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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, 2018

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)

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 and posted on its Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405) of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  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   
(Do not check if a smaller reporting company)

Accelerated filer   
Smaller reporting company   
Emerging growth company

Indicate If an emerging growth company, indicate by check by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Number of shares outstanding of the registrant's Common Stock as of July 19, 2018:

Common Stock, par value \$.01 108,816,985 shares outstanding

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QUARTER ENDED JUNE 30, 2018  
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## ARQULE, INC.

## CONDENSED BALANCE SHEETS (Unaudited)

	June 30, 2018	December 31, 2017
	(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 16,917	\$ 20,229
Marketable securities-short term	29,158	27,807
Contract receivables	3,187	-
Prepaid expenses	625	547
Total current assets	49,887	48,583
Property and equipment, net	90	115
Other assets	204	204
Total assets	<u>\$ 50,181</u>	<u>\$ 48,902</u>
<b>LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,336	\$ 8,259
Deferred revenue	-	1,500
Total current liabilities	8,336	9,759
Long-term liabilities:		
Notes payable	14,601	14,607
Warrant liability	-	1,512
Total liabilities	22,937	25,878
Commitments and contingencies		
Preferred stock, convertible, Series A \$0.01 par value; 1,000,000, shares authorized; zero and 8,370 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	-	8,843
Stockholders' equity:		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 96,102,527 and 87,110,202 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	961	871
Additional paid-in capital	560,219	547,364
Accumulated other comprehensive loss	(22)	(16)
Accumulated deficit	(533,914)	(534,038)
Total stockholders' equity	27,244	14,181
Total liabilities, preferred stock and stockholders' equity	<u>\$ 50,181</u>	<u>\$ 48,902</u>

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

ARQULE, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	June 30,		June 30,	
	2018	2017	2018	2017
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Research and development revenue	\$ 13,706	\$ —	\$ 17,844	\$ —
Costs and expenses:				
Research and development	6,787	4,983	12,599	10,177
General and administrative	2,234	1,866	4,585	3,940
Total costs and expenses	9,021	6,849	17,184	14,117
Income (loss) from operations	4,685	(6,849)	660	(14,117)
Interest income	170	37	329	59
Interest expense	(417)	(389)	(813)	(719)
Other income (expense)	718	—	(1,552)	—
Net income (loss)	5,156	(7,201)	(1,376)	(14,777)
Unrealized gain (loss) on marketable securities	19	(5)	(6)	(9)
Comprehensive income (loss)	\$ 5,175	\$ (7,206)	\$ (1,382)	\$ (14,786)
Basic and diluted net income (loss) per share:				
Basic net income (loss) per share	\$ 0.06	\$ (0.10)	\$ (0.02)	\$ (0.21)
Diluted net income (loss) per share	\$ 0.05	\$ (0.10)	\$ (0.02)	\$ (0.21)
Weighted average share used in calculating:				
Basic net income (loss) per share	92,241	71,149	89,691	71,143
Diluted net income (loss) per share	100,532	71,149	89,691	71,143

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

## ARQULE, INC.

## CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	SIX MONTHS ENDED	
	JUNE 30,	
	2018	2017
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	\$ (1,376)	\$ (14,777)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	25	38
Amortization of premium (discount) on marketable securities	121	(9)
Amortization of debt discount	163	150
Change in fair value of warrant liability	1,552	—
Non-cash stock compensation	737	828
Changes in operating assets and liabilities:		
Contract receivables	(3,187)	-
Prepaid expenses	(78)	449
Accounts payable and accrued expenses	77	(1,439)
Net cash used in operating activities	<u>(1,966)</u>	<u>(14,760)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(25,415)	(14,076)
Proceeds from sale or maturity of marketable securities	23,937	15,827
Net cash provided by (used in) investing activities	<u>(1,478)</u>	<u>1,751</u>
Cash flows from financing activities:		
Proceeds (costs) from notes payable and warrants, net	(48)	14,624
Proceeds from employee stock option exercises and employee stock purchase plan purchases	180	17
Net cash provided by financing activities	<u>132</u>	<u>14,641</u>
Net increase (decrease) in cash and cash equivalents	(3,312)	1,632
Cash and cash equivalents, beginning of period	20,229	15,267
Cash and cash equivalents, end of period	<u>\$ 16,917</u>	<u>\$ 16,899</u>

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

ARQULE, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

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

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

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

- ARQ 531, a potent and reversible inhibitor of both wild type and C481S-mutant BTK, in Phase 1 for B-cell malignancies refractory to other therapeutic options;
- Miransertib (ARQ 092), a selective inhibitor of AKT, a serine/threonine kinase, in Phase 1/2 in rare Overgrowth Diseases and in Phase 1 for the rare disease, Proteus syndrome, in partnership with the National Institutes of Health (NIH); also in Phase 1b in oncology in combination with the hormonal therapy, anastrozole, in endometrial cancer;
- ARQ 751, a next-generation inhibitor of AKT, in Phase 1 for solid tumors harboring the AKT1 or PI3K mutation;
- Derazantinib (ARQ 087), a multi-kinase inhibitor designed to preferentially inhibit the FGFR family of kinases, in a registrational trial in intrahepatic cholangiocarcinoma (iCCA) in patients with FGFR 2 fusions; and
- ARQ 761, a  $\beta$ -lapachone analog being evaluated as a promoter of NQO1-mediated programmed cancer cell death, in Phase 1/2 in multiple oncology indications in partnership with The University of Texas Southwest Medical Center.

In February 2018, we entered into a License Agreement (the "Agreement") with Sinovant Sciences Ltd. ("Sinovant") and Roivant Sciences Ltd. (Roivant), the parent of Sinovant, pursuant to which ArQule granted Sinovant a license to develop, manufacture and exclusively commercialize its FGFR inhibitor, derazantinib (ARQ 087), in Greater China. The Agreement provides for an upfront payment to ArQule of \$3 million and a guaranteed \$2.5 million development milestone within the first year. ArQule is also eligible for an additional \$82 million in regulatory and sales milestones. Upon commercialization, ArQule is entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in the Greater China territory. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. For the three months ended June 30, 2018 no revenue was recognized under this license agreement. For the six months ended June 30, 2018, we recognized revenue of \$3.0 million for completing our performance obligation under this licensing agreement.

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

Revenue in the three and six months ended June 30, 2018 totaled \$13.7 million for providing the technology license as well as certain research and development services to Basilea, recognized as revenue on a percentage of completion basis. The adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers on January 1, 2018 did not have a material effect on the amount of revenue recognized under this agreement.

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

Our uses of cash for operating activities have primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices and laboratories, fees paid in connection with preclinical and clinical studies, laboratory supplies and materials, and professional fees. The sources of our cash flow from operating activities have consisted primarily of payments received from our collaborators for services performed or upfront payments for license agreements or future services. In the six months ended June 30, 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 \$2.0 million. In the six months ended 2017, our net use of cash was primarily driven by payments for operating expenses which resulted in net cash outflows of \$14.8 million.

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

In September 2017, we sold 2.0 million shares of common stock through an at-the-market (ATM) offering and raised net proceeds of \$2.3 million. In October 2017, we entered into definitive stock purchase agreements with certain institutional investors. In conjunction with this stock offering we issued 13,938,651 shares of our common stock and warrants to purchase 3,123,674 shares of our common stock for aggregate net proceeds of \$15.6 million. Each warrant is exercisable for \$1.75 per share and expires in four years from the date of issuance. In November 2017, we entered into definitive securities purchase agreements with certain institutional investors. In conjunction with this stock offering the Company raised net proceeds of \$9.5 million through the sale of 8,370 shares of series A convertible preferred stock (Series A Preferred) and warrants to purchase 2,259 shares of Series A Preferred (Warrants). Each share of Series A Preferred together with the associated Warrant is priced at \$1,135 and automatically converted into 1,000 shares of common stock upon the effectiveness on May 8, 2018 of an amendment to the Company’s restated certificate of incorporation to increase the number of authorized shares of common stock thereunder. The Warrants had a pre-conversion exercise price of \$1,750 per share of Series A Preferred (post-conversion price of \$1.75 per share of common stock), are exercisable immediately and expire approximately four years from the date of the adoption of the amendment to the Company’s restated certificate of incorporation.

We anticipate that our cash, cash equivalents and marketable securities on hand at June 30, 2018, and financial support from our licensing agreements will be sufficient to finance our operations for at least 12 months from the issuance date of these financial statements. We expect that we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions, and due to global capital and credit market conditions or for other reasons, we may be unable to raise capital when needed, or on terms favorable to us. If necessary funds are not available, we may have to delay, reduce the scope of, or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates.

#### *Adoption and Impact of the New Revenue Standard*

The Company adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to its accounting policy for revenue recognition. Results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. We recorded a net increase to opening equity of \$1.5 million as of January 1, 2018 due to the cumulative impact of adopting this new standard. Without applying the new revenue standard, the disclosed research and development revenue would have been \$1.4 million higher than currently disclosed for the first six months of 2018. Contract receivables were \$3.2 million at June 30, 2018. The adoption of the new revenue standard did not have a material impact on any other balances within the condensed financial statements as of and for the six-months ended June 30, 2018.

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

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

## 2. COLLABORATIONS AND ALLIANCES

### *Roivant Sciences Licensing Agreement*

In February 2018, we entered into a License Agreement (the "Agreement") with Sinovant Sciences Ltd. ("Sinovant") and Roivant Sciences Ltd. (Roivant), the parent of Sinovant, pursuant to which ArQule granted Sinovant a license to develop, manufacture and exclusively commercialize its FGFR inhibitor, derazantinib (ARQ 087), in Greater China. The Agreement provides for an upfront payment to ArQule of \$3 million and a guaranteed \$2.5 million development milestone within the first year. ArQule is also eligible for an additional \$82 million in regulatory and sales milestones. Upon commercialization, ArQule is entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in the Greater China territory. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. For the three months ended June 30, 2018 no revenue was recognized under this licensing agreement. For the six months ended June 30, 2018, we recognized \$3.0 million for completing our performance obligation under this licensing agreement.

### *Basilea Licensing Agreement*

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

Revenue in the three and six months ended June 30, 2018 totaled \$13.7 million for providing the technology license as well as certain research and development services to Basilea, recognized as revenue on a percentage of completion basis. The adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers on January 1, 2018 did not have a material effect on the amount of revenue recognized under this agreement.

### *Other Licensing Agreements*

In October 2017, we entered into a non-exclusive license agreement for certain library compounds. The licensed compounds were delivered and are subject to quality and acceptance testing. In 2017, we recorded deferred revenue of \$1.5 million related to this licensing agreement which was recorded as an opening retained earnings adjustment upon the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers on January 1, 2018. For the three and six months ended June 30, 2018, we recorded revenue of \$1.1 million based upon the achievement of the quality and acceptance testing for the period.

## 3. MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

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



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

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

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

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

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

The following is a summary of the fair value of available-for-sale marketable securities we held at June 30, 2018 and December 31, 2017:

<b>June 30, 2018</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
<i>Security type</i>				
Corporate debt securities-short term	\$ 29,180	\$ 1	\$ (23)	\$ 29,158
<b>Total available-for-sale marketable securities</b>	<b>\$ 29,180</b>	<b>\$ 1</b>	<b>\$ (23)</b>	<b>\$ 29,158</b>

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

None of our available-for-sale marketable securities were in a continuous unrealized loss position for more than 12 months at June 30, 2018 or December 31, 2017.

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

	<b>June 30, 2018</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Cash equivalents	\$ 8,862	\$ 8,862	\$ —	\$ —
Corporate debt securities-short term	29,158	—	29,158	—
<b>Total</b>	<b>\$ 38,020</b>	<b>\$ 8,862</b>	<b>\$ 29,158</b>	<b>\$ —</b>

	December 31, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 19,889	\$ 19,889	\$ —	\$ —
Corporate debt securities-short term	27,807	—	27,807	—
Total	<u>\$ 47,696</u>	<u>\$ 19,889</u>	<u>\$ 27,807</u>	<u>\$ —</u>

	December 31, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liability	\$ 1,512	\$ —	\$ —	\$ 1,512

Due to the lack of market quotes relating to our preferred stock warrants, the fair value of the preferred stock warrants was determined at December 31, 2017 using the Black-Scholes model, which is based on Level 3 inputs. The inputs used in the Black-Scholes model are presented below. Based on the Black-Scholes model, the Company recorded a preferred stock warrant liability of \$1,512 at December 31, 2017. Upon conversion of the Series A Preferred to common stock on May 8, 2018 the warrant liability of \$3,064 was extinguished with an offsetting amount included as additional paid-in capital in stockholders' equity.

The following are the Black-Scholes inputs to the warrant liability valuation for December 31, 2017:

	December 31, 2017
Exercise price	\$ 1.75
Market price	1.65
Expected volatility	53.3%
Risk-free interest	2.07%
Expected term	3.85 years
Dividends	none

#### 4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at June 30, 2018 and December 31, 2017:

	June 30, 2018	December 31, 2017
Accounts payable	\$ 186	\$ 537
Accrued payroll	1,415	1,448
Accrued outsourced pre-clinical and clinical fees	5,764	5,409
Accrued professional fees	655	492
Other accrued expenses	316	373
	<u>\$ 8,336</u>	<u>\$ 8,259</u>

#### 5. NET INCOME (LOSS) PER SHARE

Net income (loss) per share is computed using the weighted average number of common shares outstanding and potential common shares when applicable. 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. Basic and diluted net loss per share amounts for three and six months ended June 30, 2017 and six months ended June 30, 2018 are equivalent for the periods presented as the inclusion of potential common shares in the number of shares used for the diluted computation would be anti-dilutive to loss per share. Potential common shares, for the 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 be issued upon the conversion of the shares from our November 2017 preferred stock offering and 2,259,000 common shares that would be issued upon the exercise of the warrants from our November 2017 preferred stock offering. The shares and warrants from our November 2017 preferred stock offering were converted on May 8, 2018 to common shares and warrants. Potential common shares, for the three and six months ended June 30, 2017, include 10,773,443 shares that would be issued upon the exercise of outstanding employee and Board of Director stock options and 354,330 shares that would be issued upon the exercise of the warrants issued in conjunction with our January 6, 2017 loan agreement.

## 6. STOCK-BASED COMPENSATION AND STOCK PLANS

Our stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employees' requisite service period (generally the vesting period of the equity grant). We estimate the fair value of stock options using the Black-Scholes valuation model. Key input assumptions used to estimate the fair value of stock options include the exercise price of the award, expected option term, expected volatility of our stock over the option's expected term, risk-free interest rate over the option's expected term, and the expected annual dividend yield. We believe that the valuation technique and approach utilized to develop the underlying assumptions are appropriate in calculating the fair values of our stock options granted in the three and six months ended June 30, 2018 and 2017.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Research and development	\$ 79	\$ 74	\$ 185	\$ 204
General and administrative	235	212	552	625
Total stock-based compensation expense	<u>\$ 314</u>	<u>\$ 286</u>	<u>\$ 737</u>	<u>\$ 829</u>

In the three and six months ended June 30, 2018 and 2017, no stock-based compensation expense was capitalized and there were no recognized tax benefits associated with the stock-based compensation expense.

Option activity under our stock plans for the six months ended June 30, 2018 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2017	10,622,455	\$ 3.01
Granted	1,456,270	2.06
Exercised	(868,221)	3.46
Cancelled	(584,587)	3.22
Outstanding as of June 30, 2018	<u>10,625,917</u>	<u>\$ 2.83</u>
Exercisable as of June 30, 2018	<u>6,284,393</u>	<u>\$ 3.72</u>

The aggregate intrinsic value of options outstanding at June 30, 2018 was \$31,726 and \$14,422 related to exercisable options. The weighted average fair value of options granted in the six months ended June 30, 2018 and 2017 was \$1.28 and \$0.72 per share, respectively. The intrinsic value of options exercised in the six months ended June 30, 2018 was \$1,653.

	Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Vested and unvested expected to vest at June 30, 2018	10,454,742	\$ 2.83	6.3	\$ 31,089
Exercisable at June 30, 2018	6,284,393	\$ 3.72	4.6	\$ 14,422

The total compensation cost not yet recognized as of June 30, 2018 related to non-vested option awards was \$3.3 million, which will be recognized over a weighted-average period of 2.8 years. During the six months ended June 30, 2018, 344,587 shares expired and 240,000 shares were forfeited. The weighted average remaining contractual life for options exercisable at June 30, 2018 was 4.6 years.

## 7. COMMON STOCK OFFERINGS

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 estimated offering expenses.

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

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

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

## 8. LOAN AGREEMENT

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

Pursuant to the terms of the Loan Agreement, the Lender issued us a loan in the principal amount of \$15.0 million. The loan bears interest at the rate equal to (a) the greater of (i) the 30 day U.S. LIBOR rate reported in the Wall Street Journal on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue or (ii) 0.65% (b) plus 6.85%. The applicable interest rate on the loan at June 30, 2018 was 8.85%. 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, 2018 is as follows:

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

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

Pursuant to the terms of the Loan Agreement, we are bound by certain affirmative covenants setting forth actions that are required during the term of the Loan Agreement, including, without limitation, certain information delivery requirements, obligations to maintain certain insurance, and certain notice requirements. Additionally, we are bound by certain negative covenants setting forth actions that are not permitted to be taken during the term of the Loan Agreement without consent, including, without limitation, incurring certain additional indebtedness, entering into certain mergers, acquisitions or other business combination transactions, or incurring any non-permitted lien or other encumbrance on our assets. We were in compliance with the loan covenants at June 30, 2018.

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

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

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

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

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

In November 2017, we entered into definitive securities purchase agreements with certain institutional investors. In conjunction with this stock offering the Company raised net proceeds of \$9.5 million through the sale of 8,370 shares of series A convertible preferred stock (Series A Preferred) and warrants covering 2,259 shares of Series A Preferred (Warrants). Each share of Series A Preferred together with the associated Warrant was priced at \$1,135 and automatically converted into 1,000 shares of common stock upon the effectiveness on May 8, 2018, of an amendment to the Company's restated certificate of incorporation to increase the number of authorized shares of common stock thereunder. The amount reported as preferred stock at June 30, 2018 is zero and at December 31, 2017 is \$8.8 million.

The terms of the Series A Preferred, specifically the terms of the liquidation preference, required the classification of the preferred stock as temporary equity, which is reflected in our balance sheet as of December 31, 2017. In addition, the terms of the Series A Preferred for which the warrants are exercisable require that the fair value allocated to the warrants at the date of issuance be recorded as a liability. The warrant liability was marked to market value through the income statement as a non-cash gain or loss at each reporting period until the conversion of the preferred stock to common stock on May 8, 2018. The Warrants had a pre-conversion exercise price of \$1,750 per share of Series A Preferred (post-conversion price of \$1.75 per share of common stock), were exercisable immediately with an expiration date approximately four years from the date of the adoption of the amendment to the Company's restated certificate of incorporation. Upon conversion of the Series A Preferred common on May 8, 2018, the warrant liability of \$3,064 was extinguished with an offsetting amount included as additional paid-in capital in stockholders' equity. In the three months ended June 30, 2018 the fair value of the warrant liability decreased by \$718 and non-cash income was recorded in other income (expense). In the six months ended June 30, 2018 the fair value of the warrant liability increased by \$1,552 and non-cash expense was recorded in other income (expense).

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

## **10. RECENT ACCOUNTING PRONOUNCEMENTS**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

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

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

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

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

## 11. INCOME TAXES

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

As of June 30, 2018 and December 31, 2017 we had no unrecognized tax benefits. We do not expect that the total amount of unrecognized tax benefits will significantly increase in the next twelve months. Our policy is to recognize interest and penalties related to uncertain tax positions in income tax expense. As of June 30, 2018 and December 31, 2017, we had no accrued interest or penalties related to uncertain tax positions. Our U.S. federal tax returns for the tax years 2013 through 2017 and our state tax returns for the tax years 2013 through 2017 remain open to examination. Prior tax years remain open to the extent of net operating loss and tax credit carryforwards.

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

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

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

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

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

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

- ARQ 531, a potent and reversible inhibitor of both wild type and C481S-mutant BTK, in Phase 1 for B-cell malignancies refractory to other therapeutic options;
- Miransertib (ARQ 092), a selective inhibitor of AKT, a serine/threonine kinase, in Phase 1/2 in rare Overgrowth Diseases and in Phase 1 for the rare disease, Proteus syndrome, in partnership with the National Institutes of Health (NIH); also in Phase 1b in oncology in combination with the hormonal therapy, anastrozole, in endometrial cancer;
- ARQ 751, a next-generation inhibitor of AKT, in Phase 1 for solid tumors harboring the AKT1 or PI3K mutation; and
- Derazantinib (ARQ 087), a multi-kinase inhibitor designed to preferentially inhibit the FGFR family of kinases, in a registrational trial in intrahepatic cholangiocarcinoma (iCCA) in patients with FGFR 2 fusions; and
- ARQ 761, a  $\beta$ -lapachone analog being evaluated as a promoter of NQO1-mediated programmed cancer cell death, in Phase 1/2 in multiple oncology indications in partnership with The University of Texas Southwest Medical Center.

In February 2018, we entered into a License Agreement (the "Agreement") with Sinovant Sciences Ltd. ("Sinovant") and Roivant Sciences Ltd., the parent of Sinovant, pursuant to which ArQule granted Sinovant a license to develop, manufacture and exclusively commercialize its FGFR inhibitor, derazantinib (ARQ 087), in Greater China. The Agreement provides for an upfront payment to ArQule of \$3 million and a guaranteed \$2.5 million development milestone within the first year. ArQule is also eligible for an additional \$82 million in regulatory and sales milestones. Upon commercialization, ArQule is entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in the Greater China territory. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. For the three months ended June 30, 2018 no revenue was recognized under this licensing agreement. For the six months ended June 30, 2018, we recognized revenue of \$3.0 for completing our performance obligation under this licensing agreement.

In April 2018, we entered into a License Agreement (the "Basilea Agreement") with Basilea Pharmaceutica Ltd. ("Basilea") pursuant to which ArQule granted Basilea an exclusive license to develop, manufacture and commercialize its FGFR inhibitor, derazantinib (ARQ 087), in the United States, EU, Japan and the rest of the world, excluding Greater China. Under the terms of the Basilea agreement, ArQule will receive an upfront payment of \$10 million and is eligible for up to \$326 million in regulatory and commercial milestones. Upon commercialization, ArQule is entitled to receive staggered royalties on future net sales of derazantinib ranging from the high-single digits to the mid-teens on direct sales and mid-single digits to low-double digits on indirect sales. Basilea will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. Under certain circumstances, ArQule may have the opportunity to promote derazantinib in the US directly. For the three and six months ended June 30, 2018, we recognized revenue of \$13.7 million for completing our performance obligations for the period under this licensing agreement.

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

We have incurred a cumulative deficit of approximately \$534 million from inception through June 30, 2018. We recorded a net loss for 2016 and 2017 and expect a net loss for 2018.

## LIQUIDITY AND CAPITAL RESOURCES

	<b>June 30, 2018</b>	<b>December 31, 2017</b>	<b>Increase (decrease)</b>	
			<b>\$</b>	<b>%</b>
	(in millions)			
Cash, cash equivalents and marketable securities-short term	\$ 46.1	\$ 48.0	(1.9)	(4)%
Working capital	41.6	38.8	2.8	7%

	<b>Six Months Ended</b>		
	<b>June 30, 2018</b>	<b>June 30, 2017</b>	<b>Increase (decrease)</b>
	(in millions)		

Cash flow from:			
Operating activities	\$ (2.0)	\$ (14.8)	\$ 12.8
Investing activities	(1.5)	1.8	(3.3)
Financing activities	0.1	14.6	(14.5)

*Cash flow from operating activities.* Our uses of cash for operating activities have primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices and laboratories, fees paid in connection with preclinical and clinical studies, laboratory supplies and materials, and professional fees. The sources of our cash flow from operating activities have consisted primarily of payments received from our collaborators for services performed or upfront payments for license agreements or future services. In the six months ended June 30, 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 \$2.0 million. In the six months ended June 30, 2017, our net use of cash was primarily driven by payments for operating expenses which resulted in net cash outflows of \$14.8 million.

*Cash flow from investing activities.* 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. Our net cash provided by investing activities of \$1.8 million for the six months ended June 30, 2017, was comprised of net maturities of marketable securities. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of our constant evaluation of conditions in financial markets, the maturity of specific investments, and our near term liquidity needs.

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

*Cash flow from financing activities.* Our net cash provided by financing activities of \$0.1 million for the six months ended June 30, 2018 was principally comprised of proceeds from employee stock option exercises. Our net cash provided by financing activities of \$14.6 million for the six months ended June 30, 2017, was principally comprised of the net proceeds from the loan and security agreement that we entered into on January 6, 2017.



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

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

In September 2017, we sold 2.0 million shares of common stock through an at-the-market (ATM) offering and raised net proceeds of \$2.3 million. In October 2017, we entered into definitive stock purchase agreements with certain institutional investors. In conjunction with this stock offering we issued 13,938,651 shares of our common stock and warrants to purchase 3,123,674 shares of our common stock for aggregate net proceeds of \$15.6 million. Each warrant is exercisable for \$1.75 per share and expires in four years from the date of issuance. In November 2017, we entered into definitive securities purchase agreements with certain institutional investors. In conjunction with this stock offering the Company raised net proceeds of \$9.5 million through the sale of 8,370 shares of series A convertible preferred stock (Series A Preferred) and warrants to purchase 2,259 shares of Series A Preferred (Warrants). Each share of Series A Preferred together with the associated Warrant is priced at \$1,135 and automatically converted into 1,000 shares of common stock upon the adoption on May 8, 2018, of an amendment to the Company's restated certificate of incorporation to increase the number of authorized shares of common stock thereunder. The Warrants had a pre-conversion exercise price of \$1,750 per share of Series A Preferred (post-conversion price of \$1.75 per share of common stock), are exercisable immediately and expire approximately four years from the date of the adoption of the amendment to the Company's restated certificate of incorporation.

In February 2018, we entered into a License Agreement (the "Agreement") with Sinovant Sciences Ltd. ("Sinovant") and Roivant Sciences Ltd., the parent of Sinovant, pursuant to which ArQule granted Sinovant a license to develop, manufacture and exclusively commercialize its FGFR inhibitor, derazantinib (ARQ 087), in Greater China. The Agreement provides for an upfront payment to ArQule of \$3 million and a guaranteed \$2.5 million development milestone within the first year. ArQule is also eligible for an additional \$82 million in regulatory and sales milestones. Upon commercialization, ArQule is entitled to receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in the Greater China territory. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. For the three and six months ended June 30, 2018, we recognized revenue of \$3.0 million for completing our performance obligation under this licensing agreement.

In April 2018, we entered into a License Agreement (the "Basilea Agreement") with Basilea Pharmaceutica Ltd. ("Basilea") pursuant to which ArQule granted Basilea an exclusive license to develop, manufacture and commercialize its FGFR inhibitor, derazantinib (ARQ 087), in the United States, EU, Japan and the rest of the world, excluding Greater China. Under the terms of the Basilea Agreement, ArQule will receive an upfront payment of \$10 million and is eligible for up to \$326 million in regulatory and commercial milestones. Upon commercialization, ArQule is entitled to receive staggered royalties on future net sales of derazantinib ranging from the high-single digits to the mid-teens on direct sales and mid-single digits to low-double digits on indirect sales. Basilea will be responsible for all costs and expenses of development, manufacture and commercialization in its territory. Under certain circumstances, ArQule may have the opportunity to promote derazantinib in the US directly. Revenue in the three and six months ended June 30, 2018 totaled \$13.7 million for providing the technology license as well as certain research and development services to Basilea, recognized as revenue on a percentage of completion basis.

In July 2018, we sold 12,650,000 shares of common stock at \$5.50 per share for aggregate net proceeds of approximately \$64.5 million after commissions and other estimated offering expenses.

We anticipate that our cash, cash equivalents and marketable securities on hand at June 30, 2018, financial support from our licensing agreements, the one year extension of our Loan Agreement and the net proceeds of approximately \$64.5 million from our July 2018 common stock offering will be sufficient to finance our operations into 2021 which is in excess of at least 12 months from the issuance date of these financial statements.

We expect that we may 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, 2018 (in thousands):

Contractual Obligations	Payment due by period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Notes payable	\$ 15,900	\$ —	\$ 9,167	6,733	\$ —
Interest on notes payable	3,143	1,159	1,702	282	—
Operating lease obligations	1,074	567	507	—	—
Purchase obligations	5,712	5,712	—	—	—
<b>Total</b>	<b>\$ 25,829</b>	<b>\$ 7,438</b>	<b>\$ 11,376</b>	<b>\$ 7,015</b>	<b>\$ —</b>

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

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

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

The Company adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to its accounting policy for revenue recognition. Results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. We recorded a net increase to opening equity of \$1.5 million as of January 1, 2018 due to the cumulative impact of adopting this new standard. The adoption of the new revenue standard did not have a material impact on any other balances within the condensed financial statements as of and for the six-months ended June 30, 2018.

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

#### RESULTS OF OPERATIONS

The following are the results of operations for the three and six months ended June 30, 2018 and 2017:

##### Revenue

	2018		2017		Increase (decrease)		
	(in millions)				\$	%	
<i>For the three months ended June 30:</i>							
Research and development revenue	\$	13.7	\$	—	\$	13.7	100%
<i>For the six months ended June 30:</i>							
Research and development revenue	\$	17.8	\$	—	\$	17.8	100%

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

Research and development revenue in the six months ended June 30, 2018 consisted of \$13.7 million from our April 2018 Basilea licensing agreement, \$3 million from our February 2018 Roivant licensing agreement and \$1.1 million from a non-exclusive license agreement for certain of our library compounds.

## Research and development

	(in millions)		Increase (decrease)	
	2018	2017	\$	%
<i>For the three months ended June 30:</i>				
Research and development	\$ 6.8	\$ 5.0	\$ 1.8	36%
<i>For the six months ended June 30:</i>				
Research and development	\$ 12.6	\$ 10.2	\$ 2.4	24%

Research and development expense in the three months ended June 30, 2018 increased by \$1.8 million primarily due to higher outsourced preclinical, clinical and product development costs.

Research and development expense in the six months ended June 30, 2018 increased by \$2.4 million primarily due to higher outsourced preclinical, clinical and product development costs.

At June 30, 2018 we had 18 employees dedicated to our research and development program compared to 19 at June 30, 2017.

### Overview

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

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

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

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

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

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

#### General and administrative

	2018		2017		Increase (decrease)	
	(in millions)				\$	%
<i>For the three months ended June 30:</i>						
General and administrative	\$	2.2	\$	1.9	\$	20%
<i>For the six months ended June 30:</i>						
General and administrative	\$	4.6	\$	3.9	\$	16%

General and administrative expense increased in the three months ended June 30, 2018 principally due to higher professional fees.

General and administrative expense increased in the six months ended June 30, 2018 due to \$0.4 million of labor and related costs, and \$0.3 million of professional fees.

General and administrative headcount was 13 and 14 at June 30, 2018 and June 30, 2017, respectively.

#### Interest income and interest expense

	2018		2017		Increase (decrease)	
	(in thousands)				\$	%
<i>For the three months ended June 30:</i>						
Interest income	\$	170	\$	37	\$	359%
Interest expense		417		389		7%
Other income (expense)		718		—		100%
<i>For the six months ended June 30:</i>						
Interest income	\$	329	\$	59	\$	458%
Interest expense		813		719		13%
Other income (expense)		(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, 2018 primarily due to an increase in our portfolio balance resulting from stock offerings in the fourth quarter of 2017 and up-front payments from our 2018 licensing agreements, in addition to increased interest rates.

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

Other expense decreased in the three months ended June 30, 2018 due to non-cash income from a decrease in fair value of our preferred stock warrant liability of \$0.7 million. Other expense increased in the six months ended June 30, 2018 due to a non-cash expense from a net increase in fair value of our preferred stock warrant liability of \$1.5 million.

## RECENT ACCOUNTING PRONOUNCEMENTS

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

## FORWARD LOOKING STATEMENTS

In addition to historical information, this report contains forward-looking statements. You can identify these forward-looking statements by their use of words such as “anticipate,” “assume,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “project,” “target,” “will”, “potential”, “goal”, and other words and terms of similar meaning. You also 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 the Company expects or anticipates will occur in the future, such as projections about its future results of operations, its financial condition, research, development and commercialization of its products and anticipated trends in its business are forward-looking statements.

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

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

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

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

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

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

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

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

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

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

### ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer (Principal Executive Officer) and President and Chief Operating Officer (Principal Financial Officer), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (“Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2018, our Chief Executive Officer (Principal Executive Officer) and President and Chief Operating Officer (Principal Financial Officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

In the six months ended June 30, 2018 the Company adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to its accounting policy for revenue recognition and implementation of related revenue recognition internal controls. There have been no changes in our internal control over financial reporting during the most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

**ITEM 1. — LEGAL PROCEEDINGS.** None.

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

**ITEM 2. — UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.** None.

**ITEM 3. — DEFAULTS UPON SENIOR SECURITIES.** None.

**ITEM 4. — MINE SAFETY DISCLOSURES.** Not applicable.

**ITEM 5. — OTHERS INFORMATION.** None.

ITEM 6. — EXHIBITS.

<u>EXHIBIT NO.</u>	<u>DESCRIPTION</u>
<a href="#">1.1</a>	<a href="#">Underwriting Agreement dated July 10, 2018 by and between ArOule, Inc. and Leerink Partners LLC as representative for the several underwriters listed therein (incorporated by reference from Exhibit 1.1 to a Current Report on Form 8-K filed on July 13, 2018).</a>
<a href="#">10.1+</a>	<a href="#">License Agreement by and between the Company and Basilea Pharmaceutica International Limited, dated April 16, 2018, filed herewith.</a>
<a href="#">31.1</a>	<a href="#">Rule 13a-14(a) Certificate of Chief Executive Officer, filed herewith.</a>
<a href="#">31.2</a>	<a href="#">Rule 13a-14(a) Certificate of Principal Financial Officer, filed herewith.</a>
<a href="#">32</a>	<a href="#">Rule 13a-14(b) Certificate of Chief Executive Officer and Chief Financial Officer, filed herewith.</a>
101	Interactive Data File

+ Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

**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.

Date: August 1, 2018

ArQule, Inc.

/s/ PETER S. LAWRENCE

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

/s/ ROBERT J. WEISKOPF

Robert J. Weiskopf  
Chief Financial Officer and Treasurer  
(Principal Accounting Officer)



*Confidential Materials omitted and filed separately with the Securities and Exchange Commission.  
\*\*\*Triple asterisks denote omissions.*

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**LICENSE AGREEMENT**

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by

**ARQULE, INC.**

and

**BASILEA PHARMACEUTICA INTERNATIONAL LIMITED**

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Licence Agreement/ArQule, Inc.

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## **LICENSE AGREEMENT**

This License Agreement (this “**Agreement**”) is made as of April 16, 2018 (the “**Effective Date**”) by and between (1) **ARQULE, INC.**, a corporation incorporated under the laws of the State of Delaware, US, with its principal place of business at One Wall Street, Burlington, MA 01803, US (“**ArQule**”); and (2) **BASILEA PHARMACEUTICA INTERNATIONAL LIMITED**, a corporation incorporated under the laws of Switzerland, with its principal place of business at Grenzacherstrasse 487, 4058 Basel, Switzerland (“**Basilea**”). ArQule and Basilea are each sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

## **RECITALS**

- A. WHEREAS ArQule owns or has the exclusive right to certain intellectual property rights, Know How and scientific data relating to the fibroblast growth factor receptor (“**FGFR**”) inhibitor designated as ARQ 087 (Derazantinib);
- B. WHEREAS ArQule wishes to grant Basilea, in each case upon the terms of this License Agreement: (a) an exclusive license under the ArQule IP to Research, Develop, register, manufacture, and Commercialise the Products in the Territory; and (b) a non-exclusive license under the ArQule Partner Excluded Territory IP and ArQule Excluded Territory IP to Research, Develop, register, manufacture, and Commercialise the Products in the Territory and Research, Develop, and manufacture the Products in the Excluded Territory for the sole purpose of Commercialisation of Products in the Territory; and
- C. WHEREAS Basilea wishes to obtain a license on the terms of this License Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the Parties, intending to be legally bound, agree as follows:

## **ARTICLE 1 DEFINITIONS AND INTERPRETATIONS**

**Definitions.** The following terms shall have the following meanings as used in this Agreement:

- 1.1 \*\*\*
- 1.2 “**Accounting Standards**” means the accounting principles used by Basilea in the preparation of its annual audited accounts, being US GAAP.
- 1.3 “**Affiliate**” means an entity directly or indirectly controlled by, controlling or under common control with another entity, where “control” means possession, directly or indirectly, of the power to direct or cause the direction of the activities, management and policies of the relevant entity and in the case of a corporate entity shall include but not be limited to the holding of more than fifty percent (50%) of the share capital of the entity or the equivalent power or authority to elect more than fifty percent (50%) of the board of directors of such entity or the equivalent management body.
- 1.4 “**Agreement**” means this agreement together with its Schedules.
- 1.5 “**API**” means any active pharmaceutical ingredient.

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- 1.6 “**Applicable Law**” means any present or future laws, statutes, rules, regulations, directives, ordinances, judgments, guidance, recommendations, orders or injunctions of any Regulatory Authority including any amendment, extension or replacement thereof which is from time to time in force and applicable to a particular activity hereunder.
- 1.7 “**ArQule \*\*\* Reports**” means the draft and final Clinical Study reports generated by ArQule in the conduct of the \*\*\*.
- 1.8 “**ArQule Background IP**” means, excluding the ArQule Excluded IP, the ArQule Territory Patents listed in Schedule 1, and the Product Know How and the Manufacturing Know How which is owned or Controlled by ArQule in the Territory as of the Effective Date of this Agreement.
- 1.9 “**ArQule Contracts**” are those contracts defined in Section 5.3 and listed in Schedule 5.
- 1.10 “**ArQule Development Activities**” shall have the meaning given in Section 5.1.
- 1.11 “**ArQule Excluded IP**” means the ArQule Excluded Patent Rights and the ArQule Excluded Know-How.
- 1.12 “**ArQule Excluded Know-How**” means the Know-How owned or Controlled by ArQule related to the combined administration of the Product with the AKT inhibitors listed in Schedule 9 and their pharmaceutically acceptable salts, solvates, hydrates, and prodrugs.
- 1.13 “**ArQule Excluded Patent Rights**” means those Patent Rights owned or Controlled by ArQule listed in Schedule 8 and any improvements thereto.
- 1.14 “**ArQule Excluded Territory IP**” means, excluding the ArQule Excluded IP and the ArQule Partner Excluded Territory IP, the Patent Rights listed in Schedule 1 and the Product Know How and the Manufacturing Know How which are owned or Controlled by ArQule in the Excluded Territory as of the Effective Date and any Improvements thereto during the Term.
- 1.15 “**ArQule Excluded Territory Patent(s)**” means all Patent Rights which form part of the ArQule Excluded Territory IP.
- 1.16 “**ArQule Improvements**” means all Improvements to the ArQule Background IP (including in the form of additional Patent Rights or Know How) which are owned or Controlled by ArQule during the Term.
- 1.17 “**ArQule IP**” means, together, the ArQule Background IP and ArQule Improvements.
- 1.18 “**ArQule Partner**” means Sinovant Sciences Ltd., an exempted limited company incorporated under the laws of Bermuda, having its registered office at 2 Church Street, Hamilton, Bermuda, and a wholly-owned subsidiary of Roivant Sciences Ltd., an exempted limited company incorporated under the laws of Bermuda, having its registered office at 2 Church Street, Hamilton, Bermuda, to which ArQule has granted a license to research, develop and commercialise the Product in the Excluded Territory.
- 1.19 “**ArQule Partner Excluded Territory IP**” means all Intellectual Property which is (a) necessary or useful for the Research, Development, registration, use, manufacture, or Commercialisation of the Product and associated biomarkers and/or diagnostic tools and (b) owned or Controlled by ArQule during the Term as a result of the grant of a license to ArQule by the ArQule Partner in the Excluded Territory.

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- 1.20 “**ArQule Partner License Agreement**” means that certain license agreement dated as of February 2, 2018 by and between ArQule and the ArQule Partner pursuant to which ArQule has granted a license to the ArQule Partner to research, develop and commercialise the Product in the Excluded Territory.
- 1.21 “**ArQule Patent(s)**” means ArQule Excluded Territory Patents and ArQule Territory Patents.
- 1.22 “**ArQule Reference Data**” means (a) the clinical data generated in the conduct of the \*\*\* and (b) all chemistry, manufacturing and controls data, including batch records, process development information, stability data, analytical test methods, and drug product data related to the Product and generated by ArQule or by Third Parties contracted by ArQule in the conduct of manufacturing Clinical Trial supplies of the Product (including API and drug product) during 2018 and 2019.
- 1.23 “**ArQule Territory Patent(s)**” means all Patent Rights which form part of the ArQule IP.
- 1.24 “**Basilea IP**” means all Intellectual Property which is (a) necessary or useful for the Research, Development, registration, use, manufacture, or Commercialisation of the Product and associated biomarkers and/or diagnostic tools, including any such Intellectual Property which is generated during the Term by Basilea, a Third Party on its behalf, or by ArQule on Basilea's behalf under this Agreement (including but not limited to pursuant to Section 5.1 (ArQule Development Activities) or Section 5.7 (ArQule Further Research and Development), and (b) owned or Controlled by Basilea during the Term.
- 1.25 “**Basilea Patent(s)**” means any Patent Rights which form part of the Basilea IP.
- 1.26 \*\*\*
- 1.27 “**Breaching Party**” has the meaning given in Section 19.5.
- 1.28 “**Business Day**” means a day other than a Saturday, Sunday, bank or other public holiday in Switzerland or in Boston, Massachusetts.
- 1.29 “**Calendar Quarter**” means each period of three months ending on 31 March, 30 June, 30 September or 31 December and “Quarterly” shall be construed accordingly, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to 1 April and the last Calendar Quarter shall end on the last day of the Term.
- 1.30 “**Calendar Year**” means each successive period of twelve calendar (12) months commencing on 1 January, except that the first Calendar Year of the Term shall commence on the Effective Date and end on 31 December of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on 1 January of the year in which the Term ends and end on the last day of the Term.

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- 1.31 “**Clinical Trial**” means a human clinical trial for any Product in the United States that would satisfy the requirements of 21 CFR 312.21(a), (b) or (c), or in any other country would satisfy the requirements of similar regulations applicable in that country, including a Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial, with a “Phase I Clinical Trial” having the principal purpose of preliminary determination of safety in healthy volunteers or patients with the aim of establishing the dosage regimen, pharmacokinetic, pharmacodynamic and early safety profile and the suitability of a product for further clinical trials, a “Phase II Clinical Trial” having the primary purpose of determination of a first indication of efficacy in patients being studied and expanding the Phase I experience; and a “Phase III Clinical Trial” being a pivotal, multi-centre, human clinical trial that is prospectively designed to demonstrate statistically whether a product is safe and effective for use in humans in the Indication being investigated.
- 1.32 “**Clinical Pharmacology Studies**” means the Clinical Trials that are specified as the clinical pharmacology studies in the Initial Development Plan (Schedule 2).
- 1.33 “**CMO(s)**” means a Third Party contract manufacturing organisation.
- 1.34 “**Commercialisation**” means any and all activities directed to the preparation for sale, marketing, promoting, detailing, importing, exporting, distributing, warehousing, offering for sale, having sold and/or selling a pharmaceutical product, including market research, market access, pre-launch marketing, educational activities, and sampling. The terms “Commercial”, “Commercialise” and “Commercialised” shall be construed accordingly.
- 1.35 “**Commercially Reasonable Efforts**” or “**Commercially Reasonable**” means, in respect of Basilea, the efforts and resources that are consistent with the level of diligence, effort and resources normally devoted by a pharmaceutical company comparable in size to Basilea in the research, development, manufacture and Commercialisation of a pharmaceutical product owned by such company that is at a similar stage in its development or product life cycle and of similar market potential as the Product, taking into account efficacy, safety, approved label, the competitiveness of alternative products in the marketplace, the Patent Rights in and other proprietary position of the Product, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the Product, and other relevant factors.
- 1.36 “**Commercial Sales Milestones**” are specified in Schedule 3.
- 1.37 “**Commercialisation Plan**” means the plan to Commercialise the Products as defined in Section 7.1.
- 1.38 “**Competitive Compound**” has the meaning specified in Section 3.6.
- 1.39 “**Confidential Information**” means, subject to the relevant carve-outs set forth in Section 16.2:
- (a) the terms and conditions of this Agreement, for which each Party will be considered a Disclosing Party and a Recipient Party;
  - (b) any non-public information, whether or not patentable, disclosed or provided by one Party to the other Party in connection with this Agreement, including, without limitation, information regarding such Party's strategy, business plans, objectives, research activities, technology, products, business affairs or finances including any non-public data relating to Commercialisation of any product and other information of the type that is customarily considered to be confidential information by parties engaged in activities that are substantially similar to the activities being engaged in by the Parties under this Agreement, for which the Party making such disclosure will be considered the Disclosing Party and the receiver will be the Recipient Party.

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- 1.40 “**Control**” (except as used in the definition of Affiliate) means, with respect to any Intellectual Property, including any information and data in the Know-How, the possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or to grant a license, sub-license or other right to or under, such Intellectual Property or to enforce any Patent Right without violating the terms of any agreement or other arrangement with any Third Party. The term “**Controlled**” shall be construed accordingly. For clarity, no Party (or an Affiliate of a Party, as applicable) shall be deemed to Control any Intellectual Property, including any information and data in the Know-How, by virtue of the license grants to that Party from or by the other Party as set forth in this Agreement. Notwithstanding the foregoing, neither Party (nor Affiliate of a Party, as applicable) will be deemed to Control any Intellectual Property or Patent Rights owned or controlled by a Third Party as a result of such Party becoming an Affiliate of such Third Party in connection with a sale or transfer of all or substantially all of such Party’s business or assets to which this Agreement relates or in connection with a merger or consolidation transaction involving such Third Party pursuant to Article 20.
- 1.41 “**Cure Period**” shall have the meaning given in Section 19.5.
- 1.42 “**Data Room**” means the data room hosted and operated by ArQule entitled “Derazantinib Data Room for Basilea” which was “closed” to future modification on the Effective Date.
- 1.43 “**Development**” (and “**Develop**”) means all pre-Regulatory Approval development and regulatory activities regarding a Product including:
- (a) studies on the toxicological, pharmacological, metabolic, diagnostic or clinical aspects of a Product (including the conduct of Clinical Trials) conducted internally or externally by individual investigators or consultants;
  - (b) the conduct of technical product development, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control including manufacturing in support thereof, statistical analysis and report writing, and
  - (c) preparing, submitting, reviewing or developing data or information for the purpose of submission to a Regulatory Authority to obtain, maintain and/or expand Regulatory Approval of a Product including data management, statistical designs and studies, document preparation, and other administration.
- 1.44 “**Development and Regulatory Milestones**” are specified in Schedule 3.
- 1.45 “**Development Plan**” means the Initial Development Plan, as amended and updated by Basilea from time to time in accordance with Section 5.5.
- 1.46 \*\*\*.



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- 1.47 “**Disclosing Party**” means the Party which discloses Confidential Information to the other Party.
- 1.48 “**Documents**” means all books, charts, designs, files, graphs, ledgers, notebooks, paper, photographs, plans, records, recordings, reports, research notes, tapes, discs, diskettes, CD-ROM, and other computer information storage means and any other graphic or written data or other media on which Know How is permanently stored.
- 1.49 “**Dossier**” means the complete registration files relating to the Product as submitted to the Regulatory Authority in a country or region for the Regulatory Approval of the Product in such country or region, consisting of administrative information and the necessary demonstration of quality, safety and efficacy of an investigational medicinal product, as may be amended from time to time.
- 1.50 “**EEA**” means the countries of the European Economic Area as of the Effective Date and such countries as are members of the EEA during the Term.
- 1.51 “**Effective Date**” means April 16, 2018.
- 1.52 “**EMA**” means the European Medicines Agency.
- 1.53 “**Encumbrance**” means a mortgage, charge, pledge, lien, option, restriction, right of first refusal, right of pre-emption, third party right or interest, other encumbrance or security interest of any kind, or another type of preferential arrangement (including, without limitation, a title transfer or retention arrangement) having similar effect but for the purposes of this Agreement, other than the Permitted Encumbrance.
- 1.54 “**EU**” means the countries of the European Union which as of the Effective Date are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom and such countries as are members of the European Union during the Term.
- 1.55 “**Europe**” means that group of countries comprised of the EU plus (if they are not EU member states at any point during the Term), Iceland, Liechtenstein, Norway, Switzerland and United Kingdom.
- 1.56 “**Excluded Territory**” means the People’s Republic of China, Taiwan, Hong Kong and Macau.
- 1.57 “**Execution Payment**” is that payment which is specified in Schedule 3.
- 1.58 “**Facility**” means the facility or facilities owned and/or operated by ArQule or its CMOs, and used by or on behalf of ArQule to manufacture, store, or package the Product and/or Product Materials which are supplied by ArQule to Basilea hereunder.
- 1.59 “**Field**” means the diagnosis, prevention and treatment of any human indications.
- 1.60 “**First Commercial Sale Date**” means the date of the first commercial sale in an arm’s length transaction to a Third Party of the Product in any country of the Territory by or on behalf of Basilea, an Affiliate or Sub-licensee or distributor after obtaining Regulatory Approval necessary for the sale of the Product in such country. For clarity, the date on which sale of Product occurs in the Territory for use on compassionate use or a named patient basis does not qualify as the First Commercial Sale Date.

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- 1.61 “**FDA**” means the United States Food and Drug Administration.
- 1.62 “**Generic Product**” means: (i) for any country where the Regulatory Authority has a process by which it establishes bioequivalence between a Third Party product and the Product, a Third Party product will be considered to be a Generic Product in such country if it is approved for sale for at least one of the approved Indications of the Product, is commercially available, contains the same API as the Product, and its bioequivalence with the Product has been established by a Regulatory Authority; and (ii) for any country where the Regulatory Authority has no process by which it establishes bioequivalence between a Third Party product and the Product, a Third Party product will be considered to be a Generic Product in such country as long as it is approved for sale for at least one of the approved Indications of the Product, is commercially available and contains the same API as the Product.
- 1.63 “**Good Clinical Practice**” or “**GCP**” means the then current set of ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting Clinical Trials in a given country or group of countries that involve the participation of human subjects including:
- (a) in relation to Clinical Trials in the EU, Directive 2001/20/EC, Directive 2001/83/EC and Directive 2005/28/EC as well as ICH-GCP and any other guidelines for good clinical practice for trials on medicinal products in Europe as amended and applicable from time to time; and
  - (b) in relation to Clinical Trials in the US, US Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time; and any other guidelines for good clinical practice for trials on medicinal products in the US as amended and applicable from time to time; and
  - (c) the equivalent Applicable Law in any other countries
- each as may be applicable and as amended from time to time.
- 1.64 “**Good Laboratory Practice**” or “**GLP**” means the then-current standards, practices and procedures for good laboratory practices, including but not limited to those promulgated or endorsed by:
- (a) the European Commission Directives 2004/9/EC and 2004/10/EC relating to the application of the principles of good laboratory practices as well as “The rules governing medicinal products in the European Union,” Volume 3, Scientific guidelines for medicinal products for human use (ex - OECD principles of GLP);
  - (b) the then-current standards, practices and procedures promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58; and
  - (c) the equivalent Applicable Law in any other countries
- each as may be applicable and as amended from time to time.

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- 1.65 “**Good Manufacturing Practice**” or “**GMP**” means the then current applicable standards issued by any Regulatory Authority relating to manufacturing practices for active pharmaceutical ingredients, intermediates, bulk drug products or finished pharmaceutical products, for supply in a given country or group of countries including:
- (d) in the case of the EU, Directive 2003/94/EC or any other applicable European Community legislation or regulation;
  - (e) in the case of the US, the principles detailed in the US Current Good Manufacturing Practices, 21 C.F.R. Parts 210, 211, 601 and 610; and the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products; and
  - (f) the principles detailed in the ICH Q7A guidelines; and
  - (g) the equivalent Applicable Law in any other countries
- each as may be applicable and as amended from time to time.
- 1.66 “**iCCA**” means intrahepatic cholangiocarcinoma.
- 1.67 \*\*\*.
- 1.68 “**Improvement**” means any modification, derivative work or improvement of any Intellectual Property that is necessary or useful for the Research, Development, registration, use, manufacture, or Commercialisation of the Product and associated biomarkers and/or diagnostic tools (whether patentable or unpatentable and whether or not reduced to practice).
- 1.69 “**IND**” means an application filed with a Regulatory Authority for authorization to commence clinical trials with respect to the Product, including (a) an Investigational New Drug Application as defined in U.S. 21 C.F.R. Part 312, (b) any equivalent of a United States IND in other countries or regulatory jurisdictions, including a Clinical Trial Application and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.
- 1.70 “**Indication**” means disease or medical condition. For the purposes of this Agreement, the following shall be considered to be different Indications: (i) a distinct primary disease or medical condition (e.g. cancer); or (ii) a different disease type within the same primary disease which targets different organs of the body or anatomical locations (e.g. within the cancer field, colon versus breast cancer), or a common molecular abnormality. Where a Product has previously gained Regulatory Approval for a specific Indication, the conduct of a confirmatory study or alternate dosing study for a previously approved label for such Product will not alone support a separate Indication. For the avoidance of doubt, medical products addressed at the same primary disease type of the same organ but having different posologies, modes of administration (including different formulations) and/or dosage schedules, including combinations with different therapies, shall not be considered to have different Indications.
- 1.71 \*\*\*.
- 1.72 “**Initial Development Plan**” means the plan for Research and Development of the Product as set out in Schedule 2.

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- 1.73 “**Insolvency Event**” means in relation to either Party, any one of the following:
- (a) a notice having been issued to convene any meeting for the purpose of passing a resolution or seeking a petition to wind up or liquidate that Party, or to seek bankruptcy or official administration, or such a resolution having been passed or such a petition having been issued (except in relation to a solvent reconstruction or reorganisation of that Party) that is not otherwise withdrawn on or before a period of \*\*\* days; or
  - (b) an involuntary petition in an insolvency proceeding having been filed against a Party and not dismissed or stayed within \*\*\* days of the filing thereof; or
  - (c) a trustee in bankruptcy, receiver, administrative receiver, receiver and manager, court appointed receiver, interim receiver, custodian, sequestrator or similar officer having been appointed in respect of that Party or over any part of that Party’s assets or any third party having taken steps to appoint such an officer in respect of that Party that continues unstayed for, and/or is not otherwise discharged or withdrawn on or before a period of \*\*\* days; or
  - (d) a Party submits to any type of voluntary arrangement with creditors that continues unstayed for, and/or is not otherwise discharged or withdrawn on or before a period of \*\*\* days.
- 1.74 “**Intellectual Property**” or “**IP**” means, collectively, all Patent Rights, Know How and Improvements.
- 1.75 “**Joint Steering Committee**” or “**JSC**” means the committee established under Article 8.
- 1.76 “**JSC Members**” has the meaning specified in Section 9.2.
- 1.77 “**Know How**” means Product Know How and/or Manufacturing Know How.
- 1.78 “**Knowledge**” means, with respect to a Party, the actual knowledge of any Named Officer of such Party; provided, that, with respect to the representations of ArQule contained in Sections 17.3(c), (i), (j), (l), (m), and (n), Knowledge means the actual knowledge of any Named Officer after good faith consultation by such Named Officer with each of the other Named Officers and with ArQule’s primary external patent counsel for the ArQule Patents, which consultation shall specifically concern the subject matter of the applicable representation, including any exceptions to the accuracy thereof and the ability of ArQule to make such representation without resulting in a breach.
- 1.79 “**Launch**” means the first commercial sale of a product in an arm’s length transaction to a Third Party after obtaining Regulatory Approval and any Pricing Approvals necessary for the sale of the product.
- 1.80 “**Losses**” shall mean any and all losses, damages, liabilities, costs and expenses (including, without limitation, reasonable attorneys’ fees and expenses).
- 1.81 “**Manufacturing Know How**” means know how related to the manufacture of a Product which has as its primary mode of action inhibition of FGFR1, FGFR2, FGFR3 and/or FGFR4 including any common technical document (“**CTD**”), specifications, data, standard operating procedures, quality assurance, and quality control processes and techniques, and all other documentation retained to comply with GMP procedures; and information relating to contract manufacturers, Facilities, and the manufacturing supply chain of the Product, including API, intermediates, bulk drug products, and finished pharmaceutical products. For clarity, Manufacturing Know How includes Documents containing such Manufacturing Know How.

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- 1.82 “**Material Adverse Effect**” has the meaning given in Section 3.1.
- 1.83 “**Material Variations**” means a material variation, modification or change to the manufacturing-related information or Specifications approved by a Regulatory Authority for the Product, including but not limited to: (i) changing the manufacturer or adding a manufacturing site, (ii) changing the manufacturing process, (iii) changing the formulation of the Product, or (iv) changing the primary packaging.
- 1.84 “**Milestone**” means any one of the Commercial Sales Milestones or Development and Regulatory Milestones, and “**Milestones**” means all of the Commercial Sales Milestones and Development and Regulatory Milestones together.
- 1.85 “**Named Officer**” means, with respect to a Party, the individuals listed on Schedule 6 attached hereto.
- 1.86 “**Net Sales**” means the gross amount invoiced by Basilea, its Affiliates, Sub-licensees or distributors for sale of Products that are the subject of a Regulatory Approval to Third Parties, less the following deductions which are actually incurred, allowed and taken or paid, prepared in accordance with Basilea's internal reports and with the Accounting Standards applied on a consistent basis:
- (a) Basilea's customary trade, cash and quantity discounts, allowances and credits actually allowed and taken or paid; provided that where any discount, allowance or credit is based on sales of a bundled set of products in which the Product is included, the discount, allowance or credit shall be allocated to the Product on a pro rata basis;
  - (b) credits, price adjustments or allowances actually granted and taken for damaged Products, returns or rejections of products, price adjustments or billing errors;
  - (c) chargeback payments and rebates (or the equivalent thereof) for the Product granted to group purchasing organisations, managed health care organisations, pharmacy benefit managers (or equivalents thereof) or to federal, state/provincial, local and other governments, including their agencies, or to trade customers;
  - (d) freight, shipping insurance and other transportation expenses related to the sale of the Product (if actually borne by Basilea, its Affiliates, Sub-licensees or distributors without reimbursement from any Third Party);
  - (e) wholesaler fee-for-service and distribution commissions/fees payable to any Third Party providing wholesaler and/or distribution services to Basilea;
  - (f) sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, to the extent that such items are included in the gross amount invoiced for the Product and actually borne by Basilea, its Affiliates, Sub-licensees or distributors without reimbursement from any Third Party (but not including taxes assessed against the income derived from such sale);
  - (g) the actual amount of any write-off recorded for bad debt directly relating to the sales of the Product recorded in Basilea's books in accordance with Accounting Standards during such period; provided such costs do not exceed \*\*\* of the gross amounts invoiced for Product sold in the applicable Calendar Quarter; and

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- (h) Third Party costs such as fees, interest, discounts and similar arrangements incurred in connection with factoring any accounts receivable; provided such costs do not exceed \*\*\* of the gross amounts invoiced for Product sold in the applicable Calendar Quarter.

The transfer of Product between or among Basilea and its Affiliates or Sub-licensees or distributors shall not be considered a sale and will be excluded from the computation of Net Sales but the subsequent final sales to a Third Party by such Affiliates or Sub-licensees or distributors will be included in the computation of Net Sales and deductions from such sales shall be made in accordance with this definition.

- 1.87 “**Net Sales Report(s)**” has the meaning given in Section 14.6.
- 1.88 “**Non-Breaching Party**” has the meaning given in Section 19.5.
- 1.89 “**Non-Prosecuting Party**” has the meaning given in Section 15.2.
- 1.90 “**Party**” means either Basilea or ArQule and together they are the “Parties.”
- 1.91 “**Patent List**” has the meaning given in Section 17.3(g).
- 1.92 “**Patent Rights**” means:
  - (a) all national, regional and international patents and patent applications, including provisional patent applications; and
  - (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications; and
  - (c) any and all patents that have issued or in the future issue from the foregoing patent applications in paragraphs (a) and (b) above, including author certificates, inventor certificates, utility models, petty patents and design patents and certificates of invention; and
  - (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications in paragraphs (a) to (c) inclusive, and
  - (e) any similar rights, including so-called pipeline protection (where the subject matter previously disclosed was not previously patentable in a particular jurisdiction but subsequently becomes patentable subject matter in such jurisdiction), or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.
- 1.93 “**Payment Adjustments**” has the meaning given in Section 14.5.
- 1.94 “**Pending Claim**” means a claim of a pending ArQule Territory Patent that was filed and is being prosecuted in good faith which has not been pending for more than \*\*\* and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.

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- 1.95 “**Permitted Encumbrance**” means the negative pledge granted by ArQule in favor of Oxford Finance LLC as set forth in that certain Loan and Security Agreement dated as of January 6, 2017, as amended.
- 1.96 “**Permitted Use**” means the Research, Development and manufacturing for Commercialization in the Territory (i) of the Product as a monotherapy (not as combined administration) or (ii) of any combined administration of the Product with any compound other than the AKT Inhibitors listed in Schedule 9 and their pharmaceutically acceptable salts, solvates, hydrates, and prodrugs.
- 1.97 “**Person**” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organisation, including a government or political subdivision, department or agency of a government.
- 1.98 “**Pricing Approval**” means (i) such approval, agreement, determination or governmental decision establishing prices for the Product that can be charged and will be reimbursed by Regulatory Authorities in countries in the Territory where Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise; and (ii) a price established in a supply contract with a Regulatory Authority following a tender process.
- 1.99 “**Product**” means any formulations and pharmaceutical dosage forms of (i) ArQule’s FGFR inhibitor designated as ARQ 087 (derazantinib), (ii) any compounds that are covered by any of the Patents that are included as part of the ArQule IP or ArQule Excluded Territory IP and (iii) any intermediates, pro-drugs, derivatives, alternative salts or polymorphs, and isomers of (i) and/or (ii).
- 1.100 “**Product Know How**” means any know how that is necessary or useful for the Research, Development, use, manufacture, or Commercialisation of a Product which has as its primary mode of action inhibition of FGFR1, FGFR2, FGFR3 and/or FGFR4 and associated biomarkers and/or diagnostic tools, including information and data comprising or relating to (i) non-clinical data including mode of action, biomarker, pharmacological, toxicological and metabolic data and results of all non-clinical studies relevant to the Product; (ii) clinical data including data analyses, study reports and information contained in protocols, filings or other submissions to and responses from ethical committees and Regulatory Authorities; (iii) safety (pharmacovigilance) data; and (iv) data or results of Investigator Initiated Trials (IITs). For clarity, Product Know How includes Documents containing Product Know How.
- 1.101 “**Product Materials**” means all raw materials necessary for the manufacturing of the Product, including without limitation, starting materials or building blocks, intermediates, API and excipients, packaging materials and components.
- 1.102 “**Prosecuting Party**” has the meaning given in Section 15.2.
- 1.103 “**Publication(s)**” shall mean any materials related to the Product which are publically published or presented whether for scientific communication or otherwise, including but not limited to articles, abstracts, presentations, summaries, and compilations.
- 1.104 “**Recall**” means a recall, correction or market withdrawal and shall include any post-sale warning or mailing of information.

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- 1.105 “**Recipient Party**” means the Party which receives Confidential Information from the other Party.
- 1.106 “**Quality Agreement**” has the meaning given in Section 12.1.
- 1.107 “**Regulatory Approval**” means any approval required from a Regulatory Authority to market and sell a pharmaceutical product in any country or region of the Territory but excluding any Pricing Approval.
- 1.108 “**Regulatory Authority**” means any supranational, national or local parliament, regional, state, country, city, town village, municipal, district, commission, department or agency, including FDA, EMA or any regulatory authority in any other applicable country, authority (including a listing authority in relation to a stock exchange), inspectorate, minister, ministry official, or other public or statutory person (whether autonomous or not), multinational organization or any other body exercising or entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power of any nature over the Parties relevant to any of the activities contemplated under this Agreement.
- 1.109 “**Relevant Patent**” has the meaning given in Section 15.2.
- 1.110 “**Representatives**” means a Party’s directors, officers, employees, agents, advisors and Affiliates.
- 1.111 “**Research**” means the scientific, technical and non-clinical activities undertaken to evaluate a compound for and during development.
- 1.112 “**Retained Rights**” means, with respect to the ArQule IP, the ArQule Excluded Territory IP and the ArQule Partner Excluded Territory IP, the rights of ArQule, its Affiliates and its and their licensors, (sub)licensees and contractors, including the ArQule Partner, to: (i) manufacture the Products within the Territory solely to Research, Develop, register, manufacture, and Commercialise the Products in the Excluded Territory subject to Section 2.4; and (ii) Research, Develop, register, manufacture, and Commercialise the Products in the Excluded Territory.
- 1.113 “**Royalty Term**” has the meaning given in Section 14.3.
- 1.114 “**Safety Data Exchange Agreement**” has the meaning given in Section 11.1.
- 1.115 “**Specifications**” means the specifications for the manufacture, processing, packaging, labeling, testing, shipping and storage of the Product, including all formulae, know-how, Product Materials requirements, analytical procedures and standards of quality control and quality assurance, which will be agreed to by the Parties and included as a schedule to the Quality Agreement.
- 1.116 “**Sub-licensee**” means a Third Party to whom Basilea or its Affiliates has granted a sublicense to Commercialise the Product under the license grants in Section 2.1, as provided in Section 2.3, but for the avoidance of doubt shall not include any Third Party sub-contractors, such as contract research organisations or CMOs, distributors, pre-wholesalers or wholesalers in each case appointed by Basilea pursuant to Section 2.3(b) to perform its obligations under this Agreement in the Territory during the ordinary course of business (whether or not a limited sub-license is granted to such Third Party to enable them to perform their obligations).



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- 1.117 “**Submission**” means a submission by or on behalf of either Party to a Regulatory Authority with respect to the Product, which may include, but shall not be limited to, submissions with respect to the Product for variations, notifications, renewals, PSUR, labelling and artwork.
- 1.118 “**Term**” has the meaning given in Section 19.1.
- 1.119 “**Territory**” means all countries and territories worldwide other than the Excluded Territory.
- 1.120 “**Third Party**” means a party other than the Parties or any of their respective Affiliates.
- 1.121 “**Third Party Actions**” has the meaning given in Section 15.7.
- 1.122 “**Third Party Claims**” has the meaning given in Section 18.1.
- 1.123 “**US**” means the United States of America.
- 1.124 “**USD**” means US dollars.
- 1.125 “**US GAAP**” means generally accepted accounting principles in effect in the US as revised from time to time.
- 1.126 “**Valid Claim**” means (a) a claim of a granted or issued and unexpired ArQule Territory Patent, which has not been held revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a Pending Claim.
- 1.127 Interpretations. In this Agreement:
- (a) the table of contents and headings are inserted for convenience only and shall not affect the interpretation of any provision of this Agreement;
  - (b) unless the context otherwise requires all references to a particular Section, paragraph or Schedule shall be a reference to that Section, paragraph or Schedule, in or to this Agreement as it may be amended from time to time pursuant to this Agreement;
  - (c) unless the contrary intention appears words importing the masculine gender shall include the feminine and vice versa and words in the singular include the plural and vice versa;
  - (d) unless the contrary intention appears words denoting persons shall include any individual, partnership, company, corporation, joint venture, trust, association, organisation or other entity, in each case whether or not having separate legal personality and that person's legal representatives, successors and permitted assigns;
  - (e) either Party may enjoy its rights or discharge any of its obligations under this Agreement through its Affiliates and all references in this Agreement to the rights and obligations of each Party shall be interpreted accordingly to include such Party's Affiliates.
  - (f) reference to the words “include” or “including” are to be construed without the limitation to the generality of the preceding words;

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- (g) reference to any statute or regulation includes any modification or re-enactment to that statute or regulation; and
- (h) references to the singular include the plural and vice versa (unless the context otherwise requires).

**ARTICLE 2 LICENSE GRANTS**

2.1 ArQule License Grants. ArQule hereby grants to Basilea:

- (a) an exclusive, royalty-bearing license in the Field, with the right to grant sublicenses pursuant to Section 2.3, to use the ArQule IP to Research, Develop, register, manufacture, and Commercialise the Products in the Territory; and
- (b) a non-exclusive, royalty-bearing license in the Field, with the right to grant sublicenses pursuant to Section 2.3, (i) to use the ArQule Excluded Territory IP and the ArQule Partner Excluded Territory IP to (A) Research, Develop, register, manufacture, and Commercialise the Products in the Territory and (B) Research, Develop, and manufacture the Products in the Excluded Territory for the sole purpose of Commercialisation of Products in the Territory, and (ii) to use the ArQule Excluded Know-How solely for the Permitted Use.

2.2 Basilea License Grant. Basilea hereby grants to ArQule a non-exclusive license in the Field, with the right to grant sublicenses pursuant to Section 2.3, to use the Basilea IP to (a) Research, Develop, register, manufacture and Commercialise the Products in the Excluded Territory, (b) subject to Section 2.4, manufacture Products in the Territory for the sole purpose of Researching, Developing, registering, manufacturing, and Commercialising the Product in the Excluded Territory and (c) subject to Section 2.5, to Research and Develop the Product in the Territory for the sole purpose of Researching, Developing, registering, manufacturing, and Commercialising the Product in the Excluded Territory.

2.3 Grant of Sublicenses.

- (a) The Parties shall have the right to grant sublicenses to their Affiliates and to Third Parties through multiple tiers, under the licenses granted in Section 2.1 (with respect to Basilea) and Section 2.2 (with respect to ArQule) provided that any such sublicenses shall:
  - (i) be subject to the granting Party providing written notice of any such Third Party sublicense to the other Party and, to the extent applicable for Basilea in granting a US sublicense, complying with Article 13, and
  - (ii) with respect to either Party, be recorded in a written agreement between that Party and the sublicensee which is consistent with the terms and conditions of this Agreement; and the Party granting a sublicense shall take such steps as may be reasonably necessary to ensure its sublicensee's compliance with the applicable terms and conditions of such written agreement which are consistent with this Agreement.

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- (b) No such permitted sublicense shall relieve the granting Party of any of its obligations or liabilities hereunder, for which obligations and liabilities the granting Party shall remain fully responsible and liable. Without the requirement of provision of written notice pursuant to Section 2.3(a) above, each Party shall have the right to engage Third Party contractors to perform any Development activities under this Agreement or Third Parties acting as logistics providers, pre-wholesalers or wholesalers engaged in routine operational activities, subject to the execution by each such Third Party contractor of an agreement containing provisions with respect to confidentiality and protection and ownership of Know How and Patent Rights that are consistent with, and comparable in scope to, Articles 15 and 16 of this Agreement.
- 2.4 ArQule Manufacturing Right in the Territory. ArQule and/or the ArQule Partner (and their Affiliates, (sub)licensees and contractors) shall have the right to perform manufacturing activities with respect to the Product in the Territory for the sole purpose of Researching, Developing, registering, manufacturing, and Commercialising the Product in the Excluded Territory, provided, that, if at any time on or after the second anniversary of the Effective Date, either ArQule or the ArQule Partner wishes to initiate such manufacturing activities using the same Third Party (or an Affiliate of such Third Party), that manufactures Product for Basilea in the Territory, then ArQule shall obtain Basilea's prior written consent to conduct such manufacturing activities, which Basilea shall not unreasonably withhold.
- 2.5 ArQule Development/ Research Request in the Territory. If ArQule, either itself or through the ArQule Partner or through any other Third Party, wishes to perform any Development or Research activities in the Territory for the sole purpose of Commercialisation in the Excluded Territory, it shall request Basilea's prior consent to do so. Basilea shall not unreasonably withhold its consent.
- 2.6 Retained Rights. Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted or reserved to ArQule pursuant to any other term or condition of this Agreement, ArQule hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its and their licensors, (sub)licensees and contractors) all right, title and interest in and to the ArQule IP, ArQule Excluded Territory IP and the ArQule Partner Excluded Territory IP that is not granted to Basilea under Section 2.1, including for purposes of performing or exercising the Retained Rights.

### ARTICLE 3 GENERAL OBLIGATIONS

- 3.1 Material Adverse Effect. Neither ArQule in the Excluded Territory, nor Basilea in the Territory shall, without the other Party's prior consent (such consent not to be unreasonably withheld or delayed), carry out any activity in their own territory that has or is reasonably likely to have any material adverse effect on the Product outside their own territory, meaning a materially negative impact on the development, regulatory status or manufacturing of the Product (a "**Material Adverse Effect**"). The following are examples of events that, regardless of effect, shall not trigger this clause: (i) pricing reductions unilaterally imposed by a Regulatory Authority; (ii) mandatory recalls required by a Regulatory Authority; (iii) actions imposed by Regulatory Authorities for safety reasons such as: clinical trial suspension, change in labelling or market restrictions, or distribution of Dear Health Care Professional (DHCP) letters; (iv) any situation where the Party who is marketing authorization holder in a certain country or region, or its responsible person for distribution or the Qualified Person responsible for batch certification, determines that Product that has been distributed such country or region must be recalled; and (v) any other actions mandated by a Regulatory Authority.

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- 3.2 Compliance with Applicable Law. The Parties shall carry out their obligations and all activities under this Agreement, the Quality Agreement and the SDEA in compliance with all Applicable Laws and shall obtain from the requisite Regulatory Authorities any consents, licenses, permits, waivers, approvals, authorizations, or orders required to be obtained for the performance of its obligations under this Agreement.
- 3.3 Diligence Obligation. Basilea shall use Commercially Reasonable Efforts to Research, Develop, register, manufacture, and Commercialise the Products in the Territory.
- 3.4 Territorial Restriction of Basilea.
- (a) Basilea shall not, and shall not permit any of its Affiliates or any of its and their licensees, Sublicensees or distributors to knowingly distribute, market, promote, offer for sale or sell the Products directly or indirectly (a) to any Person for commercial use in the Excluded Territory or (ii) to any Person in the Territory that Basilea or any of its Affiliates or any of its or their licensees, Sublicensees or distributors knows (A) is likely to distribute, market, promote, offer for sale or sell any Product for commercial use in the Excluded Territory or assist another Person to do so, or (B) has directly or indirectly distributed, marketed, promoted, offered for sale or sold any Product for commercial use in the Excluded Territory or assisted another Person to do so.
  - (b) Basilea shall cause its Affiliates and its and their licensees, Sublicensees and distributors to notify ArQule of any receipt of any orders for any Product for use in the Excluded Territory. If Basilea or any of its Affiliates receives or becomes aware of the receipt by a licensee, Sublicensee or distributor of any orders for any Product for use in the Excluded Territory, Basilea shall ensure that such Person refers such orders to ArQule.
- 3.5 Territorial Restriction of ArQule.
- (a) ArQule shall not, and shall not permit any of its Affiliates or any of its and their (sub)licensees or distributors to knowingly distribute, market, promote, offer for sale or sell the Products directly or indirectly (i) to any Person for commercial use in the Territory or (ii) to any Person in the Excluded Territory that ArQule or any of its Affiliates or any of its or their (sub)licensees or distributors knows (A) is likely to distribute, market, promote, offer for sale or sell any Product for commercial use in the Territory or assist another Person to do so, or (B) has directly or indirectly distributed, marketed, promoted, offered for sale or sold any Product for commercial use in the Territory or assisted another Person to do so.
  - (b) ArQule shall cause its Affiliates and its and their licensees, (sub)licensees and distributors to notify Basilea of any receipt of any orders for any Product for use in the Territory. If ArQule or any of its Affiliates receives or becomes aware of the receipt by a (sub)licensee or distributor of any orders for any Product for use in the Territory, ArQule shall ensure that such Person refers such orders to Basilea.

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3.6 Exclusivity (Basilea). Basilea shall not, in respect of the US, EU and Japan, for a period commencing on the First Commercial Sale Date and expiring on the earlier of

(a) \*\*\*; or

(b) \*\*\*

Launch or Commercialise a small molecule compound that has as its primary mode-of-action \*\*\* (each, a “**Competitive Compound**”) other than the Product.

3.7 Exclusivity (ArQule). During the Term, ArQule will not (unless requested by Basilea) directly or indirectly, conduct, have conducted, or fund any activity that involves the conduct of, any Research, Development or Commercialisation of any Competitive Compound for use in the Field in the Territory, including the Research, Development and Commercialisation of the Product. This Section shall not apply to:

(a) any Research or Development activities undertaken by ArQule pursuant to Sections 5.1 or 5.7; or

(b) any manufacturing activities undertaken by ArQule in accordance with and pursuant to Section 2.4; or

(c) any activities permitted by Basilea upon request of ArQule pursuant to Section 2.5; or

(d) any exercise of ArQule’s Retained Rights pursuant to Section 2.6.

3.8 Exclusivity Exception. Sections 3.6 and 3.7 do not apply to:

(a) \*\*\*; and

(b) \*\*\*.

#### **ARTICLE 4 INFORMATION SHARING AND KNOW HOW TRANSFER**

4.1 Information Sharing.

(a) Right of Reference, Access, and Use of Information. Subject to Applicable Law, solely as necessary for Basilea to pursue a registration and/or the Development or Commercialization of the Product in the Territory or for ArQule (or the ArQule Partner) to pursue a registration and/or Development or Commercialization of the Product in the Excluded Territory, each Party hereby grants the other Party, and shall grant on an ongoing basis during the Term, access rights, rights of reference, and rights to use and incorporate the following information:

(i) the Dossier for the Product filed in either China, the US, the EU or Japan, such Dossier containing the administrative, safety, efficacy, quality, non-clinical and clinical data and chemistry and manufacturing control data for the Product, and including any updates to such Dossier from time to time and any IND filed in either China, the US, the EU or Japan;

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- (ii) final non-clinical study reports related to the Product, final clinical study reports related to the Product, and the ArQule \*\*\* Reports;
  - (iii) raw data;
  - (iv) scientific publications; and
  - (v) the ArQule Reference Data.
- (b) Format for Provision of Information. Each Party shall provide the other Party the information specified in Section 4.1(a) in the following format and timing:
- (i) with respect to the Dossiers and any IND filed in either China, the US, the EU or Japan mentioned in 4.1(a)(i):
    - (A) provision of a copy of the Dossier and any IND filed in either China, the US, the EU or Japan in English in electronic/searchable format;
    - (B) if the Dossier and any IND filed in either China, the US, the EU or Japan is prepared and filed in a language other than English, provision of an English summary of the Dossier contents; and
    - (C) each Party shall inform the other of the existence of any Dossier and any IND filed in either China, the US, the EU or Japan and shall provide a copy thereof as soon as reasonably practicable thereafter.
  - (ii) with respect to the final reports mentioned in 4.1(a)(ii):
    - (A) provision of a copy of such reports in English when a final report is ready (no draft reports are required to be shared);
    - (B) if the report is prepared in a language other than English, provision of an English translation of such report;
    - (C) with respect to final reports, each Party shall inform the other of their existence and shall provide a copy thereof as soon as reasonably practicable thereafter.
  - (iii) with respect to access to raw data mentioned in 4.1(a)(iii):
    - (A) generally raw data shall not be transferred between the Parties but access shall be granted to raw data or to sites only if required or as specifically requested by Regulatory Authorities;
    - (B) data shall be provided only in standard output format and shall be in the original language;
    - (C) to the extent the raw data is stored at a site by or on behalf of a Party, such Party will grant reasonable access to such site to the other Party at mutually agreeable dates and times solely for the purpose of accessing such raw data;
    - (D) only final data and no interim data shall be provided unless specifically requested by Regulatory Authorities; and

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- (E) no clinical trial database shall be transferred unless specifically requested by Regulatory Authorities.
- (iv) with respect to the publications mentioned in 4.1(a)(iv):
  - (A) provision of a list of publications under the Control of the Party on an annual basis;
  - (B) upon request of the other Party, a copy such publication shall be provided in the original language; and
  - (C) if the publication is not in English, and the providing Party has access to an English translation of the publication, the providing Party shall additionally provide such translation.

For the avoidance of doubt, with respect to requests for information or access under this Section 4.1, the Party from whom information and/or access is requested shall use its reasonable efforts to respond promptly to any request to provide information which is already in existence and within its Control but shall not be obliged to generate or compile any new analyses, compilations, reports or collections of existing information in response to such requests.

- 4.2 Know How Transfer. ArQule agrees to make a transfer to Basilea of any Know How which forms part of the ArQule IP, the ArQule Partner Excluded Territory IP or the ArQule Excluded Territory IP that is owned or Controlled by ArQule as of the Effective Date or which becomes owned or Controlled by ArQule at any point during the Term. ArQule shall use its reasonable efforts to transfer any such Know How existing as of the Effective Date which would be necessary or useful to Basilea in the performance of its activities under the Agreement in accordance with the following timing:
- (a) Within \*\*\* Business Days of the Effective Date, ArQule will provide a full copy in electronic format of all the documents in the Data Room.
  - (b) Any Product Know How Controlled by ArQule and not contained within the Data Room will be transferred within \*\*\* days of the Effective Date.
  - (c) Any Manufacturing Know How Controlled by ArQule and not contained within the Data Room will be transferred within \*\*\* months of the Effective Date. To efficiently plan for such transfer, ArQule and Basilea will discuss and agree in good faith as soon as practicable after the Effective Date a technical transfer plan including a time plan for transfer of such Manufacturing Know How.
  - (d) With respect to Know How created or discovered during the Term, within such time as is reasonably practicable after ArQule becoming aware of the existence of such Know How.

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**ARTICLE 5 DEVELOPMENT**

- 5.1 ArQule Development Activities. As of the Effective Date, ArQule is conducting certain clinical development activities which are specified in Schedule 4 (the “**ArQule Development Activities**”). Starting from the Effective Date, the following shall apply:
- (a) ArQule shall use reasonable efforts to conduct the ArQule Development Activities on Basilea's behalf until \*\*\* and shall dedicate appropriate operational resources to manage such activities. ArQule shall keep Basilea informed with respect to the progress of the ArQule Development Activities via the Development Subcommittee specified in (g) below.
  - (b) Subject to Section 5.2, ArQule shall continue to act as sponsor of all trials which are a part of the ArQule Development Activities and shall hold the related IND and Clinical Trial Applications (CTAs) until \*\*\*.
  - (c) With respect to any material decisions needing to be made about the ArQule Development Activities, and also with respect to any communication with Regulatory Authorities about the activities:
    - (i) ArQule shall consult in advance with Basilea, and the Parties shall attempt to reach a unanimous decision;
    - (ii) If a unanimous decision is not possible, then Basilea shall have the final say, subject to (iii) below;
    - (iii) If ArQule disagrees with respect to any decision on which Basilea has the final say pursuant to (ii) above because, exercising its reasonable judgment, ArQule considers that Basilea's direction to ArQule would or would reasonably be expected to cause ArQule to be in violation of Applicable Law or the protocol for the applicable Clinical Trial or be inconsistent with any of its obligations as sponsor of the Clinical Trial (including the rules or regulations of the applicable Institutional Review Board or data monitoring committee for the Clinical Trial), then ArQule will so inform Basilea. In such a case, the Parties shall discuss in good faith a mutually acceptable solution, which may include the earlier transfer of sponsorship of the Clinical Trial to Basilea so that Basilea may undertake the action that Basilea has directed ArQule to take. For clarity, under no circumstances shall ArQule be obligated to perform any action with respect to the ArQule Development Activities which ArQule determines to be in violation of Applicable Law or the protocol for the Clinical Trial or be inconsistent with any of its obligations as sponsor of the Clinical Trial (including the rules or regulations of the applicable Institutional Review Board or data monitoring committee for the Clinical Trial).
  - (d) Basilea shall bear the out-of-pocket costs and internal costs (on an FTE basis) that are incurred by ArQule in connection with its conduct of the ArQule Development Activities. Schedule 4 provides estimates for out-of-pocket costs and internal costs (on an FTE basis) of these activities. For activities conducted by a Third Party, Basilea shall bear the costs on a pass-through basis (without mark-up). For activities conducted by ArQule, Basilea shall bear the internal costs (on an FTE basis) as specified in Schedule 4. ArQule shall invoice Basilea on a monthly basis for all out-of-pocket costs (providing copies of third party invoices) and internal costs (on an FTE basis) incurred and Basilea shall pay each such invoice within \*\*\* days of receipt.



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- (e) ArQule shall make no changes to the scope or cost of any of the ArQule Development Activities (as set forth in Schedule 4) without Basilea's prior written consent, which will not be unreasonably withheld. For the avoidance of doubt, if any specific activity listed in Schedule 4 requires, in ArQule's reasonable judgment, a different scope or different cost than as provided in Schedule 4, ArQule shall notify Basilea in advance of such proposed adjustment to scope or cost and any such adjustment shall require Basilea's prior written consent which will not be unreasonably withheld.
  - (f) ArQule shall grant Basilea a right of access to the data generated by the ArQule Development Activities and to any Clinical Trial sites, and Basilea shall have the right (but not the obligation) to conduct co-monitoring of Clinical Trial data.
  - (g) To ensure appropriate coordination between the Parties of the ArQule Development Activities, a Development Subcommittee shall be formed as a subcommittee of the JSC, and shall meet by telephone on a bi-weekly basis (every two weeks) until the ArQule Development Activities are completed. Meetings of the Development Subcommittee shall be attended by the Chief Medical Officer of each Party and by such other Party employees as are necessary to discuss all technical, scientific, and operational aspects of the ongoing activities.
- 5.2 Transfer of Sponsorship. The Parties will cooperate to transfer sponsorship for any Clinical Trial and the IND which is a part of the ArQule Development Activities no later than \*\*\*. No later than \*\*\*, the Parties shall initiate discussions of the transfer, and shall develop and agree an operational plan for the transfer no later than \*\*\*, so that the transfer may timely occur no later than \*\*\*. In connection with the transfer of sponsorship, ArQule shall transfer all information Controlled by ArQule that is necessary to enable Basilea to act as sponsor, including but not limited to the Trial Master File (TMF). For the avoidance of doubt, from the Effective Date, Basilea shall be the sponsor of all Clinical Trials with respect to the Products in the Territory other than any Clinical Trial which is a part of the ArQule Development Activities.
- 5.3 Transfer of Contracts. Schedule 5 includes a list of all contracts to which ArQule is a party that relate to the Research, Development, manufacturing and Commercialisation of the Product in the Territory ("**ArQule Contracts**"). Within \*\*\* Business Days of the Effective Date, ArQule shall notify Basilea with respect to each contract whether (i) ArQule is able and willing to assign or transfer such contract to Basilea; or (ii) ArQule is unable or unwilling to assign or transfer such contract to Basilea.
- (a) For contracts under (i), Basilea shall inform ArQule within \*\*\* days of the Effective Date whether it wishes for ArQule to assign or transfer any of the ArQule Contracts to Basilea. ArQule shall thereafter use reasonable efforts to transfer or assign the selected ArQule Contracts to Basilea as soon as reasonably practicable. If ArQule is unable to assign or transfer any of the ArQule Contracts requested by Basilea due to the refusal of the Third Party counterparty to such contracts, ArQule shall use reasonable efforts to provide Basilea with the benefit of such contracts and shall in addition, if requested by Basilea, use reasonable efforts to support Basilea in its discussion with any counterparties to such contract to support Basilea's efforts to enter its own contracts with such counterparties.

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- (b) For contracts under (ii), ArQule shall use reasonable efforts to provide Basilea with the benefit of such contracts and shall in addition, if requested by Basilea, use reasonable efforts to support Basilea in its discussion with any counterparties to such contract to support Basilea's efforts to enter its own contracts with such counterparties.
- 5.4 ArQule Support. On an ongoing basis starting from the Effective Date and continuing until the filing of the first Submission for Regulatory Approval for the Product in the Territory, subject to Basilea providing reasonable advance written notice, ArQule shall use reasonable efforts to provide such reasonable support as may be requested by Basilea which is necessary for Basilea to become operationally ready to undertake its Research, Development, and related manufacturing activities with respect to the Products. Such support may include, but is not be limited to, holding teleconferences (or meetings, if both Parties agree) for Basilea to ask questions regarding ArQule's past or ongoing Research, Development, and manufacturing activities related to the Product. Basilea may only request such support with respect to questions that Basilea cannot answer independently by exercising reasonable efforts.
- 5.5 Initial Development Plan and Development Plan. Basilea shall use Commercially Reasonable Efforts to implement the Initial Development Plan and any updates thereto (such updates being known in each case as the "**Development Plan**"). Subject to Section 5.6, Basilea may update and revise the Development Plan from time to time during the Term as it deems useful or necessary and shall in each instance share the updated Development Plan with ArQule through the JSC by providing it to the JSC at the next scheduled JSC meeting.
- 5.6 Development Commitment. Basilea shall initiate \*\*\* and shall use Commercially Reasonable Efforts to carry out such Clinical Trials and Studies. Notwithstanding the foregoing, Basilea may pursue \*\*\* in the event Basilea determines in good faith that it is Commercially Reasonable to do so. However it shall not be considered Commercially Reasonable for Basilea to pursue \*\*\*.
- 5.7 ArQule Further Research and Development. On an ongoing basis throughout the Term, Basilea may request ArQule to conduct Research and Development activities related to the Product or related biomarkers and/or diagnostic tools. If Basilea so requests and ArQule agrees, the Parties shall discuss the desired activities and related costs, with the goal of agreeing a plan for such activities and a budget therefore. Solely to the extent the Parties reach agreement on such plan and budget, ArQule shall thereafter conduct the activities in line with the agreed plan and budget and Basilea shall bear the costs incurred in line with the budget.
- 5.8 Development Records. Basilea shall, and shall cause its Affiliates and its and their Sublicensees to, maintain records pertaining to Development of Products which are: (i) appropriate for patent and regulatory purposes, when such records shall be utilized for patent or regulatory purposes, (ii) in compliance with Applicable Laws and GCP, (iii) properly reflect Development activities performed and results achieved and (iv) retained in each case for the length of time required by Applicable Laws or GCP.

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- 5.9 Development Reports. At each meeting of the JSC, during the period when Basilea is conducting Development activities, Basilea shall provide the JSC with a detailed written report of the status of its Development activities, including a summary of all Development activities completed (including an overview of the results of all Clinical Trials when final clinical study reports have been prepared), Development activities in progress, and upcoming Development activities. The report shall further include a regulatory update covering Basilea's progress with respect to applying for and/or achieving Regulatory Approvals of Products in the Territory.

**ARTICLE 6 REGULATORY MATTERS**

- 6.1 Submission Responsibility. Basilea shall have the responsibility for preparation of all Submissions to Regulatory Authorities for the Product in the Territory except Submissions in relation to the ArQule Development Activities. ArQule shall have responsibility for preparation of all Submissions to Regulatory Authorities related to the ArQule Development Activities. For the avoidance of doubt, Basilea shall have no obligation to prepare or submit any Submissions or any portions of any Submissions for the Excluded Territory.
- 6.2 Sharing of Submissions. With respect to the Submissions listed below, each Party shall share with the other Party at least \*\*\* days prior to the intended date of filing such Submission, a copy of the Submission (either in English or in original language with an English summary provided). The reviewing Party shall have the right (but no obligation) to review and comment on such Submission, and the submitting Party shall thereafter consider in good faith the reviewing Party's reasonable comments. Comments should be provided by the reviewing Party as soon as practically possible but no later than \*\*\* days of its receipt of the Submission. The Submissions which shall be shared are:
- (a) the Dossier filed in China, the EU, the US and Japan;
  - (b) Clinical Trial protocol in China, the EU, the US and Japan; and
  - (c) any other Submissions in any country in the Territory or the Excluded Territory which may have a material impact on the other Party's territory.

If either Party, either itself or through any sublicensee, including the ArQule Partner, wishes to reference, use or incorporate any of the materials described in subsections (b) and/or (c) above in order for such Party to pursue a registration and/or the Development or Commercialization of the Product in the Territory (with respect to Basilea) or the Excluded Territory (with respect to ArQule (or the ArQule Partner)), it shall request the other Party's prior written consent to do so. The other Party shall not unreasonably withhold its consent.

- 6.3 Excluded Territory Regulatory Information. For the Excluded Territory, ArQule shall, as promptly as practicable but in no event later than \*\*\* Business Days following receipt of notice of the same, inform Basilea of:
- (a) the acceptance by any Regulatory Authority of any material Submission made by ArQule;
  - (b) the approval by any Regulatory Authority of any material Submission made by ArQule (including the grant of a Regulatory Approval);

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- (c) any material adverse communication received from any Regulatory Authority in relation to the Product; or
- (d) any other material change in the regulatory status of any Regulatory Approval.

6.4 Territory Regulatory Information. For the Territory, other than as related to the ArQule Development Activities, Basilea shall, as promptly as practicable but in no event later than \*\*\* Business Days following receipt of notice of the same, inform ArQule of:

- (a) the grant by the FDA, EMA, or Regulatory Authority in Japan of a Regulatory Approval;
- (b) any material adverse communication received from the FDA, EMA, or Regulatory Authority in Japan in relation to the Product; or
- (c) any other material change in the regulatory status of the FDA, EMA, or Regulatory Authority in Japan Regulatory Approval.

If ArQule receives any material communication (adverse or otherwise) from any Regulatory Authority with respect to the conduct of the ArQule Development Activities, ArQule shall, as promptly as practicable but in no event later than \*\*\* Business Days following receipt of notice of the same, inform Basilea.

6.5 Regulatory Support. Both Parties shall cooperate with each other to provide reasonable support and information Controlled by such Party that is necessary to answer Regulatory Authority questions related to the Product for each Party's territory and specifically to provide any existing data or information owned or Controlled by a Party requested by a Regulatory Authority. For the avoidance of doubt, neither Party shall be under the obligation to produce any new data or analyses; if a Party agrees to produce any new data or analyses, costs therefore shall be borne by the requesting Party. For the further avoidance of doubt, neither Party shall ask the other to provide information or answer questions which the requesting Party could provide or answer on its own, exerting its reasonable efforts.

6.6 Regulatory Inspections and Notifications.

- (a) Regulatory Notice of Improper Conduct. If any Regulatory Authority issues a report, finding, notice or other document to a Party or its Affiliates or its or their (sub)licensees which alleges improper Development, Manufacture or Commercialisation of any Product, then the Party receiving such finding will promptly notify the other Party of such finding.
- (b) Regulatory Action with Potential Material Adverse Affect. If any Regulatory Authority takes, or gives notice of its intent to take, any regulatory action with respect to any activity of such Party or its Affiliates or its or their (sub)licensees that could reasonably be expected to adversely affect any Development, Manufacture or Commercialisation activities with respect to the Product in such other Party's territory, then such Party will promptly notify the other Party of such contact, inspection or notice.

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- (c) Regulatory Inspections. If inspections are requested by a Regulatory Authority which are reasonably related to any Development, Manufacture or Commercialisation activities with respect to the Product, and where such inspections are of sites controlled by the other Party, the Party receiving such request shall notify the other Party. Such other Party shall allow representatives of any Regulatory Authority to inspect such sites and obtain copies of all material documentation with respect to the Product as may be required by the Regulatory Authority. Such other Party shall also permit representatives of the notifying Party to be present during such inspection and to observe any such inspection to the extent permitted by Applicable Law. Such Party shall further provide reasonable support to the notifying Party with respect to the preparation for and hosting of any Regulatory Authority inspections. Each Party shall bear all of its own and Third Party costs of pre-inspection visits that it requests. Each Party shall also provide the other Party with copies of all correspondence submitted to or received from the Regulatory Authority relating to any such inspection.
- 6.7 Regulatory Meetings. During the period commencing on the Effective Date and continuing until the completion of the transfer of sponsorship from ArQule to Basilea pursuant to Section 5.2, ArQule shall, upon Basilea's reasonable request, set up meetings, calls or other interactions with Regulatory Authorities related specifically to the ArQule Development Activities and generally to the Development of the Product, support Basilea in preparing for such interactions, and attend such interactions.

## ARTICLE 7 COMMERCIALISATION

- 7.1 Commercialisation Plans.
- (a) \*\*\* months prior to the reasonably anticipated grant of the first Regulatory Approval for a Product in each of the US, the EU and Japan, respectively, Basilea will prepare and provide to the JSC a commercialisation plan for the Product(s) in the US, the EU, and Japan which shall include such information as would customarily be included by Basilea in its internal commercialisation plans prepared for other therapeutic products at comparable stages of the product life cycle, and shall in any event include (i) patient profile, (ii) the names of those countries for which Basilea will undertake pre-launch commercialisation activities and the projected dates of launch for each such country, and (iii) general strategies for selling the Product in such countries or region, including Basilea's high-level plan for marketing the Product in such countries or region (each a "**Commercialisation Plan**"). In following Calendar Years, Basilea will update each Commercialisation Plan at least \*\*\* in every Calendar Year during the Term, and shall in each instance share the updated plan with ArQule through the JSC by presenting it to the JSC at the next scheduled JSC meeting.
- (b) With respect to the rest of the Territory (other than the US, EU, and Japan), Basilea shall routinely, and not less frequently than \*\*\* in each Calendar Year, update ArQule through the JSC of: (i) the names of those countries for which Basilea will undertake pre-launch commercialisation activities and the projected dates of launch for each such country, and (ii) on a regional basis, general strategies for selling the Product in the Territory, including Basilea's high-level plan for marketing the Product in the Territory.
- 7.2 Diligence. As between the Parties, Basilea shall be solely responsible for Commercialisation of the Products in the Field throughout the Territory at Basilea's sole cost and expense. Basilea shall use Commercially Reasonable Efforts to Commercialise the Products throughout the Territory. Basilea shall and shall cause its Affiliates to, comply with all Applicable Laws with respect to the Commercialisation of Products.

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- 7.3 Commercialisation Records. Basilea shall maintain records pertaining to Commercialisation of Products which: (i) are in compliance with Applicable Laws; (ii) adequately include information and data underlying Basilea's Net Sales Report which it shall issue to ArQule in accordance with Section 14.6; and (iii) are retained in each case for the length of time required by Applicable Laws. With respect to the records which are maintained by Basilea for the purpose of calculating its payments to ArQule in accordance with this Agreement or which underlie Basilea's Net Sales Report, ArQule shall have the audit rights specified in Section 14.8.

**ARTICLE 8 SUPPLY**

- 8.1 Supply for ArQule Development Activities. ArQule shall use reasonable efforts to obtain quantities of Product Materials and/or Product under ArQule's contracts with CMOs sufficient for it to conduct the ArQule Development Activities specified in Schedule 4. Basilea shall bear the cost of such supply as specified in Section 8.3.
- 8.2 Transitional Supply. For the period commencing on the Effective Date and ending \*\*\* months after the Effective Date (the "**Transitional Supply Period**"), ArQule will use reasonable efforts to supply Basilea with Product Materials and/or with Product as follows:
- (a) ArQule shall supply Basilea subject to the terms of ArQule's agreements with ArQule's CMOs. ArQule shall use reasonable efforts to enforce the terms of its supply contracts with its Third Party manufacturers.
  - (b) Basilea shall bear the cost of such supply as specified in Section 8.3.
  - (c) The Parties will discuss and agree on appropriate supply terms to enable Basilea to order and ArQule to supply Product Materials and Product, including but not limited to binding and non-binding forecasts, lead time for orders, ordering mechanism, and delivery. Such terms will be recorded by the Parties in a written document agreed to by both Parties within \*\*\* days of the Effective Date.
- 8.3 Cost of Supply. For the supply of Product and/or Product Materials pursuant to Sections 8.1 or 8.2, Basilea shall bear the out-of-pocket costs and internal costs (on FTE basis) that are incurred by ArQule in connection with such supply. Schedule 4 provides estimates for the out-of-pocket costs and internal costs (on an FTE basis) of such supply. For supply activities provided by a Third Party, Basilea shall bear the costs on a pass-through basis (without mark-up). ArQule shall invoice Basilea on a monthly basis for all out-of-pocket costs and internal costs (on FTE basis) so incurred. Basilea shall pay each such invoice within \*\*\* days of receipt.
- 8.4 Letters of Access. Within \*\*\* days of the Effective Date, ArQule will provide letters of access to Basilea to enable Basilea to visit the Facilities and to review and, if necessary, audit the manufacturing related documentation maintained at such Facilities. Such letters of access will additionally authorize Basilea to visit the Facilities during the Term if necessary to attend ongoing manufacturing operations during the Transitional Supply Period, and/or prepare for any investigation or inspection that may be carried out by any Regulatory Authority.

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- 8.5 CMO Visits. Subject to Basilea providing ArQule reasonable advance notice, ArQule shall make appropriate personnel available to accompany Basilea to visit CMOs and facilitate any visits under Section 8.3 above for a maximum aggregate period of \*\*\* Business Days for all CMO visits.
- 8.6 CMO Interaction.
- (a) During the Transitional Supply Period, Basilea shall negotiate in good faith with either, at Basilea's sole discretion, ArQule's CMOs or alternative Third Party CMOs with the intention of concluding its own CMO contracts and establishing its own supply chain for the Product Materials and Product. If, at the end of the Transitional Supply Period, Basilea has been unable, despite using its reasonable efforts, to conclude necessary contracts with ArQule's CMOs or Third Party CMOs, ArQule agrees to use reasonable efforts to obtain quantities of Product Materials and/or Product under ArQule's contracts with CMOs in order to supply Basilea with such Product and Product Materials as it needs for the Development, under the same terms as specified in Section 8.2(a)-(b), for an additional period not to exceed \*\*\* months.
  - (b) If Basilea uses different CMOs after the Transitional Supply Period than ArQule uses, the Parties will collaborate and discuss in good faith to ensure a smooth transition from ArQule's CMOs to Basilea's CMOs at the end of the Transitional Supply Period.
- 8.7 Material Variations. In the event that either Party desires to make any Material Variations, then: to the extent such Party is ArQule or the ArQule Partner, ArQule shall notify Basilea of the proposed modification \*\*\* days prior to the required Submission of the proposed Material Variation with respect to Submissions to the Regulatory Authorities and, to the extent such Party is Basilea, Basilea shall notify ArQule of the proposed modification \*\*\* days prior to the required Submission of the proposed Material Variation with respect to Submissions to the Regulatory Authorities. Upon notification of a proposed Material Variation, the Parties shall in good faith discuss the proposed Material Variations through the JSC, with each Party considering other one's reasonable input. The costs of Material Variations in the Excluded Territory shall be borne by ArQule and in the Territory shall be borne by Basilea.

**ARTICLE 9 JOINT STEERING COMMITTEE**

- 9.1 The Parties shall establish and run a Joint Steering Committee (“JSC”) with the purpose of:
- (a) ensuring that the Parties effectively communicate with each other regarding the Research, Development, manufacture, use, and Commercialisation of the Product in the Territory and the Excluded Territory; and
  - (b) coordinating the Parties' activities where useful and to the extent permitted by Applicable Law.
- 9.2 The JSC shall be organized as follows:
- (a) The JSC shall be comprised of four persons (“JSC Members”) with each Party entitled to appoint two JSC Members, to remove any JSC Member appointed by it and to appoint any person to fill a vacancy arising from the removal or retirement of a JSC Member appointed by it.

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- (b) JSC Members shall have appropriate seniority, availability, job description, training and experience for the function of the JSC.
  - (c) Meetings of the JSC will be chaired by a representative of Basilea.
  - (d) Each Party may invite its relevant employees, consultants or advisors involved in the Development, manufacturing, regulatory activities, or Commercialization of the Product to attend relevant meetings of the JSC or its subcommittees when such Party considers that their attendance is necessary or useful in relation to the topics planned to be discussed at such JSC meeting. Any Third Party consultants or advisors may attend only subject to the consent of the other Party, such consent not to be unreasonably withheld, and further must be under obligations of confidentiality and non-use in relation to the Confidential Information of both Parties. For clarity, such persons shall not be considered JSC Members unless formally appointed by a Party as such pursuant to Section 9.2(a).
  - (e) The JSC shall hold meetings in person, by teleconference or a videoconference as frequently as the members of the JSC agree shall be necessary, but no less frequently than \*\*\* times each Calendar Year in total. Dates of meetings shall be agreed by the Parties not less than \*\*\* days in advance.
  - (f) The venue for meetings of the JSC shall alternate between the premises of the Parties, if not held by teleconference or videoconference. Each Party shall be responsible for its own expenses including travel and accommodation costs incurred in connection with JSC meetings.
  - (g) Each Party shall submit agenda items and associated materials that it will present no later than \*\*\* days prior to the meeting.
  - (h) The first meeting of the JSC will take place no later than \*\*\* days after the Effective Date. At the first meeting, the JSC will establish the date of the first meeting of the Development Subcommittee, unless it has already taken place.
  - (i) Special meetings of the JSC in the event of urgent issues may be called by either Party at any time with \*\*\* days' notice to the other Party.
  - (j) The chair shall be responsible for promptly preparing the minutes of the meeting, circulating the minutes for comments from the JSC Members, signing and dating the final minutes and promptly distributing a copy of the signed minutes to each Party.
- 9.3 The Parties will regularly update the JSC regarding the status of the Research, Development, manufacture, use, and Commercialisation of the Product both inside the Territory and inside the Excluded Territory.
- 9.4 For the avoidance of doubt, the JSC is not a forum for dispute resolution or decision making and its members shall have no voting power or authority to resolve disputes. Decision making shall remain the responsibility of each Party. This Agreement can only be amended by written agreement of the Parties, and not by the JSC.



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**ARTICLE 10 PUBLICATIONS, PRESENTATIONS, AND PRESS RELEASES**

10.1 Publications.

- (a) Publication Plan. The Parties shall share a publication plan covering a one year period through the JSC at least once in each Calendar Year. This plan shall include: (i) a list of planned Publications, and the dates, authors and brief summary of contents of such Publications; and (ii) a list of international congresses which the Party plans to attend (if the Party plans to communicate about the Product at such congress) both inside and outside the Party's respective territory. If the Party that receives the publication plan believes that any of the planned Publications listed in the plan could reasonably be expected to have a material impact on the Product in such Party's territory, it will (i) provide the Party that provided the plan with written notice which will identify such planned Publications which it requests to disclose to its sublicensees (including, with respect to ArQule, the ArQule Partner) and (ii) subject to the receipt by the notifying Party of the other Party's written consent (such consent not to be unreasonably withheld or delayed), such Party will have the right to disclose the information in the plan about the Publications so identified to its sublicensees (including, with respect to ArQule, the ArQule Partner).
- (b) Publication List. The Parties shall share through the JSC, at least once in each Calendar Year, a list of Publications made during the previous \*\*\* month period by each Party or by any Third Party on behalf of one of the Parties, or made independently by a Third Party in such Party's respective territory. Upon reasonable request, each Party shall provide the other with copies of Publications.
- (c) Publications Concerning Pivotal Trials. In the event that Basilea or its Affiliates or Sublicensees or ArQule or the ArQule Partner or any other (sub)licensee wishes to publish any Publications related to the \*\*\* and/or any \*\*\* and \*\*\* of the Product, the publishing Party shall provide the Publication to the other Party in English \*\*\* days prior to proposed submission for publication. The non-publishing Party shall then advise within \*\*\* days of receipt of such proposed Publications of any comments to the Publications, which the publishing Party shall consider in good faith, and further the non-publishing Party may advise of:
  - (i) any potential adverse consequences of disclosure of information included in the proposed Publication that in its judgment will result in a loss of Patent Rights and, in this situation, the publishing Party shall delay publication for a period of up to \*\*\* days to allow the non-publishing Party to proceed with the filing of Patent Rights; or
  - (ii) any Confidential Information of the non-publishing Party included in the proposed Publication and, in this situation, the publishing Party shall remove such Confidential Information prior to submission for publication.
- (d) Avoidance of Material Adverse Impact Through Publications. Neither Party may make a Publication including the Confidential Information or IP of the other Party without the prior written permission of that Party. For the avoidance of doubt, the data generated by Basilea in non-clinical or clinical trials is Basilea's IP, and may not be included in a Publication Controlled by ArQule or the ArQule Partner without Basilea's prior consent.

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10.2 International Conferences.

- (a) For any international congress inside the Territory where ArQule (either itself or through a Third Party including the ArQule Partner) wishes to have a presence or make a presentation related to the Product, ArQule shall notify Basilea in advance of ArQule's proposed presence and shall notify Basilea of its proposed activities, including any booths, displays, sponsorships, and presentations. Basilea may object to specified ArQule activities if it determines in its reasonable discretion that such proposed activities would constitute Commercialisation or medical affairs activities that would have a material adverse effect on the Product inside the Territory, in which case ArQule shall modify its proposal, or shall cause such Third Party (including the ArQule Partner) to modify its proposal, to avoid carrying out such activities. This provision shall not apply to ArQule in the United States in the event that ArQule receives a sublicense for the United States from Basilea in accordance with the terms of Article 13.
- (b) For any international congress inside the Excluded Territory where Basilea (either itself or through a Third Party) wishes to have a presence or make a presentation related to the Product, Basilea shall notify ArQule in advance of Basilea's proposed presence and shall notify ArQule of its proposed activities, including any booths, displays, sponsorships, and presentations. ArQule may object to specified Basilea activities if it determines in its reasonable discretion that Basilea's proposed activities would constitute Commercialisation or medical affairs activities that would have a material adverse effect on the Product inside the Excluded Territory, in which case Basilea shall modify its proposal, or shall cause such Third Party to modify its proposal to avoid carrying out such activities.

10.3 Press Releases.

- (a) The Parties agree that the public announcements of the execution of this Agreement shall be substantially in the form of the two press releases attached as Schedule 7.
- (b) Neither Party shall issue any press release or other publicity materials, or make any presentation with respect to the existence of this Agreement or the terms and conditions hereof that is not substantially in the form of the press releases attached without the prior written consent of the other Party. The Party that desires to make such a public announcement shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld. A Party commenting on such a proposed announcement shall provide its comments, if any, within \*\*\* Business Days after receiving the announcement for review, or such shorter period as may be reasonably required in order for the proposing Party to comply with any applicable deadline for making such announcement (as such deadline is communicated by the proposing Party to the commenting Party). This restriction shall not, however, apply to the extent that any such disclosures are required by Applicable Laws, including as may be required in connection with any filings required to be made with the United States Securities and Exchange Commission or the Swiss Stock Exchange or by the disclosure policies of any other applicable major stock exchange or to the extent they have been previously disclosed by the Parties.

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- (c) The Parties acknowledge that, for the purpose of giving guidance to investors under applicable stock exchange rules, general information regarding this agreement may be disclosed including upfront payments, total contingent success payments and general success payment rates, and general guidance on matters that have previously been disclosed in a press release approved by the other Party.
- (d) At least \*\*\* Business Days prior to each Party's planned financial reporting including the issuance of financial guidance, the Parties will communicate and use reasonable efforts to align on planned financial guidance \*\*\* related to the Product. For this purpose Basilea will annually share its \*\*\* for the Product in the Territory with ArQule no later than \*\*\* days following the end of each fiscal year, with the first such \*\*\* shared no later than \*\*\* months prior to the anticipated first grant of Marketing Authorisation in the Territory.

**ARTICLE 11 SAFETY DATA EXCHANGE AGREEMENT**

- 11.1 Safety Data Exchange Agreement. Within \*\*\* days of the Effective Date, the Parties shall enter into a safety data exchange agreement (the "**Safety Data Exchange Agreement**") describing the procedures which ArQule and Basilea shall implement and the responsibilities that both Parties will assume in order to ensure that:
  - (a) the relevant safety information relating to the Product is exchanged in a timely manner; and
  - (b) that both Parties can fulfil their respective pharmacovigilance obligations under Applicable Law.
- 11.2 Master Global Safety Database.
  - (a) ArQule has created the master global safety database for the Product and will continue to maintain it until \*\*\*.
  - (b) Basilea will assume responsibility for maintaining the master global safety database for the Product as of \*\*\*.
  - (c) ArQule and Basilea shall cooperate to transfer the master global safety database to Basilea. No later than \*\*\*, the Parties shall initiate discussions of the transfer, and shall develop an operational plan for the transfer no later than \*\*\*, so that the transfer may timely occur. In connection with the transfer of the master global safety database, ArQule shall transfer all information necessary, useful or reasonably requested by Basilea to enable Basilea to hold the master global safety database, and shall also make its reasonable efforts to transfer or assign or otherwise provide the benefit of any contracts with Third Parties which provide services related to the master global safety database. Prior to the transfer of the database, the Safety Data Exchange Agreement shall be reviewed and amended to reflect the revised activities of the Parties.

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- (d) Starting \*\*\*, ArQule shall provide all necessary data related to the Excluded Territory for such master global safety database in line with the Safety Data Exchange Agreement and shall bear all costs related to the maintenance of the master global safety database for the Excluded Territory.
- (e) At ArQule's reasonable cost, Basilea shall perform such queries requested by ArQule (either on its own behalf or on behalf of the ArQule Partner) in such global safety database as required to address specific data requests by a Regulatory Authority in the Excluded Territory related to the Product(s), to respond to safety issues related to the Product(s), and as otherwise required by Applicable Law. Further provisions governing the sharing of data held in the master global safety database between the Parties, and specifically covering the queries which ArQule may ask Basilea to perform either on its own behalf or on behalf of the ArQule Partner shall be set forth in the Safety Data Exchange Agreement.

**ARTICLE 12            QUALITY ASSURANCE**

- 12.1 Quality Agreement. The Parties shall discuss in good faith and agree a Quality Agreement setting forth the Parties' responsibilities and obligations related to quality matters (the "**Quality Agreement**") within \*\*\* days of the Effective Date.
- 12.2 Quality Assurance and Supply. As shall be further detailed in the Quality Agreement, during the period of time when ArQule is supplying Product or Product Materials to Basilea, ArQule shall itself or shall procure that its contracted Third Parties shall:
  - (a) manufacture the Product and Product Materials strictly in accordance with applicable Specifications and Applicable Law, and shall transport and store the Product and Product Materials in accordance with GDP, GMP, associated guidelines and Applicable Law;
  - (b) maintain detailed records with respect to the manufacturing of the Product and Product Materials in accordance with Applicable Law; and
  - (c) conduct and document tests and test results related to manufacturing of the Product and Product Materials (including but not limited to all manufacturing operations for clinical trial materials, process development and scale-up trials, process validation, cleaning validation, bulk holding and finished product stability) in compliance with the Specifications, the Quality Agreement and Applicable Law.
- 12.3 Audits. Upon reasonable prior notice and the pre-agreement of the affected Facilities, upon its reasonable request, Basilea may (either directly or via a Third Party contracted audit service provider) physically audit all Facilities, or to join routine visits of ArQule to its Facilities. Basilea shall bear its own and any Third Party costs of any audit that it initiates, and shall bear all of its own costs to join any routine visit of ArQule to a Facility.
- 12.4 Recalls.
  - (a) With respect to any Recall, the Parties shall comply with the procedures set forth in the Quality Agreement.

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- (b) Subject to subsection (d), decisions to Recall Product in the Territory shall be made by Basilea at its discretion, to the extent permitted under Applicable Law. Basilea shall notify ArQule following its determination of the need for a Recall of a Product in in the Territory and shall provide information regarding the nature of such Recall to ArQule with as much advance notice as possible. Subject to Article 18, Basilea shall be responsible for all costs and expenses of any such Recall.
- (c) Subject to subsection (d), decisions to Recall Product in the Excluded Territory shall be made by ArQule at its discretion, to the extent permitted under Applicable Law; however, ArQule shall provide Basilea with as much advance notice of such decisions as possible and shall discuss any planned or ongoing Recall with Basilea. Subject to Article 18, between the Parties, ArQule shall be responsible for all costs and expenses of any such Recall.
- (d) Notwithstanding subsections (b) and (c) above, if a global recall, market suspension or market withdrawal is mandated by a Regulatory Authority, the Parties will discuss in good faith and agree upon a mutually acceptable plan to implement the global recall, market suspension or market withdrawal in compliance with Applicable Law, including the allocation of responsibilities between the Parties for such global recall, market suspension or market withdrawal.
- (e) Subject to Article 18, each Party shall be responsible for the costs and expenses of any such Recall related to its territory.

**ARTICLE 13 US SUB-LICENSE**

13.1 Basilea may, at its entire discretion:

- (a) choose to directly Commercialise the Product in the US, \*\*\*.
- (b) grant a sub-license of its rights under Section 2.1 for the US (a “**US Sub-License**”) as follows:
  - (i) Basilea may grant a US Sub-License without ArQule’s permission and without notifying ArQule in advance of granting such US Sub-License. Sales under such a US Sub-License shall be considered \*\*\*.
  - (ii) Basilea may notify ArQule prior to granting a US Sub-License, in which case ArQule shall respond in writing to Basilea within \*\*\* days of receipt of Basilea’s notice and indicate if either:
    - (A) ArQule does not have the existing capabilities and existing infrastructure to Commercialise the Product in the US, in which case Basilea may grant a US Sub-License to a Third Party and all sales under such US Sub-License shall be considered \*\*\*;
    - (B) ArQule has the existing capabilities and existing infrastructure to Commercialise the Product in the US but does not wish to sell Product itself in the US, in which case Basilea may grant a US Sub-License to a Third Party and all sales under such US Sub-License shall be considered \*\*\*; or

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- (C) ArQule has the existing capabilities and existing infrastructure for the Commercialisation of the Product in the US and ArQule wishes to sell Product itself in the US and therefore wishes to participate in the process of negotiation for the US Sub-License, in which case Basilea shall enter into good faith negotiations with ArQule with respect to such US Sub-License under the following conditions:
- (1) ArQule shall only request to enter into negotiations if it has existing capabilities and existing infrastructure to Commercialise the Product in the US;
  - (2) such negotiations shall be non-exclusive;
  - (3) Basilea shall be under no obligation to disclose the identity of Third Parties with whom Basilea is negotiating any such Sub-license, or any or all of the terms under negotiation with such Third Parties; and
  - (4) Basilea may grant a US Sub-License to a Third Party over ArQule if that Third Party offers better terms \*\*\*.
- 13.2 If ArQule responds to Basilea in accordance with Section 13.1(b)(ii)(C) above but the Parties are unable to reach an agreement despite good faith negotiations within a \*\*\* month period, then ArQule's notice shall be considered withdrawn and Section 13.1(b)(ii)(B) above shall automatically apply.
- 13.3 If ArQule responds to Basilea in accordance with Section 13.1(b)(ii)(C) above and the Parties are able to reach an agreement for a US Sub-license after good faith negotiations, but ArQule does not sell any Product in the United States within \*\*\* months after the later of:
- (a) the execution of such agreement; or
  - (b) granting of the first Regulatory Approval in the US
- then such US Sub-License shall automatically terminate, ArQule's notice shall be considered withdrawn and Section 13.1(b)(ii)(B) above shall automatically apply.
- 13.4 If ArQule responds to Basilea in accordance with Section 13.1(b)(ii)(C) above and the Parties are able to reach an agreement for a US Sub-license after good faith negotiations, then any \*\*\*.

**ARTICLE 14 FINANCIAL PROVISIONS**

- 14.1 Execution Payment. The Execution Payment shall be due to ArQule on the Effective Date. ArQule shall within \*\*\* days of the Effective Date issue an invoice to Basilea and Basilea shall within \*\*\* days of the Effective Date pay the Execution Payment to ArQule.
- 14.2 Milestone Payments.
- (a) The Milestone payments set out in Schedule 3 shall become payable upon the first occurrence of the applicable Milestone whenever it occurs.

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- (b) Development and Regulatory Milestone Payments are made per Indication. For the avoidance of doubt, such payments shall be made only once per Indication. Therefore if a second Product is being developed for the same Indication as a previous Product, then there shall be no duplication of Milestone payments related to the second Product in that Indication that have already been made relating to the Milestones reached by the previous Product in the same Indication.
- (c) Basilea shall report the achievement of each Development and Regulatory Milestone to ArQule within \*\*\* days of its occurrence, and with respect to Commercial Sales Milestones shall report the achievement of such Milestones in its Net Sales Report to ArQule (pursuant to Section 14.6), and ArQule shall issue an invoice in USD for the relevant payment which Basilea shall pay within \*\*\* days of receipt of such invoice.
- (d) Commercial Sales Milestones will be paid based on Net Sales from all countries in the Territory during each country's respective Royalty Term. Such Milestones are not calculated with reference to a specific Indication(s) but rather on the aggregate annual sales of the Products.
- (e) In event that, notwithstanding the fact that Basilea has not given such a notice, ArQule believes any such milestone event has occurred, it shall so notify Basilea in writing and shall provide to Basilea data, documentation or other information that supports its belief. Any dispute under this Section 14.2 that relates to whether or not a milestone event has occurred shall be subject to resolution in accordance with Article 21. If at the time any given milestone payment set forth in Section 14.2 is due and one (1) or more preceding milestone payments for antecedent milestone events have not been paid, then such unpaid antecedent milestone payments shall be paid at such time as well.

14.3 Royalty Term. Subject to the Payment Adjustments, Basilea shall pay the royalties set out in Schedule 3 on the Net Sales for the Royalty Term, which is the period calculated on a country-by-country basis from the First Commercial Sale Date in a country until the longest of:

- (a) \*\*\* full Calendar Years after the First Commercial Sale Date in such country;
- (b) the expiry of the last Valid Claim, provided that the only Valid Claim is not a Pending Claim, of any ArQule Patent that absent this Agreement would be infringed by the sale or use of a Product in such country; or
- (c) the expiry of any data exclusivity period for a Product for the first Indication in such country,

such a period being the "**Royalty Term**," where "expiry" in relation to a Valid Claim for purposes of royalty calculations means expiration, revocation, or the holding, finding or decision of unenforceability by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal.

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- 14.4 Milestone and Royalty Reduction. If ArQule has authorized any Third Party to use the ArQule IP prior to the Effective Date, or if ArQule does so after the Effective Date, and such Third Party has developed or develops its own Intellectual Property that would allow such Third Party to assert a claim of infringement against Basilea in relation to the use of the ArQule Patents in the Development, manufacture, or Commercialisation of the Product(s) as determined by independent patent counsel mutually acceptable to the Parties (“**Covered IP**”), then ArQule shall be empowered to negotiate a license with such Third Party to such Covered IP \*\*\*. ArQule shall negotiate such license (which shall be sublicensable and which ArQule shall sublicense to Basilea pursuant to Section 2.1 of this Agreement) and use reasonable efforts to enter into an agreement for such license within \*\*\* months. ArQule shall keep Basilea apprised of its progress in negotiating such license, shall provide Basilea with the opportunity to comment on the terms and conditions of any proposed license agreement, and shall consider Basilea’s comments in good faith. If ArQule enters such a license agreement, ArQule shall bear \*\*\* of the \*\*\*, with Basilea bearing the remaining \*\*\*. If ArQule fails to enter into such a license agreement within \*\*\* months, then Basilea may negotiate a license to such Covered IP with such Third Party \*\*\*, in which case Basilea may then deduct from its Royalty or Milestone payments due to ArQule \*\*\* the reasonable costs actually paid by Basilea to such Third Party in connection with negotiating, finalising and executing such license, including any \*\*\*.
- 14.5 Payment Adjustments.
- (a) The following adjustments to the royalty payments due under Section 14.2 (“**Payment Adjustments**”) shall apply on a Product-by-Product and country-by-country basis where during the Royalty Term:
- (i) The royalty rates set out in Schedule 3 shall be reduced by \*\*\* if either:
- (A) there are no Valid Claims that, absent this Agreement, would be infringed by the sale or use of a Product in a country of the Territory for any Indication for which a Product is approved, or
- (B) (1) the only Valid Claims that, absent this Agreement, would be infringed by the sale or use of a Product in a country of the Territory for any Indication for which a Product is approved are Pending Claims and (2) one or more Third Parties sell a Competitive Compound in such country and sales of the Competitive Compound are equal to or greater than \*\*\* of the aggregate unit sales of the Product and the Competitive Compound in such country in any calendar month (as measured by IMS data or other similar information available from a Third Party data provider reasonably acceptable to the Parties and applicable to such country), and
- (ii) The royalty rates set out in Schedule 3 shall be reduced by \*\*\* if a Generic Product is made available in a country of the Territory (or, with respect to the EEA, such Generic Product is made available in any one or more countries of the EEA), such reduction being applied starting from the Calendar Quarter after the release of the Generic Product in such country (or, with respect to a country in the EEA, after the release in any one or more countries of the EEA) in which the Net Sales of Product in such country are reduced by more than \*\*\* compared with the average quarterly Net Sales of Product in the \*\*\* Calendar Quarters prior to the Launch of such Generic Product.



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- (b) The royalties payable in any country shall not be reduced to less than \*\*\* of the rates in Schedule 3 as a result of the Payment Adjustments.

14.6 Net Sales Reports.

- (a) All royalties due to ArQule under this Agreement shall be calculated and payable on a Calendar Quarter basis, and shall be paid by Basilea to ArQule in USD. Within \*\*\* days of the end of each Calendar Quarter, Basilea shall send to ArQule a written report setting out:
  - (i) Product-by-Product and country-by-country the amount of gross invoiced amount and Net Sales in such country during such Calendar Quarter expressed in the local currency of that country and the deductions taken to arrive at Net Sales attributable to each Product during the applicable Calendar Quarter;
  - (ii) the amount of the royalties due to ArQule in relation to such Calendar Quarter; and
  - (iii) any Commercial Sales Milestones achieved in the reporting period,such a report being a “**Net Sales Report.**”
- (b) To convert the local currency amounts set out in the report to USD the average conversion rate for the quarter published at [www.oanda.com](http://www.oanda.com) or any successor website shall be used. Upon receipt of such report ArQule shall invoice Basilea for the royalties due and Basilea shall pay the same to ArQule within \*\*\* days of the date of the invoice. Without limiting the generality of the foregoing, Basilea shall require its Affiliates and Sublicensees to account for their Net Sales and to provide such reports with respect thereto, as if such sales were made by Basilea.

14.7 Interest. Interest at an annual rate (with interest accruing on a daily basis) equal to \*\*\* above the then-current prime rate quoted by Citibank in New York City (before and after any judgment) (“Interest”) shall be paid under the following circumstances only:

- (i) If any payment due to either Party under this Agreement is not paid when due and is not disputed in good faith by the Party owing payment, then, in addition to any other rights and remedies available to the other Party under this Agreement, such owing Party shall pay Interest thereon, such Interest to run from the date on which payment of such sum became due until payment thereof in full together with Interest.
- (ii) If a Party disputes the amount of the payment in good faith (the “**Disputing Party**”) and therefore does not make payment when due, and the Disputing Party is later determined to have been incorrect in disputing the amount of the payment, then the Disputing Party shall pay the other Party Interest on such payment, such Interest to run from the date when payment was originally due (and not from the date of the notice of the dispute) until payment thereof in full together with Interest.

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- (iii) If the Disputing Party pays the full disputed amount when it is due despite such dispute, and if such payment is later determined to be an incorrect overpayment, then the other Party shall have both an obligation to promptly repay such overpayment and to pay Interest to the Disputing Party on such overpayment amount, such Interest to run from the date when the overpayment was made until repayment of the overpayment in full together with such Interest.

14.8 Records. Basilea shall keep complete and accurate records and books of account for the purpose of calculating all payments due to ArQule under this Article 14 for a minimum period of \*\*\* years after the time of generation. ArQule shall have the right to instruct an independent certified public accountant, reasonably acceptable to Basilea, for the sole purpose of verifying to ArQule whether or not Basilea correctly calculated such payments in accordance with this Agreement on the following basis:

- (a) such accountant shall be given access to and shall be permitted, during normal business hours, to examine such books and records of Basilea upon \*\*\* days' notice having been given by ArQule;
- (b) prior to any such examination taking place, such accountant shall undertake to Basilea, as appropriate, that it shall keep all information and data contained in such books and records strictly confidential and shall not disclose such information or copies of such books and records to any third person, including ArQule and shall only use the same for the purpose of the reviews and/or calculations which they need to perform in order to issue a report to ArQule on the accuracy or otherwise of the payments for the period for which the audit is being carried out;
- (c) any such audit shall occur no more frequently than once per Calendar Year and will not go back over records more than \*\*\* Calendar Years old unless a discrepancy is found; once an audit has been performed in accordance with this Section 14.8 in respect of the payments made to ArQule in any Calendar Year, there shall be no other audit in respect of such Calendar Year during the Term;
- (d) Basilea shall make available a reasonable group of personnel to answer reasonable queries on all books and records required for the purpose of the report;
- (e) any amounts reported by the independent auditor to be owed and in need of reimbursement shall be paid or refunded (as the case may be) within \*\*\* days after the independent auditor's report, plus interest from the original due date, unless challenged in good faith by a Party, in which case, any undisputed portion shall be paid in accordance with this Section and any dispute in connection with such challenge shall be resolved in accordance with Section 21 with the remaining disputed portion being payable within \*\*\* days after resolution of the dispute, and interest shall not accrue with respect to the disputed portion during such time as the dispute is being resolved; and
- (f) ArQule shall bear the full costs of such audit unless such audit reveals an underpayment by Basilea of more than \*\*\* of the amount paid in the audited period, in which case, Basilea shall bear the full costs of the applicable audit up to the amount of the underpayment, in addition to paying the underpayment.

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**ARTICLE 15 INTELLECTUAL PROPERTY**

15.1 Property Rights. Except as expressly set forth in this Agreement,

- (a) Basilea obtains no property rights in the ArQule IP, the ArQule Excluded Territory IP, or the ArQule Partner Excluded Territory IP and acknowledges ArQule's ownership of the same.
- (b) ArQule obtains no property rights in Basilea IP and acknowledges Basilea's ownership of the same.
- (c) Each Party shall be solely responsible for any fees, costs, annuities, compensation or other sums payable to any employee, inventor or other Third Party relating to any of the intellectual property it owns.

15.2 Filing, Prosecuting and Maintaining of Patents.

- (a) Basilea shall be responsible from the date \*\*\* calendar month after the Effective Date at its cost in consultation with ArQule for the filing, prosecution and maintenance of the ArQule Patents in the Territory other than any ArQule Patents which are a part of the ArQule Excluded Territory IP or the ArQule Partner Excluded Territory IP. Basilea shall use the same patent counsel for this purpose as used by ArQule as of the Effective Date, unless otherwise consented to by ArQule (which consent will not be unreasonably withheld).
- (b) ArQule shall be responsible at its cost for the filing, prosecution and maintenance of ArQule Patents in the Excluded Territory; provided, that, ArQule will consult with Basilea with respect to the filing, prosecution and maintenance in the Territory of any ArQule Patents that are a part of the ArQule Excluded Territory IP or the ArQule Partner Excluded Territory IP.
- (c) Basilea shall be responsible at its cost in its sole discretion for the filing, prosecution and maintenance of all Basilea Patents.
- (d) The Parties shall diligently prosecute the applicable Patents for which they are responsible in accordance with this Section 15.2 and in accordance with each respective Party's usual practice.
- (e) Each Party shall give such reasonable assistance as the relevant Party reasonably requests (at such relevant Party's reasonable cost) in connection with the filing, prosecution and maintenance of the Patents to be filed, prosecuted or maintained pursuant to this Section 15.2, provided that the nature of such costs that shall be paid by the relevant Party are agreed in advance of any such assistance.
- (f) The Party (the "**Prosecuting Party**") responsible for filing, prosecuting and maintaining a Patent pursuant to the above (each, a "**Relevant Patent**") shall provide regular updates on the progress and status of the Relevant Patents and shall provide the other Party (the "**Non-Prosecuting Party**") with the opportunity to give comments and recommendations as to the overall strategy regarding the filing, prosecution and maintenance of the applicable Relevant Patent.

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- (g) The Prosecuting Party shall determine which Patent Rights should be used as the basis for obtaining patent term extensions or restoration and/or supplementary protection certificates; provided, that the Prosecuting Party will reasonably consult with the Non-Prosecuting Party with respect to the foregoing and shall provide the Non-Prosecuting Party with the opportunity to give comments and recommendations as to the overall strategy regarding such patent term extensions or restoration and/or supplementary protection certificates. The Prosecuting Party shall use its reasonable efforts to apply for and maintain patent term extensions for any Relevant Patent that covers any Product(s), including supplementary protection certificates (SPC) and other equivalent extension which may be available.
- (h) Should there be any disagreement between the Non-Prosecuting Party and the Prosecuting Party as to any issue related to filing, prosecution or maintenance of any Relevant Patent, the Parties agree to try to resolve the issue in good faith within a reasonable time period. Should the Parties still disagree, the Prosecuting Party in its sole discretion will make the final decision for all filing, prosecution and maintenance issues for which the Prosecuting Party is responsible.
- (i) The Prosecuting Party shall for the purposes of this Section 15.2 provide the Non-Prosecuting Party with the opportunity to comment on all material documents and material correspondence with the patent office, including material applications, official letters, responses to official letters, notice of all interferences, reissues, re-examinations, oppositions or requests for patent term extensions and any other documents which may be of material importance for any action(s) to be taken sufficiently in time prior to the deadline for, or the intended date for the action to be taken, whichever is the earlier, but no later than \*\*\* days prior to such date. For the avoidance of doubt, administrative (such as formality documents) or duplicative documents and correspondence shall not be provided unless specifically requested. The Non-Prosecuting Party shall communicate its comments (if any) \*\*\* days from the date on which the Prosecuting Party provided such information. For clarity, if no comments are received from the Non-Prosecuting Party with respect to a particular action with sufficient time prior to the deadline for, or the intended date for, such action to be taken, the Prosecuting Party is entitled to proceed with such action at its own discretion.
- (j) In the event that the Prosecuting Party should decide not to file, prosecute or maintain any Relevant Patent, should decide not to file a national or regional patent application in any international jurisdiction from a Relevant Patent, should decide not to file (by continuation or divisional), prosecute or maintain any subject matter disclosed within any Relevant Patent, or to permit any Relevant Patent to lapse by any action or inaction (including failure to pay any fee when due), the following provisions shall apply:
  - (i) The Prosecuting Party shall promptly inform the Non-Prosecuting Party of such decision sufficiently in time prior to the deadline for, or the intended date for, the event related to such action or inaction, but no later than \*\*\* days prior to such event, so that the Non-Prosecuting Party might, at its expense, take any relevant action or inaction with respect to such Relevant Patent.

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- (ii) If the Non-Prosecuting Party so chooses to take such action, then the Non-Prosecuting Party shall assume immediately the responsibility for any costs associated with such Relevant Patent and shall acquire all of the rights with respect to such Patent. Further, upon request by the Non-Prosecuting Party in writing to the other Party, that Party shall execute a binding agreement to assign such Relevant Patent (if applicable) and to transfer responsibility for filing, prosecution and maintenance of the Relevant Patent to the Non-Prosecuting Party and thereafter such Relevant Patent will be considered the property of the Non-Prosecuting Party which will become the Prosecuting Party for such Relevant Patent with respect to any future activity related to it, including Third Party Actions pursuant to Section 15.7.

- 15.3 Improvements and Inventions – Basilea IP. Any Improvements or other inventions generated by ArQule on Basilea's behalf under this Agreement (such as pursuant to Section 5.1 (ArQule Development Activities) or Section 5.7 (ArQule Further Research and Development)) are Basilea IP. All of ArQule's rights to such Improvements or inventions, including but not limited to rights relating to patentable or non-patentable inventions and improvements as well as other rights in Intellectual Property, are herewith assigned or otherwise transferred to Basilea for no further consideration than the one to be paid according to Article 4 of this Agreement, without the need for any further action. To the extent that such a transfer of rights is not permitted by Applicable Law, ArQule hereby grants to Basilea the exclusive rights to exploitation and use for all known kinds of exploitation and use of such right in such territory. To the extent necessary to fulfill its obligations under this Section, ArQule shall secure all related rights from its employees or other Third Parties. ArQule shall further execute documents and take other actions as may be reasonably requested by Basilea, including assisting Basilea in the preparation, and signing of, any patent application, related to such rights. For the avoidance of doubt, Basilea shall have the right but not the obligation to file patents on Improvements or inventions.
- 15.4 Improvements – ArQule IP. With respect to any Improvements to the ArQule Excluded Territory IP or ArQule Partner Excluded Territory IP generated by ArQule (other than those generated by ArQule on Basilea's behalf under this Agreement which fall under Section 15.3) or by the ArQule Partner pursuant to the terms of the ArQule Partner License Agreement, ArQule or the ArQule Partner shall have the right but not the obligation to file patents on such Improvements that are ArQule Partner Excluded Territory IP (in both the Territory and the Excluded Territory) and on the ArQule Excluded Territory IP (in the Excluded Territory). If neither ArQule nor the ArQule Partner chooses to do so, ArQule shall promptly inform Basilea and Basilea shall have the option to file patents on such Improvements on its own behalf in either the Territory and/or in the Excluded Territory using the process contained in Section 15.2(j).
- 15.5 Regulatory Patent Filings. The Parties shall cooperate with each other and discuss in good faith what Patent Rights should be listed in the "Orange Book" and other similar national (or supranational) equivalents thereto. Basilea shall have the sole right, after good faith reasonable discussion with ArQule, to make all filings with the Regulatory Authorities with respect to the ArQule Patents and Basilea Patents as required or allowed in connection with: (i) in the United States, the FDA's Orange Book and (ii) under any equivalents in other countries of the Territory. ArQule shall, to the extent required in connection with any such filing and upon reasonable advance notice and at Basilea's expense, (a) provide to Basilea a correct and complete list of ArQule Patents covering any Product and any further information necessary or reasonably useful to enable Basilea to make such filings with Regulatory Authorities with respect to the Products, and (b) provide necessary administrative support in response to Basilea's reasonable requests in connection therewith, to the extent required or permitted by Applicable Law. Basilea shall notify ArQule in writing of any such filings with the Regulatory Authorities with respect to ArQule Patents.

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15.6 Infringement.

- (a) If either Party becomes aware of any actual, threatened or suspected infringement or misuse by a Third Party of any of the ArQule IP relating to the Product in the Territory, or any of the Basilea IP relating to the Product in the Territory or in the Excluded Territory, it shall promptly inform the other Party by providing a written notice including all available evidence and details available concerning said infringement.
- (b) If either Party or its Affiliates receives notice from a Third Party that the Commercialisation of Product in the Territory or the manufacturing or Development of Product in the Territory or in the Excluded Territory infringes or otherwise violates the Intellectual Property of such Third Party in the Territory or in the Excluded Territory, then such Party shall promptly notify the other Party by providing a written notice including all available evidence and details available concerning the alleged infringement or violation.

15.7 Third Party Actions.

- (a) Basilea shall have the first right, but not the obligation, at its sole cost and expense, to bring, defend, or maintain any suit, action or proceedings in any forum (and whether by claim, counterclaim, defence, observations, oppositions or otherwise) involving a Third Party (other than the relevant court or patent office) concerning the infringement, misappropriation, enforceability, validity, scope, ownership, use or other violation of any of the ArQule IP in the Field in the Territory or Basilea IP inside or outside the Field and/or the Territory (collectively "**Third Party Actions**"). In the event Basilea prosecutes any such Third Party Actions in the Field in the Territory, ArQule shall have the right to join as a party to such claim, suit or proceeding and participate with its own counsel at its sole cost and expense; provided, that, Basilea shall retain control of the prosecution of such Third Party Action, including the response to any defense or defense of any counterclaim raised in connection therewith. If Basilea or its designee does not take commercially reasonable steps to prosecute a Third Party Action (i) within \*\*\* days following the first notice provided above with respect to such Third Party Action or (ii) within \*\*\* days before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then (A) Basilea shall so notify ArQule and (B) ArQule may prosecute such alleged or threatened infringement at its sole cost and expense.
- (b) Basilea shall have, in its sole discretion, the exclusive right to control the conduct and/or settlement of any Third Party Actions, save that it shall not make any concession, stipulation or settlement of such proceedings that materially adversely affects (i) the reputation of ArQule or (ii) the rights of ArQule in the ArQule IP or in a manner that imposes any costs or liability on or involves any admission of wrongdoing by ArQule without the prior written consent of ArQule, such consent not to be unreasonably withheld or delayed.

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- (c) ArQule shall reasonably assist and cooperate with Basilea in relation to any Third Party Action and shall execute all papers, provide access to documents and personnel and perform such other acts (including bringing, continuing or joining any Third Party Action as a party), as may be reasonably requested by Basilea in relation to any Third Party Action; provided, that, Basilea shall reimburse ArQule for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith, up to the amount of any award or recovery from such Third Party Action.
- (d) Any recovery realized as a result of any Third Party Action (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by Basilea; provided that, to the extent that any award or settlement (whether by judgment or otherwise) with respect to an ArQule Patent is attributable to loss of sales or profits with respect to a Product, such award shall be deemed Net Sales in the Calendar Quarter in which payment is actually received by Basilea.

**ARTICLE 16            CONFIDENTIALITY**

- 16.1 Basilea and ArQule, on behalf of themselves and their respective Representatives, undertake that during the Term and after the expiration or any termination of this Agreement for any reason:
  - (a) all Confidential Information shall be treated in confidence by the Recipient Party and shall only be used by the Recipient Party or furnished to any Third Party for purposes consistent with this Agreement;
  - (b) the Recipient Party shall observe confidentiality of, and not disclose, the Confidential Information.
  - (c) the Recipient Party shall observe strict secrecy in respect of any of the Confidential Information and shall disclose Confidential Information only to such Representatives who have a need to know same for the purpose of performing this Agreement. Representatives who are not employees of the Recipient Party shall be obligated to substantially the same extent as set forth in this Section to hold in confidence, not disclose and not make use of such Confidential Information for any purpose other than those permitted by this Agreement.
- 16.2 The obligations set out in Section 16.1 shall not apply to Confidential Information, which the Recipient Party can show by written documentation:
  - (a) was generally available in the public domain at the time it was disclosed to the Recipient Party or subsequently came into the public domain through no fault of the Recipient Party; or

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- (b) was known to the Recipient Party at the time it was disclosed and either:
  - (i) the person that was the source of such Confidential Information had itself received it from the Disclosing Party but under no obligation of confidence to the Disclosing Party; or
  - (ii) the person that was the source of such Confidential Information was an independent Third Party, and had generated the Confidential Information independently of, and without the use of, the Confidential Information.

16.3 For clarity, specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Recipient Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Recipient Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Recipient Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Recipient Party unless the combination is in the public domain or in the possession of the Recipient Party.

16.4 Notwithstanding the above obligations of confidentiality and non-use a Recipient Party may disclose Confidential Information:

- (a) to a Regulatory Authority as reasonably necessary to obtain Regulatory Approval in a particular jurisdiction to the extent consistent with the licenses granted under terms of this Agreement; and
- (b) to the extent such disclosure is:
  - (i) reasonably necessary to comply with the order of a competent court or an administrative body; provided that if Recipient Party representatives are requested or required to disclose any such information in such manner, Recipient Party shall promptly notify in writing Disclosing Party of such request or requirement so that Disclosing Party (or its designated Affiliate) may seek a protective order, and/or take any other mutually agreed action; or
  - (ii) required to comply with a Applicable Law, including to the extent such disclosure is required in publicly filed financial statements or other public statements under rules governing a stock exchange; provided, to the extent possible bearing in mind such Applicable Law and subject to the next sentence of this Section, the Recipient Party shall provide the Disclosing Party with a copy of the proposed text of such statements or disclosure \*\*\* Business Days in advance of the date on which the disclosure is to be made to enable the Disclosing Party to review and provide comments, unless a shorter review time is reasonably required. In addition, if compliance with Applicable Law requires filing of this Agreement, the filing Party shall consult and coordinate with the other Party with respect to the preparation and submission of a confidential treatment request for this Agreement and shall provide the other Party with a copy of the proposed filings at least \*\*\* Business Days prior to filing for that Party to review and comment thereon, and the filing Party shall in good faith consider incorporating such comments. Each Party agrees that it will obtain its own legal advice with regard to its compliance with Applicable Law and will not rely on any statements made by the other Party relating to such Applicable Law. Notwithstanding the foregoing, each Party will have the right to make disclosures at the time and in the manner reasonably determined by its counsel to be required by Applicable Laws or applicable securities exchange.



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- (c) to any of the following:
  - (i) its actual or potential investment bankers;
  - (ii) existing and potential investors in connection with an offering or placement of securities for purposes of obtaining financing for its business;
  - (iii) actual and prospective lenders for the purpose of obtaining financing for its business;
  - (iv) a bona fide potential acquirer or merger partner for the purposes of evaluating entering into a merger or acquisition provided, however, any such persons must be obligated to substantially the same extent as set forth in this Section to hold in confidence and not make use of such Confidential Information for any purpose other than those permitted by this Agreement; and
  - (v) legal advisers or accountants for the purpose of seeking advice.

16.5 Notwithstanding the above obligations of confidentiality and non-use, a Recipient Party may disclose certain Confidential Information to its (sub)licensees as follows:

- (a) ArQule may disclose to the ArQule Partner the information specifically named in Section 4.1(a) and Section 6.2;
- (b) Basilea may disclose to its sublicensees under Article 2 for the United States, the EU, and Japan, the information specifically named in Section 4.1(a) and Section 6.2 which is relevant to such (sub)licensee's territory;
- (c) ArQule may disclose to the ArQule Partner the ArQule Reference Data on a rolling basis, as such data is generated, simultaneously with ArQule's disclosure of the same to Basilea pursuant to Section 4.1;
- (d) ArQule may disclose to the ArQule Partner the ArQule \*\*\* Reports on a rolling basis, simultaneously with ArQule's disclosure of the same to Basilea pursuant to Section 4.1;
- (e) a Recipient Party may disclose any Confidential Information about a material adverse communication received from a Regulatory Authority pursuant to Section 6.3 or 6.4, a regulatory inspection pursuant to Section 6.6, a Material Variation pursuant to Section 8.7, or international congresses as is specified in Section 10.2 to such Recipient Party's (sub)licensee if such information is relevant to such (sub)licensee;

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- (f) regarding Confidential Information related to Publications concerning pivotal trials as is specified in Section 10.1(c), ArQule may disclose such Confidential Information to the ArQule Partner, and Basilea may disclose such Confidential Information which it reasonably considers relevant to its sublicensees under Article 2 to such sublicensees;
- (g) a Recipient Party may disclose such Confidential Information which it reasonably considers relevant to potential or ongoing Recalls or to the safety of patients in a particular country or region to the (sub)licensee operating in such country or region;
- (h) a Recipient Party may disclose to the relevant (sub)licensee such Confidential Information which is specified in the Safety Data Exchange Agreement or Quality Agreement as being permitted to be disclosed; and
- (i) such Confidential Information as is covered by (a)-(h) above, except (b) above, may be disclosed by the ArQule Partner to its sublicensees if such disclosure is considered by the ArQule Partner in its reasonable judgment to be necessary in order to conduct activities permitted under the ArQule Partner License Agreement.

Other than as permitted pursuant to Section 16.5(a)-(h), a Recipient Party may not disclose Confidential Information to its (sub)licensees without the prior permission of the Disclosing Party, including but not limited to any information shared by the Disclosing Party in the JSC, the Development Plans and Commercialization Plans, draft press releases, information about planned financial guidance shared pursuant to Section 10.4, Net Sales Reports, and draft Patent filings.

#### **ARTICLE 17 REPRESENTATIONS AND WARRANTIES**

17.1 Mutual Representations and Warranties. Each Party makes the following representations and warranties at the Effective Date:

- (a) It is duly authorized to execute and deliver this Agreement and to perform its obligations under this Agreement. The person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action.
- (b) The Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms (subject to the applicable laws of bankruptcy and moratorium). The execution, delivery and performance of this Agreement by it will not:
  - (i) be prevented or impaired by any agreement, instrument or understanding, oral or written, to which it or its Affiliates is a party or by which they are bound; or
  - (ii) violate any Applicable Law to which it or its Affiliates are subject.
- (c) Neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCa or who is the subject of a conviction described in such section.

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- 17.2 Mutual Covenants. Each Party makes the following covenants from the Effective Date until the expiration or termination of this Agreement:
- (a) It shall comply with all Applicable Laws in connection with the performance of its obligations under this Agreement.
  - (b) It will inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.
  - (c) It shall not, and shall ensure that each of its employees, directors, officers, Affiliates, Third Party distributors, subcontractors and agents shall not, (i) offer, promise or give an advantage to another Person, or (ii) request, agree to receive or accept a financial or other advantage in violation of any anti-corruption laws, rules, regulations and decrees applicable to the respective Party, including, to the extent applicable, the United States Foreign Corrupt Practices Act, as amended (the "FCPA"), the United Kingdom Bribery Act 2010, and any implementing legislation under the OECD Convention Against the Bribery of Foreign Government Officials in International Business Transactions. It is each Party's responsibility to be familiar with, and comply with, the provisions of the applicable anti-corruption legislation.
- 17.3 ArQule Representations and Warranties. ArQule makes the following representations and warranties at the Effective Date:
- (a) ArQule is duly organized and validly existing under the laws of the State of Delaware and has full corporate power and authority to enter into this Agreement and to carry out its provisions.
  - (b) To ArQule's Knowledge, there is no action, suit, inquiry, investigation or proceeding instituted by any Regulatory Authority or by any other person that could question or threaten the validity of this Agreement.
  - (c) ArQule is the sole owner of the entire right, title and interest in and to the ArQule Background IP and ArQule has not previously entered into any agreement, whether written or oral, with respect to, or otherwise assigned, licensed, transferred, conveyed or otherwise granted any Encumbrance over, its right, title or interest in or to the ArQule Background IP in the Territory (including by granting any covenant not to sue with respect thereto). To ArQule's Knowledge, the conception, development and reduction to practice of the ArQule Background IP have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person.
  - (d) ArQule is the sole owner of the ArQule Excluded Territory IP and Controls the ArQule Partner Excluded Territory IP.
  - (e) To ArQule's Knowledge, no Patent Rights exist which are necessary for Basilea to Research, Develop, register, manufacture, and Commercialise the Products in the Territory other than the Patent Rights included in the ArQule IP.

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- (f) ArQule does not own or Control any Competitive Compounds which have been profiled by or on behalf of ArQule in animal models, other than those Competitive Compounds (such as the FGFR inhibitor designated as ARQ 087 (Derazantinib)), which are covered by the ArQule Patents.
- (g) The ArQule Patents listed in Schedule 1 (“**Patent List**”) and Schedule 8 represent all Patent Rights within ArQule's Control relating to the Product.
- (h) True, complete and correct copies of the complete file wrapper and other material correspondence with any patent office relating to the prosecution, validity and enforceability of the ArQule Patents on the Patent List have been provided to Basilea prior to the Effective Date and, in respect of the ArQule Patents, ArQule has presented all relevant prior art of which it and the inventors are aware to the relevant patent examiners at the relevant patent offices.
- (i) ArQule has not received any written notice, claim or demand alleging that the ArQule Patents are invalid or unenforceable and to ArQule's Knowledge, there is no basis for any such allegation by any Third Party.
- (j) To ArQule's Knowledge, the Research, Development, use, manufacture, and Commercialisation of the Product by Basilea pursuant to this Agreement would not infringe the Intellectual Property of a Third Party.
- (k) The ArQule Patents on the Patent List that are applications at the Effective Date are being diligently prosecuted with the respective patent offices and the ArQule Patents on the Patent List that are granted have been maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.
- (l) To ArQule's Knowledge, there are no current infringements of ArQule Patents by any Person.
- (m) No claim or litigation has been brought, and, to ArQule's Knowledge, no claim or litigation has been threatened by any Person alleging that
  - (i) the ArQule Patents are invalid, or
  - (ii) the disclosing, copying, making, licensing, assigning or exploiting of ArQule IP violates, infringes or otherwise conflicts or interferes with the Intellectual Property of any Person.
- (n) To ArQule's Knowledge, the Know How within the ArQule IP has been kept confidential or has been disclosed to Third Parties only under terms of confidentiality.
- (o) ArQule has not entered or agreed to enter into any agreement with a Third Party (including for the purposes of this Section the ArQule Partner) which would prevent it from entering into this Agreement or which would conflict with or prevent Basilea from enjoying any or all of its rights under this Agreement.
- (p) To ArQule's Knowledge, ArQule has not authorized any Third Party to own Intellectual Property which is necessary for Basilea to Research, Develop, register, manufacture, and Commercialise the Products in the Territory other than the Intellectual Property included in the ArQule IP or the ArQule Excluded Territory IP or the ArQule Partner Excluded Territory IP.

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- (q) ArQule is not researching or developing any Competitive Compounds other than those compounds which are covered by the ArQule Patents (such as ARQ 087 (Derazantinib)).
- (r) ArQule has not withheld from any Regulatory Authority any material information in its possession related to the safety, toxicity, quality or efficacy of the Product that a pharmaceutical company would reasonably consider to be material for a Regulatory Authority's evaluation of the safety, toxicity, quality and/or efficacy of the Product.
- (s) ArQule and, to ArQule's Knowledge, any Third Party contract partners (including its CMOs) engaged to work on the Product, have carried out the Research, Development and manufacture (as applicable) of the Product in accordance with GLP, GCP and GMP, as applicable, and Applicable Laws.
- (t) To ArQule's Knowledge, each of ArQule's CMOs engaged to work on the Product is in compliance with all Applicable Laws and related requirements of any authorisation issued by a relevant Regulatory Authority.
- (u) ArQule is not engaged in any proceedings in any court, arbitration, administrative or other tribunal anywhere in the world which affects or relates to the Product (including but not limited to claims relating to product liability).
- (v) ArQule has received no communication from any Regulatory Authority that could reasonably be expected to have a material adverse effect on the Product, or its Development, Manufacture or Commercialisation and, to ArQule's Knowledge, there are no grounds on which any Regulatory Authority could issue an adverse communication in relation to the Product, or its Development, Manufacture or Commercialisation.

17.4 Covenants of ArQule. ArQule makes the following covenants, from the Effective Date until the expiration or termination of this Agreement:

- (a) It shall not, subject to Section 20.1, (i) license, sell, assign or otherwise transfer to any Person any ArQule Patents in the Territory other than to Basilea pursuant to this Agreement, (ii) incur or permit to exist, with respect to any ArQule Patents, any Encumbrance, in the case of each of (i) and (ii), that is or would be inconsistent with the licenses and other rights granted to Basilea under this Agreement.
- (b) As between ArQule and Basilea, ArQule shall be responsible to reimburse the inventors named in the ArQule Patents.
- (c) Subject to Section 20.1, ArQule will remain the sole owner of the ArQule Excluded Territory IP during the Term and will continue to Control the ArQule Partner Excluded Territory IP during the Term.

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- (d) During the Term, ArQule will not enter into any agreement with a Third Party (including for the purposes of this Section the ArQule Partner) which would conflict with or prevent Basilea from enjoying any or all of its rights under this Agreement, and will not authorize any Third Party (including the ArQule Partner) to own Intellectual Property which is necessary for Basilea to Research, Develop, register, manufacture, and Commercialise the Products in the Territory other than the Intellectual Property included in the ArQule IP or the ArQule Excluded Territory IP or the ArQule Partner Excluded Territory IP.
- (e) ArQule shall not use the ArQule Excluded IP to prevent, hinder or restrict Basilea or its Affiliates or sublicensees from Researching, Developing and manufacturing for Commercialization in the Territory any combined administration of the Product with any compound other than those AKT inhibitors that are listed in Schedule 9 and their pharmaceutically acceptable salts, solvates, hydrates, and prodrugs.
- (f) If at any time during the Term of this Agreement, ArQule generates any ArQule Excluded Know-How that is necessary or useful for the Research, Development, use, manufacture, or Commercialisation of the Product for the Permitted Use, ArQule will provide prompt written notice to Basilea that it has generated such ArQule Excluded Know-How and that Basilea has \*\*\* days to respond to such notice, and Basilea will have the right, by providing a written confirmation to ArQule within \*\*\* days of the date of Basilea's receipt of such written notice, to have such additional ArQule Excluded Know-How be included as part of the non-exclusive license grant in Section 2.1(b)(ii).

17.5 Basilea Representations and Warranties. Basilea makes the following representations and warranties as of the Effective Date:

- (a) Basilea is duly organized and validly existing under the laws of Switzerland and has full corporate power and authority to enter into this Agreement and carry out the provisions of this Agreement.
- (b) To Basilea's Knowledge, there is no action, suit, inquiry, investigation or proceeding instituted by any Regulatory Authority or by any other person that could question or threaten the validity of this Agreement.

17.6 Covenants of Basilea. Basilea makes the following covenants, from the Effective Date until the expiration or termination of this Agreement:

- (a) It shall not, subject to Section 20.1, (i) license for Commercialisation of Product in the Excluded Territory, sell, assign or otherwise transfer to any Person any Basilea Patents in the Excluded Territory other than to ArQule pursuant to this Agreement, (ii) incur or permit to exist, with respect to any Basilea Patents, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other binding obligation, in the case of each of (i) and (ii), that is or would be inconsistent with the licenses and other rights granted to ArQule under this Agreement,
- (b) As between ArQule and Basilea, Basilea shall be responsible to reimburse the inventors named in the Basilea Patents;
- (c) Subject to Section 20.1, Basilea will remain the sole owner of the Basilea IP during the Term and will continue to Control the Basilea IP during the Term;

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- (d) During the Term, Basilea will not enter into any agreement with a Third Party which would conflict with or prevent ArQule from enjoying any or all of its rights under this Agreement.
- (e) The AKT-inhibitors listed in Schedule 9 and their pharmaceutically acceptable salts, solvates, hydrates, and prodrugs are the sole property of ArQule and Basilea will not claim any rights to them.
- (f) Basilea shall use the ArQule IP, the ArQule Excluded Territory IP, and the ArQule Partner Excluded Territory IP solely to Research, Develop, register, manufacture, and Commercialise a Product (either as monotherapy or in combination) which has as its primary mode of action \*\*\*. For the avoidance of doubt, such combination shall not be with the AKT-inhibitors listed in Schedule 9.

17.7 Disclaimer. Except as expressly set forth herein, each Party expressly disclaims and excludes any and all representations and warranties, express, implied, statutory or otherwise, including without limitation the warranties of merchantability and fitness for a particular purpose.

#### **ARTICLE 18 INDEMNIFICATION AND LIMITATION OF LIABILITY**

18.1 Indemnification. Each Party shall indemnify, defend and hold harmless the other Party and its respective directors, officers, employees, agents and Affiliates, from and against any and all Losses in connection with any suits, investigations, claims or demands of Third Parties (collectively, “**Third Party Claims**”) to the extent arising out of or resulting from:

- (a) the gross negligence or wrongful intentional acts or omissions of the indemnifying Party or its directors, officers, employees, agents, Affiliates, in connection with the fulfilment of the indemnifying Party’s rights and duties under this Agreement;
- (b) with respect to Basilea as the indemnifying party, the Research, Development, manufacture, or Commercialisation of Products in the Territory by Basilea or any of its Affiliates or its or their Sublicensees or its or their distributors or contractors, or the Research, Development, or manufacture of Products in the Excluded Territory by Basilea or any of its Affiliates or its or their Sublicensees or its or their contractors;
- (c) with respect to ArQule as the indemnifying party, the research, development, manufacture and Commercialisation of Products in the Excluded Territory by ArQule or any of its Affiliates or its or their sublicensees, including the ArQule Partner, or its or their distributors or contractors, or the manufacture or permitted development or research of Products in the Territory by ArQule or any of its Affiliates or its or their sublicensees, including the ArQule Partner, or its or their distributors or contractors;
- (d) any misuse of the other Party’s IP by the indemnifying Party or any misuse of the Product by the indemnifying Party; or
- (e) any material breach of any representation or warranty made by the indemnifying Party.

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Each Party shall have a duty to exert its reasonable efforts to mitigate any Losses, and therefore, in calculating Losses, the duty to use reasonable efforts to mitigate on the part of the Party suffering the Losses shall be taken into account.

- 18.2 Limit of Liability. Subject to Section 18.3, neither Party shall be liable to the other in contract, tort, negligence, breach of statutory duty or otherwise for any loss, damage, costs or expenses of any nature whatsoever incurred or suffered by the other Party or its Affiliates, directors, officers, employees or agents:
- (a) of a direct nature where the same is a loss of turnover, profits, business or goodwill; or
  - (b) an indirect or consequential or punitive nature, including any indirect or consequential economic loss or other indirect or consequential loss of turnover, profits, loss of enterprise value, business or goodwill or otherwise.
- 18.3 The foregoing limitations of liability and indemnity provisions provided in Sections 17.1 and 17.2 shall not apply:
- (a) in cases where damage is caused by gross negligence or willful misconduct of the other Party or that Party's officers, directors, employees, agents and/or Affiliates;
  - (b) in case of liability according to any applicable mandatory law;
  - (c) in the event of the loss of life, physical injury and damage to health; or
  - (d) with respect to Third Party Claims for which a Party is obligated to provide indemnification under Section 18.1.
- 18.4 Nothing in this Agreement shall be taken to exclude or limit either Party's liability to the extent that such liability cannot be excluded or limited in law including for fraud or fraudulent misrepresentation.

**ARTICLE 19            TERM AND TERMINATION**

- 19.1 Term. The Agreement shall enter into force and effect on the Effective Date and shall remain in full force and effect for the period commencing on the Effective Date and ending on the later of
- (a) the last to expire Royalty Term in the Territory; or
  - (b) \*\*\* years after the Effective Date
- (the "**Term**"), unless otherwise earlier terminated as provided in this Agreement.
- 19.2 Expiration of the Agreement. Unless the Agreement is terminated in accordance with this Article 19, the following shall apply:
- (a) for each country in the Territory in which the Product is sold and therefore a Royalty Term applies, the exclusive license granted under Section 2.1(a) and the non-exclusive license granted under Section 2.1(b) in such country shall continue on a perpetual, irrevocable, royalty-free, fully paid up basis country-by-country at the end of the Royalty Term in such country (and for the avoidance of doubt, at the end of the Term) and



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- (b) for any country in the Territory in which the Product is not sold and therefore a Royalty Term does not apply, the exclusive license granted under Section 2.1(a) and the non-exclusive license granted under Section 2.1(b) in such country shall continue on a perpetual, irrevocable, royalty-free, fully paid up basis at the end of the Term.

19.3 Termination At Will or for Change of Control.

- (a) Termination At Will. Basilea shall have the right during the Term to terminate this Agreement on a country-by-country basis or in its entirety:
  - (i) at any time prior to the First Commercial Sale Date of a Product by giving not less than \*\*\* months' prior written notice to ArQule if Basilea determines, in its sole discretion, that it is no longer Commercially Reasonable to Research and Develop the Product; or
  - (ii) at any time after the First Commercial Sale Date of a Product by giving not less than \*\*\* months' prior written notice to ArQule if Basilea determines, in its sole discretion that it is no longer Commercially Reasonable to Commercialise the Product.
- (b) Termination for Change of Control. ArQule shall have the right to terminate this Agreement in whole within \*\*\* days of a Change of Control Event as set forth in Section 20.1(b).

19.4 Termination for Safety Concern or Withdrawal. Upon giving \*\*\* days prior written notice to ArQule, Basilea shall be entitled to terminate this Agreement on a country-by-country basis or in its entirety:

- (a) if Basilea can demonstrate that there are reasonable good faith grounds to believe there is a safety concern related to the Product which Basilea reasonably believes it will not be capable of rectifying, or
- (b) in case of withdrawal of the Regulatory Approval for the Product in a country for whatever reason which Basilea reasonably believes will be permanent.

19.5 Termination for Material Breach. Either Party (the “**Non-Breaching Party**”) shall have the right to terminate this Agreement in whole or in part (on a country-by-country or region-by-region basis) on the occurrence of any material breach by the other Party (the “**Breaching Party**”) which is incapable of remedy or which, in the case of a breach capable of remedy, shall not have been remedied within \*\*\* days of the receipt by the Breaching Party of a written notice from the Non-Breaching Party identifying the breach and requiring its remedy (the “**Cure Period**”).

- (a) The Non-Breaching Party shall indicate in detail in its notice of termination for breach the grounds of such termination and whether it is terminating this Agreement in whole or in part (on a country-by-country or region-by-region basis).
  - (i) The Parties agree that a material breach that has a material impact that is limited to a single country, group of countries or region shall only provide the basis for termination of this Agreement with respect to the single country, group of countries, or region so impacted. Without limiting the foregoing, if the alleged material breach by Basilea is that it has failed to use Commercially Reasonable Efforts to Develop or Commercialize a Product in a particular country, group of countries or region in the Territory under Sections 3.3, 5.5 and/or 7.2, then ArQule will have the right to terminate this Agreement solely with respect to such country, group of countries or region (and not in its entirety).

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(ii) The Parties agree that only a significant material breach shall provide the basis for termination of this Agreement in whole. The Parties also agree that in determining whether a material breach is or is not significant enough to provide the basis for termination of this Agreement in whole, the value of the contributions and investment made by each Party in the discovery, Development and Commercialisation of the Products shall be considered by the trier of fact.

(b) If the Breaching Party in good faith disputes such material breach or disputes the failure to cure or remedy of such material breach during the Cure Period or disputes the significance of the breach and provides written notice of that dispute to the Non-Breaching Party within the above time period, then the matter will be addressed under the dispute resolution provisions in Article 20, and the Non-Breaching Party may not terminate this Agreement until it has been determined under Article 20 that the Breaching Party is in material breach or significant material breach, as the case may be, of this Agreement.

19.6 Termination for Insolvency. If an Insolvency Event occurs in relation to either Party, the other Party may terminate this Agreement immediately on written notice to the Party in relation to which the Insolvency Event has occurred. For the avoidance of doubt, the immediate termination shall be effective at the end of the \*\*\* day period referenced in each of Sections 1.60(a)-(d).

19.7 Termination for Challenge. Except to the extent the following is unenforceable under the Applicable Laws of a particular jurisdiction where a Patent application covered by the license grant of Article 2 is pending or a Patent covered by the license grant of Article 2 has issued, if one Party or any of its Affiliates Challenges the Patents belonging to the other Party and that are covered by the license grant of Article 2, or if such Party or its Affiliates Assists a Third Party in Challenging the Patents belonging to the other Party, then the non-challenging Party shall have the right to terminate this Agreement on \*\*\* days' written notice. With respect to this Section 19.7 only:

(a) “**Assist**” means providing, directly or indirectly, a Third Party with (a) any analysis of any of Patents or any portion thereof; (b) prior art or analysis of any prior art to any of the Patents; or (c) financial or technical or other support in connection with a Challenge of any of the Patents or any portion thereof; and

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- (b) “**Challenge**” means to contest or Assist in the contesting of the validity or enforceability of any of the Patents, in whole or in part, in any court, arbitration proceeding or other tribunal, including the United States Patent and Trademark Office and the United States International Trade Commission. For the avoidance of doubt, the term “contest” includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any Patents; (b) citation to the United States Patent and Trademark Office pursuant to 35 U.S.C. § 301 of prior art patents or printed publications or statements of the patent owner concerning the scope of any of the Patents; (c) filing a request under 35 U.S.C. § 302 for re-examination of any of the Patents; (d) filing, or joining in, a petition under 35 U.S.C. § 311 to institute inter partes review of any Patents or any portion thereof; (e) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of the Patents or any portion thereof; (f) provoking or becoming a party to an interference with an application for any of the Patents pursuant to 35 U.S.C. § 135; (g) filing or commencing any re-examination, opposition, cancellation, nullity or similar proceedings against any of the Patents in any country; or (h) any foreign equivalents of subsection (a) through (g) applicable in the Territory.

19.8 Effect of Termination.

- (a) ArQule Termination Pursuant to Sections 19.5 (Basilea breach), 19.6 (Basilea Insolvency), or 19.7 (Basilea Challenge to ArQule IP) or Basilea Termination Pursuant to 19.3(a) (at will) or 19.4 (Safety Concern or Withdrawal): Termination of this Agreement by ArQule pursuant to Sections 19.5 (Basilea breach) or 19.6 (Basilea insolvency) or 19.7 (Basilea Challenge to ArQule IP) or by Basilea pursuant to Section 19.3(a) (at will) or 19.4 (Safety Concern or Withdrawal) shall result in the following:
- (i) The grant to ArQule by Basilea of a royalty-bearing, non-exclusive, sub-licensable license to Basilea IP necessary for the Research, Development, use, import, export, distribution, sale, manufacture, marketing and Commercialisation of the Product. The Parties shall enter into good faith discussions regarding the terms for such license. If the Parties are unable, despite such good faith discussions, to reach agreement on the terms for such license within \*\*\* days of the termination notice, then the Parties shall refer the question of the value of such license to an independent valuation expert (agreed by the Parties in advance of such expert’s review of the matter) who shall conduct a timely review of the matter (in no event lasting longer than \*\*\* days) and the Parties agree to be bound by the decision of such expert as to the value of the license.
  - (ii) If such breach is applicable to the entire Territory and the termination is therefore for the entire Territory, then the license shall be worldwide.
  - (iii) If such breach is applicable only in relation to a country or group of countries, and the termination is therefore only in relation to a country or group of countries only in relation to a country or group of countries, then the license shall be only in relation to that same country or group of countries.

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- (b) Basilea Termination Pursuant to Sections 19.5 (ArQule breach) or 19.7 (ArQule Challenge of Basilea IP), or ArQule Termination Pursuant to Section 19.3(b) (Termination for Change of Control): In the event this Agreement is terminated (in whole or with respect to a country or group of countries) by Basilea pursuant to Section 19.5 for ArQule's material breach of this Agreement or by Basilea pursuant to Section 19.7 for Termination for Challenge, Basilea shall have the right, by providing written notice to ArQule on or before the effective date of termination, to have the exclusive license granted to Basilea under Section 2.1(a) and the non-exclusive license granted to Basilea under Section 2.1(b) continue, subject to Basilea's payment of all milestone and royalty payments due and payable to ArQule in accordance with Article 14 of this Agreement; provided that, (i) on and after the date of such written notice by Basilea, all such milestone and royalty payments shall be reduced by \*\*\* and (ii) solely to the extent that this Agreement is terminated by Basilea pursuant to Section 19.5 for ArQule's material breach of Section 2.1(a) or Section 3.6 or is terminated by Basilea pursuant to Section 19.7, all such milestone and royalty payments shall be reduced to \*\*\*. For the avoidance of doubt, if such breach is applicable in the entire Territory and the termination is therefore for the entire Territory, then the license shall be for the entire Territory (and the Excluded Territory); if such breach is applicable only in relation to a country or group of countries, and the termination is therefore only in relation to a country or group of countries only in relation to a country or group of countries, then the license shall be only in relation to that same country or group of countries.
- (c) General Effect of Termination. Except for termination pursuant to Section 19.5 (ArQule breach) or Section 19.7 (in which Basilea opts for a continuing license pursuant to Section 19.8(b)), the expiration or termination of this Agreement (including on a country-by-country basis), for whatever reason and regardless of the Party terminating shall result in the following (for the avoidance of doubt, if the termination is in relation to a country or group of countries, the following shall only apply in such country or group of countries):
- (i) All licenses granted by ArQule to Basilea under this Agreement shall terminate and, subject to completion of its obligations in this Section 19.8(c), Basilea shall cease all use of the ArQule IP and shall cease all Development, manufacturing and Commercialisation of all Products.
  - (ii) In order to ensure an orderly transition of operational activities to ArQule from Basilea, the Parties shall prepare and agree a transition plan as soon as practically possible, and no later than \*\*\* days of the termination notice, which sets forth the operational details of the transfer and assignment of information between the Parties.
  - (iii) Commensurate with Applicable Law, Basilea shall as soon as practicably possible after termination transfer to ArQule all right, title and interest in all relevant Regulatory Approvals including all applications for Regulatory Approvals held by Basilea for the Product ("**Product Registrations**"), and Basilea shall execute all necessary and appropriate letters to the Regulatory Authorities in the Territory to ensure that ownership of the Product Registrations (or applications therefore) are transferred to ArQule within \*\*\* days of termination. In the event that such a transfer is not possible under Applicable Law, Basilea shall use reasonable efforts to ensure that ArQule has the benefit of the relevant Product Registrations and, to this end, consents to any Regulatory Authority in the Territory cross-referencing to the data and information on file with any Regulatory Authority as may be necessary to facilitate the granting of second Product Registrations to ArQule in the Territory. In such circumstance, as soon as the second Product Registrations are given to ArQule, ArQule will, so far as possible under Applicable Law, cancel the corresponding first Product Registration.

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- (iv) Unless expressly prohibited by any Regulatory Authority, Basilea shall, and shall cause its Affiliates and its and their Sublicensees to: (i) transfer control to ArQule of any or all Clinical Trials involving Products being conducted by or on behalf of Basilea, an Affiliate or a Sublicensee as of the effective date of termination, if ArQule notifies Basilea of its intent to assume control of ongoing Clinical Trials, or (ii) promptly wind down such Clinical Trials in accordance with Applicable Laws, if ArQule notifies Basilea that it does not intend to assume control of ongoing Clinical Trials. ArQule shall provide its notice under (i) or (ii) within \*\*\* days of the termination.
- (v) Basilea shall, and shall cause its Affiliates and its and their Sublicensees to, provide a list to ArQule of all Product Agreements. “**Product Agreement**” means, with respect to a Product, any agreement entered into by and between Basilea or any of its Affiliates or its or their Sublicensees, on the one hand, and one (1) or more Third Parties, on the other hand, during the Term that is necessary or reasonably useful for the Development, manufacture or Commercialisation of such Product in the Field in the Territory, including (a) any agreement pursuant to which Basilea, its Affiliates or its or their Sublicensees receives any license or other rights to Develop, manufacture or Commercialise such Product, (b) supply agreements pursuant to which Basilea, its Affiliates or its or their Sublicensees obtain or will obtain quantities of such Product, (c) clinical trial agreements, (d) contract research organization agreements and (e) service agreements. Basilea shall thereafter assign to ArQule any Product Agreement requested in writing by ArQule, unless, with respect to any such Product Agreement, such Product Agreement expressly prohibits such assignment, in which case Basilea (or such Affiliate or Sublicensee, as applicable) shall reasonably co-operate with ArQule to secure the consent of the applicable Third Party to such assignment, or if the counterparty to such Product Agreement does not consent to such assignment.
- (vi) At ArQule' written request, and at ArQule's cost, Basilea shall (i) supply ArQule with such quantities of the Product Materials and Products in Basilea's inventory on the effective date of termination as may be requested by ArQule and (ii) supply to ArQule such additional quantities of the Product Materials and Products as ArQule indicates in written forecasts and orders therefore from time to time; in each case with respect to (i) and (ii) at Basilea's actual, fully-burdened cost (plus \*\*\*) to manufacture such Product Materials and Products until the earlier of: (y) such time as ArQule has established an alternate, validated source of supply for the Product Materials and Products, and ArQule is receiving supply from such alternative source, and (z) the \*\*\* year anniversary of the effective date of termination of this Agreement.

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- 19.9 Survival. Termination of this Agreement shall be without prejudice to any rights that have accrued to the benefit of either Party before such termination, including the right of either Party to receive or recover damages sustained by reason of the breach of this Agreement by the other party. In addition, the following provisions of this Agreement shall survive termination or expiration of this Agreement: Article 1 (all relevant definitions and interpretations); Section 2.6; Section 5.8; Section 10.3(b); Section 15.1; Sections 16,1-16.4; Section 17.6(e); Article 18; Section 19.8(c); Section 19.9; Article 21; Section 22.2; Section 22.7; and Section 22.11. As well as the forenamed sections, the following shall survive as specified:
- (a) In the event of termination pursuant to Section 19.8(a)(i) pursuant to which ArQule is granted a royalty-bearing, non-exclusive, sub-licensable license to the Basilea IP: Section 2.2; Section 14.7; Section 17.6(a); and Section 19.8(a) shall survive.
  - (b) In the event of termination pursuant to Section 19.8(b) pursuant to which Basilea may opt for a continuation of the exclusive license granted to Basilea under Section 2.1(a) and the non-exclusive license granted to Basilea under Section 2.1(b): Section 2.1; Section 2.4; Section 2.5; Section 7.3; Section 14.2; Section 14.3; Section 14.5; Section 14.6; Section 14.7; Section 14.8; Section 17.4(a); Section 17.4(f); and Section 19.8(b) shall survive.
  - (c) In the event of expiration pursuant to Section 19.2: Section 2.1; Section 2.4; Section 2.5; Section 17.4(e); and Section 19.2 shall survive.

**ARTICLE 20 ASSIGNMENT/SUCCESSION**

- 20.1 This Agreement shall not be assignable nor the rights licensed hereunder be transferable in any way by either Party except by prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed, provided, however, that:
- (a) either Party may assign this Agreement in whole or in part to a corporate Affiliate on reasonable prior written notice to the other Party of such assignment on the condition that the assigning Party shall remain liable hereunder for the prompt payment and performance of all obligations of the assignee;
  - (b) this Agreement may be assigned to a Third Party on concurrent written notice to the other Party of such assignment in connection with a sale or transfer of all or substantially all of the transferring Party's business or assets to which this Agreement relates or in connection with a merger or consolidation transaction involving such Third Party ("**Change of Control Event**") provided always that such Third Party gives a written deed of undertaking to the non-affected Party agreeing to abide by all the obligations under this Agreement of the assigning Party.
- 20.2 This Agreement shall be binding upon, and shall inure to the benefit of, all permitted assigns.

**ARTICLE 21 JURISDICTION AND DISPUTE RESOLUTION**

- 21.1 The interpretation and construction of this Agreement shall be governed by the laws of England excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

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- 21.2 Any dispute, controversy or claim arising out of or relating to this Agreement or the alleged breach, termination or invalidity of this Agreement shall be submitted in the first instance to appropriate management such as the Chief Executive Officer of ArQule or such person's designee of equivalent or superior position and to the Chief Executive Officer of Basilea or such person's designee of equivalent or superior position, who shall both use best efforts to meet in person to discuss the same within twenty one (21) days of the receipt by one Party of formal written notice of dispute from the other Party. If the Parties' executives fail to meet, either by telephone, videoconference or in person, to resolve a matter which has been referred to them within such twenty one (21) days or if the meeting between senior executives takes place within such twenty one (21) day period and the senior executives are unable to resolve the dispute, then either Party may refer the dispute to arbitration upon giving written notice to the other and Section 20.3 shall apply.
- 21.3 Disputes not resolved under Section 21.2 shall be referred and finally determined by arbitration with the WIPO Arbitration Rules subject to the following provisions:
- (a) the number of arbitrators shall be three (3), the seat of the arbitration shall be London; the arbitral proceedings shall be conducted in English;
  - (b) the arbitration award shall be final and binding on the Parties and shall not be appealable to any court in any jurisdiction;
  - (c) the award may be entered and enforced in any court having competent jurisdiction; and
  - (d) the fees of the arbitration shall be paid as directed by the arbitral tribunal.
- 21.4 Notwithstanding the foregoing, either Party may seek immediate injunctive or other interim relief from any court of competent jurisdiction with respect to any matter for which monetary damages would not adequately protect such Party's interests or otherwise to enforce and protect any Intellectual Property owned, Controlled or licensed to such Party.
- 21.5 Any dispute concerning the ownership or inventorship of any Patent Rights arising hereunder in a given jurisdiction shall be determined in accordance with the law of the jurisdiction where the inventive contribution was made. For the avoidance of doubt, the outcome of any such dispute shall not affect the licenses granted to Basilea under this Agreement.

**ARTICLE 22 MISCELLANEOUS**

- 22.1 Force Majeure. Neither Party shall be responsible for any delay or failure to perform its obligations under this Agreement or shall be liable to the other for loss or damages for any default or delay caused by conditions beyond its reasonable control, including but not limited to, acts of God, governmental restrictions, declared or not declared wars or insurrections, strikes, terrorism, floods, work stoppages. If either Party is so affected it shall give prompt written notice of such cause to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform. Subject to the foregoing, the Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled.

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22.2 Notices.

- (a) Any notice (which term shall in this Section include any other formal written communication) required to be given under this Agreement or in connection with the matters contemplated by it shall, except where otherwise specifically provided, be in writing in the English language.
- (b) Any such notice shall be addressed as provided in Section 22.2(c) and may be:
  - (i) Delivered by courier, in which case it shall be deemed to have been given upon delivery at the relevant address if it is delivered not later than 17.00 hours on a business day, or, if it is delivered later than 17.00 hours on a business day or at any time on a day which is not a Business Day, at 08.00 hours on the next Business Day; or
  - (ii) sent by electronic mail, in which case it shall be deemed to be given when the E-mail leaves the E-mail gateway of the sender where it leaves such gateway before 17.00 hours on any business day or in any other case at 08.00 hours on the next Business Day after it leaves such gateway and the onus shall be on the sender to prove the time that the E-mail left its gateway.
- (c) The addresses and other details of the Parties for notices are:

If to ArQule, addressed to:

ArQule, Inc.  
One Wall Street  
Burlington, MA 01803  
Attention: General Counsel  
Tel: 781-994-0300  
Fax: 781-376-6019

with a copy (which shall not constitute notice) to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.  
One Financial Center  
Boston, MA 02111  
Attention: John Cheney, Esq.  
Tel: 617-542-6000  
Fax: 617-542-2241

If to Basilea, addressed to:

Basilea Pharmaceutica International Ltd  
Grenzacherstrasse 487, CH-4058,  
Basel, Switzerland  
Attention: Chief Medical Officer



Licence Agreement/ArQule, Inc.

with a copy to:

Basilea Pharmaceutica International Ltd  
Grenzacherstrasse 487, CH-4058,  
Basel, Switzerland  
Attention: Legal Department

- (d) Any Party to this Agreement may notify the other Party of any change to the address or any of the other details specified in Section 22.2(c), provided that such notification shall only be effective on the date specified in such notice or five (5) Business Days after the notice is given, whichever is later.

- 22.3 No Other Rights. Except as otherwise expressly provided in this Agreement, no other right, express or implied, is granted by this Agreement.
- 22.4 Further Actions. Each party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 22.5 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer or director of each party.
- 22.6 Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of any party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer or director of the waiving party.
- 22.7 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement.
- 22.8 Independent Contractors. The relationship between ArQule and Basilea created by this Agreement is one of independent contractors and neither party shall have the power or authority to bind or obligate the other. There is no employee-employer relationship or partnership relationship between ArQule and Basilea or any of its representatives.
- 22.9 Local Law Requirements. Except as otherwise specifically provided herein, each party shall at their own expense in their respective countries, take such steps as may be required to satisfy any laws or requirements with respect to declaring, filing, recording or otherwise rendering this Agreement valid.
- 22.10 Expenses. Each Party shall bear its own expenses and costs incurred in the negotiations leading up to and in preparation of this Agreement and of matters incidental to this Agreement.
- 22.11 Entire Agreement of the Parties. The Agreement (including the Schedules) shall constitute and contain the complete, final and exclusive understanding and agreement of the parties and cancels and supersedes any and all prior negotiations, correspondence, understanding and agreements, whether oral or written, between ArQule and Basilea respecting the subject matter thereof.

Licence Agreement/ArQule, Inc.

- 22.12 Exclusion. The Parties exclude the application of any international statutes on the sales of goods, including the United Nations Convention on International Contracts for the Sales of Goods.
- 22.13 Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in Section 3.6 and Section 3.7 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such sections may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such sections, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other party post a bond or other security as a condition for obtaining any such relief or show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 22.13 is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.
- 22.14 Counterpart. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by PDF format via email such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[Signature Page Follows]

Licence Agreement/ArQule, Inc.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed and delivered as of the date first written above.

**Basilea Pharmaceutica International Ltd.**

/s/ Ron Scott  
By

Name: Ron Scott

Job title: CEO

Place/Date: Basel, April 16, 2018

**Basilea Pharmaceutica International Ltd.**

/s/ Adesh Kaul  
By

Name: Adesh Kaul

Job title: Chief Corporate Development Officer

Place/Date: Basel, April 16, 2018

**ArQule, Inc.**

/s/ Peter S. Lawrence  
By

Name: Peter S. Lawrence

Job title: President and COO

Place/Date: 4/16/2018





Licence Agreement/ArQule, Inc.

**SCHEDULE 2 - INITIAL DEVELOPMENT PLAN**

**The following are the major development activities for the Product:**

- 1) Clinical development in iCCA
  - a. Completion of the \*\*\*
  - b. Initiation of a \*\*\*
  - c. Continuation of the \*\*\*

- 2) \*\*\*  
Initiation of a \*\*\*

**Clinical Pharmacology Studies**

- a. Conduct of approximately \*\*\* new clinical pharmacology studies (the “**Clinical Pharmacology Studies**”); approximately \*\*\* subjects/patients in total
- b. Only if requested by regulatory authorities: \*\*\*

For the avoidance of doubt, items 1(a) and (c) contain activities which are in part ArQule Development Activities and which will therefore be undertaken by ArQule pursuant to Section 5.1.



Licence Agreement/ArQule, Inc.

**Royalties**

***	Net Sales of up to and including USD *** in the relevant Calendar Year	***
	Net Sales exceeding USD *** US Dollars) up to and including USD *** US Dollars) in the relevant Calendar Year	***
	Net Sales exceeding USD *** US Dollars) up to and including USD *** US Dollars) in the relevant Calendar Year	***
	Net Sales exceeding USD *** US Dollars) in the relevant Calendar Year	***
***	Net Sales of up to and including USD *** US Dollars) in the relevant Calendar Year	***
	Net Sales exceeding USD *** US Dollars) up to and including USD *** US Dollars) in the relevant Calendar Year	***
	Net Sales exceeding USD *** US Dollars) up to and including USD *** US Dollars) in the relevant Calendar Year	***
	Net Sales exceeding USD *** US Dollars) in the relevant Calendar Year	***

The following examples are given for illustrative purposes only:

For example, if the aggregated annual Net Sales of Commercialised Product in the Territory in a Calendar Year by a \*\*\* are USD \*\*\*, Basilea will make a royalty payment to ArQule of USD \*\*\* US Dollars) (\*\*\*) on USD \*\*\* in Net Sales, plus \*\*\* on USD \*\*\* in Net Sales plus \*\*\* on USD \*\*\* in Net Sales plus \*\*\* on USD \*\*\* in Net Sales).

For example, if the aggregated annual Net Sales (\*\*\*) of Commercialised Product in the Territory in a Calendar Year by Basilea are USD \*\*\*, Basilea will make a royalty payment to ArQule of USD \*\*\* US Dollars) (\*\*\*) on USD \*\*\* in Net Sales, plus \*\*\* on USD \*\*\* in Net Sales plus \*\*\* on USD \*\*\* in Net Sales plus \*\*\* on USD \*\*\* in Net Sales).



Licence Agreement/ArQule, Inc.

**SCHEDULE 4 - ARQULE DEVELOPMENT ACTIVITIES**

The ArQule Development Activities are the continuation of the ongoing clinical development in \*\*\*, including:

- a. Completion of the \*\*\*; and
- b. Continue to conduct the \*\*\*.

The specific activities which make up the ArQule Development Activities, and the estimates<sup>1</sup> for the related Third Party costs therefore, are provided in the following Schedules 4A, 4B, 4C, and 4D. Schedule 4E provides the FTE amounts.

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<sup>1</sup> ArQule's estimates in this Schedule 4 cover \*\*\*. Pursuant to Section 5.1, Basilea shall bear the costs of the ArQule Development Activities from the Effective Date until such activities are completed or transferred to Basilea.

Licence Agreement/ArQule, Inc.

**SCHEDULE 4A - \*\*\* AND CDX**

<u>Activity</u>	<u>Description of Activity / Major Tasks/Deliverables</u>	<u>Estimated Costs (USD mio)</u>	<u>Contractor</u>
<b>*** &amp; CDx</b>			
Central safety labs	Central safety labs ***. Storage of Tissue and PK samples and forwarded to third party labs for testing. Provision of all lab kits and shipping fees for kits and samples.	***	***
PK analysis	PK analysis and PK report***	***	***
Drug depot	Drug storage and distribution to the sites.	***	***
CRO	including Project Management, Medical Monitoring, Regulatory, Monitoring, Data Management, Stats, DMC management and site fees	***	***
Misc	Misc vendors paid directly by Arqule - ***, ***, KOL support, EU Legal rep, couriers, professional meetings & publications, USAN filings, and other as appropriate	***	***
EDC	Development of eCRFs. Coding. Hosting EDC database.	***	***
Pharmacovigilance	Host safety database, receive all SAE reports from sites and draft all SAE narratives.	***	***
Central Imaging Lab	Train/approve each site for imaging. Receive imaging scans from sites. Perform blinded imaging review (primary endpoint data)	***	***
IRT	Manage drug supply to sites. Use the IRT system also to control release of initial dose to each subject as medical monitor must pre-approve each subject in IRT. IRT also integrates with EDC and creates each new subject's initial casebook and releases eCRFs for data entry as each visit is actually performed.	***	***
Biomarker	Biomarker development and validation	***	***
Biomarker	Biomarker clinical testing (actual testing of tissue samples received from sites to confirm if *** is present)	***	***
Biomarker	Test kits, support, regulatory filings	***	***
<b>Total</b>		<b>***</b>	<b>***</b>

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**SCHEDULE 4B – \*\*\***

<b>Activity</b>	<b>Description of Activity / Major Tasks/Deliverables</b>	<b>Estimated Costs (USD mio)</b>	<b>Contractor</b>
***			
EDC	Coding, Hosting EDC database	***	***
Statistical analysis	Statistical analysis	***	***
CRO	CRO Project Management, Regulatory, Monitoring, Data Management	***	***
Report Writing	Report Writing CSR, Publication	***	***
<b>Total</b>		<b>***</b>	

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**SCHEDULE 4C - \*\*\*: CMC**

<u>Activity</u>	<u>Description of Activity / Major Tasks/Deliverables</u>	<u>Estimated Costs (USD mio)</u>	<u>Contractor</u>
<b>CMC</b>			
Stability API	***	***	***
Stability multi DP batches	***	***	***
Method evaluation and validation	Project Plan #130-ARQ 087 Disso Mtd Eval and PIII Validation. ***	***	***
Scale up	***	***	***
GMP manufacture	MCS PP# 139 GMP manufacture, packaging and release of ARQ 087, 100 mg Capsules, *** Capsules	***	***
Reference markers	ARQ 087, PP#58, Reference markers certification	***	***
API batch	*** API registration batch#2 and stability	***	***
CTM MFG	CTM MFG (incl. pkg/label, rel. test), PhIII, 100 mg capsules	***	***
Stability	Stability Testing drug product clinical batches-PROJECTED	***	***
API batch	~*** API registration batch#3 (including RSM cost) and stability	***	***
CTM 3 registration batches	CTM 3 registration batches, 100 mg capsules and stability	***	***
<b>Total</b>		***	

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**SCHEDULE 4D - \*\*\*: CMC API, CTM & INVENTORY**

<u>Activity</u>	<u>Description of Activity / Major Tasks/Deliverables</u>	<u>Estimated Costs (USD mio)</u>	<u>Contractor</u>
<b>CMC API, CTM Inventory</b>			
<i>Registration Batch #1</i>	*** API available for Drug Product manufacturing	<i>Information provided in following 7 lines</i>	
API production costs	Reg. Starting Material 1 (***)- Reg batch #1	***	***
API production costs	Reg. Starting Material 2 (***)- Reg batch #1	***	***
API production costs	***- Reg batch #1	***	***
API production costs	Starting material (***)- Reg batch #1	***	***
API production costs	cGMP Manufacturing- Reg batch #1	***	***
API production costs	cGMP Manufacturing CO- Reg batch #1	***	***
API production costs	cGMP Micronization- Reg batch #1	***	***
API registration batch#2	Reg. Starting Material 1 (***) - Reg batch #2	***	***
Starting materials on order		***	***
API registration batch#2	Reg. Starting Material 2 (***) - Reg batch #2	***	***
Starting materials on order		***	***
API registration batch#2	***- Reg batch #2	***	***
Starting materials on order		***	***
API registration batch#2	Starting material (***) estimated- Reg batch #2	***	***
Starting materials on order		***	***
Inventory as of March 2018	Drug Product, ARQ 087 100 mg capsules	***	***
<b>Total</b>		<b>***</b>	

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**SCHEDULE 4E - FTES**

**Description**

<b><i>Clinical/product development</i></b>	
Project manager	***
Program management	***
Medical monitor	***
Safety monitor	***
Clinical management	***
Documentation support	***
Admin support	***
Drug supply manager	***
Finance/contract support	***
Finance/contract management	***
Statistician	***
Regulatory manager	***
<b>TOTAL Clinical/product development</b>	<b>***</b>
<b><i>CMC</i></b>	
CMC director	***
CMC manager 1	***
CMC manager 2	***
<b>TOTAL CMC</b>	<b>***</b>
<b>Biomarker &amp; Clinical Pharmacology</b>	<b>***</b>
<b>TOTAL FTES</b>	<b>***</b>

FTE rate: \*\*\* per annum. One (1) FTE is the equivalent of one person working for a twelve (12) month period based on an average of \*\*\* working days per month.

The total FTE payments made by Basilea for a month with \*\*\* working days will be USD \*\*\*. The total FTE payments made by Basilea for a month with \*\*\* working days will be USD \*\*\*.



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**SCHEDULE 6 – NAMED OFFICERS**

**ArQule**

Peter Lawrence

Paolo Pucci

Brian Schwatz

Robert Weiskopf

Manish Tandon

Erika Volckova

Ron Savage

**Basilea**

Ron Scott

Marc Engelhardt

Guenter Ditzinger

Adesh Kaul

Laurenz Kellenberger

Donato Spota

David Veitch



Licence Agreement/ArQule, Inc.

**SCHEDULE 7 – FORM OF PRESS RELEASES**

**Contact:**

Paolo Pucci  
Chief Executive Officer (781) 994-0300  
www.ArQule.com

**ArQule and Basilea Enter into Exclusive License Agreement for Derazantinib in the US,  
EU, Japan and Rest of World excluding Greater China**  
*ArQule eligible to receive up to \$336 million including upfront, regulatory and commercial milestone  
payments*  
*ArQule to host investor conference call on April [], 2018 at 9:00 A.M. ET*

**BURLINGTON, Mass. April [], 2018** –ArQule, Inc. (NASDAQ: ARQL) today announced that it has entered into an exclusive license agreement with Basilea Pharmaceutica International Limited (Basilea, SIX: BSLN) to develop and commercialize derazantinib, a pan-FGFR (fibroblast growth factor receptor) inhibitor in the US, EU, Japan and rest of the world excluding the People’s Republic of China, Hong Kong, Macao and Taiwan, where Sinovant Sciences Ltd., a Roivant Sciences Ltd. subsidiary, has rights to develop and exclusively commercialize the drug.

Under the terms of the agreement, ArQule will receive an upfront payment of \$10 million and is eligible for up to \$326 million in regulatory and commercial milestones. ArQule is also entitled to receive staggered single-digit to double-digit royalties on net sales upon commercialization. Under certain circumstances, ArQule may have the opportunity to promote derazantinib in the US directly. Basilea will be responsible for all costs and expenses of development, manufacture and commercialization in its territory.

ArQule is currently conducting a registrational trial for derazantinib in the United States, Canada and Europe as a potential treatment for intrahepatic cholangiocarcinoma (iCCA), a form of biliary tract cancer. As part of the exclusive license agreement, Basilea intends to continue this trial and the further development of derazantinib in iCCA and other tumor types with FGFR dysregulation.

Ronald Scott, Chief Executive Officer, said: “We are very excited about this partnership with ArQule. Derazantinib is an ideal match for our existing clinical oncology portfolio. It is a targeted therapy building on a solid biomarker approach in an area where patients currently have limited treatment options. This transaction underscores our continued commitment to expand our R&D portfolio with novel compounds focused on overcoming the clinical problem of resistance in oncology and infectious diseases. Our clinical oncology portfolio now includes three drug candidates in different stages of development. We continue to focus on further broadening our R&D portfolio through internal and external innovation.”

“Partnering with Basilea, a company with global drug development experience and expertise, will propel the advancement of derazantinib in ways we could not have achieved independently,” said Paolo Pucci, chief executive officer of ArQule. “Basilea will bring a wealth of skills to the expansion of the derazantinib development plan at a time when it will benefit most from these resources, allowing it to reach its full potential in iCCA and beyond.”

ArQule will hold a conference call to discuss this agreement tomorrow, April [], beginning at 9 a.m. EDT. Paolo Pucci, chief executive officer of ArQule, will lead the call. As a result of entering into the exclusive license agreement, ArQule will be updating its financial guidance on the call.

Licence Agreement/ArQule, Inc.

The details of the call are as follows:

**April 11, 2018 @ 9 AM EDT**

Audio connection numbers:

US: 1 877-868-1831

Outside US: 1 914-495-8595 PIN: 4089669

A replay of the call will be available two hours after the completion of the call and can be accessed in the “Investors and Media” section of our website, [www.arqule.com](http://www.arqule.com), under “Events and Presentations.” The ArQule investor conference call will be archived and can be accessed in the “Investors and Media” section of ArQule’s website, [www.arqule.com](http://www.arqule.com), under “Events and Presentations.”

#### **About Derazantinib**

Derazantinib is a potent, orally administered inhibitor of the fibroblast growth factor receptor (FGFR) family, a key driver of cell proliferation, differentiation, and migration. In a Phase 1/2 study in patients with iCCA harboring FGFR2 gene fusions, treatment with derazantinib resulted in an objective response rate of 21%, nearly 3 times higher than standard-of-care chemotherapy. ArQule is currently conducting a registrational study with derazantinib in patients with FGFR2 fusion-positive second-line iCCA. The open-label single-arm trial is recruiting in both the United States and Europe with objective response rate as the primary endpoint. More information on that program is available [here](#).

#### **About Intrahepatic Cholangiocarcinoma**

Cholangiocarcinoma (CCA) is the most common biliary malignancy and the second most common hepatic malignancy after hepatocellular carcinoma (HCC).<sup>1</sup> Depending on the anatomic location, CCA is classified as intrahepatic (iCCA), perihilar (pCCA), and extrahepatic (eCCA). iCCA originates from the intrahepatic biliary ductal system and forms an intrahepatic mass. iCCA is an aggressive cancer, with a median 5-year survival rate of 15% for patients diagnosed with early-stage disease.<sup>2</sup> In China, the incidence of cholangiocarcinoma is more than 7 cases per 100,000 people, and the majority of cases are intrahepatic.<sup>3</sup>

#### **About ArQule**

ArQule is a biopharmaceutical company engaged in the research and development of targeted therapeutics to treat cancers and rare diseases. ArQule's 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. Our clinical-stage pipeline consists of five drug candidates, all of which are in targeted, biomarker-defined patient populations, making ArQule a leader among companies our size in precision medicine. ArQule's proprietary pipeline includes: Derazantinib, a multi-kinase inhibitor designed to preferentially inhibit the fibroblast growth factor receptor (FGFR) family, in a registrational trial for iCCA and in phase 1b for multiple oncology indications; Miransertib (ARQ 092), a selective inhibitor of the AKT serine/threonine kinase, in a phase 1/2 company sponsored study for Overgrowth Diseases, in a phase 1 study for ultra-rare Proteus syndrome conducted by the National Institutes of Health (NIH), as well as in multiple oncology indications; ARQ 751, a next generation AKT inhibitor, in phase 1 for patients with AKT1 and PI3K mutations; and ARQ 761, a  $\beta$ -lapachone analog being evaluated as a promoter of NQO1-mediated programmed cancer cell necrosis, in phase 1/2 in multiple oncology indications in partnership with the University of Texas Southwestern Medical Center. In addition, we have advanced ARQ 531, an investigational, orally bioavailable, potent and reversible inhibitor of both wild type and C481S-mutant BTK, in phase 1 for patients with B-cell malignancies refractory to other therapeutic options. ArQule's current discovery efforts are focused on the identification and development of novel kinase inhibitors, leveraging the Company's proprietary library of compounds. You can follow us on Twitter and LinkedIn.

Licence Agreement/ArQule, Inc.

#### **About Basilea**

Basilea Pharmaceutica Ltd. is a commercial stage biopharmaceutical company developing products that address the medical challenge of increasing resistance and non-response to current treatment options in the therapeutic areas of bacterial infections, fungal infections and cancer. With two commercialized drugs, the company is committed to discovering, developing and commercializing innovative pharmaceutical products to meet the medical needs of patients with serious and life-threatening conditions. Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Additional information can be found at Basilea's website [www.basilea.com](http://www.basilea.com).

#### *Forward Looking Statements*

*This press release contains forward-looking statements regarding the Company's clinical trials with derazantinib as well as the potential for future milestone and royalty payments under its License Agreement with Basilea. These statements are based on the Company's current beliefs and expectations, and are subject to risks and uncertainties that could cause actual results to differ materially. Positive information about pre-clinical and early stage clinical trial results does not ensure that later stage or larger scale clinical trials will be successful. For example, derazantinib may not demonstrate promising therapeutic effect. In addition, derazantinib may not demonstrate an acceptable safety profile in current or later stage or larger scale clinical trials as a result of known or as yet unanticipated side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards or to justify further development. Problems or delays may arise during clinical trials or in the course of developing, testing or manufacturing derazantinib that could lead the Company or Basilea to discontinue its development. Even if later stage clinical trials are successful, unexpected concerns may arise from subsequent analysis of data or from additional data. Obstacles may arise or issues may be identified in connection with review of clinical data with regulatory authorities. Regulatory authorities may disagree with the Company's or Basilea's view of the data or require additional data or information or additional studies. In addition, we plan to develop and use a companion diagnostic to identify patients with FGFR2 fusions and possibly other fusions for our future derazantinib clinical trials. We intend to outsource the development of such companion diagnostics to one or more third party collaborators. Such collaborators may encounter difficulties in developing and obtaining approval for such companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, concordance or clinical validation. Any delay or failure to develop or obtain regulatory approval of such companion diagnostics could delay or prevent approval of derazantinib. Moreover, Basilea has only a limited track record of drug development in oncology. If derazantinib is not successfully developed and as a result of any of the foregoing or other issues, risks or uncertainties, ArQule may not receive any future milestones or royalties under the License Agreement with Basilea. Drug development involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Furthermore, ArQule may not have the financial or human resources to successfully pursue drug discovery in the future. For more detailed information on the risks and uncertainties associated with the Company's drug development and other activities, see the Company's periodic reports filed with the Securities and Exchange Commission. The Company does not undertake any obligation to publicly update any forward-looking statements.*

<sup>1</sup> Welzel TM, et al. Impact of classification of hilar cholangiocarcinomas (Klatskin tumors) on the incidence of intra- and extrahepatic cholangiocarcinoma in the United States. *Journal of the National Cancer Institute* 2006; 98(12), 873-875.

<sup>2</sup> American Cancer Society

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<sup>3</sup> Banales JM, et al. Cholangiocarcinoma: current knowledge and future perspectives consensus statement from the European Network for the Study of Cholangiocarcinoma (ENS-CCA). *Nature Reviews: Gastroenterology & Hepatology* 2016; 13, 261-280.

Related links  
www.arqule.com  
SOURCE ArQule, Inc.

## **PRESS RELEASE**

### **Basilea licenses late-stage oncology drug candidate derazantinib from ArQule**

**Basel, Switzerland, MONTH DD, 2018** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that it has entered into a license agreement with ArQule, Inc. (NASDAQ: ARQL) for its oncology drug candidate ARQ087 (derazantinib), which targets the fibroblast growth factor receptor (FGFR) family of kinases. The exclusive license is worldwide, excluding the People’s Republic of China, Hong Kong, Macau and Taiwan.

Ronald Scott, Chief Executive Officer, said: “We are very excited about this partnership with ArQule. Derazantinib is an ideal match for our existing clinical oncology portfolio. It is a targeted therapy building on a solid biomarker approach in an area where patients currently have limited treatment options. This transaction underscores our continued commitment to expand our R&D portfolio with novel compounds focused on overcoming the clinical problem of resistance in oncology and infectious diseases. Our clinical oncology portfolio now includes three drug candidates in different stages of development. We continue to focus on further broadening our R&D portfolio through internal and external innovation.”

Derazantinib is an orally administered small-molecule inhibitor of the FGFR family of kinases and was developed by ArQule for the potential treatment of various solid tumors. It is currently in a clinical study for intrahepatic cholangiocarcinoma (iCCA), a form of biliary tract cancer for a potential registration. In addition, it is being investigated in a phase 1b study in patients with other solid tumors. FGFR alterations have been identified as potentially important therapeutic targets for various cancers, including iCCA, bladder, breast, gastric and lung cancers.<sup>1</sup> Current scientific literature suggests FGFR alterations exist in a range of 5% to 30% in these cancers.<sup>2</sup>

Under the terms of the agreement, ArQule grants Basilea rights to research, develop, manufacture and exclusively commercialize derazantinib worldwide, excluding the People’s Republic of China, Taiwan, Hong Kong and Macau. Basilea will make an upfront payment to ArQule of USD 10 million. ArQule is eligible to regulatory and sales milestone payments of up to USD 326 million upon reaching certain clinical, regulatory and commercial milestones as well as staggered single to double-digit royalties on sales upon commercialization.

About derazantinib (ARQ 087)

Derazantinib (ARQ 087) is an investigational, oral, multi-kinase inhibitor designed to preferentially inhibit the FGFR family of kinases, a key driver of cell proliferation, differentiation and migration. The drug has demonstrated favorable clinical data in a biomarker-driven Phase 1/2 study in iCCA patients. Both the FDA and EMA have granted ArQule orphan drug designation for this disease.

Licence Agreement/ArQule, Inc.

#### About ArQule

ArQule (NASDAQ: ARQL) is a biopharmaceutical company engaged in the research and development of targeted therapeutics to treat cancers and rare diseases. ArQule's 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 patients. Its clinical-stage pipeline consists of five drug candidates, all of which are in targeted, biomarker-defined patient populations, making ArQule a leading company in precision medicine. The company is based in Burlington, Massachusetts, USA. Additional information can be found at ArQule's website [www.arqule.com](http://www.arqule.com).

#### About Basilea

Basilea Pharmaceutica Ltd. is a commercial stage biopharmaceutical company developing products that address the medical challenge of increasing resistance and non-response to current treatment options in the therapeutic areas of bacterial infections, fungal infections and cancer. With two commercialized drugs, the company is committed to discovering, developing and commercializing innovative pharmaceutical products to meet the medical needs of patients with serious and life-threatening conditions. Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Additional information can be found at Basilea's website [www.basilea.com](http://www.basilea.com).

#### Disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Basilea Pharmaceutica Ltd. and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd. to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd. is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

For further information, please contact:

Peer Nils Schröder, PhD  
Head of Corporate Communications & Investor Relations  
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[media\\_relations@basilea.com](mailto:media_relations@basilea.com)  
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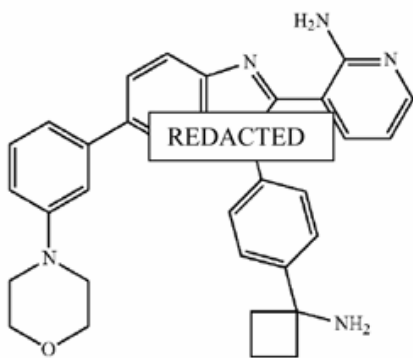
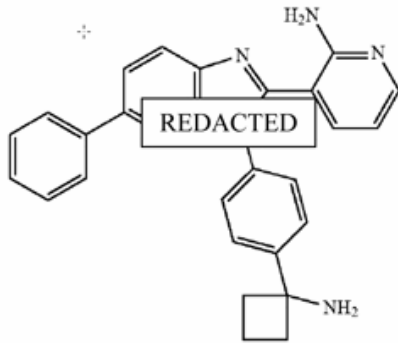
#### References

- 1 R. Porta, R. Borea, A. Coelho et al. FGFR a promising druggable target in cancer: Molecular biology and new drugs. *Critical Reviews in Oncology/Hematology* 2017 (113), 256-267
- 2 T. Helsten, S. Elkin, E. Arthur et al. The FGFR landscape in cancer: Analysis of 4,853 tumors by next-generation sequencing. *Clinical Cancer Research* 2016 (22), 259-267

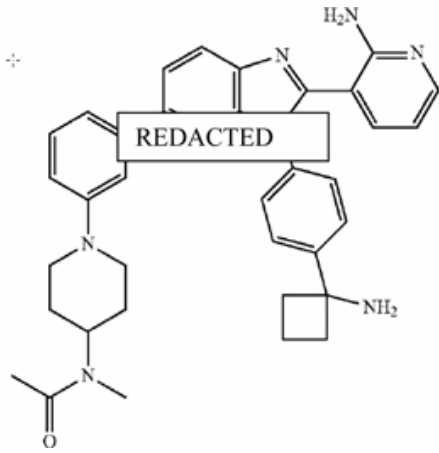


Licence Agreement/ArQule, Inc.

SCHEDULE 9 – ARQULE EXCLUDED IP - AKT INHIBITORS



Licence Agreement/ArQule, Inc.





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 1, 2018

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

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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 1, 2018

/s/ PETER S. LAWRENCE

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

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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, 2018, 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, 2018, 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 1st day of August 2018.

/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)

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