

ARQULE INC  
Form 10-Q  
May 07, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-Q**

**Quarterly report pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**For the Quarter Ended March 31, 2018**

**Commission File No. 000-21429**

**ArQule, Inc.**  
(Exact Name of Registrant as Specified in its Charter)

**Delaware**                      **04-3221586**  
(State of Incorporation) (I.R.S. Employer Identification Number)

**One Wall Street, Burlington, Massachusetts 01803**  
(Address of Principal Executive Offices)

**(781) 994-0300**  
(Registrant's Telephone Number, including Area Code)

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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 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 x No "

Indicate by check mark whether the registrant has submitted electronically and posted on its 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 x No "

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," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer "	Accelerated filer x
Non-accelerated filer "	Smaller reporting company "
(Do not check if a smaller reporting company)	Emerging growth company "

Indicate If an emerging growth company, indicate by check 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 x

Number of shares outstanding of the registrant's Common Stock as of April 20, 2018:

Common Stock, par value \$.01 87,125,327 shares outstanding

ARQULE, INC.

QUARTER ENDED MARCH 31, 2018

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**ARQULE, INC.****CONDENSED BALANCE SHEETS (Unaudited)**

	March 31, 2018	December 31, 2017
	<b>(IN THOUSANDS,</b>	
	<b>EXCEPT SHARE AND</b>	
	<b>PER SHARE DATA)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,537	\$ 20,229
Marketable securities-short term	32,347	27,807
Prepaid expenses and other current assets	1,913	547
Total current assets	44,797	48,583
Property and equipment, net	102	115
Other assets	204	204
Total assets	\$ 45,103	\$ 48,902
<b>LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,269	\$ 8,259
Deferred revenue	—	1,500
Total current liabilities	8,269	9,759
Long-term liabilities:		
Notes payable	14,517	14,607
Warrant liability	3,782	1,512
Total liabilities	26,568	25,878
Commitments and contingencies (Note 13)		
Preferred stock, convertible, Series A \$0.01 par value; 1,000,000, shares authorized; 8,370 shares issued and outstanding at March 31, 2018 and December 31, 2017, aggregate liquidation preference of \$9,500		
	8,843	8,843
Stockholders' equity:		
Common stock, \$0.01 par value; 100,000,000 shares authorized; 87,125,327 and 87,110,202 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	871	871
Additional paid-in capital	547,932	547,364

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Accumulated other comprehensive loss	(41 )	(16 )
Accumulated deficit	(539,070 )	(534,038 )
Total stockholders' equity	9,692	14,181
Total liabilities, preferred stock and stockholders' equity	\$ 45,103	\$ 48,902

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

**ARQULE, INC.****CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)**

	THREE MONTHS ENDED MARCH 31,	
	2018	2017
	(IN THOUSANDS, EXCEPT PER SHARE DATA)	
Revenue:		
Research and development revenue	\$ 4,138	\$ —
Costs and expenses:		
Research and development	5,812	5,194
General and administrative	2,351	2,074
Total costs and expenses	8,163	7,268
Loss from operations	(4,025 )	(7,268 )
Interest income	159	22
Interest expense	(396 )	(330 )
Other expense	(2,270 )	—
Net loss	(6,532 )	(7,576 )
Unrealized loss on marketable securities	(25 )	(4 )
Comprehensive loss	\$ (6,557 )	\$ (7,580 )
Basic and diluted net loss per share:		
Net loss per share	\$ (0.07 )	\$ (0.11 )
Weighted average basic and diluted common shares outstanding	87,112	71,138

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

## ARQULE, INC.

## CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	THREE MONTHS ENDED	
	March 31,	
	2018	2017
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	\$ (6,532 )	\$ (7,576 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13	24
Amortization of premium (discount) on marketable securities	56	(3 )
Amortization of debt discount	78	60
Change in fair value of warrant liability	2,270	—
Non-cash stock compensation	423	543
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,366 )	280
Accounts payable and accrued expenses	10	(1,653 )
Net cash used in operating activities	(5,048 )	(8,325 )
Cash flows from investing activities:		
Purchases of marketable securities	(13,832 )	(1 )
Proceeds from sale or maturity of marketable securities	9,211	6,556
Net cash provided by (used in) investing activities	(4,621 )	6,555
Cash flows from financing activities:		
Proceeds from notes payable and warrants, net	—	14,740
Payments for notes payable amendment costs	(48 )	—
Proceeds from stock option exercises and employee stock plan purchases	25	—
Net cash (used in) provided by financing activities	(23 )	14,740
Net (decrease) increase in cash and cash equivalents	(9,692 )	12,970
Cash and cash equivalents, beginning of period	20,229	15,267
Cash and cash equivalents, end of period	\$ 10,537	\$ 28,237

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

**ARQULE, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)**

**1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION**

We are a biopharmaceutical company engaged in the research and development of innovative therapeutics to treat cancers and rare diseases. Our mission is to discover, develop and commercialize novel small molecule drugs in areas of high unmet need that will dramatically extend and improve the lives of our patients. These product candidates target biological pathways implicated in a wide range of cancers and certain non-oncology indications. Our discovery and development efforts are guided, when possible, by an understanding of the role of biomarkers, which are indicators of a particular biological condition or process and may predict the clinical benefit of our compounds in defined patient populations. Our clinical-stage pipeline consists of five product candidates, all of which are in targeted patient populations, making ArQule a leader among companies our size in precision medicine.

ArQule has a long history of kinase drug discovery and development, having discovered and introduced ten kinase inhibitors into clinical trials. Our drug discovery efforts have been informed by our historical expertise in chemistry, our work in rational drug design and by our insight into kinase binding and regulation. We have applied this knowledge to produce significant chemical matter for a number of kinase targets and to build an extensive library of proprietary compounds with the potential to target multiple kinases in oncology and other therapeutic areas, such as rare diseases. We may bring further preclinical programs forward and interrogate our library against new targets beyond kinases either directly or with collaborators.

Our pipeline of product candidates is directed toward molecular targets and biological processes with demonstrated roles in the development of both human cancers and rare, non-oncology diseases. All of these programs are being developed in targeted, biomarker-defined patient populations. By seeking out subgroups of patients that are most likely to respond to our drugs, we intend to identify small, often orphan, indications that allow for focused and efficient development. At the same time, in addition to pursuing these potentially fast-to-market strategies, we also pursue development in other indications that could allow us to expand the utility of the drugs if approved. The pipeline includes the following compounds all of which are wholly-owned, except derazantinib, which is partnered with Basilea Pharmaceutic Ltd. in all parts of the world except the People's Republic of China, Hong Kong, Macau and Taiwan ("Greater China"), where it is partnered with Sinovant Sciences Ltd., a subsidiary of Roivant Sciences Ltd.:

ARQ 531, an orally bioavailable, potent and reversible inhibitor of both wild type and C481S-mutant BTK, in Phase 1 for B-cell malignancies refractory to other therapeutic options;

Miransertib (ARQ 092), a selective inhibitor of AKT, a serine/threonine kinase, in Phase 1/2 in rare Overgrowth Diseases and in Phase 1 for the rare disease, Proteus syndrome, in partnership with the National Institutes of Health (NIH); also in phase 1b in oncology in combination with the hormonal therapy, anastrozole, in endometrial cancer;

ARQ 751, a next-generation inhibitor of AKT, in Phase 1 for solid tumors harboring the AKT1 or PI3K mutation;

Derazantinib (ARQ 087), a multi-kinase inhibitor designed to preferentially inhibit the FGFR family of kinases, in a registrational trial in intrahepatic cholangiocarcinoma (iCCA) in patients with FGFR 2 fusions; and

ARQ 761, a  $\beta$ -lapachone analog being evaluated as a promoter of NQO1-mediated programmed cancer cell death, in Phase 1/2 in multiple oncology indications in partnership with The University of Texas Southwest Medical Center.

In February 2018, we entered into a License Agreement (the “Agreement”) with Sinovant Sciences Ltd. (“Sinovant”) and Roivant Sciences Ltd. (Roivant), the parent of Sinovant, pursuant to which ArQule granted Sinovant a license to develop, manufacture and exclusively commercialize its FGFR inhibitor, derazantinib (ARQ 087), in Greater China. The Agreement provides for an upfront payment to ArQule of \$3 million and a guaranteed \$2.5 million development milestone within the first year. ArQule is also eligible for an additional \$82 million in regulatory and sales milestones. Upon commercialization, ArQule is entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in the Greater China territory. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. For the quarter ended March 31, 2018, we recognized revenue of \$3.0 million for completing our performance obligation under this licensing agreement.

In April 2018, we entered into a License Agreement (the “Basilea Agreement”) with Basilea Pharmaceutic Ltd. (“Basilea”) pursuant to which ArQule granted Basilea an exclusive license to develop, manufacture and commercialize its FGFR inhibitor, derazantinib (ARQ 087), in the United States, EU, Japan and the rest of the world, excluding Greater China. Under the terms of the Basilea agreement, ArQule will receive an upfront payment of \$10 million and is eligible for up to \$326 million in regulatory and commercial milestones. Upon commercialization, ArQule is entitled to receive staggered royalties on future net sales of derazantinib ranging from the high-single digits to the mid-teens on direct sales and mid-single digits to low-double digits on indirect sales. Basilea will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. Under certain circumstances, ArQule may have the opportunity to promote derazantinib in the US directly.

Tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase and its biological pathway is no longer being developed. We licensed commercial rights to tivantinib for human cancer indications to Daiichi Sankyo Co., Ltd. (“Daiichi Sankyo”) in the U.S., Europe, South America and the rest of the world, excluding Japan and certain other Asian countries, where we had licensed commercial rights to Kyowa Hakko Kirin Co., Ltd. (“Kyowa Hakko Kirin”).

Our uses of cash for operating activities have primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices and laboratories, fees paid in connection with preclinical and clinical studies, laboratory supplies and materials, and professional fees. The sources of our cash flow from operating activities have consisted primarily of payments received from our collaborators for services performed or upfront payments for license agreements or future services. In the three months ended March 31, 2018 and 2017, our net use of cash was primarily driven by payments for operating expenses which resulted in net cash outflows of \$5.0 million and \$8.3 million, respectively.

Our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, our ability to enter into additional corporate collaborations and the terms of such collaborations, results of research and development, unanticipated required capital expenditures, competitive and technological advances, acquisitions and other factors. We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product. In January 2017, we entered into a loan and security agreement (the “Loan Agreement”) with a principal balance of \$15 million (see Note 8). The terms of the Loan Agreement require payments of interest on a monthly basis through September 2018 and payments of interest from October 2018 to August 2021 and with principal payments commencing on September 1, 2019. The current maturity date of the loan is August 1, 2022 with principal payments commencing on September 1, 2019.

In September 2017, we sold 2.0 million shares of common stock through an at-the-market (ATM) offering and raised net proceeds of \$2.3 million. In October 2017, we entered into definitive stock purchase agreements with certain institutional investors. In conjunction with this stock offering we issued 13,938,651 shares of our common stock and warrants to purchase 3,123,674 shares of our common stock for aggregate net proceeds of \$15.6 million. Each warrant is exercisable for \$1.75 per share and expires in four years from the date of issuance. In November 2017, we entered into definitive securities purchase agreements with certain institutional investors. In conjunction with this stock offering the Company raised net proceeds of \$9.5 million through the sale of 8,370 shares of series A convertible preferred stock (Series A Preferred) and warrants to purchase 2,259 shares of Series A Preferred (Warrants). Each share of Series A Preferred together with the associated Warrant is priced at \$1,135 and will automatically convert into 1,000 shares of common stock upon the adoption of an amendment to the Company’s restated certificate of incorporation to increase the number of authorized shares of common stock thereunder. The Warrants have a pre-conversion exercise price of \$1,750 per share of Series A Preferred (post-conversion price of \$1.75 per share of common stock), are exercisable immediately and expire approximately four years from the date of the adoption of the amendment to the Company’s restated certificate of incorporation.

We anticipate that our cash, cash equivalents and marketable securities on hand at March 31, 2018, and financial support from our licensing agreements will be sufficient to finance our operations for at least 12 months from the issuance date of these financial statements. We expect that we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions, and due to global capital and credit market conditions or for other reasons, we may be unable to raise capital when needed, or on terms favorable to us. If necessary funds are not available, we may have to delay, reduce the scope of, or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates.

*Adoption and Impact of the New Revenue Standard*

The Company adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to its accounting policy for revenue recognition. Results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. We recorded a net increase to opening equity of \$1.5 million as of January 1, 2018 due to the cumulative impact of adopting this new standard. Without applying the new revenue standard, the disclosed research and development revenue would have been \$1.5 million higher than currently disclosed for the first three months of 2018. Contract receivables of \$1.2 million are included within prepaid expenses and other current assets. The adoption of the new revenue standard did not have a material impact on any other balances within the condensed consolidated financial statements as of and for the three-months ended March 31, 2018.

Under the new revenue standards, we recognize revenues when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five step model prescribed under Topic 606: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract, and determines those that are performance obligations. Revenue is recognized when each distinct performance obligation is satisfied.

The Company has collaboration and license agreements with drug development and pharmaceutical companies. The Company's proprietary technology and intellectual property is the basis for many of these collaboration and license agreements and generally include contractual milestone events that coincide with the progression of development, regulatory and commercialization milestones. At the inception of each collaboration that includes developmental, regulatory or commercial milestone payments, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators or where attainment of the specified event is dependent on the development activities of a third-party, are not considered probable of being achieved until those approvals are received or the specified event occurs. Revenue is recognized from the satisfaction of performance obligations in the amount billable to the customer.

## 2. COLLABORATIONS AND ALLIANCES

### *Roivant Sciences Licensing Agreement*

In February 2018, we entered into a License Agreement (the "Agreement") with Sinovant Sciences Ltd. ("Sinovant") and Roivant Sciences Ltd. (Roivant), the parent of Sinovant, pursuant to which ArQule granted Sinovant a license to develop, manufacture and exclusively commercialize its FGFR inhibitor, derazantinib (ARQ 087), in Greater China. The Agreement provides for an upfront payment to ArQule of \$3 million and a guaranteed \$2.5 million development milestone within the first year. ArQule is also eligible for an additional \$82 million in regulatory and sales milestones. Upon commercialization, ArQule is entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in the Greater China territory. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. For the quarter ended March 31, 2018, we recognized revenue of \$3.0 million for completing our performance obligation under this licensing agreement.

### *Basilea Licensing Agreement*

In April 2018, we entered into a License Agreement (the "Basilea Agreement") with Basilea Pharmaceutic Ltd. ("Basilea") pursuant to which ArQule granted Basilea an exclusive license to develop, manufacture and commercialize its FGFR inhibitor, derazantinib (ARQ 087), in the United States, EU, Japan and the rest of the world, excluding Greater China. Under the terms of the Basilea agreement, ArQule will receive an upfront payment of \$10 million and is eligible for up to \$326 million in regulatory and commercial milestones. Upon commercialization, ArQule is entitled to receive staggered royalties on future net sales of derazantinib ranging from the high-single digits to the mid-teens on direct sales and mid-single digits to low-double digits on indirect sales. Basilea will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. Under certain circumstances, ArQule may have the opportunity to promote derazantinib in the US directly.

*Other Licensing Agreements*

In October 2017, we entered into a non-exclusive license agreement for certain library compounds. The licensed compounds were delivered and are subject to quality and acceptance testing. In 2017, we recorded deferred revenue of \$1.5 million related to this licensing agreement which was recorded as an opening retained earnings adjustment upon the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers on January 1, 2018. In the three months ended March 31, 2018, we recorded revenue of \$1.1 million based upon the achievement of the quality and acceptance testing for the period.

**3. MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS**

We generally classify our marketable securities as available-for-sale at the time of purchase and re-evaluate such designation as of each balance sheet date. Since we generally intend to convert them into cash as necessary to meet our liquidity requirements our marketable securities are classified as cash equivalents if the original maturity, from the date of purchase, is ninety days or less and as short-term investments if the original maturity, from the date of purchase, is in excess of ninety days but less than one year. Our marketable securities are classified as long-term investments if the maturity date is in excess of one year of the balance sheet date.

We report available-for-sale investments at fair value as of each balance sheet date and include any unrealized gains and, to the extent deemed temporary, unrealized losses in stockholders' equity. Realized gains and losses are determined using the specific identification method and are included in other income (expense) in the statement of operations and comprehensive loss.

We conduct quarterly reviews to determine the fair value of our investment portfolio and to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. In the event that the cost basis of a security exceeds its fair value, we evaluate, among other factors, the duration of the period that, and extent to which, the fair value is less than cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, and operational and financing cash flow factors, overall market conditions and trends, our intent to sell the investment and if it is more likely than not that we would be required to sell the investment before its anticipated recovery. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded in accumulated other comprehensive income (loss).

For available-for-sale debt securities with unrealized losses, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is reflected in the statement of operations and comprehensive loss as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

We invest our available cash primarily in commercial paper, money market funds, and U.S. Treasury bill funds that have investment grade ratings.

The following is a summary of the fair value of available-for-sale marketable securities we held at March 31, 2018 and December 31, 2017:

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
March 31, 2018				
Security type				
Corporate debt securities-short term	\$ 32,388	\$ —	\$ (41 )	\$32,347
Total available-for-sale marketable securities	\$ 32,388	\$ —	\$ (41 )	\$32,347

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December 31, 2017	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Security type				
Corporate debt securities-short term	\$ 27,823	\$ 1	\$ (17	) \$27,807
Total available-for-sale marketable securities	\$ 27,823	\$ 1	\$ (17	) \$27,807

None of our available-for-sale marketable securities were in a continuous unrealized loss position for more than 12 months at March 31, 2018 or December 31, 2017.

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis for the periods presented and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value. There were no transfers in or out of Level 1 or Level 2 measurements for the periods presented:

	<b>March 31, 2018</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Cash equivalents	\$ 8,484	\$ 8,484	\$ —	\$ —
Corporate debt securities-short term	32,347	—	32,347	—
<b>Total</b>	<b>\$ 40,831</b>	<b>\$ 8,484</b>	<b>32,347</b>	<b>\$ —</b>
	<b>December 31, 2017</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Cash equivalents	\$ 19,889	\$ 19,889	\$ —	\$ —
Corporate debt securities-short term	27,807	—	27,807	—
<b>Total</b>	<b>\$ 47,696</b>	<b>\$ 19,889</b>	<b>\$ 27,807</b>	<b>\$ —</b>
	<b>March 31, 2018</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Warrant liability	\$ 3,782	\$ —	\$ —	\$ 3,782
	<b>December 31, 2017</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Warrant liability	\$ 1,512	\$ —	\$ —	\$ 1,512

Due to the lack of market quotes relating to our preferred stock warrants, the fair value of the preferred stock warrants was determined at March 31, 2018 and December 31, 2017 using the Black-Scholes model, which is based on Level 3 inputs. The inputs used in the Black-Scholes model are presented below. The assumptions used may change as the underlying sources of these assumptions and market conditions change. Based on the Black-Scholes model, the Company recorded a preferred stock warrant

liability of \$3,782 at March 31, 2018 and \$1,512 at December 31, 2017.

The following are the Black-Scholes inputs to the warrant liability valuation for the periods presented:

	March 31, 2018		December 31, <b>2017</b>	
Exercise price	\$1.75		\$ 1.75	
Market price	2.88		1.65	
Expected volatility	56.7	%	53.3	%
Risk-free interest	2.44	%	2.07	%
Expected term	3.61 years		3.85 years	
Dividends	none		none	

**4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses include the following at March 31, 2018 and December 31, 2017:

	March 31, 2018	December 31, 2017
Accounts payable	\$ 396	\$ 537
Accrued payroll	793	1,448
Accrued outsourced pre-clinical and clinical fees	6,039	5,409
Accrued professional fees	721	492
Other accrued expenses	320	373
	\$ 8,269	\$ 8,259

**5. NET LOSS PER SHARE**

Net loss per share is computed using the weighted average number of common shares outstanding. Basic and diluted net loss per share amounts are equivalent for the periods presented as the inclusion of potential common shares in the number of shares used for the diluted computation would be anti-dilutive to loss per share. Potential common shares, for the quarter ended March 31, 2018, include 10,921,388 shares that would be issued upon the exercise of outstanding employee and Board of Director stock options, 354,330 shares that would be issued upon the exercise of the warrants from our January 2017 loan agreement, 93,168 shares that would be issued upon the exercise of the warrants from our February 2018 amendment to our loan agreement, 3,123,674 shares that would be issued upon the exercise of the warrants from our October 2017 common stock offering, 8,370,000 common shares that would be issued upon the conversion of the shares from our November 2017 preferred stock offering and 2,259,000 common shares that would be issued upon the exercise of the warrants from our November 2017 preferred stock offering. Potential common shares, for the three months ended March 31, 2017, include 9,504,090 shares that would be issued upon the exercise of outstanding employee stock options and 354,330 shares that would be issued upon the exercise of the warrants issued in conjunction with our January 2017 loan agreement.

**6. STOCK-BASED COMPENSATION AND STOCK PLANS**

Our stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employees' requisite service period (generally the vesting period of the equity grant). We estimate the fair value of stock options using the Black-Scholes valuation model. Key input assumptions used to estimate the fair value of stock options include the exercise price of the award, expected option term, expected volatility of our stock over the option's expected term, risk-free interest rate over the option's expected term, and the

expected annual dividend yield. We believe that the valuation technique and approach utilized to develop the underlying assumptions are appropriate in calculating the fair values of our stock options granted in the three months ended March 31, 2018 and 2017.

The following table presents stock-based compensation expense included in our Condensed Statements of Operations and Comprehensive Loss:

	Three Months Ended March 31,	
	2018	2017
Research and development	\$ 106	\$ 130
General and administrative	317	413
Total stock-based compensation expense	\$ 423	\$ 543

In the three months ended March 31, 2018 and 2017, no stock-based compensation expense was capitalized and there were no recognized tax benefits associated with the stock-based compensation expense.

Option activity under our stock plans for the three months ended March 31, 2018 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2017	10,622,455	\$ 3.01
Granted	831,270	1.73
Exercised	(15,125 )	1.68
Cancelled	(517,212 )	3.10
Outstanding as of March 31, 2018	10,921,388	\$ 2.91
Exercisable as of March 31, 2018	7,071,489	\$ 3.74

The aggregate intrinsic value of options outstanding at March 31, 2018 was \$9,055 and \$3,281 related to exercisable options. The weighted average fair value of options granted in the three months ended March 31, 2018 and 2017 was \$1.07 and \$0.93 per share, respectively. The intrinsic value of options exercised in the three months ended March 31, 2018 was \$15.

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Vested and unvested expected to vest at March 31, 2018	10,788,462	\$ 2.91	5.8	\$ 9,055
Exercisable at March 31, 2018	7,071,489	\$ 3.74	4.2	\$ 3,281

The total compensation cost not yet recognized as of March 31, 2018 related to non-vested option awards was \$2.6 million, which will be recognized over a weighted-average period of 2.8 years. During the three months ended March 31, 2018, 275,587 shares expired and 241,625 shares were forfeited. The weighted average remaining contractual life for options exercisable at March 31, 2018 was 4.2 years.

## 7. COMMON STOCK OFFERINGS

In October 2017, we entered into definitive securities purchase agreements with certain institutional investors. In conjunction with this stock offering, we issued 13,938,651 shares of our common stock and warrants for 3,123,674 shares of our common stock for aggregate net proceeds of \$15.6 million. Each warrant is exercisable for \$1.75 per share and expires in four years from the date of issuance.

In September 2017, we sold 2.0 million shares of common stock through an at-the-market (“ATM”) offering and raised net proceeds of approximately \$2.3 million.

In February 2016, we entered into definitive stock purchase agreements with certain institutional and accredited investors. In conjunction with this stock offering we issued 8,027,900 shares of our common stock and non-transferable options for 3,567,956 shares of our common stock for aggregate net proceeds of \$15.2 million. Each option was exercisable for \$2.50 per share and they all expired in March 2017.

## **8. LOAN AGREEMENT**

In January 2017, Oxford Finance LLC, as collateral agent and a lender (the “Lender”), and any additional lenders that may become parties thereto, entered into a loan and security agreement with us (the “Loan Agreement”).

Pursuant to the terms of the Loan Agreement, the Lender issued us a loan in the principal amount of \$15.0 million. The loan bears interest at the rate equal to (a) the greater of (i) the 30 day U.S. LIBOR rate reported in the Wall Street Journal on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue or (ii) 0.65% (b) plus 6.85%. The applicable interest rate on the loan at December 31, 2017 was 8.22%. The Loan Agreement required interest-only payments for 18 months, followed by an amortization period of 36 months. The original maturity date of the loan was August 1, 2021 and in February 2018 we signed an amendment with the Lender which extended the maturity date by one year to August 1, 2022 with principal payments commencing on September 1, 2019.

The expected remaining repayment of the \$15 million loan principal at March 31, 2018 is as follows:

2019	\$1,667
2020	5,000
2021	5,000
2022	3,333
	\$15,000

Upon the earlier of prepayment or the maturity date, we will pay to the Lender a final payment of 6% of the full principal amount of the loan. We may elect to prepay all amounts owed prior to the maturity date, provided that a prepayment fee also is paid equal to (i) 3% of the outstanding principal balance if prepayment occurs in months 1-12 following the closing, (ii) 2.0% of the outstanding principal balance in months 13-24 following the closing, and (iii) 1% thereafter.

Pursuant to the terms of the Loan Agreement, we are bound by certain affirmative covenants setting forth actions that are required during the term of the Loan Agreement, including, without limitation, certain information delivery requirements, obligations to maintain certain insurance, and certain notice requirements. Additionally, we are bound by certain negative covenants setting forth actions that are not permitted to be taken during the term of the Loan Agreement without consent, including, without limitation, incurring certain additional indebtedness, entering into certain mergers, acquisitions or other business combination transactions, or incurring any non-permitted lien or other encumbrance on our assets. We were in compliance with the loan covenants at March 31, 2018.

Upon the occurrence of an event of default under the Loan Agreement (subject to cure periods for certain events of default), all amounts owed by us thereunder will begin to bear interest at a rate that is 5% higher than the rate that is otherwise applicable and may be declared immediately due and payable by the Lender. Events of default under the Loan Agreement include, among other things, the following: the occurrence of certain bankruptcy events; the failure to make payments under the Loan Agreement when due; the occurrence of a material adverse change in our business, operations or financial condition; the rendering of certain types of fines or judgments against us; any breach by us of any covenant (subject to cure for certain covenants only) made in the Loan Agreement; and the failure of any representation or warranty made by us in connection with the Loan Agreement to be correct in all material respects when made.

We have granted the Lender, a security interest in substantially all of our personal property, rights and assets, other than intellectual property, to secure the payment of all amounts owed to the Lender under the Loan Agreement. We have also agreed not to encumber any of our intellectual property without required lenders' prior written consent.

In connection with entering into the Loan Agreement, we issued to the Lender warrants to purchase an aggregate of 354,330 shares of our common stock (the “Lender Warrants”). The warrants are exercisable immediately, have a per-share exercise price of \$1.27 and have a term of ten years. We have recorded the relative fair value of the warrants as a discount to the carrying value of the notes payable with a corresponding increase to additional paid in capital.

In February 2018, the Loan Agreement was amended requiring payments of interest on a monthly basis through August 2019 and payments of interest and principal from September 2019 to August 2022. In connection with entering into the amendment we issued to the Lender warrants to purchase an aggregate of 93,168 shares of our common stock. The warrants are exercisable immediately, have a per-share exercise price of \$1.61 and have a term of ten years. The amendment was determined to be a modification of debt in accordance with ASC 470 Debt. We have recorded the relative fair value of the additional warrants as a discount to the carrying value of the notes payable with a corresponding increase to additional paid in capital.

## **9. PREFERRED STOCK AND WARRANT LIABILITY**

Our amended Certificate of Incorporation authorizes the issuance of up to 1 million shares of \$0.01 par value preferred stock.

In November 2017, we entered into definitive securities purchase agreements with certain institutional investors. In conjunction with this stock offering the Company raised net proceeds of \$9.5 million through the sale of 8,370 shares of series A convertible preferred stock (Series A Preferred) and warrants covering 2,259 shares of Series A Preferred (Warrants). Each share of Series A Preferred together with the associated Warrant is priced at \$1,135 and will automatically convert into 1,000 shares of common stock upon the adoption of an amendment to the Company’s restated certificate of incorporation to increase the number of authorized shares of common stock thereunder. The amount reported as preferred stock at March 31, 2018 and December 31, 2017 is \$8.8 million.

The terms of the Series A Preferred, specifically the terms of the liquidation preference, require the classification of the preferred stock as temporary equity, which is reflected in our balance sheet as of March 31, 2018 and December 31, 2017. In addition, the terms of the Series A Preferred for which the warrants are exercisable require that the fair value allocated to the warrants at the date of issuance be recorded as a liability. The warrant liability is marked to market value through the income statement as a non-cash gain or loss at each reporting period.

The Warrants have a pre-conversion exercise price of \$1,750 per share of Series A Preferred (post-conversion price of \$1.75 per share of common stock), are exercisable immediately and expire approximately four years from the date of the adoption of the amendment to the Company's restated certificate of incorporation. In the three months ended March 31, 2018 the fair value of the warrant liability increased to \$3.8 million and consequently a \$2.3 million non-cash expense was recorded. Upon conversion of the Series A Preferred common stock the warrant liability will be extinguished with an offsetting amount included as additional paid-in capital in stockholders' equity. The Series A Preferred Stockholders vote on an as converted basis together as one class with the holders of common stock.

If declared by the board, the Series A Preferred are eligible for a dividend on an as-converted basis. If the Company's restated certificate of incorporation has not been adopted by July 1, 2018, the Series A Preferred will obtain a dividend in kind until such time as the restated certificate of incorporation is adopted. In the case of a liquidation event or deemed liquidation event defined by the definitive securities purchase agreements the holders of Series A Preferred Stock have a liquidation preference on the greater of the Series A Preferred Stock stated value or the consideration that would have been paid on such Series A Preferred Stock in the applicable liquidation event.

## **10. 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 us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In May 2017 the FASB issued Accounting Standard Update ("ASU") No. 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting. This new standard provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, Compensation-Stock Compensation, to a change to the terms or conditions of a share-based payment award. This new standard became effective for us on January 1, 2018. The adoption of this standard did not have a material impact on our financial position or results of operations.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. This new standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. This new standard also clarifies that an entity should determine each separately identifiable source of use within the cash receipts and payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. This new standard became effective for us on January 1, 2018. The adoption of this standard did not have a material impact on our statements of cash flows upon adoption.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for us on January 1, 2019. The company is currently assessing the impact that adoption of this standard will have on our financial statements.

In May 2014 the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry specific guidance. This new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The FASB subsequently issued amendments to ASU No. 2014-09 that have the same effective date and transition date. These new standards became effective for us on January 1, 2018, and we adopted them using the modified retrospective method through a \$1.5 million cumulative-effect adjustment directly to retained earnings as of that date. The adoption of these new standards may result in a change in the timing of revenue recognition related to certain of our licensing activities.

## 11. INCOME TAXES

As of December 31, 2017, we had federal NOL, state NOL, and research and development credit carryforwards of approximately \$409,409, \$228,565 and \$28,253 respectively, which expire at various dates through 2037. We recorded a deferred tax asset for previously unrecognized excess tax benefit, offset by valuation allowance upon the adoption in 2017 of ASU 2016-09, “Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.”

As of March 31, 2018 and December 31, 2017 we had no unrecognized tax benefits. We do not expect that the total amount of unrecognized tax benefits will significantly increase in the next twelve months. Our policy is to recognize interest and penalties related to uncertain tax positions in income tax expense. As of March 31, 2018 and December 31, 2017, we had no accrued interest or penalties related to uncertain tax positions. Our U.S. federal tax returns for the tax years 2013 through 2017 and our state tax returns for the tax years 2013 through 2017 remain open to examination. Prior tax years remain open to the extent of net operating loss and tax credit carryforwards.

Utilization of NOL and research and development credit carryforwards may be subject to a substantial annual limitation in the event of an ownership change that has occurred previously or could occur in the future pursuant to Section 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. An ownership change may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income, and may, in turn, result in the expiration of a portion of those carryforwards before utilization. In general, an ownership change, as defined by Section 382, results from transactions that increase the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. We undertook a detailed study of our NOL and research and development credit carryforwards through January 31, 2018, to determine whether such amounts are likely to be limited by Sections 382 or 383. As a result of this analysis, we currently do not believe any Sections 382 or 383 limitations will significantly impact our ability to offset income with available NOL and research and development credit carryforwards. However, future ownership changes under Section 382 may limit our ability to fully utilize these tax benefits.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion should be read in conjunction with our condensed financial statements and accompanying notes contained in this quarterly report on Form 10-Q and our audited financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2017.*

We are a biopharmaceutical company engaged in the research and development of innovative therapeutics to treat cancers and rare diseases. Our mission is to discover, develop and commercialize novel small molecule drugs in areas of high unmet need that will dramatically extend and improve the lives of our patients. These product candidates target biological pathways implicated in a wide range of cancers and certain non-oncology indications. Our discovery and development efforts are guided, when possible, by an understanding of the role of biomarkers, which are indicators of a particular biological condition or process and may predict the clinical benefit of our compounds in defined patient populations. Our clinical-stage pipeline consists of five product candidates, all of which are in targeted patient populations, making ArQule a leader among companies our size in precision medicine.

ArQule has a long history of kinase drug discovery and development, having discovered and introduced ten kinase inhibitors into clinical trials. Our drug discovery efforts have been informed by our historical expertise in chemistry, our work in rational drug design and by our insight into kinase binding and regulation. We have applied this knowledge to produce significant chemical matter for a number of kinase targets and to build an extensive library of proprietary compounds with the potential to target multiple kinases in oncology and other therapeutic areas, such as rare diseases. We may bring further preclinical programs forward and interrogate our library against new targets beyond kinases either directly or with collaborators.

Our pipeline of product candidates is directed toward molecular targets and biological processes with demonstrated roles in the development of both human cancers and rare, non-oncology diseases. All of these programs are being developed in targeted, biomarker-defined patient populations. By seeking out subgroups of patients that are most likely to respond to our drugs, we intend to identify small, often orphan, indications that allow for focused and efficient development. At the same time, in addition to pursuing these potentially fast-to-market strategies, we also pursue development in other indications that could allow us to expand the utility of the drugs if approved. The pipeline includes the following compounds all of which are wholly-owned, except derazantinib, which is partnered with Basilea Pharmaceutic Ltd. in all parts of the world except the People's Republic of China, Hong Kong, Macau and Taiwan ("Greater China"), where it is partnered with Sinovant Sciences Ltd., a subsidiary of Roivant Sciences Ltd.:

ARQ 531, an orally bioavailable, potent and reversible inhibitor of both wild type and C481S-mutant BTK, in Phase 1 for B-cell malignancies refractory to other therapeutic options;

Miransertib (ARQ 092), a selective inhibitor of AKT, a serine/threonine kinase, in Phase 1/2 in rare Overgrowth Diseases and in Phase 1 for the rare disease, Proteus syndrome, in partnership with the National Institutes of Health (NIH); also in phase 1b in oncology in combination with the hormonal therapy, anastrozole, in endometrial cancer;

ARQ 751, a next-generation inhibitor of AKT, in Phase 1 for solid tumors harboring the AKT1 or PI3K mutation; and

Derazantinib (ARQ 087), a multi-kinase inhibitor designed to preferentially inhibit the FGFR family of kinases, in a registrational trial in intrahepatic cholangiocarcinoma (iCCA) in patients with FGFR 2 fusions; and

ARQ 761, a  $\beta$ -lapachone analog being evaluated as a promoter of NQO1-mediated programmed cancer cell death, in Phase 1/2 in multiple oncology indications in partnership with The University of Texas Southwest Medical Center.

In February 2018, we entered into a License Agreement (the “Agreement”) with Sinovant Sciences Ltd. (“Sinovant”) and Roivant Sciences Ltd. (Roivant), the parent of Sinovant, pursuant to which ArQule granted Sinovant a license to develop, manufacture and exclusively commercialize its FGFR inhibitor, derazantinib (ARQ 087), in Greater China. The Agreement provides for an upfront payment to ArQule of \$3 million and a guaranteed \$2.5 million development milestone within the first year. ArQule is also eligible for an additional \$82 million in regulatory and sales milestones. Upon commercialization, ArQule is entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in the Greater China territory. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. For the quarter ended March 31, 2018, we recognized revenue of \$3.0 for completing our performance obligation under this licensing agreement.

In April 2018, we entered into a License Agreement (the “Basilea Agreement”) with Basilea Pharmaceutic Ltd. (“Basilea”) pursuant to which ArQule granted Basilea an exclusive license to develop, manufacture and commercialize its FGFR inhibitor, derazantinib (ARQ 087), in the United States, EU, Japan and the rest of the world, excluding Greater China. Under the terms of the Basilea agreement, ArQule will receive an upfront payment of \$10 million and is eligible for up to \$326 million in regulatory and commercial milestones. Upon commercialization, ArQule is entitled to receive staggered royalties on future net sales of derazantinib ranging from the high-single digits to the mid-teens on direct sales and mid-single digits to low-double digits on indirect sales. Basilea will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. Under certain circumstances, ArQule may have the opportunity to promote derazantinib in the US directly.

Tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase and its biological pathway is no longer being developed. We licensed commercial rights to tivantinib for human cancer indications to Daiichi Sankyo Co., Ltd. (“Daiichi Sankyo”) in the U.S., Europe, South America and the rest of the world, excluding Japan and certain other Asian countries, where we licensed commercial rights to Kyowa Hakko Kirin Co., Ltd. (“Kyowa Hakko Kirin”).

We have incurred a cumulative deficit of approximately \$539 million from inception through March 31, 2018. We recorded a net loss for 2016 and 2017 and expect a net loss for 2018.

## LIQUIDITY AND CAPITAL RESOURCES

	March 31, 2018 (in millions)	December 31, 2017	Increase (decrease)	
			\$	%
Cash, cash equivalents and marketable securities-short term	\$42.9	\$ 48.0	(5.1 )	(11 )%
Working capital	36.5	38.8	(2.3 )	(6 )%

	Q1 2018 (in millions)	Q1 2017	Increase (decrease)
Cash flow from:			
Operating activities	\$(5.0)	\$ (8.3 )	\$ 3.3
Investing activities	(4.6)	6.6	(11.2 )
Financing activities	—	14.7	(14.7 )

*Cash flow from operating activities.* Our uses of cash for operating activities have primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices and laboratories, fees paid in connection with preclinical and clinical studies, laboratory supplies and materials, and professional fees. The sources of our cash flow from operating activities have consisted primarily of payments received from our collaborators for services performed or upfront payments for future services. For the quarters ended March 31, 2018 and 2017 our net use of cash was primarily driven by payments for operating expenses which resulted in net cash outflows of \$5.0 million and \$8.3 million, respectively.

*Cash flow from investing activities.* Our net cash used by investing activities of \$4.6 for the quarter ended March 31, 2018 was comprised of net purchases of marketable securities. Our net cash provided by investing activities of \$6.6 million for the quarter ended March 31, 2017 was comprised of net maturities of marketable securities. The

composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of our constant evaluation of conditions in financial markets, the maturity of specific investments, and our near term liquidity needs.

Our cash equivalents and marketable securities typically include commercial paper, money market funds, and U.S. Treasury bill funds, which have investment grade ratings. Our cash equivalents and our portfolio of marketable securities are subject to market risk due to changes in interest rates. Fixed rate interest securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates.

*Cash flow from financing activities.* Our net cash provided by financing activities was zero for the quarter ended March 31, 2018. Our net cash provided by financing activities for the quarter ended March 31, 2017, was comprised of \$14.7 million net proceeds from the loan and security agreement that we entered into on January 6, 2017.

Our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, our ability to enter into additional corporate collaborations and the terms of such collaborations, results of research and development, unanticipated required capital expenditures, competitive and technological advances, acquisitions and other factors. We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product. In January 2017, we entered into Loan Agreement with a principal balance of \$15 million (see Note 8). The terms of the Loan Agreement required payments of interest on a monthly basis through September 2018 and payments of interest and principal from October 2018 to August 2021. In February 2018, the Loan Agreement was amended requiring payments of interest on a monthly basis through August 2019 and payments of interest and principal from September 2019 to August 2022.

In February 2016, we entered into definitive stock purchase agreements with certain institutional and accredited investors. In conjunction with this stock offering we issued 8,027,900 shares of our common stock and non-transferable options for 3,567,956 shares of our common stock for aggregate net proceeds of \$15.2 million. Each option was exercisable for \$2.50 per share and they all expired on March 22, 2017.

In September 2017, we sold 2.0 million shares of common stock through an at-the-market (ATM) offering and raised net proceeds of \$2.3 million. In October 2017, we entered into definitive stock purchase agreements with certain institutional investors. In conjunction with this stock offering we issued 13,938,651 shares of our common stock and warrants to purchase 3,123,674 shares of our common stock for aggregate net proceeds of \$15.6 million. Each warrant is exercisable for \$1.75 per share and expires in four years from the date of issuance. In November 2017, we entered into definitive securities purchase agreements with certain institutional investors. In conjunction with this stock offering the Company raised net proceeds of \$9.5 million through the sale of 8,370 shares of series A convertible preferred stock (Series A Preferred) and warrants to purchase 2,259 shares of Series A Preferred (Warrants). Each share of Series A Preferred together with the associated Warrant is priced at \$1,135 and will automatically convert into 1,000 shares of common stock upon the adoption of an amendment to the Company's restated certificate of incorporation to increase the number of authorized shares of common stock thereunder. The Warrants have a pre-conversion exercise price of \$1,750 per share of Series A Preferred (post-conversion price of \$1.75 per share of common stock), are exercisable immediately and expire approximately four years from the date of the adoption of the amendment to the Company's restated certificate of incorporation.

In February 2018, we entered into a License Agreement (the "Agreement") with Sinovant Sciences Ltd. ("Sinovant") and Roivant Sciences Ltd. (Roivant), the parent of Sinovant, pursuant to which ArQule granted Sinovant a license to develop, manufacture and exclusively commercialize its FGFR inhibitor, derazantinib (ARQ 087), in Greater China. The Agreement provides for an upfront payment to ArQule of \$3 million and a guaranteed \$2.5 million development milestone within the first year. ArQule is also eligible for an additional \$82 million in regulatory and sales milestones. Upon commercialization, ArQule is entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in the Greater China territory. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. For the quarter ended March 31, 2018, we recognized revenue of \$3.0 million for completing our performance obligation under this licensing agreement.

In April 2018, we entered into a License Agreement (the "Basilea Agreement") with Basilea Pharmaceutic Ltd. ("Basilea") pursuant to which ArQule granted Basilea an exclusive license to develop, manufacture and commercialize its FGFR inhibitor, derazantinib (ARQ 087), in the United States, EU, Japan and the rest of the world, excluding Greater China. Under the terms of the Basilea agreement, ArQule will receive an upfront payment of \$10 million and is eligible for up to \$326 million in regulatory and commercial milestones. Upon commercialization, ArQule is entitled to receive staggered royalties on future net sales of derazantinib ranging from the high-single digits to the mid-teens on direct sales and mid-single digits to low-double digits on indirect sales. Basilea will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. Under certain circumstances, ArQule may have the opportunity to promote derazantinib in the US directly.

We anticipate that our cash, cash equivalents and marketable securities on hand at March 31, 2018, financial support from our licensing agreements, and the one year extension of our Loan Agreement will be sufficient to finance our operations into 2020 which is in excess of at least 12 months from the issuance date of these financial statements.

We expect that we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions, and due to global capital and credit market conditions or for other reasons, we may be unable to raise capital when needed, or on terms favorable to us. If necessary funds are not available, we may have to delay, reduce the scope of, or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates.

Our contractual obligations were comprised of the following as of March 31, 2018 (in thousands):

Contractual Obligations	Payment due by period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Notes payable	\$15,900	\$ —	\$ 7,917	\$ 7,983	\$ —
Interest on notes payable	3,336	1,159	1,812	365	—
Operating lease obligations	1,195	564	631	—	—
Purchase obligations	6,039	6,039	—	—	—
Total	\$26,470	\$ 7,762	\$ 10,360	\$ 8,348	\$ —

In January 2015, we entered into a lease agreement for our headquarters facility. The lease commenced on May 1, 2015 for a term of five years and three months with an average annual rental rate of \$455 thousand. The obligations for this facility are included in the table above.

Purchase obligations are comprised primarily of outsourced preclinical and clinical trial expenses and payments to license certain intellectual property to support our research efforts.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

A “critical accounting policy” is one which is both important to the portrayal of our financial condition and results and requires management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For additional information, please see the discussion of our significant accounting policies in Note 2 to the Financial Statements included in our Annual Report for the fiscal year ended December 31, 2017 on Form 10-K filed with the SEC on March 5, 2018.

The Company adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to its accounting policy for revenue recognition. Results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. We recorded a net increase to opening equity of \$1.5 million as of January 1, 2018 due to the cumulative impact of adopting this new standard. The adoption of the new revenue standard did not have a material impact on any other balances within the condensed consolidated financial statements as of and for the three-months ended March 31, 2018.

Under the new revenue standards, we recognize revenues when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five step model prescribed under Topic 606: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract, and determines those that are performance obligations. Revenue is recognized when each distinct performance obligation is satisfied.

## **RESULTS OF OPERATIONS**

The following are the results of operations for the three months ended March 31, 2018 and 2017:

**Revenue**

	2018	2017	Increase (decrease)	
			\$	%
	(in millions)			
For the three months ended March 31:				
Research and development revenue	\$ 4.1	\$ —	\$ 4.1	100 %

Research and development revenue in the three months ended March 31, 2018 consisted of \$3 million from our February 2018 Roivant licensing agreement and \$1.1 million from a non-exclusive license agreement for certain of our library compounds.

Research and development revenue in the three months ended March 31, 2017 was zero due to the end of the estimated development period on December 31, 2016 for both the Daiichi Sankyo tivantinib development agreement and the Kyowa Hakko Kirin exclusive license agreement.

**Research and development**

	2018	2017	Increase (decrease)	
			\$	%
	(in millions)			
For the three months ended March 31:				
Research and development	\$ 5.8	\$ 5.2	\$ 0.6	12 %

Research and development expense in the quarter ended March 31, 2018 increased by \$0.6 million primarily due to higher outsourced preclinical, clinical and product development costs. At March 31, 2018 we had 18 employees dedicated to our research and development program compared to 20 at March 31, 2017.

### *Overview*

Our research and development expense consists primarily of salaries and related expenses for personnel, costs of contract manufacturing services, costs of facilities and equipment, fees paid to professional service providers in conjunction with our clinical trials, fees paid to research organizations in conjunction with pre-clinical animal studies, costs of materials used in research and development, consulting, license, and sponsored research fees paid to third parties and depreciation of associated laboratory equipment. We expect that our research and development expense will remain significant as we continue to develop our portfolio of oncology programs.

We have not accumulated and tracked our internal historical research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources are allocated across several projects, and many of our costs are directed to broadly applicable research endeavors. As a result, we cannot state the costs incurred for each of our oncology programs on a program-by-program basis.

Our future research and development expenses in support of our current and future oncology programs will be subject to numerous uncertainties in timing and cost to completion. We test potential products in numerous preclinical studies for safety, toxicology, and efficacy. We may conduct multiple clinical trials for each product. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty, and intended use of a product. It is not unusual for the preclinical and clinical development of each of these types of products to take nine years or more, and for total development costs to exceed \$500 million for each product.

We estimate that clinical trials of the type generally needed to secure new drug approval are typically completed over the following timelines:

<b><u>Clinical Phase</u></b>	<b><u>Estimated Completion Period</u></b>
Phase 1	1–2 years
Phase 2	2–3 years
Phase 3	2–4 years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others, the following:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the duration of patient follow-up to ensure the absence of long-term product-related adverse events; and
- the efficacy and safety profile of the product.

An element of our business strategy is to pursue the research and development of a broad pipeline of products. This is intended to allow us to diversify the risks associated with our research and development expenditures. As a result, we believe our future capital requirements and future financial success do not substantially depend on any one product. To the extent we are unable to build and maintain a broad pipeline of products, our dependence on the success of one or a few products increases.

Our strategy includes entering into alliance arrangements with third parties to participate in the development and commercialization of our products, such as our collaboration agreements with Roivant and Basilea. In the event that third parties have control over the clinical trial process for a product, the estimated completion date would be under control of that third party rather than under our control. We cannot forecast with any degree of certainty whether our products will be subject to future collaborative arrangements or how such arrangements would affect our development plans or capital requirements.

As a result of the uncertainties discussed above, we make significant estimates in determining the duration and completion costs of our oncology programs or when and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our oncology programs in a timely manner or our failure to enter into appropriate collaborative agreements could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time-to-time in order to continue with our product development strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

### General and administrative

	2018	2017	Increase (decrease)	
			\$	%
(in millions)				
For the three months ended March 31:				
General and administrative	\$ 2.4	\$ 2.1	\$ 0.3	13 %

General and administrative expense increased in the first quarter of 2018 principally due to \$0.2 million higher labor related costs, and \$0.1 million higher professional fees. General and administrative headcount was 13 at March 31, 2018, compared to 14 at March 31, 2017.

### Interest income, interest expense and other expense

	2018	2017	Increase (decrease)	
			\$	%
(in thousands)				
For the three months ended March 31:				
Interest income	\$ 159	\$ 22	\$ 137	623 %
Interest expense	(396 )	(330)	66	18 %
Other expense	(2,270)	—	2,270	100 %

Interest income is derived from our portfolio of cash, cash equivalents and investments and increased in the first quarter of 2018 primarily due to an increase in our portfolio balance from stock offerings in the fourth quarter 2017 and increased interest rates.

Interest expense is from the loan agreement we entered into on January 6, 2017.

Other expense in 2018 includes a non-cash expense from an increase in fair value of our preferred stock warrant liability of \$2.3 million.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

For a discussion of new accounting pronouncements please read Note 10, *Recent Accounting Pronouncements* to our financial statements included in this report.

## **FORWARD LOOKING STATEMENTS**

In addition to historical information, this report contains forward-looking statements. You can identify these forward-looking statements by their use of words such as “anticipate,” “assume,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “project,” “target,” “will”, “potential”, “goal”, and other words and terms of similar meaning. You also identify them by the fact that they do not relate strictly to historical or current facts. All statements which address operating performance, events or developments that the Company expects or anticipates will occur in the future, such as projections about its future results of operations, its financial condition, research, development and commercialization of its products and anticipated trends in its business are forward-looking statements.

In this report we make forward-looking statements regarding our drug development pipeline and our existing and planned clinical trials as well as future milestones and royalty payments, projected financial results and our ability to fund operations with current cash, cash equivalents and marketable securities.

Drug development involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. For example, pre-clinical efforts associated with our product pipeline may fail or prove disappointing because our technology platform did not produce candidates with the desired characteristics. Animal xenograft pre-clinical studies may be unpredictable of human response. Positive information about early stage clinical trial results will not ensure that later stage or larger scale clinical trials will be successful. Furthermore, our drugs may not demonstrate promising therapeutic effects; in addition, they may not demonstrate appropriate safety profiles in ongoing or later stage or larger scale clinical trials as a result of known or as yet unidentified side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards. Problems or delays may arise during clinical trials or in the course of developing, testing or manufacturing our drugs that could lead us or our partner to discontinue development.



Even if later stage clinical trials are successful, the risk exists that unexpected concerns may arise from analysis of data or from additional data or that obstacles may arise or issues be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with our view of the data or require additional data or information or additional studies. Also, the planned timing of initiation of clinical trials and the duration and conclusion of such trials for our drugs are subject to the ability of the company to enroll patients, enter into agreements with clinical trial sites and investigators, and other technical hurdles and issues that may not be resolved.

We also make forward-looking statements regarding the adequacy of our financial resources. Our capital resources may not be adequate because our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, the outcomes of our clinical trials, our ability to enter into additional corporate collaborations in the future and the terms of such collaborations, results of research and development, the need for currently unanticipated capital expenditures, competitive and technological advances, acquisitions, financial market conditions and other factors. Additionally, our corporate collaborators may terminate their agreements with us, thereby eliminating that source of funding, because we may fail to satisfy the prescribed terms of the collaborations or for other reasons.

We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product generating revenues. If we experience increased losses, we may have to seek additional financing from public and private sales of our securities, including equity securities. There can be no assurance that additional funding will be available when needed or on acceptable terms.

The factors, risks and uncertainties referred to above and others are more fully described under the heading “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 5, 2018, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The forward-looking statements contained herein represent our judgment as of the date of this report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We own financial instruments that are sensitive to market risk as part of our investment portfolio. We have implemented policies regarding the amount and credit ratings of investments. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. Our investments are evaluated quarterly to determine the fair value of the portfolio.

Our cash equivalents and marketable securities typically include commercial paper, money market funds, and U.S. Treasury bill funds that have investment grade ratings.

Our cash equivalents and our portfolio of marketable securities are subject to market risk due to changes in interest rates. Fixed rate interest securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates. Based on the type of securities we hold, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1%, this would not result in a material change in the fair value of our investment portfolio.

#### **ITEM 4. CONTROLS AND PROCEDURES**

Our management, with the participation of our Chief Executive Officer (Principal Executive Officer) and President and Chief Operating Officer (Principal Financial Officer), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (“Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2018, our Chief Executive Officer (Principal Executive Officer) and President and Chief Operating Officer (Principal Financial Officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

In the quarter ended March 31, 2018 the Company adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to its accounting policy for revenue recognition and implementation of related revenue recognition internal controls. There have been no changes in our internal control over financial reporting during the most recently completed fiscal quarter 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.** None.

**ITEM 1A. — RISK FACTORS.** For information regarding factors that could affect our results of operations, financial condition and liquidity, see the risk factors discussion provided under “Risk Factors” in Item 1A of ArQule’s Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 5, 2018, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See also, “Forward-Looking Statements” included in this Quarterly Report on Form 10-Q.

**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. — OTHERS INFORMATION.** None.

**ITEM 6. — EXHIBITS.**

### **EXHIBIT NO. DESCRIPTION**

<u>4.1</u>	<u>Warrant dated February 16, 2018. Filed as Exhibit 4.1 to our Current Report on Form 8-K filed on February 22, 2018 and incorporated herein by reference.</u>
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<u>10.1</u>	<u>Second Amendment to Loan and Security Agreement between and among ArQule, Inc. and Oxford Finance LLC dated February 16, 2018. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on February 22, 2018 and incorporated herein by reference.</u>
<u>31.1</u>	<u>Rule 13a-14(a) Certificate of Chief Executive Officer, filed herewith.</u>
<u>31.2</u>	<u>Rule 13a-14(a) Certificate of Principal Financial Officer, filed herewith.</u>
<u>32</u>	<u>Rule 13a-14(b) Certificate of Chief Executive Officer and Chief Financial Officer, filed herewith.</u>
101	Interactive Data File

**ARQULE, INC.**

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ArQule, Inc.

Date: May 7, 2018 /s/ PETER S. LAWRENCE  
Peter S. Lawrence  
President and Chief Operating Officer  
(Principal Financial Officer)

/s/ ROBERT J. WEISKOPF  
Robert J. Weiskopf  
Chief Financial Officer and Treasurer  
(Principal Accounting Officer)