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 September 30, 2020

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: 001-38682

KODIAK SCIENCES INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-0476525**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1200 Page Mill Road	
Palo Alto, CA	**94304**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 281-0850

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 $0.0001	KOD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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, a 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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of October 31, 2020, the registrant had 44,803,447 shares of common stock, $0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith beliefs as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, or similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those set forth under the section of this Quarterly Report on Form 10-Q titled "Part II, Item 1A — Risk Factors" and elsewhere in this report. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our development activities, preclinical studies, clinical trials and regulatory filings;
- the translation of our preclinical results and data and early clinical trial results in particular relating to safety, efficacy and durability into future clinical trials in humans;
- the continued durability, efficacy and safety of our product candidates;
- our ability to achieve our "2022 Vision" of a Biologics License Application, or BLA, of KSI-301 in 2022;
- the number, size and design of clinical trials that regulatory authorities may require to obtain marketing approval, including the order and number of clinical studies required to support a BLA in wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, retinal vein occlusion, or RVO, and diabetic retinopathy, or DR;
- the timing or likelihood of regulatory filings and approvals, including the potential to achieve the U.S. Food and Drug Administration, or FDA, approval of KSI-301 in wet AMD, DME, RVO and DR;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to develop, manufacture and commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- the success of competing products or platform technologies that are or may become available;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain approval;
- our expectation as to the concentration of retinal specialists in the United States and its impact on our sales and marketing plans;
- our expectations regarding our ability to enter into manufacturing-related commitments, and the timing thereof;
- future agreements with third parties in connection with the commercialization of our product candidates;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- existing regulations and regulatory developments in the United States and foreign countries;
- the expected potential benefits of strategic collaboration agreements and our ability to attract collaborators with development, regulatory and commercialization expertise;

- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- potential claims relating to our intellectual property and third-party intellectual property;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the pricing and reimbursement of our product candidates, if approved;
- our estimates regarding the impact of the ongoing COVID-19 pandemic on our business and operations, the business and operations of our collaborators, and on the global economy;
- our ability to attract and retain key managerial, scientific and medical personnel;
- the accuracy of our estimates regarding the sufficiency of our cash resources, expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance; and
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act.

All forward-looking statements are based on information available to us on the date of this Quarterly Report on Form 10-Q and we will not update any of the forward-looking statements after the date of this Quarterly Report on Form 10-Q, except as required by law. Our actual results could differ materially from those discussed in this Quarterly Report on Form 10-Q. The forward-looking statements contained in this Quarterly Report on Form 10-Q, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, and you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Factors that might cause such a difference include, but are not limited to, those discussed in the following discussion and within the section of this Quarterly Report on Form 10-Q titled "Part II, Item 1A — Risk Factors".

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "Kodiak" the "Company," "we," "us," and "our" refer to Kodiak Sciences Inc.

SELECTED RISKS AFFECTING OUR BUSINESS

Investing in our common stock involves numerous risks, including the risks described in "Part II—Other Information, Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q, any one of which could materially adversely affect our business, financial condition, results of operations, and prospects. These risks include, among others, the following:

- We are in the clinical stage of drug development and have a very limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur significant and increasing net losses for the foreseeable future.
- Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, and we may never generate revenue or be profitable.
- If we fail to obtain additional financing, we may be unable to complete the development and, if approved, commercialization of our product candidates.
- Our prospects are heavily dependent on our KSI-301 product candidate, which is currently in clinical development for multiple indications.
- A failure of KSI-301 in clinical development may require us to discontinue development of other product candidates based on our ABC Platform.
- Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory, including marketing, approval, which is necessary before they can be commercialized.
- We may encounter substantial delays in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may retain their market share with existing drugs, or achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.
- The manufacture of our product candidates is highly complex and requires substantial lead time to produce.
- We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.
- We contract with third parties for the manufacture of materials for our product candidates and preclinical studies and clinical trials and for commercialization of any product candidates that we may develop. This reliance on third parties carries and may increase the risk that we will not have sufficient quantities of such materials, product candidates or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- If we are unable to obtain and maintain patent protection for any product candidates we develop or for our ABC Platform, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.
- Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our ABC Platform, product candidates and other technologies.
- Our business is currently affected and could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, including the ongoing effects of the COVID-19 pandemic. The COVID-19 pandemic continues to impact our business and could materially and adversely affect our operations, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

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Item 1. Financial Statements (Unaudited).

Kodiak Sciences Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 291,585	$ 211,797
Marketable securities	88,865	124,684
Prepaid expenses and other current assets	1,295	2,749
Total current assets	381,745	339,230
Marketable securities	—	11,696
Restricted cash	11,015	140
Property and equipment, net	3,568	996
Operating lease right-of-use asset	75,542	1,790
Other assets	8,866	5,014
Total assets	$ 480,736	$ 358,866
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,269	$ 2,619
Accrued and other current liabilities	16,219	8,658
Operating lease liability	1,017	434
Total current liabilities	22,505	11,711
Operating lease liability, net of current portion	76,307	1,501
Liability related to sale of future royalties	99,877	—
Other liabilities	267	295
Total liabilities	198,956	13,507
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value, 490,000,000 shares authorized at September 30, 2020 and December 31, 2019; 44,760,513 and 44,413,404 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	5	5
Additional paid-in capital	526,174	503,475
Accumulated other comprehensive income	245	10
Accumulated deficit	(244,644)	(158,131)
Total stockholders' equity	281,780	345,359
Total liabilities and stockholders' equity	$ 480,736	$ 358,866

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

Kodiak Sciences Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses				
Research and development	$ 29,306	$ 10,115	$ 70,033	$ 24,676
General and administrative	7,357	2,617	19,132	8,330
Total operating expenses	36,663	12,732	89,165	33,006
Loss from operations	(36,663)	(12,732)	(89,165)	(33,006)
Interest income	645	277	2,551	1,070
Interest expense	(6)	(2)	(19)	(8)
Other income (expense), net	(98)	77	120	195
Net loss	$ (36,122)	$ (12,380)	$ (86,513)	$ (31,749)
Net loss per common share, basic and diluted	$ (0.80)	$ (0.33)	$ (1.92)	$ (0.85)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	45,119,885	37,330,066	44,972,085	37,291,328
Other comprehensive income (loss)				
Change in unrealized gains related to available-for-sale debt securities, net of tax	(349)	7	235	19
Total other comprehensive income (loss)	(349)	7	235	19
Comprehensive loss	$ (36,471)	$ (12,373)	$ (86,278)	$ (31,730)

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

Kodiak Sciences Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share and per share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	44,413,404	$ 5	$ 503,475	$ 10	$ (158,131)	$ 345,359
Issuance of common stock upon exercise of stock options	39,297	—	159	—	—	159
Stock-based compensation expense	—	—	6,082	—	—	6,082
Other comprehensive income	—	—	—	479	—	479
Net loss	—	—	—	—	(24,392)	(24,392)
Balances at March 31, 2020	44,452,701	5	509,716	489	(182,523)	327,687
Issuance of common stock upon exercise of stock options	203,373	—	720	—	—	720
Issuance of common stock upon vesting of restricted stock units, net of taxes withheld	10,942	—	(206)	—	—	(206)
Stock-based compensation expense	—	—	6,890	—	—	6,890
Other comprehensive income	—	—	—	105	—	105
Net loss	—	—	—	—	(25,999)	(25,999)
Balances at June 30, 2020	44,667,016	5	517,120	594	(208,522)	309,197
Issuance of common stock upon exercise of stock options	93,497	—	813	—	—	813
Stock-based compensation expense	—	—	8,241	—	—	8,241
Other comprehensive loss	—	—	—	(349)	—	(349)
Net loss	—	—	—	—	(36,122)	(36,122)
Balances at September 30, 2020	44,760,513	5	526,174	245	(244,644)	281,780

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2018	36,829,857	$ 4	$ 197,595	$ —	$ (110,766)	$ 86,833
Issuance of common stock upon exercise of stock options	80,000	—	83	—	—	83
Stock-based compensation expense	—	—	1,157	—	—	1,157
Other comprehensive income	—	—	—	6	—	6
Net loss	—	—	—	—	(7,984)	(7,984)
Balances at March 31, 2019	36,909,857	4	198,835	6	(118,750)	80,095
Issuance of common stock upon exercise of stock options	21,284	—	59	—	—	59
Stock-based compensation expense	—	—	1,244	—	—	1,244
Other comprehensive income	—	—	—	6	—	6
Net loss	—	—	—	—	(11,385)	(11,385)
Balances at June 30, 2019	36,931,141	4	200,138	12	(130,135)	70,019
Issuance of common stock upon exercise of stock options	77,855	—	272	—	—	272
Issuance of common stock upon exercise of common stock warrant	1	—	—	—	—	—
Stock-based compensation expense	—	—	1,773	—	—	1,773
Other comprehensive income	—	—	—	7	—	7
Net loss	—	—	—	—	(12,380)	(12,380)
Balances at September 30, 2019	37,008,997	4	202,183	19	(142,515)	59,691

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

Kodiak Sciences Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (86,513)	$ (31,749)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	317	405
Stock-based compensation	21,213	4,174
Amortization (accretion) of premium (discount) on marketable securities	(145)	(195)
Amortization of operating lease right-of-use asset	1,793	276
Amortization of issuance costs	36	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	1,518	1,782
Other assets	(3,654)	(4,365)
Accounts payable	1,616	620
Accrued and other current liabilities	7,566	1,480
Operating lease liability	(156)	(281)
Net cash used in operating activities	(56,409)	(27,853)
Cash flows from investing activities		
Purchase of property and equipment	(1,855)	(284)
Purchase of marketable securities	(86,317)	(40,231)
Maturities of marketable securities	134,148	16,800
Net cash provided by (used in) investing activities	45,976	(23,715)
Cash flows from financing activities		
Proceeds from issuance of common stock upon options exercise	1,692	414
Payments for restricted stock units, net of taxes withheld	(206)	—
Proceeds from sale of future royalties, net of issuance costs	99,643	—
Principal payments of capital lease	(5)	(41)
Principal payments of tenant improvement allowance payable	(28)	(26)
Net cash provided by financing activities	101,096	347
Net increase (decrease) in cash, cash equivalents and restricted cash	90,663	(51,221)
Cash, cash equivalents and restricted cash, at beginning of period	211,937	88,394
Cash, cash equivalents and restricted cash, at end of period	$ 302,600	$ 37,173
Reconciliation of cash, cash equivalents and restricted cash to consolidated balance sheets		
Cash and cash equivalents	$ 291,585	$ 37,033
Restricted cash	11,015	140
Cash, cash equivalents and restricted cash in consolidated balance sheets	$ 302,600	$ 37,173
Supplemental disclosures of non-cash investing and financing information:		
Operating lease right-of-use asset obtained in exchange for operating lease liability	$ 75,545	$ 2,163
Purchase of property and equipment under accounts payable	$ 1,034	$ 137

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

1. The Company

Kodiak Sciences Inc. (the "Company") is a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases in the United States and additional international markets. The Company devotes substantially all of its resources to the research and development of its product candidates including activities to conduct clinical studies of its product candidates, manufacture product candidates and provide general and administrative support for these operations.

Liquidity

As of September 30, 2020, the Company had cash, cash equivalents and marketable securities of $380.5 million. Although the Company has incurred significant operating losses since inception and expects to continue to incur operating losses and negative operating cash flows for the foreseeable future, the Company believes that the cash, cash equivalents and marketable securities will be sufficient to meet the anticipated operating and capital expenditure requirements for the 12 months following the date of this Form 10-Q.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") applicable to interim periods. The condensed consolidated financial statements, in the opinion of management, include all normal and recurring adjustments necessary to present fairly the Company's financial position and results of operations for the reported periods.

These condensed consolidated financial statements have been prepared on a basis substantially consistent with, and should be read in conjunction with the audited financial statements for the year ended December 31, 2019 and notes thereto, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 16, 2020. Certain information and note disclosures normally included in the audited financial statements prepared in accordance with GAAP have been condensed or omitted from this report. The results of operations for any interim period are not necessarily indicative of the results for the year ending December 31, 2020, or for any future period.

The accompanying condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Reclassification

Certain prior period amounts have been reclassified to conform to the current period presentation. Such reclassifications had no impact on subtotals in the prior year condensed consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and expenses during the reporting period. The impact of the ongoing COVID-19 pandemic continues to evolve. As a result, certain estimates and assumptions required increased judgment and carried a higher degree of variability and volatility, including but not limited to, the fair value of marketable securities, performance-based equity awards, and research and development accruals for the three and nine months ended September 30, 2020. As events continue to unfold and additional information becomes available, these estimates may change materially in future periods. Actual results could differ from those estimates.

Risks and Uncertainties

In March 2020, the World Health Organization declared a pandemic due to the global COVID-19 outbreak. The significant uncertainties caused by the ongoing COVID-19 pandemic may negatively impact the Company's operations, liquidity, and capital resources and will depend on certain evolving developments, including the duration and spread of the outbreak, regulatory and private sector responses and the impact on employees and vendors including supply chain and clinical partners, all of which are uncertain and cannot be predicted. During this pandemic, the Company continues to work closely with clinical sites towards maximal patient safety and the lowest number of missed visits and study discontinuations. The Company has taken and continues to take proactive measures to maintain the integrity of its ongoing clinical studies. Despite these efforts, the ongoing COVID-19 pandemic could significantly impact clinical trial enrollment and completion of its clinical studies. The Company will continue to monitor the COVID-19 situation and its impact on the ability to continue the development of, and seek regulatory approvals for, the Company's product candidates, and begin to commercialize any approved products.

Summary of Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and nine months ended September 30, 2020 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, except as noted below with respect to the Company's liability related to sale of future royalties and as noted within the "Recent Accounting Pronouncements – Recently Adopted Accounting Pronouncements" section.

Liability related to Sale of Future Royalties

On December 1, 2019, the Company and its subsidiary Kodiak Sciences GmbH entered into a funding agreement with Baker Bros. Advisors, LP ("BBA"), which holds more than 5% of the Company's stock, pursuant to which BBA purchased the right to receive a capped 4.5% royalty on future net sales of KSI-301, the Company's anti-VEGF antibody biopolymer conjugate therapy, in exchange for $225.0 million. Under the terms of the funding agreement, there is no obligation to repay any funding amount received, other than through the capped royalty payments on future product revenues. The Company recorded the funding amount paid by BBA as a liability on the consolidated balance sheet net of issuance costs, in accordance with ASC 730, *Research and Development*. Under ASC 730, the significant related party relationship between the Company and BBA creates an implicit obligation to repay the funding amount paid to the Company. Once royalty payments to BBA are determined to be probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest to accrete the liability on a prospective basis based on such estimates. If and when the Company makes royalty payments under the funding agreement, it would reduce the liability balance at such time. Refer to Note 7.

Credit Losses – Available-for-Sale Debt Securities

For available-for-sale debt securities in an unrealized loss position, the Company will periodically assess its portfolio for impairment. The assessment first considers the intent or requirement to sell the security. If either of these criteria are met, the amortized cost basis will be written down to fair value through earnings.

If not met, the Company will evaluate whether the decline resulted from credit losses or other factors by considering the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and any adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security is compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses will be recorded, limited by the amount that the fair value is less than the amortized cost basis. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive income or loss, as applicable.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB"), under its ASC or other standard setting bodies, and adopted by the Company as of the specified effective date, unless otherwise discussed below.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements*, which intends to improve financial reporting by requiring earlier recognition of credit losses on certain financial assets, such as available-for-sale debt securities. The Company assessed the impact of ASU 2016-13 on its available-for-sale debt securities and determined there were no credit losses within the portfolio requiring an allowance upon adoption. The Company adopted this new guidance as of January 1, 2020, which did not impact its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurements*, which eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of the FASB's disclosure framework project. Among the changes, entities will no longer be required to disclose the amount of and reasons for transfers between Levels 1 and 2 of the fair value hierarchy, but will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The Company adopted this new guidance as of January 1, 2020, which did not impact its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which clarifies the accounting for implementation, set-up, and other upfront costs incurred in cloud computing arrangements. The Company adopted this new guidance as of January 1, 2020, which did not impact its consolidated financial statements and related disclosures.

New Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2021. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial statements and related disclosures.

3. Accrued and Other Current Liabilities

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

	September 30, 2020	December 31, 2019
Accrued research and development	$ 12,364	$ 4,894
Accrued salaries and benefits	3,106	3,108
Accrued professional fees	290	195
Accrued legal fees	194	302
Accrued other liabilities	265	159
Total accrued and other current liabilities	$ 16,219	$ 8,658

4. Fair Value Measurements

The following tables present the Company's fair value hierarchy for assets measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at September 30, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 266,250	$ —	$ —	$ 266,250
Marketable securities:				
U.S. treasury securities	—	40,147	—	40,147
Commercial paper	—	5,983	—	5,983
Corporate notes	—	42,735	—	42,735
Total	$ 266,250	$ 88,865	$ —	$ 355,115

	Fair Value Measurements at December 31, 2019			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 155,276	$ —	$ —	$ 155,276
Repurchase agreements	50,000	—	—	50,000
Commercial paper	—	5,987	—	5,987
Marketable securities:				
U.S. treasury securities	—	50,185	—	50,185
Commercial paper	—	34,533	—	34,533
Corporate notes	—	51,662	—	51,662
Total	$ 205,276	$ 142,367	$ —	$ 347,643

5. Marketable Securities

The marketable securities are classified as available-for-sale and consist of U.S. treasury securities, commercial paper and corporate notes. The fair value measurement data for marketable securities is obtained from independent pricing services. The Company validates the prices provided by the third-party pricing services by understanding the valuation methods and data sources used and analyzing the pricing data in certain instances.

The following table summarizes the marketable securities held at September 30, 2020 and December 31, 2019 (in thousands):

As of September 30, 2020	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. treasury securities	$ 40,047	$ 100	$ —	$ 40,147
Commercial paper	5,983	—	—	5,983
Corporate notes	42,590	145	—	42,735
Total marketable securities, current	$ 88,620	$ 245	$ —	$ 88,865

As of December 31, 2019	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. treasury securities	$ 50,190	$ —	$ (5)	$ 50,185
Commercial paper	34,532	1	—	34,533
Corporate notes	39,956	13	(3)	39,966
Total marketable securities, current	$ 124,678	$ 14	$ (8)	$ 124,684
Corporate notes	$ 11,692	$ 4	$ —	$ 11,696
Total marketable securities, noncurrent	$ 11,692	$ 4	$ —	$ 11,696

All marketable securities held at September 30, 2020 and December 31, 2019 had contractual maturities of less than 18 months. There were no realized gains or losses recognized on the sale or maturity of available-for-sale debt securities during the three and nine months ended September 30, 2020 and 2019, respectively, and as a result, the Company did not reclassify any amounts out of accumulated comprehensive loss. As of September 30, 2020 and December 31, 2019, the Company had no allowance for credit losses for available-for-sale debt securities. There were no impairment charges or recoveries recorded during each of the three and nine months ended September 30, 2020 and 2019.

6. Commitments and Contingencies

Leases

Palo Alto, California Leases

In June 2020, the Company entered into lease agreements for two buildings at 1200 and 1250 Page Mill Road in Palo Alto, California, which are now the Company's U.S. headquarters. The facilities are approximately 82,662 square feet and 72,812 square feet, respectively and include office and laboratory space. For 1200 Page Mill Road, the monthly rent during the initial 6.5-year term will be approximately $0.6 million, with annual year-over-year increases of 3% plus certain operating expenses and taxes and total rent abatement of approximately $7.2 million. For 1250 Page Mill Road, the monthly rent during the initial 13-year term will be approximately $0.5 million, with annual year-over-year increases of 3% plus certain operating expenses and taxes and total rent abatement of approximately $6.3 million. The Landlord will provide a tenant improvement allowance of approximately $1.2 million and $10.6 million for each building, respectively. The Company executed a $10.9 million cash-collateralized letter of credit, which may be reduced in the future subject to the terms of the leases and certain reduction requirements specified therein. The cash collateralizing the letter of credit is classified as restricted cash on the Company's condensed consolidated balance sheets. Under ASC 842, the Company classified these leases as operating leases and recorded right-of-use assets and lease liabilities on the lease commencement date.

The Company continues to lease office and laboratory space at 2631 Hanover Street in Palo Alto, California. The Company entered into a lease agreement in January 2013 which was amended in March 2016 and extended the lease term until October 2023. The Company classified this lease as an operating lease and recorded a right-of-use asset and lease liability on January 1, 2019 and recognized rent expense on a straight-line basis throughout the remaining lease term.

Switzerland Lease

In April 2020, the Company entered into a lease agreement for office and laboratory space at Rottenstrasse 5 in Visp, Switzerland. The space is approximately 1,000 square meters. The monthly rent during the initial 5-year term will be approximately 0.03 million Swiss Francs plus certain operating expenses and taxes. Under ASC 842, the Company classified these leases as operating leases and recorded right-of-use assets and lease liabilities on the lease commencement date.

The maturities of the operating lease liabilities as of September 30, 2020 were as follows (in thousands):

Year ending December 31,	As of September 30, 2020
2020	$ 1,095
2021	4,617
2022	7,642
2023	15,136
2024	15,036
Thereafter	86,265
Total undiscounted lease payments	129,791
Less: imputed interest	(52,467)
Total operating lease liabilities	$ 77,324

Manufacturing Agreement

In August 2020, the Company and its subsidiary Kodiak Sciences GmbH entered into a manufacturing agreement with a contract manufacturing organization for the clinical and commercial supply of drug substance for KSI-301, the Company's proprietary therapeutic candidate for the treatment and prevention of retinal vascular diseases. A custom-built manufacturing suite is planned to be completed and dedicated to the manufacture of the Company's drug substance with an estimated capital contribution of 40 million Swiss Francs from the Company. Construction of the manufacturing suite is targeted for completion in 2021. The Company will be required to pay annual suite fees of 12 million Swiss Francs for 2021 and 16 million Swiss Francs for each year thereafter, which covers the manufacturing fees for a specified number of batches, and the Company may pay for additional batches to be manufactured. The manufacturing agreement has an initial term of eight years, and the Company has the right to extend the term up to a total of 16 years.

The Company concluded that this agreement contains an embedded lease as the custom-built manufacturing suite will be dedicated for the Company's use. As of September 30, 2020, the Company did not have control of this manufacturing space and therefore, did not record a right-of-use asset and corresponding lease liability. These commitments are not included in the above table.

Other Commitments and Contingencies

The Company has entered into service agreements with a variety of service providers, pursuant to which such service providers agreed to perform activities in connection with the manufacturing of certain materials. Such agreements, and related amendments, state that planned activities that are included in the signed work orders are, in some cases, binding and, hence, obligate the Company to pay the full price of the work order upon satisfactory delivery of products and services or obligate the Company to the binding amount regardless of whether such planned activities are in fact performed. Per the terms of the agreements, the Company has the option to cancel signed orders at any time upon written notice, which may or may not be subject to payment of a cancellation fee. The level of cancellation fees may be dependent on the timing of the written notice in relation to the commencement date of the work, with the maximum cancellation amount dependent on the agreement or the work order. As of September 30, 2020 and December 31, 2019, the total amount of cancelable and/or non-cancelable purchase obligations, including accrued amounts, under these agreements were $221.1 million and $4.7 million, respectively. Expense recognized under these agreements during the period, including amounts paid and accrued, for the three and nine months ended September 30, 2020 were $4.4 million and $12.0 million, respectively, and for the three and nine months ended September 30, 2019 were $2.7 million and $6.1 million, respectively. As of September 30, 2020, the Company had not incurred any cancellation fees. The Company has also entered into various cancellable license agreements for certain technology. The Company may be obligated to make payments on future sales of specified products associated with such license agreements. Such payments are dependent on future product sales and are not estimable.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of its business. Management is currently not aware of any matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows. The Company records a legal liability when it believes that it is both probable that a liability may be imputed, and the amount of the liability can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount.

Indemnification

To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not specified in the agreements; however, the Company has director and officer insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

7. Liability related to Sale of Future Royalties

On December 1, 2019, the Company and its subsidiary Kodiak Sciences GmbH entered into a funding agreement with Baker Bros. Advisors, LP ("BBA"), which holds more than 5% of the Company's stock, pursuant to which BBA purchased the right to receive a capped 4.5% royalty on future net sales of KSI-301, the Company's anti-VEGF antibody biopolymer conjugate therapy, in exchange for $225.0 million. The royalty terminates upon the date that BBA has received an aggregate amount equal to 4.5 times the funding amount paid to the Company, unless earlier terminated or repurchased by the Company. Under the terms of the funding agreement, there is no obligation to repay any funding amount received, other than through the capped royalty payments on future product revenues. The Company has the option, exercisable at any point during the term of the funding agreement, to repurchase 100% of the royalties due to BBA for a purchase price equal to 4.5 times the funding amount paid to the Company as of such time, less amounts paid by the Company to BBA.

The closing of the funding agreement was subject to certain conditions and occurred in February 2020. The Company received $100.0 million of the funding on February 4, 2020. The remaining $125.0 million shall be payable to the Company upon enrollment of 50% of the patients in the planned RVO clinical program.

The Company recorded the initial $100.0 million payment as a liability on the consolidated balance sheet net of issuance costs, in accordance with ASC 730, *Research and Development*. Under ASC 730, the significant related party relationship between the Company and BBA creates an implicit obligation to repay the funding amount paid to the Company. Once royalty payments to BBA are determined to be probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest to accrete the liability on a prospective basis based on such estimates. If and when the Company makes royalty payments under the funding agreement, it would reduce the liability balance at such time.

8. Stock-Based Compensation

In January 2020 and 2019, the number of shares of common stock available for issuance under the 2018 Equity Incentive Plan was increased by approximately by 1.8 million and 1.5 million shares, respectively, as a result of the automatic increase provision in the 2018 Plan.

Stock Options

Stock option activity under the 2018 Plan and 2015 Equity Incentive Plan is summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2019	6,671,542	$ 25.22	8.73	$ 362,081
Granted	1,032,085	$ 53.62		
Exercised	(336,167)	$ 5.05		
Forfeited or canceled	(129,097)	$ 23.06		
Outstanding at September 30, 2020	7,238,363	$ 23.50	8.28	$ 272,370

Restricted Shares

Restricted share activity, including restricted stock awards, restricted stock units, and performance-based restricted stock units, under the 2018 Plan and 2015 Plan is summarized as follows:

	Number of Restricted Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2019	160,747	$ 60.81
Granted	224,045	$ 49.85
Vested	(12,789)	$ 8.62
Shares withheld related to net share settlement of RSUs	(4,058)	$ 9.90
Canceled	(4,750)	$ 73.51
Unvested at September 30, 2020	363,195	$ 56.29

Performance-Based Stock Options and Restricted Stock Units

The Company granted 170,150 performance-based stock options and 128,900 performance-based restricted stock units (“RSUs”) to employees in 2019. These performance-based equity awards will vest one-quarter upon the achievement of specific clinical development milestones. The remaining shares will then vest in three equal annual installments after that date. Performance-based stock options and performance-based restricted stock units are recorded as expense beginning when vesting events are determined to be probable.

None of these performance-based equity awards vested during 2019. The Company believes that the achievement of the requisite performance condition continues to be probable. Stock-based compensation expense recognized was $1.8 million and $5.5 million during the three and nine months ended September 30, 2020, respectively, and none during the three and nine months ended September 30, 2019, respectively.

Stock-Based Compensation Expense

Stock-based compensation for options and restricted shares is classified in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 4,759	$ 987	$ 11,983	$ 2,396
General and administrative	3,482	786	9,230	1,778
Total stock-based compensation	$ 8,241	$ 1,773	$ 21,213	$ 4,174

As of September 30, 2020, the unrecognized stock-based compensation of unvested stock options, restricted stock units, and performance-based options and restricted stock units was $90.4 million and it is expected to be recognized over a weighted-average period of 3.04 years.

9. Net Loss per Common Share

The following common share equivalents were excluded from the computation of diluted net loss per common share for the periods presented because their inclusion would have been antidilutive:

	As of September 30,	
	2020	2019
Outstanding stock options	7,238,363	6,083,474
Unvested restricted shares	363,195	7,385
Total	7,601,558	6,090,859

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes included elsewhere in this report and with our audited financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2019, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 16, 2020. This discussion and analysis and other parts of this report contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section of this report titled "Part II, Item 1A — Risk Factors" and elsewhere in this report.

Overview

Our goal is to prevent and treat the major causes of blindness by developing and commercializing next-generation therapeutics for chronic, high-prevalence retinal diseases.

Throughout 2019 and 2020, we have generated clinical data with our most advanced product candidate, KSI-301, a biologic therapy built with our antibody biopolymer conjugate platform, or ABC Platform, which is designed to maintain potent and effective drug levels in ocular tissues for longer periods than the currently-marketed biologic medicines used to treat retinal diseases. To date, KSI-301 has been administered more than 1,500 times to more than 400 patients representing more than 250 patient-years of clinical experience. We believe that KSI-301, if approved, has the potential to be an important therapy to treat patients with wet age-related macular degeneration, or wet AMD, diabetic retinopathy, or DR, including diabetic macular edema, or DME, and macular edema due to retinal vein occlusion, or RVO.

In our ongoing Phase 1b clinical study, in which enrollment is complete, we have administered multiple doses of KSI-301 to treatment-naïve patients with wet AMD, DME or RVO, and we continue to observe promising safety, efficacy, and clinical durability data in each of the retinal diseases under study. We believe the data support an acceleration of efforts to bring KSI-301 to the market in these retinal diseases and that the data lend confidence to the design of our currently-ongoing and planned pivotal (registrational) studies of KSI-301. We believe these registrational clinical studies, if successful, may demonstrate a meaningfully differentiated clinical profile of KSI-301 as compared to current therapies, and we also believe that this profile would allow KSI-301 to compete effectively in the evolving commercial and product landscape. The potential clinical (and thus commercial/competitive) advantages of a long-acting retinal therapeutic such as KSI-301 go well beyond fewer and less frequent injections over time and also include the potential for patients to retain their vision over the long term due to fewer missed treatments and/or fewer drug holidays, as a result of more manageable treatment schedules. Moreover, a longer-acting medicine allows patients with vision-threatening diseases to remain on effective treatment even in context of treatment disruptions that occur in ordinary circumstances (such as missed visits due to travel or concurrent illnesses), as well as extraordinary disruptions of regular treatment such as that exemplified by the COVID-19 pandemic, where more frequent clinic visits may not be desirable, possible or allowed in certain regions or countries.

Based on the encouraging data that continue to be observed in our Phase 1b study, we have expanded the KSI-301 clinical pivotal program in the third quarter of 2020, and we have entered into the manufacturing-related commitments necessary for KSI-301's commercial scale-up and BLA submission. We believe the intersection of these clinical and manufacturing activities remain on track per our "2022 Vision" to submit a single BLA for wet AMD, DME and RVO in calendar year 2022. We successfully recruited patients into both of our paired pivotal studies in DME (GLEAM and GLIMMER) and into our pivotal study in RVO (BEACON) in the third quarter of 2020. The pivotal study for wet AMD (DAZZLE) began recruiting in the third quarter of 2019 and completed U.S. patient enrollment in the third quarter of 2020. DAZZLE patient recruitment in the EU is expected to complete in the fourth quarter of 2020.

In 2019, we completed an End of Phase 2 meeting with the FDA where we agreed on the order and number of clinical studies required to support the licensure of KSI-301 in wet AMD, DME, RVO and non-proliferative DR (NPDR without DME). We confirmed that two studies conducted in a single indication are expected by FDA in order to demonstrate the initial safety and efficacy of KSI-301 and that one study each in the additional disease indications, if successful, can be used to support approval in the additional indications. Following our communications with FDA at the time of our End of Phase 2 meetings as well as subsequent communications, we upgraded our pivotal study program to assess KSI-301 in two Phase 3 studies (our ongoing GLEAM and GLIMMER studies) in DME to provide the mutually-confirmatory studies required by FDA for initial demonstration of safety and efficacy, one Phase 2b/3 study (our ongoing DAZZLE study) in wet AMD, one Phase 3 study (our ongoing BEACON study) in RVO, and one Phase 3 study (GLOW) in NPDR without DME. By conducting paired studies in DME, we are able to generate additional data on the safety, efficacy and durability of KSI-301 in this area of high unmet need and commercial opportunity, while also narrowing the number of sites and countries required for successful enrollment of the entire pivotal program. We expect a majority of research sites to be located in the U.S. with most of the remaining sites in the EU. Given the strong new patient enrollment and low missed visit rates seen to date in our DAZZLE wet AMD pivotal study in the U.S. despite the ongoing COVID-19 pandemic, we

believe focusing the KSI-301 program in this way helps minimize uncertainty with respect to clinical trial conduct during and through the COVID-19 pandemic and towards our "2022 Vision." Additional specific reasons for running paired DME pivotals (and one RVO pivotal) include: fewer countries and sites needed for two DME studies versus two RVO studies (avoiding the cost and logistical burdens of opening and supporting clinical trial sites that would only participate in RVO studies); better oversight of operational execution (essentially all sites can concurrently enroll treatment naïve patients in wet AMD, DME and RVO); higher unmet need in DME versus RVO; marginal, if any, increase in overall trial execution costs; and the potential for an accelerated timeline for two DME versus two RVO pivotals. On top of these operational considerations, we remain pleased with the DME clinical data we are seeing in the Phase 1b study and want to align greater clinical data generation in DME given the larger number of diabetic patients and higher unmet need and market opportunity as compared to RVO.

The ABC Platform and KSI-301 were developed at Kodiak, and we own rights to these assets in key geographies including the US, EU, China and other major countries. We have applied our ABC Platform to develop additional product candidates beyond KSI-301, including KSI-501, our bispecific anti-IL-6/VEGF bioconjugate, and we are expanding our early research pipeline to include ABC Platform-based triplet inhibitors for multifactorial retinal diseases such as dry AMD and the neurodegenerative aspects of glaucoma. In October 2020, we announced that we entered a supplemental research agreement with AbCellera to generate additional therapeutic antibody candidates for novel disease targets in ophthalmology in support of our evolving research pipeline. We intend to progress these and other product candidates to address high-prevalence ophthalmic diseases.

Our overall objective is to develop our product candidates, seek FDA and worldwide health authority marketing authorization approvals, and ultimately commercialize our product candidates.

Recent Developments

We have implemented various enhancements into our ongoing study execution to help ensure the safety of patients, physicians, study site staff and Kodiak operations team members during the ongoing COVID-19 pandemic, including the use of remote study monitoring. To date, we have observed minimal disruption resulting from the evolving effects of the COVID-19 pandemic in our ongoing clinical trials. In DAZZLE, patient missed visit rates remain low (less than 5%), and clinical trial sites enrolled patients rapidly in the third quarter. This is a testament to the serious diseases we are attempting to treat and is a vote of confidence from the patients, physicians and study sites partnering with us to advance KSI-301. With $380.5 million in cash, cash equivalents and marketable securities as of September 30, 2020, and thoughtful management of our spending, we remain on a strong financial footing.

KSI-301 Pivotal Program

We initiated two Phase 3 studies in DME (GLEAM and GLIMMER) and one Phase 3 study in RVO (BEACON) in the third quarter of 2020. The randomization of treatment-naïve patients into these three pivotal studies in the third quarter is a critical step to build the clinical evidence for KSI-301 as a safe, effective and highly durable therapy for patients with retinal diseases. We have also completed U.S. patient enrollment in our ongoing Phase 2b/3 study in wet AMD (DAZZLE) and continue to recruit patients in the EU. We expect to complete DAZZLE enrollment by year end 2020. We believe that the initiation of the additional Phase 3 studies and the robust patient recruitment into DAZZLE represent strong operational progress towards our 2022 Vision of a single BLA filed for KSI-301 in wet AMD, DME and RVO in calendar year 2022. Importantly, to date the data emerging in our Phase 1b study remain consistent and provide support for and confidence in our pivotal study designs.

COVID-19

In March 2020, the World Health Organization declared a pandemic related to the global COVID-19 outbreak. Governments have taken preventative and protective actions, including but not limited to, restrictions on non-essential travel, business operations, and gatherings of individuals. The State of California, where our headquarters is located in the San Francisco Bay Area, declared a state of emergency and shelter-in-place order in March 2020. Although certain restrictions have eased, and phased re-openings are underway, it is not certain when such restrictions will be fully lifted, and recent resurgences in number and rates of infections, reactions to increased testing and/or further spreading of the virus may result in the return or implementation of more restrictive measures. Global financial markets have also experienced extreme volatility and as a result, economic uncertainties have arisen which could impact the Company's operations and its financial position. The extent of the impact of the ongoing COVID-19 pandemic will depend on certain evolving developments, including the duration and spread of the outbreak, regulatory and private sector responses, and the impact on our employees, vendors including supply chain and clinical partners, all of which are uncertain and cannot be predicted.

We continue to monitor government responses and may elect to temporarily close our office and/or laboratory space to protect our employees. We continue to assess the potential for supply chain disruptions as the pandemic may impact personnel at third party manufacturing facilities in China, Switzerland and other countries, as well as its impact on the availability and/or cost of materials. We continue to monitor financial markets and the impact on our operations and capital resources.

We and our key clinical and manufacturing partners have been able to continue to advance our operations. Because the diseases under study in the KSI-301 development program are serious, vision-threatening conditions for which patients are still seeking and receiving treatment from retina specialists during the pandemic, we have been able to continue advancing the clinical programs for KSI-301 during the pandemic towards achieving our "2022 Vision."

During this pandemic, we continue to work closely with our clinical sites towards maximal patient safety and the lowest number of missed visits and study discontinuations. We have taken and continue to take proactive measures to maintain the integrity of our ongoing clinical studies. To date, we are seeing low levels of patient missed visits (<5%).

In response to the COVID-19 global pandemic with regards to business operations, clinical trials, and manufacturing activities:

- We have taken steps in line with guidance from the U.S. Centers for Disease Control and Prevention, or CDC, and the State of California to protect the health and safety of our employees and the community. In particular, the Company has implemented remote work arrangements for non-essential employees since March 17, 2020.
- We are working closely with our clinical trial sites to monitor and attempt to minimize the potential impacts of the evolving COVID-19 pandemic on patient enrollment, continued participation of patients already enrolled in our clinical studies, protocol compliance, data quality, and overall study integrity. Some specific actions we have taken in the United States include the use of remote study monitoring, temporarily increasing study site budget overhead rates, providing additional transportation service options for patients to attend study site visits and focusing on new patient enrollment only at study sites with appropriate backup resource plans in place and where the local COVID-19 situation allows. Since the month of March 2020, the rate of missed study visits has remained <5%. As of now, we have not experienced significant delays to our ongoing or planned clinical trials; however, this could change rapidly depending on the dynamics of the pandemic.
- In June 2020, we restarted patient recruitment activities at certain sites in EU countries. DAZZLE study sites in the EU were activated in the first quarter of 2020, but we deferred study patient enrollment until June due to the pandemic.
- To minimize the potential for disruption of our pivotal studies of KSI-301, we have refined our study designs, including sample size and country selection. We began enrollment of our pivotal DME (GLEAM and GLIMMER) and RVO (BEACON) studies in the third quarter of 2020 in the United States and aim to initiate the pivotal study in non-proliferative DR (GLOW) in the first quarter of 2021, dependent on the continued evolution of the COVID-19 pandemic. Ex-U.S. clinical trial application submissions are underway for GLEAM, GLIMMER and BEACON. We believe we are still on track to achieve our "2022 Vision" objective of filing a single BLA in 2022 for KSI-301 in wet AMD, DME and RVO.
- Our supply chain and manufacturing activities remain intact, and we do not currently anticipate disruptions to our supply of KSI-301 due to COVID-19.

We will continue to monitor the COVID-19 situation closely. The ultimate impact of the ongoing COVID-19 pandemic on our business operations remains highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. See also the section titled "Risk Factors" for additional information on risks and uncertainties related to the evolving COVID-19 pandemic.

Our bispecific conjugate KSI-501 inhibits both interleukin 6, or IL-6, and Vascular Endothelial Growth Factor, or VEGF. Tissue based IL-6 mediated inflammatory response syndromes have been associated with severe COVID-19 disease. As such, IL-6 blockade is being explored as a novel therapeutic strategy in patients with COVID-19 disease. Similarly, tissue specific edema such as pulmonary edema is implicated in severe and critical COVID-19 disease. VEGF in the alveolar space is a potent inducer of vascular permeability and resultant pulmonary edema which plays a pathological role in lung dysfunction. Emerging data show VEGF levels are elevated in COVID-19 patients. OG2072, the bispecific fusion protein used to build our ophthalmology product candidate KSI-501, binds with high affinity to both of its targets simultaneously (IL-6 and VEGF). Intriguingly, we have seen synergistic inhibition in vitro and we are interested in the possible unique benefit this synergistic inhibition may have in lung and other organs that can be severely damaged by SARS-CoV2 and the associated immunologic and tissue responses. Further, unlike currently marketed anti-VEGF and anti-IL-6R antibodies, OG2072's Fc region is immunologically inert and does not activate immune effector functions. OG2072 may thus be beneficial in preventing further immune-mediated tissue damage in the lung, kidney, heart and other organs affected in critical illness due to COVID-19. To this end, we are advancing by six or more months the GMP manufacturing for OG2072, which could both enable a potential assessment of systemically administered OG2072 in patients with worsening COVID-19 disease (for example, as part of ongoing basket studies of potential COVID-19 therapeutics). Ancillary benefits of this acceleration include the use of GMP material for KSI-501 toxicology program and a more predictable IND submission and First in Human timeline for KSI-501 in patients with retinal vascular diseases featuring an inflammatory component.

Business Highlights

Recent highlights of our activities included:

- *Upgraded Pivotal Study Program*: We finalized the design of our KSI-301 pivotal study programs in RVO and DME and have launched all three studies. We are currently conducting two Phase 3 studies in DME (GLEAM and GLIMMER) to provide the mutually-confirmatory studies required by FDA for initial demonstration of safety and efficacy, one study in wet AMD (our ongoing DAZZLE study), and one study in RVO (BEACON). Each study protocol design has been optimized based on Phase 1b data and experience and will include the same treatment-naïve patient populations as in the Phase 1b, as well as tighter dosing interval ranging, tighter disease control, and decreased subjectivity for retreatments, and each has high statistical power for non-inferiority (>90%). We also intend to initiate in early 2021 a Phase 3 study of KSI-301 in non-proliferative diabetic retinopathy (GLOW).
- *DAZZLE Study Progress*: We saw robust patient enrollment through the third quarter of 2020 and have completed U.S. patient recruitment into our DAZZLE pivotal study in wet AMD – a potential reflection of the enthusiasm for KSI-301 on the part of clinical investigators and patients. EU patient enrollment commenced in June 2020 and we continue to see robust recruitment. We expect to complete overall DAZZLE study enrollment by year end 2020. With a one-year primary endpoint, we remain on track for a DAZZLE study top-line data readout in early 2022. As of November 4, 2020, over 545 of the planned 550 patients have been enrolled in DAZZLE.
- *GLEAM / GLIMMER and BEACON Study Initiations*: We initiated two Phase 3 studies in DME (GLEAM and GLIMMER) and one Phase 3 study in RVO (BEACON) in the third quarter of 2020. The randomization of treatment-naïve patients into these three studies is a critical step to build the clinical evidence for KSI-301 as a safe, effective and highly durable therapy for patients with retinal diseases. The initiation of the additional Phase 3 studies and the robust patient recruitment into DAZZLE represent strong operational progress towards our 2022 Vision of a single BLA filed for KSI-301 in wet AMD, DME, and RVO in 2022.
- *Continued maturation of Phase 1b Data*: Updated safety and efficacy results from our ongoing Phase 1b trial of KSI-301 in patients with treatment naïve wet AMD, DME, or RVO were presented at the American Society of Retina Specialists 2020 Virtual Annual Meeting in July 2020. We believe the data continue to support the “anti-VEGF Generation 2.0” profile of KSI-301. We intend to continue presenting data updates from the Phase 1b as the study progresses over its full three-year duration.
- *Commercial Manufacturing Progress*: We successfully negotiated a long-term agreement with Lonza for the manufacture of KSI-301. This agreement will provide Kodiak with a custom-built bioconjugation facility with a capacity to supply millions of doses per year. With construction targeted for completion in 2021, the Lonza-Kodiak Ibex facility will provide Kodiak with the facility needed for commercial-scale manufacturing of KSI-301. The timing of this expanded partnership is designed to support Kodiak’s BLA submission timeline in 2022, and the scale is designed to support KSI-301’s potential to achieve significant market share as a new first-line agent designed to improve outcomes for patients with common and serious retinal vascular diseases.
- *Completed Lease Agreement for Kodiak’s New U.S. Headquarters*: We have leased approximately 82,662 square feet located at 1200 Page Mill Road, Palo Alto, California and approximately 72,812 square feet located at 1250 Page Mill Road, Palo Alto, California. These newly leased buildings will serve as Kodiak’s U.S. headquarters for office and laboratory space. We also leased approximately 10,750 square feet in Visp, Switzerland, for manufacturing support and supervision.

Our current cash, cash equivalents and marketable securities provide the resources for us to advance the KSI-301 program towards achieving our “2022 Vision” and also to advance our pipeline of drug candidates including KSI-501 and our triplet inhibitor drug candidates and for working capital and general corporate purposes.

Where Kodiak is Today

Growing KSI-301 Clinical Experience: KSI-301 has been assessed in more than 1,500 injections in more than 400 patients with more than 250 patient-years of exposure. With a majority of patients in the Phase 1b clinical study achieving six months or longer between doses in wet AMD and DME and four months or longer between doses in RVO, KSI-301’s clinical durability continues to be supported with maturing data. We remain very pleased with the current clinical profile of KSI-301. Notably, KSI-301 continues to demonstrate a safety profile that is tracking with standard of care anti-VEGF agents. When and if we submit our planned single BLA in wet AMD, DME and RVO, we expect to have safety, efficacy and durability data on KSI-301 treatment in over 1,000 patients in concurrent pivotal studies.

Thoughtfully Designed Pivotal Clinical Trials: The exploratory Phase 1b study was designed to push KSI-301 in terms of dosing intervals and provide us with a broad view of our product's clinical profile. The data we are seeing in the Phase 1b study are supportive of our ability to demonstrate a strong clinical profile in registrational studies. We have applied the learnings from the exploratory Phase 1b study to further optimize each of our pivotal study protocols.

Investing with Conviction Commensurate with the Opportunity: There remains a great unmet need among patients receiving anti-VEGF therapies today. Despite the promise of today's medicines as demonstrated in their registrational clinical trials, visual gains are not maintained. In the real world, patients cannot be treated frequently enough and are over-extended between doses. Under-treatment leads to disease progression and permanent retinal damage, and high-intensity treatment regimens lead to patient and caregiver treatment fatigue and/or abandoning of treatment. A new, better, longer-lasting medicine is required to shift the curve, to reset what has been appropriately called an "epidemic of preventable blindness."

We believe KSI-301 stands the best chance among treatments currently in development to directly address this great need. We have made significant progress with enrollment in our pivotal study in wet AMD (DAZZLE), and we have reached our desired enrollment in the U.S. in the third quarter of 2020. We also initiated pivotal studies in DME (GLEAM and GLIMMER) and RVO (BEACON) in the third quarter of 2020. We are moving forward with the preparations for a study in non-proliferative diabetic retinopathy (GLOW) and are currently assessing the timing of study initiation in light of the impact of COVID-19 on this less acute yet high unmet need indication.

Kodiak remains focused on thoughtful execution of our KSI-301 pivotal program, the requisite manufacturing efforts, the regulatory strategy and the pre-commercial readiness. We continue to build our team, and we are thankful for the positive interest in KSI-301 and our ABC Platform by the retina community. As to manufacturing, in line with our "2022 Vision" which sees us submitting our initial BLA in 2022 and potentially commercializing KSI-301 in 2023, it is our intent to be able to supply millions of doses in Year 1 from our Lonza-Kodiak Ibex Dedicate facility designed from inception with Flex Up capabilities and capacity for double digit millions of doses per year to supply a growing market demand.

Poised Commercial Opportunity: We are optimistic for the future care of patients with retinal vascular diseases. The competitive landscape of intravitreally-injected anti-VEGF biologic therapies and therapeutic candidates is clearing, due to the incremental durability of competing molecules, and/or safety challenges that, even if only recently appreciated, have been observed from early in the development of these potential competitors. Adjacent surgical and gene therapy solutions may also face challenges with long-term safety, limited accessibility and the complex economics of surgical implantation.

KSI-301, with its powerful combination of design attributes, has the potential to be a Generation 2.0 anti-VEGF – a first-line anti-VEGF "product for everyone" that may achieve a significant market share.

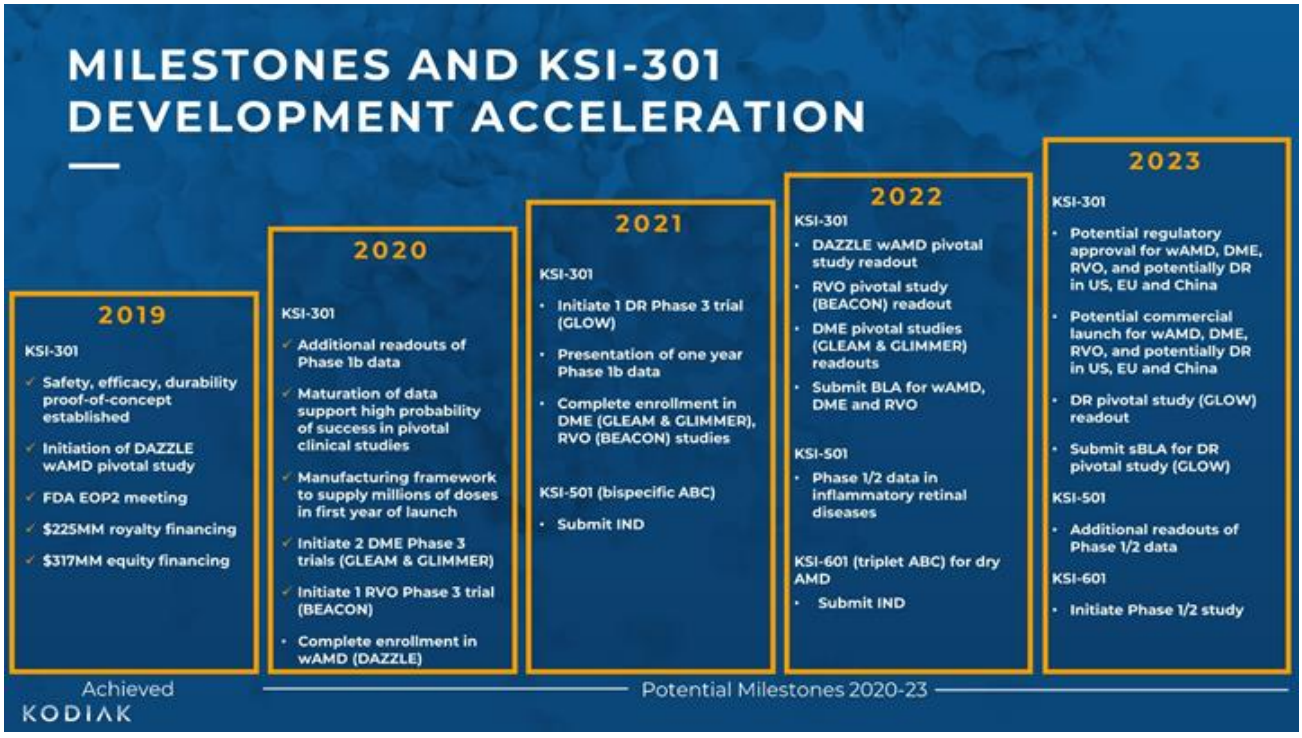
As a company, we remain independent. This independence provides us with the flexibility to adapt both R&D and commercial decision-making within the ever-changing domestic and global landscapes. We remain well capitalized and supported by a high-quality group of long-term investors who understand what is needed to build, invest and execute commensurate with the opportunity.

Kodiak's 2022 Vision and KSI-301 Accelerated Development Strategy

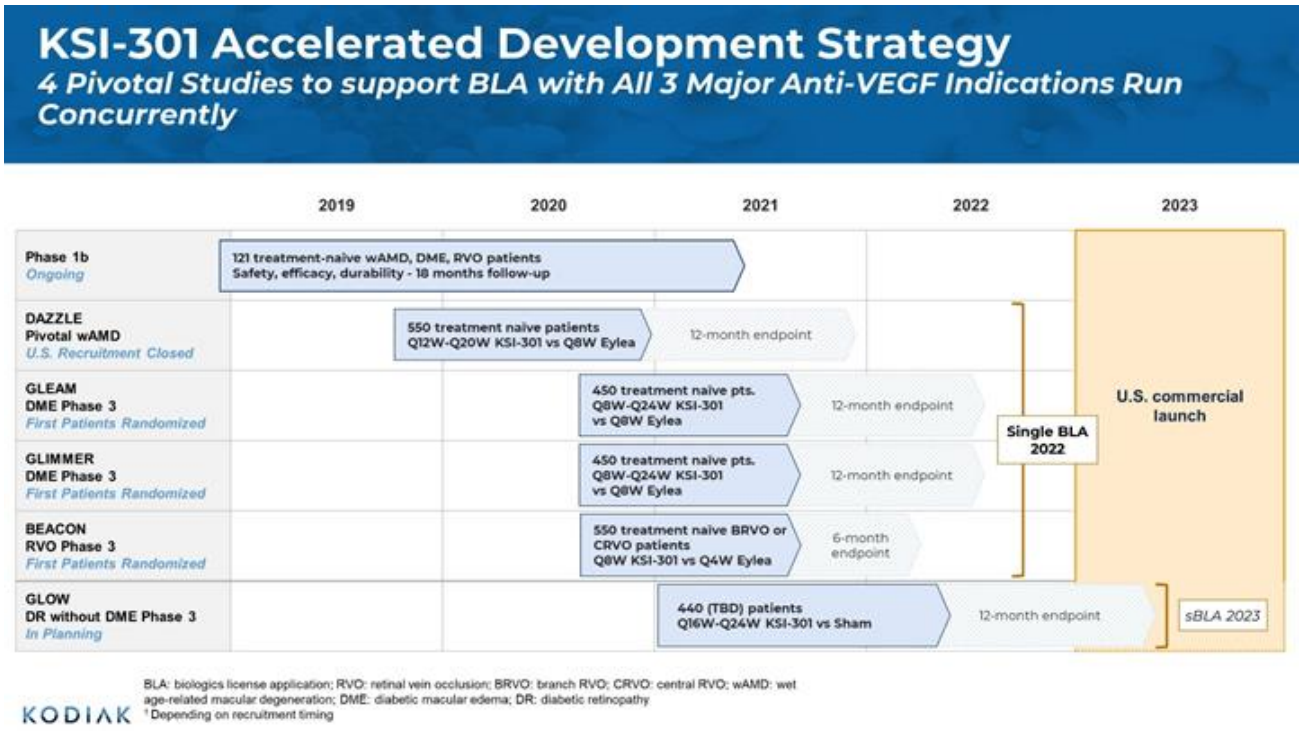
We believe we remain on track to achieve our "2022 Vision" of a single BLA submission and initial FDA approval for KSI-301 in wet AMD, DME and RVO in 2022 with a total of four pivotal trials— two in DME (GLEAM and GLIMMER), one in wet AMD (DAZZLE) and one in RVO (BEACON). We initiated three additional pivotal trials in the third quarter of 2020 – two matched studies in DME to provide the mutually-confirmatory studies required by FDA for initial demonstration of safety and efficacy and one in patients with RVO. We intend to initiate a pivotal study in DR in the first quarter of 2021. These studies, together with our ongoing pivotal study in wet AMD, will be the basis of our intended BLA and supplemental BLA submissions. We currently expect to submit the wet AMD, DME, and RVO indications in a single initial BLA for KSI-301 and the DR indication in a supplemental BLA in the United States.

We continue to invest in our science and our pipeline, including our bispecific ABC product candidate KSI-501 for retinal vascular diseases with a strong inflammatory component and our new triplet ABC product candidate KSI-601 for the high prevalence multifactorial retinal disease dry AMD.

Our "2022 Vision" includes the following potential catalysts and milestones in 2020, 2021, 2022 and 2023, along with the important milestones achieved in 2019 and 2020 that support the concurrent development program:



Our “2022 Vision” is built on the following concurrent development strategy. This table incorporates our most recent view of the KSI-301 clinical program and its execution, as described above, and we believe the successful prosecution of this program is achievable based on our currently available information and the evolving effects of the COVID-19 pandemic:

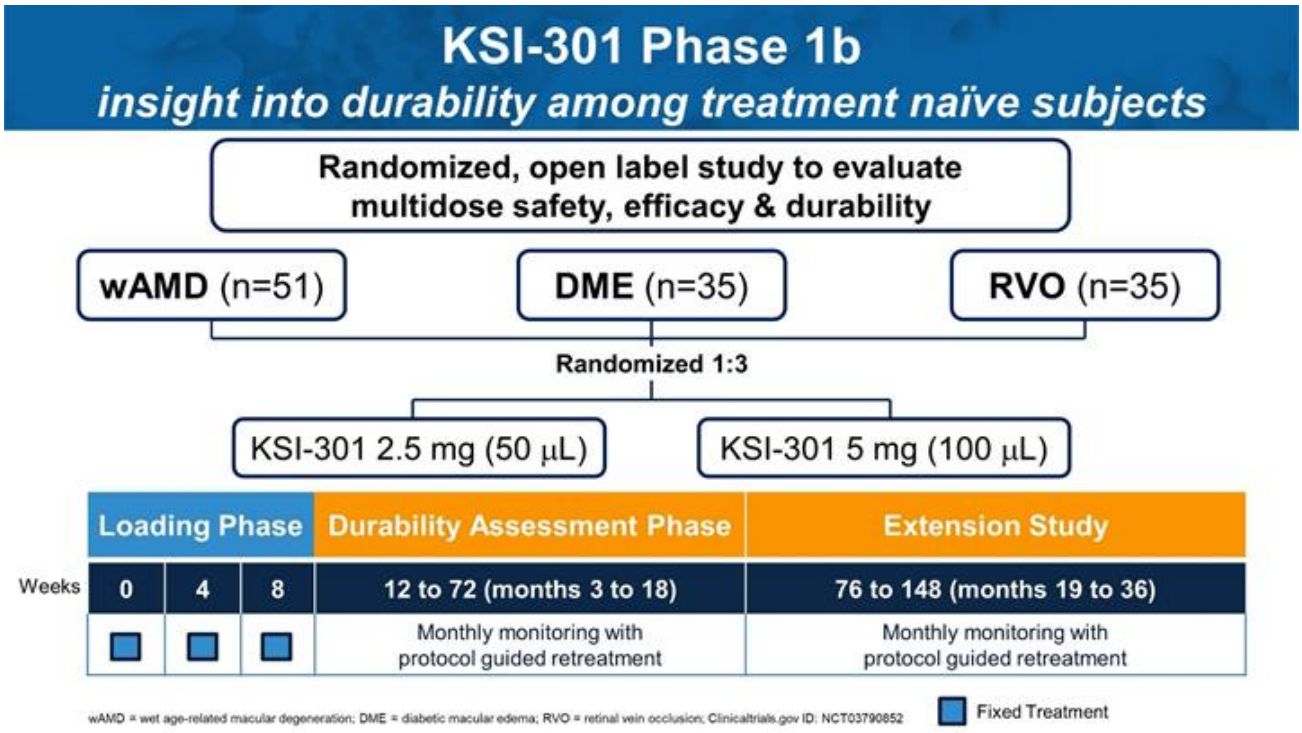


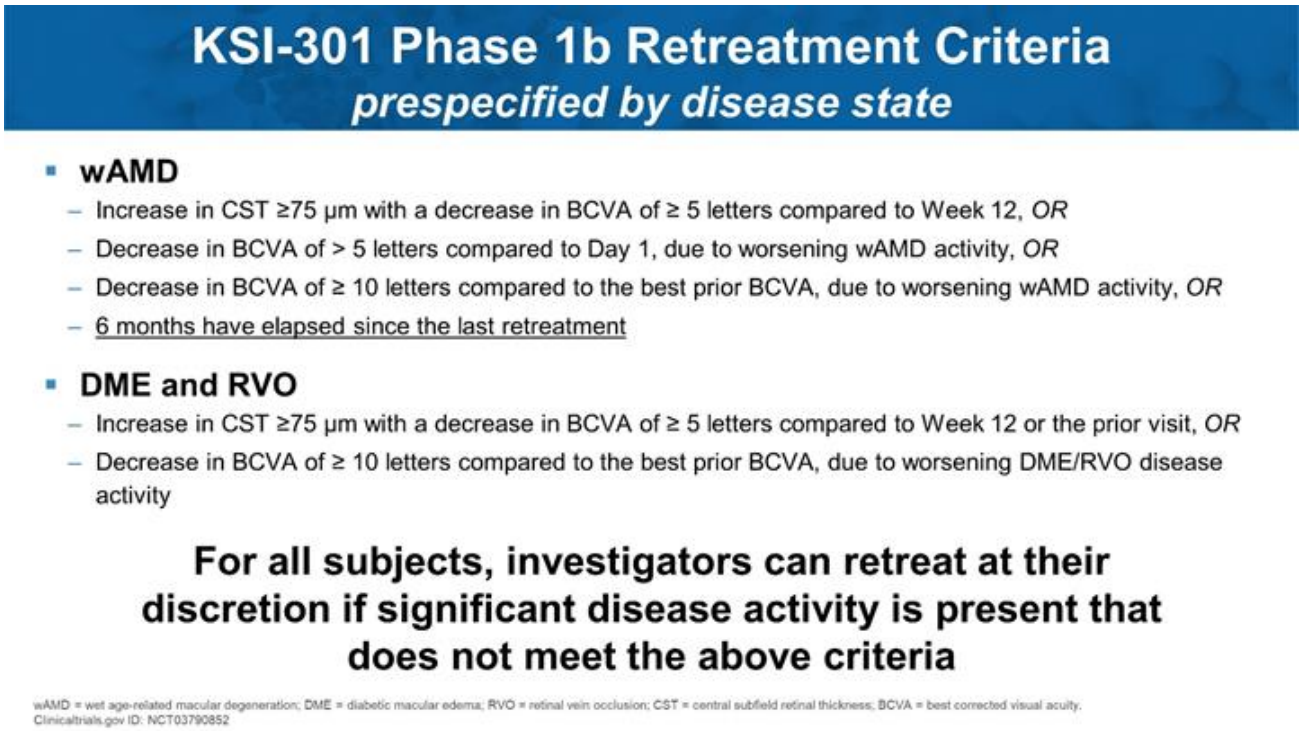
Ongoing Phase 1b Data Continue to Support KSI-301’s Differentiated Profile

We have continued to make progress with our studies of KSI-301, and the maturing durability data we continue to observe in the Phase 1b study continue to surpass our expectations. We now have 140+ patient-years of clinical experience with KSI-301 in the Phase 1b study.

The overall study duration was originally nine and then 18 months, and we have now extended the treatment and follow-up period to 36 months total, to continue generating long-term outcomes data in advance of the pivotal studies. Outcomes include vision, measured as change in best corrected visual acuity or BCVA using the standard ETDRS testing protocol, and retinal anatomy, which is measured as change in retinal central subfield thickness, or CST, using optical coherence tomography imaging, or OCT. We also obtain other images such as fluorescein angiography, color fundus photos, and OCT angiography.

The figures below present the most recent data on durability and efficacy outcomes from the ongoing Phase 1b study presented at the ASRS 2020 Virtual Annual Meeting, held in July 2020. Across all three diseases under study, improvements in vision and retinal anatomy were observed through 44 weeks of patient follow-up, with stability in OCT and BCVA over time in the monthly follow-up intervals following the three mandatory loading doses. Vision is measured as change in BCVA, on a standardized eye chart, and retinal anatomy is measured as change in retinal CST using OCT imaging.





KSI-301 Phase 1b Baseline Characteristics

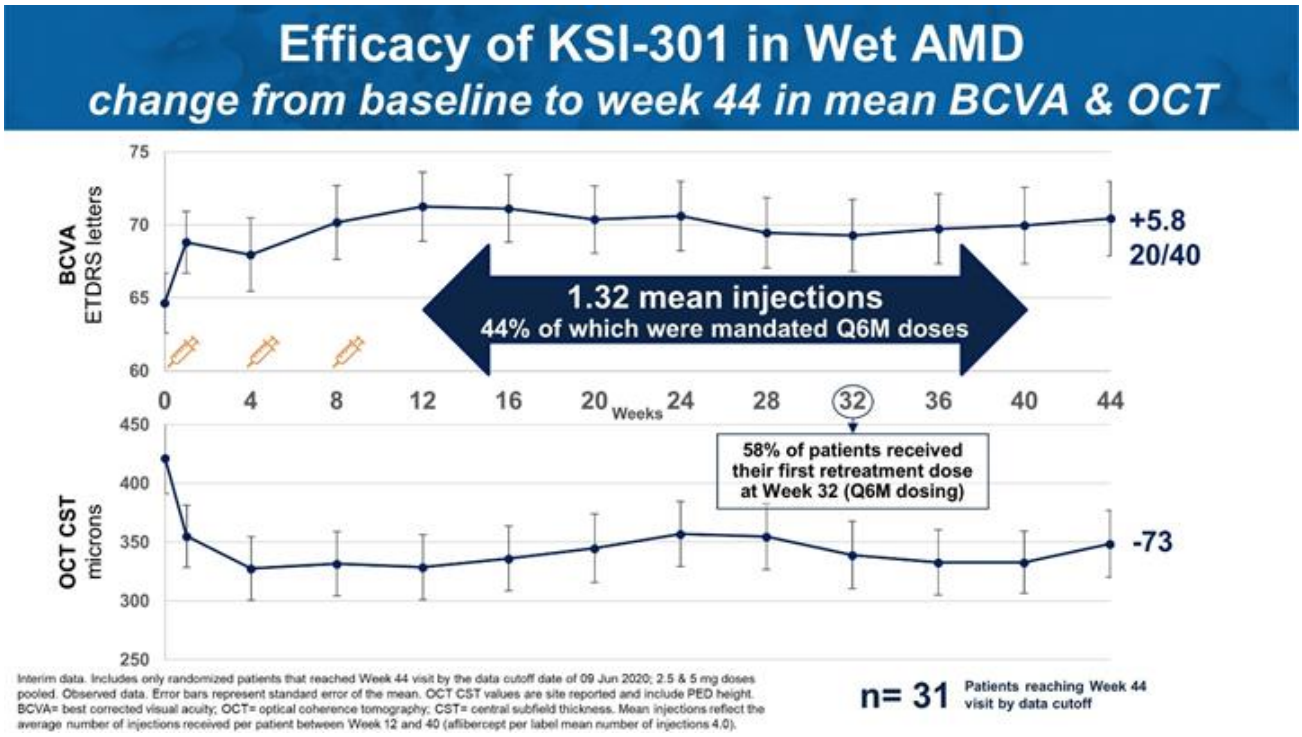
Variable	wAMD Cohort (n=51)	DME Cohort (n=35)	RVO Cohort (n=35)
Age, mean (SD), years	77.9 (10.5)	59.7 (11.7)	63.6 (12.6)
Gender, n (%), female	32 (62.7)	14 (40.0)	13 (37.1)
Race, n (%), White	48 (94.1)	28 (80.0)	31 (88.6)
BCVA, mean (SD), ETDRS letters	63.3 (13.3)	66.8 (10.2)	54.9 (15.4)
Snellen equivalent	~20/50	~20/50	20/80
BCVA, Snellen 20/40 or better, n (%)	20 (39.2)	16 (45.7)	6 (17.1)
OCT CST, mean (SD), microns	430 (162)	453 (110)	675 (237)

Includes all patients randomized as of 09 June 2020. SD= standard deviation; BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness

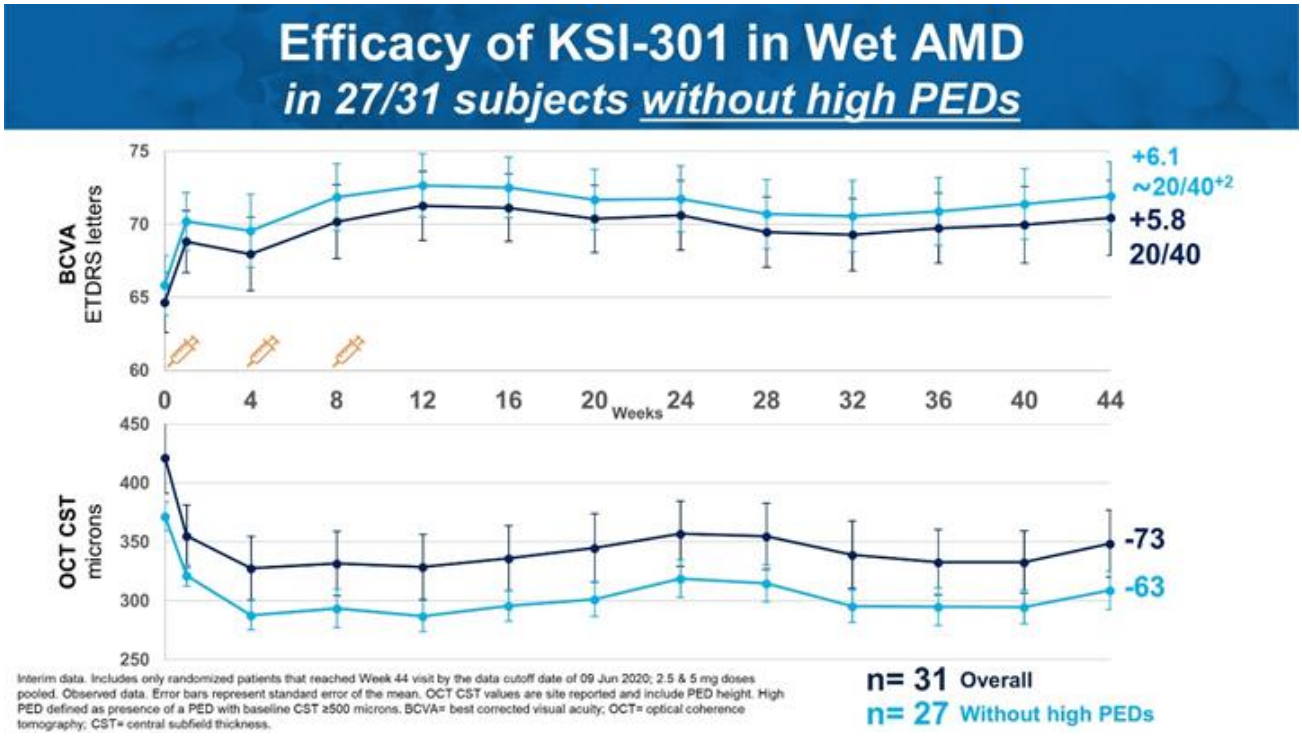
Wet AMD

The data below are from the 31 wet AMD patients who reached the week 44 visit prior to the ASRS meeting data cutoff date of June 9, 2020. Improvements in BCVA and OCT from the initial treatments are noted, as expected for an anti-VEGF. From baseline to week 12, patients gained an average of 6.7 letters off their good starting base of approximately 65 letters and an improvement in OCT CST of 93 microns. In the period between week 12 and week 44, the treatment effect is maintained both in terms of BCVA and OCT with just an average of 1.32 injections per patient, and notably 44% of those treatments were the mandatory every 6-month doses. 58% of the 31 patients received their first retreatment at week 32, six months after the last loading dose. Supporting the extended durability, we see only a very slow fluctuation in the OCT over time, which compares favorably to the OCT fluctuations observed with existing anti-VEGFs given on shorter dosing intervals. The stability in BCVA over this interval is also consistent with the prolonged duration of KSI-301.

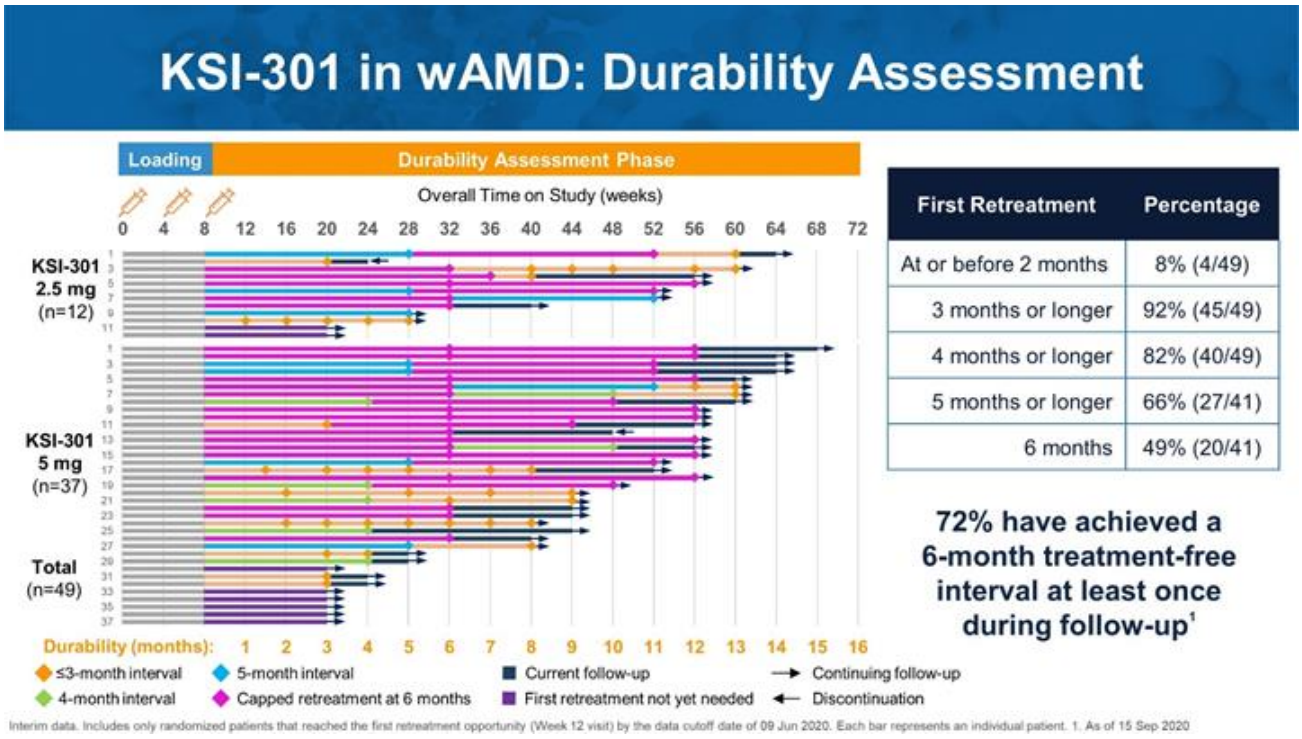
In the Phase 1b study, the average retinal thickness or OCT CST data as reported by our clinical investigators includes the height of pigment epithelial detachments or PEDs. PEDs are an anatomic feature in some patients with wet AMD; treatment success in subjects with PEDs does not necessarily imply complete flattening of the PED, but rather eliminating the intraretinal and subretinal fluid, particularly when the PED is very high prior to anti-VEGF treatment. Additionally, comparison across studies of OCT mean CST values is difficult because it is often not clear or not disclosed in presentations and publications whether the data include or exclude the height of the PED, and whether or how the data are corrected for different OCT machine, among other reasons.



When comparing subjects with and without very high PED at baseline, which we defined as 500 microns or more total CST, the BCVA and OCT CST curves are similar in shape to those of the full cohort. Excluding the high PED patients, the OCT CST values are lower at baseline and over time, and the standard error of the mean (SEM) error bars are narrower. Those four patients with high PEDs thus pull the overall average CST value up. Excluding those four patients, the average retinal center subfield thickness is around 300 microns after initiation of treatment with KSI-301.



Overall, 92% of our wet AMD patients have achieved a time to first retreatment of three months or longer. Of these patients, 82% went four months or longer, and most patients have not received their first retreatment until five to six months after the last loading dose. 49% reached the six-month cap without retreatment after the initial loading doses. Remarkably, 72%, of these wet AMD patients have achieved a six-month treatment interval at least once during follow-up. As this is an anti-VEGF treatment naïve population, there is no pre-selection for "anti-VEGF responders" or patients who might require less frequent dosing.



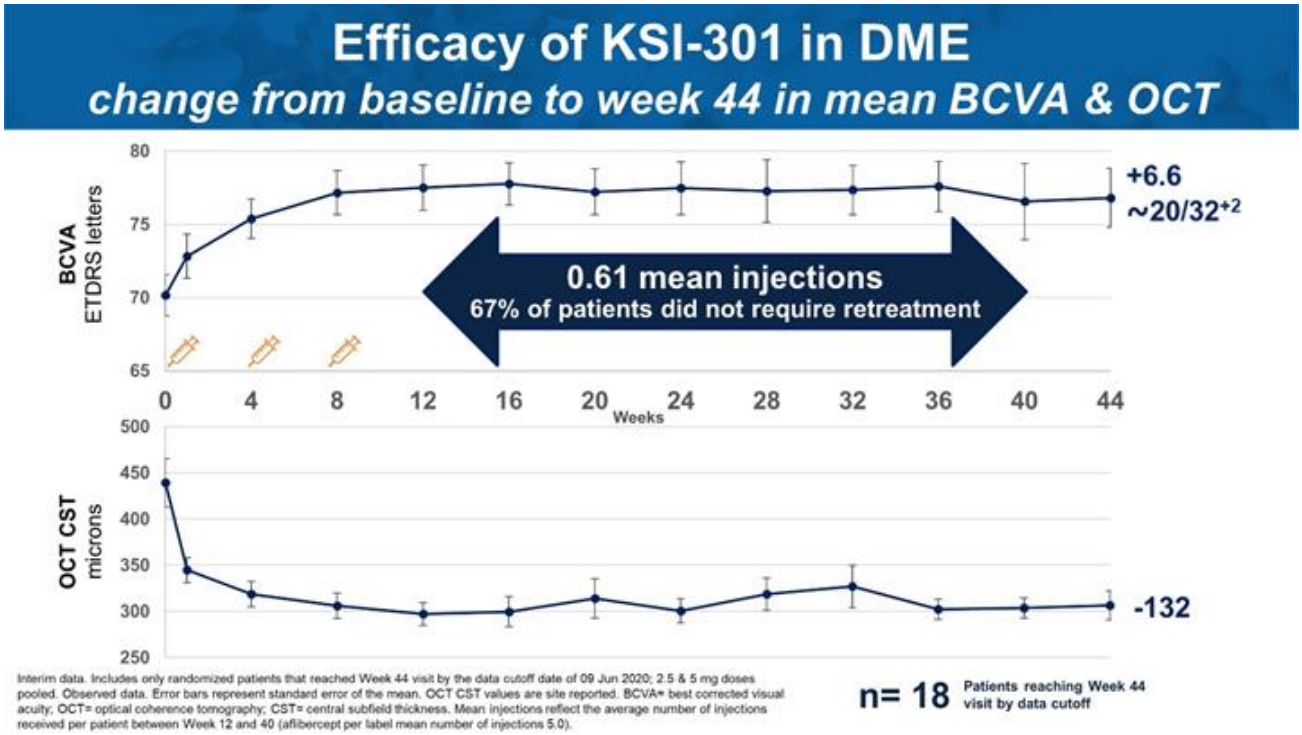
It is reassuring to see that as the Phase 1b data mature, the vision, OCT and durability outcomes have remained consistent. For example, when comparing the outcomes presented at the Angiogenesis meeting earlier in 2020 versus the data presented in July 2020 at the ASRS virtual meeting, the durability proportions remain stable, as do the visual acuity and OCT outcomes.

KSI-301 in wAMD: *Maturing dataset is consistent over time*

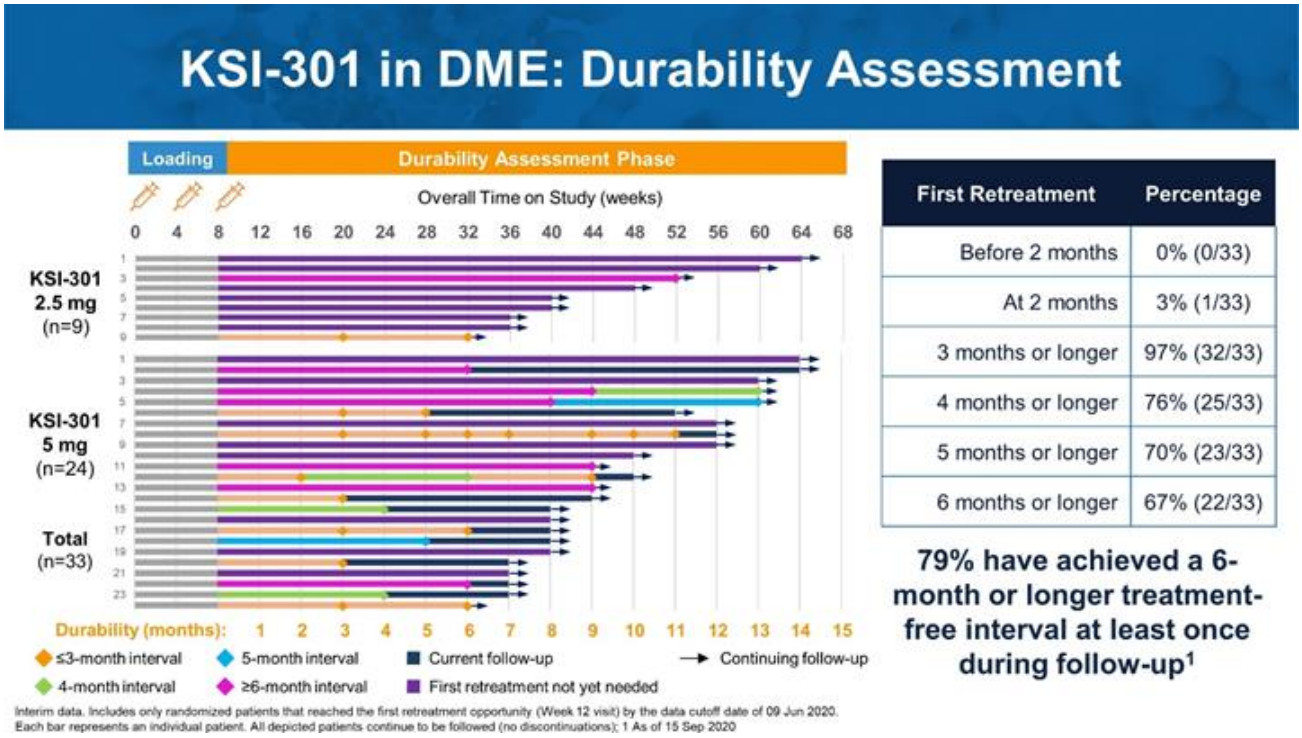
	Angiogenesis Meeting (21 January 2020 cutoff)	ASRS Meeting (09 June 2020 cutoff)
Patient-years Clinical Experience	**22.0**	**41.7**
Efficacy Analyses (functional and anatomical)	**Week 24 (n=31)**	**Week 44 (n=31)**
Mean change in BCVA	**5.9** letters	**5.8** letters
Mean change in OCT CST	**-58** microns	**-73** microns
Mean number injections since week 12	**0.16**	**1.32**
Durability Analyses (time to first retreatment)	**n=35**	**n=49**
At or before 2 months	**9%** (3/35)	**8%** (4/49)
3 months or longer	**91%** (32/35)	**92%** (45/49)
4 months or longer	**84%** (27/32)	**82%** (40/49)
5 months or longer	**72%** (21/29)	**66%** (27/41)
6 months	**55%** (16/29)	**49%** (20/41)

Diabetic Macular Edema (DME)

We measure KSI-301 efficacy data in treatment naïve DME as change from baseline in BCVA and OCT CST. Below are data from the 18 DME patients who reached the week 44 visit prior to the data cutoff date. These patients had good starting vision, approximately 70 letters. They experienced a visual acuity increase after 3 loading doses and maintained a gain of 6.6 letters with a mean of just 0.61 retreatments. Notably, two thirds of patients never required retreatment during this nine-month follow-up period. Consistent with the extended durability effect of KSI-301, we see again only slight fluctuations in the OCT over time, which compares favorably to the OCT fluctuations observed with existing anti-VEGF agents that are given on shorter dosing intervals.



The swim lane plot for DME durability is shown below. So far, 97% of DME patients have gone three months or longer before their first retreatment; only one patient of 33 required their first retreatment at two months after the loading doses. Of these patients, 76% have gone four months or longer, and 70% five months or longer before their first treatment. Further, 67% have gone six-months or longer – as there is no cap to the treatment interval in the DME cohort. Almost half of the patients, or 45%, have not required retreatment to date, denoted by the purple bars. 79% of patients have achieved a 6-month or longer treatment-free interval at least once during follow-up. Some of these patients have gone for a year without needing any additional treatment. The data set has also remained consistent over time, comparing the follow-up data available at the Angiogenesis meeting earlier in 2020 to the data presented at ASRS.



First Retreatment	Percentage
Before 2 months	0% (0/33)
At 2 months	3% (1/33)
3 months or longer	97% (32/33)
4 months or longer	76% (25/33)
5 months or longer	70% (23/33)
6 months or longer	67% (22/33)

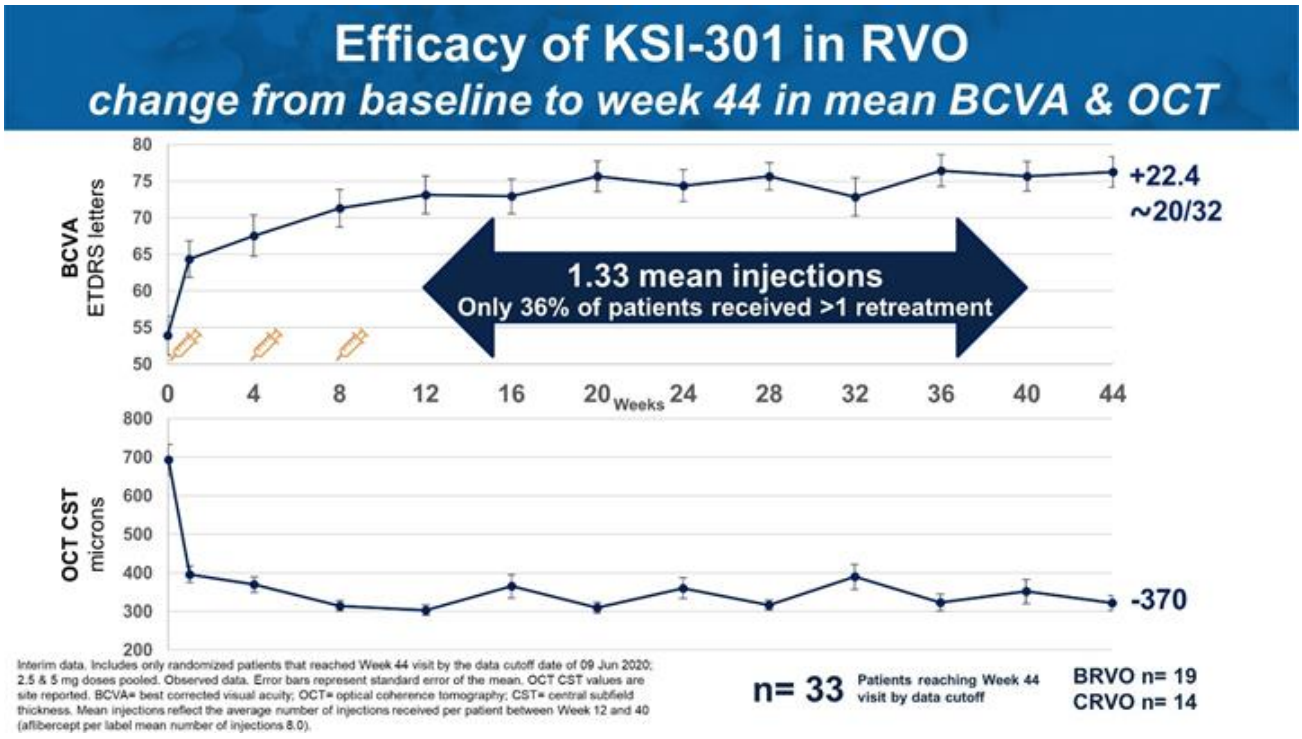
79% have achieved a 6-month or longer treatment-free interval at least once during follow-up[1]

KSI-301 in DME: *Maturing dataset is consistent over time*

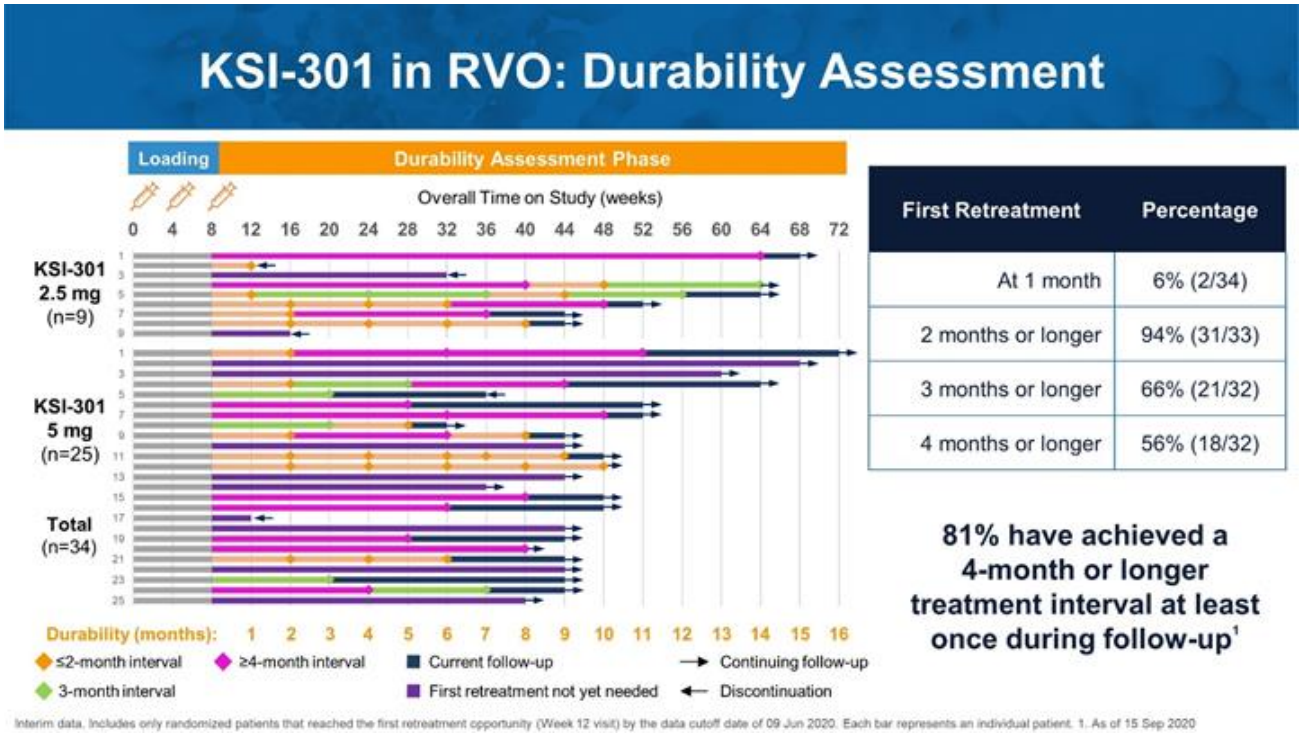
	Angiogenesis Meeting (21 January 2020 cutoff)	ASRS Meeting (09 June 2020 cutoff)
Patient-years Clinical Experience	**16.8**	**29.8**
Efficacy Analyses (functional and anatomical)	**Week 24 (n=19)**	**Week 44 (n=18)**
Mean change in BCVA	**6.8** letters	**6.6** letters
Mean change in OCT CST	**-133** microns	**-132** microns
Mean number injections since week 12	**0.21**	**0.61**
Durability Analyses (time to first retreatment)	**n=33**	**n=33**
At 2 months	**3%** (1/32)	**3%** (1/33)
3 months or longer	**97%** (31/32)	**97%** (32/33)
4 months or longer	**76%** (16/21)	**76%** (25/33)
5 months or longer	**68%** (11/16)	**70%** (23/33)
6 months or longer	**64%** (9/14)	**67%** (22/33)

Retinal Vein Occlusion (RVO)

KSI-301 efficacy in treatment naïve RVO is also measured as change from baseline in BCVA and OCT CST. The 33 RVO patients that completed their week 44 visit began with a lower visual acuity baseline of approximately 55 letters, typical of this disease. After three loading doses, their visual acuity substantially improved, with a 22.4 letter improvement at week 44, which is over four lines of vision gained on the standardized eye chart. The vision gain was maintained with an average of just 1.33 injections, with only a third of patients requiring more than one retreatment in this period. A sustained OCT response with a decrease of 370 microns was also noted.



In this swim lane plot of the durability of individual patients with RVO, the disease with arguably the highest VEGF load, the bars in pink and orange now denote retreatment intervals of four months or longer and two months or shorter, respectively. 94% of RVO patients, 31 of the 33 patients, have gone two months or longer before their first retreatment. Only 6% of patients had their first retreatment at one month after the loading doses. 66% had their first retreatment three months or later since the loading doses, and 56% achieved a first interval of four months or longer. Remarkably, given that many RVO patients require monthly therapy for the best results with existing medicines, 81% of patients have achieved a four month or longer interval at least once during follow-up.



Looking at the recent efficacy and durability data compared to where they stood earlier this year, we see the consistency in the maturing Phase 1b data, both with longer follow-up and more patients. In particular, the OCT and VA outcomes were stable from week 24, presented at Angiogenesis, to week 44, presented at the recent ASRS meeting.

KSI-301 in RVO: *Maturing dataset is consistent over time*

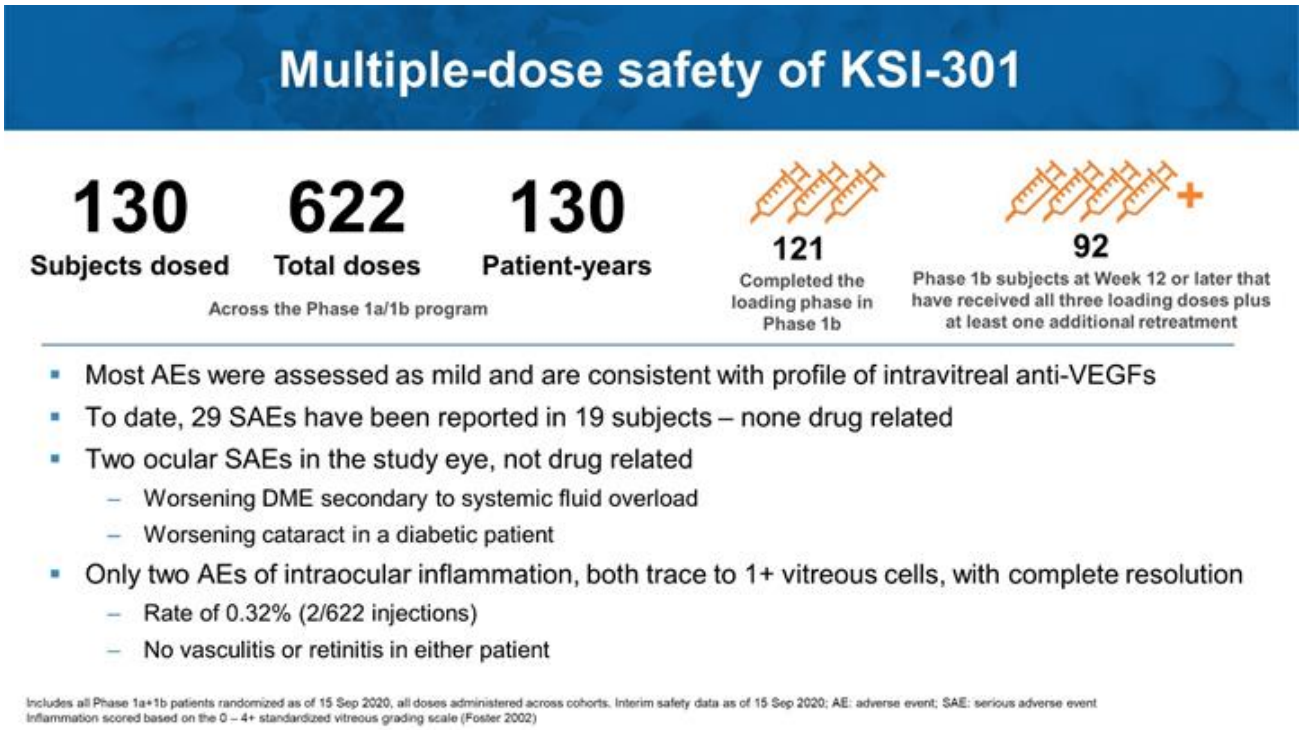
	Angiogenesis Meeting (21 January 2020 cutoff)	ASRS Meeting (09 June 2020 cutoff)
Patient-years Clinical Experience	**18.8**	**29.8**
Efficacy Analyses (functional and anatomical)	**Week 24 (n=30)**	**Week 44 (n=33)**
Mean change in BCVA	**22.2** letters	**22.4** letters
Mean change in OCT CST	**-350** microns	**-370** microns
Mean number of injections since week 12	**0.46**	**1.33**
Durability Analyses (first retreatment)	**n=33**	**n=34**
At 1 month	**6%** (2/33)	**6%** (2/34)
2 months or longer	**94%** (30/32)	**94%** (31/33)
3 months or longer	**64%** (20/31)	**66%** (21/32)
4 months or longer	**53%** (16/30)	**56%** (18/32)

Safety of KSI-301 Injections

We believe the safety profile of KSI-301 continues to be very encouraging. Now with 622 injections given in the Phase 1a/1b program (as of September 15, 2020), and with patients followed for as long as 22 months, we are continuing to track with the expectations set by the safety profile of the current standard of care intravitreal medicines.

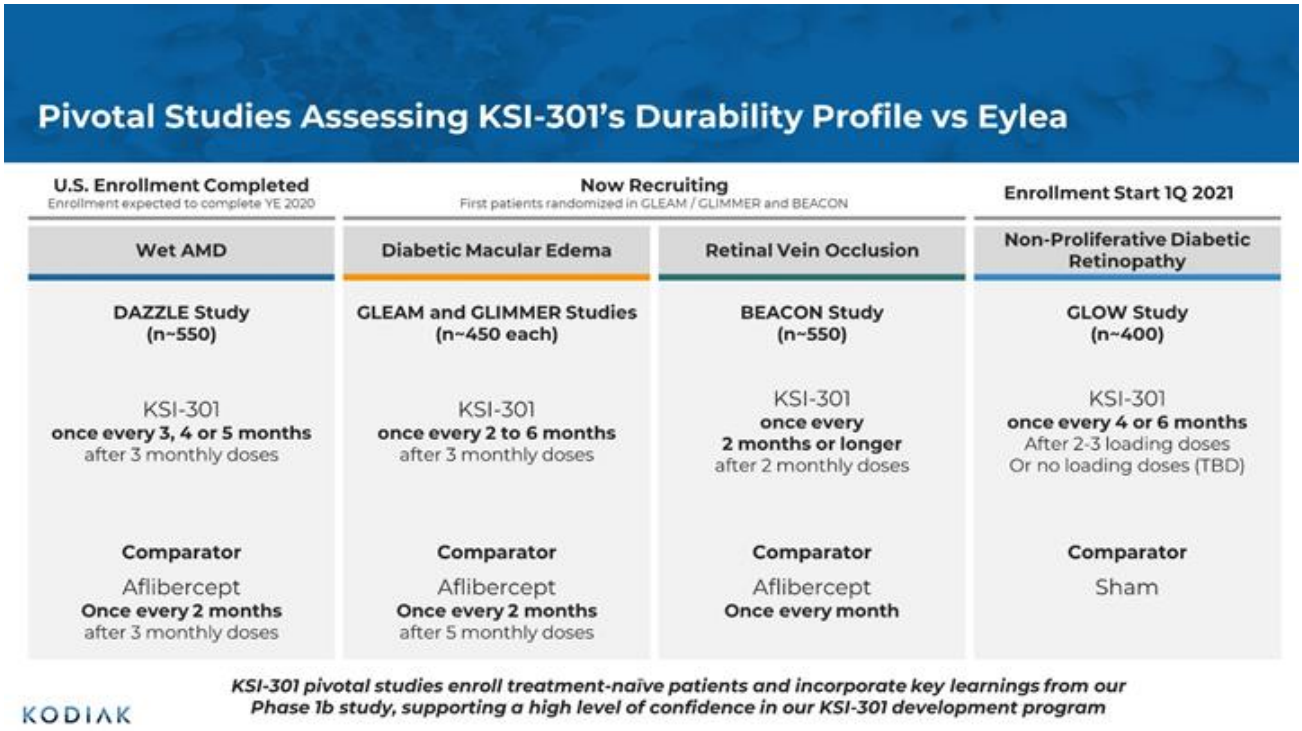
None of the serious adverse events, or SAEs, observed have been reported as or deemed drug-related, and they are typical of the systemic SAEs expected in these patient populations. The ocular SAE of worsening cataract was in a diabetic patient with pre-existing cataract, was not drug-related, and resolved with routine cataract surgery.

There are only two events (previously described) of intraocular inflammation. The events were mild in nature, both trace to 1+ grade cells in the vitreous, on a standardized scale where 0 is none and 4+ is severe. They resolved completely, and there was no vasculitis or retinitis in either patient. Both patients have done very well with substantial improvements in vision from baseline; each of them had gained 30 letters or 6 lines of vision as of their last visits.



KSI-301 Pivotal Study Designs

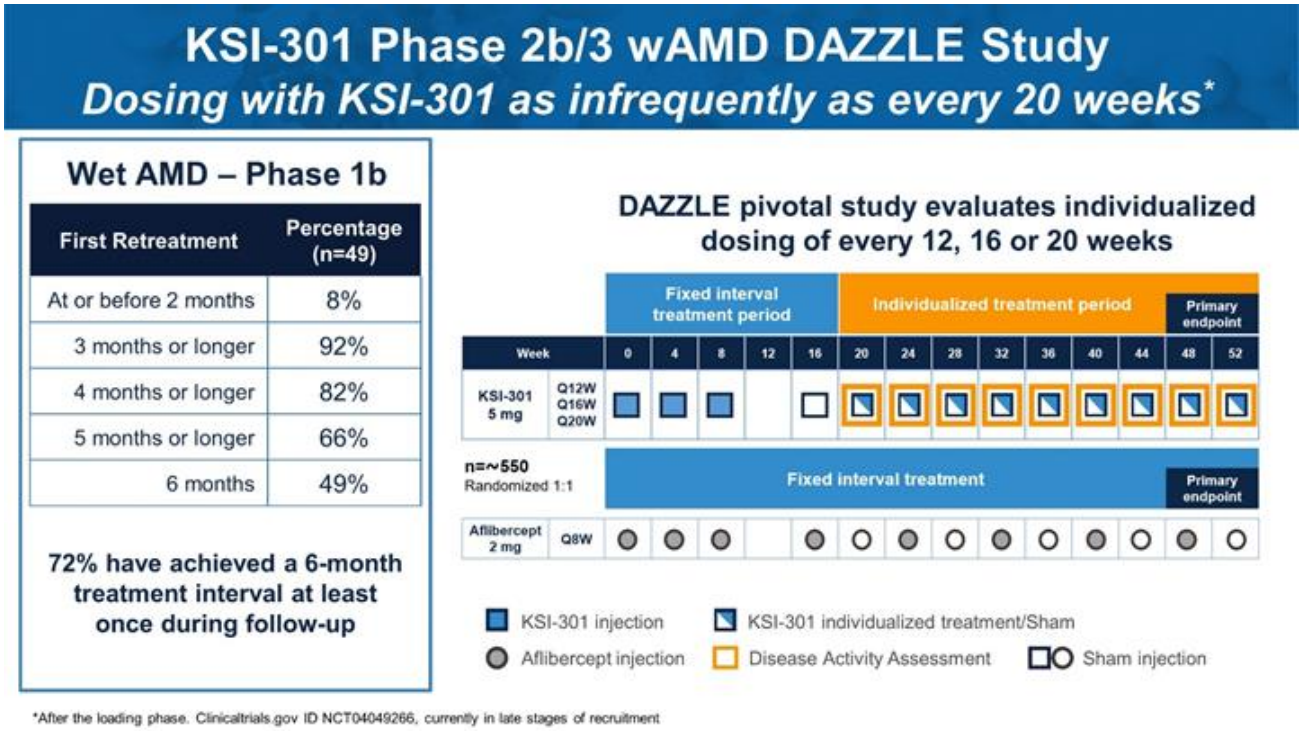
Our pivotal study designs for wet AMD (our ongoing DAZZLE study), DME (our ongoing GLEAM and GLIMMER studies), and RVO (our ongoing BEACON study) have been optimized based on Phase 1b data and experience.



Wet AMD DAZZLE Study

DAZZLE (NCT04049266) assesses patients with treatment naïve wet AMD and are randomized 1:1 to receive KSI-301 every 12 to 20 weeks or Eylea every 8 weeks, each after 3 monthly loading doses. The determination of treatment interval for the patients assigned to KSI-301 is based on disease activity assessments where both OCT and BCVA are measured and compared against prior data, similar to other recent and ongoing Phase 3 studies in the field. By default, patients are on an every 20 week regimen. If disease activity criteria are met before 20 weeks, that is, 12 or 16 weeks after the last dose, then the treatment interval is correspondingly shortened.

The primary endpoint is at one year and is a non-inferiority comparison to Eylea, with a four-letter non-inferiority margin. The one year endpoint is measured as the average of the BCVA change from baseline to weeks 48 and 52. All of the KSI-301 patients are analyzed together as a single group with respect to the primary comparison to Eylea. In the second year of the study, patients whose disease is stable can have their KSI-301 treatment interval extended, and patients originally randomized to Eylea, will be re-randomized 1:1 to either continued Eylea or switched to every eight week KSI-301.



*After the loading phase. Clinicaltrials.gov ID NCT04049266, currently in late stages of recruitment

Disease assessment criteria are used to determine whether the treatment interval is 12, 16 or 20 weeks. These criteria are tightened, and subjectivity has been reduced, compared to the retreatment criteria used in the Phase 1b study. The DAZZLE criteria, and the overall approach to dosing regimen determination in DAZZLE, are very similar to other recent Phase 3 programs in wet AMD. The aim is to customize the dose interval per patient, in a way that is feasible in a large, multicenter, double-masked trial.

How do DAZZLE Study Disease Activity Assessment Criteria Compare to Phase 1b?

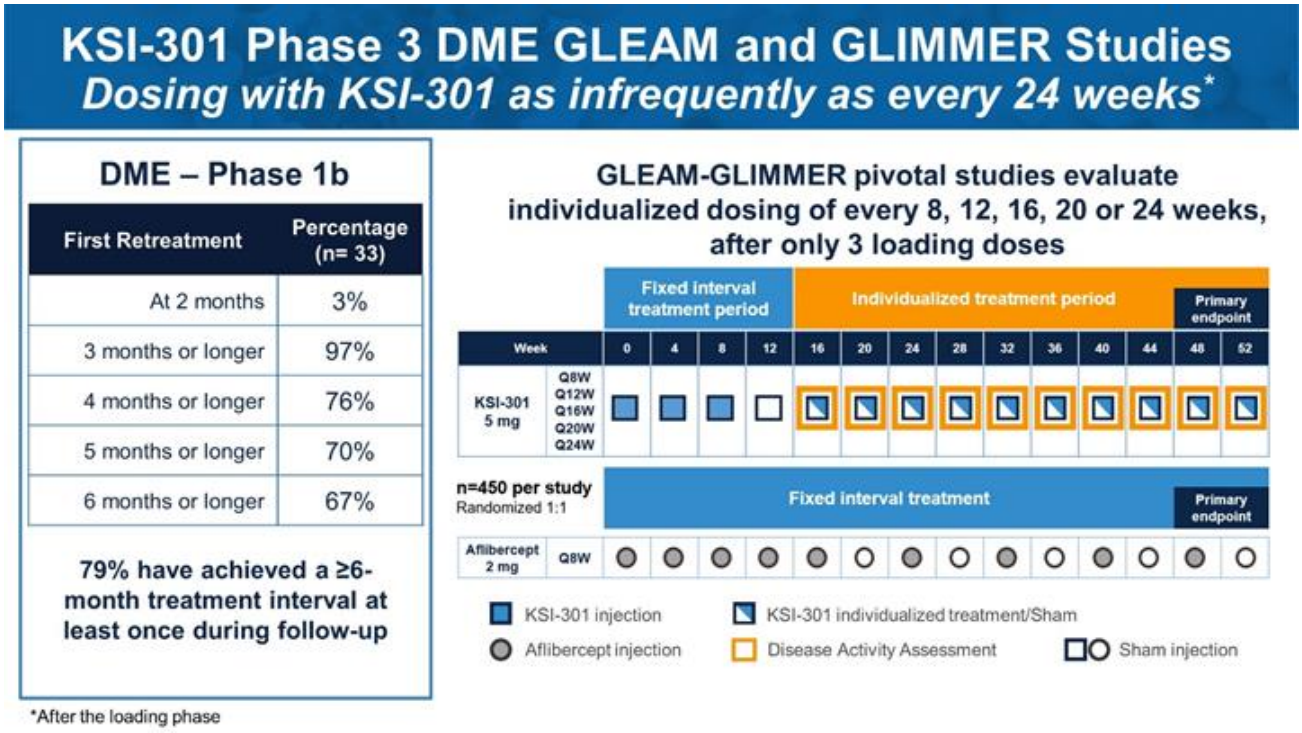
Parameters	Phase 1b Study	DAZZLE study	Change
Visual *and* anatomical	Increase in CST ≥75 µm with a decrease in BCVA of ≥ 5 letters compared to Week 12, *OR*	Increase in CST ≥50 µm with a decrease in BCVA of ≥ 5 letters compared to Week 12, *OR*	**Tighter CST control (25 microns)**
Visual only	Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening wAMD activity, *OR*	Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening wAMD activity, *OR*	**No change**
	Decrease in BCVA of > 5 letters compared to Day 1, due to worsening wAMD activity	N/A	**Eliminated to reduce subjectivity and unnecessary retreatments**
Anatomical only	N/A	Increase of ≥ 75 microns compared to Week 12, *OR*	**Added two anatomical-only criteria**
	N/A	New Macular Hemorrhage	

wAMD = wet age-rhfcelated macular degeneration; CST = central subfield retinal thickness; BCVA = best corrected visual acuity. Clinicaltrials.gov ID: NCT03790852

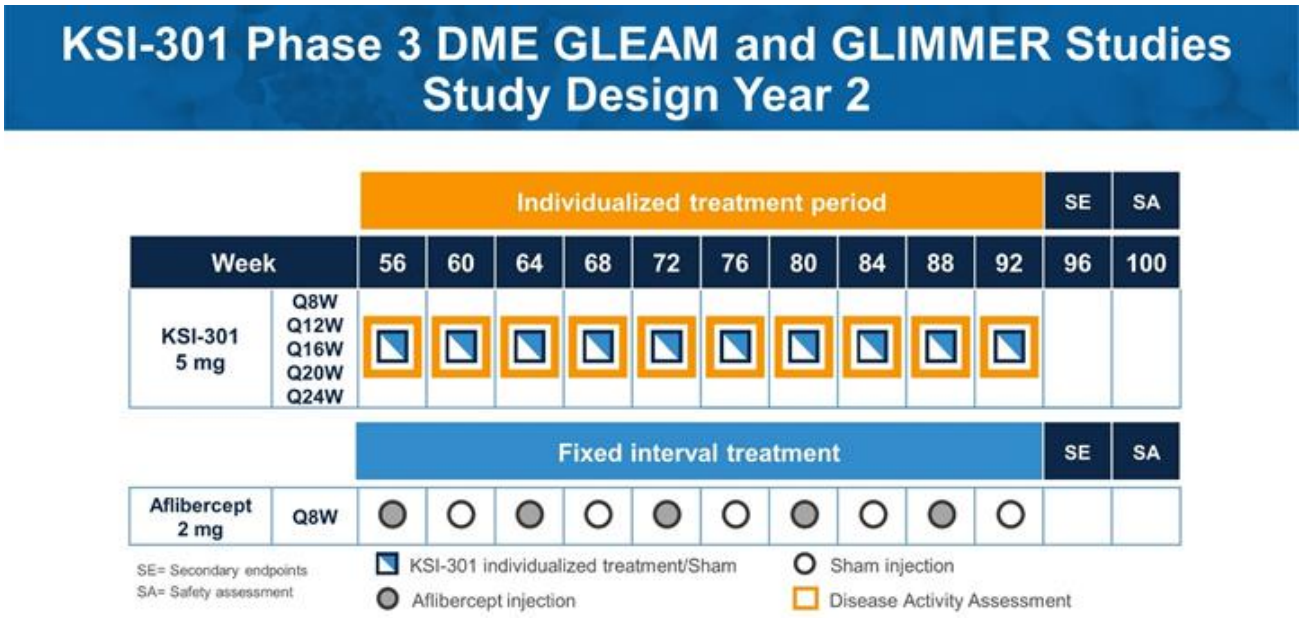
Diabetic Macular Edema Paired Studies, GLEAM and GLIMMER

In DME, we are conducting two Phase 3 studies in parallel with identical design. In each of the two studies, called GLEAM (NCT04611152) and GLIMMER (NCT04603937), we will randomize 450 treatment-naïve DME patients to either KSI-301 every 8 to 24 weeks after 3 loading doses, or Eylea every 8 weeks after 5 loading doses. The primary endpoint is the change from baseline in BCVA at one year, again the average of the week 48 and 52 visits. The studies are non-inferiority studies with a margin of 4.5 letters.

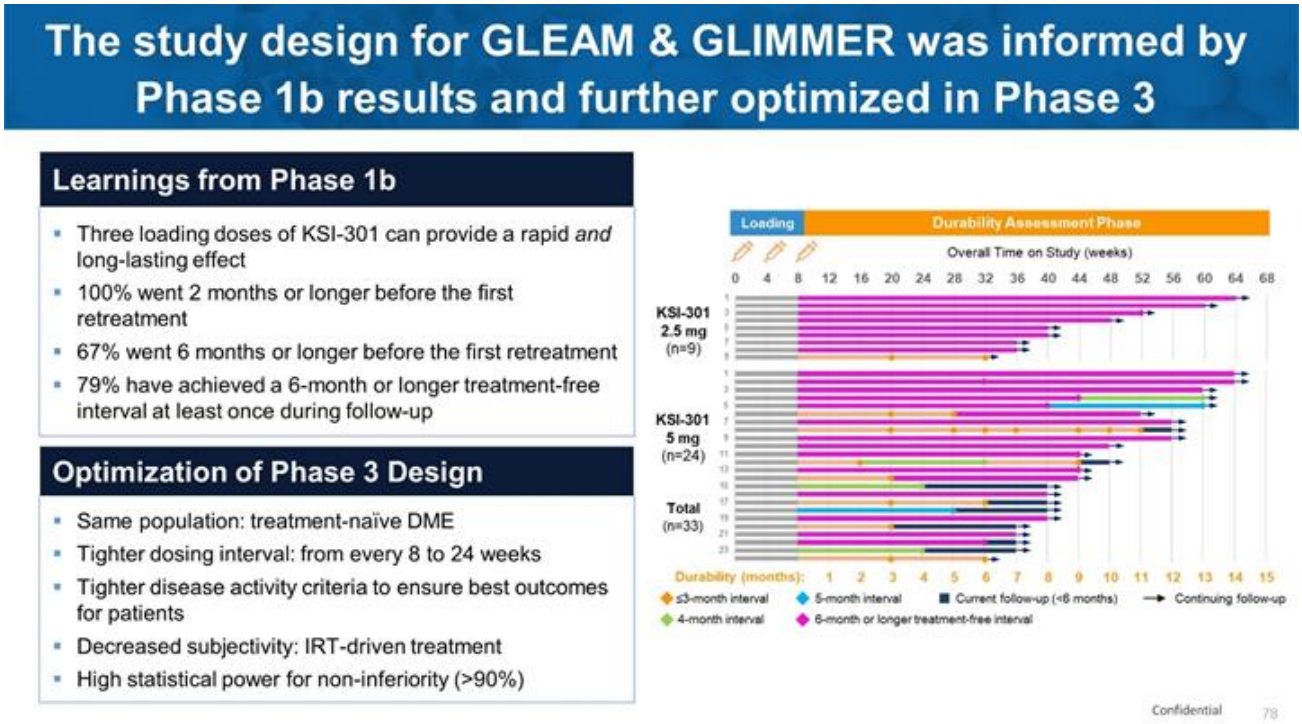
At each monthly study visit, patients who have been randomized to KSI-301 will undergo a disease activity assessment, using data from both BCVA and OCT measurements. Depending on their disease activity status, the dosing interval can be shortened, lengthened, or maintained at the same interval. This is different from the DAZZLE wet AMD study design where the interval can only be maintained or shortened in the first year. In DME, patients may experience disease modification (improvement in the severity of the underlying retinopathy) that curtails the need for therapy over time, an event that has been seen in many DME patients treated with KSI-301 allowing for the treatment interval to be potentially further prolonged after the first retreatment. The minimum KSI-301 treatment interval in GLEAM and GLIMMER is every eight weeks, and the maximum interval is every 24 weeks or six months.



In the second year of both studies, the same approach is maintained. Eylea will stay on its q8 week regimen, and patients on KSI-301 will continue to be on an 8 to 24 week regimen based on disease activity.



The GLEAM and GLIMMER study design was also optimized using learnings from the Phase 1b study results to maintain Phase 1b study population (treatment-naïve DME patients), tighten dosing intervals and disease activity criteria, decrease subjectivity and incorporate high statistical power for non-inferiority (>90%).



To determine the treatment interval for KSI-301 patients, we are employing disease activity assessments and protocol-specified criteria. All patients randomized to KSI-301 are on the longest interval by default. If patients meet any of these disease activity criteria at earlier timepoints, the retreatment interval is shortened. The criteria for shortening the treatment interval are tighter than they are in Phase 1b, and the subjectivity is reduced. Additional anatomic criteria have also been included.

How do GLEAM/GLIMMER Studies Disease Activity Assessment Criteria Compare to Phase 1b?

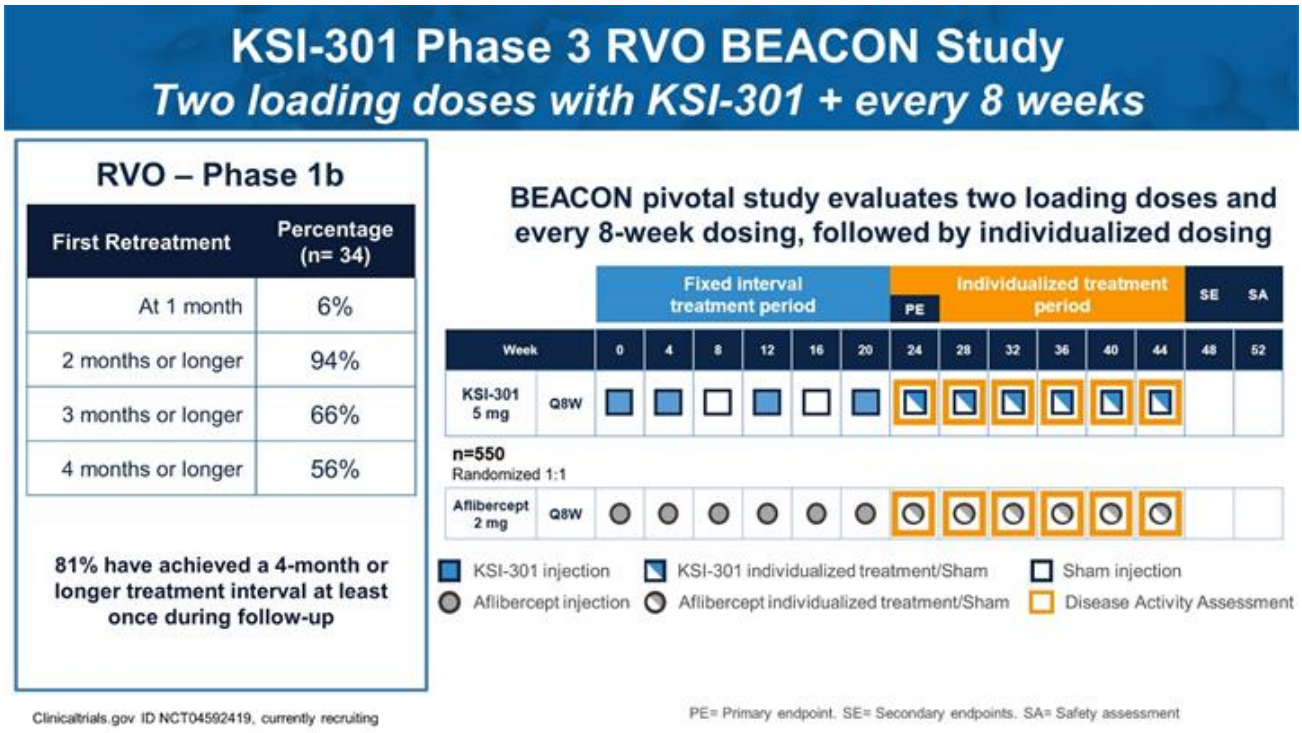
Parameters	Phase 1b Study	GLEAM/GLIMMER Studies	Change
Visual *and* anatomical	Increase in CST ≥75 µm with a decrease in BCVA of ≥ 5 letters compared to Week 12 or the prior visit, *OR*	Increase in OCT CST ≥ 50 µm compared to lowest previous measurement and a decrease in BCVA of ≥ 5 letters compared to the average of the 2 best previous BCVA assessments, due to worsening of DME disease activity, *or*	**Tighter and dynamic control of both vision and anatomy**
Visual only	Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening DME activity	N/A	**Eliminated to reduce subjectivity and unnecessary retreatments**
Anatomical only	N/A	Increase in OCT CST ≥ 75 µm compared to lowest previous measurement due to worsening of DME disease activity; *or*	**Added two anatomical-only criteria**
	N/A	New or worsening proliferative DR (PDR)	

DME = diabetic macular edema; OCT = optical coherence tomography; CST = central subfield retinal thickness; BCVA = best corrected visual acuity.

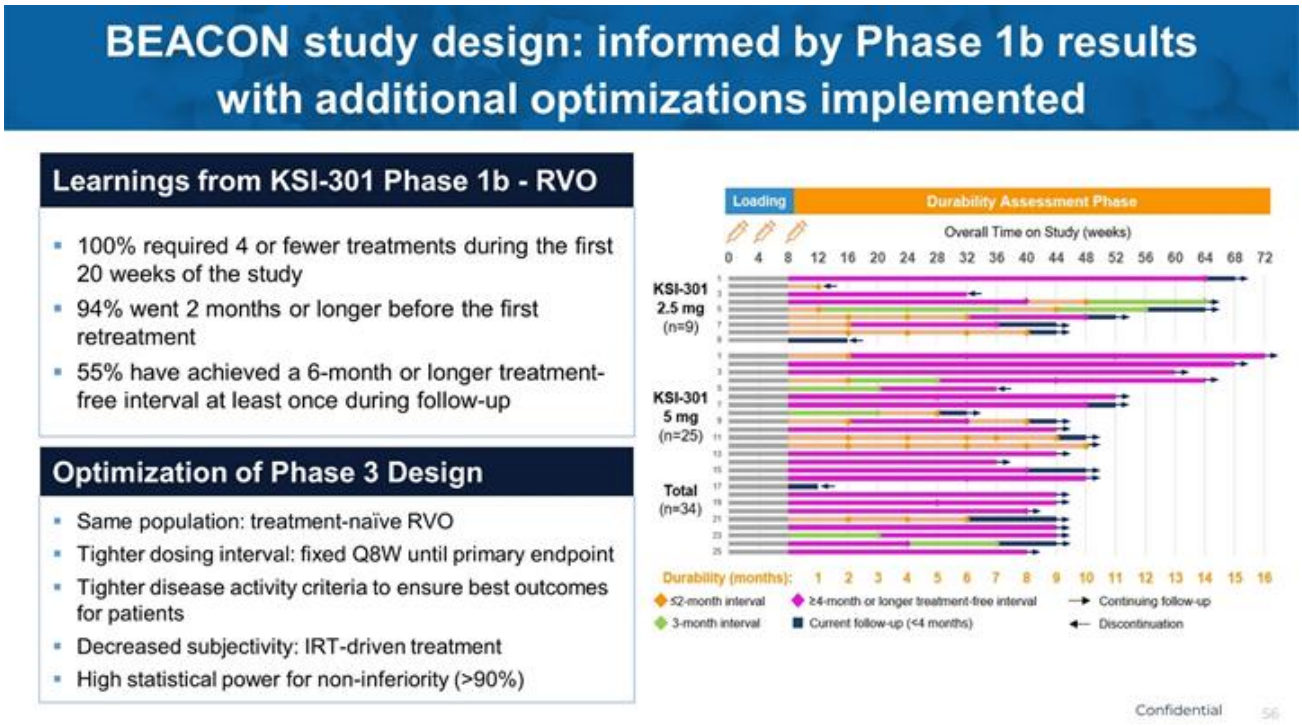
Retinal Vein Occlusion BEACON Study Design

The Phase 3 BEACON study (NCT04592419) in patients with RVO is a year-long study in which we will randomize 550 patients with treatment-naïve RVO, either branch or central vein type, to either every 8 week KSI-301 after two loading doses, or to monthly Eylea, for the first six months. The primary endpoint is at six months, with a non-inferiority margin of 4.5 letters.

In the second six months, patients in both groups will receive treatment on an individualized regimen, again using typical disease activity assessments. This phase of the study will provide a direct, head-to-head comparison of Eylea and KSI-301 on the same criteria-driven regimen. The minimum interval is monthly and there is no upper limit to the retreatment interval in this six-month period.



The BEACON study design was optimized using learnings from the Phase 1b study results to maintain Phase 1b study population (treatment-naïve RVO patients), tighten dosing intervals and disease activity criteria, decrease subjectivity and incorporate high statistical power for non-inferiority (>90%).



Because the first six months of the study are fixed-interval dosing, the disease activity assessment criteria are only used to determine dosing in the second six months of the RVO study. The criteria are similar to our DME studies, and tighter than they are in Phase 1b, with the OCT and BCVA measured against the best previous measurements; subjectivity is also reduced.

How do BEACON Study Disease Activity Assessment Criteria Compare to Phase 1b?

Parameters	Phase 1b Study	BEACON Study	Change
Visual *and* anatomical	Increase in CST ≥75 µm with a decrease in BCVA of ≥ 5 letters compared to Week 12 or the prior visit, *OR*	Increase in OCT CST ≥ 50 µm compared to lowest previous measurement and a decrease in BCVA of ≥ 5 letters compared to the average of the 2 best previous BCVA assessments, due to worsening of RVO disease activity, *or*	**Tighter and dynamic control of both vision and anatomy**
Visual only	Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening RVO activity	N/A	**Eliminated to reduce subjectivity and unnecessary retreatments**
Anatomical only	N/A	Increase in OCT CST ≥ 75 µm compared to lowest previous measurement due to worsening of RVO disease activity; *or*	**Added one anatomical-only criteria**

RVO = retinal vein occlusion; OCT = optical coherence tomography; CST = central subfield retinal thickness; BCVA = best corrected visual acuity.

Conclusions

Overall, we believe that the continued maturation of the safety, efficacy, and durability data of KSI-301, as shown in the Phase 1b study, support our efforts to bring KSI-301 to the market as a ‘Generation 2.0’ anti-VEGF in these retinal diseases and that the data lend confidence to the design of our current and planned pivotal studies of KSI-301. We believe these clinical studies, if successful, may demonstrate a meaningfully differentiated clinical profile of KSI-301 as compared to current therapies,, and we also believe that this profile would allow KSI-301 to compete effectively in the evolving commercial and product landscape.

Since inception in June 2009, we have devoted substantially all of our resources to discovering and developing product candidates and manufacturing processes, building our ABC Platform and assembling our core capabilities in drug development for high prevalence retinal diseases. We plan to continue to use third-party clinical research organizations, or CROs, to carry out our preclinical and clinical development. We rely on third-party contract manufacturing organizations, or CMOs, to manufacture and supply our preclinical and clinical materials to be used during the development of our product candidates. We are investing in commercial manufacturing capacity. We do not have any products approved for sale and have not generated any product revenue since inception.

We have funded our operations primarily through equity securities. In October 2018, we completed our initial public offering, or IPO. In December 2019, we completed a follow-on offering. In addition, we entered into a royalty funding agreement and received an initial payment of $100.0 million in February 2020.

We have incurred significant operating losses to date and expect that our operating losses will increase significantly as we advance our product candidates, particularly KSI-301, through preclinical and clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization; broaden and improve our platform; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. Our net loss was $86.5 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of $244.6 million.

Our ability to generate product revenue will depend on the successful development and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of KSI-301 for wet AMD, RVO, DME or DR without DME or delay our efforts to advance and expand our product pipeline.

As of September 30, 2020, we had cash, cash equivalents and marketable securities of $380.5 million.

Components of Operating Results

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our ABC Platform and product candidates. These expenses include certain payroll and personnel expenses, including stock-based compensation, for our research and product development employees; laboratory supplies and facility costs; consulting costs; contract manufacturing and fees paid to CROs to conduct certain research and development activities on our behalf; and allocated overhead, including rent, equipment, depreciation and utilities. We expense both internal and external research and development expenses as they are incurred. Costs of certain activities, such as manufacturing and preclinical and clinical studies, are generally recognized based on an evaluation of the progress to completion of specific tasks. Nonrefundable payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized. The capitalized amounts are recognized as expense as the goods are delivered or the related services are performed.

We are focusing substantially all of our resources and development efforts on the development of our product candidates, in particular KSI-301. We expect our research and development expenses to increase substantially during the next few years as we conduct our Phase 3 studies, complete our clinical program, pursue regulatory approval of our drug candidates and prepare for a possible commercial launch. Predicting the timing or the final cost to complete our clinical program or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our drug candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including stock-based compensation; professional fees for legal, consulting, accounting and tax services; allocated overhead, including rent, equipment, depreciation and utilities; and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and accounting services associated with maintaining compliance with requirements of the stock exchange listing and the Securities and Exchange Commission, or SEC, investor relations costs and director and officer insurance premiums.

Interest Income

Interest income consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

Other Income (Expense), Net

Other income (expense), net consists primarily of accretion income and amortization expense on marketable debt securities net of amortized issuance costs from the liability related to the future sale of royalties to BBA in 2019.

Results of Operations

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Operating expenses						
Research and development	$ 29,306	$ 10,115	$ 19,191	$ 70,033	$ 24,676	$ 45,357
General and administrative	7,357	2,617	4,740	19,132	8,330	10,802
Loss from operations	(36,663)	(12,732)	(23,931)	(89,165)	(33,006)	(56,159)
Interest income	645	277	368	2,551	1,070	1,481
Interest expense	(6)	(2)	(4)	(19)	(8)	(11)
Other income (expense), net	(98)	77	(175)	120	195	(75)
Net loss	$ (36,122)	$ (12,380)	$ (23,742)	$ (86,513)	$ (31,749)	$ (54,764)

Research and Development Expenses

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
KSI-301 program external expenses (1)	$ 15,415	$ 5,808	$ 9,607	$ 37,587	$ 11,691	$ 25,896
ABC Platform external expenses (2)	2,174	440	1,734	5,345	1,911	3,434
KSI-501 program external expenses (3)	453	300	153	922	1,120	(198)
Other research and development expenses (4)	3,160	669	2,491	5,329	1,807	3,522
Payroll and personnel expenses (5)	8,104	2,898	5,206	20,850	8,147	12,703
Total research and development expenses	$ 29,306	$ 10,115	$ 19,191	$ 70,033	$ 24,676	$ 45,357

(1) KSI-301 program external expenses relates to development of KSI-301, including manufacturing and clinical trial costs. These expenses are primarily for services provided by CMOs and CROs.
(2) ABC Platform external expenses primarily relates to manufacturing of biopolymer intermediate drug substance which can be used with multiple product candidates. These expenses are primarily for services provided by CMOs.
(3) KSI-501 program external expenses relates to research and development of KSI-501.
(4) Other research and development expenses includes direct costs related to research and development activities other than those listed above.
(5) Payroll and personnel expenses includes salaries, benefits and stock-based compensation for our personnel involved in research and development activities. These expenses are separately classified and not allocated to specific programs because these expenses relate to multiple programs.

KSI-301 program external expenses increased $9.6 million and $25.9 million during the three and nine months ended September 30, 2020, respectively, as compared to 2019. The increase was primarily due to clinical trial costs to support ongoing trials and planned trials, as well as manufacturing progress for KSI-301. Our pivotal Phase 2b/3 clinical study in wAMD (DAZZLE) dosed the first patient in October 2019, and patient recruitment is expected to complete in the fourth quarter of 2020. We initiated two pivotal Phase 3 clinical studies in DME (GLEAM and GLIMMER) and one pivotal Phase 3 clinical study in RVO (BEACON) in the third quarter of 2020.

ABC Platform external expenses increased $1.7 million and $3.4 million during the three and nine months ended September 30, 2020, respectively, as compared to 2019. The increase was primarily driven by manufacturing runs to support our product candidate pipeline.

KSI-501 program external expenses remained relatively constant during the three and nine months ended September 30, 2020, as compared to 2019.

Other research and development expenses increased $2.5 million and $3.5 million during the three and nine months ended September 30, 2020, respectively, as compared to 2019, primarily due to the allocation of lease costs for Palo Alto and Switzerland.

Payroll and personnel expenses increased $5.2 million and $12.7 million during the three and nine months ended September 30, 2020, respectively, as compared to 2019, due to increased headcount and stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses increased $4.7 million and $10.8 million during the three and nine months ended September 30, 2020, respectively, as compared to 2019. The increase was primarily driven by increased headcount and stock-based compensation expense as well as professional services related to consulting, legal and accounting, and due to the allocation of lease costs for Palo Alto and Switzerland.

Liquidity and Capital Resources; Plan of Operations

Sources of Liquidity

We have funded our operations primarily through the sale of equity securities. In addition, we entered into a royalty funding agreement and received an initial payment of $100.0 million in February 2020. As of September 30, 2020, we had cash, cash equivalents and marketable securities of $380.5 million.

Future Funding Requirements

We have incurred net losses since our inception. For the nine months ended September 30, 2020, we had net loss of $86.5 million, and we expect to continue to incur additional losses in future periods. As of September 30, 2020, we had an accumulated deficit of $244.6 million.

We have based these estimates on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we expect. Because of the risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors.

To date, we have not generated any product revenue. We do not expect to generate any product revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates or enter into collaborative agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect our losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We have based these estimates on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. The timing and amount of our operating expenditures and capital requirements will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the extent to which we acquire or in-license other product candidates and technologies;

- the cost, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- 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;
- the costs associated with being a public company; and
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. 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 programs and clinical trials. We may also be required to sell or license rights to our product candidates in certain territories or indications to others that we would prefer to develop and commercialize ourselves.

The significant uncertainties caused by the evolving effects of the ongoing COVID-19 pandemic may also negatively impact our operations and capital resources. We and our key clinical and manufacturing partners have been able to continue to advance our operations, and we continue to monitor the impact of COVID-19 on our ability to continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. This pandemic may ultimately have a material adverse effect on our liquidity and operating plans, although we are unable to make any prediction with certainty given the spread and rapidly changing nature of the pandemic and the evolving global actions taken to contain and treat the novel coronavirus.

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. See the section of this report titled “Part II, Item 1A — Risk Factors” for additional risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods presented below, in thousands:

	Nine Months Ended September 30,	
	2020	**2019**
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (56,409)	$ (27,853)
Investing activities	45,976	(23,715)
Financing activities	101,096	347
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 90,663	$ (51,221)

Cash Flows from Operating Activities

The $28.6 million increase in cash used in operating activities for the nine months ended September 30, 2020 as compared to 2019 was primarily driven by the increase in net loss during this period due to increased payroll and personnel expenses and manufacturing and clinical trial costs to support overall growth. Cash used in operating activities was also driven by changes in operating assets and liabilities.

Cash Flows from Investing Activities

The $69.7 million increase in cash provided by investing activities for the nine months ended September 30, 2020 as compared to 2019 was driven by the investment of funds from maturities of marketable securities into money market funds during 2020.

Cash Flows from Financing Activities

The $100.7 million increase in cash provided by financing activities for the nine months ended September 30, 2020 as compared to 2019 was due to the proceeds from sale of future royalties to BBA and proceeds from stock option exercises.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments is set forth under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations” in our Annual Report on Form 10-K for the year ended December 31, 2019. There have been no material changes in our contractual obligations and commitments since December 31, 2019, except as otherwise described in Note 6 to our unaudited condensed consolidated financial statements included in this report.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

During the nine months ended September 30, 2020, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on March 16, 2020, except as otherwise described in Note 2 to our unaudited condensed consolidated financial statements included in this report.

Off-Balance Sheet Arrangements

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

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012, or JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until such pronouncements are made applicable to private companies, unless we otherwise irrevocably elect not to avail ourselves of this exemption. However, we have chosen to irrevocably “opt out” of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to not take advantage of the extended transition period for complying with new or revised accounting standards is irrevocable.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is discussed under Note 2 to our unaudited condensed consolidated financial statements included in this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the nine months ended September 30, 2020, there were no material changes to our market risk disclosures as reported in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on March 16, 2020.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon such evaluation, management concluded that the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2020.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2020, that has materially affected, or is 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 become involved in litigation relating to claims arising from the ordinary course of business. As of the date of this report, there are no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors.

You should consider carefully the following risk factors, together with all the other information in this report, including the section of this report titled "Part I, Item 2 — Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed financial statements and notes thereto. The occurrence of any events described in the following risk factors and the risks described elsewhere in this report could harm our business, operating results, financial condition, and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements that we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Related to Our Business, Financial Condition and Capital Requirements

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

We are a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases. We commenced operations in June 2009, have no products approved for commercial sale and have not generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. Except for KSI-301, we have not initiated clinical trials for any of our other product candidates. To date, we have not completed a pivotal clinical trial, obtained marketing approval for any product candidates, manufactured a commercial scale product, or conducted sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company and early stage of drug development make any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur significant and increasing net losses for the foreseeable future.

We have incurred net losses in each reporting period since our inception, including net loss of $86.5 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of $244.6 million.

We have invested significant financial resources in research and development activities, including for our product candidates and our ABC Platform. We do not expect to generate revenue from product sales for several years, if at all. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We expect to continue to incur significant and increasingly higher expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- progress our current and any future product candidates through preclinical and clinical development;
- work with our contract manufacturers to scale up the manufacturing processes for our product candidates or, in the future, establish and operate a manufacturing facility;
- continue our research and discovery activities;
- continue the development of our ABC Platform;
- initiate and conduct additional preclinical, clinical or other studies for our current and any future product candidates;
- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates, including KSI-301;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;

- acquire or in-license product candidates, intellectual property and technologies;
- make milestone, royalty or other payments due under any current or future collaboration or license agreements;
- obtain, maintain, expand, protect and enforce our intellectual property portfolio;
- attract, hire and retain qualified personnel;
- experience any delays or encounter other issues related to our operations;
- meet the requirements and demands of being a public company; and
- defend against any product liability claims or other lawsuits related to our products.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, and we may never generate revenue or be profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. We do not anticipate generating any revenue from product sales until after we have successfully completed clinical development and received regulatory approval for the commercial sale of a product candidate, if ever.

Our ability to generate revenue and achieve profitability depends significantly on many factors, including:

- successfully completing research and preclinical and clinical development of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and any commercial demand for our product candidates;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- launching and successfully commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized;
- obtaining adequate reimbursement for our product candidates from payors;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory agencies, to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable, and we will need to obtain additional funding through one or more debt or equity financings in order to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even 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 could decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of our common stock, all or any of which may adversely affect our viability.

If we fail to obtain additional financing, we may be unable to complete the development and, if approved, commercialization of our product candidates.

Our operations have required substantial amounts of cash since inception. To date, we have funded our operations primarily through the sale of equity securities. Developing our product candidates is expensive, and we expect to continue to increase our spending as we conduct the Phase 3 clinical trials for our KSI-301 product candidate. Even if we are successful in developing our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial additional funding.

As of September 30, 2020, we had cash, cash equivalents and marketable securities of $380.5 million. Our estimate as to how long we expect our existing cash, cash equivalents and marketable securities to be available to fund our operations is based on assumptions that may prove inaccurate, and we could deplete our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

We will require additional capital for the further development and, if approved, commercialization of our product candidates. Additional capital may not be available when we need it, on terms acceptable to us or at all. For example, the ongoing COVID-19 pandemic has significantly disrupted world financial markets, negatively impacted US market conditions, increased the volatility of trading prices for biopharmaceutical companies, and may reduce opportunities for us to seek out additional funding when needed. We currently have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations and cause the price of our common stock to decline.

Due to the significant resources required for the development of our product candidates, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on product candidates that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain product candidates may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the biopharmaceutical industry, in particular for retinal diseases, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

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

Our prospects are heavily dependent on our KSI-301 product candidate, which is currently in clinical development for multiple indications.

KSI-301 is our only product candidate currently in clinical trials. It may be years before any registrational type trial is completed, if at all. Further, we cannot be certain that either KSI-301 or any of our product candidates will be successful in clinical trials.

Our early encouraging preclinical and Phase 1/1b clinical trial results for KSI-301 in the respective indications are not necessarily predictive of the results of our ongoing or future discovery programs or any future preclinical or clinical studies. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical studies after achieving positive results in early-stage development, including early-stage clinical studies, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway or safety or efficacy observations made in preclinical studies and clinical studies, including previously unreported adverse events.

There can be significant variability in safety or efficacy results between different clinical studies of the same product candidate due to numerous factors, including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical study protocols and the rate of dropout among clinical study participants. 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 studies nonetheless failed to obtain FDA approval.

We may in the future advance product candidates into clinical trials and terminate such trials prior to their completion. While we have certain preclinical programs in development and intend to develop other product candidates, it will take additional investment and time for such programs to reach the same stage of development as KSI-301.

A failure of KSI-301 in clinical development may require us to discontinue development of other product candidates based on our ABC Platform.

If KSI-301 fails in development as a result of any underlying problem with our platform, then we may discontinue development of some or all of our product candidates that are based on our ABC Platform. If we discontinue development of KSI-301, or if KSI-301 were to fail to receive regulatory approval or were to fail to receive regulatory approval in one or more of our four planned key clinical indications or were to fail to achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability.

Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory, including marketing, approval, which is necessary before they can be commercialized.

We are at an early stage of development of our product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- our competitors may develop platform technologies that render our ABC Platform obsolete or less attractive;
- the product candidates and ABC Platform that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights or may be covered by third party patents or other intellectual property or exclusive rights;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a product candidate or candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Failure of a product candidate may occur at any stage of preclinical or clinical development, and, because our product candidates and our ABC Platform are in an early stage of development, there is a relatively higher risk of failure and we may never succeed in developing marketable products or generating product revenue.

We may not be successful in our efforts to further develop our ABC Platform and current product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates is in the early stages of development and will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all. Any clinical studies that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical studies are inconclusive with respect to the efficacy of our product candidates or if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates.

If any of our product candidates successfully completes clinical trials, we generally plan to seek regulatory approval to market our product candidates in the United States, the EU, and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing, and distribution of our product candidates. We may also rely on our collaborators or partners to conduct the required activities to support an application for regulatory approval, and to seek approval, for one or more of our product candidates. We cannot be sure that our collaborators or partners will conduct these activities successfully or do so within the timeframe we desire. Even if we (or our collaborators or partners) are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. That approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical studies to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a modified Risk Evaluation and Mitigation Strategy, or REMS. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

Investment in biopharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates.

We may encounter substantial delays in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an IND application or a clinical trial application, or CTA, will result in the FDA, European Medicines Agency, or EMA, the Center for Drug Evaluation under the China National Medical Products Administration, or CDE, or any other regulatory authority as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory agencies on study design or, in the case of China, the registration category for the drug candidate to be studied in the clinical trial;

- the determination by the reviewing regulatory authority to require more costly or lengthy clinical trials than we currently anticipate;
- delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites; developments on trials conducted by competitors for related technology that raises FDA, EMA, CDE or any other regulatory authority concerns about risk to patients of the technology broadly; or if the FDA, EMA, CDE or any other regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's current good clinical practices, or cGCPs, requirements, or applicable EMA, CDE or other regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by CMOs or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA, CDE or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, CDE or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Delays in the commencement or completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA, CDE or other comparable foreign regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates has side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results and financial condition.

Our most advanced product candidate, KSI-301, is an anti-VEGF biologic that we are studying in wet AMD, DME/DR and RVO. There are some potential side effects associated with intravitreal anti-VEGF therapies such as intraocular hemorrhage, intraocular pressure elevation, retinal detachment, inflammation, vasculitis, artery occlusion or infection inside the eye and over-inhibition of VEGF, as well as the potential for potential systemic side effects such as heart attack, stroke, wound healing problems, and high blood pressure. Recent trends in the development of anti-VEGF therapies have favored increased molar dosages, as compared to currently marketed treatments. To date these heightened dosages have not exhibited a safety profile significantly worse than that of current treatments, as attributable to molar dose. However, anti-VEGF product candidates featuring higher molar dosages, including KSI-301, may heighten the risk of adverse effects associated with anti-VEGF treatments generally, both in the eye and in the rest of the body. There are risks inherent in the intravitreal injection procedure of drugs like KSI-301 which can cause injury to the eye and other complications including conjunctival hemorrhage, punctate keratitis, eye pain, conjunctival hyperemia, intra-ocular inflammation, and endophthalmitis.

Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study and/or result in potential product liability claims. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

We may encounter difficulties enrolling patients in our clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol, including certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have such patient eligibility criteria;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to a trial site;
- the effects of health epidemics, including the ongoing COVID-19 pandemic and the resulting shelter-in-place, travel or similar restrictions;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason.

For example, because patients with early stages of DR often lack symptoms, it may be challenging to identify and enroll patients at early stages of disease that may be required for a clinical trial. Our inability to enroll a sufficient number of patients for our clinical trials could 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, delay or halt the development of and approval processes for our product candidates and jeopardize our ability to commence sales of and generate revenues from our product candidates, which may harm our business and results of operation.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy or durability of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. For those product candidates that are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. This is especially true for anti-VEGF biologic agents where Lucentis and Eylea are established products with accepted safety profiles.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety, efficacy or durability results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Product candidates in later stages of clinical trials may fail to show the desired safety, efficacy and durability profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We may be unable to design and execute clinical trials that support marketing approval. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

We may not be successful in our efforts to continue to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited.

One of our strategies is to identify and pursue clinical development of additional product candidates through our ABC Platform. Our ABC Platform may not produce a pipeline of viable product candidates, or our competitors may develop platform technologies that render our ABC Platform obsolete or less attractive. Our research methodology may be unsuccessful in identifying potential product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make them unmarketable or unlikely to receive marketing approval. Identifying, developing, obtaining regulatory approval and commercializing additional product candidates for the treatment of retinal diseases will require substantial additional funding and is prone to the risks of failure inherent in drug development. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may retain their market share with existing drugs, or achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of the retinal disease indications for which we have product candidates, including wet AMD and DME/DR. Certain of our competitors have commercially approved products for the treatment of retinal diseases that we are pursuing or may pursue in the future, including Roche, Regeneron and Novartis for the treatment of wet AMD and DME/DR. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to convince these parties to switch to KSI-301. Companies that we are aware are developing therapeutics in the retinal disease area include large companies with significant financial resources, such as Roche, Novartis, Bayer and Regeneron, AbbVie/Allergan, Mylan, Momenta and Samsung Bioepis. In addition to competition from other companies targeting retinal indications, any products we may develop may also face competition from other types of therapies, such as gene-editing therapies and drug delivery devices.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of retinal disease indications, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA, CDE or other regulatory approval for their products more rapidly than we may obtain approval for ours. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. For more information regarding potential disputes concerning intellectual property, see the subsection of this report titled "Risks Related to Our Intellectual Property."

The manufacture of our product candidates is highly complex and requires substantial lead time to produce.

Manufacturing our product candidates involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells, and harvesting and purifying the biologic produced by them. These processes require specialized facilities, highly specific raw materials and other production constraints. As a result, the cost to manufacture a biologic is generally far higher than traditional small molecule chemical compounds, and the biologics manufacturing process is less reliable and is difficult to reproduce. Because of the complex nature of our products, we need to oversee the manufacture of multiple components that require a diverse knowledge base and specialized personnel.

Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as our product candidates generally cannot be adequately characterized prior to manufacturing the final product. As a result, an assay of the finished product is not sufficient to ensure that the product will perform in the intended manner. Accordingly, we expect to employ multiple steps to attempt to control our manufacturing process to assure that the process works and the product or product candidate is made strictly and consistently in compliance with the process

Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, improper storage or transfer, inconsistency in yields and variability in product characteristics. Even minor deviations from normal manufacturing, distribution or storage processes could result in reduced production yields, product defects and other supply disruptions. Some of the raw materials required in our manufacturing process are derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt commercialization. Production of additional drug substance and drug product for any of our product candidates may require substantial lead time. For example, currently any new large-scale batches of KSI-301 would require at least 12 months to manufacture. In the event of significant product loss and materials shortages, we may be unable to produce adequate amounts of our product candidates or products for our operational needs.

Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and 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.

These challenges are magnified by the international nature of our supply chain, which, for KSI-301, requires drug substance and drug product sourced from single source suppliers from China, Japan, the United Kingdom, and Switzerland. For example, the effects of health epidemics, including the ongoing COVID-19 pandemic and the resulting shelter-in-place, travel or similar restrictions may impact the timing of clinical resupply facing and BLA facing manufacturing activities.

We have no experience manufacturing any of our product candidates at a commercial scale. If we or any of our third-party manufacturers encounter difficulties in production, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to establish a commercially viable cost structure.

In order to conduct clinical trials of our product candidates, or supply commercial products, if approved, we will need to manufacture them in small and large quantities. Our third-party manufacturer has made only a limited number of lots of KSI-301 to date and has not made any commercial lots. The manufacturing processes for KSI-301 have never been tested at commercial scale and the process validation requirement (the requirement to consistently produce the active pharmaceutical ingredient used in KSI-301 in commercial quantities and of specified quality on a repeated basis and document its ability to do so) has not yet been satisfied. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of our product candidates may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to any internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity.

In addition, the manufacturing process for any products that we may develop is subject to FDA, EMA, CDE and foreign regulatory authority approval processes and continuous oversight. We will need to contract with manufacturers who can meet all applicable FDA, EMA, CDE and foreign regulatory authority requirements, including complying with current good manufacturing practices, or cGMPs, on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, EMA, CDE or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA, CDE or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the ability to offer appropriate patient access programs, such as co-pay assistance;
- the extent to which physicians recommend our products to their patients;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by FDA, EMA, CDE or other regulatory agencies;

- product labeling or product insert requirements of the FDA, EMA, CDE or other comparable foreign regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs, or VA, hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. 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. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, that the level of reimbursement will be sufficient.

Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to get reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may 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.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, EMA, CDE or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Our product candidates for which we intend to seek approval as biologic products may face competition from biological products that are biosimilar to or interchangeable with our product candidates sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA, CDE 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, CDE 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 studies. 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 for many reasons, including but not limited to the following:

- the FDA, EMA, CDE or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA, CDE 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 of our products;
- 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;
- we may be unable to demonstrate to the FDA, EMA, CDE or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication, when compared to the standard of care, is acceptable;
- the FDA, EMA, CDE 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 an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA, EMA, CDE 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, CDE 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.

We plan to conduct clinical trials for our product candidates outside the United States, and the FDA, EMA, CDE and applicable foreign regulatory authorities may not accept data from such trials.

We plan to conduct one or more of our clinical trials outside the United States, including Europe, China and other foreign countries. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA, CDE or applicable foreign regulatory authority 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 (1) the data are applicable to the U.S. population and U.S. medical practice and (2) the trials were performed by clinical investigators of recognized competence and pursuant to cGCP 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, CDE or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction, including any trials that we may conduct in China. If the FDA, EMA, CDE 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, would 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, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA, EMA or CDE grants marketing approval of a product candidate, we would not be permitted to manufacture, market or promote the product candidate in other countries unless and until comparable regulatory authorities in foreign jurisdictions had approved the candidate for use in their countries. 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. There can be no assurance that any clinical trials conducted in one jurisdiction will be accepted by regulatory authorities in other jurisdictions.

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 collaborator 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 we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA, CDE and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA or marketing authorization application, or MAA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a REMS), or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA, CDE and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;

- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain international jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since the ACA's enactment, there have been, and continue to be, numerous challenges to the ACA. Since January 2017, President Trump has signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In addition, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the ongoing COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Moreover, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. At the federal level, the Trump administration's budget proposal for fiscal 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. In addition, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has started implementing some of these measures under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, the Trump administration announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie certain Medicare Part B drug prices to international drug prices, or the "most favored nation price," the details of which were released on September 13, 2020 and also expanded the policy to cover certain Part D drugs; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. The FDA also recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved. Further, it is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements or insider trading violations, which could significantly harm our business.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA, EMA, CDE and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA, EMA, CDE and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA

approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. Employee misconduct could also involve the improper use of, including improper trading based upon, information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation.

In connection with our IPO, we adopted a code of business conduct and ethics that applies to all our employees, including management, and our directors. However, it is not always possible to identify and deter misconduct by employees and third parties, 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 be in compliance with such laws. 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 healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. The laws that may impact our operations include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws, including the False Claims Act, which can be enforced by private citizens on behalf of the government through civil whistleblower or qui tam actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services under the Open Payments Program, information related to payments or other transfers of value made to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and 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 civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Our business is subject to complex and evolving U.S. and foreign laws and regulations relating to privacy and data protection. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, or monetary penalties, and otherwise may harm our business.

A wide variety of provincial, state, national, and international laws and regulations apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data. These data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions. For example, the European Union General Data Protection Regulation, or GDPR, which became fully effective on May 25, 2018, imposes stringent data protection requirements and provides for penalties for noncompliance of up to the greater of 20 million euros or four percent of worldwide annual revenues. Additionally, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, that, effective January 1, 2020, among other things, requires covered companies to provide new disclosures to California consumers, and afford such consumers new abilities to opt-out of certain sales of personal information. The GDPR, CCPA and many other laws and regulations relating to privacy and data protection are still being tested in courts, and they are subject to new and differing interpretations by courts and regulatory officials. We are working to comply with the GDPR, CCPA and other privacy and data protection laws and regulations that apply to us, and we anticipate needing to devote significant additional resources to complying with these laws and regulations. It is possible that the GDPR, CCPA or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our current policies and practices.

European data protection laws, including the GDPR, generally restrict the transfer of personal information from Europe, including the European Economic Area, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. One of the primary safeguards allowing U.S. companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the Court of Justice of the European Union recently invalidated the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the United States or most other countries. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Although we and third party service providers rely primarily on individuals' explicit consent to transfer certain information from Europe to the United States and other countries, in certain cases we and third parties have relied on the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Authorities in the United Kingdom and Switzerland, whose data protection laws are similar to those of the European Union, may similarly invalidate use of the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield, respectively, as mechanisms for lawful personal information transfers from those countries to the United States. As such, if we are unable to rely on explicit consent to transfer individuals' personal information from Europe, which can be revoked, or implement other valid compliance solutions, we may face increased exposure to fines under European data protection laws as well as injunctions against processing personal information from Europe. Inability to import personal information from the European Economic Area or Switzerland may also impact our operations in the European Economic Area and Switzerland and require us to increase our data processing capabilities in Europe. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

Our actual or perceived failure to adequately comply with applicable laws and regulations relating to privacy and data protection, or to protect personal data and other data we process or maintain, could result in regulatory fines, investigations and enforcement actions, penalties and other liabilities, claims for damages by affected individuals, and damage to our reputation, any of which could materially affect our business, financial condition, results of operations and growth prospects.

If we or any contract manufacturers and suppliers we engage 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 the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. 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. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate or may operate in the future, including the UK Bribery Act. 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 can be no assurance that all of our employees, agents, contractors or collaborators, 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 ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Risks Related to Our Reliance on Third Parties

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct some aspects of our research, preclinical testing and clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities, but does not relieve us of our responsibilities. For example, we 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 cGCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and to post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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 any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of materials for our product candidates and preclinical studies and clinical trials and for commercialization of any product candidates that we may develop. This reliance on third parties carries and may increase the risk that we will not have sufficient quantities of such materials, product candidates or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely exclusively on a third-party manufacturer, Lonza AG, for the manufacture of our materials for preclinical studies and clinical trials and expect to continue to do so for preclinical studies, clinical trials and for commercial supply of any product candidates that we may develop.

We may be unable to establish any further 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 breach of the manufacturing agreement by the third party or us;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible early termination of the agreement by us at a time that requires us to pay a cancellation fee;
- reliance on the third party for regulatory compliance, quality assurance, safety and pharmacovigilance and related reporting; and
- the inability to produce required volume in a timely manner and to quality standards.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in clinical holds on our trials, sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations, and prospects.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for any of our product candidates. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer and may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, securing and reserving production capacity with contract manufacturers may result in significant costs.

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

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Reliance on third parties to conduct clinical trials, assist in research and development and to manufacture our product candidates, will at times require us to share trade secrets with them. We seek to protect our proprietary technology by in part entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

We rely on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Our reliance on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

We may depend on collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates.

We may seek third-party collaborators for the research, development and commercialization of certain of the product candidates we may develop. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, biotechnology companies and academic institutions. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our product candidates we may develop, pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may decide not to pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished or terminated;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how or intellectual property of the collaborator relating to our products, product candidates;

- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates or our ABC Platform; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and 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 the product candidate for which we are seeking to collaborate or 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. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for our ABC Platform, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our ABC Platform and any proprietary product candidates and other technologies we may develop. We seek to protect our proprietary position by in-licensing intellectual property and filing patent applications in the United States and abroad relating to our ABC Platform, product candidates and other technologies that are important to our business. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio directed to certain aspects of our technology and product candidates is also at an early stage. We have filed or intend to file patent applications on core aspects of our technology and product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we only have filed provisional patent applications on certain aspects of our technology and product candidates, and none of these provisional patent applications is eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our ABC Platform and product candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture for protection of such ABC Platform, product candidates and other technologies. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our ABC Platform and product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If any of our patent applications does not issue as a patent in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, and obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. In addition, our own fixed applications may become prior art against our current or future patent applications. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our ABC Platform, product candidates or other technologies or that effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents may be challenged, narrowed, circumvented, rendered unenforceable or invalidated by third parties. Consequently, we do not know whether our ABC Platform, product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our ABC Platform, product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions and other challenges in a foreign patent office or administrative tribunal, that challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our ABC Platform, product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

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

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

Filing, prosecuting and defending patents relating to our ABC Platform, product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as U.S. laws. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our 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 have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our 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, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult, costly or impossible for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 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.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. Payment within these late fee windows may be employed in order to simplify the payment of these fees generally. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, while not relevant for KSI-301, if we rely on a different product, its development could involve the use of government funds, which can require additional compliance aspects to make certain all rights are transferred to or remain with us.

Issued patents may be challenged or invalidated, and recent changes in U.S. patent law have diminished and may further diminish the value of patents in general. We rely on patents to protect our products, and any diminishment in the scope or value of our patents would adversely affect our business.

If we initiated legal proceedings against a third party to enforce a patent directed to our ABC Platform, product candidates or other technologies, the defendant could allege that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including obviousness, lack of novelty, lack of written description, or non-enablement. Grounds for an unenforceability challenge include an allegation that someone connected with prosecution of the patent withheld material information from the USPTO with an intent to deceive the USPTO, or made a misleading statement, during prosecution. The filing of a legal proceeding could also result in the third party challenging the patent at the USPTO, such as in post-grant and inter partes review.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For patent filings beginning in March 2013, the United States employs a first inventor to file system in which, assuming that other requirements for patentability 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. Under the current patent laws, a third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our ABC Platform, product candidates or other technologies or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications.

Changes to U.S. patent laws since 2011 also include allowing third party submissions of prior art to the USPTO during patent prosecution and additional procedures for attacking the validity of a patent through USPTO administered post-grant proceedings, including re-examination, post-grant review, inter partes review, interference proceedings and derivation proceedings. Some of these changes apply to patents issued prior to 2011. These and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings) could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our ABC Platform, product candidates or other technologies. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standards applied in United States federal courts that apply to actions seeking to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if challenged in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not otherwise have been invalidated if first challenged by the third party as a defendant in a district court action.

As compared to intellectual property-reliant companies generally, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. These rulings have created uncertainty with respect to the validity and enforceability of patents, even once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Any future changes to patent laws could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our ABC Platform, product candidates or other technologies. Increased uncertainty with respect to, or loss of, patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. Patent term extension in the United States and/or foreign countries and territories may not be available if, among other things, we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to the expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension received is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor or owner or co-owner. For example, we may have inventorship disputes arise from conflicting obligations of employees, collaborators, consultants or others who are involved in developing our ABC Platform, product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our ABC Platform, product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our ABC Platform, product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. Over time, we expect our trade secrets and know-how to be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, train our employees not to bring or use proprietary information or technology from former employers to us or in their work and remind former employees when they leave their employment of their confidentiality obligations to us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to contain such breaches or disclosures or obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed without the protection of a confidentiality agreement found unenforceable by relevant courts or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors 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 individuals have improperly used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. Where post-filing date patent assignments are not executed by an inventor, it is our practice to employ and record the assignment provision that can be found in the employee's employment agreement. This is done when possible, and when the intellectual property is of interest to us.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our ABC Platform, product candidates and other technologies.

The field of discovering treatments for retinal diseases is highly competitive and dynamic. Due to the focused research and development that is taking place in this field by several companies, including us and our competitors, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to ABC technology and in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our ABC Platform, product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our ABC Platform, product candidates and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued or that a third party, including a competitor in the fields in which we are developing our ABC Platform, product candidates and other technologies, might assert are infringed by our current or future ABC Platform, product candidates or other technologies. Such a dispute may concern claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our ABC Platform, product candidates or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our ABC Platform, product candidates or other technologies, could be found to be infringed by our ABC Platform, product candidates or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that later result in issued patents that our ABC Platform, product candidates or other technologies may infringe.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our ABC Platform, product candidates or other technologies infringes these patents. If a third party alleges that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our ABC Platform, product candidates or other technologies, even if we believe such claims are without merit. In that event, the successful plaintiff may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees, royalties or both. Any license granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our ABC Platform, product candidates or other technologies, or our commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

We are aware of a number of patents and applications that are directed to one or more aspects of KSI-301. Our intent is to maintain our development efforts under 35 U.S.C. Section 271(e)(1) (which provides a safe harbor from patent infringement claims related to certain drug development activities) through to at least the launch of any KSI-301 product. As such, we do not intend to launch KSI-301 when any valid patent is still in force. We are aware of at least one pending application with claims that are directed to some aspect of KSI-301, and that could, if issued, result in a patent term beyond our intended launch date of KSI-301. If this were to occur, we may challenge the validity of the claims, obtain a license, modify KSI-301, or delay launch.

If we choose to further the pipeline and develop a different product, such a product would be delayed until the expiration of any valid patent that is still in force on such product. Alternatively, our options for addressing any such patents relating to these non-KSI-301 products would include the following: challenge the validity of the claims, obtain a license, or modify the non-KSI-301 product.

Defending against infringement claims, regardless of their merit, would involve substantial litigation expense, would be a substantial diversion of management and other employee resources from our business and may adversely impact our reputation. We may be subject to an injunction that prevents or delays us from commercializing our ABC Platform technology, product candidates or other technologies during ongoing litigation even if we ultimately prevail in the litigation proceedings or the litigation is settled in our favor. We may be subject to an injunction that prevents or delays us from commercializing our ABC Platform, product candidates or other technologies during ongoing litigation even if we ultimately prevail in the litigation proceedings or the litigation is settled in our favor. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing ABC Platform, product candidates or other technologies. In addition, we may have to pay substantial damages (including treble damages and attorneys' fees for willful infringement) obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. If we were unable to further develop and commercialize our ABC Platform, product candidates or other technologies, it would harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. If we assert our intellectual property against others, it could increase the likelihood that our patents or the patents of our licensing partners become involved in inventorship, priority or validity disputes. As discussed above, countering or defending against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1), or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated, rendered unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if we prevail in asserting our intellectual property, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately or to assert all claims we believe to be viable. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We rely on trademarks, service marks, tradenames and brand names. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, any registered or unregistered trademarks or trade names that we currently have or may in the future acquire may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. We own a registered trademark for the mark "KODIAK" in the United States. The application for registration of the mark "KODIAK SCIENCES" in the United States has been allowed. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We engage a third party watching service to monitor use by third parties of names that are identical or similar to our name. We have identified at least two companies that are using names that we continue to monitor. We have sent a cease and desist letter to one of the companies. If we deem it appropriate, we may decide to take further action with respect to those companies. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we may license or own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Operations

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, particularly our Chief Executive Officer, Dr. Victor Perlroth, and our scientific and medical personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business.

We conduct our U.S. operations at our facilities in Palo Alto, California, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock option grants, including early exercise stock options exercisable for restricted stock that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of all of these individuals or the lives of any of our other employees. If we are unable to attract, incentivize and retain quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2020, we had 62 employees, all of whom were full-time. As our development plans and strategies develop, and as we continue operating as a public company, we must add a significant number of additional managerial, operational, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties;
- expanding our operational, financial and management controls, reporting systems and procedures; and
- managing increasing operational and managerial complexity.

Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage 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. There can be no assurance that the services of these 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 consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

A failure to maintain an effective system of internal control over financial reporting could result in material misstatements of our financial statements in future periods and may impair our ability to comply with the accounting and reporting requirements applicable to public companies.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

If we engage in acquisitions, in-licensing 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 engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- 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 regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge, we have not experienced any such material system failure or security breach to date, if such an event were to occur, it could result in a material disruption of our development programs and our business operations, whether due to a loss of trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third-party research institution collaborators, CROs, other contractors and consultants for many aspects of our business, including research and development activities and manufacturing of our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business.

The secure maintenance of information is critical to our business and reputation. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past few years, cyber-attacks have become more prevalent and much harder to detect and defend against.

Our network and storage applications and those of our collaborators, CROs and vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. Additionally, the increased usage of computers operated on home networks due to the shelter-in-place or similar restrictions related to the ongoing COVID-19 pandemic may make our systems and those of our CROs and vendor more susceptible to security breaches. It is often difficult to anticipate or immediately detect such incidents and the damage caused by them. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information. A data security breach could also lead to public exposure of personal information of our employees. Cyber-attacks could cause us to incur significant remediation costs, disrupt key business operations and divert attention of management and key information technology resources. Our network security and data recovery measures and those of our collaborators, CROs and vendors may not be adequate to protect against such security breaches and disruptions. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. For example, in connection to the ongoing COVID-19 pandemic, the various quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, could adversely affect our business, financial condition or results of operations by limiting our ability to manufacture product, forcing temporary closure of facilities that we rely upon or increasing the costs associated with obtaining clinical supplies of our product candidates. The extent to which the ongoing COVID-19 pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of the COVID-19 pandemic and the actions to contain the coronavirus or treat its impact, among others.

Our operations are located at facilities in Palo Alto, California and Switzerland. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

We recently implemented a new enterprise resource planning, or ERP, system as well as other systems as part of our ongoing technology and process improvements. Our ERP system is critical to our ability to accurately maintain books and records and prepare our financial statements. If we encounter unforeseen problems with our ERP system or other systems and infrastructure, our business, operations, and financial results could be adversely affected.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and collaborative relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements, pricing and reimbursement regimes in non-U.S. countries;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- potential liability under the FCPA or comparable foreign laws; and
- business interruptions resulting from geo-political actions, including war and terrorism or natural disasters.

In June 2016, the United Kingdom, or UK, held a referendum in which a majority of the eligible members of the electorate voted for the U.K. to leave the EU. The U.K's withdrawal from the EU is commonly referred to as Brexit. The U.K. and the EU agreed to a withdrawal agreement (the Withdrawal Agreement) pursuant to which the U.K. formally left the EU on January 31, 2020. Under the Withdrawal Agreement, the U.K. is subject to a transition period until December 31, 2020 (the Transition Period), during which EU rules will continue to apply. Negotiations between the U.K. and the European Union are expected to continue in relation to the customs and trading relationship between the U.K. and the European Union following the expiry of the Transition Period. Under the formal withdrawal arrangements between the U.K. and the EU, the parties had until June 30, 2020 to agree to extend the Transition Period if required. No such extension was agreed prior to such date. No agreement has yet been reached between the U.K. and the EU and it may be the case that no formal customs and trading agreement will be reached prior to the expiry of the Transition Period on December 31, 2020. The withdrawal may cause increased economic volatility, affecting our operations and business. Brexit may adversely impact our ability to obtain regulatory approvals of our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain profitable operations.

Our business is currently affected and could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, including the ongoing effects of the COVID-19 pandemic. The COVID-19 pandemic continues to impact our business and could materially and adversely affect our operations, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business could be materially and adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations and could cause significant disruption in the operations of third party manufacturers and CROs upon whom we rely. For example, in March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. In response, we delayed initiation of the next set of KSI-301 pivotal studies by one quarter from June to September 2020 in order to assess how best to minimize the impact of COVID-19 on clinical trial conduct. We implemented and continue to implement various enhancements into our ongoing study execution to help ensure the safety of patients, physicians, study site staff and Kodiak operations team members during the ongoing COVID-19 pandemic, including the use of remote study monitoring. To date, we have observed minimal disruption resulting from the evolving effects of the COVID-19 pandemic, and we and our key clinical and manufacturing partners have been able to continue to advance our operations. during the pandemic towards achieving our "2022 Vision."

The COVID-19 pandemic continues to unfold and we will continue to monitor our operations in response. We continue to observe government recommendations and may elect to temporarily close our office and/or laboratory space to protect our employees. Quarantines for COVID-19 or other viruses could impact personnel at third party manufacturing facilities, or the availability or cost of materials, which would disrupt our supply chain. While many of these materials may be obtained by more than one supplier, port closures and other restrictions resulting from the coronavirus outbreak in the region may disrupt our supply chain or limit our ability to obtain sufficient materials for our drug products.

In addition, our current and future clinical trials may be materially and adversely affected by the COVID-19 outbreak in the future. Site initiation and patient enrollment may be further delayed due to prioritization of hospital resources toward the COVID-19 outbreak. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations. Kodiak staff and/or our CRO partners may not be able to travel to study sites, impacting further site initiations. Other Kodiak vendors on whom we depend, such as supply chain and logistics partners and our image reading centers may be disrupted, and our operations could be affected. Our clinical studies enroll patients who have underlying risk factors such as advanced age, hypertension and/or diabetes which could lead to higher than expected study discontinuation rates if these patients are adversely affected by the COVID-19 outbreak. To date, we are seeing low levels of patient missed visits (<5%).

The global outbreak of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

To the extent the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

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

As of December 31, 2019, we had federal net operating loss carryforwards, or NOLs, of $31.8 million. A portion of the federal net operating loss carryforwards begins to expire in 2035. Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

The Tax Cuts and Jobs Act (the "Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") enacted in March 2020, among other things, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards. Federal NOLs arising in tax years beginning after December 31, 2017 are permitted to be carried forward indefinitely, but carryback of such NOLs is generally permitted to the prior five taxable years only for NOLs arising in taxable years beginning before 2021. In addition, under the Tax Act, as modified by the CARES Act, the deductibility of federal NOLs incurred in taxable years beginning after December 31, 2017 is limited in taxable years beginning after December 31, 2020. For state income tax purposes, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023. The new limitations on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares.

The market price of our common stock may be volatile. As a result, you may not be able to sell your common stock at or above the price that you paid for such shares. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive products or technologies;
- the timing and results of clinical trials for our current product candidates and any future product candidates that we may develop;
- commencement or termination of collaborations for our product candidates;
- failure or discontinuation of any of our product candidates;
- failure to develop our ABC Platform;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of 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 personnel;
- the commencement of litigation;
- the level of expenses related to any of our research programs, product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- expiration of market standoff or lock-up agreements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions, including fluctuations attributable to the ongoing COVID-19 pandemic and other unforeseeable circumstances; and
- the other factors described in this “Risk Factors” section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Future sales of our common stock in the public market could cause our share price to decline, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales, particularly sales by our directors, executive officers and significant stockholders, may have on the prevailing market price of our common stock. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates. In addition, the shares of common stock subject to outstanding options under our equity incentive plans and the shares reserved for future issuance under our equity incentive plans, as well as shares issuable upon vesting of restricted stock unit awards, will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, certain holders of our common stock have the right, subject to various conditions and limitations, to request we include their shares of our common stock in registration statements we may file relating to our securities. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We will seek additional capital through one or a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Our principal stockholders own a significant percentage of our common stock, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors, executive officers, significant holders of outstanding common stock and their respective affiliates beneficially own a significant amount of our common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We are an "emerging growth company," and a "smaller reporting company," and the reduced disclosure requirements applicable us may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, to the extent that we continue to qualify as a "smaller reporting company," as defined in the Exchange Act, we may choose to provide the scaled disclosure available to smaller reporting companies. As a result, the information we provide stockholders may be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we 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 continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. SOX, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are continually evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

While we remain an emerging growth company, we will not 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 SOX Section 404 within the prescribed period, we will be engaged 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, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

As a public company, we are subject to reporting and other obligations under the Exchange Act, including the requirements of SOX Section 404, which require annual management assessments of the effectiveness of our internal control over financial reporting.

The rules governing the standards that must be met for management to determine that our internal control over financial reporting is effective 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 SOX. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

We have broad discretion in the use of proceeds from any offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds received from any offering. Our management may spend a portion or all of the net proceeds from any offering in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from any offering in a manner that does not produce income or that loses value.

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

Provisions in our certificate of incorporation and bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or 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 certificate of incorporation, 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 bylaws provide 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 bylaws provide that the Court of Chancery of the State of Delaware will be 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 certificate of incorporation, or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our bylaws further provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

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 bylaws 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. Our bylaws further provide that unless we otherwise consent in writing, the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
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 Accounting and 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 Accounting and 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	Inline 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	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)				

* The certifications attached as Exhibits 32.1 and 32.2 are deemed "furnished" and not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of Kodiak Sciences Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.

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.

KODIAK SCIENCES INC.

Date: November 9, 2020

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2020

By: /s/ John Borgeson

John Borgeson
Senior Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 31.1

CERTIFICATION 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

I, Victor Perlroth, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kodiak Sciences Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2020

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, John Borgeson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kodiak Sciences Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2020

By: /s/ John Borgeson

John Borgeson
Senior Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION 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 Kodiak Sciences Inc. (the "Company") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, 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: November 9, 2020

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Kodiak Sciences Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION 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 Kodiak Sciences Inc. (the "Company") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, 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: November 9, 2020

By: /s/ John Borgeson

John Borgeson
Senior Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Kodiak Sciences Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.