as "believe," "anticipate," "plan," "seek," "expect," "intend" and similar expressions.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward looking statements due to a number of factors, including those set forth in Part I, Item 1A, entitled "Risk Factors," of our Annual Report on Form 10-K for the year ended December 31, 2018, as updated and supplemented by Part II, Item 1A, entitled "Risk Factors," of our Quarterly Reports on Form 10-Q, and elsewhere in this report. These factors as well as other cautionary statements made in this Quarterly Report on Form 10-Q, should be read and understood as being applicable to all related forward-looking statements wherever they appear herein. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our judgment as of the date hereof. We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements. In this report, "Cyclacel," the "Company," "we," "us," and "our" refer to Cyclacel Pharmaceuticals, Inc.

#### Overview

Through the first half of 2019, our primary focus has been on our transcriptional regulation program where we are evaluating CYC065, our cyclin dependent kinase, or CDK, inhibitor, as a single agent and in combination with venetoclax in Phase 1 studies in patients with solid tumors and hematological malignancies. In our DNA damage response, or DDR, program we are evaluating sapacitabine in combination with venetoclax in Phase 1 studies in patients with solid tumors. In our anti-mitotic program, we are evaluating CYC140, a PLK1 inhibitor, in Phase 1 studies in patients with hematological malignancies. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a pipeline of novel drug candidates.

#### **Transcriptional Regulation Program**

CDKs are a family of enzymes first discovered as regulators of the cell cycle, but that are now understood to also provide pivotal functions in the regulation of transcription, DNA repair and metastatic spread. The precise selectivity of an individual CDK inhibitor molecule for certain specific CDKs is key to targeting particular tumor types and minimizing undesirable side effects through non-specific antiproliferative activity.

In general, cell cycle regulation is less well controlled in cancer cells than in normal cells, which explains in part why cancer cells divide uncontrollably. Different CDKs are responsible for control of different aspects of proliferation, and when dysregulated, can be drivers of particular cancer sub-sets. Modulating CDK activity with targeted therapies is an attractive strategy to reinforce cell cycle control and decrease the rate of abnormal proliferation of cancer cells. The FDA approval of CDK inhibitors, palbociclib, ribociclib and abemaciclib, for a type of breast cancer, has led to great interest in the development of this class of drugs as oncology therapeutics.

Cyclacel's founding scientist, Professor Sir David Lane, is a globally recognized authority in cell cycle biology, who discovered p53, a key tumor suppressor that malfunctions in about two-thirds of human cancers. Under his guidance, Cyclacel's drug discovery and development programs concentrated on the CDK2/9 isoforms, which operate as key components of the p53 pathway. These efforts resulted in bringing two molecules into clinical trials: seliciclib, a first-generation CDK inhibitor, and CYC065, a second-generation CDK inhibitor, which has benefited from the Company's clinical experience with seliciclib.

CYC065 has been evaluated in a first-in-human, Phase 1 trial in patients with advanced solid tumors and a recommended Phase 2 dose was established. The study demonstrated that at the recommended Phase 2 dose CYC065 durably suppresses MCL1, a member of the BCL2 family of survival proteins. CYC065 is under investigation in combination with other anticancer drugs, including BCL2 inhibitors such as venetoclax with this combination currently being evaluated in two clinical studies enrolling patients with relapsed refractory chronic lymphocytic leukemia (CLL) and relapsed or refractory acute myeloid leukemia (AML) respectively. Preclinical data suggests that CYC065 may benefit adults and children with hematological malignancies, including AML, acute lymphocytic leukemias (ALL), and in particular leukemias with rearrangement of the Mixed Lineage Leukemia gene (MLL-r), CLL, B-cell lymphomas, multiple myelomas, and patients with certain solid tumors, including breast and uterine cancers, and neuroblastomas.

## DNA Damage Response, or DDR, Program

Many cancers have defects in the way in which cells monitor and repair damaged DNA, collectively termed DNA damage response, or DDR. These deficiencies in DDR pathways render cells more susceptible to DNA damage. Many traditional cancer treatments, such as DNA-damaging chemotherapy and radiotherapy, are based on this finding. However, such treatments are often accompanied by significant and unwanted side effects. Developing treatments which target specific DDR deficiencies to preferentially kill cancer cells, while minimizing the impact on normal cells, has potential for more selective, better tolerated therapies to improve survival in multiple cancers.

We have focused on developing treatments targeting DNA damage pathways for several years. For example, sapacitabine is an oral nucleoside analogue prodrug whose metabolite, CNDAC, generates single-strand DNA breaks, or SSB, either leading to arrest of the cell cycle at G2 phase or development of double-strand DNA breaks, or DSB. Repair of CNDAC-induced DSB is dependent on the homologous recombination, or HR repair pathway. BRCA mutations in cancer cells are a cause of HR deficiency, making such cancer cells more susceptible to cell death induced by sapacitabine.

We have dosed the first patient in a Phase 1/2 study evaluating the safety and effectiveness of sapacitabine, in an all oral regimen in combination with venetoclax in patients with relapsed or refractory AML or myelodysplastic syndromes (MDS). The Phase 1/2 study (NCT01211457) is intended to enroll up to 40 patients with relapsed or refractory AML or MDS with the objective of determining the safety and efficacy of the combination. Secondary objectives include duration of response, CR, CRp, PR, or major HI, transfusion requirements, number of hospitalized days and overall survival. We are also evaluating sapacitabine in a Phase 1/2 combination study with seliciclib in patients with BRCA mutations. A Phase 1b/2 investigator-sponsored clinical trial is evaluating the safety and effectiveness of sapacitabine in combination with olaparib in patients with BRCA mutant breast cancer. The trial is being conducted at the Dana-Farber Cancer Institute with collaborators Cyclacel and AstraZeneca providing sapacitabine investigational drug and the approved PARP inhibitor olaparib, respectively.

#### **CYC140**

CYC140 is a novel, small molecule, selective polo-like-kinase 1 (PLK1) inhibitor in a first-in-human Phase 1 study in patients with advanced leukemias and MDS. CYC140 is differentiated from previous clinical-stage PLK1 inhibitors, demonstrating potent and selective target inhibition and high activity in xenograft models of human cancers when dosed orally at non-toxic doses. CYC140 is the subject of a translational biology program focused on acute leukemias and esophageal cancer.



## **MD** Anderson Clinical Collaboration

On October 1, 2018, the Company entered into a three-year Clinical Collaboration Agreement, or CCA, with The University of Texas MD Anderson Cancer Center, or MD Anderson. The main objective of the CCA is to clinically evaluate the safety and efficacy of three Cyclacel medicines in patients with hematological malignancies, including chronic lymphocytic leukemias, acute myeloid leukemias, MDS and other advanced leukemias. Under the terms of the CCA, MD Anderson will conduct four clinical studies, all of which are now open for patients, with a total projected enrollment of up to 170 patients. Under the risk-sharing agreement, MD Anderson will assume the patient costs for all studies and Cyclacel, who is the sponsor, will provide investigational drugs and other limited support. Upon first commercial sale in specific indications studied in the alliance, Cyclacel will make certain payments to MD Anderson.

Cyclacel currently retains virtually all marketing rights worldwide to the compounds associated with the Company's drug programs.

#### **Results of Operations**

Three Months Ended June 30, 2018 and 2019

## **Results of Continuing Operations**

#### Revenues

Revenues for the three months ended June 30, 2018 and 2019 were \$nil and \$nil.

## The future

Recognition of any further revenue from milestones under a collaboration, licensing and supply agreement with ManRos Therapeutics SA is dependent on the clinical progress of the program, which we do not control.

## **Research and development expenses**

From our inception, we have focused on drug discovery and development programs, with a particular emphasis on orally-available anticancer agents, and our research and development expenses have represented costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for sapacitabine, seliciclib, and sapacitabine in combination with seliciclib. We have also incurred costs in the advancement of product candidates toward clinical and pre-clinical trials and the development of in-house research to advance our biomarker program and technology platforms. We expense all research and development costs as they are incurred. Research and development expenses primarily include:

- · Clinical trial and regulatory-related costs;
- · Payroll and personnel-related expenses, including consultants and contract research organizations;
- · Preclinical studies and laboratory supplies and materials;
- Technology license costs;
- · Stock-based compensation; and
- · Rent and facility expenses for our laboratories.

The following table provides information with respect to our research and development expenditures for the three months ended June 30, 2018 and 2019 (in \$000s except percentages):

		Three 1	Mon	ths					
	Ended June 30,					Difference			
		2018		2019		\$	%		
Transcriptional Regulation	\$	637	\$	684	\$	47	7		
DNA Damage Response		23		34		11	48		
Sapacitabine		340		109		(231)	(68)		
Other research and development programs and expenses		182		326		144	79		
Total research and development expenses	\$	1,182	\$	1,153	\$	(29)	(2)		

Total research and development expenses represented 48% and 49% of our operating expenses for the three months ended June 30, 2018 and 2019, respectively.

Research and development expenses remained flat at \$1.2 million for the three months ended June 30, 2018 and 2019. Research and development expenses relating to transcriptional regulation increased by \$47,000 from \$0.6 million for the three months ended June 30, 2018 to \$0.7 million for the three months ended June 30, 2019, primarily due to progression of the clinical evaluation of CYC065. Research and development expenses relating to sapacitabine decreased by \$0.2 million from \$0.3 million for the three months ended June 30, 2018 to \$0.1 million for the three months ended June 30, 2019, primarily as a result of a reduction in expenses associated with the SEAMLESS Phase 3 trial and related costs.

#### The future

We anticipate that overall research and development expenses for the year ended December 31, 2019 will increase compared to the year ended December 31, 2018, as we progress the clinical development of CYC065 and our other clinical-stage drugs. The timing and extent of any future SEAMLESS expenditure, including the possibility of registration submissions to regulatory authorities in Europe and the U.S., are dependent upon the outcome of discussions with regulatory authorities.

#### General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the general and administrative expenses for the three months ended June 30, 2018 and 2019 (in \$000s except percentages):

	Three Mo	nths E	nded			
	Jun	e 30,		Difference		
	2018		2019		\$	%
Total general and administrative expenses	\$ 1,283	\$	1,184	\$	(99)	(8)

Total general and administration expenses represented 52% and 51% of our operating expenses for the three months ended June 30, 2018 and 2019, respectively. General and administrative expenses decreased by \$0.1 million from \$1.3 million for the three months ended June 30, 2018 to \$1.2 million for the three months ended June 30, 2019 due to a reduction in legal and professional costs.

#### The future

We expect general and administrative expenditures for the year ended December 31, 2019 to decrease as compared to our expenditures for the year ended December 31, 2018 due to reduced recruitment and professional consultancy costs.

#### Other income (expense), net

The following table summarizes other income for the three months ended June 30, 2018 and 2019 (in \$000 except percentages):

	Three Mon June	 	Difference			
	2018	2019	 \$	%		
Foreign exchange gains (losses)	\$ (39)	\$ 21	\$ 60	154		
Interest income	84	56	(28)	(33)		
Other income, net	66	170	104	158		
Total other income	\$ 111	\$ 247	\$ 136	123		

Total other income increased by approximately \$0.1 million from \$0.1 million for the three months ended June 30, 2018 to \$0.2 million for the three months ended June 30, 2019. The increase in other income is wholly related to royalty receivable under a December 2005 Asset Purchase Agreement, or APA, whereby Xcyte Therapies, Inc., or Xcyte (a business acquired by the Company in March 2006) sold certain assets and intellectual property to ThermoFisher Scientific Company, or TSC (formerly Invitrogen Corporation) through the APA and other related agreements. The assets and technology were not part of the Company's product development plan following the transaction between Xcyte and Cyclacel in March 2006. Accordingly, the company recognized \$66,000 and \$170,000 of other income arising from sales related to this transaction during the three months ended June 30, 2018 and 2019 respectively. We have no knowledge of TSC's activities and cannot predict when we may receive income under the APA, if any.

## Foreign exchange gains (losses)

Foreign exchange gains increased by approximately \$60,000, from a loss of \$39,000 for the three months ended June 30, 2018, to a gain of \$21,000 for the three months ended June 30, 2019.

## The future

Other income (expense), net for the year ended December 31, 2019, will continue to be impacted by changes in foreign exchange rates and the receipt of income under the APA. As we are not in control of sales made by TSC, we are unable to estimate the level and timing of income under the APA, if any.

Because the nature of funding advanced through intercompany loans is that of a long-term investment, unrealized foreign exchange gains and losses on such funding will be recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable.

#### Income tax benefit

Credit is taken for research and development tax credits, which are claimed from the United Kingdom's revenue and customs authority, or HMRC, in respect of qualifying research and development costs incurred.

The following table summarizes total income tax benefit for the three months ended June 30, 2018 and 2019 (in \$000s except percentages):

	]	Three Mor	nths En	ded		
		June	e 30,		Differen	се
	2	018		2019	\$	%
Total income tax benefit	\$	502	\$	307	\$ (195)	(39)

The total income tax benefit, which comprised of research and development tax credits recoverable, decreased by \$0.2 million from an income tax benefit of \$0.5 million for the three months ended June 30, 2018 to an income tax benefit of \$0.3 million for the three months ended June 30, 2019. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year and the availability of trading losses.

#### The future

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so. The amount of tax credits we will receive is entirely dependent on the amount of eligible expenses we incur and having sufficient trading losses. We expect our qualifying research and development expenditure to increase for the year ended December 31, 2019 in comparison to the year ended December 31, 2018.

## Six Months Ended June 30, 2018 and 2019

## **Results of Continuing Operations**

#### Revenues

Revenues for the six months ended June 30, 2018 and 2019 were \$nil and \$nil.

#### The future

Recognition of any further revenue from milestones under a collaboration, licensing and supply agreement with ManRos Therapeutics SA is dependent on the clinical progress of the program, which we do not control.



## **Research and development expenses**

The following table provides information with respect to our research and development expenditures for the six months ended June 30, 2018 and 2019 (in \$000s except percentages):

		Six M	lonth	IS				
	Ended June 30,				Difference			
		2018		2019		\$	%	
Transcriptional Regulation	\$	1,106	\$	1,304	\$	198	18	
DNA Damage Response		60		65		5	8	
Sapacitabine		482		211		(271)	(56)	
Other research and development programs and expenses		332		585		253	76	
Total research and development expenses	\$	1,980	\$	2,165	\$	185	9	

Total research and development expenses represented 43% and 48% of our operating expenses for the six months ended June 30, 2018 and 2019, respectively.

Research and development expenses increased by \$0.2 million from \$2.0 million for the six months ended June 30, 2018 to \$2.2 million for the six months ended June 30, 2019. Research and development expenses relating to transcriptional regulation increased by \$0.2 million from \$1.1 million for the six months ended June 30, 2018 to \$1.3 million for the six months ended June 30, 2019, as the clinical evaluation CYC065 progresses. Research and development expenses relating to sapacitabine decreased by \$0.3 million from \$0.5 million for the six months ended June 30, 2018 to \$0.2 million for the six months ended June 30, 2019, primarily as a result of a reduction in expenditures associated with the SEAMLESS Phase 3 trial and related costs. Research and development expenses relating to other research and development increased by \$0.3 million from \$0.3 million for the six months ended June 30, 2018 to \$0.6 million for the six months ended June 30, 2019 primarily due to the progression of the clinical evaluation of the CYC140 program.

#### The future

We anticipate that overall research and development expenses for the year ended December 31, 2019 will increase compared to the year ended December 31, 2018, as we progress the clinical development of CYC065. The timing and extent of any future SEAMLESS expenditure, including the possibility of registration submissions to regulatory authorities in Europe and the U.S., are dependent upon the outcome of discussions with regulatory authorities.

## General and administrative expenses

The following table summarizes the general and administrative expenses for the six months ended June 30, 2018 and 2019 (in \$000s except percentages):

	Six Mont	hs Er	nded			
	Jun	e 30,		Difference		
	 2018		2019	\$	%	
Total general and administrative expenses	\$ 2,647	\$	2,376	\$ (271)	(10)	

Total general and administration expenses represented 57% and 52% of our operating expenses for the six months ended June 30, 2018 and 2019, respectively. General and administrative expenses decreased by \$0.3 million from \$2.7 million for the six months ended June 30, 2018 to \$2.4 million for the six months ended June 30, 2019 due to a reduction in legal and professional costs.

## The future

We expect general and administrative expenditures for the year ended December 31, 2019 to decrease as compared to our expenditures for the year ended December 31, 2018 due to reduced recruitment and professional consultancy costs.

## Other income (expense), net

The following table summarizes other income, net for the six months ended June 30, 2018 and 2019 (in \$000 except percentages):

	Six Months Ended June 30,				Difference			
	 2018		2019		\$	%		
Foreign exchange losses	\$ (43)	\$	36	\$	79	184		
Interest income	153		135		(18)	(12)		
Other income, net	632		170		(462)	(73)		
Total other income	\$ 742	\$	341	\$	(401)	(54)		

Total other income decreased by approximately \$0.4 million, from \$0.7 million for the six months ended June 30, 2018 to \$0.3 million for the six months ended June 30, 2019. The decrease in other income is primarily related to royalty payments receivable under a December 2005 APA, whereby Xcyte sold certain assets and intellectual property to TSC through an APA and other related agreements. We have no knowledge of TSC's activities and cannot predict when we may receive income under the APA, if any.

#### Foreign exchange losses

Foreign exchange gains increased by approximately \$79,000, from a loss of \$43,000 for the six months ended June 30, 2018, to a gain of \$36,000 for the six months ended June 30, 2019.

## The future

Other income (expense), net for the year ended December 31, 2019 will continue to be impacted by changes in foreign exchange rates and the receipt of income under the APA. As we are not in control of sales made by TSC we are unable to estimate the level and timing of income under the APA, if any.

Because the nature of funding advanced through intercompany loans is that of a long-term investment in nature, unrealized foreign exchange gains and losses on such funding will be recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable.

#### Income tax benefit

The following table summarizes total income tax benefit for the six months ended June 30, 2018 and 2019 (in \$000s except percentages):

	Six Mont	hs End	ed		
	 Jun	e 30,		 Differen	ice
	2018	2	2019	 \$	%
Total income tax benefit	\$ 684	\$	575	\$ (109)	(16)

The total income tax benefit, which comprised of research and development tax credits recoverable, decreased by \$0.1 million from an income tax benefit of \$0.7 million for the six months ended June 30, 2018 to an income tax benefit of \$0.6 million for the six months ended June 30, 2019. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year.

#### The future

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so. The amount of tax credits we will receive is entirely dependent on the amount of eligible expenses we incur. We expect our qualifying research and development expenditure to increase for the year ended December 31, 2019 in comparison to the year ended December 31, 2018.

## Liquidity and Capital Resources

The following is a summary of our key liquidity measures as of June 30, 2018 and 2019 (in thousands):

Six Months Ended June 30,				
2018	2019			
\$ 19,824	\$	15,159		
\$ 22,687	\$	18,150		
(3,994)		(2,500)		
\$ 18,693	\$	15,650		
\$	<b>June 2018 \$</b> 19,824 <b>\$</b> 22,687 (3,994)	June 30,           2018         \$           \$         19,824         \$           \$         22,687         \$           (3,994)		

Since our inception, we have relied primarily on the proceeds from sales of common and preferred equity securities to finance our operations and internal growth. Additional funding has come through research and development tax credits, government grants, the sale of product rights, interest on investments, licensing revenue, and a limited amount of product revenue from operations discontinued in September 2012. We have incurred significant losses since our inception. As of June 30, 2019, we had an accumulated deficit of \$ 353.4 million.

## Cash Flows

Cash used in operating, investing and financing activities for the six months ended June 30, 2018 and 2019 is summarized as follows (in thousands):

	S	Six Months Ended June 30,		
		2018	2019	
Net cash used in operating activities	\$	(3.942)	\$ (6,319)	
Net cash provided by (used in) investing activities		(31)	26	
Net cash provided by (used in) financing activities		(101)	3,955	

#### **Operating** activities

Net cash used in operating activities increased by \$2.4 million, from \$3.9 million for the six months ended June 30, 2018 to \$6.3 million for the six months ended June 30, 2019. The increase in cash used by operating activities was primarily the result of a change in working capital of \$2.0 million and an increase in net loss of \$0.4 million.

## Investing activities

Net cash provided by investing activities increased by approximately \$57,000 for the six months ended June 30, 2019 due to a reduction in capital expenditures on IT equipment, along with proceeds from sale of property and equipment.

#### Financing activities

Net cash provided by financing activities increased by \$4.1 million, for the six months ended June 30, 2019 as a direct result of receiving approximately \$4.1 million in net proceeds from the issuance of common stock under the Sales Agreement with Wainwright.

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

We expect to continue to incur substantial operating losses in the future and cannot guarantee that we will generate any significant product revenues until a product candidate has been approved by the FDA or EMA in other countries and successfully commercialized.

We believe that existing funds together with cash generated from operations, such as the R&D tax credit, and recent financing activities, are sufficient to satisfy our planned working capital, capital expenditures and other financial commitments through to the end of 2020. However, we do not currently have sufficient funds to complete development and commercialization of any of our drug candidates. Current business and capital market risks could have a detrimental effect on the availability of sources of funding and our ability to access them in the future, which may delay or impede our progress of advancing our drugs currently in the clinical pipeline to approval by the FDA or EMA for commercialization. Additionally, we plan to continue to evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

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 EMA 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. Although we are not reliant on institutional credit finance and therefore not subject to debt covenant compliance requirements or potential withdrawal of credit by banks, we are reliant on 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 partner 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.

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

As a smaller reporting company, we are not required to provide information in response to this item.

#### **Item 4. Controls and Procedures**

Under the supervision and with the participation of our management, including our chief executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of June 30, 2019, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based upon such evaluation, our chief executive officer and principal financial and accounting officer have concluded that, as of June 30, 2019, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to our management, including our chief executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure.

#### **Changes in Internal Control over Financial Reporting**

Beginning January 1, 2019, we implemented ASU 2016-02, Leases (Topic 842). There were no significant changes made in our internal controls over financial reporting as a result of the implementation.

#### Inherent Limitation on the Effectiveness of Internal Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute, assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

## PART II. Other Information

## **Item 1. Legal Proceedings**

None.

# Item 1A. Risk Factors

There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2018. For a further discussion of our Risk Factors, refer to Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the year ended December 31, 2018.

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

None.

Item 3. Defaults upon Senior Securities

None.

## Item 4. Mine Safety Disclosures

Not applicable.

#### Item 5. Other Information

None.

#### Item 6. Exhibits

Exhibit Number 31.1*	Description
	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<u>31.2*</u>	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<u>32.1*</u>	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
<u>32.2*</u>	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	The following materials from Cyclacel Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the period ended June 30, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.

# SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned.

# CYCLACEL PHARMACEUTICALS, INC.

Date: August 13, 2019

By: /s/ Paul McBarron

Paul McBarron Chief Operating Officer, Chief Financial Officer and Executive Vice President, Finance

## Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Spiro Rombotis, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended June 30, 2019 of Cyclacel 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: August 13, 2019

/s/ Spiro Rombotis Spiro Rombotis President & Chief Executive Officer (Principal Executive Officer)

## Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Paul McBarron, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended June 30, 2019 of Cyclacel 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: August 13, 2019

/s/ Paul McBarron Paul McBarron Chief Operating Officer, Chief Financial Officer and Executive Vice President, Finance (Principal Financial Officer)

## Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. s 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Cyclacel Pharmaceuticals, Inc. ( the "Company") hereby certifies, to such officer's knowledge, that:

(i) the Quarterly Report on Form10-Q of the Company for the three months ended June 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: August 13, 2019

/s/ Spiro Rombotis

Spiro Rombotis President & Chief Executive Officer

## Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. s 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Cyclacel Pharmaceuticals, Inc. ( the "Company") hereby certifies, to such officer's knowledge, that:

(i) the Quarterly Report on Form10-Q of the Company for the three months ended June 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: August 13, 2019

/s/ Paul McBarron

Paul McBarron Chief Operating Officer, Chief Financial Officer and Executive Vice President, Finance