

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 June 30, 2019

Commission File No. 000-21429

ArQule, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State of Incorporation)

04-3221586
(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)

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.01 par value	ARQL	The NASDAQ Stock Market LLC (NASDAQ Global Market)

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 No

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 No

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

Number of shares outstanding of the registrant's Common Stock as of July 24, 2019:

Common Stock, par value \$.01 120,260,385 shares outstanding

ARQULE, INC.
QUARTER ENDED JUNE 30, 2019
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ARQULE, INC.

CONDENSED BALANCE SHEETS (Unaudited)

	June 30, 2019	December 31, 2018
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 108,685	\$ 19,236
Marketable securities-short term	70,436	80,322
Contract receivables	1,450	5,984
Prepaid expenses	1,428	861
Total current assets	<u>181,999</u>	<u>106,403</u>
Marketable securities-long term	3,638	—
Property and equipment, net	455	69
Operating lease assets	852	—
Other assets	249	204
Total assets	<u>\$ 187,193</u>	<u>\$ 106,676</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,795	\$ 12,948
Notes payable – current portion	4,166	1,667
Operating lease liability – current portion	552	—
Total current liabilities	<u>14,513</u>	<u>14,615</u>
Long-term liabilities:		
Notes payable – long term	10,753	13,093
Operating lease liability – long term	311	—
Total liabilities	<u>25,577</u>	<u>27,708</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 1,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 120,260,385 and 109,003,637 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	1,203	1,090
Additional paid-in capital	727,712	625,993
Accumulated other comprehensive income (loss)	80	(95)
Accumulated deficit	<u>(567,379)</u>	<u>(548,020)</u>
Total stockholders' equity	<u>161,616</u>	<u>78,968</u>
Total liabilities and stockholders' equity	<u>\$ 187,193</u>	<u>\$ 106,676</u>

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

ARQULE, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS) (Unaudited)

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	June 30,		June 30,	
	2019	2018	2019	2018
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Research and development revenue	\$ 281	\$ 13,706	\$ 1,626	\$ 17,844
Costs and expenses:				
Research and development	6,330	6,787	13,778	12,599
General and administrative	3,168	2,234	7,468	4,585
Total costs and expenses	<u>9,498</u>	<u>9,021</u>	<u>21,246</u>	<u>17,184</u>
Income (loss) from operations	(9,217)	4,685	(19,620)	660
Interest income	558	170	1,124	329
Interest expense	(433)	(417)	(863)	(813)
Other income (expense)	—	718	—	(1,552)
Net income (loss)	<u>(9,092)</u>	<u>5,156</u>	<u>(19,359)</u>	<u>(1,376)</u>
Unrealized gain (loss) on marketable securities	58	19	175	(6)
Comprehensive income (loss)	<u>\$ (9,034)</u>	<u>\$ 5,175</u>	<u>\$ (19,184)</u>	<u>\$ (1,382)</u>
Basic and diluted net income (loss) per share:				
Basic net income (loss) per share	<u>\$ (0.08)</u>	<u>\$ 0.06</u>	<u>\$ (0.18)</u>	<u>\$ (0.02)</u>
Diluted net income (loss) per share	<u>\$ (0.08)</u>	<u>\$ 0.05</u>	<u>\$ (0.18)</u>	<u>\$ (0.02)</u>
Weighted average common shares used in calculating:				
Basic net income (loss) per share	<u>109,860</u>	<u>92,241</u>	<u>109,442</u>	<u>89,691</u>
Diluted net income (loss) per share	<u>109,860</u>	<u>100,532</u>	<u>109,442</u>	<u>89,691</u>

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

ARQUE, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)

(IN THOUSANDS, EXCEPT SHARE DATA)

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME/(LOSS)	ACCUMULATED DEFICIT	TOTAL STOCK- HOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	PAR VALUE				
Balance at December 31, 2017	8,370	\$ 8,843	87,110,202	\$ 871	\$ 547,364	\$ (16)	\$ (534,038)	\$ 14,181
Stock option exercises and issuance of common stock	—	—	15,125	—	25	—	—	25
Stock based compensation expense	—	—	—	—	423	—	—	423
Warrants issued upon debt extension	—	—	—	—	120	—	—	120
Change in unrealized loss on marketable securities	—	—	—	—	—	(25)	—	(25)
Increase to opening accumulated deficit upon adoption of new accounting standard	—	—	—	—	—	—	1,500	1,500
Net loss	—	—	—	—	—	—	(6,532)	(6,532)
Balance at March 31, 2018	8,370	\$ 8,843	87,125,327	\$ 871	\$ 547,932	\$ (41)	\$ (539,070)	\$ 9,692
Issuance of common stock and warrants due to conversion of preferred stock to common stock and preferred warrants to common warrants	(8,370)	(8,843)	8,370,000	84	11,823	—	—	11,907
Stock option exercises and issuance of common stock	—	—	337,616	3	152	—	—	155
Shares issued from exercise of warrants	—	—	269,584	3	(2)	—	—	1
Stock based compensation expense	—	—	—	—	314	—	—	314
Change in unrealized gain on marketable securities	—	—	—	—	—	19	—	19
Net income	—	—	—	—	—	—	5,156	5,156
Balance at June 30, 2018	—	\$ —	96,102,527	\$ 961	\$ 560,219	\$ (22)	\$ (533,914)	\$ 27,244

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME/(LOSS)	ACCUMULATED DEFICIT	TOTAL STOCK- HOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	PAR VALUE				
Balance at December 31, 2018	—	\$ —	109,003,637	\$ 1,090	\$ 625,993	\$ (95)	\$ (548,020)	\$ 78,968
Stock option exercises and issuance of common stock	—	—	92,122	1	143	—	—	144
Stock based compensation expense	—	—	—	—	2,124	—	—	2,124
Change in unrealized gain on marketable securities	—	—	—	—	—	117	—	117
Net loss	—	—	—	—	—	—	(10,267)	(10,267)
Balance at March 31, 2019	—	\$ —	109,095,759	\$ 1,091	\$ 628,260	\$ 22	\$ (558,287)	\$ 71,086
Issuance of common stock from stock offering, net	—	—	10,637,500	106	97,234	—	—	97,340
Stock option exercises and issuance of common stock	—	—	527,126	6	1,301	—	—	1,307
Stock based compensation expense	—	—	—	—	917	—	—	917
Change in unrealized gain on marketable securities	—	—	—	—	—	58	—	58
Net loss	—	—	—	—	—	—	(9,092)	(9,092)
Balance at June 30, 2019	—	\$ —	120,260,385	\$ 1,203	\$ 727,712	\$ 80	\$ (567,379)	\$ 161,616

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

ARQUE, INC.

CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	SIX MONTHS ENDED	
	JUNE 30,	
	2019	2018
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	\$ (19,359)	\$ (1,376)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	45	25
Amortization of premium on marketable securities	437	121
Amortization of debt discount	159	163
Change in fair value of warrant liability	—	1,552
Non-cash stock compensation	3,041	737
Changes in operating assets and liabilities:		
Contract receivables	4,489	(3,187)
Prepaid expenses and other, net	(556)	(78)
Accounts payable and accrued expenses	(3,287)	77
Net cash used in operating activities	(15,031)	(1,966)
Cash flows from investing activities:		
Purchases of marketable securities	(46,764)	(25,415)
Proceeds from sale or maturity of marketable securities	52,749	23,937
Purchases of property and equipment	(431)	—
Net cash provided by (used in) investing activities	5,554	(1,478)
Cash flows from financing activities:		
Costs from notes payable and warrants, net	—	(48)
Proceeds from stock offering, net of offering costs	97,475	—
Proceeds from stock option exercises and employee stock plan purchases	1,451	180
Net cash provided by financing activities	98,926	132
Net increase (decrease) in cash and cash equivalents	89,449	(3,312)
Cash and cash equivalents, beginning of period	19,236	20,229
Cash and cash equivalents, end of period	\$ 108,685	\$ 16,917

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION (IN THOUSANDS):

Accrued offering costs of \$135 are included in Accounts payable and accrued expenses.

The accompanying notes are an integral part of these condensed 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 four 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 proprietary pipeline of orally bioavailable 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 product candidates, we seek 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 product candidates if approved. Our clinical pipeline includes the following product candidates:

- ARQ 531 is a potent and reversible dual inhibitor of both wild type and C481S-mutant Bruton's tyrosine kinase (BTK) that is in Phase 1 clinical development for B-cell malignancies refractory to other therapeutic options;
- Miransertib (ARQ 092) is a potent and selective inhibitor of protein kinase B (AKT), a serine/threonine kinase. We expect to commence a registrational clinical trial of miransertib for the treatment of Proteus syndrome and PIK3CA-Related Overgrowth Syndromes (PROS) in the third quarter of 2019;
- ARQ 751 is a next-generation, highly potent and selective inhibitor of AKT that is in Phase 1 clinical development for solid tumors harboring AKT, phosphoinositide 3-kinase (PI3K) or phosphatase and tensin homolog (PTEN) loss mutations; and
- Derazantinib (ARQ 087) is a multi-kinase inhibitor designed to preferentially inhibit the fibroblast growth factor receptor (FGFR) family of kinases that is in a registrational clinical trial in intrahepatic cholangiocarcinoma (iCCA) in patients with FGFR2 fusions. Derazantinib was exclusively licensed to Basilea Pharmaceutica Limited (Basilea) in April 2018 in the United States, European Union, Japan and the rest of the world, excluding the People's Republic of China, Hong Kong, Macau, and Taiwan (collectively, Greater China) where derazantinib was exclusively licensed to Sinovant Sciences Ltd., a subsidiary of Roivant Sciences Ltd. (Sinovant) in February 2018.

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 historically consisted primarily of upfront and other payments received from our collaborators in connection with license agreements. In the six months ended June 30, 2019 and 2018, our net use of cash was primarily driven by payments for operating expenses which resulted in net cash outflows of \$15.0 million and \$2.0 million, respectively.

Our cash requirements may vary materially from those now planned depending on 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 product candidates into a commercial product.

In January 2017, we entered into a loan and security agreement with Oxford Finance, LLC (the “Loan Agreement”) with a principal balance of \$15 million (see Note 8). The terms of the Loan Agreement, which was amended in February 2018, require payments of interest on a monthly basis through August 2019 and payments of principal and interest from September 2019 to August 2022. The maturity date of the loan is August 1, 2022.

In November 2017, we entered into definitive securities purchase agreements with certain institutional investors. In conjunction with this stock offering we 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 converted into 1,000 shares of common stock and each associated Warrant converted into 1,000 common stock warrants in May 2018. The Warrants have a post-conversion exercise price of \$1.75 per share, are exercisable immediately and expire in May 2022.

In February 2018, we entered into a License Agreement with Sinovant pursuant to which we granted Sinovant an exclusive license to develop and commercialize derazantinib in Greater China. The agreement provided for an upfront payment to ArQule of \$3 million and a \$2.5 million development milestone that was paid in the first quarter of 2019. We are also eligible for up to an additional \$12.0 million in regulatory milestone payments and \$70.0 million in commercial milestone payments. Upon commercialization, we are entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in Greater China. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in Greater China. In the three and six months ended June 30, 2019, we recognized revenue of \$0.3 million and \$1.4 million, respectively, for providing certain manufacturing services to Sinovant. During the three and six months ended June 30, 2018, we recognized revenue of zero and \$3.0 million, respectively, related to the transfer of the license to Sinovant.

In April 2018, we entered into a License Agreement with Basilea pursuant to which we granted Basilea an exclusive license to develop and commercialize derazantinib in the United States, European Union, Japan and the rest of the world, excluding Greater China. Under the terms of the agreement, we received an upfront payment of \$10 million and are eligible for up to \$63.0 million in development and regulatory milestone payments and up to \$262.5 million in commercial milestone payments. Upon commercialization, we are entitled to receive tiered 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, we may have the opportunity to promote derazantinib in the United States directly. In the three and six months ended June 30, 2019, we recognized revenue of \$0.03 million and \$0.2 million, respectively, for providing certain research and development services to Basilea, recognized as revenue on a “cost-to-cost method”. Revenue in each of the three and six months ended June 30, 2018 totaled \$13.7 million related to the transfer of the license to Basilea as well as the provision of certain research and development services to Basilea.

In July 2018, we sold 12,650,000 shares of common stock at \$5.50 per share for aggregate net proceeds of approximately \$64.6 million after commissions and other offering expenses.

In June 2019, we sold 10,637,500 shares of common stock at \$9.75 per share for aggregate net proceeds of approximately \$97.3 million after commissions and other offering expenses.

We anticipate that our cash, cash equivalents and marketable securities on hand at June 30, 2019 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.

2. COLLABORATIONS AND ALLIANCES

Basilea Agreement

In April 2018, we entered into a License Agreement with Basilea (the “Basilea Agreement”) pursuant to which we granted Basilea an exclusive license to develop and commercialize derazantinib in the United States, European Union, Japan and the rest of the world, excluding Greater China (the “Basilea Territory”). Under the terms of the Basilea Agreement, we received an upfront payment of \$10.0 million. In addition, we are eligible to receive up to \$63.0 million in development and regulatory milestone payments across multiple indications in the United States, European Union and Japan, none of which exceed \$12.0 million on an individual basis, and up to \$262.5 million in commercial milestone payments based upon the attainment of specified calendar year net sales levels for all indications in the Basilea Territory. Upon commercialization, we are entitled to receive tiered royalties on future net sales of derazantinib ranging from the high-single digits to the mid-teens on direct sales in the Basilea Territory and mid-single digits to low-double digits on indirect sales in the Basilea Territory. Basilea is responsible for all costs and expenses of development, manufacture and commercialization in its territory. Under certain circumstances, we may have the opportunity to promote derazantinib in the United States directly.

We evaluated the Basilea Agreement in accordance with ASC 606, *Revenue from Contracts with Customers*. We concluded there were two performance obligations under the Basilea Agreement at contract inception: (1) the grant of the exclusive license (the “Basilea License”) to derazantinib in the Basilea Territory and (2) the provision of specified research and development services to Basilea (the “R&D Services”).

The total transaction price for the Basilea Agreement at contract inception was determined to be \$19.8 million, which was comprised of the \$10.0 million upfront payment and an estimated \$9.8 million of variable consideration to be received for the R&D Services. As of June 30, 2019, the R&D Services performance obligation was substantially complete. At contract inception, the variable consideration associated with development and regulatory milestone payments was excluded from the transaction price, and as of June 30, 2019 continued to be excluded from the transaction price, as achievement of the milestones is contingent upon future events and is not considered the most-likely outcome. We update our estimates for development and regulatory milestone variable consideration at each reporting date and will recognize revenue associated with a particular milestone when achieving the milestone is considered the most-likely outcome and it is probable that a significant reversal of cumulative revenue under the contract will not occur. The commercial milestone and royalty consideration were excluded from the transaction price because the Basilea License was determined to be the predominant item in the contract. As a result, we will recognize revenue associated with the commercial milestones and royalties at the later of when (i) the related sales occur or (ii) the performance obligation to which some or all of the applicable commercial milestone and/or royalty has been allocated has been satisfied (or partially satisfied). As of June 30, 2019, we have not recognized any commercial milestone or royalty revenue under the Basilea Agreement.

The total transaction price was allocated to the two performance obligations based on the relative standalone selling price of each performance obligation at contract inception. The standalone selling price for the Basilea License was determined on a discounted cash flow basis. At contract inception, \$10.3 million of the total transaction price was allocated to the Basilea License and was recognized when control of the Basilea License was transferred and the license period began. The standalone selling price for the R&D Services was determined based upon a cost-plus margin approach. At contract inception, \$9.5 million of the transaction price was allocated to the R&D Services. Revenue related to the R&D Services is recognized on a “cost-to-cost” percentage of completion basis as the services are performed.

For the three and six months ended June 30, 2019, we recognized revenue of \$0.03 million and \$0.2 million, respectively, under the Basilea Agreement related to R&D Services provided to Basilea. For the three and six months ended June 30, 2018, we recognized revenue of \$13.7 million related to the transfer of the Basilea License as well as providing R&D Services to Basilea.

Sinovant Agreement

In February 2018, we entered into a License Agreement with Sinovant (the “Sinovant Agreement”) pursuant to which we granted Sinovant an exclusive license to develop, manufacture and commercialize derazantinib in Greater China. Under the terms of the Sinovant Agreement, we have received an upfront payment of \$3.0 million and recognized a \$2.5 million regulatory milestone payment in the third quarter of 2018. We are also eligible to receive up to an additional \$12.0 million in regulatory milestone payments across multiple indications in Greater China and \$70.0 million in commercial milestone payments based upon the attainment of specified calendar year net sales levels for all indications in Greater China. Upon commercialization, we are entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in Greater China. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in Greater China.

We evaluated the Sinovant Agreement in accordance with ASC 606, *Revenue from Contracts with Customers*. We concluded that the only performance obligation under the Sinovant Agreement at contract inception was the grant of the exclusive license (the “Sinovant License”) to derazantinib in Greater China. The Sinovant Agreement also contemplated that we might provide certain manufacturing services (the “Manufacturing Services”), which we concluded was not a separate performance obligation at contract inception.

The total transaction price for the Sinovant Agreement at contract inception was determined to be \$3.0 million, which was equal to the upfront payment under the Sinovant Agreement. The \$3.0 million was fully allocable to the Sinovant License and was recognized as revenue when control was transferred and the license period began. Our right to receive regulatory milestone payments is considered variable consideration. At contract inception, the variable consideration associated with regulatory milestone payments was excluded from the transaction price as achievement of the milestones was contingent upon future events and achievement of the milestones is not considered the most-likely outcome. We update our estimates for regulatory milestones at each reporting date and will recognize revenue associated with a particular milestone when we determine that achieving the milestone is the most-likely outcome and it is probable that a significant reversal of cumulative revenue under the contract will not occur. Based on the above analysis, we recognized \$2.5 million in revenue associated with a regulatory milestone in the third quarter of 2018. The commercial milestones and royalty consideration were excluded from the transaction price because the Sinovant License is the only performance obligation and therefore considered the predominant item under the contract. As a result, we recognize revenue associated with the commercial milestones and royalties at the later of when (i) the related sales occur or (ii) the performance obligation to which some or all of the applicable commercial milestone and/or royalty has been allocated has been satisfied (or partially satisfied). As of June 30, 2019, we have not recognized any commercial milestone or royalty revenue under the Sinovant Agreement.

In December 2018, we entered into a Supply Agreement with Sinovant where we agreed to provide the Manufacturing Services to Sinovant beyond the term contemplated for those services under the Sinovant Agreement. The Manufacturing Services are the only performance obligation under the Supply agreement and revenue related to the Supply Agreement is recognized on a “cost-to-cost” percentage of completion basis as the services are performed.

For the three and six months ended June 30, 2019, we recognized revenue of \$0.3 million and \$1.4 million, respectively, under the Sinovant Agreement related to the Manufacturing Services that we provided. For the three and six months ended June 30, 2018, we recognized revenue of zero and \$3.0 million, respectively, related to transfer of the Sinovant License.

Other Licensing Agreements

In October 2017, we granted a third party a non-exclusive license to certain of our library compounds. The licensed compounds were delivered and were accepted by the third party in 2018. Accordingly, revenue for the three and six months ended June 30, 2019 was zero. For the three and six months ended June 30, 2018, we recorded revenue of zero and \$1.1 million, based upon the achievement of the quality and acceptance testing.

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 an available-for-sale debt 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 June 30, 2019 and December 31, 2018 (in thousands):

June 30, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<i>Security type</i>				
Corporate debt securities-short term	\$ 70,360	\$ 82	\$ (6)	\$ 70,436
Corporate debt securities-long term	3,634	4	—	3,638
Total available-for-sale marketable securities	<u>\$ 73,994</u>	<u>\$ 86</u>	<u>\$ (6)</u>	<u>\$ 74,074</u>
December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<i>Security type</i>				
Corporate debt securities-short term	\$ 80,417	\$ 2	\$ (97)	\$ 80,322
Total available-for-sale marketable securities	<u>\$ 80,417</u>	<u>\$ 2</u>	<u>\$ (97)</u>	<u>\$ 80,322</u>

None of our available-for-sale marketable securities were in a continuous unrealized loss position for more than 12 months at June 30, 2019 or December 31, 2018.

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 (in thousands):

	June 30, 2019	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 107,491	\$ 107,491	\$ —	\$ —
Corporate debt securities-short term	70,436	—	70,436	—
Corporate debt securities-long term	3,638	—	3,638	—
Total	<u>\$ 181,565</u>	<u>\$ 107,491</u>	<u>\$ 74,074</u>	<u>\$ —</u>
	December 31, 2018	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 14,444	\$ 14,444	\$ —	\$ —
Corporate debt securities-short term	80,322	—	80,322	—
Total	<u>\$ 94,766</u>	<u>\$ 14,444</u>	<u>\$ 80,322</u>	<u>\$ —</u>

4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019	December 31, 2018
Accounts payable	\$ 983	\$ 1,329
Accrued payroll	1,686	1,971
Accrued outsourced preclinical and clinical fees	5,950	8,497
Accrued professional fees	870	666
Other accrued expenses	306	485
	<u>\$ 9,795</u>	<u>\$ 12,948</u>

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 three and six months ended June 30, 2019 and the six months ended June 30, 2018 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. For the three months ended June 30, 2018 shares used for the basic computation of net income per share totaled 92,241,124 and shares used for the diluted computation included an additional 8,290,388 potential common shares. Potential common shares, for the three and six months ended June 30, 2019, include 12,662,646 shares that would be issued upon the exercise of outstanding employee and Board of Director stock options, 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 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 and six months ended June 30, 2018, include 10,625,917 shares that would be issued upon the exercise of outstanding employee and Board of Director stock options, 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 have been 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. The preferred shares and warrants from our November 2017 preferred stock offering were converted to common stock and common stock warrants in May 2018.

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 and six months ended June 30, 2019 and 2018.

The following table presents stock-based compensation expense included in our condensed statement of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	\$ 215	\$ 79	\$ 517	\$ 185
General and administrative	702	235	2,524	552
Total stock-based compensation expense	<u>\$ 917</u>	<u>\$ 314</u>	<u>\$ 3,041</u>	<u>\$ 737</u>

In the six months ended June 30, 2019, we recorded stock-based compensation expense of \$1.0 million related to the modification of awards to our former Chief Financial Officer in connection with his retirement in March 2019. In the three and six months ended June 30, 2019 and 2018, 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 six months ended June 30, 2019 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2018	10,748,157	\$ 2.90
Granted	2,657,010	4.05
Exercised	(594,458)	2.30
Cancelled	(148,063)	2.41
Outstanding as of June 30, 2019	12,662,646	\$ 3.17
Exercisable as of June 30, 2019	7,365,665	\$ 3.26

The aggregate intrinsic value of options outstanding at June 30, 2019 was \$99.2 million, including \$57.1 million related to exercisable options. The weighted average fair value of options granted in the six months ended June 30, 2019 and 2018 was \$2.53 and \$1.28 per share, respectively. The intrinsic value of options exercised in the six months ended June 30, 2019 was \$2.4 million.

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Vested and unvested expected to vest at June 30, 2019	12,662,646	\$ 3.17	6.3	\$ 97,997
Exercisable at June 30, 2019	7,365,665	\$ 3.26	4.5	\$ 57,072

The total compensation cost not yet recognized as of June 30, 2019 related to non-vested option awards was \$8.2 million, which will be recognized over a weighted-average period of 2.9 years. During the six months ended June 30, 2019, 28,350 shares expired and 119,713 shares were forfeited. The weighted average remaining contractual life for options exercisable at June 30, 2019 was 4.45 years.

7. COMMON STOCK OFFERINGS

In June 2019, we sold 10,637,500 shares of common stock at \$9.75 per share for aggregate net proceeds of approximately \$97.3 million after commissions and other offering expenses.

In July 2018, we sold 12,650,000 shares of common stock at \$5.50 per share for aggregate net proceeds of approximately \$64.6 million after commissions and other offering expenses.

8. LOAN AGREEMENT

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

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 June 30, 2019 was 9.28%. 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 June 30, 2019 is as follows (in thousands):

2019	\$ 1,667
2020	5,000
2021	5,000
2022	3,333
	<u>\$ 15,000</u>

Upon prepayment of the loan or on 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 1% of the outstanding principal balance.

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 June 30, 2019.

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 the Lender's prior written consent.

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 Restated Certificate of Incorporation, as amended, 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 we 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 converted into 1,000 shares of common stock and each associated Warrant converted into 1,000 common stock warrants in May 2018.

The terms of the Series A Preferred for which the warrants were exercisable required that the fair value allocated to the warrants at the date of issuance be recorded as a liability on our balance sheet. The warrant liability was marked to market value through the statement of operations and comprehensive loss as a non-cash gain or loss at each reporting period until the conversion of the Series A Preferred to common stock in May 2018. Upon conversion, the warrant liability of \$3,064 was extinguished with an offsetting amount included as additional paid-in capital in stockholders' equity. Accordingly, at each of December 31, 2018 and June 30, 2019, the warrant liability was zero. In the three and six months ended June 30, 2018, we recognized a non-cash income of \$0.7 million and non-cash expense of \$1.5 million, respectively, recorded in other income (expense) on the statement of operations and comprehensive loss related to the change in the fair value of the warrant liability.

10. RECENT ACCOUNTING PRONOUNCEMENTS

Recently Adopted Accounting Pronouncements

In February 2016 the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2016-02, Leases (Topic 842). This standard established a right-of-use model that requires all lessees to recognize right-of-use assets and liabilities on their balance sheet that arise from leases with terms longer than 12 months as well as provide disclosures with respect to certain qualitative and quantitative information related to their leasing arrangements. This standard became effective for us on January 1, 2019 ("the Effective Date").

The FASB has subsequently issued the following amendments to ASU 2016-02, which also became effective on January 1, 2019, and which we collectively refer to as the new leasing standards:

- ASU No. 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842, which permits an entity to elect an optional transition practical expedient to not evaluate under Topic 842 land easements that exist or expired prior to adoption of Topic 842 and that were not previously accounted for as leases under the prior standard, ASC 840, Leases.
- ASU No. 2018-10, Codification Improvements to Topic 842, Leases, which amends certain narrow aspects of the guidance issued in ASU 2016-02.
- ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of accumulated deficit in the period of adoption as well as an additional practical expedient for lessors to not separate non-lease components from the associated lease component.
- ASU No. 2018-20, Narrow-Scope Improvements for Lessors, which contains certain narrow scope improvements to the guidance issued in ASU 2016-02.

We adopted the new lease accounting standard on January 1, 2019, using a modified retrospective transition approach of applying the new standard to all leases existing as of, or entered into after, the Effective Date and with remaining terms of 12 months or more. Our assessment included the lease of our headquarters in Burlington, MA which commenced in May 2015 and expires in July 2020 and our laboratory space in Woburn, MA which commenced in March 2019 and expires in April 2024.

The adoption of the new standard on January 1, 2019 resulted in the recording of a right-of-use asset and lease liability of \$0.7 million related to the lease of our headquarters in Burlington, MA that existed on the Effective Date. The lease liability is based on the present value of the remaining minimum lease payments, discounted using our secured incremental borrowing rate at the Effective Date. As permitted under ASC 842, we elected several practical expedients and therefore did not reassess at the Effective Date (1) whether any existing contract is or contains a lease, (2) the classification of existing leases, and (3) whether previously capitalized costs continue to qualify as initial indirect costs. We also elected the practical expedient to not separate lease and non-lease components. The application of the practical expedients did not have a significant impact on the measurement of the operating lease liability. In addition, we implemented internal controls to enable the preparation of financial information on adoption. The adoption did not have a material impact on our condensed financial statements related to the existing lease of our headquarters in Burlington, MA for the three and six months ended June 30, 2019. As a result, there was no cumulative-effect adjustment.

For contracts entered into on or after the Effective Date, at the inception of a contract we assess whether the contract is, or contains, a lease. Our assessment is based on: (1) whether the contract involves the use of a distinct identified asset, (2) whether we obtain the right to substantially all the economic benefit from the use of the asset throughout the period, and (3) whether we have the right to direct the use of the asset. At inception of a lease, we allocate the consideration in the contract to each lease component based on its relative stand-alone price to determine the lease payments.

Leases are classified as either finance leases or operating leases. A lease is classified as a finance lease if any one of the following criteria are met: (1) the lease transfers ownership of the asset by the end of the lease term, (2) the lease contains an option to purchase the asset that is reasonably certain to be exercised, (3) the lease term is for a major part of the remaining useful life of the asset or (4) the present value of the lease payments equals or exceeds substantially all of the fair value of the asset. A lease is classified as an operating lease if it does not meet any one of these criteria. Our leases are comprised of operating leases related to our headquarters in Burlington, MA and laboratory space in Woburn, MA.

For all leases at the lease commencement date, a right-of-use asset and a lease liability are recognized. The right-of-use asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease.

The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial direct costs incurred, consisting mainly of brokerage commissions, less any lease incentives received. All right-of-use assets are reviewed for impairment. The lease liability is initially measured at the present value of the lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the secured incremental borrowing rate. For our operating leases, we use our secured incremental borrowing rate if the implicit lease rate cannot be determined.

Lease payments included in the measurement of the lease liability comprise the following: the fixed noncancelable lease payments, payments for optional renewal periods where it is reasonably certain the renewal period will be exercised, and payments for early termination options unless it is reasonably certain the lease will not be terminated early.

Lease expense for operating leases consists of the lease payments plus any initial direct costs and is recognized on a straight-line basis over the lease term. Certain leases contain rent escalation clauses and variable lease payments that require additional rental payments in later years of the term, including payments based on an index or inflation rate. Payments based on the change in an index or inflation rate, or payments based on a change in our portion of the operating expenses, including real estate taxes and insurance, are not included in the initial lease liability and are recorded as a period expense when incurred. Our operating leases may include an option to renew the lease term for various renewal periods and/or to terminate the leases early. As an option to exercise the renewal or early termination of our operating leases were either non-existent or not reasonably certain as of the ASC 842 Effective Date for our headquarters in Burlington, MA and the lease commencement date our laboratory space in Woburn, MA, we have not included such options in our initial lease liability.

As of June 30, 2019, we recognized right-of-use assets related to our headquarters in Burlington, MA and laboratory space in Woburn, MA of \$0.9 million and the related net lease liabilities of \$0.9 million, which represents the net present value of the remaining lease payments of approximately \$1.0 million, discounted using the Company's incremental borrowing rate of 9.34%. We have included the right-of-use assets and lease liabilities in the condensed balance sheet as of June 30, 2019.

The following table summarizes future minimum lease payments for our non-cancelable operating leases as of June 30, 2019 (in thousands):

Year Ending December 31,	
2019 (six months ending December 31, 2019)	\$ 303
2020	394
2021	98
2022	98
2023	98
Thereafter	26
Total minimum lease payments	\$ 1,017

As previously disclosed in our 2018 Annual Report on Form 10-K and under the previous lease accounting standard, ASC 840, *Leases*, the total commitment for our non-cancelable operating lease was \$0.8 million as of December 31, 2018 (in thousands):

Year Ending December 31,	
2019	\$ 523
2020	296
Thereafter	—
Total minimum lease payments	\$ 819

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, (“ASU 2018-13”). The new standard removes certain disclosures, modifies certain disclosures and adds additional disclosures related to fair value measurement. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2018-13 will have on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, (“ASU 2018-15”). The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this update. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. The amendments in this update should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. We are currently evaluating the impact that the adoption of ASU 2018-15 will have on our consolidated financial statements.

11. INCOME TAXES

As of December 31, 2018, we had federal net operating losses (“NOL”), state NOL, and research and development credit carryforwards of approximately \$422,045, \$240,916 and \$28,378 respectively, which expire at various dates through 2037.

As of June 30, 2019, and December 31, 2018 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 June 30, 2019, and December 31, 2018, we had no accrued interest or penalties related to uncertain tax positions. Our U.S. federal tax returns for the tax years 2015 through 2018 and our state tax returns for the tax years 2015 through 2018 remain open to examination. Prior tax years remain open to the extent of NOL 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, 2019, 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, 2018.

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 four 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 orally bioavailable 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 product candidates, we seek 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 product candidates if approved. Our clinical pipeline includes the following product candidates:

- ARQ 531 is a potent and reversible dual inhibitor of both wild type and C481S-mutant Bruton's tyrosine kinase (BTK) that is in Phase 1 clinical development for B-cell malignancies refractory to other therapeutic options;
- Miransertib (ARQ 092) is a potent and selective inhibitor of protein kinase B (AKT), a serine/threonine kinase. We expect to commence a registrational clinical trial of miransertib for the treatment of Proteus syndrome and PIK3CA-Related Overgrowth Syndromes (PROS) in the third quarter of 2019;
- ARQ 751 is a next-generation, highly potent and selective inhibitor of AKT that is in Phase 1 clinical development for solid tumors harboring AKT, phosphoinositide 3-kinase (PI3K) or phosphatase and tensin homolog (PTEN) loss mutations; and
- Derazantinib (ARQ 087) is a multi-kinase inhibitor designed to preferentially inhibit the fibroblast growth factor receptor (FGFR) family of kinases that is in a registrational clinical trial in intrahepatic cholangiocarcinoma (iCCA) in patients with FGFR2 fusions. Derazantinib was exclusively licensed to Basilea Pharmaceutica Limited (Basilea) in April 2018 in the United States, European Union, Japan and the rest of the world, excluding the People's Republic of China, Hong Kong, Macau, and Taiwan (collectively, Greater China) where derazantinib was exclusively licensed to Sinovant Sciences Ltd., a subsidiary of Roivant Sciences Ltd. (Sinovant) in February 2018.

We have incurred a cumulative deficit of approximately \$567 million from inception through June 30, 2019. We recorded a net loss for 2018 and expect a net loss for 2019.

LIQUIDITY AND CAPITAL RESOURCES

	June 30, 2019	December 31, 2018	Increase (decrease)	
	(in millions)		\$	%
Cash, cash equivalents and marketable securities	\$ 182.8	\$ 99.6	\$ 83.2	84%
Working capital	167.5	91.8	75.7	82%

	Six Months Ended		Increase (decrease)
	June 30, 2019	June 30, 2018	
	(in millions)		
Cash flow from:			
Operating activities	\$ (15.0)	\$ (2.0)	\$ (13.0)
Investing activities	5.6	(1.5)	7.1
Financing activities	98.9	0.1	98.8

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 upfront and other payments received from our collaborators in connection with license agreements. In the six months ended June 30, 2019 and 2018, our net use of cash was primarily driven by the difference between cash received from our collaborations and payments for operating expenses which resulted in net cash outflows of \$15.0 million and \$2.0 million, respectively.

Cash flow from investing activities. Our net cash provided by investing activities of \$5.6 million for the six months ended June 30, 2019 was comprised of net maturities of marketable securities. Our net cash used by investing activities of \$1.5 million for six months ended June 30, 2018 was comprised of net purchases 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 of \$98.9 million for the six months ended June 30, 2019, was primarily comprised of \$97.5 million in net proceeds from our June 2019 stock offering and \$1.5 million from stock option exercises. Our net cash provided by financing activities of \$0.1 million for the six months ended June 30, 2018 was principally comprised of proceeds from stock option exercises.

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 require payments of interest on a monthly basis through August 2019 and payments of interest and principal from September 2019 to August 2022.

In November 2017, we entered into definitive securities purchase agreements with certain institutional investors. In conjunction with this stock offering, we 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 converted into 1,000 shares of common stock and each associated Warrant converted into 1,000 common stock warrants in May 2018. The Warrants have a post-conversion exercise price of \$1.75 per share, are exercisable immediately and expire in May 2022.

In February 2018, we entered into a License Agreement with Sinovant pursuant to which we granted Sinovant an exclusive license to develop and commercialize derazantinib in Greater China. The agreement provided for an upfront payment to ArQule of \$3 million and a \$2.5 million development milestone that was paid in the first quarter of 2019. We are also eligible for up to an additional \$12.0 million in regulatory milestone payments and \$70.0 million in commercial milestone payments. Upon commercialization, we are entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in Greater China. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in Greater China. For the three and six months ended June 30, 2019, we recognized revenue of \$0.3 million and \$1.4 million, respectively, for providing certain manufacturing services to Sinovant. For the three and six months ended June 30, 2018, we recognized revenue of zero and \$3.0 million, respectively, related to the transfer of the license to Sinovant.

In April 2018, we entered into a License Agreement with Basilea pursuant to which we granted Basilea an exclusive license to develop and commercialize derazantinib in the United States, European Union, Japan and the rest of the world, excluding Greater China. Under the terms of the agreement, we received an upfront payment of \$10 million and are eligible for up to \$63.0 million in development and regulatory milestone payments and up to \$262.50 million in commercial milestone payments. Upon commercialization, we are entitled to receive tiered 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, we may have the opportunity to promote derazantinib in the United States directly. For the three and six months ended June 30, 2019, we recognized revenue of \$0.03 million and \$0.2 million, respectively, for providing certain research and development services to Basilea, recognized as revenue on a “cost-to-cost” method. Revenue in each of the three and six months ended June 30, 2018 totaled \$13.7 million related to the transfer of the license to Basilea as well as the provision of certain research and development services to Basilea.

In July 2018, we sold 12,650,000 shares of common stock at \$5.50 per share for aggregate net proceeds of approximately \$64.6 million after commissions and other offering expenses.

In June 2019, we sold 10,637,500 shares of common stock at \$9.75 per share for aggregate net proceeds of approximately \$97.3 million after commissions and other offering expenses.

We anticipate that our cash, cash equivalents and marketable securities on hand at June 30, 2019 and the financial support from our licensing agreements will be sufficient to finance our operations into 2022 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 June 30, 2019 (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	\$ 4,167	\$ 10,000	\$ 1,733	\$ —
Interest on notes payable	1,983	1,041	934	8	—
Operating lease obligations	1,017	605	337	75	—
Purchase obligations	5,950	5,950	—	—	—
Total	\$ 24,850	\$ 11,763	\$ 11,271	\$ 1,816	\$ —

In January 2015, we entered into a lease agreement for our headquarters facility in Burlington, MA. 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. In January 2019, we entered into a lease agreement for our laboratory space in Woburn, MA. The lease commenced on March 6, 2019 for a term of five years and one month. The lease agreement for the laboratory space includes a rent escalation clause, and accordingly, rent expense is being recognized on a straight-line basis over the lease term. The obligations for our operating leases 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, 2018 on Form 10-K filed with the Securities and Exchange Commission (“SEC”) on March 7, 2019.

RESULTS OF OPERATIONS

The following are the results of operations for the three and six months ended June 30, 2019 and 2018:

Revenue

	2019		2018		Increase (decrease)	
					\$	%
(in millions)						
<i>For the three months ended June 30:</i>						
Research and development revenue	\$	0.3	\$	13.7	\$	(13.4) (98)%
<i>For the six months ended June 30:</i>						
Research and development revenue	\$	1.6	\$	17.8	\$	(16.2) (91)%

Research and development revenue in the three months ended June 30, 2019 consisted of \$0.3 million from our Sinovant licensing and supply agreements. Research and development revenue in the three months ended June 30, 2018 consisted of \$13.7 million from our Basilea licensing agreement.

Research and development revenue in the six months ended June 30, 2019 consisted of \$1.4 million from our Sinovant licensing and supply agreements and \$0.2 million from our Basilea licensing agreement. Research and development revenue in the six months ended June 30, 2018 consisted of \$13.7 million from our Basilea licensing agreement, \$3.0 million from our Sinovant licensing agreement and \$1.1 million from a non-exclusive license agreement for certain of our library compounds.

Research and development

	2019		2018		Increase (decrease)	
					\$	%
(in millions)						
<i>For the three months ended June 30:</i>						
Research and development	\$	6.3	\$	6.8	\$	(0.5) (7)%
<i>For the six months ended June 30:</i>						
Research and development	\$	13.8	\$	12.6	\$	1.2 9%

Research and development expense in the three months ended June 30, 2019 decreased by \$0.5 million as compared to the three months ended June 30, 2018, primarily due to lower outsourced preclinical, clinical and product development costs. Research and development expense in the six months ended June 30, 2019 increased \$1.2 million as compared to the six months ended June 30, 2018, primarily due to higher labor related costs. At June 30, 2019 we had 24 employees dedicated to our research and development program compared to 18 employees at June 30, 2018.

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 preclinical 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 our research and development expense to remain significant, yet consistent, as we continue to develop our portfolio of oncology and rare disease 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 programs on a program-by-program basis.

Our future research and development expenses in support of our current and future 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 and cost of development generally varies substantially according to the type, complexity, novelty, and intended use of a product.

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

Clinical Phase	Estimated Completion Period
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 Basilea and Sinovant. 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 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 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

	(in millions)		Increase (decrease)	
	2019	2018	\$	%
<i>For the three months ended June 30:</i>				
General and administrative	\$ 3.2	\$ 2.2	\$ 1.0	42%
<i>For the six months ended June 30:</i>				
General and administrative	\$ 7.5	\$ 4.6	\$ 2.9	63%

General and administrative expense increased by \$1.0 million in the three months ended June 30, 2019 as compared to the three months ended June 30, 2018, principally due to higher labor related costs and professional fees.

General and administrative expense increased by \$2.9 million in the six months ended June 30, 2019 as compared to the six months ended June 30, 2018, principally due to a \$1.0 million increase in stock-based compensation expense, a \$0.4 million increase in labor related costs and professional fees and \$1.3 million of non-recurring executive retirement costs.

General and administrative headcount was 13 employees at each of June 30, 2019 and June 30, 2018.

Interest income, interest expense and other expense

	2019		2018		Increase (decrease)		
	(in thousands)				\$	%	
<i>For the three months ended June 30:</i>							
Interest income	\$	558	\$	170	\$	388	228%
Interest expense		433		417		16	4%
Other income		—		718		(718)	(100)%
<i>For the six months ended June 30:</i>							
Interest income	\$	1,124	\$	329	\$	795	242%
Interest expense		863		813		50	6%
Other expense		—		1,552		(1,552)	(100)%

Interest income is derived from our portfolio of cash, cash equivalents and investments and increased in the three and six months ended June 30, 2019 as compared to the three and six months ended June 30, 2018, respectively, primarily due to an increase in our portfolio balance resulting from (i) net proceeds from our public stock offerings, (ii) cash invested from recent business development agreements and (iii) increased interest rates.

Interest expense is related to our loan agreement with Oxford.

Other expense was zero in the three and six months ended June 30, 2019 due to the elimination of our preferred stock warrant liability upon the conversion of the preferred shares into common shares in May 2018. Other expense in the three and six months ended June 30, 2018 reflected a non-cash income and non-cash income expense, respectively, resulting from the change in the fair value of our preferred stock warrant liability.

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 can 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 we expect or anticipate will occur in the future, such as projections about our future results of operations, our financial condition, research, development and commercialization of our products and anticipated trends in our 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, preclinical efforts associated with our product pipeline may fail or prove disappointing because our technology platform did not produce candidates with the desired characteristics. Animal preclinical 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 or will satisfy applicable regulatory standards. Furthermore, our drugs 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. 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 collaborators to discontinue development.

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 collaborators may terminate their agreements with us, thereby eliminating that source of funding.

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, 2018 filed with the SEC on March 7, 2019, 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 June 30, 2019. 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 June 30, 2019, 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.

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, 2018 filed with the SEC on March 7, 2019, 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
10.1*	Letter Agreement, dated April 11, 2019, by and between the Company and Marc Schegerin. Filed as Exhibit 10.5 to the Company’s Quarterly Report on Form 10-Q filed on May 1, 2019 (File No. 000-21429) and incorporated herein by reference.
31.1	Rule 13a-14(a) Certificate of Chief Executive Officer, filed herewith.
31.2	Rule 13a-14(a) Certificate of Principal Financial Officer, filed herewith.
32	Rule 13a-14(b) Certificate of Chief Executive Officer and Chief Financial Officer, filed herewith.
101	Interactive Data File

* Indicates a management contract or compensatory plan.

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: August 7, 2019

/s/ PETER S. LAWRENCE

Peter S. Lawrence
President and Chief Operating Officer
(Duly Authorized Officer and Principal Financial Officer)

CERTIFICATE OF THE CHIEF EXECUTIVE OFFICER

I, Paolo Pucci, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ArQule, 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 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, 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 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 7, 2019

/s/ PAOLO PUCCI
Paolo Pucci
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATE OF THE PRINCIPAL FINANCIAL OFFICER

I, Peter S. Lawrence, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ArQule, 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 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, 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 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 7, 2019

/s/ PETER S. LAWRENCE

Peter S. Lawrence
President and Chief Operating Officer
(Principal Financial Officer)

ARQULE, INC.

CERTIFICATE OF THE CHIEF EXECUTIVE OFFICER AND
PRINCIPAL FINANCIAL OFFICER

The undersigned, Paolo Pucci Chief Executive Officer (Principal Executive Officer) of ArQule, Inc. (the “Company”) and Peter S. Lawrence, President and Chief Operating Officer (Principal Financial Officer), of the Company, both duly elected and currently serving, hereby certify that, to the best of his or her knowledge:

1. the quarterly report on Form 10-Q for the period ending June 30, 2019, filed on behalf of the Company pursuant to the Securities Exchange Act of 1934 (the “Exchange Act”) and containing the financial statements of the Company, fully complies with the requirements of section 13(a) of the Exchange Act; and
2. the information contained in such quarterly report fairly presents, in all material respects, the financial condition and results of operations of the Company for the dates and periods covered by such quarterly report.

This certification accompanies the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2019, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (the “2002 Act”) and shall not be deemed filed by the Company for purposes of Section 18 of the Exchange Act.

This certification is being made for the exclusive purpose of compliance by the Principal Executive Officer and Principal Financial Officer of the Company with the requirements of Section 906 of the 2002 Act, and may not be disclosed, distributed or used by any person for any reason other than as specifically required by law.

IN WITNESS WHEREOF, the undersigned have executed this Certificate as of the 7th day of August 2019.

/s/ PAOLO PUCCI

Name: Paolo Pucci
Title: Chief Executive Officer
(Principal Executive Officer)

/s/ PETER S. LAWRENCE

Name: Peter S. Lawrence
Title: President and Chief Operating Officer
(Principal Financial Officer)
