

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 2019**

OR

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

For the transition period from _____ to _____

Commission File Number: **001-38582**

Allakos Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
975 Island Drive, Suite 201
Redwood City, California
(Address of principal executive offices)

45-4798831
(I.R.S. Employer
Identification No.)

94065
(Zip Code)

(650) 597-5002

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 Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001	ALLK	The Nasdaq Global Select Market

As of July 31, 2019, the registrant had 43,185,253 shares of common stock outstanding.

ALLAKOS INC.
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited).

ALLAKOS INC.
BALANCE SHEETS
(in thousands, except per share data)

	June 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,457	\$ 33,660
Investments in marketable securities	116,614	145,246
Prepaid expenses and other current assets	1,270	2,703
Total current assets	154,341	181,609
Property and equipment, net	8,734	8,848
Operating lease right-of-use assets	5,908	—
Other long-term assets	802	802
Total assets	<u>\$ 169,785</u>	<u>\$ 191,259</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,966	\$ 2,092
Accrued expenses and other current liabilities	6,343	3,164
Total current liabilities	9,309	5,256
Other long-term liabilities	8,326	2,009
Total liabilities	17,635	7,265
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 20,000 shares authorized as of June 30, 2019 and December 31, 2018; no shares issued and outstanding as of June 30, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value per share; 200,000 shares authorized as of June 30, 2019 and December 31, 2018; 43,184 and 42,117 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	43	42
Additional paid-in capital	295,130	288,079
Accumulated other comprehensive gain (loss)	114	(15)
Accumulated deficit	(143,137)	(104,112)
Total stockholders' equity	<u>152,150</u>	<u>183,994</u>
Total liabilities and stockholders' equity	<u>\$ 169,785</u>	<u>\$ 191,259</u>

See accompanying notes to unaudited interim financial statements

ALLAKOS INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	\$ 14,111	\$ 7,149	\$ 29,209	\$ 13,550
General and administrative	5,946	2,375	11,775	4,683
Total operating expenses	<u>20,057</u>	<u>9,524</u>	<u>40,984</u>	<u>18,233</u>
Loss from operations	(20,057)	(9,524)	(40,984)	(18,233)
Interest income, net	971	292	2,001	516
Other income (expense), net	14	(145)	(42)	(145)
Net loss	(19,072)	(9,377)	(39,025)	(17,862)
Unrealized gain on marketable securities, net of tax	84	3	129	3
Comprehensive loss	<u>\$ (18,988)</u>	<u>\$ (9,374)</u>	<u>\$ (38,896)</u>	<u>\$ (17,859)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.44)</u>	<u>\$ (4.17)</u>	<u>\$ (0.91)</u>	<u>\$ (8.36)</u>
Weighted-average number of common shares outstanding:				
Basic and diluted	<u>43,115</u>	<u>2,248</u>	<u>42,868</u>	<u>2,137</u>

See accompanying notes to unaudited interim financial statements

ALLAKOS INC.
STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands)
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	—	\$ —	42,117	\$ 42	\$ 288,079	\$ (15)	\$ (104,112)	\$ 183,994
Stock-based compensation expense	—	—	—	—	2,834	—	—	2,834
Issuance of common stock upon exercise of stock options	—	—	968	1	367	—	—	368
Issuance of common stock upon 2018 ESPP purchase	—	—	39	—	595	—	—	595
Vesting of restricted common stock	—	—	—	—	6	—	—	6
Unrealized gain on marketable securities, net of tax	—	—	—	—	—	45	—	45
Net loss	—	—	—	—	—	—	(19,953)	(19,953)
Balance at March 31, 2019	—	\$ —	43,124	\$ 43	\$ 291,881	\$ 30	\$ (124,065)	\$ 167,889
Stock-based compensation expense	—	—	—	—	3,105	—	—	3,105
Issuance of common stock upon exercise of stock options	—	—	60	—	138	—	—	138
Vesting of restricted common stock	—	—	—	—	6	—	—	6
Unrealized gain on marketable securities, net of tax	—	—	—	—	—	84	—	84
Net loss	—	—	—	—	—	—	(19,072)	(19,072)
Balance at June 30, 2019	—	\$ —	43,184	\$ 43	\$ 295,130	\$ 114	\$ (143,137)	\$ 152,150

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	30,971	\$ 142,969	2,114	\$ 3	\$ 1,803	\$ —	\$ (60,574)	\$ (58,768)
Stock-based compensation expense	—	—	—	—	614	—	—	614
Vesting of restricted common stock	—	—	—	—	6	—	—	6
Net loss	—	—	—	—	—	—	(8,485)	(8,485)
Balance at March 31, 2018	30,971	\$ 142,969	2,114	\$ 3	\$ 2,423	\$ —	\$ (69,059)	\$ (66,633)
Stock-based compensation expense	—	—	—	—	438	—	—	438
Proceeds from repayment of recourse promissory note	—	50	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	416	—	291	—	—	291
Vesting of restricted common stock	—	—	—	—	6	—	—	6
Unrealized gain on marketable securities, net of tax	—	—	—	—	—	3	—	3
Net loss	—	—	—	—	—	—	(9,377)	(9,377)
Balance at June 30, 2018	30,971	\$ 143,019	2,530	\$ 3	\$ 3,158	\$ 3	\$ (78,436)	\$ (75,272)

See accompanying notes to unaudited interim financial statements

ALLAKOS INC.
STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (39,025)	\$ (17,862)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	732	119
Accretion of tenant improvement allowance	—	(21)
Stock-based compensation	5,939	1,052
Net amortization of premiums and discounts on marketable securities	(1,330)	(89)
Noncash lease expense	142	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,508	(2,051)
Other long-term assets	—	(22)
Accounts payable	874	(647)
Accrued expenses and other current liabilities	3,314	1,861
Other long-term liabilities	144	211
Net cash used in operating activities	(27,702)	(17,449)
Cash flows from investing activities		
Purchases of marketable securities	(115,984)	(44,746)
Purchases of property and equipment	(618)	(1,650)
Proceeds from maturities of marketable securities	146,000	—
Net cash provided by (used in) investing activities	29,398	(46,396)
Cash flows from financing activities		
Proceeds from issuance of common stock under the 2018 ESPP	595	—
Proceeds from exercise of stock options, net of repurchases	506	291
Proceeds from the repayment of recourse promissory note	—	50
Payments for deferred financing costs	—	(1,606)
Net cash provided by (used in) financing activities	1,101	(1,265)
Net increase (decrease) in cash, cash equivalents and restricted cash	2,797	(65,110)
Cash, cash equivalents and restricted cash, beginning of period	34,462	85,207
Cash, cash equivalents and restricted cash, end of period	\$ 37,259	\$ 20,097
Supplemental disclosures		
Noncash investing and financing items:		
Right-of-use assets obtained in exchange for lease obligations (1)	\$ 6,050	\$ —
Property and equipment purchased in accounts payable	\$ —	\$ 14
Lessor funded lease incentives included in property and equipment	\$ —	\$ 1,386
Deferred initial public offering costs in accounts payable and accrued expenses	\$ —	\$ 858
Vesting of restricted common stock subject to repurchase	\$ 12	\$ 12

(1) Amount for the six months ended June 30, 2019 includes a transition adjustment recorded as part of the Company's adoption of a new lease accounting policy effective January 1, 2019.

See accompanying notes to unaudited interim financial statements

ALLAKOS INC.
NOTES TO UNAUDITED INTERIM FINANCIAL STATEMENTS

1. Organization and Business

Allakos Inc. (“Allakos” or the “Company”) was incorporated in the state of Delaware in March 2012. Allakos is a clinical stage biopharmaceutical company focused on the development of AK002 for the treatment of eosinophil and mast cell related diseases. The Company’s primary activities to date have included establishing its facilities, recruiting personnel, conducting research and development of its product candidates and raising capital. The Company’s operations are located in Redwood City, California.

Liquidity Matters

Since inception, the Company has incurred net losses and negative cash flows from operations. During the six months ended June 30, 2019, the Company incurred a net loss of \$39.0 million and used \$27.7 million of cash in operations. At June 30, 2019, the Company had an accumulated deficit of \$143.1 million and does not expect to experience positive cash flows from operating activities in the foreseeable future. The Company has financed its operations to date primarily through the sale of common stock and issuance of convertible preferred stock. Management expects to incur additional operating losses in the future as the Company continues to further develop, seek regulatory approval for and, if approved, commence commercialization of its product candidates. The Company had \$153.1 million of cash, cash equivalents and marketable securities at June 30, 2019. Management believes that this amount is sufficient to fund the Company’s operations for at least the next 12 months from the issuance date of these financial statements.

Initial Public Offering and Related Transactions

On July 23, 2018, the Company completed an initial public offering (“IPO”), selling 8,203,332 shares of common stock at an offering price of \$18.00 per share. Proceeds from the IPO, net of underwriting discounts and commissions, were \$137.3 million. Concurrently with the IPO, the Company completed a private placement of 250,000 shares of common stock at the IPO offering price of \$18.00 per share to an existing stockholder. Proceeds from this private placement were \$4.5 million.

In connection with the completion of the IPO on July 23, 2018, all then outstanding shares of convertible preferred stock were converted into 30,971,627 shares of common stock.

Upon the completion of the IPO, the Company’s certificate of incorporation was amended and restated. Under the amended and restated certificate of incorporation, the Company’s authorized capital stock consists of 200,000,000 shares of common stock with a par value \$0.001 per share and 20,000,000 shares of convertible preferred stock with a par value \$0.001 per share.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited interim financial statements have been prepared in accordance with United States generally accepted accounting principles (“U.S. GAAP”). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes.

The interim balance sheet as of June 30, 2019, the statements of operations and comprehensive loss, statements of convertible preferred stock and stockholders’ equity (deficit) and statements of cash flows for the six months ended June 30, 2019 and 2018 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company’s financial position as of June 30, 2019 and its results of operations and comprehensive loss for the three and six months ended June 30, 2019 and 2018 and its cash flows for the six months ended June 30, 2019 and 2018. Certain information and note disclosures normally included in annual audited financial statements prepared in accordance with U.S. GAAP have been omitted. The financial data and the other financial information disclosed in these notes to the interim financial statements are also unaudited. The results of operations for any interim period are not necessarily indicative of the results to be expected for the entire year or for any other future annual or interim period. The balance sheet as of December 31, 2018 included herein was derived from the audited financial statements as of that date. These interim financial statements should be read in conjunction with the Company’s audited financial statements included in the Company’s Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (the “SEC”) on March 14, 2019.

Use of Estimates

Management uses significant judgment when making estimates related to common stock valuation and related stock-based compensation expense, accrued expenses related to clinical trials, calculation of right-of-use assets and lease liabilities, and deferred tax valuation allowances. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets

and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates under different assumptions or conditions, and those differences could be material to the financial position and results of operations.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk principally consist of cash, cash equivalents and marketable securities. These financial instruments are held in accounts at a single financial institution that management believes possesses high credit quality. Amounts on deposit with this financial institution have and will continue to exceed federally-insured limits. The Company has not experienced any losses on its cash deposits. Additionally, the Company's investment policy limits its investments to certain types of securities issued by the U.S. government and its agencies.

The Company is subject to a number of risks similar to that of other early-stage biopharmaceutical companies, including, but not limited to, the need to obtain adequate additional funding, possible failure of current or future clinical trials, its reliance on third-parties to conduct its clinical trials, the need to obtain regulatory and marketing approvals for its product candidates, competitive developments, the need to successfully commercialize and gain market acceptance of the Company's product candidates, its right to develop and commercialize its product candidates pursuant to the terms and conditions of the licenses granted to the Company, protection of proprietary technology, the ability to make milestone, royalty or other payments due under licensing agreements, and the need to secure and maintain adequate manufacturing arrangements with third-parties. If the Company does not successfully commercialize or partner its product candidates, it will be unable to generate product revenue or achieve profitability.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Restricted cash as of June 30, 2019 represents \$0.8 million in deposits restricted from withdrawal and held by a bank in the form of collateral for an irrevocable standby letter of credit held as security for the lease of the Company's facility in Redwood City, California. The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Company's balance sheets and which, in aggregate, represent the amounts reported in the accompanying statements of cash flows (in thousands):

	June 30, 2019	December 31, 2018
Cash and cash equivalents	\$ 36,457	\$ 33,660
Restricted cash in other long-term assets, deposit for lease facility	802	802
Total cash, cash equivalents and restricted cash	<u>\$ 37,259</u>	<u>\$ 34,462</u>

	June 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 19,295	\$ 85,207
Restricted cash in other long-term assets, deposit for lease facility	802	—
Total cash, cash equivalents and restricted cash	<u>\$ 20,097</u>	<u>\$ 85,207</u>

The tables above exclude the fair value of the Company's investments in marketable securities that are considered available-for-sale.

Marketable Securities

The Company invests in marketable securities, primarily securities issued by the U.S. government and its agencies. The Company's marketable securities are considered available-for-sale and are classified as current assets even when the stated maturities of the underlying securities exceed one year from the date of the current balance sheet being reported. This classification reflects management's ability and intent to utilize proceeds from the sale of such investments to fund ongoing operations. Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated comprehensive income (loss). The cost of securities sold is determined using the specific-identification method. Interest earned and adjustments for the amortization of premiums and discounts on investments are included in interest income, net, on the statements of operations and comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on investments in marketable securities are included in other income (expense), net, on the statements of operations and comprehensive loss.

Leases

Effective January 1, 2019, the Company accounts for its leases in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, "Leases" ("ASC 842"). Prior period amounts continue to be reported in

accordance with the Company's historic accounting under previous lease guidance. Additionally, the Company elected a number of optional practical expedients made available under the ASC 842 transition guidance. Such elections include (i) carrying forward the Company's historical lease classifications, (ii) foregoing a re-evaluation of historical contracts to identify embedded leases, (iii) foregoing a re-assessment of initial direct costs related to leases that existed prior to adoption, (iv) combining lease and non-lease components, and (v) recognizing lease expense for all contracts with an initial term of 12 months or less within the statements of operations and comprehensive loss on a straight-line basis over the requisite lease term.

The Company accounts for its leases by recording right-of-use assets and lease liabilities on the Balance Sheet. Right-of-use assets represent the Company's right to use an underlying asset over the lease term and include any lease payments made prior to the lease commencement date and exclude lease incentives. Lease liabilities represent the present value of the total lease payments over the lease term, calculated using the Company's incremental borrowing rate. In determining the Company's incremental borrowing rate, consideration is given to the term of the lease and the Company's credit risk. The Company's recognizes options to extend or terminate a lease when it is reasonably certain that the Company will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development costs include, among others, consulting costs, salaries, benefits, travel, stock-based compensation, laboratory supplies and other non-capital equipment utilized for in-house research, allocation of facilities and overhead costs and external costs paid to third-parties that conduct research and development activities on the Company's behalf. Amounts incurred in connection with license agreements are also included in research and development expense.

Advance payments for goods or services to be rendered in the future for use in research and development activities are deferred and included in prepaid expenses and other current assets. The deferred amounts are expensed as the related goods are delivered or the services are performed.

Accrued Research and Development Costs

Service agreements with contract research organizations ("CROs") and contract development and manufacturing organizations ("CDMOs") comprise a significant component of the Company's research and development activities. External costs for CROs and CDMOs are recognized as the services are incurred. The Company accrues for expenses resulting from obligations under agreements with its third-parties for which the timing of payments does not match the periods over which the materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CROs, CDMOs and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services.

The Company makes judgements and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CRO, CDMO or other outside service provider, the payments are recorded within prepaid expenses and other current assets and subsequently recognized as research and development expense when the associated services have been performed. As actual costs become known, the Company adjusts its liabilities and assets. Inputs, such as the extent of services received and the duration of services to be performed, may vary from the Company's estimates, which will result in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. The Company's historical estimates have not been materially different from actual amounts recorded.

Comprehensive Loss

Comprehensive loss is defined as the change in stockholders' equity (deficit) during a period from transactions and other events and circumstances from non-owner sources and consists primarily of unrealized gains and losses on the Company's investments in marketable securities.

Net Loss per Share

The Company calculates basic net loss per share by dividing the net loss attributable to common stockholders by the weighted-average shares of common stock outstanding during the period. The Company calculates diluted net loss per share after giving consideration to all potentially dilutive securities outstanding during the period using the treasury-stock and if-converted methods, except where the effect of including such securities would be anti-dilutive. Because the Company has reported net losses since

inception, the effect from potentially dilutive securities would have been anti-dilutive and therefore has been excluded from the calculation of diluted net loss per share.

Basic and diluted net loss per share was calculated as follows (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	\$ (19,072)	\$ (9,377)	\$ (39,025)	\$ (17,862)
Denominator:				
Weighted-average shares of common stock outstanding, basic and diluted	43,115	2,248	42,868	2,137
Net loss per share, basic and diluted	\$ (0.44)	\$ (4.17)	\$ (0.91)	\$ (8.36)

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect for the periods indicated (in thousands):

	Three and Six Months Ended June 30,	
	2019	2018
Series A convertible preferred stock	—	20,866
Series B convertible preferred stock	—	10,105
Options to purchase common stock	6,976	6,529
Warrants to purchase common stock	—	48
Unvested restricted common stock	19	76
Shares issuable under 2018 Employee Stock Purchase Plan	27	—
Total	7,022	37,624

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASC 842 which became effective for fiscal years beginning after December 15, 2018. ASC 842 requires an entity to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. The recognition, measurement and presentation of expenses will depend on the lease's classification as a finance or operating lease. ASC 842 also requires certain quantitative and qualitative disclosures about leasing arrangements. The Company adopted ASC 842 using a modified retrospective approach effective January 1, 2019, recording a right-of-use asset of \$6.1 million and a long-term lease liability of \$8.2 million. Adoption of ASC 842 did not result in a cumulative effect adjustment to accumulated deficit. See Note 6 for further disclosure.

In August 2018, the SEC adopted amendments to certain disclosure requirements in the Securities Act Release No. 33-10532, Disclosure Update and Simplification. Under the amendments, the Company must provide an analysis of changes in each caption of stockholders' equity (deficit) presented in the balance sheet in a note or separate statement. The Company adopted the amendments during the three months ended March 31, 2019. The adoption of the amendments did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-13, *Fair Value Measurement* (ASC Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement. This ASU eliminates, modifies and adds disclosure requirements for fair value measurements. The amendments in this ASU are effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the effects of this ASU on its financial statements and related disclosures and does not expect there to be a material impact.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses* (ASC Topic 326): Measurement of Credit Losses on Financial Instruments, as clarified in ASU No. 2019-04 and ASU No. 2019-05. This guidance will require Companies to recognize an allowance for credit losses on available-for-sale debt securities rather than the current approach of recording a reduction to the carrying value of the asset. The ASU is effective for fiscal years beginning after December 15, 2019 and interim periods therein. Early adoption is permitted for annual periods beginning after December 15, 2018 and interim periods therein. The Company is currently evaluating the effects of this ASU on its financial statements and related disclosures and does not expect there to be a material impact.

3. Fair Value Measurements

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The Company's financial assets measured at fair value on a recurring basis were as follows (in thousands):

	June 30, 2019			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ 34,122	\$ —	\$ —	\$ 34,122
Total cash equivalents	\$ 34,122	\$ —	\$ —	\$ 34,122
Marketable securities				
U.S. treasuries	\$ 116,614	\$ —	\$ —	\$ 116,614
Total marketable securities	\$ 116,614	\$ —	\$ —	\$ 116,614
Total cash equivalents and marketable securities	\$ 150,736	\$ —	\$ —	\$ 150,736
	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ 31,555	\$ —	\$ —	\$ 31,555
Total cash equivalents	\$ 31,555	\$ —	\$ —	\$ 31,555
Marketable securities				
U.S. treasuries	\$ 145,246	\$ —	\$ —	\$ 145,246
Total marketable securities	\$ 145,246	\$ —	\$ —	\$ 145,246
Total cash equivalents and marketable securities	\$ 176,801	\$ —	\$ —	\$ 176,801

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the three and six months ended June 30, 2019 and 2018.

4. Marketable Securities

All marketable securities were considered available-for-sale at June 30, 2019. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type at June 30, 2019 and December 31, 2018 are summarized in the table below (in thousands):

	June 30, 2019			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities				
U.S. treasuries	\$ 116,500	\$ 114	\$ —	\$ 116,614
Total marketable securities	\$ 116,500	\$ 114	\$ —	\$ 116,614
	December 31, 2018			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities				
U.S. treasuries	\$ 145,261	\$ —	\$ (15)	\$ 145,246
Total marketable securities	\$ 145,261	\$ —	\$ (15)	\$ 145,246

The Company had no other-than-temporary impairments on its marketable securities during the three and six months ended June 30, 2019 and 2018. The Company has the intent and ability to hold all marketable securities until their maturities.

5. Balance Sheet Components and Supplemental Disclosures

Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
Laboratory equipment	\$ 3,825	\$ 3,272
Furniture and office equipment	1,695	1,666
Leasehold improvements	4,581	4,545
	10,101	9,483
Less accumulated depreciation	(1,367)	(635)
Property and equipment, net	<u>\$ 8,734</u>	<u>\$ 8,848</u>

Depreciation and amortization expense for the three months ended June 30, 2019 and 2018 was \$0.4 million and \$0.1 million, respectively. Depreciation and amortization expense for the six months ended June 30, 2019 and 2018 was \$0.7 million and \$0.1 million, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
Accrued outside professional services	\$ 3,236	\$ 1,964
Accrued compensation and benefits	2,827	1,041
Lease liability, current	273	—
Lease incentive obligation, current	—	123
Other current liabilities	7	36
Total	<u>\$ 6,343</u>	<u>\$ 3,164</u>

6. Commitments and Contingencies

Lease Obligations

As described in Note 2, the Company adopted ASC 842 effective January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with the Company's previous accounting method. The Company terminated its previous lease agreement for its San Carlos, California office during the year ended December 31, 2018 and as of June 30, 2019, the Company's outstanding lease obligations primarily relate to leased office and laboratory space under a single noncancelable operating lease entered into during January 2018. The lease agreement includes a contractual lease term which commenced upon substantial completion and delivery of the premises in November 2018. The base term of the lease is 10.75 years and includes an option to extend for an additional term of 5 years. This option to extend the lease term has not been included in the Company's calculations under ASC 842 as the exercise of the option is highly uncertain and therefore deemed not probable.

The Company's lease agreement included a \$1.4 million tenant improvement allowance that has been applied to the total cost of tenant improvements made to the leased premises. Tenant improvement allowances received were recorded as leasehold improvements with an offsetting adjustment included in the Company's calculation of its right-of-use asset under ASC 842. Leasehold improvements are depreciated over the term of the lease.

The Company has performed an evaluation of its other contracts with vendors in accordance with ASC 842 and has determined that, except for the lease described above, none of its other contracts contain a lease.

The balance sheet classification of the Company's lease liabilities at June 30, 2019 was as follows (in thousands):

Operating lease liabilities	
Current portion included in accrued expenses and other current liabilities	\$ 273
Non-current portion included in other long-term liabilities	8,326
Total operating lease liabilities	<u>\$ 8,599</u>

The components of lease costs, which were included in operating expenses in the Company's statements of operations and comprehensive loss were as follows (in thousands):

	Three Months Ended	Six Months Ended
	June 30, 2019	June 30, 2019
Operating lease cost	\$ 280	\$ 560
Variable cost	91	178
Total lease costs	<u>\$ 371</u>	<u>\$ 738</u>

As of June 30, 2019, the maturities of the Company's operating lease liabilities are as follows (in thousands):

Fiscal Year Ending December 31,	
2019 (remaining 6 months)	\$ 503
2020	1,233
2021	1,270
2022	1,308
2023	1,348
Thereafter	8,304
Total lease payments	<u>13,966</u>
Less:	
Present value adjustment	5,367
Operating lease liabilities	<u>\$ 8,599</u>

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used its incremental borrowing rate based on the information available at the lease commencement date. As of June 30, 2019, the remaining lease term is 10.1 years and the discount rate used to determine the operating lease liability was 10.0%.

As of June 30, 2019, the Company is not party to any lease agreements containing material residual value guarantees or material restrictive covenants.

Purchase Obligations

The Company has entered into contractual agreements with various research and development organizations and suppliers in the normal course of its business. All contracts are terminable, with varying provisions regarding termination. If a contract were to be terminated, the Company would only be obligated for the products or services that the Company had received through the time of termination as well as any non-cancelable minimum payments contractually agreed upon prior to the effective date of termination. In the case of terminating a clinical trial agreement with an investigational site conducting clinical activities on behalf of the Company, the Company would also be obligated to provide continued support for appropriate safety procedures through completion or termination of the associated study. At June 30, 2019, the Company had \$14.7 million of non-cancelable purchase obligations under these agreements.

In-Licensing Agreements

The Company has entered into exclusive and non-exclusive, royalty bearing license agreements with third-parties for certain intellectual property. Under the terms of the license agreements, the Company is obligated to pay milestone payments upon the achievement of specified clinical, regulatory and commercial milestones. Actual amounts due under the license agreements will vary depending on factors including, but not limited to, the number of products developed and the Company's ability to further develop and commercialize the licensed products. The Company is also subject to future royalty payments based on sales of the licensed products. In-licensing payments to third-parties for milestones are recognized as research and development expense in the period of achievement.

The Company recognized \$0.3 million of milestone expense for the three and six months ended June 30, 2018. The Company did not recognize any milestone expense during the three and six months ended June 30, 2019. Milestone payments are not creditable against royalties. As of June 30, 2019, the Company has not incurred any royalty liabilities related to its license agreements, as product sales have not yet commenced.

Exclusive License Agreement with The Johns Hopkins University

In December 2013, the Company entered into a license agreement with The Johns Hopkins University ("JHU") for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including AK002, which was amended in September 2016. Under the terms of the agreement, the Company has made upfront and milestone payments of \$0.3 million through June 30, 2019 and may be required to make aggregate additional milestone payments of up to \$4.0 million. The Company also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, the Company is also subject to single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by the Company and its affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

Non-exclusive License Agreement with BioWa Inc. and Lonza Sales AG

In October 2013, the Company entered into a tripartite agreement with BioWa Inc. ("BioWa"), and Lonza Sales AG ("Lonza"), for the non-exclusive worldwide license to develop and commercialize product candidates including AK002 that are manufactured using a technology jointly developed and owned by BioWa and Lonza. Under the terms of the agreement, the Company has made milestone payments of \$0.4 million through June 30, 2019 and may be required to make aggregate additional milestone payments of up to \$41.0 million. In addition to milestone payments, the Company is also subject to minimum annual commercial license fees of \$40,000 per year to BioWa until such time as BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza. Royalties are based on future net sales by the Company and its affiliates and sublicensees and vary dependent on Lonza's participation as sole manufacturer for commercial production.

Indemnification Agreements

The Company has entered into indemnification agreements with certain directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no such matters have arisen and the Company does not believe that the outcome of any claims under indemnification arrangements will have a material adverse effect on its financial positions, results of operations or cash flows. Accordingly, the Company has not recorded a liability related to such indemnifications at June 30, 2019.

7. Stock-Based Compensation

Total stock-based compensation expense recognized is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	\$ 1,044	\$ 167	\$ 2,097	\$ 335
General and administrative	2,061	272	3,842	717
Total	<u>\$ 3,105</u>	<u>\$ 439</u>	<u>\$ 5,939</u>	<u>\$ 1,052</u>

No income tax benefits for stock-based compensation expense have been recognized for the three and six months ended June 30, 2019 and 2018 as a result of the Company's full valuation allowance applied to net deferred tax assets and net operating loss carryforwards.

Equity Incentive Plans

In July 2018, the Board of Directors adopted the 2018 Equity Incentive Plan (the “2018 Plan”). The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The Company initially reserved 4,000,000 shares of common stock for issuance under the 2018 Plan. The number of shares of common stock that may be issued under the 2018 Plan will automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 5,000,000 shares, (ii) 5% of the outstanding shares of common stock as of the last day of the preceding fiscal year and (iii) such other amount as the Board of Directors may determine.

Following the IPO and upon the effectiveness of the 2018 Plan, the Company’s 2012 Equity Incentive Plan, as amended, (the “2012 Plan”), terminated and no further awards will be granted thereunder. All outstanding awards under the 2012 Plan will continue to be governed by their existing terms. Any shares subject to awards granted under the 2012 Plan that, on or after the termination of the 2012 Plan, expire or terminate and shares previously issued pursuant to awards granted under the 2012 Plan that, on or after the termination of the 2012 Plan, are forfeited or repurchased by the Company will be transferred into the 2018 Plan. As of June 30, 2019, the maximum number of shares that may be added to the 2018 Plan pursuant to the preceding clause is 5,470,458 shares.

Prior to its termination, the 2012 Plan provided for the grant of stock options, stock appreciation rights, restricted stock and restricted stock units to employees, directors and consultants. Stock options granted under the 2012 Plan generally vest over four years and expire no more than 10 years from the date of grant.

The following weighted-average assumptions were used to calculate the fair value of stock-based awards granted to employees and directors during the periods indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Risk-free interest rate	2.19%	2.93%	2.22%	2.66%
Expected volatility	67.68%	75.00%	67.81%	76.66%
Expected dividend yield	—	—	—	—
Expected term (in years)	5.86	6.08	5.88	5.99

The Company’s stock option activity during the six months ended June 30, 2019 is summarized as follows (number of shares in thousands):

	Options Outstanding	Weighted- Average Exercise Price
Balance at December 31, 2018	7,811	\$ 8.60
Granted	238	\$ 39.65
Exercised	(1,029)	\$ 0.69
Forfeited	(44)	\$ 39.11
Balance at June 30, 2019	6,976	\$ 10.64
Options exercisable	3,359	\$ 1.74
Options vested and expected to vest	6,940	\$ 10.60

During the three and six months ended June 30, 2019 and 2018, the Company did not grant any stock options with performance-based or market-based vesting conditions, nor did the Company grant any stock options to non-employees in exchange for services.

As of June 30, 2019, total unrecognized stock-based compensation expense relating to unvested stock options was \$37.3 million. This amount is expected to be recognized over a weighted-average period of 3.1 years.

2018 Employee Stock Purchase Plan

In July 2018, the Company’s Board of Directors and stockholders approved the 2018 Employee Stock Purchase Plan (the “2018 ESPP”). There are 500,000 shares of common stock initially reserved for issuance under the 2018 ESPP. The number of shares of common stock that may be issued under the 2018 ESPP will automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 1,000,000 shares, (ii) 1% of the outstanding shares of common stock as of the last

day of the immediately preceding fiscal year and (iii) such other amount determined by the 2018 ESPP administrator. Under the 2018 ESPP, employees may purchase shares of the Company's common stock at a price per share equal to 85% of the lower of the fair market value of the common stock on the first trading day of the offering period or on the exercise date. The 2018 ESPP provides for consecutive, overlapping 24-month offering periods, each of which will include purchase periods. The first offering period commenced on July 18, 2018 and will end on the first trading day on or before August 15, 2020. The second offering period commenced on February 15, 2019. During the three and six months ended June 30, 2019, stock-based compensation expense related to the 2018 ESPP was \$0.2 million and \$0.3 million, respectively.

8. Defined Contribution Plans

In January 2018, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) plan"). The 401(k) plan covers all employees who meet defined minimum age and service requirements. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under U.S. federal tax regulations. The Company makes matching contributions of up to 4% of the eligible employees' compensation to the 401(k) plan. During the three and six months ended June 30, 2019, the Company made contributions to the 401(k) plan of \$0.1 million and \$0.2 million, respectively. During each of the three and six months ended June 30, 2018, the Company made contributions to the 401(k) plan of \$0.1 million.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the other financial information appearing elsewhere in this Quarterly Report on Form 10-Q. These statements generally relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The following discussion and analysis contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Our actual results and the timing of events may differ materially from those discussed in our forward-looking statements as a result of various factors, including those discussed below and those discussed in the section entitled "Risk Factors" included in this Quarterly Report on Form 10-Q.

Forward-looking statements include, but are not limited to, statements about:

- the impact that the adoption of new accounting pronouncements will have on our financial statements;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- our plans relating to commercializing AK002, if approved, including the geographic areas of focus and sales strategy;
- the size of the market opportunity for AK002 in each of the diseases we are targeting;
- the number of diseases represented in the patient population enrolled in our clinical trials, and our ability to evaluate response to treatment of AK002 in diseases other than the primary indication in our clinical trials;
- our estimates of the number of patients in the United States who suffer from the diseases we are targeting and the number of patients that will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of AK002;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for AK002 or our other product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of AK002 or our other product candidates;
- our plans relating to the further development of AK002 and our other product candidates;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our continued reliance on third-parties to conduct additional clinical trials of AK002 and our other product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"); and
- our anticipated use of the proceeds from our initial public offering and the concurrent private placement.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including, but not limited to, those described in "Risk Factors". In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this

Quarterly Report on Form 10-Q and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled “Risk Factors” included in Part II, Item 1A and elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Quarterly Report on Form 10-Q by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

We are a clinical stage biotechnology company developing AK002, our wholly owned monoclonal antibody, for the treatment of various eosinophil and mast cell related diseases. AK002 selectively targets both eosinophils and mast cells, white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated eosinophils and mast cells have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. As such, AK002 has the potential to treat a large number of severe diseases. AK002 has demonstrated activity in clinical trials in patients with eosinophilic gastritis (“EG”), eosinophilic gastroenteritis (“EGE”), chronic urticaria (“CU”), indolent systemic mastocytosis (“ISM”) and severe allergic conjunctivitis (“SAC”). The activity observed in these studies suggest that AK002 could provide significant benefit to patients suffering from these diseases and highlight AK002’s potential to broadly inhibit mast cells and deplete eosinophils in different disease settings.

Despite the knowledge that eosinophils and mast cells drive many pathological conditions, there are no approved therapies that selectively target both eosinophils and mast cells. AK002 binds to Siglec-8, an inhibitory receptor found on eosinophils and mast cells, which represents a novel way to selectively deplete or inhibit these important immune cells and thereby resolve inflammation. We believe AK002 is the only Siglec-8 targeting antibody currently in clinical development and has the potential to have advantages over current treatments for the diseases we are pursuing.

Since our inception in 2012, we have devoted substantially all of our resources and efforts towards the research and development of our product candidates. We initially began developing two product candidates, AK001 and AK002, both of which are monoclonal antibodies targeting Siglec-8. These compounds entered clinical trials in 2015 and 2016, respectively. Due to the greater activity of AK002, we decided to focus our development efforts on AK002 and discontinued the development of AK001 in 2017. We have no current plans to continue development of AK001 at this time but may choose to do so in the future. In addition to activities conducted internally at our facilities, we have utilized significant financial resources to engage contractors, consultants and other third-parties to conduct various preclinical and clinical development activities on our behalf.

To date, we have not had any products approved for sale and have not generated any revenue nor been profitable. Further, we do not expect to generate revenue from product sales until such time, if ever, that we are able to successfully complete the development and obtain marketing approval for one of our product candidates. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We have incurred significant operating losses to date and expect to incur significant operating losses for the foreseeable future. Our net losses were \$39.0 million and \$17.9 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated deficit of \$143.1 million.

Our operations have been financed primarily through the private placements of convertible debt instruments and convertible preferred stock. These private placements provided gross proceeds of \$146.9 million. As of June 30, 2019, we had cash, cash equivalents and marketable securities of \$153.1 million, which we believe will be sufficient to fund our planned operations for at least the next 12 months from the issuance of our financial statements.

Initial Public Offering

On July 23, 2018, we completed an IPO, selling 8,203,332 shares of common stock at \$18.00 per share. Proceeds from our IPO, net of underwriting discounts and commissions, were \$137.3 million. Concurrently with our IPO, we completed a private placement of 250,000 shares of common stock at \$18.00 per share to an existing stockholder. Proceeds from this private placement were \$4.5 million.

In connection with the completion of our IPO on July 23, 2018, all then outstanding shares of convertible preferred stock converted into 30,971,627 shares of common stock.

Components of Operating Results

Revenue

We have not generated any revenue from product sales or otherwise, and do not expect to generate any revenue for at least the next several years.

Operating Expenses

We classify operating expenses into two categories: (i) research and development and (ii) general and administrative.

Research and Development Expenses

Research and development expenses represent the following costs incurred by us for the discovery, development and manufacturing of our product candidates:

- consultant and personnel-related costs including salaries, benefits, travel and stock-based compensation expense;
- costs incurred under service agreements with CROs that conduct nonclinical and clinical research activities on our behalf;
- costs incurred under service agreements with CDMOs for the manufacture and fill finish of our preclinical and clinical materials;
- costs related to in-house research and development activities conducted at our facilities including laboratory supplies, non-capital laboratory equipment and depreciation of capital laboratory equipment and leasehold improvements to laboratories;
- costs incurred under exclusive and non-exclusive license agreements with third-parties; and
- allocated facility and other costs including the rent and maintenance of our facilities, insurance premiums, depreciation of shared-use leasehold improvements and general office supplies.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as clinical site activations, patient enrollment or information provided to us by our vendors and our clinical investigative sites, along with analysis by our in-house clinical operations personnel. Advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized as prepaid expenses, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

The successful development of our product candidates is highly uncertain. Accordingly, it is difficult to estimate the nature, timing and extent of costs necessary to complete the remainder of the development of our product candidates. We are also unable to predict when, if ever, we will be able to generate revenue from our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty surrounding:

- demonstrating sufficient safety and tolerability profiles of product candidates;
- successful enrollment and completion of clinical trials;
- requisite clearance and approvals from applicable regulatory authorities;
- establishing and maintaining commercial manufacturing capabilities with CDMOs;
- obtaining and maintaining protection of intellectual property; and
- commercializing product candidates, if and when approved, alone or in collaboration with third-parties.

A change pertaining to any of these variables would significantly impact the timing and extent of costs incurred with respect to the development and commercialization of our product candidates.

External costs incurred from third-party CROs and CDMOs have comprised a significant portion of our research and development expenses since inception. We track external CRO and CDMO costs on a program-by-program basis following the advancement of a product candidate into clinical development. Consulting and personnel-related costs, laboratory supplies and non-capital equipment utilized in the conduct of in-house research, in-licensing fees and general overhead, are not tracked on a program-by-program basis, nor are they allocated, as they commonly benefit projects in our pipeline or span multiple programs.

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
AK002 contract research and development	\$ 7,093	\$ 2,386	\$ 14,719	\$ 4,685
Consulting and personnel-related costs	5,172	3,196	10,799	5,775
Other unallocated research and development costs	1,846	1,567	3,691	3,090
Total	\$ 14,111	\$ 7,149	\$ 29,209	\$ 13,550

General and Administrative Expenses

General and administrative expenses consist of fees paid to consultants, salaries, benefits and other personnel-related costs, including stock-based compensation, for our personnel in executive, finance, accounting and other administrative functions, legal costs, fees paid for accounting and tax services and facility costs not otherwise included in research and development expenses. Legal costs include general corporate and patent legal fees and related costs.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities including costs related to personnel, outside consultants, attorneys and accountants, among others. Additionally, we expect to incur incremental costs associated with operating as a public company, including expenses related to maintaining compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, additional insurance premiums, investor relations activities and other ancillary administrative and professional services.

Interest Income, Net

Interest income, net primarily consists of interest and investment income earned on our cash, cash equivalents and marketable securities included on the balance sheets.

Other Income (Expense), Net

Other income (expense), net, primarily consists of amounts realized from gains and losses related to fluctuations in foreign currencies.

In-Licensing Agreements

We have entered into a number of exclusive and nonexclusive, royalty bearing license agreements with third-parties for certain intellectual property. Under the terms of the license agreements described below, we are obligated to pay milestone payments upon the achievement of specified clinical, regulatory and commercial milestones. Actual amounts due under the license agreements vary depending on factors including, but not limited to, the number of product candidates we develop and our ability to successfully develop and commercialize our product candidates covered under the respective agreements. In addition to milestone payments, we are also subject to future royalty payments based on sales of our product candidates covered under the agreements, as well as certain minimum annual royalty and commercial reservation fees. Because the achievement of milestones and the timing and extent of future royalties is not fixed and determinable, these contingent amounts have not been included on our balance sheets or as part of Contractual Obligations and Commitments discussion below.

We recognized zero and \$0.3 million of milestone expense for the three and six months ended June 30, 2019 and 2018, respectively. Milestone payments are not creditable against royalties. As of June 30, 2019, we have not incurred any royalty liabilities related to our license agreements, as product sales have not yet commenced.

Exclusive License Agreement with The Johns Hopkins University

In December 2013, we entered into a license agreement with JHU for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including AK002, which was amended in September 2016. Under the terms of the agreement, we have made upfront and milestone payments of \$0.3 million through June 30, 2019 and we may be required to make aggregate additional milestone payments of up to \$4.0 million. We also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, we are also subject to single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by us and our affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

Non-exclusive License Agreement with BioWa Inc. and Lonza Sales AG

In October 2013, we entered into a tripartite agreement with BioWa and Lonza for the non-exclusive worldwide license to develop and commercialize product candidates including AK002 that are manufactured using a technology jointly developed and owned by BioWa and Lonza. Under the terms of the agreement, we have made milestone payments of \$0.4 million through June 30, 2019 and we may be required to make aggregate additional milestone payments of up to \$41.0 million. In addition to milestone payments, we are also subject to minimum annual commercial license fees of \$40,000 per year to BioWa until such time as BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza. Royalties are based on future net sales by us and our affiliates and sublicensees and vary dependent on Lonza's participation as sole manufacturer for commercial production.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. On January 1, 2019, we adopted ASC 842 resulting in changes to our accounting policies for leases. During the six months ended June 30, 2019, there were no other changes to our critical accounting policies as disclosed in our 2018 Annual Report on Form 10-K.

Recent Accounting Pronouncements

See Note 2 to our financial statements for recently issued accounting pronouncements, including the respective effective dates of adoption and effects on our results of operations and financial condition.

JOBS Act

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company ("EGC"), can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, (the "Securities Act"), for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of \$1.07 billion or more, (ii) the date on which we are deemed to be a “large accelerated filer” under the rules of the SEC with at least \$700.0 million of outstanding equity securities held by non-affiliates, (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the previous three years or (iv) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO.

Based on our public float at June 30, 2019, we will cease to be an emerging growth company at December 31, 2019 and, accordingly, we will be required to comply with the auditor attestation requirements of Section 404 to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting for our 2019 Annual Report on Form 10-K.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended June 30,	
	2019	2018
Operating expenses		
Research and development	\$ 14,111	\$ 7,149
General and administrative	5,946	2,375
Total operating expenses	20,057	9,524
Loss from operations	(20,057)	(9,524)
Interest income, net	971	292
Other income (expense), net	14	(145)
Net loss	(19,072)	(9,377)
Unrealized gain on marketable securities, net of tax	84	3
Comprehensive loss	\$ (18,988)	\$ (9,374)

Research and Development Expenses

Research and development expenses were \$14.1 million for the three months ended June 30, 2019 compared to \$7.1 million for the three months ended June 30, 2018, an increase of \$7.0 million. The period-over-period increase in research and development expenses includes \$4.8 million of incremental AK002 contract research and development costs, primarily attributable to \$3.1 million of CDMO services and \$1.7 million of CRO services. Increased hiring of R&D personnel during fiscal year 2019 contributed to an additional \$1.9 million of consulting and personnel-related costs and an additional \$0.3 million of unallocated research and development costs related to the conduct of in-house research.

General and Administrative Expenses

General and administrative expenses were \$5.9 million for the three months ended June 30, 2019 compared to \$2.4 million for the three months ended June 30, 2018, an increase of \$3.5 million. The period-over-period increase in general and administrative expenses was primarily attributable to an additional \$2.8 million of personnel-related costs resulting from our increased hiring of G&A personnel and \$0.7 million of incremental facilities and other administrative costs not otherwise included in research and development expenses.

Interest Income, Net

Interest income, net, was \$1.0 million for the three months ended June 30, 2019 compared to \$0.3 million for the three months ended June 30, 2018, an increase of \$0.7 million. The period-over-period change is directly attributable to increased interest income earned on capital raised by our July 2018 IPO.

Comparison of the Six Months Ended June 30, 2019 and 2018

The following table summarizes our results of operations for the periods indicated (in thousands):

	Six Months Ended June 30,	
	2019	2018
Operating expenses		
Research and development	\$ 29,209	\$ 13,550
General and administrative	11,775	4,683
Total operating expenses	40,984	18,233
Loss from operations	(40,984)	(18,233)
Interest income, net	2,001	516
Other income (expense), net	(42)	(145)
Net loss	(39,025)	(17,862)
Unrealized gain on marketable securities, net of tax	129	3
Comprehensive loss	<u>\$ (38,896)</u>	<u>\$ (17,859)</u>

Research and Development Expenses

Research and development expenses were \$29.2 million for the six months ended June 30, 2019 compared to \$13.6 million for the six months ended June 30, 2018, an increase of \$15.6 million. The period-over-period increase in research and development expenses includes \$11.3 million of incremental AK002 contract research and development costs, primarily attributable to \$8.3 million of CDMO services and \$3.0 million of CRO services. Increased hiring of R&D personnel during fiscal year 2019 contributed to an additional \$5.1 million of consulting and personnel-related costs. Period-over-period increases were offset by a \$0.8 million decrease to other unallocated research and development costs related to reduced spend on historical product candidates that are no longer in development.

General and Administrative Expenses

General and administrative expenses were \$11.8 million for the six months ended June 30, 2019 compared to \$4.7 million for the six months ended June 30, 2018, an increase of \$7.1 million. The period-over-period increase in general and administrative expenses was primarily attributable to an additional \$5.1 million of personnel-related costs resulting from our increased hiring of G&A personnel, as well as \$0.6 million of incremental expense incurred from outside professional service providers for legal, information technology, and investor relations activities associated with becoming a publicly traded company in July 2018. Finally, we incurred incremental facilities and other administrative costs of \$1.4 million, which includes general business insurance premiums and other such costs not otherwise included in research and development expenses.

Interest Income, Net

Interest income, net, was \$2.0 million for the six months ended June 30, 2019 compared to \$0.5 million for the six months ended June 30, 2018, an increase of \$1.5 million. The period-over-period change is directly attributable to increased interest income earned on capital raised by our July 2018 IPO.

Liquidity and Capital Resources

Sources of Liquidity

We are a clinical stage biotechnology company with a limited operating history. As a result of our significant research and development expenditures, we have generated net losses since our inception. Prior to completing our IPO, we historically financed our operations primarily through the private placement of convertible preferred stock. These private placements provided gross proceeds of \$146.9 million. We also had a debt facility with SVB, for an aggregate of \$5.0 million, which was fully repaid and terminated during 2017.

On July 23, 2018, we completed our IPO, selling 8,203,332 shares of common stock at a price of \$18.00 per share. Proceeds from the initial public offering, net of underwriting discounts and commissions, were \$137.3 million. Concurrently with our IPO, we completed a private placement of 250,000 shares of common stock at \$18.00 per share to an existing stockholder. Proceeds from this private placement were \$4.5 million.

As of June 30, 2019, we had cash, cash equivalents and marketable securities of \$153.1 million.

Based on our existing business plan, we believe that our current cash, cash equivalents and marketable securities will be sufficient to fund our anticipated level of operations through at least the next 12 months from the issuance of our financial statements.

Summary Cash Flows

Comparison of the Six Months Ended June 30, 2019 and 2018

The following table summarizes the primary sources and uses of our cash, cash equivalents, and restricted cash for the periods indicated (in thousands):

	Six Months Ended June 30,	
	2019	2018
Net cash used in operating activities	\$ (27,702)	\$ (17,449)
Net cash provided by (used in) investing activities	29,398	(46,396)
Net cash provided by (used in) financing activities	1,101	(1,265)
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 2,797</u>	<u>\$ (65,110)</u>

Cash Used in Operating Activities

Net cash used in operating activities was \$27.7 million for the six months ended June 30, 2019 which was primarily attributable to our net loss of \$39.0 million adjusted for net noncash charges of \$5.5 million and net changes in operating assets and liabilities of \$5.8 million. Noncash charges included \$5.9 million in stock-based compensation expense, \$0.7 million in depreciation and amortization expense and \$0.1 million in amortization of right-of-use assets, partially offset by \$1.3 million in net amortization of premiums and discounts on marketable securities.

Net cash used in operating activities was \$17.4 million for the six months ended June 30, 2018, which was primarily attributable to our net loss of \$17.9 million. Cash used in operating activities included a net decrease of \$0.6 million in operating assets and liabilities, adjusted for net non-cash charges of \$1.0 million primarily related to stock-based compensation and depreciation and amortization expense.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$29.4 million for the six months ended June 30, 2019, which consisted of \$146.0 million in proceeds from maturities of marketable securities, partially offset by \$116.0 million for the purchases of marketable securities and \$0.1 million for the purchases of property and equipment.

Net cash used in investing activities was \$46.4 million for the six months ended June 30, 2018, which consisted of \$44.7 million for the purchases of marketable securities and \$1.7 million for the purchases of property and equipment.

Cash Provided by (Used In) Financing Activities

Net cash provided by financing activities was \$1.1 million for six months ended June 30, 2019, which consisted primarily of \$0.5 million in proceeds received from employees for the exercise of stock options and \$0.6 million received from employees for the purchase of shares of common stock through the 2018 ESPP.

Net cash used in financing activities was \$1.3 million for the six months ended June 30, 2018, which consisted primarily of \$1.6 million in payments made for deferred IPO costs, partially offset by \$0.3 million in proceeds received from employees for the exercise of stock options, net of repurchases.

Funding Requirements

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise funding through private or public equity or debt financings, or other sources such as strategic collaborations. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies.

The timing and amount of our capital expenditures will depend on many factors, including:

- the number and scope of clinical indications and clinical trials we decide to pursue;

- the scope and costs of commercial manufacturing activities;
- the extent to which we acquire or in-license other product candidates and technologies, if any;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost and timing of establishing sales and marketing capabilities for product candidates receiving marketing approval, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates; and
- the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development and commercialization efforts. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

The issuance of additional equity securities may cause our stockholders to experience dilution. Future equity or debt financings may contain terms that are not favorable to us or our stockholders including debt instruments imposing covenants that restrict our operations and limit our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation, licensing or asset sale transactions.

Contractual Obligations and Commitments

Our contractual obligations and commitments relate primarily to our operating leases and non-cancelable purchase obligations under agreements with various research and development organizations and suppliers in the ordinary course of business. See Note 6, Commitments and Contingencies, to our financial statements for further information.

Off-Balance Sheet Arrangements

Since our inception, we have not entered into any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents, are in money market funds that invest in U.S. Treasury obligations. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Due to the short-term maturities and low credit risk profile of our balances held in money market funds, a hypothetical 10% change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities.

Foreign Currency Sensitivity

Our primary operations are transacted in U.S. Dollars, however, certain service agreements with third parties are denominated in currencies other than the U.S. Dollar, primarily the British Pound and Euro. As such, we are subject to foreign exchange risk and therefore, fluctuations in the value of the U.S. Dollar against the British Pound and Euro may impact the amounts reported for expenses and obligations incurred under such agreements. We do not currently engage in any hedging activity to reduce our potential exposure to currency fluctuations, although we may choose to do so in the future. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial condition or results of operations.

Item 4. Controls and Procedures.**Evaluation of Disclosure Controls and Procedures**

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. As of June 30, 2019, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended June 30, 2019 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.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Position and Need for Additional Capital

We are in the early stages of clinical drug development and have a very limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are an early clinical stage biopharmaceutical company with a limited operating history. We were incorporated and commenced operations in 2012, have no products approved for commercial sale and have not generated any revenue. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying and developing potential product candidates, conducting preclinical and clinical studies of our product candidates, including Phase 1 and Phase 2 clinical trials of AK002, our lead compound. All of our product candidates currently under development, other than AK002, are in preclinical development. We have not yet demonstrated our ability to successfully complete any large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale drug or arrange for a third-party to do so on our behalf or conduct sales and marketing activities. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through the sale and issuance of common stock and preferred stock. Our net loss was \$43.5 million for the year ended December 31, 2018 and \$39.0 million for the six months ended June 30, 2019. As of June 30, 2019, we had an accumulated deficit of \$143.1 million. We have devoted substantially all of our resources and efforts to research and development. Our lead compound, AK002, is in clinical development, and our other product candidates are in preclinical development. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenues from sales of any products. We have no products approved for commercial sale and do not anticipate generating

any revenue from product sales until some time after we have successfully completed clinical development and received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including:

- successful and timely completion of preclinical and clinical development of our lead compound, AK002, and any other future product candidates;
- timely receipt of marketing approvals for AK002 and any future product candidates for which we successfully complete clinical development and clinical trials from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for AK002 and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third-parties to obtain finished products that are appropriately packaged for sale;
- successful launch of commercial sales following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance of AK002 and any future product candidates as viable treatment options by patients, the medical community and third-party payors;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidates; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and/or continue our operations.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, AK002 and our other product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. We have also incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of June 30, 2019, we had \$153.1 million in cash, cash equivalents and marketable securities, which includes proceeds from our IPO and concurrent private placement that we completed on July 23, 2018. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. Our estimate as to how long we expect our existing cash, cash equivalents and marketable securities to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our existing cash, cash equivalents and marketable securities to fund our development of AK002 and for other research and development activities, working capital and other general corporate purposes. This may include additional research, hiring additional personnel, capital expenditures and the costs of operating as a public company. Advancing the development of AK002 and any other product candidates will require a significant amount of capital. Our existing cash, cash equivalents and marketable securities will not be sufficient to fund all of the actions that are necessary to complete the development of AK002 or any of our other product candidates. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are dependent on the success of our lead compound, AK002, which is currently in multiple clinical trials. If we are unable to obtain approval for and commercialize AK002 for one or more indications in a timely manner, our business could be materially harmed.

Our future success is dependent on our ability to timely complete clinical trials and obtain marketing approval for, and then successfully commercialize AK002, our lead compound, for one or more indications. AK002 is in the early stages of development and we are investing the majority of our efforts and financial resources in the research and development of AK002 for multiple indications. AK002 will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote AK002, or any other product candidates, before we receive marketing approval from the U.S. Food and Drug Administration (“FDA”) and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of AK002 will depend on several factors, including the following:

- successful and timely completion of our clinical trials of AK002;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- efficacy, safety and tolerability profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals for AK002 from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers;
- the maintenance of existing or the establishment of new scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator.

The regulatory approval processes of the FDA, European Medicines Agency (“EMA”) and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA, EMA and comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval in an initial or subsequent indication for many reasons, including but not limited to the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application (“BLA”) or New Drug Application (“NDA”), or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or comparable foreign regulatory authorities that a product candidate’s risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. In particular, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates.

The clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise produce positive results.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining marketing approval to commence a trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtaining institutional review board approval at each clinical trial site;
- recruiting suitable patients to participate in a trial;
- patients failing to comply with trial protocol or dropping out of a trial;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the need to add new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including:

- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- regulators revising the requirements for approving our product candidates.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be delayed in obtaining marketing approval, if at all, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

We currently have no drugs approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. In particular, no compound with the mechanism of action of AK002 has been commercialized, and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials.

From time to time, we may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In addition, we use patient-reported outcome assessments in our clinical trials, which involve patients' subjective assessments of efficacy of the treatments they receive in the trial. Such assessments can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

Our product candidates may not achieve adequate market acceptance among physicians, hospitals, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, hospitals, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in planned clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our products, if approved, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-parties and government authorities;
- relative convenience and ease of administration;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to the product candidate; and
- the approval of other new therapies for the same indications.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be harmed. AK002 is currently administered as an intravenous treatment, which is less convenient for patients than some other methods of administration, such as an orally delivered drug.

The sizes of the patient populations suffering from some of the diseases we are targeting are small and based on estimates that may not be accurate.

Our projections of both the number of people who have some of the diseases we are targeting, as well as the subset of people with these diseases who have the potential to benefit from treatment with AK002 and any other future product candidates, are estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, physician interviews, patient foundations and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for AK002 and any other future product candidates may be limited or may not be amenable to treatment with AK002 and any other products, if and when approved. Even if we obtain significant market share for AK002 and any other products (if and when they are approved), small potential target populations for certain indications means we may never achieve profitability without obtaining market approval for additional indications.

Our business will be impacted by our ability to advance additional product candidates beyond AK002 into clinical development and through to regulatory approval and commercialization. Our other product candidates are at even earlier stages of development than AK002 and may fail in development or suffer delays that adversely affect their commercial viability.

All of our product candidates are in the early stages of development and may fail in development or suffer delays that adversely affect their commercial viability. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later-stage clinical trials of the product candidate.

Our future operating results are dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize other product candidates in addition to AK002. The success of any product candidates we may develop will depend on many factors, including, among other things, the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials;

- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that we will ever be able to develop, obtain regulatory approval of, commercialize or generate significant revenue from any other product candidates.

Any drugs we develop may become subject to unfavorable third-party reimbursement practices and pricing regulations.

The availability and extent of coverage and adequate reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. In the United States, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private payors often follow CMS’s decisions regarding coverage and reimbursement to a substantial degree. However, one payor’s determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical drug products. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific drug products on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The biotechnology industry is highly competitive and subject to rapid and significant technological change. Products we may develop in the future are likely to face competition from other drugs and therapies, some of which we may not currently be aware. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

We are not aware of any other company or organization that is conducting clinical trials of a product candidate that targets both eosinophils and mast cells, including any product candidate that specifically targets Siglec-8. The competition we may face with respect to the indications we are targeting with AK002 includes, without limitation, Regeneron, AstraZeneca, Celgene, Shire, and Dr. Falk Pharma for EGIDs, Blueprint Medicines for ISM, and Novartis Pharmaceuticals, Genentech, and Gossamer Bio for CU. In addition, we are currently evaluating a host of other indications, and if we were to initiate trials in any such indication, we would likely face significant competition from a number of additional competitors. These companies, or other major multinational pharmaceutical and biotechnology companies, emerging and start-up companies, universities and other research institutions, could focus their future efforts on developing competing therapies and treatments for any of the indications we are currently targeting or may target in the future. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA or foreign regulatory authorities or discovering, developing and commercializing products in our field before we do.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for planned clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biotechnology industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We have limited resources and are currently focusing our efforts on developing AK002 for particular indications. As a result, we may fail to capitalize on other product candidates or indications that may ultimately have proven to be more profitable.

We are currently focusing our efforts on a small number of indications. As a result, we may forego or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development activities for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target markets for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA investigation could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. For example, despite the recent completion of our Phase 2 clinical trial in patients with EG and/or EGE, significant regulatory hurdles remain, both near term and long term, before AK002 can obtain regulatory approval in the United States. In the near term, we must schedule an end of Phase 2 meeting with the FDA and if we are unable to do so in a timely manner, our timeline for the commercialization of our product candidate could be extended. In the longer term, we will need to reach agreement with the FDA on the design for our Phase 3 clinical trial, and of course conduct such trial. There can be no assurance we will be able to successfully conclude these undertakings in a timely manner, and it is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us to begin selling them.

Our company has not conducted or managed clinical trials through regulatory approval, including FDA approval. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy ("REMS"), plan as part of a BLA or NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or biologic. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

Our clinical trials may reveal significant adverse events, toxicities or other side effects and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

In order to obtain marketing approval for any of our product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in preclinical studies or clinical trials, or have unexpected characteristics, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

We have conducted Phase 1 and Phase 2 clinical trials in healthy volunteers, as well as in patients with EG, EGE, CU, ISM and SAC. However, we do not know the predictive value of these trials for our future clinical trials, and we cannot guarantee that any positive results in preclinical studies or previous clinical trials will successfully translate to patients in our future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Because Siglec-8 is only naturally expressed in humans and certain other primates, there is no standard animal toxicology model for anti-Siglec-8 therapies, and the acceptability of our preclinical safety data for AK002 depends on the continued acceptance by the FDA and EMA, and the acceptance by other regulatory authorities, of the use of our proprietary transgenic mice models for toxicology studies.

AK002 has generally been well tolerated in our clinical trials. The most common adverse event has been the occurrence of mild to moderate infusion-related reactions (“IRRs”) (consisting of flushing, feeling of warmth, headache, nausea or dizziness) which occurred mostly, but not exclusively, during the first infusion. Temporal interruption of the AK002 infusion and minimal intervention generally resulted in prompt resolution of symptoms and ability to resume the infusion without further complications, although there have been instances when an IRR has resulted in a subject being discontinued from a trial. Subjects in our ongoing and planned clinical trials may in the future suffer other significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. If clinical trials of our product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, development and commercialization of our product candidates.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, the EMA, other applicable regulatory authorities or an institutional review board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical testing.

The FDA, EMA and applicable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We currently conduct clinical trials both in the United States and in other countries. We may in the future choose to conduct additional clinical trials in countries outside the United States, including in Europe. The acceptance of study data by the FDA, EMA or applicable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice and (ii) the trials are performed by clinical investigators of recognized competence and pursuant to current good clinical practices regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements.

Any regulatory approvals that we may receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements, such as boxed warning on the packaging, to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices (“cGMPs”) and good clinical practices (“GCPs”), for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and foreign regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending BLAs or supplements to approved BLAs.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

We may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA, from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. We have obtained orphan drug designation for EG and EGE in the United States and for ISM in the United States and European Union. We expect to seek orphan drug designation for AK002 for other gastrointestinal diseases and may seek orphan drug designations for other indications or for other of our product candidates. There can be no assurances that we will be able to obtain such designations.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full BLA or NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Although we may seek a breakthrough therapy designation for AK002 or one or more of our other product candidates, we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek a breakthrough therapy designation for AK002 in one or more indications or for other product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The Trump Administration and certain members of Congress have made various efforts to repeal all or portions of the Affordable Care Act (“ACA”), including suspending the penalties for failing to comply with the individual insurance mandate, removing funds designed to drive enrollment in the program, repealing the “Cadillac tax” on certain high-cost, employee-sponsored health insurance plans and coming within a single vote in the U.S. Senate of repealing the ACA altogether. There is uncertainty with respect to the impact future actions by the Trumps Administration or Congress may have and any changes likely will take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any further healthcare reform legislation or the impact of potential legislation on us. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. For example, the Trump Administration has contemplated certain executive actions and campaigned upon policies aiming to lower the cost of prescription drugs in the U.S., including possibly implementing a “most favored nations” clause where the U.S. would pay no more than the country with the lowest prescription drug prices. Similarly, many of Democratic candidates for the 2020 Presidential election have made drug price reform a focal point of their presidential campaigns. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

If we fail to comply with applicable U.S. and foreign privacy and data protection laws and regulations, we may be subject to liabilities that adversely affect our business, operations and financial performance.

We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, disclosure and storage of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act (the “CCPA”), which takes effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that

may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

We may also be subject to or affected by foreign laws and regulations, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials and our other operations in the U.S. and abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. For example, the EU has adopted the General Data Protection Regulation (the “GDPR”), which introduces strict requirements for processing personal data. The GDPR increases our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. The processing of sensitive personal data, such as information about health conditions, entails heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4% of annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR’s various requirements, significant effort and expense are required to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR and guidance issued by different EU member states may change periodically or may be modified, and such changes or modifications could have an adverse effect on our business operations if compliance becomes substantially costlier than under current requirements. It is also possible that each of these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Further, Brexit has created uncertainty with regard to data protection regulation in the UK. In particular, it is unclear whether, post Brexit, the UK will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program,

with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information was made publicly available on a searchable website in September 2014 and will be disclosed on an annual basis; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third-parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third-parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential

liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business activities may be subject to the Foreign Corrupt Practices Act (“FCPA”), the UK Bribery Act 2010 (“UK Bribery Act”), and other similar anti-bribery and anti-corruption laws of other countries in which we operate.

We have conducted and have ongoing studies in international locations, and may in the future initiate additional studies in countries other than the United States. Our business activities may be subject to the FCPA, the UK Bribery Act and other similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

Our success is highly dependent on the services of our Chief Executive Officer, Dr. Robert Alexander, and our President and Chief Operating Officer, Dr. Adam Tomasi, and our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff, particularly our Chief Executive Officer, Dr. Robert Alexander, and our President and Chief Operating Officer, Dr. Adam Tomasi. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers, including Dr. Alexander or Dr. Tomasi, could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

If we are unable to establish sales or marketing capabilities or enter into agreements with third-parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team for the marketing, sales and distribution of any of our product candidates that may be able to obtain regulatory approval. In order to commercialize any product candidates, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third-parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third-parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third-parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third-parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third-parties, our future product revenue will suffer and we may incur significant additional losses.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

At June 30, 2019, we had 68 full-time employees, including 46 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for AK002 and any other future product candidates, while complying with any contractual obligations to contractors and other third-parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize AK002 and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of clinical management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of AK002 and any other future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize AK002 and any other future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We may experience disruptions and delays or incur financial damages as a result of system failures or security breaches.

Despite the implementation of security measures, any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Any system failure, accident or security breach that causes interruptions in our own or in third-party service providers' operations could result in a material disruption of our drug discovery and development programs. A system failure or security breach that causes the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. In addition, to the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our drug discovery programs and competitive position may be adversely affected, and further development of our product candidates may be delayed. Any such disruption, failure or security breach could also cause us to incur additional costs to remedy the damages that arise from such disruption, failure or security breach.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business.

Our facility is located in a seismically active region and in a state, which also experiences large scale wildfires from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. We maintain multiple copies of each of our antibody sequences and electronic data records, most of which we maintain at our headquarters. If our facility were impacted by a seismic event, we could lose all our antibody sequences, which would have an adverse effect on our ability to perform our obligations under our collaborations and discover new targets.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2018, we had gross U.S. federal and state net operating loss carryforwards of \$101.2 million and \$39.5 million, respectively, which expire beginning in 2032. As of December 31, 2018, the Company had federal and California research and other tax credit carryforwards of \$3.8 million and \$2.5 million, respectively. It is possible that we will not generate taxable income in time to use our net operating loss carryforwards before their expiration or at all. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. We have not yet undertaken an analysis under Sections 382 and 383 of the Internal Revenue Code to see if any of our net operating loss carryforwards were limited as a result of our prior stock sales, including those made as part of our initial public offering. As a result, we may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Accordingly, our ability to utilize our net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to our company.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our and our current or future licensors' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have developed. We have also licensed from third-parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, and other licenses may not give us such rights.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current and future licensors will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third-parties and are reliant on our current and future licensors. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current and future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are highly uncertain. Our and our current or future licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current and future licensors to narrow the scope of the claims of our or our current and future licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained.

We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third-parties may initiate an opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our current or future licensors' patent applications cannot be enforced against third-parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our current and future licensors were the first to file any patent application related to a product candidate. Furthermore, if third-parties have filed such patent applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third-parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third-parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third-parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications. For example, some of the patents that we exclusively licensed from The Johns Hopkins University will expire in 2021, one of our owned patent families that claims one of the product candidates will expire in 2035 in the United States and similar patent applications are pending in foreign jurisdictions with a projected expiration date in 2034, at which time the underlying technology covered by such patents can be used by any third-party, including competitors. Although the patent term extensions under the Hatch-Waxman Act in the United States may be available to extend the patent term, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long.

Due to the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical

to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA and the U.S. Patent and Trademark Office (“USPTO”) in the United States, and any equivalent foreign regulatory authority, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our current and future licensors’ intellectual property rights may not exist in some countries outside the United States or may be less extensive in some countries than in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our current and future licensors may not be able to prevent third-parties from practicing our and our current or future licensors’ inventions in all countries outside the United States, or from selling or importing products made using our and our current or future licensors’ inventions in and into the United States or other jurisdictions. Competitors may use our and our current or future licensors’ technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our current and future licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our and our current or future licensors’ patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us and our current and future licensors to stop the infringement of our and our current or future licensors’ patents or marketing of competing products in violation of our and our current or future licensors’ proprietary rights generally. Proceedings to enforce our and our current or future licensors’ patent rights in foreign jurisdictions could result in substantial costs and divert our and our current or future licensors’ efforts and attention from other aspects of our business, could put our and our current or future licensors’ patents at risk of being invalidated or interpreted narrowly and our and our current or future licensors’ patent applications at risk of not issuing and could provoke third-parties to assert claims against us or our current and future licensors. We or our current and future licensors may not prevail in any lawsuits that we or our current and future licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third-parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or our current and future licensors are forced to grant a license to third-parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (“Leahy-Smith Act”), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the

U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our current and future licensors fail to maintain the patents and patent applications covering our product candidates, our patent protection could be reduced or eliminated and our competitors might be better able to enter the market with competing products.

If our trademark and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

We cannot assure you that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. In addition, we do not own any registered trademarks for the mark “ALLAKOS.” We cannot assure you that any future trademark applications that we will file will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third-parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings, which may force us to rebrand our name.

If we breach the license agreements related to our product candidates, we could lose the ability to continue the development and commercialization of our product candidates.

Our commercial success depends upon our ability, and the ability of our current and future licensors, to develop, manufacture, market and sell our product candidates and use our and our current or future licensors’ wholly-owned technologies without infringing the proprietary rights of third-parties. A third-party may hold intellectual property, including patent rights that are important or necessary to the development of our products. As a result, we are a party to a number of technology licenses that are important to our business. For example, we have obtained an exclusive license under certain intellectual property related to Siglec-8 from The Johns Hopkins University to develop certain products and a non-exclusive license from BioWa and Lonza to develop and commercialize products manufactured in a particular mammalian host cell line. If we fail to comply with the obligations under these agreements, including payment and diligence terms, our current and future licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current and future licensors and us; and

- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Third-parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third-parties to challenge the validity or scope of intellectual property rights controlled by third-parties, the outcome of which would be uncertain and could have an adverse effect on the success of our business.

Third-parties may initiate legal proceedings against us or our current and future licensors alleging that we or our current and future licensors infringe their intellectual property rights, or we or our current and future licensors may initiate legal proceedings against third-parties to challenge the validity or scope of intellectual property rights controlled by third-parties, including in oppositions, interferences, reexaminations, *inter partes* reviews or derivation proceedings in the United States or other jurisdictions. These proceedings can be expensive and time-consuming, and many of our or our current and future licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our current and future licensors.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. An unfavorable outcome could require us or our current and future licensors to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our current and future licensors a license on commercially reasonable terms or at all. Even if we or our current and future licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our current and future licensors. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business.

We may be subject to claims by third-parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biopharmaceutical companies, including potential competitors. Some of these employees executed proprietary rights, non-disclosure and/or non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Trade secrets can be difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, contract manufacturers, consultants, advisors and other third-parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of the parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or

information to compete with us. Failure on our part to adequately protect our trade secrets and our confidential information would harm our business and our competitive position.

Risks Related to Our Dependence on Third-Parties

We rely on third-parties to conduct our clinical trials and those third-parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

We do not have the ability to independently conduct our clinical trials. We currently rely on third-parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials of AK002 and expect to continue to rely upon third-parties to conduct additional clinical trials of AK002 and our other product candidates. Third-parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third-parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third-party will devote to our clinical trials. Some of these third-parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our drug development activities.

Our reliance on these third-parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third-parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. If these third-parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We contract with third-parties for the production of our product candidates for preclinical studies and, in the case of AK002, our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third-parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. In the case of AK002, we rely on a single third-party manufacturer, Lonza, and we currently have no alternative manufacturer in place. We do not have long-term supply agreements and we purchase our required drug product on a purchase order basis. If we were to experience an unexpected loss of supply of AK002, or any of our other product candidates, for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Replacement of our sole manufacturer of AK002 would result in substantial delay and interrupt our clinical trials involving AK002.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third-party to manufacture our product candidate according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;

- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible failure of the third-party to manufacture our product candidates according to our specifications;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners, including Lonza, for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers, including Lonza, cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs and harm our business and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

We may not gain the efficiencies we expect from further scale-up of manufacturing of AK002, and our third-party manufacturers may be unable to successfully scale-up manufacturing in sufficient quality and quantity for AK002 or our other product candidates, which could delay or prevent the conducting of our clinical trials or the development or commercialization of our other product candidates.

Our third-party manufacturer, Lonza, is currently manufacturing AK002 at a scale that is sufficient for us to complete our planned clinical trials and, if we receive marketing approval, to commercialize AK002 for the indications we are currently targeting. However, we may consider increasing the batch scale to gain cost efficiencies. If Lonza is unable to scale-up the manufacture of AK002 at such time, we may not gain such cost efficiencies and may not realize the benefits that would typically be expected from further scale-up of manufacturing of AK002.

In addition, in order to conduct clinical trials of any of our other product candidates, we may need to manufacture them in large quantities. Our third-party manufacturers, including Lonza, may be unable to successfully increase the manufacturing capacity for any of these product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our third-party manufacturers are unable to successfully scale up the manufacture of our other product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical and late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform

differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing biologics, especially in large quantities, is complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. Lonza, our current third-party manufacturer, has, and our future third-party manufacturers may have, multiple locations at which they conduct manufacturing. However, AK002 and our other product candidates are currently only being manufactured at one of Lonza's locations. If this location becomes unavailable at its anticipated capacity or the location of the manufacture of AK002 or our other product candidates is changed for any reason, it could result in a delay or disruption to the manufacturing process or lead to difficulties that we did not experience at the original manufacturing location. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If we decide to establish collaborations, but are not able to establish those collaborations, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third-parties.

We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Risks Related to Ownership of Our Common Stock

The market price of our stock may continue to be volatile, which could result in substantial losses for investors.

The trading price of our common stock has been, and is likely to continue to be, highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. We priced our IPO at \$18.00 per share on July 19, 2018 and, our common stock reached a high of \$65.48 per share during the fourth quarter of 2018. As of July 31, 2019, the closing price of our common stock was \$34.77. The trading price of our common stock could be subject to wide fluctuations in response to various factors, which in addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, include:

- the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts covering us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. In addition, if one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Raising additional capital may restrict our operations or require us to relinquish rights to our technologies or product candidates, and if we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, partnerships and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. We may also from time to time issue additional shares of common stock at a discount from the then current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee’s requisite

service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical trials for AK002 and any of our future product candidates or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with AK002 and any of our future product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of AK002 or any of our future product candidates;
- the level of demand for AK002 and any of our future product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future products that compete with AK002 and any of our future product candidates;
- our ability to commercialize AK002 and any of our future product candidates, if approved, inside and outside of the United States, either independently or working with third-parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of June 30, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 79.5% of our outstanding voting stock. As a result, this group of stockholders has the ability to significantly influence all matters requiring stockholder approval, including the election of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (“Sarbanes-Oxley Act”), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (ii) the date on which we have issued more than \$1 billion in non-convertible debt during the prior three-year period.

Based on our public float at June 30, 2019, we will cease to be an emerging growth company at December 31, 2019 and, accordingly, we will be required to comply with the auditor attestation requirements of Section 404 to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting for our 2019 Annual Report on Form 10-K.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We will likely incur significant additional costs in order to comply with the SEC rules implementing Section 404 of the Sarbanes-Oxley Act.

We will likely incur significant additional costs in order to comply with the SEC rules implementing Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our annual report on Form 10-K for the year ending December 31, 2019, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We have not paid and do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware ("DGCL"), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (such provision, the "Federal Forum Provision"). However, on December 19, 2018, the Delaware Court of Chancery issued a decision in *Matthew Sciabacucchi v. Matthew B. Salzberg et al.*, C.A. No. 2017-0931-JTL (Del. Ch.), finding that such provisions such as the Federal Forum Provision are not valid under Delaware law. In light of this decision of the Delaware Court of Chancery, we do not intend to enforce the federal forum provision in our amended and restated certificate of incorporation unless and until such time there is a final determination by the Delaware Supreme Court regarding the validity of such provisions. If the decision is not appealed or if the Delaware Supreme Court affirms the Delaware Chancery Court's decision, then we will seek approval by our stockholders to amend our certificate of incorporation at our next regularly-scheduled annual meeting of stockholders to remove the Federal Forum Provision.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

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

There were no unregistered securities sold by us during the six months ended June 30, 2019.

Use of Proceeds

On July 18, 2018, our Registration Statement on Form S-1 (File No. 333-225836) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 8,203,332 shares of our common stock, including 1,069,999 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price of \$18.00 per share. The aggregate offering price for shares sold in the offering was \$147.7 million. Goldman Sachs & Co. LLC and Jefferies LLC acted as joint book-running managers for the offering, and William Blair & Company, L.L.C. acted as the lead manager for the offering. On July 23, 2018, we closed the sale of such shares, resulting in aggregate cash proceeds to us of approximately \$133.9 million, net of underwriting discounts, commissions and offering expenses paid or payable by us. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO, as described in our final prospectus filed with the SEC on July 19, 2018 pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

Item 3. Defaults Upon Senior Securities.

Not applicable

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

None

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Number	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38582	3.1	7/24/2018
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-38582	3.2	7/24/2018
10.8+	Employment Letter between the Registrant and Leo Redmond.				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

** Furnished herewith.

+ Indicates management contract or compensatory plan.

SIGNATURES

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

Allakos Inc.

Date: August 5, 2019

By: /s/ Robert Alexander

Robert Alexander
Chief Executive Officer
(Principal Executive Officer)

Date: August 5, 2019

By: /s/ Leo Redmond

Leo Redmond
Chief Financial Officer
(Principal Financial and Accounting Officer)

July 24, 2019

Leo Redmond
2711 Martinez Dr.
Burlingame, CA 94010

Re: Employment Offer Letter

Dear Leo:

I am pleased to provide you this offer of employment with Allakos Inc. (the “Company”) on the terms set forth below. Subject to all conditions in this offer letter, your employment will begin on August 1, 2019 (“Start Date”).

1. *Title; Position.* You will serve as the Company’s Chief Financial Officer. You will report to the Company’s Chief Executive Officer and will perform the duties and responsibilities customary for such position and such other related duties as are lawfully assigned by the Company’s Chief Executive Officer. You will report for work to the Company’s Redwood City office: 975 Island Dr., Redwood City, CA 94065 on your Start Date.

While you render services to the Company, you will not engage in any other employment, consulting or other business activity (whether full-time or part-time) that would create a conflict of interest with the Company. You may engage in civic and not-for-profit activities as long as such activities do not interfere with the performance of your duties under this letter. By signing this letter, you confirm that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties for the Company.

2. *Base Salary.* As of the Start Date, your annual base salary will be \$390,000, which will be payable, less any applicable withholdings, in accordance with the Company’s normal payroll practices. Your annual base salary will be subject to review and adjustment from time to time by our Board or its Compensation Committee (the “Committee”), as applicable, in its sole discretion.
 3. *Annual Bonus.* You will have the opportunity to earn an annual target cash bonus initially equal to 40% of your annual base salary, based on achieving performance objectives established by the Board or Committee, as applicable, in its sole discretion and payable upon achievement of those objectives as determined by the Committee. For the first year, you will be eligible to receive a pro-rated amount of any achieved portion of your bonus based on the number of days during the calendar year in which you are employed with the Company.
-

Unless determined otherwise by the Board or Committee, as applicable, any such bonus will be subject to your continued employment through and until the date of payment. Your annual bonus opportunity and the applicable terms and conditions may be adjusted from time to time by our Board or the Committee, as applicable, in its sole discretion.

4. *Stock Option.* Subject to the approval of the Board or the Committee, as applicable, you will be granted an option to purchase 120,000 shares of the Company's common stock (the "*Option*"). The Option will be granted under and subject to the terms and conditions of the Company's 2018 Equity Incentive Plan (the "*Plan*") and the applicable stock option agreement thereunder (collectively, the "*Option Documents*"). The Option will have an exercise price per share equal to the closing price per share of the Company's common stock on the date the Option is granted. The Option will vest as to 25% of the shares subject to the Option on the one (1) year anniversary of your Start Date, and as to 1/48th of the shares subject to the Option monthly thereafter on the same day of the month as the Start Date (and if there is no corresponding day, the last day of the month) so that the Option will be fully vested and exercisable 4 years from your Start Date, for so long as you remain in service with the Company. No right to any stock will be earned or accrued until such time that vesting occurs, nor does the grant of the Option confer any right to continued vesting or employment.
5. *Employee Benefits.* You will be eligible to participate in the benefit plans and programs established by the Company for its employees from time to time, subject to their applicable terms and conditions, including without limitation any eligibility requirements. The Company reserves the right to modify, amend, suspend or terminate the benefit plans and programs it offers to its employees at any time.
6. *Severance.* You will be eligible to participate in the Company's Change in Control and Severance Policy (the "*Policy*") based on your position within the Company. The Policy and a participation agreement thereunder (the "*Participation Agreement*") will specify the severance payments and benefits you may become entitled to receive in connection with certain qualifying terminations of your employment with the Company.
7. *Confidentiality Agreement.* As an employee of the Company, you will continue to have access to certain confidential information of the Company and you may, during the course of your employment, develop certain information or inventions that will be the property of the Company. To protect the interests of the Company, your acceptance of this letter confirms that the terms of the Company's At-Will Employment, Confidential Information, Invention Assignment, Nonsolicitation, and Arbitration Agreement you previously signed with the Company (the "*Confidentiality Agreement*") still apply.
8. *At-Will Employment.* This letter does not imply any right to your continued employment for any period with the Company or any of its affiliates. Your employment with the Company will continue to be "at will." It is for no specified term, and may be terminated by you or the Company at any time, with or without cause or advance notice.
9. *Documentation.* To comply with applicable laws, you must complete an Employee Eligibility Form (I-9) and provide proof of identity and authorization to work in the United

States. You must provide the Company with such documentation within three (3) business days of your Start Date, or your employment may be terminated.

10. *Miscellaneous.* This letter, together with the Confidentiality Agreement, the Option Documents, the Policy, the Participation Agreement, and any outstanding equity awards granted to you by the Company under its equity plans(s) and the applicable award agreements thereunder, constitute the entire agreement between you and the Company regarding the material terms and conditions of your employment, and they supersede and replace all prior negotiations, representations or agreements between you and the Company. This letter may be modified only by a written agreement signed by you and a duly authorized officer of the Company.

To accept this offer of employment, please sign and date in the spaces indicated and return it to me as soon as possible.

Sincerely,

Allakos Inc.

By: /s/ Robert Alexander
Robert Alexander

Agreed to and accepted:

/s/ Leo Redmond
Leo Redmond

Dated: July 31, 2019

Enclosures:

At-Will Employment, Confidential Information, Invention Assignment, Nonsolicitation, and Arbitration Agreement
Background Check Authorization Form

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Allakos Inc. (the "Company") on Form 10-Q for the period ending June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 5, 2019

By: _____ /s/ Robert Alexander

Robert Alexander
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Allakos Inc. (the "Company") on Form 10-Q for the period ending June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 5, 2019

By: _____ /s/ Leo Redmond
Leo Redmond
Chief Financial Officer
(Principal Financial and Accounting Officer)