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, 2023
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 (State or other jurisdiction of incorporation or organization)	**27-0604595** (I.R.S. Employer Identification No.)
1167 Massachusetts Avenue **Arlington, MA** (Address of principal executive offices)	**02476** (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 2,693,116 shares of Common Stock, $0.001 par value per share, outstanding as of November 10, 2023.

TABLE OF CONTENTS

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 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 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 financial impact, synergies, growth prospects and benefits of our acquisition of Combangio, Inc., or Combangio, or the Combangio Acquisition, including our expectations with respect to, and the amount of, future milestone payments we may pay in connection with 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 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;
- 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
- our anticipated annualized reduction in operating expenses associated with our workforce reduction completed during the second half of 2022.

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, 2023, we had an accumulated deficit of $620.8 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.
- 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, could result in an event of default and acceleration of amounts due.
- 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.
- 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.
- 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 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, may 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.
- 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 product candidates may be impaired.
- 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 and when approved, will be harmed.

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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 56,063	$ 70,495
Prepaid expenses and other current assets (Note 8)	1,839	7,852
Current assets held for sale (Note 4)	—	7,595
Total current assets	57,902	85,942
Non-current assets:		
Property and equipment, net	802	400
Right-of-use assets	2,102	16
Restricted cash and other long-term assets	314	462
Total assets	$ 61,120	$ 86,820
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 787	$ 2,832
Accrued expenses and other current liabilities	6,260	8,910
Deferred gain on sale of commercial business	—	4,189
Deferred grant income	2,930	—
Current portion of lease liabilities	324	13
Current portion of long-term debt	—	5,000
Current portion of contingent consideration	—	4,146
Current portion of deferred purchase consideration	—	595
Total current liabilities	10,301	25,685
Long-term liabilities:		
Long-term lease liabilities	1,880	—
Long-term debt	33,878	37,937
Long-term contingent consideration	3,838	4,224
Total long-term liabilities	39,596	42,161
Total liabilities	49,897	67,846
Commitments and Contingencies (Note 17)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 51,246 and 53,144 shares of Series E Convertible Non-Redeemable Preferred Stock issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value; 120,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 2,693,116 and 1,706,971 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	632,001	606,182
Accumulated other comprehensive income	1	—
Accumulated deficit	(620,782)	(587,210)
Total stockholders' equity	11,223	18,974
Total liabilities and stockholders' equity	$ 61,120	$ 86,820

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA BIO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME

(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Product revenues, net	$ —	$ 420	$ —	$ 3,892
Costs and expenses:				
Cost of product revenues	—	11	—	2,560
Selling, general and administrative	4,952	9,549	15,944	59,204
Research and development	5,554	5,391	13,868	14,330
(Gain) loss on fair value remeasurement of deferred purchase consideration	—	(57)	(230)	205
(Gain) loss on fair value remeasurement of contingent consideration	(1,744)	95	462	(952)
Total costs and expenses	8,762	14,989	30,044	75,347
Loss from operations	(8,762)	(14,569)	(30,044)	(71,455)
Other income (expense):				
Interest income	708	234	2,101	310
Interest expense	(1,459)	(1,447)	(4,346)	(5,689)
Grant income	2,970	—	2,970	—
Loss on extinguishment of debt	—	(2,583)	—	(2,583)
Gain on sale of commercial business	—	46,995	—	46,995
Other (expense) income, net	(2,161)	443	(4,253)	443
Total other income (expense)	58	43,642	(3,528)	39,476
Net (loss) income	$ (8,704)	$ 29,073	$ (33,572)	$ (31,979)
Net (loss) income per share attributable to common stockholders—basic	$ (3.41)	$ 19.39	$ (14.36)	$ (21.46)
Net (loss) income per share attributable to common stockholders—diluted	$ (3.41)	$ 19.25	$ (14.36)	$ (21.46)
Weighted average shares outstanding—basic	2,550,210	1,499,001	2,337,492	1,490,159
Weighted average shares outstanding—diluted	2,550,210	1,510,421	2,337,492	1,490,159
Net (loss) income	$ (8,704)	$ 29,073	$ (33,572)	$ (31,979)
Other comprehensive (loss) income:				
Change in unrealized (loss) gain on investments	(8)	1	1	—
Total other comprehensive (loss) income	(8)	1	1	—
Total comprehensive (loss) income	$ (8,712)	$ 29,074	$ (33,571)	$ (31,979)

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA BIO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY (DEFICIT)

(UNAUDITED)

(In thousands, except share and per share amounts)

Three Months Ended September 30, 2023

	Mezzanine Equity		Stockholders' Equity							
	Series D Preferred Stock $0.001 Par Value		Series E Preferred Stock $0.001 Par Value		Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	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

Three Months Ended September 30, 2022

	Mezzanine Equity		Stockholders' Equity (Deficit)							
	Series D Preferred Stock $0.001 Par Value		Series E Preferred Stock $0.001 Par Value		Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of June 30, 2022	—	$ —	—	$ —	1,465,949	$ 1	$ 571,886	$ (1)	$ (603,440)	$ (31,554)
Issuance of common stock under employee stock purchase plan	—	—	—	—	10,688	—	138	—	—	138
Issuance of redeemable Series D preferred stock	73,208	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,374	—	—	1,374
Change in fair value of investments	—	—	—	—	—	—	—	1	—	1
Net income	—	—	—	—	—	—	—	—	29,073	29,073
Balance as of September 30, 2022	73,208	$ —	—	$ —	1,476,637	$ 1	$ 573,398	$ —	$ (574,367)	$ (968)

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA BIO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY (DEFICIT)

(UNAUDITED)

(In thousands, except share and per share amounts)

	Nine Months Ended September 30, 2023									
	Mezzanine Equity		Stockholders' Equity							
	Series D Preferred Stock $0.001 Par Value		Series E 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	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

	Nine Months Ended September 30, 2022									
	Mezzanine Equity		Stockholders' Equity (Deficit)							
	Series D Preferred Stock $0.001 Par Value		Series E 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 (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2021	—	$ —	—	$ —	1,322,464	$ 1	$ 559,191	$ —	$ (542,388)	$ 16,804
Exercise of stock options	—	—	—	—	102	—	3	—	—	3
Issuance of common stock for vested restricted stock units	—	—	—	—	3,966	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	—	—	—	—	13,791	—	298	—	—	298
Issuance of common stock to satisfy deferred purchase consideration	—	—	—	—	136,314	—	7,936	—	—	7,936
Issuance of redeemable Series D preferred stock	73,208	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	5,970	—	—	5,970
Change in fair value of investments	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(31,979)	(31,979)
Balance as of September 30, 2022	73,208	$ —	—	$ —	1,476,637	$ 1	$ 573,398	$ —	$ (574,367)	$ (968)

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,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (33,572)	$ (31,979)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	233	457
Non-cash operating lease cost	94	421
Gain on sale of commercial business	—	(46,995)
Loss on extinguishment of debt	—	2,583
(Gain) loss on fair value remeasurement of deferred purchase consideration	(230)	205
Loss (gain) on fair value remeasurement of contingent consideration	462	(952)
Amortization of debt discount and other non-cash interest	941	1,130
Stock-based compensation	5,089	6,048
Other non-cash (gains) losses, net	(4,322)	76
Change in operating assets and liabilities:		
Accounts receivable	78	15,143
Prepaid expenses and other current assets	5,892	(16,928)
Inventory and assets held for sale	7,544	(1,011)
Other long-term assets	(143)	—
Accounts payable	(2,036)	2,433
Accrued expenses and other current liabilities	(319)	4,531
Lease liabilities and other long-term liabilities	58	(335)
Net cash used in operating activities	(20,231)	(65,173)
Cash flows from investing activities:		
Proceeds from sale of commercial business, net of transaction costs	—	62,908
Purchases of property and equipment and other assets	(603)	(291)
Proceeds from sale of property and equipment	47	41
Purchases of short-term investments	(9,866)	(4,992)
Proceeds from sales or maturities of short-term investments	10,000	5,000
Net cash (used in) provided by investing activities	(422)	62,666
Cash flows from financing activities:		
Payment of principal, prepayment premium and final payment fee on debt	(10,000)	(40,000)
Proceeds from common stock offerings, net of offering costs	17,966	—
Contingent consideration related to Combangio acquisition	(2,041)	—
Payment of principal on finance lease	—	(29)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	46	301
Net cash provided by (used in) financing activities	5,971	(39,728)
Net decrease in cash, cash equivalents and restricted cash:	(14,682)	(42,235)
Cash, cash equivalents and restricted cash at beginning of period	70,745	94,878
Cash, cash equivalents and restricted cash at end of period	$ 56,063	$ 52,643
Reconciliation of cash, cash equivalents and restricted cash:		
Cash, cash equivalents, and restricted cash at end of period	$ 56,063	$ 52,643
Less restricted cash	—	(250)
Cash and cash equivalents at end of period	$ 56,063	$ 52,393
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ —	$ 16
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	—
Supplemental disclosure:		
Cash paid for interest	$ 3,477	$ 4,747
Right-of-use assets obtained in exchange of operating lease obligations	2,180	424

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"), formerly known as Kala Pharmaceuticals, Inc., 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 eye. On August 2, 2023, the Company changed its name from Kala Pharmaceuticals, Inc. to KALA BIO, Inc.

On November 15, 2021, the Company and its newly formed, direct wholly owned subsidiary, Ceres Merger Sub, Inc. (the "Merger Subsidiary"), entered into an Agreement and Plan of Merger (the "Merger Agreement") with Combangio, Inc. ("Combangio") and Fortis Advisors LLC, solely in its capacity as Combangio Equityholder Representative in connection with the Merger Agreement, pursuant to which on November 15, 2021, the Merger Subsidiary merged with and into Combangio with Combangio surviving such merger and becoming a direct wholly owned subsidiary of the Company (the "Combangio Acquisition"). In connection with the Combangio Acquisition, the Company acquired Combangio's mesenchymal stem cell secretomes ("MSC-S") platform, including its lead product candidate for the treatment of persistent corneal epithelial defects ("PCED"), which the Company refers to as KPI-012. PCED is a rare disease of impaired corneal healing. The Company submitted an investigational new drug application ("IND") to the U.S. Food and Drug Administration, ("FDA"), which was accepted in December 2022. 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, including the development of KPI-287, its receptor tyrosine kinase inhibitor, and its selective glucocorticoid receptor modulators.

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. See Note 3, "Sale of Commercial Business to Alcon", for additional information about the Alcon Transaction.

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)

Reverse Stock Split— On October 20, 2022, the Company effected a 1-for-50 reverse stock split of the Company's shares of common stock either issued and outstanding or held by the Company as treasury stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, every 50 shares of issued and outstanding common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share. No fractional shares were issued as a result of the Reverse Stock Split. Any fractional shares that would otherwise have resulted from the Reverse Stock Split were rounded up to the next whole number. The number of authorized shares of common stock under the Company's Restated Certificate of Incorporation, as amended, remained unchanged at 120,000,000 shares. All historical share and per share amounts reflected throughout these financial statements have been adjusted to reflect the Reverse Stock Split. Proportionate adjustments were made to the per share exercise price and the number of shares of common stock that may be purchased upon exercise of outstanding stock options and warrants, and the number of shares of common stock reserved for future issuance under the Company's 2017 Equity Incentive Plan and Employee Stock Purchase Plan.

Liquidity— Since inception, the Company has incurred significant losses from operations and negative cash flows from operations including a net loss of $8,704 and $33,572 for the three and nine months ended September 30, 2023, respectively, net income of $29,073 (which includes the gain on the sale of the Company's Commercial Business to Alcon) and a net loss $31,979 for the three and nine months ended September 30, 2022, respectively, and cash used in operating activities of $20,231 and $65,173, in the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, the Company had an accumulated deficit of $620,782. As the Company commenced a full promotional launch of EYSUVIS in early January 2021 and commercially launched its first product, INVELTYS, in January 2019, the Company generated only limited revenues from product sales 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 common stock offerings 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 private placement of common stock and preferred stock for gross proceeds of approximately $31,000 in December 2022 (the "Private Placement")), borrowings under credit facilities and the Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford Finance"), convertible promissory notes and warrants. In August 2023, following entry into the award agreement with the California Institute for Regenerative Medicine ("CIRM"), Combangio received an initial $5,900 disbursement from CIRM, and the balance of the total $15,000 award is payable to Combangio upon the achievement of specified milestones (see Note 7, "Grant Income" for further information about the CIRM Award (as defined below)). 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. As a result of the Combangio Acquisition and the sale of the Commercial Business to Alcon, the Company is devoting substantial financial resources to the research and development and potential commercialization of KPI-012 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. 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.

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

The Company expects that its cash and cash equivalents as of September 30, 2023, 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.

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 statements relate to, but are not limited to, revenue recognition, inventory, the present value of lease liabilities and the corresponding right-of-use assets, the fair value of warrants, stock-based compensation, accrued expenses, deferred purchase consideration, contingent consideration, assets held for sale 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) Income per Share Attributable to Common Stockholders—The Company follows the two-class method when computing net (loss) income per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net (loss) income 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, 2023 and reported net income attributable to common stockholders for the three months ended September 30, 2022 and a net loss attributable to common stockholders for the nine months ended September 30, 2022. (See Note 15, "(Loss) Income Per Share").

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

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, 2022 (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.

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 September 30, 2023, other than as described below:

Grant Income

Grant income consists of amounts earned from incurring costs to support the CHASE Phase 2b clinical trial of KPI-012 for PCED, as well as product process characterization and analytical development from the program due to the receipt of the CIRM Award. The grant between the Company and CIRM generally provides for the Company to meet certain milestones in order for funds to be provided. The Company accounts for grants received to perform research and development activities in accordance with Accounting Standards Codification ("ASC") Topic 730-20, *Research and Development Arrangements*, which requires an assessment, at the inception of the grant, of whether the grant is a liability or a contract to perform research and development activities. If the Company is obligated to repay the grant funds to the grantor regardless of the outcome of the research and development activities, then the Company is required to estimate and recognize that liability. Alternatively, if the Company is not required to repay, or if it is required to repay the grant funds only if the research and development activities are successful, then the grant agreement is accounted for as a contract to perform research and development activities, in which case, grant income is recognized as the related research and development expenses are incurred. Costs of grant income are recorded as a component of research and development expenses in the Company's condensed consolidated statements of operations and comprehensive (loss) income as opposed to grant revenue.

Grant funds received in advance are recorded as deferred grant income on the condensed consolidated balance sheets. Management has determined that the Company is the principal participant under the Company's CIRM Award, and accordingly, the Company records amounts earned under this arrangement as grant income on the condensed consolidated statements of operations and comprehensive (loss) income.

Recent Accounting Pronouncements

Management has considered all recent accounting pronouncements issued since the last audit of the Company's consolidated financial statements. The Company's management believes that these recent pronouncements will not have a material effect on the Company's consolidated financial statements.

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

3. SALE OF COMMERCIAL BUSINESS TO ALCON

On July 8, 2022, the Company closed the Alcon Transaction contemplated by the Asset Purchase Agreement, pursuant to which Alcon purchased the Commercial Business and assumed certain liabilities with respect to the Commercial Business. 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.

Pursuant to the Asset Purchase Agreement, on July 8, 2022, the Company entered into supply and commercial agreements under which the Company agreed to supply EYSUVIS and INVELTYS to Alcon and distribute EYSUVIS and INVELTYS to third-party customers of the Commercial Business on behalf of Alcon for a period of six months following the closing of the Alcon Transaction. In addition, the Company entered into a transition services agreement under which the Company provided certain transition services to Alcon on a cost-plus pricing arrangement for six months following the closing of the Alcon Transaction. Pursuant to the supply agreement, Alcon purchased from the Company, at the closing of the Alcon Transaction, $5,027 of EYSUVIS and INVELTYS inventory on-hand at the Company. Together, the supply, commercial and transition services agreements are referred to herein as the “Transition Agreement.”

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

The Company has determined that the disposition of these assets does not qualify for reporting as a discontinued operation as it was not considered a component of an entity that comprises operations and cash flows that can be clearly distinguished, operationally and for financial reporting purposes, from the rest of the Company. During the year ended December 31, 2022, the Company recognized a net gain on the sale of the Commercial Business as follows:

Gross consideration from the sale of the Commercial Business	$	65,027
Closing and transaction costs		2,119
Net proceeds from the sale of the Commercial Business		62,908
Book value of assets transferred		
Inventories		8,915
Prepaid expenses and other current assets		556
Property and equipment, net		1,819
Other long-term assets		434
Total book value of assets transferred		11,724
Gain on sale of Commercial Business		51,184
Deferred gain on sale of Commercial Business		4,189
Net gain on sale of Commercial Business	$	46,995

The Company deferred a portion of the gross consideration related to the discounted pricing on any remaining inventory owned by the Company (the “Remaining Inventory”) that Alcon could have purchased. The deferred gain on the sale of the Commercial Business of $4,189 was recorded on the condensed consolidated balance sheet as of the transaction date as deferred gain on sale of Commercial Business. The Remaining Inventory and deferred gain on the sale of the Commercial Business were written off during the three and nine months ended September 30, 2023, and is recorded in the other (expense) income, net line item in the condensed consolidated statements of operations and comprehensive (loss) income.

The Company collected cash on behalf of Alcon for revenue generated by sales of EYSUVIS and INVELTYS from July 8, 2022 through the transition period and the Company transferred all cash generated by such sales to Alcon as of December 31, 2022.

As of September 30, 2023, the total receivables due from Alcon and from third parties in connection with the Transition Agreement were *de minimis*. The Company recorded income from the Transition Agreement of $157 which is presented in other income (expense), net on the condensed consolidated statement of operations and comprehensive (loss) income for the nine months ended September 30, 2023 and which offsets operating expenses related to the Transition Agreement captured within loss from operations. There was no income from the Transition Agreement recorded in the three months ended September 30, 2023. There were no payables due to third parties related to amounts the Company is obligated to pay on Alcon’s behalf included on the Company’s condensed consolidated balance sheet as of September 30, 2023.

As of December 31, 2022, the Company had total receivables due from Alcon and third parties of $5,394 and $26, respectively, and total payables to third parties related to the Transition Agreement of $3,981 of which $1,737 was included in accounts payable and $2,244 within accrued expenses and other current liabilities related to invoices the Company was obligated to pay on Alcon’s behalf. As of December 31, 2022, the Company had a net receivable due from Alcon and third parties in connection with the Transition Agreement of $1,439.

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

4. ASSETS HELD FOR SALE

As of December 31, 2022, the Company presented assets to be disposed of that met the criteria as held for sale as a single asset in its condensed consolidated financial statements. The EYSUVIS and INVELTYS product inventory classified as held for sale represented the net realizable value of the Remaining Inventory which Alcon, and solely Alcon, had the right to purchase. As noted in Note 3, "Sale of Commercial Business to Alcon" above, the Company deferred a portion of the gain on the sale of the Commercial Business related to the discounted pricing on the Remaining Inventory of $4,189. The Remaining Inventory and deferred gain on the sale of the Commercial Business were written off during the three and nine months ended September 30, 2023 and included in other (expense) income, net on the condensed consolidated statements of operations and comprehensive (loss) income. No held for sale assets remained on the condensed consolidated balance sheet as of September 30, 2023.

The following is a summary of the major categories of assets that had been reclassified to held for sale on the condensed consolidated balance sheet as of December 31, 2022:

	December 31, 2022
Inventories	$ 7,544
Property and equipment, net	51
Current assets held for sale	$ 7,595

See Note 3, "Sale of Commercial Business to Alcon", for further information on the sale of the Commercial Business.

5. 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, 2023 and December 31, 2022 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.

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

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 (the "Upfront Shares") 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 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. Changes in these estimates and assumptions could have had a significant impact on the fair value of the Deferred Purchase Consideration. 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) income. During the nine months ended September 30, 2022, the Company settled $7,935 of the liability upon issuance of the Upfront Shares and during the nine months ended September 30, 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 months ended September 30, 2023. The change in the fair value of the Deferred Purchase Consideration was a gain of $57 during the three months ended September 30, 2022, and was a gain of $230 and a loss of $205 during the nine months ended September 30, 2023 and 2022, respectively, primarily due to the change in the fair value of the underlying stock price and is recognized as the (gain) loss on fair value remeasurement of deferred purchase consideration in the condensed consolidated statements of operations and comprehensive (loss) income.

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. To date and during the nine months ended September 30, 2023, of the $105,000 in contingent milestone payments, the Company has paid to the Combangio Equityholders 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) 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 "Dosing Milestone"). The Company will pay the remaining amount due in connection with the Dosing Milestone of $146 in cash in January 2024, of which the discounted amount of $140 is included within accrued expenses and other current liabilities on the condensed consolidated balance sheet as of September 30, 2023. 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) income. During the three months ended September 30, 2023 and 2022, the change in fair value of the contingent consideration liabilities was a gain of $1,744 and a loss of $95 respectively, and during the nine months ended September 30, 2023 and 2022, the change in the fair value of the contingent consideration liabilities was a loss of $462 and a gain of $952, respectively, primarily due to changes in discount rates, as well as changes in the expected timing and probability of payment, partially offset by the passage of time, and were recognized as a (gain) loss on fair value remeasurement of contingent consideration in the condensed consolidated statements of operations and comprehensive (loss) income for the three and nine months ended September 30, 2023 and 2022.

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

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, 2023 and December 31, 2022:

	September 30, 2023			
	Fair Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 49,537	$ 49,537	$ —	$ —
Total Assets	$ 49,537	$ 49,537	$ —	$ —
Liabilities:				
Contingent consideration	$ 3,838	$ —	$ —	$ 3,838
Total Liabilities	$ 3,838	$ —	$ —	$ 3,838

	December 31, 2022			
	Fair Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 31,587	$ 31,587	$ —	$ —
Total Assets	$ 31,587	$ 31,587	$ —	$ —
Liabilities:				
Deferred purchase consideration	$ 595	$ —	$ —	$ 595
Contingent consideration	8,370	—	—	8,370
Total Liabilities	$ 8,965	$ —	$ —	$ 8,965

The following tables summarize quantitative information and assumptions pertaining to the fair value measurement of the Level 3 inputs as of September 30, 2023 and December 31, 2022:

Financial Instrument	Fair Value at September 30, 2023	Valuation Technique	Unobservable Input	Range (Average)
Contingent consideration	$ 3,838	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	17.3%

Financial Instrument	Fair Value at December 31, 2022	Valuation Technique	Unobservable Input	Range (Average)
Deferred purchase consideration	$ 595	Option pricing model	Discount for lack of marketability	20%
Contingent consideration	$ 8,370	Probability-adjusted discounted cash flow model	Period of expected milestone achievement	2023 - 2027 (2025)
			Probabilities of achievement	19.9% - 95.0% (44.9%)
			Discount rate	19.0%
			Discount for lack of marketability	20.0%

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, 2023 and 2022:

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	$	—
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, 2022	$	7,892
Fair value adjustments		1,051
Settlements		(7,935)
Balance at March 31, 2022	$	1,008
Fair value adjustments		(789)
Balance at June 30, 2022	$	219
Fair value adjustments		(57)
Balance at September 30, 2022	$	162
Contingent consideration		
Balance at January 1, 2022	$	8,658
Fair value adjustments		(988)
Balance at March 31, 2022	$	7,670
Fair value adjustments		(59)
Balance at June 30, 2022	$	7,611
Fair value adjustments		95
Balance at September 30, 2022	$	7,706

During the three and nine months ended September 30, 2023 and the year ended December 31, 2022, there were no transfers between Level 1, Level 2, and Level 3.

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

6. REVENUE

Following the sale of its Commercial Business to Alcon in July 2022, the Company no longer has any commercial products in its portfolio. The Company accounted for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods or services. The Company performed the following five steps to recognize revenue under ASC Topic 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognized revenue when it was probable that it would collect the consideration to which it was entitled in exchange for the goods or services that would be transferred to the customer.

Product revenues, net

The Company sold EYSUVIS and INVELTYS primarily to wholesalers in the United States (collectively, "Customers"). These Customers subsequently resold the Company's products to specialty and other retail pharmacies. In addition to agreements with Customers, the Company entered into arrangements with third-party payors that provided for government-mandated and/or privately-negotiated rebates, chargebacks and discounts for the purchase of the Company's products.

The goods promised in the Company's product sales contracts represented a single performance obligation. The Company recognized revenue from product sales at the point the Customer obtained control of the product, which occurred upon delivery. The transaction price ("net sales price") that was recognized as revenue for product sales included the selling price to the Customer and an estimate of variable consideration. Components of variable consideration included prompt pay and other discounts, product returns, government rebates, third-party payor rebates, coverage gap rebates, incentives such as patient co-pay assistance, and other fees paid to Customers and other third-party payors where a distinct good or service was not received. Variable consideration was recorded on the condensed consolidated balance sheet as either a reduction of accounts receivable, if payable to a Customer, or as a current liability, if payable to a third-party other than a Customer. The Company considered all relevant information when estimating variable consideration such as assessment of its then current and anticipated sales and demand forecasts, actual payment history, information from third parties regarding the payor mix for products, information from third parties regarding the units remaining in the distribution channel, specific known market events and trends, industry data and current contractual and statutory requirements that were reasonably available. The Company included estimated amounts for variable consideration in the net sales price to the extent it was determined probable that a significant reversal of cumulative revenue recognized would not occur when the uncertainty associated with the variable consideration was resolved.

Payment terms with Customers did not exceed one year and, therefore, the Company did not account for a significant financing component in its arrangements. The Company expensed the incremental cost of obtaining a contract with a Customer when incurred as the period of benefit was generally less than one year.

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

Reserves for Variable Consideration:

Trade Discounts and Allowances

The Company provided its Customers with certain trade discounts and allowances including discounts for prompt payments and other discounts and fees paid for distribution, data and administrative services. These discounts and fees were based on contractually-determined percentages and were recorded as a reduction of revenue and accounts receivable in the period in which the related product revenue was recognized.

Chargebacks

Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchased the product from the Company. Customers charged the Company for the difference between what they paid for the product and the ultimate selling price to the qualified healthcare providers. These components of variable consideration were established in the same period that the related revenue was recognized, resulting in a reduction of product revenue and accounts receivable. Reserves for chargebacks consisted of credits the Company expected to issue for units that remained in the distribution channel at the end of each reporting period and that the Company expected would be sold to qualified healthcare providers, as well as chargebacks that Customers had claimed, but for which the Company had not yet issued a credit.

Product Returns

Consistent with industry practice, the Company has a product returns policy that provides Customers right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The Company estimated the amount of its products that may be returned and presented this amount as a reduction of revenue in the period the related product revenue was recognized, in addition to establishing a liability. The Company's estimates for product returns were based upon available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel as well as historical returns, which developed over time.

Commercial Payor and Medicare Part D Rebates

The Company contracted with certain third-party payors, primarily pharmacy benefit managers ("PBMs") and health plans ("Plans"), for the payment of rebates with respect to utilization of its product. These rebates were based on contractual percentages applied to the amount of product prescribed to patients who were covered by the PBMs or the Plans with which it contracted. The Company estimated the rebates for commercial and Medicare Part D payors based on the contractual discount percentage, the various payor mix for EYSUVIS and INVELTYS as well as future rebates that would be made for product that had been recognized as revenue but remained in the distribution channel at the end of each reporting period. The Company also estimated the number of patients in the prescription drug coverage gap for whom it would owe an additional liability under the Medicare Part D program. Such estimates were recorded in the same period the related revenue was recognized, resulting in a reduction of product revenue and the establishment of a current liability.

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

Government Rebates

The Company was subject to discount obligations under Medicaid and other government programs. For Medicaid, reserves were based on actual payment history, and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Centers for Medicaid and Medicare Services. The Company's liability for these rebates consisted of estimates of claims for the current period and estimated future claims that would be made for product that had been recognized as revenue but remained in the distribution channel at the end of each reporting period. These reserves were recorded in the same period the related revenue was recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Co-pay Assistance Programs

The Company offered co-pay assistance programs (the "co-pay programs"), which were intended to provide financial assistance to patients who may or may not be covered by commercial insurance or, with respect to INVELTYS, who opt out of Medicare Part D programs. The calculation of accruals for the co-pay programs was based on actual claims processed during the period as well as an estimate of the number and cost per claim that the Company expected to receive associated with product that had been recognized as revenue but remained in the distribution channel at the end of each reporting period. Allowances for estimated co-pay claims were recorded in the same period the related revenue was recognized, resulting in a reduction of product revenue and the establishment of a current liability.

The following tables summarize activity in each of the Company's product revenue provision and allowance categories for the three and nine months ended September 30, 2023 and 2022:

	Trade Discounts, Allowances and Chargebacks (1)	Product Returns (2)	Rebates and Incentives (3)
Balance as of December 31, 2022	$ 11	$ 518	$ 772
Credit/payments made	(2)	(49)	(484)
Balance as of March 31, 2023	$ 9	$ 469	$ 288
Changes in estimate related to prior period sales	(9)	249	(240)
Credit/payments made	—	(111)	(38)
Balance as of June 30, 2023	$ —	$ 607	$ 10
Changes in estimate related to prior period sales	—	1,106	—
Credit/payments made	—	(64)	—
Balance as of September 30, 2023	$ —	$ 1,649	$ 10

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

	Trade Discounts, Allowances and Chargebacks (1)	Product Returns (2)	Rebates and Incentives (3)
Balance as of December 31, 2021	$ 2,672	$ 1,140	$ 11,280
Provision related to current period sales	2,133	210	13,359
Changes in estimate related to prior period sales	(1)	(138)	(242)
Credit/payments made	(3,261)	(415)	(10,108)
Balance as of March 31, 2022	$ 1,543	$ 797	$ 14,289
Provision related to current period sales	2,602	214	15,413
Changes in estimate related to prior period sales	(41)	(199)	(107)
Credit/payments made	(2,041)	(112)	(14,878)
Balance as of June 30, 2022	$ 2,063	$ 700	$ 14,717
Provision related to current period sales	91	4	525
Changes in estimate related to prior period sales	176	150	(680)
Credit/payments made	(2,310)	(263)	(9,562)
Balance as of September 30, 2022	$ 20	$ 591	$ 5,000

(1) Trade discounts, allowances and chargebacks included fees for distribution service fees, prompt pay and other discounts, and chargebacks. Estimated trade discounts, allowances and chargebacks were deducted from gross revenue at the time revenues were recognized and were recorded as a reduction to accounts receivable on the Company's condensed consolidated balance sheets.

(2) Estimated provisions for product returns were generally deducted from gross revenues at the time revenues were recognized and were included in accrued expenses and other current liabilities on the Company's condensed consolidated balance sheets.

(3) Rebates and incentives included managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances. Estimated provisions for rebates and discounts were deducted from gross revenues at the time revenues were recognized and were included in accrued expenses and other current liabilities on the Company's condensed consolidated balance sheets.

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

7. 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 (the "CIRM Award") to support Combangio's KPI-012 program for the treatment of PCED. The 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 the balance of the award is payable to Combangio upon the achievement of specified milestones that are primarily related to Combangio's progress in conducting the CHASE Phase 2b clinical trial. CIRM may permanently cease disbursements if the milestones are not met within four months of the scheduled completion dates. 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.

During each of the three and nine months ended September 30, 2023, the Company recognized $2,970 of grant income related to the CIRM Award on its condensed consolidated statement of operations. As of September 30, 2023, the Company had deferred grant income of $2,930 on its condensed consolidated balance sheet.

8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets, consists of the following:

	September 30, 2023	December 31, 2022
Insurance	$ 918	$ 698
Non-trade receivables	143	908
Trade receivables, net	117	195
Due from Alcon	12	5,394
Other	649	657
Prepaid expenses and other current assets	$ 1,839	$ 7,852

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

9. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2023	December 31, 2022
Compensation and benefits	$ 2,783	$ 3,334
Professional services	487	948
Accrued revenue reserves (1)	1,659	807
Development costs	547	446
Contract manufacturing	375	453
Commercial costs	153	271
Due to third parties in connection with Transition Agreement (2)	—	2,244
Other	256	407
Accrued expenses and other current liabilities	$ 6,260	$ 8,910

(1) There were additional revenue reserves included in accounts payable of $483 as of December 31, 2022. There were no such amounts included in accounts payable as of September 30, 2023.
(2) There were additional amounts due to third parties in connection with the Transition Agreement included in accounts payable of $1,737 as of December 31, 2022. There were no such amounts included in accounts payable as of September 30, 2023.

10. LEASES

Operating leases

Menlo Park, California Office Lease

In April 2023, Combangio, a wholly owned subsidiary of the Company, 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 nine months ended September 30, 2023 which is included in other long-term assets on the condensed consolidated balance sheet as of September 30, 2023. Upon the lease commencement, the Company recorded a right-of-use asset of $2.2 million and corresponding $2.1 million of lease liability.

As of September 30, 2023, the Company recognized $2.1 million of right-of-use asset and a corresponding $2.2 million 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, 2023, the remaining lease term on the lease was 4.9 years. Variable lease expense for the lease, includes real estate taxes, common area maintenance, and management fees.

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

Terminated Vehicle Fleet Lease

During the year ended December 31, 2019, the Company entered into a master fleet lease agreement (the "Vehicle Fleet Lease"), pursuant to which it leased vehicles. The Vehicle Fleet Lease commenced upon the delivery of the initial vehicles in March 2019 and had been subject to modifications as the number of leased vehicles increased or decreased. During the year ended December 31, 2022, in connection with the closing of the Alcon Transaction, the Company terminated the Vehicle Fleet Lease and, as of December 31, 2022, there was no remaining right-of-use asset or corresponding lease liability. In connection with the Vehicle Fleet Lease, the Company issued a letter of credit for $450 which was released in September 2022. As of December 31, 2022, the Company had a receivable of $775 due from the vendor for the sale of used vehicles following the lease termination, which was included within prepaid expenses and other current assets on the consolidated balance sheet. The remaining receivable from the vendor as of September 30, 2023 is *de minimis.*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Lease cost				
Operating lease cost	$ 149	$ 9	$ 165	$ 404
Short-term lease cost	20	49	132	143
Variable lease cost	46	114	52	740
Total lease cost	$ 215	$ 172	$ 349	$ 1,287
Operating cash outflows from operating leases	$ 48	$ 338	$ 61	$ 1,308

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

	September 30, 2023	December 31, 2022
Weighted average remaining lease term	4.9 years	0.5 years
Weighted average discount rate	13.1%	10.4%

As of September 30, 2023, the Company expects that its future minimum lease payments will become due and payable as follows:

Years Ending December 31,	
2023 (remaining three months)	$ 143
2024	581
2025	601
2026	622
2027	644
Thereafter	440
Less: interest	(827)
Total	$ 2,204

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

11. 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.

Through June 30, 2023, the term loans 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 loans bear 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 has 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 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 embedded derivatives have a *de minimis* value as of September 30, 2023. 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) income.

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) income. As of September 30, 2023, the effective interest rate was 17.21%, 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, 2023 and 2022, the Company recognized interest expense of $1,459 and $1,447, respectively, for the Loan Agreement. This consisted of amortization of debt discount of $68 and $52 for the three months ended September 30, 2023 and 2022, respectively, accretion of the final payment fee of $241 and $206 for the three months ended September 30, 2023 and 2022, respectively, and the contractual coupon interest expense of $1,150 and $1,189 for the three months ended September 30, 2023 and 2022, respectively. During the nine months ended September 30, 2023 and 2022, the Company recognized interest expense of $4,346 and $5,703, respectively, for the Loan Agreement. This consisted of amortization of debt discount of $204 and $281 for the nine months ended September 30, 2023 and 2022, respectively, accretion of the final payment fee of $737 and $849 for the nine months ended September 30, 2023 and 2022, respectively, and the contractual coupon interest expense of $3,405 and $4,573 for the nine months ended September 30, 2023 and 2022, respectively.

The components of the carrying value of the debt as of September 30, 2023 and December 31, 2022 are detailed below:

	September 30, 2023	December 31, 2022
Principal loan balance	$ 33,957	$ 43,303
Unamortized debt discount and issuance cost	(602)	(806)
Cumulative accretion of exit fee	523	440
Total debt	$ 33,878	$ 42,937
Less: current portion of long-term debt	—	(5,000)
Long-term debt, net	$ 33,878	$ 37,937

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

The annual principal payments due under the Loan Agreement as of September 30, 2023 were as follows:

Years Ending December 31,	
2023 (remaining three months)	$ —
2024	—
2025	23,970
2026	9,987
2027	—
Total	$ 33,957

12. WARRANTS

The following table summarizes the common stock warrants outstanding as of September 30, 2023 and December 31, 2022, 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, 2023	Shares Exercisable at December 31, 2022
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

13. 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 under the ATM Offering pursuant to the terms of the Amended and Restated Sales Agreement, resulting in net proceeds of $9,994. The Company did not sell any shares of its common stock under the at-the-market offering pursuant to the terms of the Amended and Restated Sales Agreement during the three or nine months ended September 30, 2022. 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 shares of its common stock under such agreement for aggregate gross proceeds of $75,000.

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

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 190,000 shares of its common stock under its at-the-market offering pursuant to 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.

Private Placement

On November 28, 2022, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain institutional investors named therein (the "Purchasers"), pursuant to which the Company agreed to issue and sell, in a private placement priced at-the-market under Nasdaq rules, shares of common stock and shares of Series E Convertible Non-Redeemable Preferred Stock, par value $0.001 per share, of the Company (the "Series E Preferred Stock"), in two tranches for aggregate gross proceeds of up to $31,000 (collectively, the "Private Placement"). Pursuant to the Securities Purchase Agreement, on December 1, 2022, the Company issued and sold to the Purchasers at the first closing of the Private Placement, (i) 76,813 shares of common stock, at a price per common share equal to $5.75 and (ii) 9,666 shares of Preferred Stock, at a price per share equal to $575.00, for aggregate gross proceeds of approximately $6,000. On December 27, 2022, following the certification by the Chief Executive Officer of the Company that the FDA accepted the Company's IND for KPI-012, the Company issued and sold to the Purchasers at a second closing of the Private Placement a total of 43,478 Preferred Shares, at a price per share equal to $575.00, for aggregate gross proceeds of approximately $25,000. Costs incurred in connection with the Private Placement were $240, which were recorded as a reduction to additional paid-in capital.

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

14. STOCK-BASED COMPENSATION

On June 22, 2023, the Company's stockholders approved the Company's Amended and Restated 2017 Equity Incentive 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 Amended and Restated 2017 Equity 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, 2023, there were 112,597 shares of common stock available for grant under the Amended and Restated 2017 Equity Incentive Plan.

During the nine months ended September 30, 2023, the Company granted options for the purchase of 666,962 shares of common stock and 824,190 RSUs. In January 2023 and July 2023, employees of the Company purchased an aggregate of 461 shares and 3,229 shares under the Employee Stock Purchase Plan, respectively.

The assumptions used in determining fair value of the stock options granted during the nine months ended September 30, 2023 are as follows:

	Nine Months Ended September 30, 2023		
Expected volatility	108.4%	–	123.1%
Risk-free interest rate	3.55%	–	4.43%
Expected dividend yield		0%	
Expected term (in years)	5.50	–	6.10

During the nine months ended September 30, 2023, the weighted average grant-date fair value of options granted was $12.82.

On May 1, 2023, the Company commenced a one-time stock option exchange program (the "Option Exchange Program"), under which the Company's eligible executive officers, other employees and non-employee directors (collectively, "Eligible Holders") were given the opportunity to exchange outstanding options to purchase shares of the Company's common stock held by them for an equal number of RSUs that are subject to vesting conditions. The Option Exchange Program expired on May 30, 2023. A total of 36 Eligible Holders participated in the Option Exchange Program. Pursuant to the terms and conditions of the Option Exchange Program, the Company accepted for exchange options to purchase a total of 182,251 shares of the Company's common stock. All surrendered options were cancelled effective as of the expiration of the Option Exchange Program, and immediately thereafter, in exchange therefor, the Company granted a total of 182,251 RSUs pursuant to the terms of the Option Exchange Program and the 2017 Plan. A *de minimis* number of eligible options were not surrendered for exchange and remain outstanding. The Company elected to recognize any unrecognized compensation cost remaining from the original awards plus the incremental compensation cost of $1,210 as a result of the modification over the remaining service period of the modified awards.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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In January 2022, the Company granted stock options to purchase up to 14,850 shares of common stock to certain executives tied to certain performance criteria. On March 14, 2023, the Compensation Committee of the Company's Board of Directors determined that certain of the performance conditions were achieved at specific levels of achievement, resulting in vesting of options to purchase an aggregate of 3,960 shares of common stock. All outstanding stock options tied to performance criteria were surrendered in the Option Exchange Program and as such, there were none outstanding as of September 30, 2023.

As of September 30, 2023, a total of 827,658 RSUs were outstanding, consisting of 824,998 unvested RSUs and 2,660 vested and deferred shares by directors.

Stock-based compensation expense was classified in the condensed consolidated statements of operations and comprehensive (loss) income as follows for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of product revenues	$ —	$ 4	$ —	$ 166
Research and development	657	238	1,454	1,085
Selling, general and administrative	1,746	1,085	3,635	4,797
Total	$ 2,403	$ 1,327	$ 5,089	$ 6,048

15. (LOSS) INCOME PER SHARE

Basic and diluted net (loss) income per share attributable to common stockholders was calculated as follows for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net (loss) income attributable to common stockholders	$ (8,704)	$ 29,073	$ (33,572)	$ (31,979)
Denominator:				
Weighted-average common shares outstanding, basic (1)	2,550,210	1,499,001	2,337,492	1,490,159
Effect of dilutive securities	—	11,420	—	—
Weighted-average common shares outstanding, diluted (1)	2,550,210	1,510,421	2,337,492	1,490,159
Net (loss) income per share attributable to common stockholders, basic	$ (3.41)	$ 19.39	$ (14.36)	$ (21.46)
Net (loss) income per share attributable to common stockholders, diluted	$ (3.41)	$ 19.25	$ (14.36)	$ (21.46)

(1) Included in the weighted-average common shares outstanding, basic and diluted for the three and nine months ended September 30, 2022 is an aggregate of 19,350 shares of common stock that were held back by the Company as partial security for the satisfaction of indemnification obligations and other payment obligations of the Combangio Equityholders and were issued in March 2023.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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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 for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Options to purchase shares of common stock	670,064	221,747	509,914	242,234
Unvested RSUs and PSUs	824,998	—	598,210	11,328
Unexercised warrants	4,303	4,303	4,303	4,303
Convertible preferred stock (as converted to common stock)	5,124,600	—	5,238,000	—
	6,623,965	226,050	6,350,427	257,865

16. INCOME TAXES

The Company did not record a provision or benefit for income taxes during the three and nine months ended September 30, 2023 and 2022. The Company continues to maintain a full valuation allowance for its U.S. federal and state deferred tax assets.

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, as amended, 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 previously completed an analysis and determined that an ownership change materially limited the net operating loss carryforwards. During December 2022, an additional ownership change occurred as a result of the Company's entry into the Securities Purchase Agreement. As a result of the most recent ownership change, the utilization of the Company's net operating loss carryforwards is subject to an annual limitation of $222.

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, 2023 and December 31, 2022, 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, 2023 and 2022.

KALA BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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17. 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 and milestone payments upon the achievement of specified development, regulatory and sales milestones, as well as tiered royalties 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, 2023 and 2022 were *de minimis*.

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

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 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 will pay the remaining amount due in connection with the Dosing Milestone of $146 in cash in January 2024. Additionally, pursuant to the Merger Agreement, the Company could trigger potential future sales-based milestone payments of up to $65,000. Because the achievement of these sales-based milestones related to KPI-012 was not considered probable as of September 30, 2023 or December 31, 2022, 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, 2022, which was filed with the Securities and Exchange Commission on March 3, 2023. 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.

Unless otherwise indicated, all information in this Quarterly Report on Form 10-Q gives effect to a 1-for-50 reverse stock split of our common stock that became effective on October 20, 2022, and all references to historical share and per share amounts give effect to the reverse stock split.

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 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.

On March 27, 2023, we announced positive safety data from the first cohort of the CHASE Phase 2b clinical trial. The CHASE trial includes two patient cohorts. The first cohort 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.

The second cohort is a multicenter, randomized, double-masked, vehicle-controlled, parallel-group study 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. The primary endpoint of the trial is the complete healing of the PCED as measured by corneal fluorescein staining. We are targeting reporting topline safety and efficacy data in the second half of 2024. 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 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, 2022 and see Note 1, “Nature of Business and Basis of Presentation”, Note 5, “Fair Value of Financial Instruments” and Note 17, “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 closed the transaction, or the Alcon Transaction, contemplated by the asset purchase agreement, dated as of May 21, 2022, or the Asset Purchase Agreement, by and between us, Alcon Pharmaceuticals Ltd. and Alcon Vision, LLC, which we refer to collectively 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 AMPPLIFY Drug Delivery Technology, which we collectively refer to as the Commercial Business. 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, 2022 and Note 3, “Sale of Commercial Business to Alcon” of our condensed consolidated financial statements, included herein.

On July 8, 2022, we announced that we had committed to a course of action to terminate 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. We completed the workforce reduction by the end of 2022.

Since inception, we have incurred significant losses from operations and negative cash flows from operations. Our net loss was $8.7 million and $33.6 million for the three and nine months ended September 30, 2023, respectively, and $44.8 million for the year ended December 31, 2022. As of September 30, 2023, we had an accumulated deficit of $620.8 million. As we commenced a full promotional launch of EYSUVIS in early January 2021 and commercially launched our first product, INVELTYS, in January 2019, we had generated only limited revenues from product sales 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 in July 2022, 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 preferred stock (including our private placement of common stock and preferred stock for gross proceeds of approximately $31.0 million in December 2022, or our Private Placement), borrowings under credit facilities and our Loan Agreement with Oxford Finance, convertible promissory notes and warrants. In August 2023, following entry into the award agreement with the California Institute for Regenerative Medicine, or CIRM, Combangio received an initial $5.9 million disbursement from CIRM, and the balance of the $15.0 million award is payable to Combangio upon the achievement of specified milestones. 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. 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

Product Revenues, Net

On July 8, 2022, we sold our Commercial Business, including EYSUVIS and INVELTYS, to Alcon and ceased recording gross revenue on sales of EYSUVIS and INVELTYS. Our product revenues for the periods presented herein are recorded net of provisions relating to estimates for (i) trade discounts and allowances, such as discounts for prompt payment and other discounts and distributor fees, (ii) estimated rebates, chargebacks and co-pay assistance programs, and (iii) reserves for expected product returns. These estimates reflect current contractual and statutory requirements, known market events and trends, industry data and forecasted customer buying and payment patterns. Actual amounts may ultimately differ from these estimates. If actual results vary, estimates may be adjusted in the period such change in estimate becomes known, which could have an impact on earnings in the period of adjustment.

We currently have no commercial products in our portfolio. Moreover, we only recently commenced the CHASE trial of KPI-012 for PCED in the United States and, accordingly, 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.

Cost of Product Revenues

Cost of product revenues consisted primarily of materials, third-party manufacturing costs, freight and distribution costs, royalty expense, allocation of labor, quality control and assurance, reserves for defective inventory, reserves for excess and obsolete inventory, losses on inventory purchase commitments, and other manufacturing overhead costs. Prior to the sale of our Commercial Business in July 2022, write-downs of inventory were recorded as a cost of product revenues in the consolidated statements of operations and comprehensive (loss) income. Following the sale of our Commercial Business, any adjustments to the remaining EYSUVIS and INVELTYS inventory, or the Remaining Inventory, were recorded within other expense in the condensed consolidated statements of operations and comprehensive (loss) income. Following the sale of the Commercial Business, the only customer for our current inventory was Alcon. The Remaining Inventory balance, net of the deferred gain on sale of Commercial Business, was written off during the three and nine months ended September 30, 2023, and is recorded in other (expense) income in the condensed consolidated statements of operations and comprehensive (loss) income. As a result of the sale of our Commercial Business to Alcon, we do not expect to generate cost of product revenues unless we commercialize another product candidate.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits, commissions, stock-based compensation and travel expenses related to our commercial infrastructure and our executive, finance, human resources, legal, compliance, information technology and business development functions. Selling, general and administrative expenses also include external selling and marketing costs related to EYSUVIS and INVELTYS prior to the sale of the Commercial Business to Alcon, costs to manufacture sample units and 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 selling, general and administrative expenses for 2023 will decrease as compared to such expenses for the year ended December 31, 2022 as a result of our workforce reduction completed during the second half of 2022 and the sale of our Commercial Business to Alcon in July 2022. We anticipate that our selling, general and administrative expenses will stabilize at 2023 expense levels for the foreseeable future as we continue to support our development efforts for KPI-012 and seek marketing approval for KPI-012 and any other product candidate we may develop in the future. If we obtain marketing approval for KPI-012 or any product candidates we may develop, we expect that our selling, 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) income 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 2023 will increase as compared to such expenses for the year ended December 31, 2022 as we 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 ongoing and 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) Loss 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 and 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) income.

(Gain) Loss 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. To date and during the nine months ended September 30, 2023, of the up to $105.0 million in contingent milestone payments, we paid to the Combangio Equityholders an aggregate of $2.5 million in cash and $2.4 million in shares of 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, or the Dosing Milestone. We will pay the remaining amount due in connection with the Dosing Milestone of $0.1 million in cash in January 2024. 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) income.

The potential payments and milestones are more fully described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and Note 5, “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 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.

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 $5.9 million disbursement from CIRM, and the balance of the award is payable to Combangio 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. 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.

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. During each of the three and nine months ended September 30, 2023, we recognized $3.0 million of grant income related to the CIRM Award on our condensed consolidated statements of operations and comprehensive (loss) income and as of September 30, 2023, we had deferred grant income of $2.9 million on our condensed consolidated balance sheet.

Loss on Extinguishment of Debt

Loss on extinguishment of debt primarily consists of unamortized debt discount and issuance costs, a prepayment premium and unaccreted final payment fees paid on our Loan Agreement with Oxford Finance as a result of the partial extinguishment of debt on July 8, 2022 in connection with the closing of the Alcon Transaction.

Gain on Sale of Commercial Business

Gain on sale of Commercial Business represents the gain recognized as a result of the sale of our Commercial Business to Alcon on July 8, 2022.

Other Income (Expense), Net

Other income (expense), net consists of expense recorded to assets held for sale for the write-off the remaining inventory balance and to write-off the deferred gain 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.

In addition to the critical accounting policies that are described "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, 2022, we believe that the following critical accounting policy was critical to the judgments and estimates used in the preparation of our financial statements and involves a significant level of estimation uncertainty.

Grant Income

We account for grants received to perform research and development activities in accordance with Accounting Standards Codification Topic 730-20, *Research and Development Arrangements*, which requires an assessment, at the inception of the grant, of whether the grant is a liability or a contract to perform research and development activities. If we are obligated to repay the grant funds to the grantor regardless of the outcome of the research and development activities, then we are required to estimate and recognize that liability. Alternatively, if we are not required to repay, or if we were required to repay the grant funds only if the research and development activities are successful, then the grant agreement is accounted for as a contract to perform research and development activities, in which case, grant income is recognized as the related research and development expenses are incurred. Costs of grant income are recorded as a component of research and development expenses in our statements of operations and comprehensive (loss) income.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes the results of our operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		
	2023	2022	Change
	(in thousands)		
Product revenues, net	$ —	$ 420	$ (420)
Costs and expenses:			
Cost of product revenues	—	11	(11)
Selling, general and administrative	4,952	9,549	(4,597)
Research and development	5,554	5,391	163
Gain on fair value remeasurement of deferred purchase consideration	—	(57)	57
(Gain) loss on fair value remeasurement of contingent consideration	(1,744)	95	(1,839)
Total operating expenses	8,762	14,989	(6,227)
Loss from operations	(8,762)	(14,569)	5,807
Other income (expense)			
Interest income	708	234	474
Interest expense	(1,459)	(1,447)	(12)
Grant income	2,970	—	2,970
Loss on extinguishment of debt	—	(2,583)	2,583
Gain on sale of Commercial Business	—	46,995	(46,995)
Other (expense) income, net	(2,161)	443	(2,604)
Net (loss) income	$ (8,704)	$ 29,073	$ (37,777)

Product revenues, net

We did not have any product revenues during the three months ended September 30, 2023 due to the sale of our Commercial Business to Alcon in July 2022. Product revenues, net were $0.4 million for the three months ended September 30, 2022, consisting of $0.4 million from EYSUVIS sales and less than $0.1 million from INVELTYS sales. As a result of the sale of our Commercial Business, we no longer have any commercial products in our portfolio.

Cost of product revenues

We did not have any cost of product revenues during the three months ended September 30, 2023 due to the sale of our Commercial Business to Alcon in July 2022. Cost of product revenues was less than $0.1 million for the three months ended September 30, 2022.

Selling, general and administrative expenses

Selling, general and administrative expenses were $5.0 million for the three months ended September 30, 2023, compared to $9.5 million for the three months ended September 30, 2022, which was a decrease of $4.6 million. The decrease in selling, general and administrative expenses for the three months ended September 30, 2023 was primarily due to the sale of our Commercial Business to Alcon and our related workforce reduction completed during the second half of 2022 and includes a $1.4 million decrease in external sales and marketing costs, a $2.1 million decrease in employee-related expenses and a decrease in certain medical affairs costs attributable to our former commercial products. Also contributing to the decrease as compared to the three months ended September 30, 2022, was a $1.4 million decrease in administrative and professional service fees, 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 three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		
	2023	2022	Change
	(in thousands)		
KPI-012 development costs	$ 2,445	$ 2,379	$ 66
Employee-related costs	2,685	2,427	258
Other research and development costs	424	585	(161)
Total research and development	$ 5,554	$ 5,391	$ 163

Research and development expenses were $5.6 million for the three months ended September 30, 2023, compared to $5.4 million for the three months ended September 30, 2022, an increase of $0.2 million. The increase was primarily related to a $0.3 million increase in employee-related costs and KPI-012 development costs, partially offset by a decrease of $0.2 million of other research and development costs, which primarily included preclinical studies related to our former pipeline programs.

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 three months ended September 30, 2023 due to the final settlement of the liability in March 2023. The gain on fair value remeasurement of Deferred Purchase Consideration for the three months ended September 30, 2022 was $0.1 million, which was primarily due to a change in the fair value of our underlying stock price.

(Gain) loss on fair value remeasurement of contingent consideration

Gain on fair value remeasurement of contingent consideration for the three months ended September 30, 2023 was $1.7 million primarily due to changes in the expected timing and probability of payment. Loss on fair value remeasurement of contingent consideration for the three months ended September 30, 2022 was $0.1 million, and was primarily due to changes in discount rates, partially offset by the passage of time.

Interest income

Interest income was $0.7 million for the three months ended September 30, 2023 and was $0.2 million for the three months ended September 30, 2022. Interest income consists of interest earned on our cash, cash equivalents and short-term investments, if any. The increase was attributable to higher interest rates during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, as well as a higher cash balance and the quantity and mix of investments.

Interest expense

We incurred interest expense of $1.5 million for the three months ended September 30, 2023 and $1.4 million for the three months ended September 30, 2022. Interest expense for the three months ended September 30, 2023 and 2022 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 three months ended September 30, 2023, $34.0 million of indebtedness was outstanding under our Loan Agreement. During the three months ended September 30, 2022, $80.0 million of indebtedness was outstanding under our Loan Agreement until $36.7 million was repaid on July 8, 2022 resulting in an outstanding indebtedness of $43.3 million. While the principal balance on the debt decreased in the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, interest expense increased due to the variable rate on the debt and the rising interest rates.

Grant income

Grant income for the three months ended September 30, 2023 was $3.0 million related to the CIRM Award. There was no grant income recognized during the three months ended September 30, 2022.

Loss on extinguishment of debt

There was no loss on extinguishment of debt for the three months ended September 30, 2023. The loss on extinguishment of debt was $2.6 million for the three months ended September 30, 2022. Upon the partial repayment of $36.7 million of indebtedness under our Loan Agreement, the prepayment premium, unaccreted amount of the final payment fee due and a pro-rata portion of the debt discount were recorded as loss on extinguishment of debt for the three months ended September 30, 2022.

Gain on sale of Commercial Business

There was no gain on sale of Commercial Business for the three months ended September 30, 2023. The gain on sale of Commercial Business was $47.0 million for the three months ended September 30, 2022, which was comprised of the $65.0 million in cash consideration received from Alcon less $4.2 million of deferred gain on sale of Commercial business, $11.7 million net book value of assets transferred and $2.1 million of transaction costs.

Other (expense) income, net

Other expense, net was $2.2 million for the three months ended September 30, 2023, consisting of $5.3 million of expense recorded to assets held for sale to write-off the remaining inventory balance 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.

Other income, net was $0.4 million for the three months ended September 30, 2022 and represents $2.4 million of reimbursable transition related services we provided to Alcon following the sale of the Commercial Business to Alcon, partially offset by a $1.9 million expense recorded for expiring inventory and a loss on the sale of property and equipment of $0.1 million.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes the results of our operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		
	2023	2022	Change
	(in thousands)		
Product revenues, net	$ —	$ 3,892	$ (3,892)
Costs and expenses:			
Cost of product revenues	—	2,560	(2,560)
Selling, general and administrative	15,944	59,204	(43,260)
Research and development	13,868	14,330	(462)
(Gain) loss on fair value remeasurement of Deferred Purchase Consideration	(230)	205	(435)
Loss (gain) on fair value remeasurement of contingent consideration	462	(952)	1,414
Total operating expenses	30,044	75,347	(45,303)
Loss from operations	(30,044)	(71,455)	41,411
Other income (expense)			
Interest income	2,101	310	1,791
Interest expense	(4,346)	(5,689)	1,343
Grant income	2,970	—	2,970
Loss on extinguishment of debt	—	(2,583)	2,583
Gain on sale of Commercial Business	—	46,995	(46,995)
Other (expense) income, net	(4,253)	443	(4,696)
Net loss	$ (33,572)	$ (31,979)	$ (1,593)

Product revenues, net

We did not have any product revenues during the nine months ended September 30, 2023 due to the sale of our Commercial Business to Alcon in July 2022. Product revenues, net were $3.9 million for the nine months ended September 30, 2022, consisting of $2.3 million from EYSUVIS sales and $1.6 million from INVELTYS sales. As a result of the sale of our Commercial Business, we no longer have any commercial products in our portfolio.

Cost of product revenues

We did not have any cost of product revenues during the nine months ended September 30, 2023 due to the sale of our Commercial Business to Alcon in July 2022. Cost of product revenues was $2.6 million for the nine months ended September 30, 2022.

Selling, general and administrative expenses

Selling, general and administrative expenses were $15.9 million for the nine months ended September 30, 2023, compared to $59.2 million for the nine months ended September 30, 2022, which was a decrease of $43.3 million. The decrease in selling, general and administrative expenses for the nine months ended September 30, 2023 was primarily due to the sale of our Commercial Business to Alcon and our related workforce reduction completed during the second half of 2022 and includes a $19.2 million decrease in employee-related expenses, a $18.3 million decrease in external sales and marketing costs and a $1.1 million decrease in stock-based compensation costs. Also contributing to the decrease as compared to the nine months ended September 30, 2022, was a $2.5 million decrease in administrative and professional service fees and a $1.4 million decrease in facility related costs as well as $0.8 million of transaction costs related to the Alcon Transaction incurred in the nine months ended September 30, 2022, which were not incurred in the nine months ended September 30, 2023.

Research and development expenses

The following table summarizes the research and development expenses incurred during the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		
	2023	2022	Change
	(in thousands)		
KPI-012 development costs	$ 5,838	$ 4,698	$ 1,140
Employee-related costs	7,250	7,279	(29)
Other research and development costs	780	2,353	(1,573)
Total research and development	$ 13,868	$ 14,330	$ (462)

Research and development expenses were $13.9 million for the nine months ended September 30, 2023, compared to $14.3 million for the nine months ended September 30, 2022, a decrease of $0.5 million. The decrease was primarily the result of a $1.6 million decrease in other research and development costs, which primarily related to preclinical studies for our former pipeline programs and other facility related costs, partially offset by a $1.1 million increase in KPI-012 development costs.

(Gain) loss on fair value remeasurement of Deferred Purchase Consideration

Gain on fair value remeasurement of Deferred Purchase Consideration for the nine months ended September 30, 2023 was $0.2 million and loss on fair value remeasurement of Deferred Purchase Consideration for the nine months ended September 30, 2022 was $0.2 million, which were primarily due to a change in the fair value of our underlying stock price.

Loss (gain) on fair value remeasurement of contingent consideration

Loss on fair value remeasurement of contingent consideration for the nine months ended September 30, 2023 was $0.5 million primarily due to changes in discount rates, partially offset by changes in the expected timing and probability of payment. Gain on fair value remeasurement of contingent consideration for the nine months ended September 30, 2022 was $1.0 million, and was primarily due to changes in discount rates, partially offset by the passage of time.

Interest income

Interest income was $2.1 million for the nine months ended September 30, 2023 and was $0.3 million for the nine months ended September 30, 2022. Interest income consists of interest earned on our cash, cash equivalents and short-term investments, if any. The increase was attributable to higher interest rates during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, as well as a higher cash balance and the quantity and mix of investments.

Interest expense

We incurred interest expense of $4.3 million for the nine months ended September 30, 2023 and $5.7 million for the nine months ended September 30, 2022. Interest expense for the nine months ended September 30, 2023 and 2022 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, 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. During the nine months ended September 30, 2022, $80.0 million of indebtedness was outstanding under our Loan Agreement until $36.7 million was repaid on July 8, 2022 resulting in an outstanding indebtedness of $43.3 million. While interest expense decreased during the nine months ended September 30, 2023 due to the lower outstanding principal balance, this decrease was partially offset by the variable rate on the debt and the rising interest rates.

Grant income

Grant income for the nine months ended September 30, 2023 was $3.0 million related to the CIRM Award. There was no grant income recognized during the nine months ended September 30, 2022.

Loss on extinguishment of debt

There was no loss on extinguishment of debt for the nine months ended September 30, 2023. The loss on extinguishment of debt was $2.6 million for the nine months ended September 30, 2022. Upon the partial repayment of $36.7 million of indebtedness under our Loan Agreement, the prepayment premium, unaccreted amount of the final payment fee due and a pro-rata portion of the debt discount were recorded as loss on extinguishment of debt for the nine months ended September 30, 2022.

Gain on sale of Commercial Business

There was no gain on sale of Commercial Business for the nine months ended September 30, 2023. The gain on sale of Commercial Business was $47.0 million for the nine months ended September 30, 2022, which was comprised of the $65.0 million in cash consideration received from Alcon less $4.2 million of deferred gain on sale of Commercial business, $11.7 million net book value of assets transferred and $2.1 million of transaction costs.

Other (expense) income, net

Other expense, net was $4.3 million for the nine months ended September 30, 2023 consisting of a $7.6 million expense recorded to assets held for sale to write-off the remaining inventory balance 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.

Other income, net was $0.4 million for the nine months ended September 30, 2022 representing $2.4 million of reimbursable transition related services we provided to Alcon following the sale of the Commercial Business to Alcon, partially offset by a $1.9 million expense recorded for expiring inventory and a loss on the sale of property and equipment of $0.1 million.

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 preferred stock (including our Private Placement), borrowings under credit facilities and our Loan and Security Agreement, or the Loan Agreement, with Oxford Finance LLC, or Oxford Finance, convertible promissory notes and warrants. Upon entry into the CIRM Award in August 2023, Combangio received an initial $5.9 million disbursement from CIRM, and the balance of the $15.0 million award is payable to Combangio upon the achievement of specified milestones.

On May 7, 2020, we filed our shelf registration statement on Form S-3 that was declared effective by the SEC on May 7, 2020, or the 2020 Shelf Registration, under which 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 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, 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 ATM Offering pursuant to the terms of 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. We did not sell any shares of our common stock under the at-the-market offering pursuant to the terms of the Amended and Restated Sales Agreement during the three or nine months ended September 30, 2022.

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 Registration, 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 190,000 shares of our common stock under our at-the-market offering pursuant to 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) our Amended and Restated Sales Agreement and our 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.

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 loans 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 loans bear 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 Asset Purchase Agreement, 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.

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 pursuant to the Asset Purchase Agreement, 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 milestone payments pursuant to the Asset Purchase Agreement. 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.

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 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 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.

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, 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, 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. On January 25, 2023, we paid the Third Amendment Prepayments and the principal loan balance under the Loan Agreement following the Prepayments was $34.0 million.

We paid a facility fee of $0.4 million on the closing date of the Loan Agreement. 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 11, “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 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 which the Lender and Agent consented to our entry into the CIRM Award and certain provisions of the Loan Agreement were amended in connection therewith.

On November 28, 2022, in connection with the Private Placement, we entered into a Securities Purchase Agreement, or the Securities Purchase Agreement, with certain institutional investors names therein, or the 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. Pursuant to the Securities Purchase Agreement, at the first closing of the Private Placement on December 1, 2022, we issued and sold to the 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 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 Purchasers at a second closing of the Private Placement a total of 43,478 shares of Series E Preferred Stock, at a price per share equal to $575.00, for aggregate gross proceeds of approximately $25.0 million. For further information about the Private Placement and the Securities Purchase Agreement, see Item 1, “Business” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

As a result of the acquisition of Combangio, we may be required to pay additional contingent consideration to the former Combangio Equityholders. Pursuant to the Merger Agreement, 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 will be 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, 2022 and Note 5, “Fair Value of Financial Instruments”, of our condensed consolidated financial statements.

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 $5.9 million during the three months ended September 30, 2023. For a further description of the CIRM Award, see “Financial Operations Overview – Grant Income” above.

Our other material cash requirements from known contractual and other obligations as of September 30, 2023 primarily related to our licensing agreement with Stanford University and our operating lease. For information related to our future commitments relating to our licensing agreement, see Note 17, “Commitments and Contingencies”, of our condensed consolidated financial statements. For information related to our operating lease commitments, see Note 10, “Leases”, of our condensed consolidated financial statements.

Cash Flows

As of September 30, 2023 and December 31, 2022, we had $56.1 million and $70.5 million in cash and cash equivalents, respectively. As of September 30, 2023 and December 31, 2022, we had $34.0 million and $43.3 million in indebtedness, respectively, 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,		
	2023	2022	Change
	(in thousands)		
Net cash used in operating activities	$ (20,231)	$ (65,173)	$ 44,942
Net cash (used in) provided by investing activities	(422)	62,666	(63,088)
Net cash provided by (used in) financing activities	5,971	(39,728)	45,699
Decrease in cash and restricted cash	$ (14,682)	$ (42,235)	$ 27,553

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2023 was $20.2 million, compared to $65.2 million for the nine months ended September 30, 2022, a decrease of $44.9 million, primarily due to the decrease in the net loss adjusted for non-cash charges of $37.7 million and a $7.2 million decrease due to the timing of working capital fluctuations. Notable working capital fluctuations included a $15.1 million decrease in accounts receivable due to the collection of receivables and no trade receivables generated in 2023 as a result of the sale of our Commercial Business. Prepaid expenses and other current assets decreased by $5.9 million during the nine months ended September 30, 2023, as compared to an increase of $16.9 million during the nine months ended September 30, 2022, as a result of receivables due from Alcon and third parties in connection with transition related services. Inventory and assets held for sale decreased by $7.6 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, as compared to an increase of $1.0 million during the nine months ended September 30, 2022. These changes in working capital from the period ended September 30, 2022 to September 30, 2023 were partially offset by a decrease of $9.3 million in accounts payable and accrued expenses and other current liabilities due to the timing of payables.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2023 was $0.4 million compared to net cash provided by investing activities of $62.7 million for the nine months ended September 30, 2022, a change of $63.1 million. Net cash used in investing activities for the nine months ended September 30, 2023 primarily 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. Net cash provided by investing activities for the nine months ended September 30, 2022 related to proceeds from the disposition of the Commercial Business, net of transaction costs, of $62.9 million, proceeds from the sales or maturities of short-term investments of $5.0 million and proceeds from the sale of property and equipment of less than $0.1 million, partially offset by the purchases of short-term investments of $5.0 million and purchases of property and equipment and other assets of $0.3 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 was $6.0 million, compared to net cash used in financing activities of $39.7 million for the nine months ended September 30, 2022, a change of $45.7 million. 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 Dosing Milestone reflected in financing activities. Net cash used in financing activities for the nine months ended September 30, 2022 largely consisted of $40.0 million of repayment of principal, prepayment premium and final payment fee on our Loan Agreement, partially offset by $0.3 million of proceeds from the exercise of stock options and the issuance of common stock under our employee stock purchase plan.

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, including our ongoing preclinical studies under our KPI-014 program. If we obtain marketing approval for KPI-012 or any product candidates we may develop in the future, we expect that our selling, 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, 2023, together with the $9.1 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 second 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 funds awarded under the CIRM Award. As a result, we could deplete our available capital resources sooner or later 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;
- obtaining, maintaining and protecting our intellectual property rights; and
- adapting our business in response to any health epidemic event, such as from COVID-19, and its collateral consequences.

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 Agreement, 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 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.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our financial instruments consist primarily of cash equivalents. Our cash equivalents as of September 30, 2023 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, 2023 and 2022, the aggregate principal amount outstanding under the Loan Agreement was $34.0 million and $43.3 million, respectively. 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, 2023. 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, 2023, 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, 2023 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 $8.7 million and $33.6 million for the three and nine months ended September 30, 2023, respectively, and $44.8 million for the year ended December 31, 2022. As of September 30, 2023, we had an accumulated deficit of $620.8 million. Prior to the sale of our 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 preferred stock, borrowings under credit facilities and the Loan and Security Agreement with Oxford Finance LLC, or the Loan Agreement, convertible promissory notes and warrants. Upon entry into the CIRM award in August 2023, Combangio received an initial $5.9 million disbursement from CIRM, and the balance of the $15.0 million award is payable to Combangio upon the achievement of specified milestones. 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 of result of the acquisition of Combangio in November 2021 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, 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 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 ongoing 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 selling, 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.

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.

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.

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.

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 $56.1 million as of September 30, 2023, together with $9.1 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 second 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 funds awarded under the CIRM Award. 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 agreement for our December 2022 private placement, we have agreed that we will not, without the prior approval of the requisite investors in the private placement: (1) issue or authorize the issuance of any equity security that is senior or *pari passu* to the Series E Convertible Non-Redeemable 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.

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.

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, could result in an event of default and acceleration of amounts due.

We have a substantial amount of indebtedness. As of September 30, 2023, 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 loans bear 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, or SOFR, (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. 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 effect our financial condition and ability to pursue our business strategy.

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. In addition to the upfront payment of $60.0 million we received from Alcon at closing, we are eligible to receive 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.

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 inventory, the fair value of warrants, contingent consideration, stock-based compensation, accrued expenses 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. In particular, to report historical product revenue, we estimated the amount of our products that may be returned and presented this amount as a reduction of revenue in the period the related product revenue was recognized, in addition to establishing a liability. If our product return estimates are lower than the actual amount of product returns we experience, our existing reserves will be insufficient to cover future returns. 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.

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 12 patients 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.

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, as such, we may have difficulty identifying and enrolling a sufficient number of patients in our ongoing and planned 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 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 may 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 trials, 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 clinical trials 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.

Combangio has in the past chosen, and we may in the future choose, to conduct one or more of our clinical trials outside the United States. 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, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. In 2020 and 2021, Combangio conducted a Phase 1b clinical trial of KPI-012 for PCED in 12 patients 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. 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.

Public health epidemics, including the COVID-19 pandemic, could impact the development of KPI-012 or any other product candidate we 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. In addition, the FDA ended 22 COVID-19-related policies when the public health emergency ceased on May 11, 2023 and allowed 22 related-policies to continue for 180 days. The FDA plans to retain 24 COVID-19-related policies with appropriate changes and four whose duration is not tied to the end of the public health emergency. 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.

The COVID-19 pandemic had negatively impacted our revenues from INVELTYS. In addition, the COVID-19 pandemic generally had an adverse impact on the launch of pharmaceutical products, and we believe the pandemic impacted our launch of EYSUVIS. We cannot predict whether the COVID-19 pandemic will impact Alcon's ability to commercialize EYSUVIS and INVELTYS, and as a result, we cannot be certain whether the COVID-19 pandemic might adversely affect when we may receive milestone payments from Alcon, which milestone payments we may receive and if we will receive any milestone payments at all.

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.

While the public health emergency declared for the COVID-19 pandemic has terminated, we cannot be certain what the overall impact of the COVID-19 pandemic 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. The uncertainty with respect to the future progression of the COVID-19 pandemic and its long-term effects may adversely impact the accuracy of such estimates and our potential market opportunity for KPI-012.

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. 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 committed to a course of action to terminate 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 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), Recordati S.p.A. (Udonitrectag) 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.

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 standards, commonly referred to as Good Clinical Practices, 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 practices, 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 a significant portion of the award is payable to Combangio 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 timeframe 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. 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.

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.

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. 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. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in 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.

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.

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.

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.

In order to market and sell KPI-012 or any other product candidate we may develop in the European Union and many other jurisdictions, 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.

The terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any potential collaborators we may have in the future, must therefore comply with requirements concerning advertising and promotion for any product candidate for which we obtain marketing approval. Promotional communications with respect to biologic products and medical devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, if any of our product candidates receives marketing approval, the accompanying label may limit the approved use of any other product for which we obtain marketing approval, which could limit sales of such product.

The FDA may also impose requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of risk evaluation and mitigation strategies. The FDA closely regulates the post-approval marketing and promotion of products to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not restrict the marketing of our products only to their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and/or enforcement actions by the FDA, Department of Justice and state Attorneys General alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have various consequences, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions and warnings in the labeling and marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- exclusion and debarment from federal healthcare reimbursement programs; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements or laws of other countries regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's or other countries' requirements regarding the protection of personal information can lead to significant penalties and sanctions. Further, the marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83EC, as amended, and are also subject to EU Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the European Union.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any contract manufacturers we may engage in the future, our future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

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 European Medicines Agency 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 European Medicines Agency, or 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 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 ten 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 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. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

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. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our 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. Moreover, 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.

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;

- 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;

- 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 the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for clinician administered drugs. In addition, this legislation provided authority for limiting the number of products that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Affordable Care Act, or 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 that started in 2013 and, due to subsequent legislative amendments, will stay in effect through 2031. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which was enacted on March 27, 2020, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. Pursuant to subsequent legislation, the reductions were suspended and reduced through the end of June 2022, with the full 2% cut resuming thereafter. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of 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%.

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.

The costs of prescription pharmaceuticals has also been the subject of considerable discussion in the United States, and members of Congress and the Biden Administration have stated that they will address such costs through new legislative and administrative measures. To date, 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 drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for products. For example, on July 9, 2021, President Biden signed an executive order, which focuses on, among other things, the price of pharmaceuticals. The executive order directs the Department of Health and Human Services, or HHS, to create a plan to combat “excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging.” On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (1) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (2) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (3) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The new legislation 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., Inc., 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 U.S. Constitution. Subsequently, other parties, including the U.S. Chamber of Commerce, or Chamber of Commerce, Bristol Myers Squibb Company, the Pharmaceutical Research and Manufacturers of America, Astellas Pharma US, Inc., Novo Nordisk Inc., Janssen Pharmaceuticals, Inc., Novartis Pharmaceutical Corporation, AstraZeneca L.P. and Boehringer Ingelheim Pharmaceuticals, Inc., also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

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. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which 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, at least eleven 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 before the end of 2026. 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 2023 legislative sessions that will go into effect in 2024 and beyond, including New York and New Jersey. 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. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. 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 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 went into effect in May 2018 and 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 EU 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 EU 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 also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses for transfers of personal data from the EEA to the United States. 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 initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022 and the European Commission adopted the adequacy decision on July 10, 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.

Following the withdrawal of the UK from the European Union, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the UK and the European Union have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the UK Data Protection Act and the GDPR, respectively. The UK and the U.S. have also agreed to a US-UK "data bridge", which would function similarly to the EU-U.S. Data Privacy Framework and provide an additional legal mechanism for companies to transfer data from the UK to the United States. Any changes or updates to these developments have 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. 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, 2022, we had federal net operating loss, or NOL, carryforwards of $349.4 million, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030. As of December 31, 2022, we also had state NOL carryforwards of $390.6 million, which may be available to offset future state income tax liabilities and expire at various dates beginning in 2023. As of December 31, 2022, we had no 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 the most recent 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 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, Darius Kharabi, our Chief Business Officer, and Eric L. Trachtenberg, our Chief Legal Officer, Chief Compliance Officer and Corporate Secretary, 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, and our workforce reduction completed during the second half of 2022 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 internal computer 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 General Data Protection Regulation (EU) 2016/679, 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.

We terminated our lease for office and laboratory space at our former corporate headquarters in Watertown, Massachusetts, effective January 11, 2022. While we have retained 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. By migrating to a remote workforce, 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. Furthermore, our transition to a largely remote workplace will increase our 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

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.

Our October 2022 reverse stock split may decrease the liquidity of the shares of our common stock.

The liquidity of the shares of our common stock may be affected adversely by the 1-for-50 reverse stock split we effected in October 2022 given the reduced number of shares that are outstanding following the reverse stock split, which may lead to reduced trading and a smaller number of market makers for our common stock, particularly if the price per share of our common stock is not sustained. In addition, the reverse stock split has increased the number of stockholders who own "odd lots" of less than 100 shares of our common stock. A purchase or sale of less than 100 shares of common stock may result in incrementally higher trading costs through certain brokers, particularly "full service" brokers. Therefore, those stockholders who own fewer than 100 shares of our common stock following the reverse stock split may be required to pay higher transaction costs if they sell their common stock.

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;
- 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.

Sale 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 10, 2023, we had outstanding 2,693,116 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 December 2022, we sold to certain institutional investors shares of our common stock and shares of our Series E Convertible Non-Redeemable Preferred Stock in a private placement. We have filed a registration statement on Form S-3 covering the resale of the common stock held by such investors in the private placement and the common stock issuable upon conversion of the Series E Preferred Stock issued in the private placement, and we have agreed to keep such registration statement 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 will 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.

Our existing stockholders will experience dilution upon any future conversion of the outstanding shares of our Series E Convertible Non-Redeemable Preferred Stock into shares of our common stock.

Each outstanding share of Series E Convertible Non-Redeemable Preferred Stock is initially convertible into 100 shares of our common stock at any time at the option of the holder, subject to certain beneficial ownership limitations. Our existing stockholders will experience dilution upon any future conversion of the outstanding shares of our Series E Convertible Non-Redeemable Preferred Stock into shares of our common stock.

Investors in our December 2022 private placement may have the ability to exercise significant influence over certain of our business decisions.

Pursuant to the terms of the securities purchase agreement for the private placement transaction, investors in the private placement transaction have consent rights over certain significant matters of the Company's business. Specifically, we have agreed that we will not, without the prior approval of the requisite investors (1) issue or authorize the issuance of any equity security that is senior or *pari passu* to the Series E Convertible Non-Redeemable 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. We have also granted the investors in our private placement the right to have our board of directors nominate and recommend for election by the stockholders up to three investor designees to our board of directors, subject to certain requirements and exceptions. In addition, such investors have 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, 2022. As a result, these stockholders, may have the ability to exercise significant influence over certain matters affecting our business.

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 a minimum market value of listed securities or a minimum amount of stockholders equity, or risk delisting, which would have a material adverse effect on our business. 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.

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.

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. Any potential delisting of our common stock from The Nasdaq Capital Market would likely harm our ability to raise capital and may result in the potential loss of confidence by investors and employees and fewer business development opportunities.

In addition, as discussed above, 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, which could adversely effect our financial condition and ability to pursue our business strategy.

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. 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" as of December 31, 2022, 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 agreement entered into with certain institutional investors for our December 2022 private placement 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.

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

On July 14, 2023, we granted stock options to one new employee to purchase a total of 450 shares of our common stock at an exercise price of $14.43 per share and on September 15, 2023, we granted stock options to one new employee to purchase a total of 1,910 shares of our common stock at an exercise price of $10.63 per share. These options were inducement grants made outside of our Amended and Restated 2017 Equity Incentive Plan in accordance with Nasdaq Listing Rule 5635(c)(4) and Section 4(a)(2) of the Securities Act of 1933, as amended. The options have a ten-year term and vest over four years, with 25% of the shares underlying the option awards vesting on the one-year anniversary of the applicable employee's new hire date and the remaining 75% of the shares underlying the award vesting monthly thereafter for three-years. Vesting of the options is subject to the applicable employee's continued service with our company through the applicable vesting dates. We intend to file a registration statement on a Form S-8 to register the shares of common stock underlying these options prior to the time at which these options become exercisable.

Other than as stated above, 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 6. Exhibits

Exhibit Index

EXHIBIT 3.1	Restated Certificate of Incorporation of the Registrant, as amended as of August 2, 2023, including Certificate of Designation of the Series D Preferred Stock of Registrant, Certificate of Elimination of Number of Shares of Preferred Stock Designated as Series D Preferred Stock of Registrant, Certificate of Designations, Preferences and Rights of Series E Convertible Non-Redeemable Preferred Stock of Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)
EXHIBIT 3.2	Third Amended and Restated By-Laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on August 2, 2023)
EXHIBIT 10.1	Fourth Amendment to Loan and Security Agreement, dated August 1, 2023, by and among the Registrant, Combangio, Inc. and Oxford Finance LLC, as collateral agent and lender (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)
EXHIBIT 10.2	Fifth Amendment to Loan and Security Agreement, dated August 2, 2023, by and among the Registrant, Combangio, Inc. and Oxford Finance LLC, as collateral agent and lender (incorporated by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)

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 13, 2023

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

Dated: November 13, 2023

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 13, 2023

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 13, 2023

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, 2023, 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 13, 2023

/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, 2023, 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 13, 2023

/s/ Mary Reumuth

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