Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2024
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 001-38150

KALA BIO, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-0604595**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1167 Massachusetts Avenue **Arlington, MA**	**02476**
(Address of principal executive offices)	(Zip Code)

(781) 996-5252
(Registrant's telephone number, including area code)

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, $0.001 par value per share	**KALA**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities 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 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 ☒

There were 4,610,139 shares of Common Stock, $0.001 par value per share, outstanding as of November 11, 2024.

TABLE OF CONTENTS

		Page
PART I – FINANCIAL INFORMATION		7
Item 1.	Financial Statements (Unaudited)	7
	Condensed Consolidated Balance Sheets as of September 30, 2024 and December 31, 2023	7
	Condensed Consolidated Statement of Operations and Comprehensive Loss for the three and nine months ended September 30, 2024 and 2023	8
	Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and nine months ended September 30, 2024 and 2023	9
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2024 and 2023	11
	Notes to Condensed Consolidated Financial Statements	12
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	30
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	46
Item 4.	Controls and Procedures	47
PART II – OTHER INFORMATION		47
Item 1.	Legal Proceedings	47
Item 1A.	Risk Factors	47
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	103
Item 5.	Other Information	103
Item 6.	Exhibits	104
SIGNATURES		105

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our expectations with respect to our dependency on and potential advantages of KPI-012, our product candidate for the treatment of persistent corneal epithelial defects, or PCED;
- our expectations with respect to the potential impacts the sale of our commercial business to Alcon Pharmaceuticals Ltd. and Alcon Vision, LLC, which we refer collectively as Alcon, will have on our business, results of operations and financial condition;
- our expectations with respect to, and the amount of, future milestone payments we may receive from Alcon in connection with the sale of our commercial business;
- our expectations with respect to, and the amount of, future milestone payments we may pay in connection with the acquisition of Combangio, Inc., or Combangio, or the Combangio Acquisition;
- our development efforts for KPI-012 and our ability to discover and develop new programs and product candidates;
- the timing, progress and results of clinical trials for KPI-012, including statements regarding the timing of initiation and completion of clinical trials, dosing of subjects and the period during which the results of the trials will become available;
- the timing, scope and likelihood of regulatory filings, including the filing of any biologics license applications for KPI-012 and any other product candidate we may develop in the future;
- our ability to obtain regulatory approvals for KPI-012;
- our commercialization, marketing and manufacturing capabilities and strategy for KPI-012, if approved;
- our estimates regarding potential future revenue from sales of KPI-012, if approved;
- our ability to negotiate, secure and maintain adequate pricing, coverage and reimbursement terms and processes on a timely basis, or at all, with third-party payors for KPI-012, if approved;
- the rate and degree of market acceptance and clinical utility of KPI-012 and our estimates regarding the market opportunity for KPI-012, if approved;
- plans to pursue the development of, and the timing, progress and results of preclinical studies of, KPI-012 for indications in addition to PCED, including Limbal Stem Cell Deficiency;

- our expectations with respect to our determination to cease the development of our preclinical pipeline programs that are unrelated to our mesenchymal stem cell secretome, or MSC-S, platform;
- the timing, progress and results of preclinical studies for our KPI-014 program;
- our expectations regarding our ability to fund our operating expenses, lease and debt service obligations, and capital expenditure requirements with our cash on hand;
- our expectations regarding our ability to achieve the specified milestones under our award from the California Institute for Regenerative Medicine, or CIRM, and obtain the full funding under the CIRM award;
- our expectations regarding our ability to comply with the covenants under our loan agreement with Oxford Finance LLC;
- our intellectual property position, including intellectual property acquired in the Combangio Acquisition;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our estimates regarding expenses, future revenue, timing of any future revenue, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry;
- our ability to maintain and establish collaborations or obtain additional funding;
- our business and business relationships, including with employees and suppliers; and
- the potential impact of global economic and geopolitical developments on our business, operations, strategy and goals.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements except as required by applicable law.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by us and third parties as well as our estimates of potential market opportunities. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunity for KPI-012 include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

Risk Factor Summary

Our business is subject to a number of risks that if realized could materially affect our business, financial condition, results of operations, cash flows and access to liquidity. These risks are discussed more fully in the "Risk Factors" section of this Quarterly Report on Form 10-Q. Our principal risks include the following:

- We have incurred significant losses from operations and negative cash flows from operations since our inception. We expect to incur additional losses and may never achieve or maintain profitability. As of September 30, 2024, we had an accumulated deficit of $659.7 million.
- Our limited operating history and our limited experience in developing biologics may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development efforts or otherwise cease operations. The milestone consideration we are eligible to receive in connection with the sale of our commercial business to Alcon is subject to various risks and uncertainties.
- Our substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business and a failure to comply with the covenants under our loan agreement, such as the requirement that our common stock continue to be listed on The Nasdaq Stock Market, or to avoid the occurrence of specified events of default could result in an acceleration of amounts due.
- We are substantially dependent on the success of our product candidate, KPI-012. If we are unable to successfully complete the clinical development of, and obtain marketing approval for, KPI-012 or any other product candidate we may develop in the future, or experience significant delays in doing so, or if, after obtaining marketing approvals, we fail to successfully commercialize such product candidates, our business will be materially harmed.
- If clinical trials of KPI-012 or any other biological product candidate that we develop fail to demonstrate potency, safety and purity to the satisfaction of the U.S. Food and Drug Administration, or FDA, or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later stage clinical trials, and interim results of a clinical trial do not necessarily predict final results.
- If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented, and our competitors could bring products to market before we do.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- If serious adverse or unacceptable side effects are identified during the development or commercialization of our product candidates, we may need to abandon or limit our development and/or commercialization efforts for such product candidates.

- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- KPI-012 has been evaluated in a clinical trial outside of the United States and we may in the future conduct clinical trials for product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations.
- Public health epidemics, including the COVID-19 pandemic, could impact the development of KPI-012 or any other product candidate we may develop, and may adversely affect our business, results of operations and financial condition.
- Even if KPI-012 or any other product candidates that we may develop in the future receives marketing approval, such products may fail to achieve market acceptance by clinicians and patients, or adequate formulary coverage, pricing or reimbursement by third-party payors and others in the medical community, and the market opportunity for these products may be smaller than we estimate.
- If we are unable to establish and maintain sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, if and when necessary, we may not be successful in commercializing KPI-012 or any other product candidate that we may develop if and when they are approved.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. Our competitors include major pharmaceutical companies with significantly greater financial resources. KPI-012 and any other product candidate we may develop, if approved, will also compete with existing branded, generic and off-label products.
- We have relied, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
- We contract with third parties for the manufacture of KPI-012 and plan to contract with third parties for preclinical, clinical and commercial supply of any other product candidates we develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of product candidates for clinical trials or products for patients, if approved, could be delayed or prevented.
- Our reliance on CIRM funding for KPI-012 adds uncertainty to our research and development efforts, imposes certain compliance obligations on us and imposes requirements that may increase the costs of commercializing KPI-012.
- KPI-012 is protected by patent rights exclusively licensed from other companies or institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our products, if any and when approved, will be harmed.
- If we fail to comply with the continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. Any delisting of our common stock from The Nasdaq Capital Market or a transfer of the listing of our common stock to another nationally recognized stock exchange having listing standards that are less restrictive than The Nasdaq Capital Market, in each case after a specified cure period, are each events of default under our loan agreement, which could adversely effect our financial condition and ability to pursue our business strategy.
- Our largest stockholder may have the ability to exercise significant influence over certain of our business decisions and could influence matters submitted to stockholders for approval.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

KALA BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 49,202	$ 50,895
Prepaid expenses and other current assets	2,077	1,975
Total current assets	51,279	52,870
Non-current assets:		
Property and equipment, net	762	753
Right-of-use assets	1,778	2,025
Other long-term assets	260	301
Total assets	$ 54,079	$ 55,949
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 711	$ 919
Accrued expenses and other current liabilities	4,497	6,018
Deferred grant income	314	1,075
Current portion of lease liabilities	368	334
Current portion of long-term debt	17,977	—
Total current liabilities	23,867	8,346
Long-term liabilities:		
Long-term lease liabilities	1,532	1,799
Long-term debt, net of current portion	17,162	34,190
Long-term contingent consideration	4,659	4,110
Total long-term liabilities	23,353	40,099
Total liabilities	47,220	48,445
Commitments and Contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 51,246 shares of Series E Convertible Non-Redeemable Preferred Stock issued and outstanding as of September 30, 2024 and December 31, 2023, 2,928 shares of Series F Convertible Non-Redeemable Preferred Stock issued and outstanding as of September 30, 2024 and December 31, 2023, 10,901 and 0 shares of Series G Convertible Non-Redeemable Preferred Stock issued and outstanding as of September 30, 2024 and December 31, 2023, and 9,393 and 0 shares of Series H Convertible Non-Redeemable Preferred Stock issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.001 par value; 120,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 4,610,139 and 2,759,372 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	5	3
Additional paid-in capital	666,599	636,910
Accumulated deficit	(659,745)	(629,409)
Total stockholders' equity	6,859	7,504
Total liabilities and stockholders' equity	$ 54,079	$ 55,949

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA BIO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Costs and expenses:				
General and administrative	$ 4,400	$ 4,952	$ 14,139	$ 15,944
Research and development	5,168	5,554	16,836	13,868
Gain on fair value remeasurement of deferred purchase consideration	—	—	—	(230)
Loss (gain) on fair value remeasurement of contingent consideration	420	(1,744)	549	462
Total costs and expenses	9,988	8,762	31,524	30,044
Loss from operations	(9,988)	(8,762)	(31,524)	(30,044)
Other income (expense):				
Interest income	570	708	1,578	2,101
Interest expense	(1,478)	(1,459)	(4,391)	(4,346)
Grant income	1,946	2,970	4,001	2,970
Other expense, net	—	(2,161)	—	(4,253)
Total other income (expense)	1,038	58	1,188	(3,528)
Net loss	$ (8,950)	$ (8,704)	$ (30,336)	$ (33,572)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.93)	$ (3.41)	$ (8.68)	$ (14.36)
Weighted average shares outstanding—basic and diluted	4,627,578	2,550,210	3,494,339	2,337,492
Net loss	$ (8,950)	$ (8,704)	$ (30,336)	$ (33,572)
Other comprehensive (loss) income:				
Change in fair value of investments	—	(8)	—	1
Total other comprehensive (loss) income	—	(8)	—	1
Total comprehensive loss	$ (8,950)	$ (8,712)	$ (30,336)	$ (33,571)

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA BIO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended September 30, 2024												
	Series E Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series F Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series G Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series H Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of June 30, 2024	51,246	$ —	2,928	$ —	10,901	$ —	9,393	$ —	4,598,419	$ 5	$ 664,507	$ (650,795)	$ 13,717
Issuance of common stock under employee stock purchase plan	—	—	—	—	—	—	—	—	7,869	—	47	—	47
Issuance of common stock for vested restricted stock units	—	—	—	—	—	—	—	—	2,570	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	—	—	1,281	—	9	—	9
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,036	—	2,036
Net loss	—	—	—	—	—	—	—	—	—	—	—	(8,950)	(8,950)
Balance as of September 30, 2024	51,246	$ —	2,928	$ —	10,901	$ —	9,393	$ —	4,610,139	$ 5	$ 666,599	$ (659,745)	$ 6,859

	Three Months Ended September 30, 2023							
	Series E Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2023	52,750	$ —	2,538,687	$ 3	$ 629,558	$ 9	$ (612,078)	$ 17,492
Issuance of common stock for vested restricted stock units	—	—	800	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	—	—	3,229	—	40	—	—	40
Issuance of common stock upon conversion of Series E preferred stock	(1,504)	—	150,400	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,403	—	—	2,403
Change in fair value of investments	—	—	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	—	—	(8,704)	(8,704)
Balance as of September 30, 2023	51,246	$ —	2,693,116	$ 3	$ 632,001	$ 1	$ (620,782)	$ 11,223

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA BIO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(UNAUDITED)

(In thousands, except share and per share amounts)

	Nine Months Ended September 30, 2024												
	Series E Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series F Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series G Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series H Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2023	51,246	$ —	2,928	$ —	—	$ —	—	$ —	2,759,372	$ 3	$ 636,910	$ (629,409)	$ 7,504
At the market offering, net of offering costs of $50	—	—	—	—	—	—	—	—	387,500	1	2,470	—	2,471
Exercise of stock options	—	—	—	—	—	—	—	—	1,281	—	9	—	9
Issuance of common stock for vested restricted stock units	—	—	—	—	—	—	—	—	249,224	—	—	—	—
Issuance of common stock under employee stock purchase plan	—	—	—	—	—	—	—	—	11,448	—	68	—	68
Issuance of common stock to satisfy service contract	—	—	—	—	—	—	—	—	4,000	—	29	—	29
Common stock offering, net of offering costs of $122	—	—	—	—	—	—	—	—	1,197,314	1	6,881	—	6,882
Issuance of convertible Series G preferred stock, net of issuance cost of $62	—	—	—	—	10,901	—	—	—	—	—	8,538	—	8,538
Issuance of convertible Series H preferred stock, net of issuance cost of $96	—	—	—	—	—	—	9,393	—	—	—	5,399	—	5,399
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	6,295	—	6,295
Net loss	—	—	—	—	—	—	—	—	—	—	—	(30,336)	(30,336)
Balance as of September 30, 2024	51,246	$ —	2,928	$ —	10,901	$ —	9,393	$ —	4,610,139	$ 5	$ 666,599	$ (659,745)	$ 6,859

	Nine Months Ended September 30, 2023							
	Series E Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2022	53,144	$ —	1,706,971	$ 2	$ 606,182	$ —	$ (587,210)	$ 18,974
At the market offering, net of offering costs of $446	—	—	665,265	1	17,965	—	—	17,966
Issuance of common stock for vested restricted stock units	—	—	3,002	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	—	—	3,690	—	46	—	—	46
Issuance of common stock to satisfy deferred purchase consideration	—	—	19,350	—	365	—	—	365
Issuance of common stock to satisfy contingent consideration	—	—	105,038	—	2,354	—	—	2,354
Issuance of common stock upon conversion of Series E preferred stock	(1,898)	—	189,800	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	5,089	—	—	5,089
Change in fair value of investments	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(33,572)	(33,572)
Balance as of September 30, 2023	51,246	$ —	2,693,116	$ 3	$ 632,001	$ 1	$ (620,782)	$ 11,223

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(In thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (30,336)	$ (33,572)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	190	233
Non-cash operating lease cost	247	94
Gain on fair value remeasurement of deferred purchase consideration	—	(230)
Loss on fair value remeasurement of contingent consideration	549	462
Amortization of debt discount and other non-cash interest	949	941
Stock-based compensation	6,295	5,089
Other non-cash losses (gains)	129	(4,322)
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(102)	5,970
Inventory and assets held for sale	—	7,544
Other long-term assets	—	(143)
Accounts payable	(208)	(2,036)
Accrued expenses and other current liabilities	(2,264)	(319)
Lease liabilities and other long-term liabilities	(233)	58
Net cash used in operating activities	(24,784)	(20,231)
Cash flows from investing activities:		
Purchases of property and equipment and other assets	(139)	(603)
Proceeds from sale of property and equipment	—	47
Purchases of short-term investments	—	(9,866)
Proceeds from sales or maturities of short-term investments	—	10,000
Net cash used in investing activities	(139)	(422)
Cash flows from financing activities:		
Proceeds from issuance of Series G preferred stock, net of issuance costs of $62	8,538	—
Proceeds from issuance of common stock and Series H preferred stock, net of issuance costs of $218	12,281	—
Proceeds from common stock offerings, net of offering costs	2,471	17,966
Payment of principal, prepayment premium and final payment fee on debt	—	(10,000)
Contingent consideration related to Combangio acquisition	(119)	(2,041)
Payment of principal on finance lease	(18)	—
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	77	46
Net cash provided by financing activities	23,230	5,971
Net decrease in cash and cash equivalents:	(1,693)	(14,682)
Cash and cash equivalents at beginning of period	50,895	70,745
Cash and cash equivalents at end of period	$ 49,202	$ 56,063
Non-cash investing and financing activities:		
Issuance of common stock to satisfy deferred purchase consideration in additional paid-in capital	$ —	$ 365
Issuance of common stock to satisfy contingent consideration in additional paid-in capital	—	2,354
Issuance of common stock to satisfy service contract in additional paid-in capital	29	—
Supplemental disclosure:		
Cash paid for interest	$ 3,459	$ 3,477
Right-of-use assets obtained in exchange of operating lease obligations	—	2,180
Right-of-use assets obtained in exchange of finance lease obligations	160	—

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Nature of Business— KALA BIO, Inc. (the "Company") was incorporated on July 7, 2009, and is a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare and severe diseases of the front and back of the eye. On August 2, 2023, the Company changed its name from Kala Pharmaceuticals, Inc. to KALA BIO, Inc.

On November 15, 2021, the Company acquired Combangio, Inc. ("Combangio"), including its mesenchymal stem cell secretomes ("MSC-S") platform and lead product candidate for the treatment of persistent corneal epithelial defects ("PCED"), which the Company refers to as KPI-012 (collectively, the "Combangio Acquisition"). For accounting purposes, the transaction was accounted for as an asset acquisition, as substantially all of the fair value of the gross assets acquired was concentrated in a single asset, KPI-012. PCED is a rare disease of impaired corneal healing. In February 2023, the Company dosed its first patient in the CHASE ("**C**orneal **H**ealing **A**fter **SE**cretome therapy") Phase 2b clinical trial of KPI-012 for PCED in the United States. KPI-012 has received both Orphan Drug and Fast Track designations from the FDA for the treatment of PCED. The Company expects to commercialize in the United States any of its product candidates that receive marketing approval. In connection with the determination to focus its research and development efforts on KPI-012, in 2022, the Company ceased the development of its preclinical pipeline programs that are unrelated to its MSC-S platform.

The Company previously developed and commercialized two marketed products, EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25%, for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease, and INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%, a topical twice-a-day ocular steroid for the treatment of post-operative inflammation and pain following ocular surgery. Both products applied a proprietary mucus-penetrating particle drug delivery technology, which the Company referred to as the AMPPLIFY® Drug Delivery Technology. On July 8, 2022, the Company closed the transaction (the "Alcon Transaction"), contemplated by the asset purchase agreement, dated as of May 21, 2022 (the "Asset Purchase Agreement"), by and between the Company, Alcon Pharmaceuticals Ltd. and Alcon Vision, LLC (together referred to as "Alcon"), pursuant to which Alcon purchased the rights to manufacture, sell, distribute, market and commercialize EYSUVIS and INVELTYS and to develop, manufacture, market and otherwise exploit the Company's AMPPLIFY Drug Delivery Technology (collectively, the "Commercial Business"). Alcon also assumed certain liabilities with respect to the Commercial Business at the closing of the Alcon Transaction. Alcon paid to the Company an upfront cash payment of $60,000 upon the closing of the Alcon Transaction. In addition, pursuant to the Asset Purchase Agreement, the Company is eligible to receive from Alcon up to four commercial-based sales milestone payments as follows: (1) $25,000 upon the achievement of $50,000 or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (2) $65,000 upon the achievement of $100,000 or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (3) $75,000 upon the achievement of $175,000 or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029 and (4) $160,000 upon the achievement of $250,000 or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029. Each milestone payment will only become payable once, if at all, upon the first time such milestone is achieved, and only one milestone payment will be paid with respect to a calendar year. In the event that more than one milestone is achieved in a calendar year, the higher milestone payment will become payable and the lower milestone payment will become payable only if the corresponding milestone is achieved again in a subsequent calendar year. The Company has not been entitled to any milestone payment to date.

The Company's success is dependent upon its ability to develop, obtain regulatory approval for and commercialize KPI-012 and any other product candidate it may develop in the future, the success of its research and development efforts, whether it receives any commercial-based sales milestone payments from Alcon, its ability to raise additional capital when needed and, ultimately, attain profitable operations.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

Liquidity— Since inception, the Company has incurred significant losses from operations and negative cash flows from operations including a net loss of $8,950 and $30,336 for the three and nine months ended September 30, 2024, respectively, a net loss of $8,704 and $33,572 for the three and nine months ended September 30, 2023, respectively, and cash used in operating activities of $24,784 and $20,231 in the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, the Company had an accumulated deficit of $659,745. The Company generated only limited revenues from product sales of EYSUVIS and INVELTYS prior to the sale of the Commercial Business to Alcon in July 2022. The Company has financed its operations to date primarily through proceeds from the sale of the Commercial Business to Alcon, its initial public offering of common stock, follow-on public offerings of common stock and sales of its common stock under its at-the-market offering facility, private placements of common stock and preferred stock (including the Company's most recent private placements in March and June 2024), borrowings under credit facilities and the Loan and Security Agreement with Oxford Finance LLC (the "Loan Agreement"), disbursements under a grant from California Institute for Regenerative Medicine ("CIRM") (including the Company's most recent disbursement of $3,240 in August 2024 from CIRM upon achievement of a specified milestone), convertible promissory notes and warrants.

The Company has devoted substantially all of its financial resources and efforts to research and development, including preclinical studies and clinical trials, and, prior to the sale of the Commercial Business to Alcon in July 2022, engaging in activities to launch and commercialize EYSUVIS and INVELTYS. The Company is devoting substantial financial resources to the research and development and potential commercialization of KPI-012 for PCED and any other indications the Company determines to pursue, including Limbal Stem Cell Deficiency. The Company has no revenue-generating commercial products and, as a result of the Combangio Acquisition, may be required to pay certain milestones and royalty payments to former equityholders of Combangio. Although the Company is eligible to receive up to $325,000 in payments from Alcon based upon the achievement of specified commercial sales-based milestones with respect to EYSUVIS and INVELTYS, there can be no assurance when the Company may receive such milestone payments or of the amount of milestone payments the Company may receive, if any. Additionally, the Company cannot be certain that it will achieve the remaining milestones under the CIRM Award within the required timeframes, or at all, and as such the Company may never receive the remaining $5,860 under the award (see Note 4, "Grant Income" for further information about the CIRM Award). The Company expects to continue to incur significant expenses and operating losses for the foreseeable future, including in connection with its continued development, regulatory approval efforts and commercialization, if any, of KPI-012. The Company may never achieve or maintain profitability. Net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

The Company expects that its cash and cash equivalents as of September 30, 2024, will enable it to fund its operating expenses, lease and debt service obligations and capital expenditure requirements for at least twelve months from the date these condensed consolidated financial statements were issued. This evaluation is based on relevant conditions and events that are known and reasonably knowable at the date that the condensed consolidated financial statements are issued. To the extent these conditions or events change, the Company could deplete its available capital resources sooner than it currently expects. This evaluation also assumes that the Company remains in compliance with the covenants and no event of default occurs under its Loan Agreement with Oxford Finance. If an event of default occurs under the Loan Agreement and Oxford Finance exercises its rights under the Loan Agreement to foreclose on the Company's cash, the Company's ability to fund its operations, lease and debt service obligations will be shorter than it currently expects.

Use of Estimates— The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expense, and related disclosures. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Estimates and assumptions relied upon in preparing these condensed consolidated financial

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

statements relate to, but are not limited to, the present value of lease liabilities and the corresponding right-of-use assets, the fair value of warrants, stock-based compensation, accrued expenses, contingent consideration, grant income and deferred grant income, the valuation of embedded derivatives and the recoverability of the Company's net deferred tax assets and related valuation allowance. Actual results may differ from these estimates under different assumptions or conditions.

Net Loss per Share Attributable to Common Stockholders—The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The two-class method is not applicable during periods with a net loss, as the holders of the convertible preferred stock have no contractual obligation to share in losses. For all periods presented, the two-class method was not applicable.

Basic net loss per share attributable to common stockholders is computed using the weighted-average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders is computed using the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants, the issuance of unvested restricted stock units ("RSUs") and performance-based restricted stock units ("PSUs") and convertible preferred stock using the if-converted method.

The weighted average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, unvested RSUs and PSUs and convertible preferred stock using the if-converted method. Common stock equivalent shares are excluded from the computation of diluted net loss per share attributable to common stockholders if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the three and nine months ended September 30, 2024 and 2023. (See Note 11, "Loss Per Share").

Unaudited Interim Financial Information—The condensed consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. The accompanying condensed consolidated financial statements reflect all adjustments consisting of normal, recurring adjustments, that are necessary for a fair presentation of the financial position, results of operations, statement of stockholders' equity and cash flows for the interim periods presented. Interim results are not necessarily indicative of results for a full year. Accordingly, these condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "Annual Report").

The unaudited condensed consolidated financial statements include the accounts of KALA BIO, Inc. and its wholly owned subsidiaries, Kala Pharmaceuticals Security Corporation and Combangio, Inc. All intercompany transactions and balances have been eliminated in consolidation.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," to the consolidated financial statements included in the Annual Report. There have been no material changes to the significant accounting policies during the three months ended September 30, 2024.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The guidance includes the requirements that a public entity disclose, on an annual and interim basis, significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, the title and position of the chief operating decision maker, and an explanation of how the chief operating decision maker uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. The guidance also requires that a public entity that has a single reportable segment provide all the disclosures required by the guidance and all existing segment disclosures in ASC 280, *Segment Reporting*. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. A public entity should apply the amendments in the guidance retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact that this guidance may have on its consolidated financial statements.

3. FAIR VALUE OF FINANCIAL INSTRUMENTS

ASC 820, *Fair Value Measurements and Disclosures,* establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and its own assumptions (unobservable inputs). The hierarchy consists of three levels:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's financial instruments as of September 30, 2024 and December 31, 2023 consisted primarily of cash equivalents and contingent consideration. Cash equivalents and contingent consideration are reported at their respective fair values on the Company's condensed consolidated balance sheets.

The Company acquired Combangio in November 2021 and in connection with the closing of the Combangio Acquisition, the Company agreed to issue an aggregate of 155,664 shares (the "Deferred Purchase Consideration") of the Company's common stock to former Combangio stockholders and other equityholders (the "Combangio Equityholders") consisting of (i) an aggregate of 136,314 shares of common stock issued on January 3, 2022 and (ii) an aggregate of 19,350 shares of common stock that were held back as partial security for the satisfaction of indemnification obligations and other payment obligations of the Combangio Equityholders and were issued on March 10, 2023 (the "Holdback Shares"). The Company established liabilities for these considerations. The Deferred Purchase Consideration

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

related to the Combangio Acquisition was measured at fair value each reporting period using Level 3 unobservable inputs. The fair value of the Deferred Purchase Consideration was based on the fair value of the underlying stock and a discount for lack of marketability. Any change in the fair value of the Deferred Purchase Consideration was included in loss from operations in the condensed consolidated statements of operations and comprehensive loss. During the three months ended March 31, 2023, the Company settled the remaining liability of $365 upon the issuance of the Holdback Shares and therefore there was no change in the fair value of the Deferred Purchase Consideration during the three or nine months ended September 30, 2024 or the three months ended September 30, 2023. The change in the fair value of the Deferred Purchase Consideration was a gain of $230 during the nine months ended September 30, 2023, primarily due to the change in the fair value of the underlying stock price and was recognized as the gain on fair value remeasurement of deferred purchase consideration in the condensed consolidated statement of operations and comprehensive loss.

Additionally, the purchase price in connection with the Combangio Acquisition included potential future payments of up to $105,000 that are contingent upon the achievement of specified development, regulatory and commercialization milestones and are required to be recorded at fair value. As of September 30, 2024, of the $105,000 in contingent milestone payments, the Company has paid to the Combangio Equityholders an aggregate of $2,646 in cash and $2,354 in shares of the Company's common stock (representing an aggregate of 105,038 shares of the Company's common stock) following dosing of the first patient in the Company's CHASE Phase 2b clinical trial of KPI-012 for PCED in the United States in February 2023 (the "First Dosing Milestone"). Contingent consideration liabilities related to acquisitions are measured at fair value each reporting period using Level 3 unobservable inputs. The fair values of the contingent consideration liabilities were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements. Changes in these estimates and assumptions could have a significant impact on the fair value of the contingent consideration liabilities. Any changes in the fair value of these contingent consideration liabilities are included in loss from operations in the condensed consolidated statements of operations and comprehensive loss. During the three months ended September 30, 2024, the change in fair value of the contingent consideration liabilities was a loss of $420 as compared to a gain of $1,744 during the three months ended September 30, 2023, and during the nine months ended September 30, 2024 and 2023, the change in the fair value of the contingent consideration liabilities was a loss of $549 and $462, respectively, primarily due to changes in discount rates, the passage of time and changes in the expected timing and probability of payment, and were recognized as a gain or loss on fair value remeasurement of contingent consideration in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023.

The following tables set forth the fair value of the Company's financial instruments by level within the fair value hierarchy as of September 30, 2024 and December 31, 2023:

	September 30, 2024			
	Fair Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 39,272	$ 39,272	$ —	$ —
Total Assets	$ 39,272	$ 39,272	$ —	$ —
Liabilities:				
Contingent consideration	$ 4,659	$ —	$ —	$ 4,659
Total Liabilities	$ 4,659	$ —	$ —	$ 4,659

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

	December 31, 2023			
	Fair Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 44,639	$ 44,639	$ —	$ —
Total Assets	$ 44,639	$ 44,639	$ —	$ —
Liabilities:				
Contingent consideration	$ 4,110	$ —	$ —	$ 4,110
Total Liabilities	$ 4,110	$ —	$ —	$ 4,110

The following tables summarize quantitative information and assumptions pertaining to the fair value measurement of the Level 3 inputs as of September 30, 2024 and December 31, 2023:

Financial Instrument	Fair Value at September 30, 2024	Valuation Technique	Unobservable Input	Range (Average)
Contingent consideration	$ 4,659	Probability-adjusted discounted cash flow model	Period of expected milestone achievement	2025 - 2028 (2028)
			Probabilities of achievement	16.6% - 35.5% (23.4%)
			Discount rate	14.3%

Financial Instrument	Fair Value at December 31, 2023	Valuation Technique	Unobservable Input	Range (Average)
Contingent consideration	$ 4,110	Probability-adjusted discounted cash flow model	Period of expected milestone achievement	2025 - 2028 (2027)
			Probabilities of achievement	16.6% - 35.5% (23.4%)
			Discount rate	16.3%

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

The following table summarizes the changes in the Deferred Purchase Consideration and contingent consideration liabilities measured at fair value using Level 3 inputs for the three and nine months ended September 30, 2024 and 2023:

Contingent consideration		
Balance at January 1, 2024	$	4,110
Fair value adjustments		158
Balance at March 31, 2024	$	4,268
Fair value adjustments		(29)
Balance at June 30, 2024	$	4,239
Fair value adjustments		420
Balance at September 30, 2024	$	4,659
Contingent consideration		
Balance at January 1, 2023	$	8,370
Fair value adjustments		1,847
Settlements		(4,854)
Reclassification to accrued expenses and other current liabilities		(129)
Balance at March 31, 2023	$	5,234
Fair value adjustments		359
Reclassification to accrued expenses and other current liabilities		(5)
Balance at June 30, 2023	$	5,588
Fair value adjustments		(1,744)
Reclassification to accrued expenses and other current liabilities		(6)
Balance at September 30, 2023	$	3,838
Deferred purchase consideration		
Balance at January 1, 2023	$	595
Fair value adjustments		(230)
Settlements		(365)
Balance at March 31, 2023, June 30, 2023 and September 30, 2023	$	—

During the three and nine months ended September 30, 2024 and the year ended December 31, 2023, there were no transfers between Level 1, Level 2, and Level 3.

4. GRANT INCOME

CIRM Award

On August 2, 2023, Combangio, a wholly owned subsidiary of the Company, entered into an award agreement with CIRM for a $15,000 grant (as amended from time to time, the "CIRM Award") to support Combangio's KPI-012 program for the treatment of PCED. The CIRM Award includes funding for the CHASE Phase 2b clinical trial of KPI-012 for PCED, as well as product and process characterization and analytical development for the program. The CIRM Award is subject to a co-funding requirement under which Combangio is obligated to spend a specified minimum amount on the development of KPI-012 to obtain the full award amount. Upon entry into the CIRM Award, Combangio received an initial $5,900 disbursement from CIRM, and in August 2024, Combangio received a second disbursement of $3,240 from CIRM upon the achievement of a specified milestone. The balance of the award is payable to Combangio upon the achievement of other specified milestones that are primarily related to Combangio's progress in conducting the

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

CHASE Phase 2b clinical trial. CIRM may permanently cease disbursements if the milestones are not met within four months of the scheduled completion dates or if the delay is not addressed to CIRM's satisfaction, as determined by CIRM in its sole discretion. Additionally, if CIRM determines, in its sole discretion, that Combangio has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements. Under the terms of the CIRM Award, Combangio is obligated to pay a royalty on net sales of any product, service or approved drug resulting in whole or in part from the CIRM Award in the amount of 0.1% per $1,000 of funds utilized by the Company until the earlier of ten years from the date of first commercial sale of such product, service or approved drug and such time as nine times the amount of funds awarded by CIRM has been paid in royalties (the "Base Royalty"). In addition, following the satisfaction of the Base Royalty, Combangio is obligated to pay a 1.0% royalty on net sales of any CIRM-funded invention in excess of $500,000 per year until the last to expire patent covering such invention expires.

During the three and nine months ended September 30, 2024, the Company recognized $1,946 and $4,001 of grant income, respectively, and recognized $2,970 of grant income during each of the three and nine months ended September 30, 2023, related to the CIRM Award on its condensed consolidated statement of operations. As of September 30, 2024 and December 31, 2023, the Company had deferred grant income of $314 and $1,075 on its condensed consolidated balance sheet, respectively.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2024	December 31, 2023
Compensation and benefits	$ 2,533	$ 2,616
Development costs	775	837
Accrued revenue reserves	408	1,659
Professional services	364	515
Contract manufacturing	222	11
Other	195	380
Accrued expenses and other current liabilities	$ 4,497	$ 6,018

6. LEASES

Operating leases

Menlo Park, California Office Lease

In April 2023, Combangio entered into a lease agreement with Menlo Prepi I, LLC, pursuant to which Combangio leases approximately 6,135 square feet of office, laboratory and research and development space in Menlo Park, California. The Company entered into a guaranty of lease agreement guarantying the obligations of Combangio under the lease agreement. The initial term of the lease is for 62 months which commenced on the lease commencement date of July 1, 2023, unless earlier terminated pursuant to the terms of the lease. The lease provides Combangio with an option to extend the lease for an additional five-year term. Combangio was required to make a payment in the amount of $144, as a security deposit pursuant to the lease during the year ended December 31, 2023, which is included in other long-term assets on the condensed consolidated balance sheets as of September 30, 2024 and December 31, 2023. Upon the lease commencement, the Company recorded a right-of-use asset of $2,154 and corresponding $2,133 of lease liability.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

As of September 30, 2024, the Company recognized $1,778 of right-of-use asset and a corresponding $1,900 of lease liability (current and non-current) by calculating the present value of lease payments, discounted at 13.1%, the Company's estimated incremental borrowing rate, over the expected term of the lease. As of September 30, 2024, the remaining lease term on the lease was 3.9 years. Variable lease expense for the lease, includes real estate taxes, common area maintenance, and management fees.

The components of lease expenses and related cash flows were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Lease cost				
Operating lease cost	$ 149	$ 149	$ 447	$ 165
Short-term lease cost	9	20	26	132
Variable lease cost	49	46	159	52
Total lease cost	$ 207	$ 215	$ 632	$ 349
Operating cash outflows from operating leases	$ 148	$ 48	$ 433	$ 61

The weighted average remaining lease term and weighted average discount rate of operating leases were as follows:

	September 30, 2024	December 31, 2023
Weighted average remaining lease term	3.9 years	4.7 years
Weighted average discount rate	13.1%	13.1%

As of September 30, 2024, the Company expects that its future minimum lease payments will become due and payable as follows:

Years Ending December 31,	
2024 (remaining three months)	$ 148
2025	601
2026	622
2027	644
2028	440
Less: interest	(555)
Total	$ 1,900

7. DEBT

On May 4, 2021, the Company entered into the Loan Agreement with Oxford Finance, in its capacity as lender (in such capacity, the "Lender"), and in its capacity as collateral agent (in such capacity, the "Agent"), pursuant to which a term loan of up to an aggregate principal amount of $125,000 was available to the Company, consisting of a tranche A term loan that was disbursed on the closing date in the aggregate principal amount of $80,000 and additional tranches that are no longer available to the Company. The Company utilized substantially all of the proceeds from the tranche A term loan to repay a prior credit facility.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

Through June 30, 2023, the term loan bore interest at a floating rate equal to the greater of (i) 30-day LIBOR and (ii) 0.11%, plus 7.89%. Effective July 1, 2023, the term loan bears interest at a floating rate equal to the greater of (i) 8.00% and (ii) the sum of (a) the 1-Month CME Term Secured Overnight Financing Rate, (b) 0.10% and (c) 7.89%. The Loan Agreement, prior to the Second Loan Amendment and Third Loan Amendment (as defined below), provided for interest-only payments until December 1, 2024 if neither the tranche B term loan nor the tranche C term loan are made, and until June 1, 2025 if either the tranche B term loan or the tranche C term loan is made (the "Amortization Date"). The aggregate outstanding principal balance of the term loans were required to be repaid in monthly installments starting on the Amortization Date based on a repayment schedule equal to (i) 18 months if neither the tranche B term loan nor the tranche C term loan is made and (ii) 12 months if either the tranche B term loan or the tranche C term loan is made. All unpaid principal and accrued and unpaid interest with respect to each term loan was due and payable in full on May 1, 2026 (the "Maturity Date").

The Company paid a facility fee of $400 on the closing date of the Loan Agreement and agreed to pay a facility fee of $100 upon closing of the tranche B term loan and a $125 facility fee upon the closing of the tranche C term loan. The Company will be required to make a final payment fee of 7.00% of the original principal amount of any funded term loan payable on the earlier of (i) the prepayment of the term loan in full or (ii) the Maturity Date. At the Company's option, the Company may elect to make partial repayments of the term loan to the Lender, subject to specified conditions, including the payment of applicable fees and accrued and unpaid interest on the principal amount of the term loan being repaid.

In connection with its entry into the Loan Agreement, the Company granted the Agent a security interest in substantially all of the Company's personal property owned or later acquired, including intellectual property and the Commercial Business. The Company also agreed to maintain its cash balance in one or more controlled accounts in favor of the Agent, subject to specified exceptions. The Loan Agreement also contains customary representations and warranties and affirmative and negative covenants, as well as customary events of default. Certain of the customary negative covenants limit the ability of the Company and certain of its subsidiaries, among other things, to incur future debt, grant liens, make investments, make acquisitions, distribute dividends, make certain restricted payments and sell assets, subject in each case to certain exceptions.

The Loan Agreement includes features requiring (i) additional interest rate upon an event of default accrued at an additional 5%, and (ii) the Lender's right to declare all outstanding principal and interest immediately payable upon an event of default. These two features were analyzed and determined to be embedded derivatives to be valued as separate financial instruments. These embedded derivatives were bundled and valued as one compound derivative in accordance with the applicable accounting guidance for derivatives and hedging transactions. The Company determined that, due to the unlikely event of default, the value of the embedded derivatives is not material as of September 30, 2024. The derivative liability will be remeasured at fair value at each reporting date, with changes in fair value being recorded as other income (expense) in the condensed consolidated statements of operations and comprehensive loss.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

On May 21, 2022, in connection with its entry into the Asset Purchase Agreement with Alcon, the Company entered into an amendment to the Loan Agreement (the "Second Loan Amendment"). Pursuant to the Second Loan Amendment, the Lender and Agent consented to the entry by the Company into the Asset Purchase Agreement and the sale of the Commercial Business to Alcon and agreed to release its liens on the Commercial Business in consideration for the payment by the Company at the closing of the Alcon Transaction of an aggregate amount of $40,000 (the "Second Amendment Prepayment") to the Lender and Agent, representing a partial prepayment of principal in the amount of $36,697 of the $80,000 principal amount outstanding under the term loan advanced by the Lender under the Loan Agreement, plus a prepayment fee of $734 and a final payment fee of $2,569. In addition, the Company was required to pay all accrued and unpaid interest on the principal amount of the term loan being repaid.

In addition, under the Second Loan Amendment, the Lender and Agent agreed that, following the closing of the Alcon Transaction and the Second Amendment Prepayment, the Amortization Date would be extended from December 1, 2024 to January 1, 2026, at which time the aggregate principal balance of the term loan then outstanding under the Loan Agreement is required to be repaid in five monthly installments. Pursuant to the Second Loan Amendment, the Company may also make partial prepayments of the term loan to the Lender, subject to specified conditions, including the payment of applicable fees and accrued and unpaid interest on the principal amount of the term loan being repaid.

On July 8, 2022, the Second Amendment Prepayment was paid in connection with the closing of Alcon Transaction, and as such, the Amortization Date was extended to January 1, 2026. The transaction resulted in a loss on extinguishment of debt of $2,583 for the year ended December 31, 2022, consisting of the prepayment premium, a pro-rata portion of the unamortized debt discount and issuance costs and the unaccreted exit fee due upon the Second Amendment Prepayment.

On December 27, 2022, the Company entered into an amendment to the Loan Agreement (the "Third Loan Amendment"). Pursuant to the Third Loan Amendment, the Lender and Agent agreed to amend certain provisions of the Loan Agreement to permit the transfer of the listing of the Company's common stock from The Nasdaq Global Select Market to The Nasdaq Capital Market. Pursuant to the Third Loan Amendment, the Company agreed (A) to make partial prepayments of the principal amount of the term loan outstanding under the Loan Agreement as follows (the "Third Amendment Prepayments"): (1) a payment of $5,000 on or before June 30, 2023, representing a partial prepayment of principal in the amount of $4,673, plus a final payment fee of $327 and (2) a payment of $5,000 on or before January 31, 2024, representing a partial prepayment of principal in the amount of $4,673, plus a final payment fee of $327 and (B) that the Amortization Date under the Loan Agreement shall be changed from January 1, 2026 to January 1, 2025.

Pursuant to the Third Loan Amendment, in addition to the Third Amendment Prepayments, if the Company makes an additional prepayment under the Loan Agreement equal to $5,000 (inclusive of the final payment fee) on or prior to December 31, 2024 (the "First Extension Prepayment"), the Amortization Date will be automatically changed to July 1, 2025, and the maturity date of the Loan Agreement will be automatically changed from May 1, 2026 to November 1, 2026. If, in addition to the Third Amendment Prepayments and the First Extension Prepayment, the Company makes an additional prepayment under the Loan Agreement equal to $2,500 (inclusive of the final payment fee) on or prior to June 30, 2025 (the "Second Extension Prepayment"), the Amortization Date will be automatically changed to January 1, 2026, and the maturity date of the Loan Agreement will be automatically changed to May 1, 2027.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

Under the Third Loan Amendment, the Lender and Agent also agreed to waive the prepayment fees for the Third Amendment Prepayments, the First Extension Prepayment, the Second Extension Prepayment and any other prepayments under the Loan Agreement. Pursuant to the Loan Agreement, the Company also will be required to pay all accrued and unpaid interest on the principal amounts of the term loan being repaid at the time of repayment. The Company paid the Third Amendment Prepayments on January 25, 2023, following which the Company became required to repay the Loan Agreement in monthly installments from January 1, 2025 through May 1, 2026. The principal loan balance under the Loan Agreement following the Third Amendment Prepayments was $33,957.

On August 1, 2023, the Company entered into an amendment to the Loan Agreement with Combangio and Oxford Finance (the "Fourth Loan Amendment"). Pursuant to the Fourth Loan Amendment, certain provisions of the Loan Agreement were amended in connection with the change of the Company's name and the cessation of the U.S. Dollar LIBOR rate. On August 2, 2023, the Company entered into an amendment to the Loan Agreement with Combangio and Oxford Finance (the "Fifth Loan Amendment"). Pursuant to the Fifth Loan Amendment, Oxford Finance consented to the Company's entry into the CIRM Award and certain provisions of the Loan Agreement were amended in connection therewith.

In addition, in connection with the Loan Agreement, the Company paid certain fees to the Lender and other third-party service providers. The fees paid to the Lender were recorded as a debt discount while the fees paid to other third-party service providers were recorded as debt issuance cost. These costs are being amortized using the effective interest method over the term of the Loan Agreement. The amortization of debt discount and debt issuance cost is included in interest expense within the condensed consolidated statements of operations and comprehensive loss. As of September 30, 2024, the effective interest rate was 17.07%, which takes into consideration the non-cash accretion of the exit fee and the amortization of the debt discount and issuance costs.

During the three months ended September 30, 2024 and 2023, the Company recognized interest expense of $1,462 and $1,459, respectively, for the Loan Agreement. This consisted of amortization of debt discount of $79 and $68 for the three months ended September 30, 2024 and 2023, respectively, accretion of the final payment fee of $243 and $241 for the three months ended September 30, 2024 and 2023, respectively, and the contractual coupon interest expense of $1,140 and $1,150 for the three months ended September 30, 2024 and 2023, respectively. During the nine months ended September 30, 2024 and 2023, the Company recognized interest expense of $4,388 and $4,346, respectively, for the Loan Agreement. This consisted of amortization of debt discount of $226 and $204 for the nine months ended September 30, 2024 and 2023, respectively, accretion of the final payment fee of $723 and $737 for the nine months ended September 30, 2024 and 2023, respectively, and the contractual coupon interest expense of $3,439 and $3,405 for the nine months ended September 30, 2024 and 2023, respectively.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

The components of the carrying value of the debt as of September 30, 2024 and December 31, 2023 are detailed below:

	September 30, 2024	December 31, 2023
Principal loan balance	$ 33,957	$ 33,957
Unamortized debt discount and issuance cost	(306)	(532)
Cumulative accretion of exit fee	1,488	765
Total debt	$ 35,139	$ 34,190
Less: current portion of long-term debt	(17,977)	—
Long-term debt, net	$ 17,162	$ 34,190

The annual principal payments due under the Loan Agreement as of September 30, 2024 were as follows:

Years Ending December 31,	
2024 (remaining three months)	$ —
2025	23,970
2026	9,987
Total	$ 33,957

8. WARRANTS

The following table summarizes the common stock warrants outstanding as of September 30, 2024 and December 31, 2023, each exercisable into the number of shares of common stock set forth below as of the specified dates:

Issued	Exercise Price Per Share	Expiration Date	Exercisable From	Shares Exercisable at September 30, 2024	Shares Exercisable at December 31, 2023
2014	$ 375.00	November 2024	July 2017	320	320
2016	$ 413.50	October 2026	September 2017	290	290
2018	$ 609.23	October 2025	October 2018	3,693	3,693
				4,303	4,303

9. EQUITY FINANCINGS

Registered Offerings

On May 7, 2020, the Company filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on May 19, 2020 (the "2020 Shelf Registration"). Under the 2020 Shelf Registration, the Company may offer and sell up to $350,000 of a variety of securities including common stock, preferred stock, warrants, depositary shares, debt securities or units during the three-year period that commenced upon the 2020 Shelf Registration becoming effective. In connection with the filing of the 2020 Shelf Registration, the Company entered into an amended and restated sales agreement (the "Amended and Restated Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company could issue and sell, from time to time, up to an aggregate of $75,000 of its common stock in an at-the-market equity offering through Jefferies, as a sales agent. From January 1, 2023 to January 10, 2023, the Company sold 245,887 shares of its common stock pursuant to the terms of the Amended and Restated Sales Agreement, resulting in net proceeds of $9,994. On January 10, 2023, the Amended and Restated Sales Agreement terminated in accordance with its terms when the Company completed the sale of $75,000 of its shares of common stock thereunder. As of the date of termination of the Amended and Restated Sales Agreement, the Company had sold an aggregate of 565,974

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

shares of its common stock under such agreement for aggregate gross proceeds of $75,000.

On January 19, 2023, the Company entered into an Open Market Sale Agreement with Jefferies (the "Open Market Sale Agreement"), pursuant to which the Company may issue and sell, from time to time, shares its common stock under an at-the-market equity offering. The Company filed a prospectus supplement relating to the Open Market Sale Agreement under its 2020 Shelf Registration (the "2020 Shelf ATM Prospectus Supplement"), pursuant to which the Company could offer and sell shares of common stock having an aggregate offering price of up to $40,000 under the Open Market Sale Agreement. From January 19, 2023 to May 11, 2023, the Company sold 229,378 shares of its common stock under its at-the-market offering pursuant to the Open Market Sale Agreement under the 2020 Shelf ATM Prospectus Supplement, resulting in net proceeds of $4,899.

On March 3, 2023, the Company filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on May 11, 2023 (the "2023 Shelf Registration"). Under the 2023 Shelf Registration, the Company may offer and sell up to $350,000 of a variety of securities including common stock, preferred stock, warrants, depositary shares, debt securities, subscription rights or units after such time as the shelf registration statement is declared effective by the SEC. In accordance with the terms of the Open Market Sale Agreement, the Company may issue and sell, from time to time, up to $40,000 of its common stock in an at-the-market equity offering through Jefferies, as sales agent. Upon effectiveness of the 2023 Shelf Registration, the Company ceased any further offers or sales of its common stock pursuant to the 2020 Shelf ATM Prospectus Supplement and the 2020 Shelf Registration.

During the nine months ended September 30, 2023, the Company sold an aggregate of 190,000 shares of its common stock under the Open Market Sale Agreement under the 2023 Shelf Registration for total net proceeds of $3,073, none of which were sold during the three months ended September 30, 2023. During the nine months ended September 30, 2023, the Company sold an aggregate of 665,265 shares of its common stock pursuant to (1) the Amended and Restated Sales Agreement and the Open Market Sale Agreement under the 2020 Shelf Registration and (2) the Open Market Sale Agreement under the 2023 Shelf Registration, for total net proceeds of $17,966.

During the nine months ended September 30, 2024, the Company sold an aggregate of 387,500 shares of its common stock under the Open Market Sale Agreement under the 2023 Shelf Registration for total net proceeds of $2,471, none of which were sold during the three months ended September 30, 2024.

Private Placements

On December 21, 2023, the Company entered into a Securities Purchase Agreement (the "2023 Securities Purchase Agreement") with certain institutional investors named therein, pursuant to which the Company agreed to issue and sell, in a private placement priced at-the-market under Nasdaq rules, shares of Series F Convertible Non-Redeemable Preferred Stock, par value $0.001 per share, of the Company (the "Series F Preferred Stock"), for aggregate gross proceeds of approximately $2,000 (the "2023 Private Placement"). Pursuant to the 2023 Securities Purchase Agreement, the Company issued and sold to the purchasers at the closing of the 2023 Private Placement, 2,928 shares of Series F Preferred Stock, at a price per preferred share equal to $683.00. Costs incurred in connection with the 2023 Private Placement were $35, which were recorded as a reduction to additional paid-in capital.

On March 25, 2024, the Company entered into a Securities Purchase Agreement (the "March 2024 Securities Purchase Agreement") with certain institutional investors named therein, pursuant to which the Company agreed to issue and sell, in a private placement priced at-the-market under Nasdaq rules, shares of Series G Convertible Non-Redeemable Preferred Stock, par value $0.001 per share, of the Company (the "Series G Preferred Stock"), for aggregate gross proceeds of approximately $8,600 (the "March 2024 Private Placement"). Pursuant to the March 2024 Securities Purchase Agreement, the Company issued and sold to the purchasers at the closing of the March 2024 Private Placement, 10,901 shares of Series G Preferred Stock, at a price per preferred share equal to $788.90. Costs incurred in

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

connection with the March 2024 Private Placement were $62, which were recorded as a reduction to additional paid-in capital.

On June 26, 2024, the Company entered into a Securities Purchase Agreement (the "June 2024 Securities Purchase Agreement") with certain institutional investors named therein, pursuant to which the Company agreed to issue and sell, in a private placement, shares of common stock and shares of Series H Convertible Non-Redeemable Preferred Stock, par value $0.001 per share, of the Company (the "Series H Preferred Stock"), for aggregate gross proceeds of approximately $12,499 (the "June 2024 Private Placement"). Pursuant to the June 2024 Securities Purchase Agreement, the Company issued and sold to the purchasers at the closing of the June 2024 Private Placement, 1,197,314 shares of common stock, at a price per common share equal to $5.85, and 9,393 shares of Series H Preferred Stock, at a price per preferred share equal to $585.00. Costs incurred in connection with the June 2024 Private Placement were $218, which were recorded as a reduction to additional paid-in capital.

10. STOCK-BASED COMPENSATION

On June 22, 2023, the Company's stockholders approved the Company's Amended and Restated 2017 Equity Incentive Plan (the "2017 Plan"), which amended and restated the Company's 2017 Equity Incentive Plan, as amended (the "2017 Plan"), to (i) increase the number of shares of common stock authorized for issuance thereunder by 1,250,000 shares; (ii) limit the number of incentive stock options that can be granted under the plan to 7,738,761 shares of common stock; (iii) add an annual limit on non-employee director compensation, including cash and the value of equity awards, of $750,000 for incumbent directors and $1,000,000 in a director's first year of service; and (iv) extend the term of the plan (including the duration of the evergreen) to 10 years from June 22, 2023, the date that stockholders approved the plan. In addition, the 2017 Plan provides for an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2024 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2033, equal to the lower of (i) 4% of the sum of (I) the number of outstanding shares of common stock on such date and (II) the number of shares of common stock issuable upon conversion of any outstanding shares of convertible preferred stock of the Company on such date (without giving effect to any restrictions or limitations on conversion) and (ii) an amount determined by the Company's board of directors.

As of September 30, 2024, there were 236,576 shares of common stock available for grant under the 2017 Plan.

During the nine months ended September 30, 2024, the Company granted options for the purchase of 317,139 shares of common stock, including inducement grant options to purchase 3,125 shares of common stock to a new employee made outside of the 2017 Plan in accordance with Nasdaq Listing Rule 5635(c)(4), and 71,830 RSUs. During the nine months ended September 30, 2024, employees of the Company purchased an aggregate of 11,448 shares under the Employee Stock Purchase Plan.

The assumptions used in determining fair value of the stock options granted during the nine months ended September 30, 2024 are as follows:

	Nine Months Ended September 30, 2024		
Expected volatility	107.9%	–	110.3%
Risk-free interest rate	3.46%	–	4.41%
Expected dividend yield		0%	
Expected term (in years)	5.50	–	6.07

During the nine months ended September 30, 2024, the weighted average grant-date fair value of options granted was $5.79.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

As of September 30, 2024, a total of 564,323 RSUs were outstanding, consisting of 544,117 unvested RSUs and 20,206 vested and deferred shares by directors.

Stock-based compensation expense was classified in the condensed consolidated statements of operations and comprehensive loss as follows for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 657	$ 657	$ 1,975	$ 1,454
General and administrative	1,379	1,746	4,320	3,635
Total	$ 2,036	$ 2,403	$ 6,295	$ 5,089

11. LOSS PER SHARE

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss attributable to common stockholders	$ (8,950)	$ (8,704)	$ (30,336)	$ (33,572)
Denominator:				
Weighted-average common shares outstanding, basic and diluted (1)	4,627,578	2,550,210	3,494,339	2,337,492
Net loss per share attributable to common stockholders, basic and diluted	$ (1.93)	$ (3.41)	$ (8.68)	$ (14.36)

(1) Included in the weighted-average common shares outstanding, basic and diluted are vested but deferred shares for which all contingencies have been satisfied.

The following potential common stock equivalents, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Options to purchase shares of common stock	885,430	670,064	914,859	509,914
Unvested RSUs and PSUs	544,117	824,998	647,809	598,210
Unexercised warrants	4,303	4,303	4,303	4,303
Convertible preferred stock (as converted to common stock)	7,446,800	5,124,600	7,133,700	5,238,000
	8,880,650	6,623,965	8,700,671	6,350,427

12. INCOME TAXES

The Company did not record a provision or benefit for income taxes during the three and nine months ended September 30, 2024 and 2023. The Company continues to maintain a full valuation allowance for its U.S. federal and state deferred tax assets.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its generation of limited revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Management reevaluates the positive and negative evidence at each reporting period.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of Section 382 of the Internal Revenue Code of 1986, certain substantial changes in the Company's ownership, including a sale of the Company, or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss carryforwards, which could be used annually to offset future taxable income. The Company completed an analysis as of December 31, 2022 and determined that an ownership change occurred during December 2022 which materially limited the net operating loss carryforwards and research and development tax credits. As a result of this most recent ownership change, the utilization of the Company's net operating loss carryforwards is subject to an annual limitation of $222. The Company has not completed an analysis as of December 31, 2023 but does not expect any change would further limit the net operating loss carryforwards.

The Company files its corporate income tax returns in the United States and various states. All tax years since the date of incorporation remain open to examination by the major taxing jurisdictions (state and federal) to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service ("IRS") or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax year.

As of September 30, 2024 and December 31, 2023, the Company had no uncertain tax positions. The Company's policy is to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the three and nine months ended September 30, 2024 and 2023.

13. COMMITMENTS AND CONTINGENCIES

Stanford License Agreement— In October 2019, Combangio entered into a license agreement with The Board of Trustees of The Leland Stanford Junior University ("Stanford"), which was amended in February 2020 and subsequently transferred to the Company by operation of law upon the Combangio Acquisition. Pursuant to the license agreement with Stanford (the "Stanford Agreement"), the Company has a worldwide, exclusive, sublicensable license under certain patent rights ("licensed patents"), directed to methods to promote eye wound healing, to make, have made, use, import, offer to sell and sell products ("licensed products") that are covered by the licensed patents for use in all fields. Under the Stanford Agreement, the Company is required to pay Stanford annual license maintenance fees in the low-to-mid five figures which are creditable against earned royalties owed to Stanford for the same year, an aggregate of up to $1,075 for the achievement of specified development and regulatory milestones, and an aggregate of up to $1,100 for the achievement of specified sales milestones. Stanford is also entitled to receive tiered royalties in a low single digit percentage range on net sales of licensed products that are covered by a valid claim of a licensed patent. During the nine months ended September 30, 2023, the Company paid Stanford a $175 milestone payment which was triggered by the commencement of the CHASE Phase 2b clinical trial of KPI-012 for PCED in the United States. Additional amounts paid to Stanford in the three and nine months ended September 30, 2024 and 2023 were *de minimis*.

Litigation— The Company is not currently subject to any material legal proceedings.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share amounts)

Contingencies related to the Merger Agreement— In connection with the Combangio Acquisition, the Company agreed to make additional payments based on the achievement of certain milestone events related to KPI-012. The Company recognized certain contingent consideration liabilities at fair value on the acquisition date, and revalues the remaining obligations each reporting period. The total potential maximum payout for the milestone payments, which have been recorded as liabilities at fair value, is $40,000 and the milestone payments are contingent upon the achievement of specified development, regulatory and commercialization milestones. Following the achievement of the First Dosing Milestone in February 2023, the Company paid an aggregate of $2,500 in cash and $2,354 in shares of the Company's common stock (representing an aggregate of 105,038 shares of the Company's common stock) to the former Combangio Equityholders in March 2023. The Company paid the remaining amount due in connection with the First Dosing Milestone of $146 in cash in January 2024. Additionally, pursuant to the merger agreement for the Combangio Acquisition, the Company could trigger potential future sales-based milestone payments of up to $65,000 and cash royalty payment obligations in the mid-to-high single digits. Because the achievement of these sales-based milestones related to KPI-012 was not considered probable as of September 30, 2024 or December 31, 2023, such contingencies have not been recorded in the Company's condensed consolidated financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory or commercial milestones.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and related notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the Securities and Exchange Commission on March 29, 2024. This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. The words "anticipate," "believe," "continue" "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the section entitled "Risk Factors" in Part II, Item 1A that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

Overview

We are a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare and severe diseases of the front and back of the eye. Our product candidate, KPI-012, which we acquired from Combangio, Inc., or Combangio, on November 15, 2021, is a mesenchymal stem cell secretome, or MSC-S, and is currently in clinical development for the treatment of persistent corneal epithelial defects, or PCED, a rare disease of impaired corneal healing. Based on the positive results of a Phase 1b clinical safety and efficacy trial of KPI-012 in patients with PCED, along with favorable preclinical safety and efficacy results, we submitted an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA, which was accepted in December 2022. In February 2023, we dosed our first patient in our CHASE (**C**orneal **H**ealing **A**fter **SE**cretome therapy) Phase 2b clinical trial of KPI-012 for PCED in the United States, or the CHASE trial.

The CHASE trial is comprised of two patient cohorts. On March 27, 2023, we announced positive safety data from the first cohort of the CHASE trial, which is an open-label study to evaluate the safety of the high dose of KPI-012 ophthalmic solution (3 U/mL) dosed topically four times per day, or QID, in two patients. Both patients in the first cohort successfully completed at least one week of dosing with no safety issues observed. We have initiated the second and final patient cohort of the CHASE trial in the United States, which is a multicenter, randomized, double-masked, vehicle-controlled, parallel-group trial to evaluate the safety and tolerability of two doses of KPI-012 ophthalmic solution (3 U/mL and 1 U/mL) versus vehicle dosed topically QID for 56 days in approximately 90 patients. We have opened 44 trial sites for the CHASE trial in the United States. We have also initiated several clinical trial sites in Argentina for the CHASE trial and we are in the process of initiating additional clinical trial sites in Latin America, subject to regulatory clearance.

The primary endpoint of the CHASE trial is the complete healing of the PCED as measured by corneal fluorescein staining. We are targeting reporting topline safety and efficacy data from the CHASE trial in the second quarter of 2025. If the results are positive, and subject to discussion with regulatory authorities, we believe this trial could serve as the first of two pivotal trials required to support the submission of a Biologics License Application, or BLA, for KPI-012 to the FDA.

KPI-012 has received Orphan Drug and Fast Track designations from the FDA for the treatment of PCED.

We believe the multifactorial mechanism of action of KPI-012 also makes our MSC-S a platform technology. We are evaluating the potential development of KPI-012 for additional rare front-of-the-eye diseases, such as for the treatment of Limbal Stem Cell Deficiency and other rare corneal diseases that threaten vision. In addition, we have initiated preclinical studies under our KPI-014 program to evaluate the utility of our MSC-S platform for inherited retinal degenerative diseases, such as Retinitis Pigmentosa and Stargardt Disease. In connection with the determination to focus our research and development efforts on KPI-012, in 2022, we determined to cease the development of our preclinical pipeline programs that are unrelated to our MSC-S platform. We expect to commercialize in the United States any of our product candidates that receive marketing approval. For a further description of our acquisition of Combangio, KPI-012 and PCED, see our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and see Note 1, "Nature of Business and Basis of Presentation", Note 3, "Fair Value of Financial Instruments" and Note 13, "Commitments and Contingencies" of our condensed consolidated financial statements included herein.

We previously developed and commercialized two marketed products, EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25%, for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease, and INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%, a topical twice-a-day ocular steroid for the treatment of post-operative inflammation and pain following ocular surgery. Both products applied a proprietary mucus-penetrating particle drug delivery technology, which we referred to as the AMPPLIFY® Drug Delivery Technology.

On July 8, 2022, we sold to Alcon Pharmaceuticals Ltd. and Alcon Vision, LLC, which we refer to collectively as Alcon, the rights to manufacture, sell, distribute, market and commercialize EYSUVIS and INVELTYS and to develop, manufacture, market and otherwise exploit the AMPPLIFY Drug Delivery Technology, which we collectively refer to as the Commercial Business. We refer to this transaction as the Alcon Transaction. Alcon also assumed certain liabilities with respect to the Commercial Business at the closing of the Alcon Transaction. For a further description of the Alcon Transaction, see our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and Note 1, "Nature of Business and Basis of Presentation" of our condensed consolidated financial statements, included herein.

During 2022, we terminated our entire commercial sales force and certain employees in our commercial, scientific, manufacturing, finance and administrative functions. The determination to proceed with the workforce reduction was made in the context of the closing of the Alcon Transaction and the changes to the scope of our research and development activities of KPI-012 as more fully described above.

Since inception, we have incurred significant losses from operations and negative cash flows from operations. Our net loss was $9.0 million and $30.3 million for the three and nine months ended September 30, 2024, respectively, and $42.2 million for the year ended December 31, 2023. As of September 30, 2024, we had an accumulated deficit of $659.7 million. We generated only limited revenues from product sales of EYSUVIS and INVELTYS prior to the sale of the Commercial Business to Alcon in July 2022. We have financed our operations primarily through proceeds from the sale of our Commercial Business to Alcon, our initial public offering, or IPO, follow-on public common stock offerings and sales of our common stock under our sales agreement with Jefferies, LLC, or Jefferies, in at-the-market offerings, private placements of common stock and/or preferred stock (including our most recent private placements resulting in net proceeds of approximately $8.5 million in March 2024 and $12.3 million in June 2024), borrowings under credit facilities and our Loan Agreement with Oxford Finance, or the Loan Agreement, disbursements under a grant from California Institute for Regenerative Medicine, or CIRM (including our most recent disbursement of $3.2 million from CIRM in August 2024 upon the achievement of a specified milestone), convertible promissory notes and warrants.

We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and, prior to the sale of our Commercial Business to Alcon in July 2022, engaging in activities to launch and commercialize EYSUVIS and INVELTYS. As a result of our acquisition of Combangio and the sale of our Commercial Business to Alcon, we are devoting substantial financial resources to the research and development and potential commercialization of KPI-012 for PCED and any other indications we determine to pursue, including Limbal Stem Cell Deficiency. We have no revenue-generating commercial products and, as a result of our acquisition of Combangio, we may be required to pay certain milestones and royalty payments to former equityholders of Combangio, which are more fully described in the "Liquidity and Capital Resources" section. Although we are eligible to receive up to $325.0 million in payments from Alcon based upon the achievement of specified commercial sales-based milestones with respect to EYSUVIS and INVELTYS, there can be no assurance when we may receive such

milestone payments or of the amount of milestone payments we may receive, if any. Additionally, we cannot be certain that we will achieve the remaining milestones under CIRM award within the required timeframes, or at all, and as such we may never receive the remaining $5.9 million under the award. We expect to continue to incur significant expenses and operating losses for the foreseeable future, including in connection with our continued development, regulatory approval efforts and commercialization, if any, of KPI-012. We may never achieve or maintain profitability. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

Financial Operations Overview

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits, stock-based compensation and travel expenses related to our executive, finance, human resources, legal, compliance, information technology and business development functions. General and administrative expenses also include professional fees for auditing, tax, information technology, consultants, legal services and allocated facility-related costs not otherwise included in research and development expenses.

We expect that our general and administrative expenses for 2024 will be comparable to such expenses for the year ended December 31, 2023 and expect that our general and administrative expenses will continue at similar levels for the next several years. If we obtain marketing approval for KPI-012 or any product candidates we may develop, we expect that our general and administrative expenses will increase substantially if and as we incur commercialization expenses related to product marketing, sales and distribution.

Research and Development Expenses

Research and development expenses consist of costs associated with our research activities, including compensation and benefits for full-time research and development employees, an allocation of facilities expenses, overhead expenses and certain outside expenses. Our research and development expenses include:

- employee-related expenses, including salaries, related benefits, travel and stock-based compensation;
- expenses incurred for the preclinical and clinical development of our product candidates and under agreements with contract research organizations, including costs of manufacturing product candidates prior to the determination that FDA approval of a drug candidate is probable and before the future economic benefit of the drug is expected to be realized; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and supplies.

We expense research and development costs as they are incurred. We expense costs relating to the production of inventory for our product candidates, as research and development expenses within our condensed consolidated statements of operations and comprehensive loss in the period incurred, unless we believe regulatory approval and subsequent commercialization of the product candidate is probable and we expect the future economic benefit from sales of the drug to be realized. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense until incurred. We track outsourced development costs by development program but do not allocate personnel costs, payments made under license agreements or other costs to specific product candidates or development programs. These costs are included in employee-related costs and other research and development costs in the line items in the tables under “Results of Operations”.

We expect that our research and development costs for 2024 will be higher than such expenses for the year ended December 31, 2023 as we continue to advance the clinical development of KPI-012 and as we conduct any necessary preclinical studies and clinical trials and other development activities for any other product candidate we may develop in the future, including our planned preclinical studies under our KPI-014 program. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time-consuming. We may

never succeed in obtaining marketing approval for any of our product candidates. The probability of success for each product candidate may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability.

KPI-012 is in Phase 2b clinical development and all of our other research and development programs are in preclinical development. Successful development and completion of preclinical studies and clinical trials is uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each product candidate and future product candidate and are difficult to predict. We will continue to make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the scientific and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of product candidates and our ability to enter into collaborations with respect to each product candidate. We will need to raise additional capital and may seek collaborations in the future to advance KPI-012 and any product candidate we may develop. Additional private or public financings may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy.

Gain on Fair Value Remeasurement of Deferred Purchase Consideration

In connection with the closing of the Combangio Acquisition on November 15, 2021, we agreed to issue an aggregate of 155,664 shares, or the Deferred Purchase Consideration, of our common stock to former Combangio stockholders and other equityholders, or the Combangio Equityholders, consisting of (i) an aggregate of 136,314 shares of common stock which were issued on January 3, 2022 and (ii) an aggregate of 19,350 shares of common stock that were held back by us as partial security for the satisfaction of indemnification obligations and other payment obligations of the Combangio Equityholders which were issued on March 10, 2023. We recorded an obligation for such Deferred Purchase Consideration at fair value on the acquisition date. We then revalued our Deferred Purchase Consideration obligations each reporting period. Changes in the fair value of our Deferred Purchase Consideration obligations, other than changes due to issuance, are recognized as a gain or loss on fair value remeasurement of Deferred Purchase Consideration in our condensed consolidated statements of operations and comprehensive loss.

Loss (gain) on Fair Value Remeasurement of Contingent Consideration

In addition to the Deferred Purchase Consideration, consideration payable to the Combangio Equityholders includes potential payments of up to $105.0 million that are contingent upon the achievement of specified development, regulatory and commercialization milestones. As of September 30, 2024, of the up to $105.0 million in contingent milestone payments, we paid to the Combangio Equityholders an aggregate of $2.6 million in cash and $2.4 million in shares of common stock (representing an aggregate of 105,038 shares of our common stock) as a result of our dosing the first patient in our CHASE trial in February 2023, or the First Dosing Milestone. All potential milestone payments to the Combangio Equityholders are payable in cash going forward.

We recorded an obligation for such contingent consideration at fair value on the acquisition date. We then revalue our contingent consideration obligations each reporting period. Changes in the fair value of our contingent consideration obligations, other than changes due to issuance, are recognized as a gain or loss on fair value remeasurement of contingent consideration in our condensed consolidated statements of operations and comprehensive loss.

The potential payments and milestones are more fully described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and Note 3, “Fair Value of Financial Instruments” of our condensed consolidated financial statements.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and short-term investments, if any.

Interest Expense

Interest expense primarily consists of contractual coupon interest, amortization of debt discounts and debt issuance costs and accretion of the final payment fee recognized on our debt arrangements.

Grant Income

On April 28, 2023, CIRM awarded Combangio a $15.0 million grant, or the CIRM Award, subject to entering into a final award agreement, to support Combangio's ongoing KPI-012 program for the treatment of PCED as well as product and process characterization and analytical development for the program. On August 2, 2023, Combangio entered into the CIRM Award and received an initial $5.9 million disbursement from CIRM. On May 17, 2024, Combangio became entitled to receive a disbursement of $3.2 million from CIRM upon the achievement of a specified milestone, which was received in August 2024.

The CIRM Award is subject to a co-funding requirement under which Combangio is obligated to spend a specified minimum amount on the development of KPI-012 to obtain the full award amount. The remaining $5.9 million available under the CIRM Award is payable to Combangio only upon the achievement of specified milestones that are primarily related to Combangio's progress in conducting the CHASE clinical trial. CIRM may permanently cease disbursements if the milestones are not met within four months of the scheduled completion dates or if the delay is not addressed to CIRM's satisfaction, as determined by CIRM in its sole discretion. Additionally, if CIRM determines, in its sole discretion, that Combangio has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements. Under the terms of the CIRM Award, Combangio is obligated to pay a royalty on net sales of any product, service or approved drug resulting in whole or in part from the CIRM Award in the amount of 0.1% per $1.0 million of funds utilized by us until the earlier of ten years from the date of first commercial sale of such product, service or approved drug and such time as nine times the amount of funds awarded by CIRM has been paid in royalties, or the Base Royalty. In addition, following the satisfaction of the Base Royalty, Combangio is obligated to pay a 1.0% royalty on net sales of any CIRM-funded invention in excess of $500 million per year until the last to expire patent covering such invention expires.

The CIRM Award is not in the scope of the contracts with customers accounting guidance as the government entity is not a customer under the agreement. Rather, the CIRM Award is accounted for as a contract to perform research and development activities. As a result, grant income is recognized as the related research and development expenses are incurred.

Other Income (Expense), Net

Other income (expense), net consists of expenses recorded to assets held for sale for the write-off of the remaining inventory balance related to the Alcon Transaction, partially offset by reimbursable transition-related services we provided to Alcon following the sale of the Commercial Business.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be 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.

There have been no material changes to our critical accounting estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes the results of our operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Costs and expenses:			
General and administrative	$ 4,400	$ 4,952	$ (552)
Research and development	5,168	5,554	(386)
Loss (gain) on fair value remeasurement of contingent consideration	420	(1,744)	2,164
Total operating expenses	9,988	8,762	1,226
Loss from operations	(9,988)	(8,762)	(1,226)
Other income (expense)			
Interest income	570	708	(138)
Interest expense	(1,478)	(1,459)	(19)
Grant income	1,946	2,970	(1,024)
Other expense, net	—	(2,161)	2,161
Net loss	$ (8,950)	$ (8,704)	$ (246)

General and administrative expenses

General and administrative expenses were $4.4 million for the three months ended September 30, 2024, compared to $5.0 million for the three months ended September 30, 2023, which was a decrease of $0.6 million. The decrease in general and administrative expenses for the three months ended September 30, 2024 was due to a decrease of $0.4 million in stock-based compensation costs, $0.3 million in employee-related costs and $0.1 million in facility related costs, partially offset by an increase of $0.2 million in administrative and professional service fees.

Research and development expenses

The following table summarizes the research and development expenses incurred during the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
KPI-012 development costs	$ 2,090	$ 2,445	$ (355)
Employee-related costs	2,740	2,685	55
Other research and development costs	338	424	(86)
Total research and development	$ 5,168	$ 5,554	$ (386)

Research and development expenses were $5.2 million for the three months ended September 30, 2024, compared to $5.6 million for the three months ended September 30, 2023, a decrease of $0.4 million. The decrease was primarily due to the timing of manufacturing costs related to KPI-012 development.

Loss (gain) on fair value remeasurement of contingent consideration

Loss on fair value remeasurement of contingent consideration for the three months ended September 30, 2024 was $0.4 million as compared to a gain of $1.7 million for the three months ended September 30, 2023, primarily due to changes in discount rates, the passage of time and changes in the expected timing.

Interest income

Interest income was $0.6 million for the three months ended September 30, 2024 and was $0.7 million for the three months ended September 30, 2023. Interest income consists of interest earned on our cash, cash equivalents and short-term investments, if any. The decrease was attributable to a lower cash balance and the quantity and mix of investments, partially offset by higher interest rates during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023.

Interest expense

We incurred interest expense of $1.5 million for the three months ended September 30, 2024 and $1.5 million for the three months ended September 30, 2023. Interest expense for the three months ended September 30, 2024 and 2023 was comprised of the contractual coupon interest expense, the amortization of the debt discount and the accretion of the final payment fee associated with our Loan Agreement with Oxford Finance. During both the three months ended September 30, 2024 and 2023, $34.0 million of indebtedness was outstanding under our Loan Agreement.

Grant income

Grant income for the three months ended September 30, 2024 and 2023 was $1.9 million and $3.0 million, respectively, related to the CIRM Award.

Other expense, net

There was no other expense, net for the three months ended September 30, 2024. Other expense, net was $2.2 million for the three months ended September 30, 2023, which represented an expense recorded to assets held for sale.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes the results of our operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Costs and expenses:			
General and administrative	$ 14,139	$ 15,944	$ (1,805)
Research and development	16,836	13,868	2,968
Gain on fair value remeasurement of deferred purchase consideration	—	(230)	230
Loss on fair value remeasurement of contingent consideration	549	462	87
Total operating expenses	31,524	30,044	1,480
Loss from operations	(31,524)	(30,044)	(1,480)
Other income (expense)			
Interest income	1,578	2,101	(523)
Interest expense	(4,391)	(4,346)	(45)
Grant income	4,001	2,970	1,031
Other expense, net	—	(4,253)	4,253
Net loss	$ (30,336)	$ (33,572)	$ 3,236

General and administrative expenses

General and administrative expenses were $14.1 million for the nine months ended September 30, 2024, compared to $15.9 million for the nine months ended September 30, 2023, which was a decrease of $1.8 million. The decrease in general and administrative expenses for the nine months ended September 30, 2024 was primarily due to a $1.8 million decrease in administrative and professional service fees, a $0.5 million decrease in employee-related costs and a $0.2 million decrease in facility related costs, partially offset by a $0.7 million increase in stock-based compensation costs.

Research and development expenses

The following table summarizes the research and development expenses incurred during the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
KPI-012 development costs	$ 7,321	$ 5,838	$ 1,483
Employee-related costs	8,348	7,250	1,098
Other research and development costs	1,167	780	387
Total research and development	$ 16,836	$ 13,868	$ 2,968

Research and development expenses were $16.8 million for the nine months ended September 30, 2024, compared to $13.9 million for the nine months ended September 30, 2023, which was an increase of $3.0 million. The increase was primarily related to a $1.5 million increase in KPI-012 development costs, as we advance the clinical development of KPI-012, a $1.1 million increase in employee-related costs and a $0.4 million increase in other research and development costs, which primarily included facility costs.

Gain on fair value remeasurement of Deferred Purchase Consideration

There was no gain or loss on fair value remeasurement of Deferred Purchase Consideration for the nine months ended September 30, 2024 due to the final settlement of the liability in March 2023. The gain on fair value

remeasurement of Deferred Purchase Consideration for the nine months ended September 30, 2023 was $0.2 million, which was primarily due to a change in the fair value of our underlying stock price.

Loss on fair value remeasurement of contingent consideration

Loss on fair value remeasurement of contingent consideration for the nine months ended September 30, 2024 and 2023 was $0.5 million and $0.5 million, respectively, primarily due to changes in discount rates, the passage of time and changes in the expected timing and probability of payment.

Interest income

Interest income was $1.6 million for the nine months ended September 30, 2024 and was $2.1 million for the nine months ended September 30, 2023. Interest income consists of interest earned on our cash, cash equivalents and short-term investments, if any. The decrease was attributable to a lower cash balance and the quantity and mix of investments, partially offset by higher interest rates during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023.

Interest expense

We incurred interest expense of $4.4 million for the nine months ended September 30, 2024 and $4.3 million for the nine months ended September 30, 2023. Interest expense for the nine months ended September 30, 2024 and 2023 was comprised of the contractual coupon interest expense, the amortization of the debt discount and the accretion of the final payment fee associated with our Loan Agreement with Oxford Finance. During the nine months ended September 30, 2024, $34.0 million of indebtedness was outstanding under our Loan Agreement. During the nine months ended September 30, 2023, $43.3 million of indebtedness was outstanding under our Loan Agreement until $9.3 million was repaid on January 25, 2023 resulting in an outstanding indebtedness of $34.0 million.

Grant income

Grant income for the nine months ended September 30, 2024 and 2023 was $4.0 million and $3.0 million, respectively, related to the CIRM Award.

Other expense, net

There was no other expense, net for the nine months ended September 30, 2024. Other expense, net was $4.3 million for the nine months ended September 30, 2023 and represented a $7.6 million expense recorded to assets held for sale for expiring inventory and $1.1 million related to an adjustment for the returns' reserve associated with our former commercial products, partially offset by the $4.2 million write-off related to the deferred gain recorded on the sale of the Commercial Business and $0.2 million of reimbursable transition related services we provided to Alcon following the sale of the Commercial Business.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We only generated limited revenues from product sales of EYSUVIS and INVELTYS prior to the sale of our Commercial Business to Alcon in July 2022. We have financed our operations primarily through proceeds from the sale of our Commercial Business to Alcon in July 2022, our IPO, follow-on public common stock offerings and sales of our common stock under our at-the-market equity offerings, private placements of common stock and/or preferred stock, borrowings under credit facilities and our Loan and Security Agreement, or the Loan Agreement, with Oxford Finance LLC, or Oxford Finance, disbursements under a grant from CIRM, convertible promissory notes and warrants.

Sale of Commercial Business

In July 2022, we sold our Commercial Business to Alcon. In addition to the upfront cash payment of $60.0 million we received from Alcon, we are also eligible to receive from Alcon up to four commercial-based sales milestone payments as follows: (1) $25.0 million upon the achievement of $50.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (2) $65.0 million upon the achievement of $100.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (3) $75.0 million upon the achievement of $175.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029 and (4) $160.0 million upon the achievement of $250.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029. Each milestone payment will only become payable once, if at all, upon the first time such milestone is achieved, and only one milestone payment will be paid with respect to a calendar year. In the event that more than one milestone is achieved in a calendar year, the higher milestone payment will become payable and the lower milestone payment will become payable only if the corresponding milestone is achieved again in a subsequent calendar year. To date, we have not received any such milestone payments. We now have no revenue-generating commercial products, and although we are eligible to receive up to $325.0 million in milestone-based payments from Alcon, there can be no assurance as to when we may receive such milestone payments or the amount of milestone payments we may receive, if any.

Offerings under Registration Statements

In connection with the filing of a registration statement on Form S-3 with the SEC, or the 2020 Shelf Registration, we entered into an amended and restated sales agreement with Jefferies, or the Amended and Restated Sales Agreement, pursuant to which we could issue and sell, from time to time, up to an aggregate of $75.0 million of our common stock under our at-the-market offering. From January 1, 2023 to January 10, 2023, we sold 245,887 shares of our common stock under the Amended and Restated Sales Agreement, resulting in net proceeds of $10.0 million. On January 10, 2023, the Amended and Restated Sales Agreement terminated in accordance with its terms when we completed the sale of $75.0 million of our shares of common stock thereunder. As of the date of termination of the Amended and Restated Sales Agreement, we had sold an aggregate of 565,974 shares of our common stock under such agreement for aggregate gross proceeds of $75.0 million.

On January 19, 2023, we entered into a new sales agreement with Jefferies, or the Open Market Sale Agreement, pursuant to which we may issue and sell, from time to time, shares of our common stock through Jefferies under our at-the-market offering. We filed a prospectus supplement relating to the Open Market Sale Agreement under our 2020 Shelf Registration, or the 2020 Shelf ATM Prospectus Supplement, pursuant to which we could offer and sell shares of common stock having an aggregate offering price of up to $40.0 million under the Open Market Sale Agreement. From January 19, 2023 to May 11, 2023, we sold 229,378 shares of our common stock under our at-the-market offering pursuant to the Open Market Sale Agreement under the 2020 Shelf ATM Prospectus, resulting in net proceeds of $4.9 million.

On March 3, 2023, we filed a shelf registration statement on Form S-3 with the SEC, or the 2023 Shelf Registration, which was declared effective on May 11, 2023. Under the 2023 Shelf Registration we may offer and sell up to $350.0 million of a variety of securities including common stock, preferred stock, warrants, depositary shares, debt securities, subscription rights or units. In accordance with the terms of the Open Market Sale Agreement, we may issue and sell, from time to time, up to an aggregate of $40.0 million of our common stock in an at-the-market equity offering through Jefferies. Upon effectiveness of the 2023 Shelf Registration, we ceased any further offers or sales of our common stock pursuant to the 2020 Shelf ATM Prospectus Supplement and the 2020 Shelf Registration.

During the nine months ended September 30, 2023, we sold an aggregate of 190,000 shares of our common stock under the Open Market Sale Agreement under the 2023 Shelf Registration for total net proceeds of $3.1 million, none of which were sold during the three months ended September 30, 2023. During the nine months ended September 30, 2023, we sold an aggregate of 665,265 shares of our common stock pursuant to (1) the Amended and Restated Sales Agreement and the Open Market Sale Agreement under the 2020 Shelf Registration and (2) the Open Market Sale Agreement under the 2023 Shelf Registration, for total net proceeds of $18.0 million.

During the nine months ended September 30, 2024, we sold an aggregate of 387,500 shares of our common stock under the Open Market Sale Agreement under the 2023 Shelf Registration for total net proceeds of $2.5 million, none of which were sold during the three months ended September 30, 2024.

Loan Agreement

On May 4, 2021, we entered into the Loan Agreement with Oxford Finance, in its capacity as lender, or the Lender, and in its capacity as collateral agent, or Agent, pursuant to which a term loan of up to an aggregate principal amount of $125.0 million became available to us, consisting of a tranche A term loan that was disbursed on the closing date of the Loan Agreement in the aggregate principal amount of $80.0 million and additional tranches that are no longer available to us. Through June 30, 2023, the term loan bore interest at a floating rate equal to the greater of 30-day LIBOR and 0.11%, plus 7.89%. Effective July 1, 2023, the term loan bears interest at a floating rate equal to the greater of (a) 8.00% and (b) the sum of (i) the 1-Month CME Term Secured Overnight Financing Rate, or SOFR, (ii) 0.10% and (iii) 7.89%. Certain of the customary negative covenants limit our and certain of our subsidiaries' ability, among other things, to incur future debt, grant liens, make investments, make acquisitions, distribute dividends, make certain restricted payments and sell assets, subject in each case to certain exceptions. In connection with our entry into the purchase agreement for the sale of our Commercial Business to Alcon on May 21, 2022, we entered into an amendment to the Loan Agreement, or the Second Loan Amendment, pursuant to which the Lender and Agent consented to the entry by us into the asset purchase agreement and the sale of the Commercial Business to Alcon and agreed to release its liens on the Commercial Business in consideration for the payment by us at the closing of the Alcon Transaction of an aggregate amount of $40.0 million, or the Second Amendment Prepayment, to the Lender and Agent. The Second Amendment Prepayment, which represented a partial prepayment of principal in the amount of $36.7 million of the $80.0 million principal amount outstanding under the term loan advanced by the Lender under the Loan Agreement, plus a prepayment fee of $0.7 million and a final payment fee of $2.6 million, was paid on July 8, 2022 in connection with the closing of the Alcon Transaction.

On December 27, 2022, we entered into an amendment to the Loan Agreement with Combangio and Oxford Finance, or the Third Loan Amendment, pursuant to which Oxford Finance agreed to amend certain provisions of the Loan Agreement to permit the transfer of the listing of our common stock from The Nasdaq Global Select Market to The Nasdaq Capital Market. Pursuant to the Third Loan Amendment, we agreed (A) to make partial prepayments of the principal amount of the term loan outstanding under the Loan Agreement as follows, or the Third Amendment Prepayments: (1) a payment of $5.0 million on or before June 30, 2023, representing a partial prepayment of principal in the amount of $4.7 million, plus a final payment fee of $0.3 million and (2) a payment of $5.0 million on or before January 31, 2024, representing a partial prepayment of principal in the amount of $4.7 million, plus a final payment fee of $0.3 million and (B) the start date for us to make amortization payments under the Loan Agreement was changed from January 1, 2026 to January 1, 2025, or the Amortization Date. On January 25, 2023, we paid the Third Amendment Prepayments and the principal loan balance under the Loan Agreement following such prepayments was $34.0 million.

Pursuant to the Third Loan Amendment, in addition to the Third Amendment Prepayments, if we make an additional prepayment under the Loan Agreement equal to $5.0 million (inclusive of the final payment fee) on or prior to December 31, 2024, or the First Extension Prepayment, the Amortization Date will be automatically changed to July 1, 2025, and the maturity date of the Loan Agreement will be automatically changed from May 1, 2026 to November 1, 2026. If, in addition to the Third Amendment Prepayments and the First Extension Prepayment, we make an additional prepayment under the Loan Agreement equal to $2.5 million (inclusive of the final payment fee) on or prior to June 30, 2025, or the Second Extension Prepayment, the Amortization Date will be automatically changed to January 1, 2026, and the maturity date of the Loan Agreement will be automatically changed to May 1, 2027.

Under the Third Loan Amendment, Oxford Finance also agreed to waive the prepayment fees for the Third Amendment Prepayments, the First Extension Prepayment, the Second Extension Prepayment and any other prepayments under the Loan Agreement. Pursuant to the Loan Agreement, we also will be required to pay all accrued and unpaid interest on the principal amounts of the term loan being repaid at the time of repayment.

We will be required to make a final payment fee of 7.00% of the original principal amount of any funded term loan payable on the earlier of (i) the prepayment of the term loan in full or (ii) the maturity date. At our option, we may

elect to make partial repayments of the term loan to the Lender, subject to specified conditions, including the payment of applicable fees and accrued and unpaid interest on the principal amount of the term loan being repaid. For further information about the Loan Agreement, see Note 7, "Debt", of our condensed consolidated financial statements.

On August 1, 2023, we entered into a fourth amendment to the Loan Agreement pursuant to which certain provisions of the Loan Agreement were amended in connection with the change in our corporate name and the cessation of the U.S. Dollar LIBOR rate. On August 2, 2023, we entered into a fifth amendment to the Loan Agreement pursuant to which Oxford Finance consented to our entry into the CIRM Award and certain provisions of the Loan Agreement were amended in connection therewith.

Private Placements

On November 28, 2022, we entered into a Securities Purchase Agreement, with certain institutional investors named therein, or the Series E Purchasers, pursuant to which we agreed to issue and sell, in a private placement priced at-the-market under Nasdaq rules, shares of our common stock and shares of our Series E Convertible Non-Redeemable Preferred Stock, or the Series E Preferred Stock, in two tranches for aggregate gross proceeds of up to $31.0 million, which we refer collectively as the 2022 Private Placement. At the first closing of the 2022 Private Placement on December 1, 2022, we issued and sold to the Series E Purchasers (i) 76,813 shares of common stock, at a price per share equal to $5.75 and (ii) 9,666 shares of Series E Preferred Stock, at a price per share of Series E Preferred Stock equal to $575.00, for aggregate gross proceeds of approximately $6.0 million. On December 27, 2022, following the certification by our Chief Executive Officer that the FDA accepted our IND application for KPI-012, we issued and sold to the Series E Purchasers at a second closing of the 2022 Private Placement a total of 43,478 shares of Series E Preferred Stock, at a price per share of Series E Preferred Stock equal to $575.00, for aggregate gross proceeds of approximately $25.0 million.

On December 21, 2023, we entered into a securities purchase agreement with certain institutional investors named therein pursuant to which we agreed to issue and sell, in a private placement priced at-the-market under Nasdaq rules, 2,928 shares of our Series F Convertible Non-Redeemable Preferred Stock, or the Series F Preferred Stock, at a price per share of $683.00, for aggregate gross proceeds of approximately $2.0 million.

On March 25, 2024, we entered into a securities purchase agreement with certain institutional investors named therein pursuant to which we agreed to issue and sell, in a private placement priced at-the-market under Nasdaq rules, 10,901 shares of our Series G Convertible Non-Redeemable Preferred Stock, or the Series G Preferred Stock, at a price per share of $788.90, for aggregate gross proceeds of approximately $8.6 million.

On June 26, 2024, we entered into a securities purchase agreement with certain institutional investors named therein pursuant to which we agreed to issue and sell, in a private placement, (i) 1,197,314 shares of our common stock, at a price per common share equal to $5.85, and (ii) 9,393 shares of our Series H Convertible Non-Redeemable Preferred Stock, or the Series H Preferred Stock, at a price per preferred share of $585.80, for aggregate gross proceeds of approximately $12.5 million.

CIRM Award

On April 28, 2023, CIRM awarded Combangio a $15 million grant, subject to entering into a final award agreement, to support its ongoing KPI-012 program for the treatment of PCED as well as product and process characterization and analytical development for the program. On August 2, 2023, Combangio entered into the CIRM Award and received a $5.9 million disbursement from CIRM, and in August 2024, Combangio received an additional $3.2 million disbursement from CIRM upon achievement of a specified milestone under the CIRM Award. For a further description of the CIRM Award and the potential milestone payments we may receive, see "Financial Operations Overview – Grant Income" above.

Combangio Acquisition

As a result of the acquisition of Combangio, we may be required to pay additional contingent consideration to the former Combangio Equityholders. Former Combangio Equityholders are entitled to receive from us, subject to the terms and conditions of the merger agreement, contingent consideration, which would become payable upon our achievement of various development, regulatory and sales milestones and as a result of certain cash royalty payment obligations which are in the mid-to-high single digits. The total potential maximum payout for the milestone payments which are contingent upon the achievement of specified development, regulatory and commercialization milestones is $40.0 million and the total potential maximum payout for future sales-based milestone payments is an additional $65.0 million. To date, of the $40.0 million of contingent consideration payable upon achievement of specified development, regulatory and commercialization milestones, in March 2023 we paid to the former Combangio Equityholders an aggregate of $2.5 million in cash and $2.4 million in shares of our common stock (representing an aggregate of 105,038 shares of our common stock) following dosing of the first patient in our CHASE trial in February 2023. The remaining amount of $0.1 million for this milestone was paid in cash in January 2024. For a full description of the consideration payable as a result of the Combangio Acquisition, see our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and Note 3, “Fair Value of Financial Instruments”, of our condensed consolidated financial statements.

Other Contractual Obligations

Our other material cash requirements from known contractual and other obligations as of September 30, 2024 primarily related to our license agreement with Stanford University and our operating lease. For information related to our future commitments relating to our license agreement, see Note 13, “Commitments and Contingencies”, of our condensed consolidated financial statements. For information related to our future commitments for our lease related obligations, see Note 6, “Leases”, of our condensed consolidated financial statements.

Cash Flows

As of September 30, 2024 and December 31, 2023, we had $49.2 million and $50.9 million in cash and cash equivalents, respectively. As of September 30, 2024 and December 31, 2023, we had $34.0 million in indebtedness, which represented the aggregate principal amount that was outstanding under the Loan Agreement with Oxford Finance.

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Net cash used in operating activities	$ (24,784)	$ (20,231)	$ (4,553)
Net cash used in investing activities	(139)	(422)	283
Net cash provided by financing activities	23,230	5,971	17,259
Net decrease in cash and cash equivalents	$ (1,693)	$ (14,682)	$ 12,989

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2024 was $24.8 million, compared to $20.2 million for the nine months ended September 30, 2023, an increase of $4.6 million, primarily due to a $13.9 million increase due to the timing of working capital fluctuations, partially offset by the decrease in the net loss adjusted for non-cash charges of $9.3 million. Notable working capital fluctuations included a $6.0 million decrease in prepaid expenses and other current assets during the nine months ended September 30, 2023, as compared to a $0.1 million increase during the nine months ended September 30, 2024, as a result of the collection of receivables due from Alcon and third parties in connection with transition-related services. Inventory and assets held for sale decreased by $7.5 million during the nine months ended September 30, 2023, as a result of the expense recorded to assets held for sale to write-off the remaining inventory balance, whereas there was no fluctuation related to inventory for the nine months ended September 30, 2024.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2024 was $0.1 million compared to $0.4 million for the nine months ended September 30, 2023, a decrease of $0.3 million. Net cash used in investing activities for the nine months ended September 30, 2024 related to purchases of property and equipment and other assets. Net cash used in investing activities for the nine months ended September 30, 2023 related to purchases of short-term investments of $9.9 million and purchases of property and equipment and other assets of $0.6 million, partially offset by proceeds from the sale or maturities of short-term investments of $10.0 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was $23.2 million, compared to $6.0 million for the nine months ended September 30, 2023, an increase of $17.3 million. Net cash provided by financing activities for the nine months ended September 30, 2024 largely consisted of $12.3 million of net proceeds from the sale of common stock and shares of our Series H Preferred Stock in our June 2024 private placement, $8.5 million of net proceeds from the sale of shares of our Series G Preferred Stock in our March 2024 private placement and $2.5 million of net proceeds from the sale of shares of our common stock through Jefferies under our at-the-market equity offering, partially offset by a $0.1 million payment for the First Dosing Milestone reflected in financing activities. Net cash provided by financing activities for the nine months ended September 30, 2023 largely consisted of $18.0 million of net proceeds from the sale of shares of our common stock through Jefferies under our at-the-market equity offering, partially offset by $10.0 million of repayment of principal and final payment fee on our Loan Agreement and a $2.0 million payment for the First Dosing Milestone reflected in financing activities.

Funding Requirements

We anticipate that our research and development expenses will increase substantially in the future as compared to prior periods as we advance the clinical development of KPI-012. Our research and development expenses will also increase in the future as we conduct any necessary preclinical studies and clinical trials and other development activities for any other product candidates we may develop in the future, including our planned preclinical studies under our KPI-014 program. If we obtain marketing approval for KPI-012 or any product candidates we may develop, we expect that our general and administrative expenses will increase substantially if and as we incur commercialization expenses related to product marketing, sales and distribution.

Our expenses will also increase if and as we:

- continue the clinical development of KPI-012 for PCED;
- initiate and continue the research and development of KPI-012 for additional indications, such as Limbal Stem Cell Deficiency, including initiating and conducting preclinical studies and clinical trials;
- scale up our manufacturing processes and capabilities to manufacture the clinical supply of KPI-012;
- seek regulatory approval for KPI-012 for PCED in the United States and other jurisdictions;

- seek regulatory approval for KPI-012 for additional indications;
- grow our sales, marketing and distribution capabilities in connection with the commercialization of any product candidates for which we may submit for and obtain marketing approval;
- initiate and progress any preclinical development programs under our MSC-S platform, including from our KPI-014 program;
- conduct clinical trials and other development activities and/or seek marketing approval for any product candidates we may develop in the future;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel to support our operations;
- expand our operational, financial and management systems; and
- increase our product liability insurance coverage if we initiate commercialization efforts for our product candidates.

We expect to continue to incur significant expenses and operating losses. Net losses may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our cash and cash equivalents as of September 30, 2024, together with the $5.9 million of remaining funding anticipated under the CIRM Award, will enable us to fund our operations, lease and debt service obligations, and capital expenditure requirements into the fourth quarter of 2025. We expect that our existing cash resources will be sufficient to enable us to obtain safety and efficacy data from our ongoing CHASE trial of KPI-012 in PCED. However, we do not expect that our existing cash resources will be sufficient to enable us to complete the clinical development of KPI-012 for PCED or for any other indication. We have based our estimates on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. For example, we may not receive all of the remaining funds under the CIRM Award. In addition, our estimates also assume that we remain in compliance with the covenants and no event of default occurs under our Loan Agreement with Oxford Finance. If we do not receive all of the funding from CIRM we currently expect or if an event of default occurs under our Loan Agreement and Oxford Finance exercises its rights under the Loan Agreement to foreclose on our cash, our ability to fund our operations, lease and debt service obligations will be shorter than we currently expect. As a result, we could deplete our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase from what we anticipate if:

- we elect or are required by the FDA or non-U.S. regulatory agencies to perform clinical trials or studies in addition to those expected;
- there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates;
- we in-license or acquire rights to other products, product candidates or technologies; or
- there are any third-party challenges to our intellectual property portfolio, or the need arises to defend against intellectual property-related claims or enforce our intellectual property rights.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate revenue from KPI-012 or any other product candidate we may develop for the foreseeable future, if at all. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- completing the clinical development of KPI-012 for PCED and any other indications we determine to pursue, including Limbal Stem Cell Deficiency;
- subject to obtaining favorable results from our ongoing and planned clinical trials of KPI-012, applying for and obtaining marketing approval of KPI-012;
- successfully commercializing KPI-012, if approved;
- discovering, developing and successfully seeking marketing approval and commercialization of any additional product candidates we may develop in the future, including under our KPI-014 program;
- hiring and building a full commercial organization required for marketing, selling and distributing those products for which we obtain marketing approval;
- manufacturing at commercial scale, marketing, selling and distributing those products for which we obtain marketing approval;
- achieving an adequate level of market acceptance, and obtaining and maintaining coverage and adequate reimbursement from third-party payors for any products we commercialize; and
- obtaining, maintaining and protecting our intellectual property rights.

As a company, we have limited experience commercializing products, and we may not be able to commercialize a product successfully in the future. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us. We may never succeed in the foregoing activities and we may never generate revenue that is sufficient to achieve profitability. 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 would 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 product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include pledging of assets as collateral, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our pledge of our assets as collateral to secure our obligations under our Loan Agreement may limit our ability to obtain additional debt financing. Under our Loan Agreement, we are also restricted from incurring future debt, granting liens, making investments, making acquisitions, distributing dividends on our common stock, making certain restricted payments and selling assets and making certain other uses of our cash, without the lenders' consent, subject in each case to certain exceptions. In addition, under the securities purchase agreements for our 2022, 2023 and March 2024 private placements, we also agreed that we will not, without the prior approval of the requisite purchasers, (i) issue or authorize the issuance of any equity security that is senior or *pari passu* to the Series E Preferred Stock, the Series F Preferred Stock, or the Series G Preferred Stock with respect to liquidation preference, (ii) incur any additional indebtedness for borrowed money in excess of $1.0 million, in the aggregate, outside the ordinary course of business, subject to specified exceptions, including the refinancing of our existing indebtedness or (iii) pay or declare any dividend or make any distribution on, any shares of our capital stock, subject to specified exceptions. Under the securities purchase agreement for our June 2024 private placement, we agreed that we will not without the prior

approval of the requisite purchasers, issue or authorize the issuance of any equity security that is senior or *pari passu* to the Series H Preferred Stock with respect to liquidation preference.

We will need to raise additional capital in the future to advance our business. Additional private or public financings may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy. If we raise additional funds through collaborations, strategic alliances, licensing arrangements, royalty agreements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or current or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves or cease operations and, potentially, wind down the company under the bankruptcy laws or otherwise. If we were to cease operations and wind down the company under the bankruptcy laws or otherwise, we cannot assure our stockholders or other stakeholders of any specific level of recovery, or any recovery at all on their specific claims or interest.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our financial instruments consist primarily of cash equivalents. Our cash equivalents as of September 30, 2024 consisted of money market accounts and U.S. treasury securities that have contractual maturities of less than 90 days from the date of acquisition. Due to the short-term maturities of our cash equivalents, and the fixed income nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our cash equivalents.

As of September 30, 2024 and 2023, the aggregate principal amount outstanding under the Loan Agreement was $34.0 million. The aggregate principal amount outstanding under the Loan Agreement bore interest through June 30, 2023 at a floating rate equal to the greater of (i) 30-day LIBOR and (ii) 0.11%, plus 7.89%. Effective July 1, 2023, the aggregate principal amount outstanding under the Loan Agreement bears interest at a floating rate equal to the greater of (i) 8.00% and (ii) the sum of (a) the 1-Month CME Term SOFR, (b) 0.10% and (c) 7.89% per annum. An immediate 10% change in the 1-Month CME Term SOFR rate would not have a material impact on our operating results or cash flows.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting that occurred during the three-month period ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q, including our financial statements and the related notes appearing at the end of our Annual Report on Form 10-K and included in this Quarterly Report on Form 10-Q, before deciding to invest in our common stock. These risks, some of which have occurred and any of which may occur in the future, can have a material adverse effect on our business, prospects, operating results and financial condition. In such event, the trading price of our common stock could decline and you might lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business, prospects, operating results and financial condition.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses from operations and negative cash flows from operations since our inception. We expect to incur additional losses and may never achieve or maintain profitability.

Since inception, we have incurred significant losses from operations and negative cash flows from operations. Our net losses were $9.0 million and $30.3 million for the three and nine months ended September 30, 2024, respectively, and $42.2 million for the year ended December 31, 2023. As of September 30, 2024, we had an accumulated deficit of $659.7 million. Prior to the sale of the rights to manufacture, sell, distribute, market and commercialize EYSUVIS and INVELTYS and to develop, manufacture, market and otherwise exploit the AMPPLIFY

Drug Delivery Technology, which we collectively refer to as the Commercial Business, to Alcon Pharmaceuticals Ltd. and Alcon Vision, LLC, or collectively Alcon, in July 2022, we generated only limited revenues from sales of EYSUVIS and INVELTYS. We have financed our operations primarily through proceeds from the sale of our Commercial Business to Alcon in July 2022, our initial public offering, follow-on public offerings of common stock and sales under our at-the-market offering facilities, private placements of common stock and/or preferred stock (including our most recent private placement of common stock and preferred stock for net proceeds of approximately $12.3 million in June 2024), borrowings under credit facilities and the Loan and Security Agreement with Oxford Finance LLC, or the Loan Agreement, disbursements under a grant from CIRM (including our most recent disbursement of $3.2 million from CIRM in August 2024 upon achievement of a specified milestone), convertible promissory notes and warrants. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials, and prior to the sale of our Commercial Business to Alcon in July 2022, engaging in activities to launch and commercialize EYSUVIS and INVELTYS. We are devoting substantial financial resources to the research and development and potential commercialization of KPI-012, our product candidate in clinical development for the treatment of persistent corneal epithelial defects, or PCED, and any other indications we determine to pursue, including Limbal Stem Cell Deficiency. We have no revenue-generating commercial products, our cash flows have diminished as a result of the sale of our Commercial Business to Alcon and, as a result of our acquisition of Combangio, we may be required to pay certain milestones and royalty payments to former equityholders of Combangio. Although we are eligible to receive up to $325.0 million in payments from Alcon based upon the achievement of specified commercial sales-based milestones with respect to EYSUVIS and INVELTYS, there can be no assurance as to when we may receive such milestone payments or of the amount of milestone payments we may receive, if any. We also cannot assure you that we will achieve the remaining milestones under the CIRM award within required timeframes, or at all, and as such we may never receive the remaining $5.9 million under the award. We expect to continue to incur significant expenses and operating losses for the foreseeable future, including in connection with our continued development, regulatory approval efforts and commercialization, if any, of KPI-012. We may never achieve or maintain profitability. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

We anticipate that our research and development expenses will increase substantially in the future as compared to prior periods as we advance the clinical development of KPI-012. Our research and development expenses will also increase in the future as we conduct any necessary preclinical studies and clinical trials and other development activities for any other product candidates we may develop in the future, including our planned preclinical studies under our KPI-014 program, which is a mesenchymal secretome formulation that is in preclinical development for the treatment of inherited retinal degenerative diseases, such as Retinitis Pigmentosa and Stargardt Disease. If we obtain marketing approval for KPI-012 or any product candidates we may develop, we expect that our general and administrative expenses will increase substantially if and as we incur commercialization expenses related to product marketing, sales and distribution.

Our expenses will also increase if and as we:

- continue the clinical development of KPI-012 for PCED;
- initiate and continue the research and development of KPI-012 for additional indications, such as Limbal Stem Cell Deficiency, including initiating and conducting preclinical studies and clinical trials;
- scale up our manufacturing processes and capabilities to manufacture the clinical supply of KPI-012;
- seek regulatory approval for KPI-012 for PCED in the United States and other jurisdictions;
- seek regulatory approval for KPI-012 for additional indications;
- grow our sales, marketing and distribution capabilities in connection with the commercialization of any product candidates for which we may submit for and obtain marketing approval;
- initiate and progress any preclinical development programs under our mesenchymal stem cell secretome, or MSC-S platform, including from our KPI-014 program;
- conduct clinical trials and other development activities and/or seek marketing approval for any product candidates we may develop in the future;

- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel to support our operations;
- expand our operational, financial and management systems; and
- increase our product liability insurance coverage if we initiate commercialization efforts for our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase from what we anticipate if:

- we elect or are required by the U.S. Food and Drug Administration, or FDA, or non-U.S. regulatory agencies to perform clinical trials or studies in addition to those expected;
- there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates;
- we in-license or acquire rights to other products, product candidates or technologies; or
- there are any third-party challenges to our intellectual property portfolio, or the need arises to defend against intellectual property-related claims or enforce our intellectual property rights.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate revenue from KPI-012 or any other product candidate we may develop for the foreseeable future, if at all. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- completing the clinical development of KPI-012 for PCED and any other indications we determine to pursue, including Limbal Stem Cell Deficiency;
- subject to obtaining favorable results from our ongoing and planned clinical trials of KPI-012, applying for and obtaining marketing approval of KPI-012;
- successfully commercializing KPI-012, if approved;
- discovering, developing and successfully seeking marketing approval and commercialization of any additional product candidates we may develop in the future, including under our KPI-014 program;
- hiring and building a full commercial organization required for marketing, selling and distributing those products for which we obtain marketing approval;
- manufacturing at commercial scale, marketing, selling and distributing those products for which we obtain marketing approval;
- achieving an adequate level of market acceptance, and obtaining and maintaining coverage and adequate reimbursement from third-party payors for any products we commercialize; and
- obtaining, maintaining and protecting our intellectual property rights.

As a company, we have limited experience commercializing products, and we may not be able to commercialize a product successfully in the future. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us.

We may never succeed in the foregoing activities and we may never generate revenue that is sufficient to achieve profitability. 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 would 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 product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development efforts or cease operations.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct research and development activities, and initiate clinical trials of, and seek regulatory approval for, KPI-012 and any other product candidate that we develop in the future. If we do obtain regulatory approval for KPI-012 or any other product candidate that we develop, we expect to incur commercialization expenses related to product sales, marketing, distribution and manufacturing capabilities. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or cease operations and, potentially, wind down the company under the bankruptcy laws or otherwise. If we were to cease operations and wind down the company under the bankruptcy laws or otherwise, we cannot assure our stockholders or other stakeholders of any specific level of recovery, or any recovery at all on their specific claims or interest.

Our future capital requirements will depend on many factors, including:

- the timing and amount of milestone payments we ultimately receive from Alcon under the asset purchase agreement;
- the timing and amount of our future milestone payments to Combangio equityholders under the merger agreement;
- the timing and amount of milestone payments we ultimately receive from CIRM in connection with the CIRM Award;
- the progress, costs and results of our ongoing and planned clinical trials of KPI-012;
- the costs and timing of process development and manufacturing scale-up activities associated with KPI-012 for PCED and any other indications we determine to pursue;
- the costs, timing and outcome of regulatory review of KPI-012;
- the costs and timing of commercialization activities for KPI-012, if approved, including establishing and/or expanding product sales, marketing, medical affairs, distribution and outsourced manufacturing capabilities;
- our ability to successfully commercialize KPI-012, if approved, in the United States and other jurisdictions and the amount of revenue received from commercial sales;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of research and development of any other product candidates that we may develop, including under our KPI-014 program;
- the extent to which we successfully advance and/or in-license or acquire rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

We expect to continue to incur significant expenses and operating losses. Net losses may fluctuate significantly from quarter-to-quarter and year-to-year. We expect that our cash and cash equivalents of $49.2 million as of September 30, 2024 and the $5.9 million of remaining funding anticipated under the CIRM Award, will enable us to

fund our operations, lease and debt service obligations and capital expenditure requirements into the fourth quarter of 2025. We expect that our existing cash resources will be sufficient to enable us to obtain safety and efficacy data from our ongoing CHASE Phase 2b clinical trial of KPI-012 in PCED. However, we do not expect that our existing cash resources will be sufficient to enable us to complete the clinical development of KPI-012 for PCED or for any other indication. We have based our estimates on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. For example, we may not receive all of the remaining funds under the CIRM Award. In addition, our estimates also assume that we remain in compliance with the covenants and no event of default occurs under our Loan Agreement with Oxford Finance. If we do not receive all of the funding from CIRM we currently expect or if an event of default occurs under our Loan Agreement and Oxford Finance exercises its rights under the Loan Agreement to foreclose on our cash, our ability to fund our operations, lease and debt service obligations will be shorter than we currently expect. As a result, we could deplete our available capital resources sooner than we currently expect.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We may never generate the necessary data or results required to obtain marketing approval and achieve product sales from KPI-012 or any other product candidate we develop. Also, even if we successfully develop KPI-012 or any other product candidate and one or more of those are approved, we may not achieve commercial success with them. Accordingly, we will require additional financing to achieve our business objectives. In addition, we may opportunistically raise additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. Adequate additional financing may not be available to us on acceptable terms, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize any product candidate for which we obtain approval.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other rights and preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include pledging of assets as collateral and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

For example, our pledge of our assets as collateral to secure our obligations under our Loan Agreement may limit our ability to obtain additional debt financing. Under the Loan Agreement, we are also restricted from paying dividends on our common stock, granting liens, making investments, making acquisitions, making certain restricted payments, selling assets and making certain other uses of our cash without the lenders' consent, subject in each case to certain exceptions. In addition, under our securities purchase agreements for our 2022, 2023 and March 2024 private placements, we have agreed that we will not, without the prior approval of the requisite purchasers: (1) issue or authorize the issuance of any equity security that is senior or *pari passu* to the Series E Preferred Stock, the Series F Preferred Stock or the Series G Preferred Stock with respect to liquidation preference, (2) incur any additional indebtedness for borrowed money in excess of $1.0 million, in the aggregate, outside the ordinary course of business, subject to specified exceptions, including the refinancing of its existing indebtedness or (3) pay or declare any dividend or make any distribution on, any of our shares of capital stock, subject to specified exceptions. Under our securities purchase agreement for our June 2024 private placement, we also agreed that we will not, without the prior approval of the requisite holders of Series H Preferred Stock, issue or authorize the issuance of any equity security that is senior or *pari passu* to the Series H Preferred Stock with respect to liquidation preference.

In addition, if we raise additional funds through collaborations, strategic alliances, licensing arrangements, royalty agreements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or current or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves or cease operations and, potentially, wind down the company under the bankruptcy laws or otherwise. If we were to cease operations and wind down the company under the bankruptcy laws or otherwise, we cannot assure our stockholders or other stakeholders of any specific level of recovery, or any recovery at all on their specific claims or interest.

Our substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business and a failure to comply with the covenants under our Loan Agreement, such as the requirement that our common stock continue to be listed on The Nasdaq Stock Market, or to avoid the occurrence of specified events of default could result in an acceleration of amounts due.

We have a substantial amount of indebtedness. As of September 30, 2024, we had $34.0 million of outstanding borrowings under the tranche A term loan under the Loan Agreement, which through June 30, 2023 bore interest at a floating rate equal to the greater of 30-day LIBOR and 0.11%, plus 7.89%. Effective July 1, 2023, the term loan bears interest at a floating rate equal to the greater of (i) 8.00% and (ii) the sum of (a) the 1-Month CME Term Secured Overnight Financing Rate, (b) 0.10% and (c) 7.89%. Fluctuations in interest rates could materially affect the interest expense on our Loan Agreement. The start date for amortization payments under the Loan Agreement is January 1, 2025, at which time the aggregate principal balance of the term loan then outstanding under the Loan Agreement is required to be repaid in monthly installments through May 1, 2026. Pursuant to the Loan Agreement, we may also make partial prepayments of the term loan to the lender, subject to specified conditions, including the payment of applicable fees and accrued and unpaid interest on the principal amount of the term loan being repaid. Our obligations under the Loan Agreement are secured by substantially all of our assets.

Our debt combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of cash flow from operations or cash on hand to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to acquire other businesses for cash, take certain other corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt, particularly if we are in default under our Loan Agreement and all of our indebtedness under the Loan Agreement is due, and funds from external sources may not be available on a timely basis or acceptable terms, if at all. In addition, a failure to comply with the covenants under our Loan Agreement could result in an event of default and acceleration of amounts due. In particular, a delisting of our common stock from The Nasdaq Capital Market or a transfer of the listing of our common stock to another nationally recognized stock exchange having listing standards that are less restrictive than The Nasdaq Capital Market, in each case after a specified cure period, are events of default under our Loan Agreement. Our lender could also declare a default upon the occurrence of any event that is determined to be a material adverse change as defined under our Loan Agreement. In such events, we may not be able to make accelerated payments, and the lender could seek to enforce security interests in the collateral securing such indebtedness, including by foreclosing on our cash, potentially requiring us to renegotiate our agreement on terms less favorable to us, or to

immediately cease operations. Acceleration of the repayment of the outstanding indebtedness would raise substantial doubt about our ability to continue as a going concern, shorten the period for which we will be able to fund our operations and capital expenditure requirements, would adversely effect our financial condition and ability to pursue our business strategy and may cause us to cease operations and seek protection and wind down the company under the bankruptcy laws or otherwise. For more information about risks related to compliance with The Nasdaq Capital Market listing standards, please see "Risks Related to Our Common Stock - If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. If our common stock is delisted from Nasdaq, we will be in default under our Loan Agreement."

The milestone consideration we are eligible to receive in connection with the sale of our Commercial Business to Alcon is subject to various risks and uncertainties.

The milestone consideration we are eligible to receive for the sale of our Commercial Business to Alcon is subject to various risks and uncertainties. We are eligible to receive up to four commercial-based sales milestone payments from Alcon as follows: (1) $25.0 million upon the achievement of $50.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (2) $65.0 million upon the achievement of $100.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (3) $75.0 million upon the achievement of $175.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029 and (4) $160.0 million upon the achievement of $250.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029. To date, we have not received any such milestone payments.

We cannot predict what success, if any, Alcon and its affiliates may have with respect to sales of EYSUVIS and INVELTYS and, therefore, it is uncertain as to when we may receive the milestone payments, which milestone payments we may receive and if we will receive any milestone payments at all. If we do not receive some or all of the milestone payments, our business will be harmed.

If our estimates or judgments relating to our critical accounting policies, or any of our projections, prove to be inaccurate or financial reporting standards or interpretations change, our results of operations could be adversely affected.

The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities and expenses. Such estimates and judgments include the present value of lease liabilities and the corresponding right-of-use assets, the fair value of warrants, stock-based compensation, accrued expenses, contingent consideration, grant income and deferred grant income, the valuation of embedded derivatives and the recoverability of our net deferred tax assets and related valuation allowance. We base our estimates and judgments on historical experience, expected future experience and on various other assumptions that we believe to be reasonable under the circumstances. In addition, from time to time, we may rely on projections regarding our expected future performance that represent our management's then-current estimates. However, any of these estimates, judgments or projections, or the assumptions underlying them, may change over time or may otherwise prove to be inaccurate. Our results of operations may be adversely affected if our estimates, assumptions or projections change or if actual circumstances differ from those in our estimates or assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock.

Additionally, we regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards and changes in their interpretation, we might be required to change our accounting policies, alter our operational policies and implement new or enhance existing systems so that they reflect new or amended financial reporting standards, or we may be required to restate our published financial statements. Such changes to existing

standards or changes in their interpretation may have an adverse effect on our reputation, business, financial position and results of operations.

Our limited operating history and our limited experience in developing biologics may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, conducting research and development activities, and prior to the sale of our Commercial Business to Alcon in July 2022, developing and commercially launching EYSUVIS and INVELTYS. While we have had experience with obtaining marketing approval for and commercially launching two commercial products, we no longer have any commercial products following the sale of our Commercial Business to Alcon, we have only one product candidate in clinical development and we cannot be certain that we will be able to develop, obtain marketing approval for and commercialize a product in the future. If we are successful in developing and obtaining marketing approval for KPI-012 or any product candidate we may develop in the future, we will again have to transition from a company with a research and development focus to a company capable of supporting commercial activity. We may not be successful in such a transition. In addition, prior to our acquisition of KPI-012 in November 2021, we had no prior experience developing biological product candidates. As such, we may encounter delays or difficulties in our efforts to develop and commercialize KPI-012.

Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had prior experience developing biological product candidates or a longer operating and commercialization history.

We expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Risks Related to Product Development

We are substantially dependent on the success of our product candidate, KPI-012. If we are unable to successfully complete the clinical development of, and obtain marketing approval for, KPI-012 or any other product candidate we may develop in the future, or experience significant delays in doing so, or if, after obtaining marketing approvals, we fail to successfully commercialize such product candidates, our business will be materially harmed.

We are substantially dependent on the success of KPI-012 and any other product candidate we may develop in the future. As a result, we intend to devote a substantial portion of our research and development resources and business efforts to the development of KPI-012.

The success of KPI-012 and any other product candidates we may develop in the future will depend on many factors, including the following:

- completing and obtaining favorable results from our ongoing and planned clinical trials of KPI-012 and any other product candidate we develop;
- clearance of any investigational new drug application, or IND, submission for any other product candidates we develop;
- applying for and receiving marketing approvals from the FDA and any other regulatory authorities for KPI-012 and any other product candidate we develop;
- if approved, successfully launching and commercializing KPI-012 or any other product candidate we develop in the United States, including establishing and maintaining sales, marketing, manufacturing and distribution capabilities for KPI-012 or any other product candidate we develop;

- if approved, obtaining acceptance of KPI-012 and any other product candidate we develop by patients, the medical community and third-party payors;
- obtaining and maintaining coverage, adequate pricing, and adequate reimbursement from third-party payors, including government payors, for our product candidates;
- obtaining and maintaining regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities and obtaining and maintaining adequate supply of any such approved products;
- maintaining a workforce of experienced scientists and others with experience in eye diseases and biologics to continue to develop our product candidates;
- effectively competing with other therapies;
- maintaining an acceptable potency, purity and safety profile of our products following approval;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- protecting our rights in our intellectual property portfolio; and
- not infringing, misappropriating or otherwise violating others' intellectual property rights.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize KPI-012 or any other product candidate we may develop in the future, which would materially harm our business. We may never generate the necessary data or results required to obtain regulatory approval of KPI-012 or any other product candidate we develop and the commercialization of KPI-012 or any other product candidate we develop may never occur.

If clinical trials of KPI-012 or any other biological product candidate that we develop fail to demonstrate potency, safety and purity to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.

The risk of failure in developing product candidates is high. It is impossible to predict when or if any product candidate would prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the potency, purity and safety for a biologic product in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, the results of Combangio's Phase 1b clinical trial of KPI-012 in twelve patients, including nine with PCED, may not be indicative of future results in later stage clinical trials, including in our ongoing CHASE Phase 2b clinical trial of KPI-012 in patients with PCED. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Furthermore, the failure of any product candidates to demonstrate potency, safety and purity in any clinical trial could negatively impact the perception of our other product candidates and/or cause the FDA or other regulatory authorities to require additional testing before approving any of our product candidates. For example, in our STRIDE 2 Phase 3 clinical trial evaluating the safety and efficacy of EYSUVIS versus placebo in patients with dry eye disease, we did not achieve statistical significance for the primary symptom endpoint of ocular discomfort severity, and subsequently we received a complete response letter from the FDA indicating that positive efficacy data from an additional clinical trial was needed to support a new drug application for EYSUVIS.

If we are required to conduct additional clinical trials or other testing of KPI-012 or any other product candidate we develop beyond those that we currently expect, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented, and our competitors could bring products to market before we do.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize KPI-012 or any other product candidate that we may develop, including:

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may recommend or require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their obligations to us in a timely manner, or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may be delayed;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate trials;

- restrictions resulting from health epidemics, including COVID-19, and their collateral consequences may result in internal and external operational delays and limitations; and
- 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.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors, such as those developing treatments for PCED, to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

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

We may not be able to initiate or continue clinical trials for KPI-012 or any other product candidate we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

Patient enrollment is affected by a variety of factors, including:

- the prevalence and severity of the disease or condition under investigation;
- the patient eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under study;
- the existence of existing treatments for the indications for which we are conducting clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of clinicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- the conducting of clinical trials by competitors for product candidates that treat the same indications as our product candidates;
- the impact of public health epidemics, such as COVID-19; and
- the lack of adequate compensation for prospective patients.

We are developing KPI-012 for PCED, which is a rare condition with an estimated incidence in the United States of 100,000 cases per year, and, we have in the past and may in the future have difficulty identifying and enrolling a sufficient number of patients in our clinical trials of KPI-012 given the limited number of patients with PCED. Our inability to locate and enroll a sufficient number of patients for our clinical trials could result in significant delays, could cause us to reduce the number of patients that we enroll in a trial, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials have in the past and may in the future result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development or commercialization of our product candidates, we may need to abandon or limit our development and/or commercialization efforts for such product candidates.

If KPI-012 or any other product candidate we develop are associated with serious adverse events or undesirable side effects in clinical trials or following approval and/or commercialization, or if any of our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development or marketing to narrower uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. While KPI-012 was generally well-tolerated in Combangio's Phase 1b clinical trial, it was only administered in 12 subjects. Compounds that initially show promise in clinical or earlier stage testing for treating eye disease or other diseases may later be found to cause side effects that prevent further development and commercialization of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later, even following approval and/or commercialization, be found to be caused by the study treatment. Moreover, incorrect or improper use of a product by patients could result in additional unexpected side effects or adverse events. There can be no assurance that any product we may develop will be used correctly, and if used incorrectly, such misuse could hamper commercial adoption or market acceptance of such products or product candidates, if approved, at the rate we currently expect.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. In July 2022, we sold our Commercial Business, including EYSUVIS and INVELTYS, to Alcon and we made a strategic determination to cease the development of our preclinical pipeline programs that are unrelated to our MSC-S platform and to focus our research and development efforts solely on this platform.

We may never realize the anticipated benefits of these decisions and, as a result, we may be required to forego or delay other opportunities. In addition, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and KPI-012 for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

KPI-012 has been evaluated in a clinical trial outside of the United States and we may in the future conduct clinical trials for product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, where data from foreign clinical trials are not intended to serve as the sole basis for approval in the United States, the FDA will not accept the data as support for a marketing application unless the clinical trial was well designed and conducted in accordance with good clinical practices, or GCP requirements. The FDA must also be able to validate the data from the trial through an onsite inspection, if necessary. In addition, these clinical trials are subject to the applicable local laws of the jurisdictions where the trials are conducted. There can be no assurance that the FDA will accept data from trials conducted outside of the United States.

If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

In addition, conducting clinical trials outside the United States could have a significant adverse impact on us. Risks inherent in conducting international clinical trials include: clinical practice patterns and standards of care that vary

widely among countries; non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials; compliance with foreign manufacturing, customs, shipment and storage requirements; administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema; foreign exchange fluctuations; diminished protection of intellectual property in some countries; and interruptions or delays resulting from geopolitical events, such as wars.

In 2020 and 2021, Combangio conducted a Phase 1b clinical trial of KPI-012 in nine patients with PCED in Mexico. Based on the results of the Phase 1b clinical trial conducted in Mexico, we initiated a full preclinical development program and submitted an IND application to the FDA for KPI-012 which was approved in December 2022, and in February 2023, we dosed our first patient in the CHASE Phase 2b clinical trial of KPI-012 for PCED in the United States. We have initiated several clinical trial sites in Argentina for the CHASE Phase 2b clinical trial and we are in the process of initiating additional clinical trial sites in Latin America, subject to regulatory clearance. If the FDA does not accept the data from any trial that we conduct outside the United States, it could delay or permanently halt our development of the applicable product candidates.

Public health epidemics, including the COVID-19 pandemic, could impact the development of KPI-012 or any other product candidate we may develop, and may adversely affect our business, results of operations and financial condition.

Public health epidemics, including the COVID-19 pandemic, may affect our ability to initiate and complete preclinical studies and clinical trials for KPI-012 and any other product candidates we develop, including disruptions in procuring supplies that are essential for our research and development activities, manufacturing disruptions, disruptions in our ability to obtain necessary trial site approvals, as well as delays in or difficulties with enrollment and other delays at clinical trial sites. The public health emergency declarations related to COVID-19 ended on May 11, 2023, and the FDA ended certain COVID-19 related policies and retained others. As a result of these and other measures, we may in the future face disruptions to our business. We do not know the extent to which public health epidemics, including the COVID-19 pandemic, will impact our development of KPI-012, including our ongoing CHASE Phase 2b clinical trial, or any other product candidates that we develop. Additionally, while we currently are not experiencing interruptions in our manufacturing of KPI-012, any reinstatement of quarantines, travel restrictions and other measures related to a public health emergency may significantly impact the ability of employees of our third-party suppliers to get to their places of work to manufacture and deliver future supplies if and when needed.

Public health epidemics may cause disruptions in financial markets, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. Moreover, the impact of COVID-19 on economies worldwide could result in adverse effects on our business and operations.

We cannot be certain what the overall impact of COVID-19 or any other public health emergencies or pandemics will be on our business in the future and a continuation of the pandemic has the potential to adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Commercialization of our Product Candidates

Even if KPI-012 or any other product candidates that we may develop in the future receives marketing approval, such products may fail to achieve market acceptance by clinicians and patients, or adequate formulary coverage, pricing or reimbursement by third-party payors and others in the medical community, and the market opportunity for these products may be smaller than we estimate.

If KPI-012 or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by clinicians, patients, third-party payors and others in the medical community. We are developing KPI-012 for PCED, which is a rare disease. Our understanding of both the number of people who have a PCED, as well as the subset of people with PCED diseases who have the potential to benefit from treatment with KPI-012, are based on estimates. These estimates may prove to be incorrect. The number of patients with PCED may turn out to be lower than expected, may not be otherwise amenable to treatment with KPI-012 or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

Biosimilar and generic versions of any products that compete with KPI-012 or any other product candidates we may develop would likely be offered at a substantially lower price than we expect to offer for our product candidates, if approved. As a result, clinicians, patients and third-party payors may choose to rely on such products rather than our product candidates.

Our assessment of the potential market opportunity for KPI-012 is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. The potential market opportunity for the treatment of PCED is difficult to precisely estimate. Our estimates of the potential market opportunities for KPI-012 include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for KPI-012 for PCED may be smaller than we expect, and as a result our future product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

If KPI-012 or any other product candidate for which we may obtain marketing approval does not achieve adequate levels of acceptance by physicians and patients, formulary coverage, pricing or reimbursement, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of KPI-012 or any other product candidate for which we may obtain marketing approval, will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared to alternative treatments, including the existing standard of care;
- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the availability of third-party formulary coverage and adequate reimbursement;
- the clinical indications for which the product is licensed or approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of clinicians to prescribe these therapies;
- the strength of our marketing and distribution support;

- the timing of market introduction of competitive products;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

Even if we are able to successfully commercialize KPI-012 or any other product candidate that we may develop, if and when they are approved, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to successfully commercialize KPI-012 or any other product candidate that we may develop if and when they are approved will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans 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. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for KPI-012 or any other product candidate that we may commercialize and, even if they are available, the level of reimbursement may be limited or not satisfactory.

Inadequate reimbursement may adversely affect the demand for, or the price of KPI-012 or any other product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize KPI-012 or any other product candidate if and when they are approved.

There may be significant delays in obtaining coverage and reimbursement for newly approved products and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. Reimbursement agencies in Europe may be more conservative than the Centers for Medicare & Medical Services, or CMS, in the United States. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries.

Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, 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 product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products 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 products 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 adequate reimbursement rates from both government-funded and private payors for any approved products that we develop would compromise our ability to generate revenues and become profitable.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new products vary widely from country to country. Current and future 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 product 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 revenues we are able to generate from the sale of the product in that country. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Even if a product candidate we develop is approved for sale in the United States or in other countries, there can be no assurance that such product candidate will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell such product candidate profitably.

If we are unable to establish and maintain sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, if and when necessary, we may not be successful in commercializing KPI-012 or any other product candidate that we may develop if and when they are approved.

We established a sales, marketing and distribution infrastructure for the commercial launch of EYSUVIS and INVELTYS, and, as a company, we have limited experience in the sales, marketing and distribution of therapeutic products. Following the sale of our Commercial Business to Alcon in July 2022 and our determination to focus our research and development efforts on KPI-012 and our MSC-S platform, we terminated our entire commercial sales force and certain employees in our commercial, scientific, manufacturing, finance and administrative functions. To achieve commercial success for any product for which we obtain marketing approval in the future, we will again need to establish sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties.

There are risks involved with establishing, maintaining and expanding, if and when necessary, our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming, may divert our management and business development resources and could delay any future product launch. Establishing and maintaining a sales force would require us to continue to implement and improve our managerial, operational and financial systems, which we may not do effectively. Any inability to manage growth, when necessary, could delay the execution of our business plans or disrupt our operations. Further, we may overestimate or underestimate the size of the sales force required for a successful product launch.

We have not yet established our own commercial organization or distribution capabilities specific to KPI-012. While we believe that we will be able to commercialize KPI-012, if approved, for the treatment of PCED with a small, targeted, internal sales force in the United States and potentially other major markets, our assumptions may prove inaccurate. In the future, we may need a larger sales force and at a higher cost than previously anticipated. If the commercial launch of any product candidate for which we establish a commercial infrastructure is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition any such sales, marketing and distribution personnel.

Factors that may inhibit our efforts to commercialize on our own KPI-012 or any other product candidate we develop, if and when approved, include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to obtain and maintain coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- the inability of sales personnel to obtain access to clinicians or persuade adequate numbers of clinicians to prescribe our products;

- 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 establishing, maintaining and expanding, if and when necessary, an independent sales, marketing and distribution organization.

While we cannot be certain when, if ever, we will seek and/or receive marketing approval to commercialize any of our product candidates outside the United States, we may seek marketing approval and explore commercialization of KPI-012 in certain markets outside the United States utilizing a variety of collaboration, distribution, co-promotion and other marketing arrangements with one or more third parties. Our product revenues and our profitability, if any, under any such third-party collaboration, distribution or other marketing arrangements are likely to be lower than if we were to market, sell and distribute KPI-012 ourselves. We may also consider seeking marketing approval outside the United States for other product candidates we may develop in the future. If we decide to seek regulatory approval for any of our product candidates outside the United States, we may need to seek additional patent approvals, seek licenses to patents held by third parties and/or face claims of infringing third-party patent rights.

In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute KPI-012 or any other product candidate we may develop or we may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market effectively any product candidate for which we obtain marketing approval. If we do not establish and maintain our sales, marketing and distribution capabilities successfully, when needed, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidate for which we obtain marketing approval.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. Our competitors include major pharmaceutical companies with significantly greater financial resources. KPI-012 and any other product candidate we may develop, if approved, will also compete with existing branded, generic and off-label products.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our product candidate, KPI-012, and we will face competition with respect to any other product candidate that we may 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.

If approved, we expect KPI-012 to compete with Oxervate®, which is the only approved prescription pharmaceutical product in the PCED space. Oxervate (cenegermin-bkbj) was approved in August 2018 for the treatment of neurotrophic keratitis, or NK, a degenerative disease characterized by decreased corneal sensitivity and poor corneal healing, which we believe to represent approximately one-third of all PCED cases. Oxervate is a topical eye drop that is administered six times per day at two-hour intervals for eight weeks. Each administration of Oxervate requires the use of a vial containing the drug product, a vial adapter, a single-use pipette and disinfectant wipes. To our knowledge, there are currently only two product candidates in active clinical development for the treatment of a broad PCED population. KIO-201, a chemically modified form of the natural polymer hyaluronic acid administered as an eye drop, is currently being studied in a Phase 2 clinical trial in patients with PCED by Kiora Pharmaceuticals, Inc. Nexagon®, an antisense oligonucleotide that inhibits connexin43 being developed by Amber Ophthalmics, is currently being studied in a Phase 2/3 clinical trial in patients with PCED resulting from severe ocular chemical and/or thermal injuries. Amber Ophthalmics has also indicated that it plans to study Nexagon ® in a broad PCED population. A number of companies are pursuing development of product candidates for the treatment of NK, including ReGenTree, LLC (Timbetasin) and Claris Biotherapeutics, Inc. (CSB-001).

We are also aware of potential competitors for KPI-012 for Limbal Stem Cell Deficiency, or LSCD. Competitive products and product candidates in LSCD include two stem cell-based approaches. ABCB5+ limbal stem cells, which are being studied in Phase 1/2 clinical trials and are being developed by RHEACELL GmbH & Co. KG, utilize allogeneic limbal stem cells derived from human corneal rims, which are expanded ex-vivo and manufactured as an advanced-therapy medicinal product. Holoclar utilizes autologous limbal stem cells derived from the healthy portion of the patient's eye. Holoclar is approved in the European Union for treatment of LSCD caused by ocular burns and is developed by Chiesi. Additionally, Claris Biotherapeutics, Inc. has initiated a Phase 1 study in LSCD of its recombinant hepatocyte growth factor product candidate, CSB-001.

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 our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Our competitors may develop products that are available on a generic basis, and our product candidates may not demonstrate sufficient additional clinical benefits to clinicians, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of biosimilar and generic products.

Many of the companies against which we are competing or which we may compete against in the future 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 and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the use of our product candidates that we develop in human clinical trials, including KPI-012. We face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to successfully commercialize any products that we may develop.

We currently hold $10 million in product liability insurance coverage in the aggregate, with a per incident limit of $10 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage if we expand our ongoing and planned clinical trials for KPI-012. We will need to further increase

our insurance coverage when and if we begin commercialization of KPI-012 or any other product candidate for which we obtain marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

We have relied, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We have relied on third parties, such as clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, in conducting our clinical trials and expect to continue to rely on such parties to conduct clinical trials of any product candidate that we develop. We or these third parties may terminate their engagements with us at any time for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities.

Our reliance on these third parties for clinical 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 GCP standards for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified 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 our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors.

We also have relied, and expect to continue 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 our product candidates or commercialization of products, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of KPI-012 and plan to contract with third parties for preclinical, clinical and commercial supply of any other product candidates we develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of preclinical and clinical quantities of any product candidates. We do not own or operate, and currently have no plans to establish, any manufacturing facilities for KPI-012. We rely, and expect to continue to rely, on third parties for the manufacture of both drug substance and finished product for KPI-012 for preclinical and clinical testing, as well as for commercial manufacture of KPI-012 if it receives marketing approval. We also rely, and expect to continue to rely, on third parties for packaging, labeling, sterilization, storage, distribution and other production logistics for KPI-012. We have only limited supply agreements in place with respect to KPI-012, and these arrangements do not extend to commercial supply. We obtain supplies of drug substance and finished product for KPI-012 on a purchase order basis and do not have long term committed supply arrangements with respect to KPI-012. We may be unable to maintain our current arrangements for KPI-012 or enter into agreements for commercial supply of KPI-012 on acceptable terms or at all. We also expect to rely on third-party manufacturers to manufacture preclinical, clinical and commercial supplies of any other product candidates we develop, as well as for packaging, serialization, storage, distribution and other production logistics.

We are subject to risks related to our reliance on third-party manufacturers for the manufacture of the drug substance and product of KPI-012, a biological product candidate. Manufacturing biologics is complex, especially in large quantities. Biologic products must be made consistently and in compliance with a clearly defined manufacturing process. KPI-012 is a bone-marrow derived MSC-S therapeutic composed of biologically active components, including protease inhibitors and growth factors, and is produced from a proprietary cell bank. The manufacturing process for KPI-012 is comprised of three stages: (1) cultivation of mesenchymal stem cells from a working cell bank and production of unprocessed conditioned media (cell-free secretome), (2) production of drug substance as a chemically defined solution and (3) formulation and filling of drug product. While the drug product for Combangio's early research and Phase 1b clinical trial was cultivated using a planar culture model, we implemented a bioreactor cultivation model for our ongoing CHASE Phase 2b clinical trial of KPI-012. We also plan to utilize a bioreactor cultivation model for our planned clinical trials and for commercial supply of KPI-012. We are continuing the process of scaling up our manufacturing processes and capabilities with our third-party manufacturers to support longer term clinical development. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. In addition, KPI-012 drug product is manufactured from a vial of a working cell bank, which in turn was produced from a vial of master cell bank. KPI-012 master cell bank and working cell bank is stored in two separate locations. It is possible that we could lose the cell bank in both locations and have our manufacturing severely impacted by the need to replace the cell bank.

Our third party manufacturers may encounter shortages in the raw materials necessary to produce our product candidates in the quantities needed for our clinical trials, or our product candidates, if approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials, including shortages caused by the purchase of such raw materials by our competitors or others and shortages related to epidemics or pandemics, such as the COVID-19 pandemic. The failure of us or our third party manufacturers to obtain the raw materials necessary to manufacture sufficient quantities of KPI-012 or any other product candidates we may develop, may have a material adverse effect on our business.

The FDA maintains strict requirements governing the manufacturing process and third-party manufacturers are subject to inspection and approval by the FDA before a company can commence the manufacture and sale of any of its products or product candidates, and thereafter subject to FDA inspection from time to time. Failure by third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to products or product candidates may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. Depending on the severity of any potential regulatory action, our clinical or commercial supply could be interrupted or limited, which could have a material adverse effect on our business. When a manufacturer seeks to modify or make even seemingly minor changes to the manufacturing process, the FDA may require the applicant to conduct a comparability study that evaluates the potential differences in the product resulting from the change in the manufacturing process. In connection with any application for approval to market product candidates in the United States, we may be required to conduct a comparability study if the product we intend to market is supplied by a manufacturer different from the one who supplied the product evaluated in our clinical studies. Delays in designing and completing this study to the satisfaction of the FDA could delay or preclude our development and commercialization plans and thereby limit our revenues and growth.

Reliance on third-party manufacturers entails additional risks, including reliance on the third-party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third-party, the possible misappropriation of our proprietary information, including our trade secrets and know-how, and the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing practice, or 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 sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations.

KPI-012 and any other product candidate that we may develop may compete with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under cGMP regulations. For example, we were previously required to change our third-party manufacturer when the manufacturer was purchased by a third-party and exited the contract manufacturing business. The process of changing manufacturers can cause substantial time delays, and if we are required to change our manufacturer again in the future, it may delay our ongoing and planned clinical trials or development timeline.

Our current and anticipated future dependence upon others for the manufacture of KPI-012 or any other product candidate we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

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

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for KPI-012 or any product candidates we may develop in the future, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our reliance on CIRM funding for KPI-012 adds uncertainty to our research and development efforts, imposes certain compliance obligations on us and imposes requirements that may increase the costs of commercializing KPI-012.

Our development of KPI-012 is currently being funded, in part, by an award from the California Institute for Regenerative Medicine, or CIRM. On August 2, 2023, our wholly-owned subsidiary, Combangio, entered into an award agreement with CIRM for a $15.0 million grant, or the CIRM Award, to support the ongoing KPI-012 program for the treatment of PCED as well as product and process characterization and analytical development for the program. The CIRM Award is subject to a co-funding requirement under which Combangio is obligated to spend a specified minimum amount on the development of KPI-012 to obtain the full award amount and the remaining $5.9 million under the award is payable to Combangio only upon the achievement of specified milestones that are primarily related to Combangio's progress in conducting the CHASE clinical trial. If we fail to satisfy the co-funding requirement under the CIRM Award or fail to achieve the milestones within the timeframes required by the CIRM Award, we may not receive full funding under the CIRM Award. CIRM may permanently cease disbursements under the CIRM Award if the milestones are not met within four months of their scheduled completion dates or if the delay is not addressed to CIRM's satisfaction, as determined by CIRM in its sole discretion. We cannot be certain that we will achieve the remaining milestones under the CIRM Award within the required timeframes, or at all, and as such we may never receive the remaining $5.9 million under the award. Additionally, if CIRM determines, in its sole discretion, that Combangio has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements. Moreover, disbursements under the CIRM Award are contingent upon the availability of funds in the state of California's Stem Cell Research and Cures Fund, which is outside of our control.

The CIRM Award also imposes financial conditions that may increase the costs of commercializing KPI-012, if approved. Under the terms of the CIRM Award, Combangio is obligated to pay a royalty on net sales of any product, service or approved drug resulting in whole or in part from the CIRM Award in the amount of 0.1% per $1.0 million of funds utilized by us until the earlier of 10 years from the date of first commercial sale of such product, service or approved drug and such time as nine times the amount of funds awarded by CIRM has been paid in royalties, or the Base Royalty. In addition, following the satisfaction of the Base Royalty, Combangio is obligated to pay a 1.0% royalty on net sales of any CIRM-funded invention in excess of $500 million per year until the last to expire patent covering such invention expires.

Additionally, there are significant compliance requirements associated with the CIRM Award, such as reporting, notification, recordkeeping and audit requirements, for which internal and external resources may be needed and which may increase our costs of doing business.

Noncompliance with the requirements of the CIRM Award may cause a default under our Loan Agreement with Oxford Finance. It is an event of default under our Loan Agreement if we receive funding under the CIRM Award and are required to return such funds to CIRM in an amount in excess of $500,000 due to our or Combangio's failure to comply with the requirements of the CIRM Award, or if we are required to return funds to CIRM in excess of $1.0 million due to non-utilization of such funds or because CIRM exercises its rights to recover such funds for any reason. Such an event of default could result in the acceleration of amounts due under our Loan Agreement. In such event, we may not be able to make accelerated payments, and the lender could seek to enforce security interests in the collateral securing such indebtedness. Acceleration of the repayment of the outstanding indebtedness would raise substantial doubt about our ability to continue as a going concern, shorten the period for which we will be able to fund our operations and capital expenditure requirements and would adversely affect our financial condition and ability to pursue our business strategy.

In addition, as a result of the CIRM Award, we may not have the right to prohibit the State of California from using certain technologies developed by us. Under the CIRM Award, the California government can exercise march-in rights, which may include granting a third party nonexclusive, partially exclusive, or exclusive rights to CIRM-funded technology in any territory and field of use, if it determines that such action is necessary, if Combangio fails to make reasonable efforts to achieve practical application of a CIRM-funded technology, fails to comply with agreed to access and pricing requirements, or because action is necessary to address a public health emergency declared by the governor of California.

We may enter into collaborations with third parties for the development or commercialization of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to develop and commercialize KPI-012 or any other product candidate we develop and for which we seek or obtain marketing approval in markets outside the United States. We also may enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States for our product candidates or if we determine that such third-party arrangements are otherwise beneficial. We also may seek third-party collaborators for development and commercialization of our product candidates. For example, we may consider potential collaborative partnership opportunities prior to initiating IND-enabling studies on product candidates we may develop. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement. However, if we do enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations that we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may not pursue commercialization of our product candidates that receive marketing approval or may elect not to continue or renew commercialization programs based on changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, 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;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own products or product candidates, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to

product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates or products in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed, and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described herein also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might de-emphasize or terminate the development or commercialization of any product or product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

For some of our product candidates, we may decide to collaborate with pharmaceutical or biotechnology companies for the development of our product candidates or the potential commercialization of our product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay the potential commercialization of a product candidate 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 fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary

development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform.

Risks Related to Our Intellectual Property

We may be unable to obtain and maintain patent protection for our technology or product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology, products and product candidates similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

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 proprietary technology and product candidates, including KPI-012. We have sought to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our proprietary technologies and product candidates.

The patent prosecution process is expensive and time-consuming, and we may not have filed, maintained, or prosecuted and may not be able to file, maintain and prosecute all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of pharmaceutical, biotechnology, and medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may fail to result in issued patents in the United States or in other foreign countries which protect our technology or product candidates, or which effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and the standards applied by the U.S. Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, unlike patent law in the United States, European patent law precludes the patentability of methods of treatment of the human body and imposes substantial restrictions on the scope of claims it will grant if broader than specifically disclosed embodiments. 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, or in some cases not at all. Therefore, we cannot be certain whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Databases for patents and publications, and methods for searching them, are inherently limited so we may not know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies, products and product candidates. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection for our proprietary technology and product candidates, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies, products or product candidates in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable,

in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology, products or product candidates, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration, and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Also, the regulatory review period of an FDA-approved product may not serve as a basis for a patent term extension if the active ingredient of such product was subject to regulatory review and approval in an earlier product approved by the FDA. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be able to seek or be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering our product candidates even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the U.S. Patent and Trademark Office, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the U.S. Patent and Trademark Office.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our owned and licensed patents, trade secrets, or other intellectual property rights. As a result, to counter infringement, misappropriation or unauthorized use, we may be required to file infringement or misappropriation claims or other intellectual property related proceedings, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our asserted patents are invalid. In addition, in a patent infringement or other intellectual property related proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent. 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 or trade secrets could be compromised by disclosure during this type of litigation.

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in other contested proceedings such as opposition, derivation, reexamination, inter partes review, post-grant review, or interference proceedings in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In the United States, the FDA does not prohibit clinicians from prescribing an approved product for uses that are not described in the product's labeling. Although use of a product directed by off-label prescriptions may infringe our method-of-treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent, or prosecute and may have negative impacts on our business, operating results and financial condition.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market, and sell KPI-012 and any other product candidate we may develop in the future and to use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is a considerable amount of intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, infringement litigation claims regarding our product candidates and technology, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to future adversarial proceedings or litigation regarding our patent portfolio or the patents of third parties. Such proceedings could also include contested post-grant proceedings such as oppositions, inter partes review, reexamination, interference, or derivation proceedings before the U.S. Patent and Trademark Office or foreign patent offices.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if our product candidates commence commercialization. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that any of our product candidates or our development and commercialization thereof, do not and will not infringe or otherwise violate any third-party's intellectual property.

If we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing, manufacturing, marketing and selling any products, if and when approved, product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology, products or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent and could be forced to indemnify our customers or collaborators. A finding of infringement could also result in an injunction that prevents us from commercializing our product candidates or forces us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Periodic maintenance, renewal and annuity fees on any issued patent must be paid to the U.S. Patent and Trademark Office and foreign patent agencies in several stages or annually over the lifetime of our owned and licensed patents and patent applications. The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we may rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business.

KPI-012 is protected by patent rights exclusively licensed from other companies or institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our products, if any when approved, will be harmed.

A portion of our patent portfolio is in-licensed. As such, we are a party to license agreements and certain aspects of our business depend on patents and/or patent applications owned by other companies or institutions. In particular, we hold an exclusive license for a patent family relating to KPI-012. We rely on a license from Stanford University for certain patent rights related to KPI-012. The license agreement between Combangio and Stanford University, or Stanford University License Agreement, imposes specified diligence, milestone payment, royalty and other obligations on us and requires that we meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the license. Our rights with respect to in-licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated or if we fail to satisfy the obligations under the Stanford University License Agreement. We are likely to enter into additional license agreements to in-license patents and patent applications as part of the development of our business in the future, under which we may not retain control of the preparation, filing, prosecution, maintenance, enforcement and defense of such patents. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize our product candidates could be materially harmed.

Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability.

Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements. If our intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our intellectual property agreements are terminated, our former licensors and/or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our financial condition, results of operations and our business prospects.

Some intellectual property which we own or have licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for United States industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we own or have licensed have been generated through the use of United States government funding and may therefore be subject to certain federal regulations. For example, certain aspects of KPI-012 were developed using United States government funds. As a result, the United States government may have certain rights to intellectual property embodied in KPI-012 pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole. These United States government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The United States government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the United States government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Further, to the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of Bayh-Dole may similarly apply. Accordingly, any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

Moreover, in December 2023, the National Institute of Standards and Technology, or NIST, released for public comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, or the Draft Framework. The Draft Framework sets forth the factors that an agency may consider when deciding whether to exercise march-in rights pursuant to Bayh-Dole, and includes a first-ever specification that price can be a factor in determining that a drug or other taxpayer-funded invention is not accessible to the public. NIST is currently seeking public comments on the proposed Draft Framework. The potential inclusion of price as a factor in a march-in determination and the exercise of "march-in" rights by the federal government could result in decreased demand for our future products, which could have a material adverse effect on our results of operations and financial condition. In addition, any failure to comply with applicable laws or regulations could harm our business and divert our management's attention.

If we fail to comply with our obligations under our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

Our Stanford University License Agreement, under which we license certain patent rights related to KPI-012, imposes royalty and other financial obligations on us and other substantial performance obligations. We also may enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or product candidate that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of any product or product candidate. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements

with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

In addition, it is possible that Stanford may conclude that we have materially breached the Stanford University License Agreement and might therefore terminate the agreement, thereby removing our ability to market products covered by our license agreement with Stanford. If the Stanford University License Agreement is terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our Stanford University License Agreement is terminated, Stanford and/or its assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. If we breach the agreement (including by failing to meet our payment obligations) and do not adequately cure such breach, the rights in the technology licensed to us under the Stanford University License Agreement will revert to Stanford at no cost to Stanford. This could have a material adverse effect on our competitive business position, our financial condition, our results of operations and our business prospects.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected product or product candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

Filing, prosecuting, and defending patents on our product candidates 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 the laws of the United States. 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 or licenses, 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 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.

Beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court, or UPC. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is minimal precedent for the court, increasing the uncertainty of any litigation. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful,

could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is 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.

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

Many of our and our licensors' employees and contractors were previously employed at other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the 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 develops intellectual property that we regard as our own. Furthermore, we are unable to control whether our licensors have obtained similar assignment agreements from their own employees and contractors. Our and their assignment agreements may not be self-executing or may be breached, and we or our licensors may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products, which may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management 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. 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 may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

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 technology and our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and 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, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate significant revenue will be materially impaired. The marketing approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain marketing approval to commercialize KPI-012 or any product candidates we may develop in the future.

KPI-012 and any other future product candidate and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, potency, purity, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate.

Other than EYSUVIS and INVELTYS, which we sold to Alcon in July 2022, we have not received approval to market any product candidate from regulatory authorities in any jurisdiction. We may never generate the necessary data or results required to obtain regulatory approval of KPI-012 or any other product candidate we may develop with the market potential sufficient to enable us to achieve profitability. We have only limited experience in submitting and supporting the applications necessary to gain marketing approvals and have relied on, and expect to continue to rely on, third-party consultants and vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish a biologic product candidate's purity, safety and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that KPI-012 or any other product candidate that we develop does not satisfy these standards or has undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of 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. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

Further, under the Pediatric Research Equity Act, or PREA, a Biologics License Application, or BLA or supplement to a BLA for certain biological products must contain data to assess the safety, potency and purity of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe, potent and pure, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety, potency and purity data need to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the European Medicines Agency, or EMA, or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

In addition, disruptions at the FDA and other agencies may prolong the time necessary for new biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. The ability of the FDA to review and approve new biologics can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years. Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, including as a result of Congress failing to timely raise the U.S. debt ceiling, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Further, our ability to develop and market new products may be impacted by litigation challenging the FDA's approval of mifepristone. In April 2023, the U.S. District Court for the Northern District of Texas stayed the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market, but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that FDA authorized in 2016 and 2021 were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states filed an amended complaint in the U.S. District Court for the Northern District of Texas challenging the FDA's actions. Depending on the outcome of this litigation, if it continues, our ability to develop and market new drug products could be delayed, undermined or subject to protracted litigation.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidate that we develop, the commercial prospects for such product candidate may be harmed and our ability to generate revenues will be materially impaired.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. We may be subject to additional risks in commercializing any of our product candidates that receive marketing approval in foreign jurisdictions.

In order to market and sell KPI-012 or any other product candidate we may develop in the European Union and many other jurisdictions outside of the United States, we or our potential third-party collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. Clinical trials of any product candidate in the United States may not be sufficient to support an application for marketing approval outside the United States.

The time required to obtain approval outside of the United States may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks

associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or our potential collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the European Union pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (including potentially reducing the duration of regulatory data protection and exclusivity periods for orphan drugs, and revising the eligibility for expedited pathways) was published in April 2023 and the European Parliament has requested several amendments. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

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

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and ongoing surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labelling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;

- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- revisions to the labelling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions; and
- requirements to conduct additional post-market clinical trials to assess the safety of the product.

The FDA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and if we are found to have improperly promoted such off-label uses, we may become subject to significant liability.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability, which would materially adversely affect our business and financial condition. The FDA, EMA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted in the United States for uses that are not approved by the FDA as reflected in the product's approved labelling, or in other jurisdictions for uses that differ from the labelling or uses approved by the applicable regulatory authorities. While physicians may prescribe products for off-label uses, the FDA, EMA and other regulatory authorities actively enforce laws and regulations that prohibit the promotion of off-label uses by companies, including promotional communications made by companies' sales force with respect to off-label uses that are not consistent with the approved labelling. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in October 2023, the FDA published draft guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices.

We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products. Additionally, if another company with a competing product candidate were to obtain orphan drug exclusivity for its competing product candidate before we do, we may be barred from marketing our product candidate for the same indication as the competing product candidate during the exclusivity period.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. KPI-012 has received orphan drug designation from the FDA for the treatment of PCED.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and currently ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified. If a competing product candidate with an orphan designation for PCED were to obtain regulatory approval before we are able to obtain approval of KPI-012 for PCED, we could be barred from marketing KPI-012 for PCED in the United States during the seven-year orphan exclusivity period, which would have a severe adverse effect on our business.

In order for the FDA to grant orphan drug exclusivity to one of our products, the FDA must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which orphan drug exclusivity is sought does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition.

In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA Reauthorization Act of 2017, or FDARA, requires that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. FDARA reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term “same disease or condition” means the designated “rare disease or condition” and could not be interpreted by the FDA to mean the “indication or use.” Thus, the Court of Appeals concluded that orphan drug exclusivity applies to the entire designated disease or condition rather than the “indication or use.” Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the United States, and PRIME Designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track review products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track review product may be effective. In April 2023, the FDA designated KPI-012 for the treatment of PCED for Fast Track review.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal is for the FDA to review an application for marketing approval in six months, rather than the standard review period of 10 months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, such as the Fast Track designation for KPI-012 for the treatment of PCED, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the European Union, we may seek PRIME designation for some of our product candidates in the future. The PRIME program focuses on product candidates that target conditions for which there exists no satisfactory method of treatment in the European Union, or even if such a method exists, the product candidate may offer a major therapeutic advantage over existing treatments. To be accepted for PRIME designation, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a rapporteur of the Committee for Medicinal Products for Human Use to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME designation enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

If approved, our products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic 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 regulatory exclusivity, another company may still market a competing version of the reference product if the FDA approves a 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 the other company's product.

In December 2022, Congress clarified through the Food and Drug Omnibus Reform Act, that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination under the BPCIA.

To date, we have not had a product candidate approved as a biologic product. We believe that any of our product candidates that may be approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. Nonetheless, the approval of biosimilar products referencing any of our product candidates would have a material adverse impact on our business due to increased competition and pricing pressures. Moreover, there is a risk that any exclusivity we do receive could be shortened due to congressional action or otherwise, or that the FDA will not consider our products 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. The extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain regulatory approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. The ultimate impact, implementation, and meaning of the BPCIA are subject to uncertainty, and any new regulations, guidance, policies or processes adopted by the FDA to implement the law could have a material adverse effect on the future commercial prospects for our biological product candidates.

Our relationships with customers and third-party payors may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare

program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or transfers of value made to physicians, other healthcare providers and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state and foreign 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 or otherwise restrict payments that may be made to healthcare providers, state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to clinicians and other healthcare providers or marketing expenditures, 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 often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, integrity obligations, and the curtailment or restructuring of our operations. Any penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from funded healthcare programs, or curtailment or restructuring of our operations could adversely affect our financial results. Our corporate compliance program is designed to ensure that we will develop, market and sell our products and product candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative

penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the clinicians or other healthcare providers or entities with whom we do or expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

Existing and future legislation may affect our ability to commercialize our products, if and when approved, and increase the difficulty and cost for us to obtain reimbursement for our products, if and when approved.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our ability to profitably sell or commercialize any product candidate for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and have been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2021, the Budget Control Act of 2011, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year which went into effect in 2013 and will remain in effect through the first half of 2032.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory PAYGO sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

We expect that additional healthcare reforms may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any product which receives regulatory approval and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Since enactment of the ACA, there have been and continue to be numerous legal challenges and Congressional actions to repeal and replace provisions of the law and litigation and legislation over the ACA is likely to continue with unpredictable and uncertain results. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the 2017 Tax Act, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which required most Americans to carry a minimal level of health insurance, became effective in 2019.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, but those were rescinded by the Biden Administration. President Biden issued an executive order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this executive order, federal agencies are directed to re-examine: policies that

undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

We expect that additional healthcare reforms may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any product which receives regulatory approval and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Current and future legislation designed to reduce prescription drug costs may affect the prices we and any collaborators may obtain for our product candidates.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In October 2020, Health Insurance Portability and Accountability Act of 1996, or HHS, and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. At least nine states have passed laws allowing for the importation of drugs from Canada. Certain of these states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. On January 5, 2024, the FDA approved Florida’s plan for Canadian drug importation.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. The Inflation Reduction Act of 2022, or IRA, further delayed implementation of this rule to January 1, 2032.

The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028 and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at 2,000 a year.

Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition. For example, based on current guidance from CMS concerning the application of the IRA's drug pricing provisions to orphan drugs, we may be eligible for reduced reimbursement if and when, if ever, KPI-012 is approved as an orphan drug for PCED and a different rare disease or condition.

On June 6, 2023, Merck & Co. filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, other parties, including the U.S. Chamber of Commerce and certain pharmaceutical companies have also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

Further, in December 2023, NIST released for public comment the Draft Framework. The Draft Framework sets forth the factors that an agency may consider when deciding whether to exercise march-in rights pursuant to Bayh-Dole, and includes a first-ever specification that price can be a factor in determining that a drug or other taxpayer-funded invention is not accessible to the public. NIST is currently seeking public comments on the proposed Draft Framework. The potential inclusion of price as a factor in a march-in determination and the exercise of "march-in" rights by the federal government could result in decreased demand for our future products, which could have a material adverse effect on our results of operations and financial condition. In addition, any failure to comply with applicable laws or regulations could harm our business and divert our management's attention.

At the state level, individual states are increasingly aggressive in passing legislation and implementing 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. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

If we or any third-party manufacturers we engage or may engage in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

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

Although we maintain general liability insurance as well as 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.

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

Further, with respect to the operations of any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing, manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010, or Bribery Act, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA, Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union,

including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA, Bribery Act and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the U.S., EU and U.K. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the Federal Trade Commission, or the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the Federal Trade Commission Act, as well as the types of activities it views to trigger the Health Breach Notification Rule, which the FTC also has the authority to enforce. The FTC is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement, depending on the nature of the alleged violations. If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.

States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation, or GDPR, described below, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. The California Privacy Rights Act, or the CPRA, went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, and other California privacy laws, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, a number of other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime over the next few years. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2024 legislative sessions. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe, Latin America and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found to offer adequate data protection legislation, such as the United States. There are

ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision has resulted in increased scrutiny on data transfers generally and may increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Commission adopted the adequacy decision in July 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business.

Beyond GDPR and similar laws in the United States, there are privacy and data security laws in a growing number of countries around the world, including countries in Latin America where we have initiated several clinical trial sites in the CHASE Phase 2b clinical trial. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws may impact our ability to conduct our business activities.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2023, we had federal net operating loss, or NOL, carryforwards of $369.3 million, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030. As of December 31, 2023, we also had state NOL carryforwards of $413.7 million, which may be available to offset future state income tax liabilities and expire at various dates beginning in 2024. As of December 31, 2023, we had $1,154 federal and state research and development credit carryforwards. Our NOL carryforwards could expire unused and be unavailable to offset our future income tax liabilities.

In general, under Sections 382 and 383 of the Code, the amount of benefits from our NOL and research and development tax credit carryforwards, respectively, may be impaired or limited if we incur an “ownership change,” generally defined as a greater than 50% change (by value) in our equity ownership by certain stockholders, over a three-year period. We previously completed an analysis and determined that an ownership change has materially limited our net operating loss carryforwards and research and development tax credits available to offset future tax liabilities. During December 2022, an additional ownership change occurred as a result of our entry into the securities purchase agreement for the private placement transaction. As a result of this ownership change, the utilization of our net operating loss carryforwards is subject to an annual limitation of $0.2 million. We may be further limited by any changes that may have

occurred or may occur subsequent to December 31, 2022. Any such limitations may result in greater tax liabilities than we would incur in the absence of such limitations and increased liabilities could adversely affect our business, results of operations, financial position and cash flows. If our ability to use our historical NOL and research and development tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs and research and development tax credit carryforwards could expire or otherwise become unavailable to offset future income tax liabilities. As described below in "Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition," the 2017 Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that have significantly impacted our ability to utilize our NOLs to offset taxable income in the future. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we will likely be unable to use a material portion of our NOLs and other tax attributes.

Risks Related to Employee Matters

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, business development and commercialization expertise of Mark Iwicki, our Chief Executive Officer, Todd Bazemore, our President and Chief Operating Officer, Mary Reumuth, our Chief Financial Officer, Kim Brazzell, Ph.D., our Head of Research and Development and Chief Medical Officer and Darius Kharabi, our Chief Business Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we are highly dependent on the employees who joined us in connection with the Combangio Acquisition and their expertise developing biologics.

Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and other personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our decision to sell our Commercial Business to Alcon, our determination to solely focus our research and development efforts on our MSC-S platform, including KPI-012, could harm our ability to attract and retain qualified personnel who are critical to our business. In addition, we rely on consultants and advisors, including scientific, clinical and regulatory advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to successfully develop and commercialize KPI-012 and any other product candidate we may develop in the future will be harmed.

Our internal computer systems, or those of our vendors, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our information technology systems and those of our current and any future vendors, contractors or consultants, including any collaborator, are vulnerable to damage from cyber-attacks, computer viruses, worms and other destructive or disruptive software, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber incidents or attacks could include the deployment of

harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber incidents also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. System failures, accidents, cyberattacks or security breaches could cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential, personal or proprietary information, we could incur liability, including civil fines and penalties under the GDPR, HIPAA and other relevant state and federal privacy laws in the United States and abroad, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. In addition, we may not have adequate insurance coverage to provide compensation for any losses associated with such events.

While we have not experienced any material losses relating to cyber-attacks, we have been the subject of a successful phishing attempt. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company, including personal information of our employees. In addition, outside parties may attempt to penetrate our systems or those of our vendors, contractors or consultants or fraudulently induce our employees or employees of our vendors, contractors or consultants to disclose sensitive information in order to gain access to our data. Like other companies, we may experience threats to our data and systems, including malicious codes and viruses, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our security or that of our vendors, contractors or consultants occurs, the market perception of the effectiveness of our security measures could be harmed, we could lose business and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely.

A partially or fully remote workplace could negatively impact our business.

Although we have a nominal amount of office space on a short-term basis to conduct in-person meetings from time-to-time in Arlington, Massachusetts and lease office and laboratory space in Menlo Park, California, the vast majority of our employees no longer have individual offices. As a result, our management team and the vast majority of our employees will work remotely and without dedicated office space, until such time as we determine to obtain a new operating lease. Our employees are accessing our servers remotely through home or other networks to perform their job responsibilities, which may be less secure. The risk of cyber incidents or other privacy or data security incidents may be heightened as a result of our remote work environment. Remote working arrangements could also impact employee productivity and morale, impede employee training, strain our technology resources and introduce operational risks, all of which could negatively impact our business. Because we are a largely remote workplace, we have an increased reliance on third parties to conduct a significant portion of our research and development activities. We have limited ability to control the amount or timing of resources that any such third party will devote to our research and development activities, and such third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with such third parties, and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs.

Risks Related to Our Common Stock

If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. If our common stock is delisted from Nasdaq, we will be in default under our Loan Agreement.

Our common stock is currently listed on The Nasdaq Capital Market. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum closing bid price of $1.00 per share and either a minimum stockholders' equity of $2,500,000, or a minimum market value of our common stock of at least $35,000,000, or risk delisting, which would have a material adverse effect on our business. The market value of our common stock has not exceeded $35,000,000 on a sustained basis since August 2023, and as such, in order to avoid the delisting of our common stock, we have had to maintain a minimum stockholders' equity of $2.5 million. There are many factors that may adversely affect our ability comply with the requirements for continued listing on The Nasdaq Capital Market, including those described throughout this "Risk Factors" section. Many of these factors are outside of our control. As a result, we cannot assure you that we will continue to comply with the requirements for continued listing on The Nasdaq Capital Market, including the minimum stockholders' equity requirement.

A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors and employees and fewer business development opportunities. In addition, any potential delisting of our common stock from Nasdaq would also make it more difficult for our stockholders to sell their shares in the public market.

We have a history of receiving deficiency letters from Nasdaq. During 2022, we received multiple deficiency letters from Nasdaq notifying us of our noncompliance with various listing standards for continued inclusion on The Nasdaq Global Select Market. On each of March 2, 2022 and May 24, 2022, we received a deficiency letter from Nasdaq notifying us that, for 30 consecutive business days, the bid price of our common stock had closed below the $1.00 per share minimum bid price requirement for continued inclusion on The Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1), or the Bid Price Requirement. We were provided a period of 180 calendar days to regain compliance with the Bid Price Requirement, and in each case, we regained compliance within the cure period, including in the second instance by implementing a reverse stock split of our common stock.

On July 6, 2022, we received another deficiency letter from Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5450(b)(2)(A), or the Minimum MVLS Requirement, for continued listing on The Nasdaq Global Select Market, as the market value of our common stock was less than $50,000,000 for the previous 30 consecutive business days. Nasdaq also noted that we were not in compliance with Nasdaq Listing Rule 5450(b)(1)(A), as our stockholders' equity was less than $10,000,000 and Nasdaq Listing Rule 5450(b)(3)(A), as our total assets and total revenue for the most recently completed fiscal year or for two of the three most recently completed fiscal years were less than $50,000,000. A company that has its primary equity security listed on The Nasdaq Global Select Market must satisfy at least one of the standards in Nasdaq Listing Rule 5450(b).

On December 5, 2022, we received another deficiency letter from Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5450(b)(2)(C), or the Minimum MVPHS Requirement, for continued listing on The Nasdaq Global Select Market, as the market value of our publicly held shares was less than $15,000,000 for each of the previous 30 consecutive business days.

In accordance with Nasdaq Listing Rule 5810(c)(3), we were provided until January 2, 2023 to regain compliance with the Minimum MVLS Requirement and until June 5, 2023 to regain compliance with the Minimum MVPHS Requirement. Alternatively, if we did not regain compliance with the Minimum MVLS Requirement or the Minimum MVPHS Requirement by the applicable compliance date, we were eligible to transfer the listing of our common stock to The Nasdaq Capital Market, provided that we met the applicable requirements for continued listing on The Nasdaq Capital Market.

Following the receipt of the proceeds from the second tranche of a private placement in December 2022 and after amending our Loan Agreement to permit a transfer, we applied to transfer the listing of our common stock to The Nasdaq Capital Market. The transfer was approved effective January 11, 2023 following Nasdaq's determination that we met the applicable requirements for continued listing on The Nasdaq Capital Market, including Nasdaq Listing Rule 5550(b)(1), the minimum stockholders equity requirement for continued listing on The Nasdaq Capital Market. In addition, Nasdaq advised us that, upon the transfer of our listing to The Nasdaq Capital Market, we would be in compliance with Nasdaq Listing Rule 5550(a)(5), the market value of publicly held shares requirement for continued listing on The Nasdaq Capital Market.

Any delisting of our common stock from The Nasdaq Capital Market or a transfer of the listing of our common stock to another nationally recognized stock exchange having listing standards that are less restrictive than The Nasdaq Capital Market, in each case after a specified cure period, are events of default under our Loan Agreement, which could adversely effect our financial condition and ability to pursue our business strategy.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors are responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- provide for a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three-years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our common stock may not be sustained.

From July 20, 2017 through January 10, 2023, our common stock traded on The Nasdaq Global Select Market. On January 11, 2023, our common stock began trading on The Nasdaq Capital Market. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price for our common stock and thereby affect your ability to sell your shares. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The price of our common stock is volatile and fluctuates substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is volatile and fluctuates substantially. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price you paid for such common stock. The market price for our common stock may be influenced by many factors, including:

- whether we receive, and the amount of, any future milestone payments from Alcon in connection with the sale of our Commercial Business;
- our strategic decision to focus our research and development efforts on our MSC-S platform, including KPI-012;
- results of preclinical studies and clinical trials of KPI-012 or any other product candidates we may develop;
- our ability to receive marketing approval for and to successfully commercialize KPI-012 or any other product candidate we may develop;
- results of clinical trials of product candidates of our competitors;
- changes in the structure of healthcare payment systems;
- the success of competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific, commercial or management personnel;
- the level of expenses related to the development of KPI-012 and any other product candidate we develop;
- the results of our efforts to discover, develop, acquire or in-license additional products, product candidates or technologies for the treatment of diseases or conditions, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others, or the anticipation of such sales;
- the concentration of our stock ownership;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors;
- the societal and economic impact of public health epidemics, such as the COVID-19 pandemic;
- general economic, industry and market conditions;

- political instability in the United States and Europe, including as a result of Congress failing to timely raise the U.S. debt ceiling; or
- the other factors described in this "Risk Factors" section.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approval for or fail to successfully commercialize KPI-012 or any other product candidate we develop. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources.

Sales of a substantial number of shares of our common stock could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of November 11, 2024, we had outstanding 4,610,139 shares of common stock.

Shares of our common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act, or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates of ours. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. In addition, we have filed or intend to file registration statements registering all shares of common stock that we may issue under our equity compensation plans or pursuant to equity awards made to newly hired employees outside of equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

In 2022, 2023 and 2024, we sold to certain institutional investors shares of our common stock and/or shares of our preferred stock in private placements. We have filed registration statements on Form S-3 covering the resale of such shares of common stock and the common stock issuable upon conversion of the preferred stock issued in the private placements, and we have agreed to keep each such registration statements effective until the date the shares covered by it have been sold or can be resold without restriction under Rule 144 of the Securities Act.

The sale or resale of these shares in the public market, or the market's expectation of such sales, may result in an immediate and substantial decline in our stock price. Such a decline would adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Certain existing stockholders will experience dilution upon any future conversion of the outstanding shares of our preferred stock into shares of our common stock.

Each outstanding share of Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock and Series H Preferred Stock is initially convertible into 100 shares of our common stock at any time at the option of the applicable holder, subject to certain beneficial ownership limitations which prohibit any such conversion if the holder would own, following such conversion, in excess of 9.99% of the outstanding shares of our common stock. Such holder of preferred stock can also elect for its beneficial ownership limitation to be increased up to 19.99% upon 61 days' notice. Certain existing stockholders will experience dilution upon any future conversion of the outstanding shares of our preferred stock into shares of our common stock.

Our largest stockholder may have the ability to exercise significant influence over certain of our business decisions and could influence matters submitted to stockholders for approval.

Bakers Brothers Life Sciences, L.P. and 667, L.P., which are affiliates of Baker Bros. Advisors LP, which we refer to collectively as Baker Brothers owned, in the aggregate, shares of common stock representing approximately 19.33% of our outstanding common stock as of November 11, 2024. Such stockholder also holds all of the outstanding

shares of our Series E Preferred Stock, Series F Preferred Stock and Series G Preferred Stock, and 24.48% of the outstanding shares of our Series H Preferred Stock. Such stockholder could elect, upon 61 days' notice to us, to convert a portion of its shares of preferred stock into common stock, up to the beneficial ownership limitation of 19.99%.

Baker Brothers holds a significant percentage of our outstanding shares of common stock and could exercise significant influence matters submitted to our stockholders for approval.

In addition, pursuant to the terms of our securities purchase agreements for the 2022, 2023 and March 2024 private placement transactions, we have agreed that we will not, without the prior approval of Baker Brothers (1) issue or authorize the issuance of any equity security that is senior or *pari passu* to the Series E Preferred Stock, the Series F Preferred Stock or the Series G Preferred Stock with respect to liquidation preference, (2) incur any additional indebtedness for borrowed money in excess of $1.0 million, in the aggregate, outside the ordinary course of business, subject to specified exceptions, including the refinancing of our existing indebtedness or (3) pay or declare any dividend or make any distribution on, any of our shares of capital stock, subject to specified exceptions. Additionally, pursuant to the terms of our securities purchase agreement for the June 2024 private placement transaction, we have agreed that we will not, without the prior approval of the stockholders holding two-thirds of the outstanding shares of Series H Preferred Stock, issue or authorize the issuance of any equity security that is senior or *pari passu* to the Series H Preferred Stock with respect to liquidation preference. As a holder of our Series E Preferred Stock, Baker Brothers has the right to have our board of directors nominate and recommend for election by the stockholders up to three designees to our board of directors, subject to certain requirements and exceptions. In addition, as a holder of our Series E Preferred Stock, Baker Brothers has certain rights to participate in our future equity offerings, which rights are more fully described in Item 1, "Business" of our Annual Report on Form 10-K for the year ended December 31, 2023.

As a result of the foregoing, Baker Brothers may have the ability to exercise significant influence over certain matters affecting our business. Such stockholder may have interests that differ from your interests, and it may vote as a stockholder or act in a way with which you disagree and that may be adverse to your interests. This concentrated control could delay, defer, or prevent a change of control, merger, consolidation, or sale of all or substantially all of our assets that our other stockholders support, or conversely this concentrated control could result in the consummation of such a transaction that our other stockholders do not support. This concentrated control could also discourage a potential investor from acquiring our common stock due to the limited voting power of such stock relative to the common stock held by Baker Brothers and may adversely affect the market price of our common stock and, in turn, the market value of our common stock for Nasdaq listing purposes.

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

We are a "smaller reporting company," as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. We would cease to be a smaller reporting company if we have a public float in excess of $250 million or have annual revenues in excess of $100 million and a public float in excess of $700 million, determined on an annual basis.

As a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation;
- being permitted to provide only two years of audited financial statements in our annual report on Form 10-K, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure; and
- not being required to furnish a stock performance graph in our annual report.

We cannot predict whether investors will find our common stock less attractive as a result of our reliance 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 have incurred and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, and particularly since we ceased being an "emerging growth company", we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market 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. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs relative to prior years and will make some activities more time-consuming and costly.

For as long as we remain a smaller reporting company, we may take advantage of certain exemptions from various reporting requirements as described in the preceding risk factor.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non-accelerated filer and a smaller reporting 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 Section 404 within the prescribed period, we 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 and 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 Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our Loan Agreement and our securities purchase agreements for our 2022, 2023 and March 2024 private placements restrict us from paying dividends. Any future debt agreements that we may enter into may preclude us from paying dividends without the lenders' consent or at all. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our certificate of incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or any action asserting a claim against us governed by the internal affairs doctrine.

We do not expect this choice of forum provision will apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which federal courts have exclusive jurisdiction.

This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

General Risk Factors

Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition.

Changes in tax law may adversely affect our business or financial condition. The 2017 Tax Act, as amended by the CARES Act, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% and the limitation of the deduction for NOLs to 80% of current year taxable income for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely). In addition, beginning in 2022, the 2017 Tax Act eliminates the option to deduct research and development expenditures currently and requires corporations to capitalize and amortize them over five years or 15 years for expenditures attributable to foreign research.

In addition to the CARES Act, as part of Congress's response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The Inflation Reduction Act, or IRA, was also signed into law in August 2022. The IRA introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases.

Regulatory guidance under the 2017 Tax Act, the IRA, and such additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to the 2017 Tax Act, the IRA and such additional legislation.

Patent reform legislation under Leahy-Smith America Invents Act could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office has been developing new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Although it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, the Leahy-Smith Act provides a new administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have

resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining, defending and enforcing them.

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

Sales of Unregistered Securities

We did not sell any shares of our common stock, shares of our preferred stock or warrants to purchase shares of our stock, or grant any stock options, restricted stock units or restricted stock awards, during the period covered by this Quarterly Report on Form 10-Q that were not registered under the Securities Act of 1933, as amended and that have not otherwise been described in a Current Report on Form 8-K.

Use of Proceeds from our Public Offering of Common Stock

None.

Repurchase of Shares or of Company Equity Securities

None.

Item 5. Other Information.

Director and Officer Trading Arrangements

None of our directors or officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this report.

Item 6. Exhibits

Exhibit Index

EXHIBIT 31.1+	-	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
EXHIBIT 31.2+	-	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
EXHIBIT 32.1++	-	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by Mark Iwicki, Chief Executive Officer of the Company.
EXHIBIT 32.2++	-	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by Mary Reumuth, Chief Financial Officer of the Company.
EXHIBIT 101.INS	-	Inline XBRL Instance Document. (the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document)
EXHIBIT 101.SCH	-	Inline XBRL Taxonomy Extension Schema Document.
EXHIBIT 101.CAL	-	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
EXHIBIT 101.DEF	-	Inline XBRL Taxonomy Extension Definition Linkbase Document.
EXHIBIT 101.LAB	-	Inline XBRL Taxonomy Extension Label Linkbase Document.
EXHIBIT 101.PRE	-	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
EXHIBIT 104	-	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

+ Filed herewith
++ Furnished herewith

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.

KALA BIO, Inc.

Dated: November 12, 2024

By: /s/ Mark Iwicki
Mark Iwicki
Chair of the Board and Chief Executive Officer
(Principal Executive Officer)

Dated: November 12, 2024

By: /s/ Mary Reumuth
Mary Reumuth
Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, Mark Iwicki, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of KALA BIO, 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 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 12, 2024

By: /s/ Mark Iwicki
Mark Iwicki
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Mary Reumuth, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of KALA BIO, 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 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 12, 2024

By: /s/ Mary Reumuth
Mary Reumuth
Chief Financial Officer
(Principal Financial and Accounting 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 on Form 10-Q of KALA BIO, Inc. (the "Company") for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark Iwicki, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge on the date hereof:

(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 12, 2024

/s/ Mark Iwicki
Mark Iwicki
Chief Executive Officer
(Principal Executive Officer)

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 on Form 10-Q of KALA BIO, Inc. (the "Company") for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mary Reumuth, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of her knowledge on the date hereof:

(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 12, 2024

/s/ Mary Reumuth

Mary Reumuth
Chief Financial Officer
(Principal Financial and Accounting Officer)