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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, 2021
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 PHARMACEUTICALS, 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.)
490 Arsenal Way, Suite 120 **Watertown, MA** (Address of principal executive offices)	**02472** (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 Global Select 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 65,500,275 shares of Common Stock, $0.001 par value per share, outstanding as of November 12, 2021.

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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," "target," "should," "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 financial impact, synergies, growth prospects and benefits of our acquisition of Combangio, Inc., or Combangio, which was completed on November 15, 2021, or the Acquisition, pursuant to the Agreement and Plan of Merger dated November 15, 2021, by and among Ceres Merger Sub, Inc., Combangio and the Combangio equityholder representative, or the Merger Agreement, including the estimated costs and potential realization of the expected benefits from the Acquisition;
- our expectations with respect to, and the amount of, future milestone payments pursuant to the Merger Agreement;
- our expectations with respect to potential advantages of KPI-012 (previously known as CMB-012);
- the anticipated and unanticipated costs, fees, expenses and liabilities related to the Acquisition, including the estimated costs for development of KPI-012;
- our ability to successfully integrate Combangio's business into our business;
- our commercialization efforts for EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25% and INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%;
- our development efforts for our product candidates, including KPI-012, and our ability to discover and develop new programs and product candidates, including those from our receptor Tyrosine Kinase Inhibitor program and novel selective glucocorticoid receptor modulators program;
- the timing, progress and results of clinical trials for KPI-012 and other product candidates, 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 an investigational new drug application and biologics license application for KPI-012 and any other product candidate we develop;
- our estimates regarding potential future revenue from sales of EYSUVIS, INVELTYS and, if approved, KPI-012;
- 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 EYSUVIS, INVELTYS and, if approved, KPI-012;

- our ability to maintain regulatory approvals for EYSUVIS and INVELTYS and our ability to obtain regulatory approvals for KPI-012;
- our expectations regarding our ability to fund our operating expenses, lease and debt service obligations, and capital expenditure requirements with our cash on hand and anticipated revenue from product sales;
- the potential advantages of EYSUVIS, INVELTYS and our product candidates, including KPI-012;
- the rate and degree of market acceptance and clinical utility of our products and KPI-012;
- our estimates regarding the potential market opportunity for EYSUVIS, INVELTYS and our product candidates, including KPI-012;
- plans to pursue the development of KPI-012 for indications in addition to persistent corneal epithelial defects;
- our commercialization, marketing and manufacturing capabilities and strategy for EYSUVIS, INVELTYS and, if approved, KPI-012;
- our intellectual property position, including intellectual property acquired in the 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;
- the impact of COVID-19 on our business and operations; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart our Business Startups Act of 2012.

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, third-party and our own 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 opportunities for EYSUVIS, INVELTYS and our product candidates, including 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.

Risks 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, 2021, we had an accumulated deficit of $494.8 million.
- We may 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 programs or commercialization efforts.
- We may fail to realize the anticipated benefits of our acquisition of Combangio, those benefits may take longer to realize than expected, and we may encounter significant integration difficulties.
- Our substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business.
- The ongoing novel coronavirus pandemic and the efforts to prevent its spread have adversely impacted our operations and the market for INVELTYS, could impact the commercialization of EYSUVIS and the development of KPI-012 and may continue to adversely affect our business, results of operations and financial condition.
- EYSUVIS, INVELTYS, KPI-012 or any other product candidate that receives marketing approval 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.
- Even if we are able to successfully commercialize EYSUVIS, INVELTYS, KPI-012 or any other product candidate that we may develop, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.
- If we are unable to maintain our sales, marketing and distribution capabilities, establish additional capabilities if and when necessary, or enter into sales, marketing and distribution agreements with third

parties, we may not be successful in commercializing EYSUVIS, INVELTYS, 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. EYSUVIS, INVELTYS, KPI-012 and our product candidates will also compete with existing branded, generic and off-label products.

- If we are unable to successfully complete the clinical development of KPI-012 and obtain marketing approval, or experience significant delays in doing so, or if, after obtaining marketing approvals, we fail to commercialize our products and product candidates, our business will be materially harmed.

- We contract with third parties for the manufacture of EYSUVIS, INVELTYS and KPI-012 and plan to contract with third parties for 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 products and product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- We rely, 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 may be unable to obtain and maintain patent protection for our technology, products and 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, products and product candidates may be impaired.

- EYSUVIS, INVELTYS, KPI-012 and certain aspects of our AMPPLIFY technology are protected by patents 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 approved products will be harmed. 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.

- 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.

- Recently enacted and future legislation may affect our ability to commercialize our products and product candidates and the prices we obtain for any products that are approved in the United States or foreign jurisdictions.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

KALA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share and per share amounts)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 124,503	$ 77,264
Short-term investments	—	76,276
Accounts receivable, net	12,630	9,604
Inventory	7,708	5,229
Prepaid expenses and other current assets	4,245	3,006
Total current assets	149,086	171,379
Non-current assets:		
Property and equipment, net	3,142	3,166
Long-term inventory	11,039	6,219
Right-of-use assets	27,339	27,853
Restricted cash and other long-term assets	3,208	12,989
Total assets	$ 193,814	$ 221,606
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,845	$ 1,724
Accrued expenses and other current liabilities	19,465	18,971
Current portion of lease liabilities	1,885	1,530
Total current liabilities	27,195	22,225
Long-term liabilities:		
Long-term lease liabilities	26,659	27,143
Long-term debt	78,491	72,243
Total long-term liabilities	105,150	99,386
Total liabilities	132,345	121,611
Commitments and Contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.001 par value; 120,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 65,085,224 and 58,915,375 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	65	59
Additional paid-in capital	556,224	499,715
Accumulated other comprehensive income	—	4
Accumulated deficit	(494,820)	(399,783)
Total stockholders' equity	61,469	99,995
Total liabilities and stockholders' equity	$ 193,814	$ 221,606

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenues, net	$ 3,067	$ 2,220	$ 9,384	$ 4,124
Costs and expenses:				
Cost of product revenues	908	701	2,679	1,814
Selling, general and administrative	25,349	23,893	81,034	54,602
Research and development	2,881	3,468	9,101	14,955
Total costs and expenses	29,138	28,062	92,814	71,371
Loss from operations	(26,071)	(25,842)	(83,430)	(67,247)
Other income (expense):				
Interest and other income	16	51	92	451
Interest and other expense	(2,072)	(2,157)	(6,304)	(6,419)
Loss on extinguishment of debt	—	—	(5,395)	—
Total interest and other expense	(2,056)	(2,106)	(11,607)	(5,968)
Net loss	$ (28,127)	$ (27,948)	$ (95,037)	$ (73,215)
Net loss per share—basic and diluted	$ (0.43)	$ (0.50)	$ (1.49)	$ (1.44)
Weighted average shares outstanding—basic and diluted	65,050,481	56,030,717	63,766,052	50,851,167
Net loss	$ (28,127)	$ (27,948)	$ (95,037)	$ (73,215)
Other comprehensive loss:				
Change in unrealized gains on investments	—	14	(4)	(3)
Total other comprehensive loss	—	14	(4)	(3)
Total comprehensive loss	$ (28,127)	$ (27,934)	$ (95,041)	$ (73,218)

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended September 30, 2021					
	Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of June 30, 2021	64,770,219	$ 65	$ 550,898	$ —	$ (466,693)	$ 84,270
At the market offering, net of offering costs of $9	114,128	—	333	—	—	333
Issuance of common stock under employee stock purchase plan	200,877	—	906	—	—	906
Stock-based compensation expense	—	—	4,087	—	—	4,087
Net loss	—	—	—	—	(28,127)	(28,127)
Balance as of September 30, 2021	65,085,224	$ 65	$ 556,224	$ —	$ (494,820)	$ 61,469

	Three Months Ended September 30, 2020					
	Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of June 30, 2020	55,831,021	$ 56	$ 469,627	$ (17)	$ (340,723)	$ 128,943
Exercise of stock options	1,500	—	7	—	—	7
Issuance of common stock under employee stock purchase plan	228,844	—	746	—	—	746
Stock-based compensation expense	—	—	4,268	—	—	4,268
Change in fair value of investments	—	—	—	14	—	14
Net loss	—	—	—	—	(27,948)	(27,948)
Balance as of September 30, 2020	56,061,365	$ 56	$ 474,648	$ (3)	$ (368,671)	$ 106,030

See accompanying notes to these unaudited condensed consolidated financial statements.

	Nine Months Ended September 30, 2021					
	Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2020	58,915,375	$ 59	$ 499,715	$ 4	$ (399,783)	$ 99,995
At the market offering, net of offering costs $1,171	5,697,457	6	41,057	—	—	41,063
Exercise of stock options	88,888	—	248	—	—	248
Issuance of vested restricted stock units	107,780	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	275,724	—	1,337	—	—	1,337
Stock-based compensation expense	—	—	13,867	—	—	13,867
Change in fair value of investments	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	(95,037)	(95,037)
Balance as of September 30, 2021	65,085,224	$ 65	$ 556,224	$ —	$ (494,820)	$ 61,469

	Nine Months Ended September 30, 2020					
	Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2019	36,086,254	$ 36	$ 325,112	$ —	$ (295,456)	$ 29,692
At the market offering, net of offering costs of $388	2,352,671	3	12,543	—	—	12,546
Exercise of stock options	312,528	—	945	—	—	945
Common stock offering, net of issuance cost and underwriting fees of $8,475	16,979,371	17	125,406	—	—	125,423
Issuance of common stock under employee stock purchase plan	314,397	—	1,016	—	—	1,016
Stock-based compensation expense	—	—	9,626	—	—	9,626
Warrant exercises	16,144	—	—	—	—	—
Change in fair value of investments	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(73,215)	(73,215)
Balance as of September 30, 2020	56,061,365	$ 56	$ 474,648	$ (3)	$ (368,671)	$ 106,030

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (95,037)	$ (73,215)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	763	674
Non-cash operating lease cost	1,711	1,437
Loss on extinguishment of debt	5,395	—
Amortization of debt discount and other non-cash interest	1,080	782
Stock-based compensation	13,340	9,249
Amortization of discount on available-for-sale securities	22	—
Gain on disposal of property and equipment	(14)	—
Change in operating assets and liabilities:		
Accounts receivable	(3,026)	4,108
Prepaid expenses and other current assets	(1,239)	(223)
Inventory	(6,772)	(1,423)
Accounts payable	4,251	(332)
Accrued expenses and other current liabilities	495	(4,882)
Lease liabilities and other long-term liabilities	(1,300)	(950)
Net cash used in operating activities	(80,331)	(64,775)
Cash flows from investing activities:		
Purchases of property and equipment and other assets	(874)	(1,459)
Proceeds from sale of property and equipment	50	—
Purchases of short-term investments	—	(113,592)
Proceeds from sales or maturities of short-term investments	76,250	—
Net cash provided by (used in) investing activities	75,426	(115,051)
Cash flows from financing activities:		
Proceeds from issuance of debt, net of debt issuance costs of $2,218	77,782	—
Payment of principal, prepayment premium and exit fee on debt	(78,010)	—
Proceeds from common stock offerings, net of offering costs	41,063	137,969
Payment of principal on finance lease	(26)	(24)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	1,585	1,961
Net cash provided by financing activities	42,394	139,906
Net increase (decrease) in cash, cash equivalents and restricted cash:	37,489	(39,920)
Cash, cash equivalents and restricted cash at beginning of period	89,756	98,031
Cash, cash equivalents and restricted cash at end of period	$ 127,245	$ 58,111
Reconciliation of cash, cash equivalents and restricted cash:		
Cash, cash equivalents, and restricted cash at end of period	$ 127,245	$ 58,111
Less restricted cash (Notes 8 and 9)	(2,742)	(12,585)
Cash and cash equivalents at end of period	$ 124,503	$ 45,526
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable	$ —	$ 34
Supplemental disclosure:		
Cash paid for interest	$ 5,200	$ 5,636
Right-of-use assets obtained in exchange of operating lease obligations	1,211	—

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA PHARMACEUTICALS, 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 Pharmaceuticals, Inc. (the "Company") was incorporated on July 7, 2009, and is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for diseases of the eye. The Company has applied its AMPPLIFY® mucus-penetrating particle ("MPP") Drug Delivery Technology to loteprednol etabonate ("LE"), a corticosteroid designed for ocular applications, resulting in the U.S. Food and Drug Administration's (the "FDA") approval of 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% as the first and only topical twice-daily ocular corticosteroid for treatment of post-operative inflammation and pain following ocular surgery.

In January 2019, the Company launched its first commercial product, INVELTYS, in the United States and began shipping its second commercial product, EYSUVIS, to wholesalers in the United States in late December 2020 with the full promotional launch commencing in early January 2021. The Company is engaged in the commercialization of EYSUVIS and INVELTYS, research and development activities for its product candidates, including KPI-012 for the treatment of persistent corneal epithelial defects, raising capital and recruiting skilled personnel. The Company is subject to a number of risks similar to those of other companies conducting high-risk, research and development of pharmaceutical product candidates and launching products for the first time. Principal among these risks are dependence on key individuals and intellectual property, competition from other products and companies and the technical risks associated with the successful research, development and marketing of its product candidates. The Company's success is dependent upon its ability to successfully commercialize its products, the success of its research and development efforts, its ability to obtain regulatory approval of its product candidates, its ability to raise additional capital when needed and, ultimately, attain profitable operations.

The Company is also progressing its pipeline of proprietary preclinical development programs targeted to address front and back of the eye diseases. These preclinical development programs, all of which are new chemical entities, include its receptor Tyrosine Kinase Inhibitor program, that is designed to inhibit the vascular endothelial growth factor pathway, for the treatment of retinal diseases, including wet age-related macular degeneration; and its selective glucocorticoid receptor modulators, which are a novel class of therapies designed to modify the downstream activity of the receptors to exhibit the anti-inflammatory and immunomodulatory properties of the corticosteroid class of therapies without their associated side effects. The Company owns all intellectual property and worldwide rights to these pipeline preclinical development programs.

Liquidity— Since inception, the Company has incurred significant losses from operations and negative cash flows from operations. As of September 30, 2021, the Company had an accumulated deficit of $494,820. As the Company commenced a full promotional launch of EYSUVIS in early January 2021 and commercially launched its first product, INVELTYS, in January 2019, it has had only limited revenues to date from product sales and has financed operations primarily through proceeds from its initial public offering of common stock ("IPO"), follow-on public common stock offerings and sales of its common stock under its at-the-market offering ("ATM Offering") facility, private placements of preferred stock, borrowings under credit facilities, convertible promissory notes and warrants. The Company has devoted substantially all of its financial resources and efforts to research and development, including preclinical studies and clinical trials, and engaging in activities to commercialize EYSUVIS and INVELTYS. Although the Company expects to continue to generate revenue from sales of EYSUVIS and INVELTYS, there can be no assurance as to the amount or timing of any such revenue, and it expects to continue to incur significant expenses and operating losses. Net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

The Company expects that its cash and cash equivalents as of September 30, 2021, together with anticipated net revenue from sales of EYSUVIS and INVELTYS, will enable it to fund its operating expenses, 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. As a result, the Company could deplete its available capital resources sooner than it currently expects.

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

COVID-19 –In order to safeguard the health of its employees from the ongoing novel coronavirus pandemic, or COVID-19, the Company is following, and will continue to follow, recommendations from the U.S. Centers for Disease Control and Prevention, as well as federal, state and local governments, regarding working-from-home practices for non-essential employees. The Company previously suspended its sales force from substantially all in-person interactions with physicians and was limited to conducting educational and promotional activities virtually. Commencing in the fourth quarter of 2020, the Company's sales force resumed substantially all in-person interactions in the field, but if the Company suspends all or some in-person interactions with physicians in the future, or to the extent physicians limit in-person interactions, the Company may be limited to conducting educational and promotional activities virtually, which may continue to hamper its ability to market and commercialize EYSUVIS and INVELTYS.

In addition, government restrictions have at times led to moratoria on elective ocular surgeries in many jurisdictions, which had significantly reduced, and may in the future continue to significantly reduce, the demand for INVELTYS, which is indicated for the treatment of post-operative inflammation and pain following ocular surgery. The extent of the impact of the COVID-19 pandemic on the Company's commercialization efforts of EYSUVIS and INVELTYS and its operational and financial performance will depend on certain developments, including the length and severity of this pandemic, the timing and extent of any resurgence of the COVID-19 virus or any variant strains of the virus, the availability and effectiveness of vaccines, and the impact of the foregoing on its customers, employees and vendors and government agencies, all of which are uncertain and cannot be predicted. The Company cannot reasonably estimate the extent to which the disruption may materially impact its condensed consolidated results of operations or financial position.

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 and the recoverability of the Company's net deferred tax assets and related valuation allowance. Actual results may differ from these estimates under different assumptions or conditions.

Net Loss per Share—Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share 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 and the issuance of unvested restricted stock units ("RSUs") and performance-based restricted stock units ("PSUs").

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 and unvested RSUs and PSUs. Common stock equivalent shares are excluded from the computation of diluted net loss per share 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 each of the three and nine months ended September 30, 2021 and 2020.

As of September 30, 2021 and 2020, potentially dilutive securities excluded from the calculation of diluted net loss per share because including such securities would have an anti-dilutive effect consisted of outstanding options to purchase 10,172,896 and 8,516,163 shares of the Company's common stock, respectively, an aggregate of 1,252,737 and 946,767 unvested RSUs and PSUs, respectively, and an aggregate of 215,172 and 248,505 unexercised warrants, respectively.

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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, 2020 (the "Annual Report").

The unaudited condensed consolidated financial statements include the accounts of Kala Pharmaceuticals, Inc. and its wholly owned subsidiary, Kala Pharmaceuticals Security Corporation. 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 ended September 30, 2021.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 significantly changes the impairment model for most financial assets and certain other instruments. ASU 2016-13 will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets, which will generally result in earlier recognition of allowances for credit losses on loans and other financial instruments. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)* ("ASU 2019-10"), which is effective for Smaller Reporting Companies ("SRCs") as defined by the SEC for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Upon adoption, beginning January 1, 2023, the Company does not expect ASU 2019-10 to have a material effect on its condensed consolidated financial statements.

3. FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company from time to time has short-term investments which are considered financial instruments that are measured on a recurring basis. 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.

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The Company's financial instruments as of September 30, 2021 consisted primarily of cash equivalents. The Company's financial instruments as of December 31, 2020 consisted primarily of cash equivalents and short-term investments in money market funds and short-term securities. Cash equivalents and short-term investments are reported at their respective fair values on the Company's condensed consolidated balance sheets. See Note 4, "Investments" for additional information.

The following tables set forth the fair value of the Company's financial assets by level within the fair value hierarchy as of September 30, 2021 and December 31, 2020:

	September 30, 2021			
	Fair Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 106,128	$ 106,128	$ —	$ —
Total Assets	$ 106,128	$ 106,128	$ —	$ —

	December 31, 2020			
	Fair Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 63,811	$ 63,811	$ —	$ —
Short-term investments	76,276	76,276	—	—
Total Assets	$ 140,087	$ 140,087	$ —	$ —

During the three and nine months ended September 30, 2021 and the year ended December 31, 2020, there were no transfers between Level 1, Level 2, and Level 3.

4. INVESTMENTS

The Company held no short-term investments as of September 30, 2021. Investments by security type consisted of the following as of December 31, 2020:

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 26,744	$ 2	$ —	$ 26,746
U.S. government agencies securities	49,528	2	—	49,530
Total	$ 76,272	$ 4	$ —	$ 76,276

As of December 31, 2020, all of the Company's investments had a contractual maturity within one year. The fair value of all of the Company's investments are classified as short-term on its condensed consolidated balance sheets.

5. REVENUE & ACCOUNTS RECEIVABLE, NET

The Company accounts 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 performs 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 recognizes revenue when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer.

Product revenues, net

The Company sells EYSUVIS and INVELTYS primarily to wholesalers in the United States (collectively, "Customers"). These Customers subsequently resell the Company's products to specialty and other retail pharmacies. In addition to agreements with Customers, the Company enters into arrangements with third-party payors that provide 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 represent a single performance obligation. The Company recognizes revenue from product sales at the point the Customer obtains control of the product, which occurs upon delivery. The transaction price ("net sales price") that is recognized as revenue for product sales includes the selling price to the Customer and an estimate of variable consideration. Components of variable consideration include 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 is not received. Variable consideration is 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 considers all relevant information when estimating variable consideration such as assessment of its 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 are reasonably available. The Company includes estimated amounts for variable consideration in the net sales price to the extent it is determined probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved.

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

Reserves for Variable Consideration:

Trade Discounts and Allowances

The Company provides 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 are based on contractually-determined percentages and are recorded as a reduction of revenue and accounts receivable in the period in which the related product revenue is 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 purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Reserves for chargebacks consist of credits the Company expects to issue for units that remain in the distribution channel at the end of each reporting period and that the Company expects will be

sold to qualified healthcare providers, as well as chargebacks that Customers have claimed, but for which the Company has 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 estimates the amount of its products that may be returned and presents this amount as a reduction of revenue in the period the related product revenue is recognized, in addition to establishing a liability. The Company's estimates for product returns are 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 develop over time.

Commercial Payor and Medicare Part D Rebates

The Company contracts 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 are based on contractual percentages applied to the amount of product prescribed to patients who are covered by the PBMs or the Plans with which it contracts. The Company estimates 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 will be made for product that has been recognized as revenue but remains in the distribution channel at the end of each reporting period. The Company also estimates the number of patients in the prescription drug coverage gap for whom it will owe an additional liability under the Medicare Part D program. Such estimates are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Government Rebates

The Company is subject to discount obligations under Medicaid and other government programs. For Medicaid, reserves are 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 consists of estimates of claims for the current period and estimated future claims that will be made for product that has been recognized as revenue but remains in the distribution channel at the end of each reporting period. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Co-pay Assistance Programs

The Company offers co-pay assistance programs (the "co-pay programs"), which are 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 is based on actual claims processed during the period as well as an estimate of the number and cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel at the end of each reporting period. Allowances for estimated co-pay claims are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

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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, 2021 and 2020:

	Trade Discounts, Allowances and Chargebacks (1)	Product Returns (2)	Rebates and Incentives (3)
Balance as of December 31, 2020	$ 1,157	$ 600	$ 4,904
Provision related to current period sales	2,201	245	10,216
Changes in estimate related to prior period sales	3	30	(26)
Credit/payments made	(1,823)	(419)	(7,880)
Balance as of March 31, 2021	$ 1,538	$ 456	$ 7,214
Provision related to current period sales	2,103	356	11,193
Changes in estimate related to prior period sales	30	142	(353)
Credit/payments made	(2,260)	(253)	(9,801)
Balance as of June 30, 2021	$ 1,411	$ 701	$ 8,253
Provision related to current period sales	2,137	490	11,686
Changes in estimate related to prior period sales	18	109	(647)
Credit/payments made	(2,110)	(632)	(9,861)
Balance as of September 30, 2021	$ 1,456	$ 668	$ 9,431

	Trade Discounts, Allowances and Chargebacks (1)	Product Returns (2)	Rebates and Incentives (3)
Balance as of December 31, 2019	$ 1,783	$ 180	$ 10,044
Provision related to current period sales	725	—	4,576
Changes in estimate related to prior period sales	2	(66)	93
Credit/payments made	(1,114)	—	(8,090)
Balance as of March 31, 2020	$ 1,396	$ 114	$ 6,623
Provision related to current period sales	335	—	2,194
Changes in estimate related to prior period sales	3	(51)	(234)
Credit/payments made	(1,336)	1	(3,013)
Balance as of June 30, 2020	$ 398	$ 64	$ 5,570
Provision related to current period sales	1,235	—	7,584
Changes in estimate related to prior period sales	(1)	(1)	(93)
Credit/payments made	(815)	1	(6,347)
Balance as of September 30, 2020	$ 817	$ 64	$ 6,714

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

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

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

(In thousands, except share and per share amounts)

Accounts Receivable, net

Accounts receivable are reported on the condensed consolidated balance sheets at outstanding amounts due from Customers for product sales. The Company deducts sales discounts for prompt payments and other discounts, contractual fees for service arrangements and chargebacks from accounts receivable. The Company evaluates the collectability of accounts receivable on a regular basis, by reviewing the financial condition and payment history of Customers, an overall review of collections experience on other accounts, and economic factors or events expected to affect future collections experience. An allowance for doubtful accounts is recorded when a receivable is deemed to be uncollectible.

The Company recorded no allowance for doubtful accounts as of September 30, 2021 or December 31, 2020. The Company recorded an allowance of $1,456 and $1,157 for expected sales discounts, related to prompt pay discounts and other discounts, contractual fee for service arrangements and chargebacks, to wholesalers and distributors as of September 30, 2021 and December 31, 2020, respectively.

6. INVENTORY

Inventory consists of the following:

	September 30, 2021	December 31, 2020
Raw materials	$ 1,328	$ 801
Work in progress	11,888	6,437
Finished goods	5,531	4,210
Total inventory	$ 18,747	$ 11,448

As of September 30, 2021, the Company had $7,708 of current inventory and $11,039 of long-term inventory. As of December 31, 2020, the Company had $5,229 of current inventory and $6,219 of long-term inventory.

7. ACCRUED EXPENSES

Accrued expenses consist of the following:

	September 30, 2021	December 31, 2020
Compensation and benefits	$ 8,648	$ 9,676
Accrued revenue reserves (1)	6,696	5,224
Commercial costs	2,125	2,103
Professional services	706	926
Contract manufacturing	622	336
Development costs	114	154
Other	554	552
Accrued expenses	$ 19,465	$ 18,971

(1) There were additional revenue reserves included in accounts payable of $3,402 and $280, as of September 30, 2021 and December 31, 2020, respectively.

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8. LEASES

Operating leases

In connection with the lease of the Company's corporate headquarters (the "Watertown Lease"), the Company issued a letter of credit to the landlord for $2,042. The Company secured the letter of credit for the full amount of the letter with cash on deposit, which is reported as restricted cash on the condensed consolidated balance sheets as of September 30, 2021 and December 31, 2020.

For the three and nine months ended September 30, 2021, the variable lease expense for the Watertown Lease, which includes common area maintenance and real estate taxes, was $354 and $1,050, respectively. For the three and nine months ended September 30, 2020, the variable lease expense for the Watertown Lease, which includes common area maintenance and real estate taxes, was $363 and $1,472, respectively. The remaining lease term was 10.1 years as of September 30, 2021.

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 65 vehicles. In connection with the Vehicle Fleet Lease, the Company issued a letter of credit for $450, which was reported as restricted cash on the condensed consolidated balance sheets as of September 30, 2021 and December 31, 2020. The lease has an expected term of three years, which commenced upon the delivery of the vehicles in March 2019.

During the nine months ended September 30, 2021, the Company modified the Vehicle Fleet Lease to add 54 additional vehicles to the fleet. The new component of the lease has an expected term of approximately three years, which commenced upon the delivery of the additional vehicles in March 2021.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Lease cost				
Operating lease cost	$ 1,266	$ 1,185	$ 3,750	$ 3,556
Variable lease cost	528	404	1,621	1,472
Total lease cost	$ 1,794	$ 1,589	$ 5,371	$ 5,028
Operating cash outflows from operating leases	$ 1,675	$ 1,431	$ 4,918	$ 4,561

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

	September 30, 2021	December 31, 2020
Weighted average remaining lease term	9.7 years	10.3 years
Weighted average discount rate	9.6%	9.8%

9. DEBT

Athyrium Credit Facility

On October 1, 2018, the Company entered into a credit agreement (the "Athyrium Credit Facility") with Athyrium Opportunities III Acquisition LP ("Athyrium") for up to $110,000. The Athyrium Credit Facility provided for a Term Loan A in the aggregate principal amount of $75,000 (the "Term Loan A"), and a Term Loan B in the aggregate principal amount of $35,000 (the "Term Loan B"). On October 1, 2018, the Company borrowed the entire principal amount of the Term Loan A. The maturity date of the Athyrium Credit Facility was October 1, 2024, the six-year anniversary of the close.

As of December 31, 2020, the unpaid principal balance under the Athyrium Credit Facility was $75,000 and the unamortized debt discount was $3,088. On May 4, 2021, the Company repaid all amounts owed under the Athyrium Credit Facility and terminated all commitments by Athyrium to extend further credit thereunder and all guarantees and security interests granted by the Company to the lenders thereunder. In connection with the termination of the Athyrium Credit Facility, the Company paid to the lenders a prepayment premium of $2,250 and an exit fee of $750. The transaction resulted in a loss on extinguishment of debt of $5,395, consisting of the prepayment premium, the unamortized debt discount and issuance costs and the unaccreted exit fee. Additionally, the Company released $10,000 of restricted cash previously recorded to comply with a financial covenant required by the Athyrium Credit Facility.

Loan and Security Agreement

On May 4, 2021 (the "Closing Date"), the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC, 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 is available to the Company, consisting of (i) a tranche A term loan that was disbursed on the Closing Date in the aggregate principal amount of $80,000; (ii) a contingent tranche B term loan in the aggregate principal amount of $20,000 available to the Company through June 30, 2023 and within 90 days of the Company achieving trailing 6-month product revenue equal to or greater than $75,000, subject to certain other terms and conditions; and (iii) a contingent tranche C term loan in the aggregate principal amount of $25,000 available to the Company through December 31, 2023 and within 90 days of the Company achieving trailing 6-month product revenue equal to or greater than $100,000, subject to certain other terms and conditions. The Company utilized substantially all of the proceeds from the tranche A term loan to repay the Athyrium Credit Facility (as more fully described above).

The term loans bear interest at a floating rate equal to the greater of (i) 30-day LIBOR and (ii) 0.11%, plus 7.89%. The Loan Agreement provides 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 are 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 is due and payable in full on May 1, 2026 (the "Maturity Date").

The Company paid a facility fee of $400 on the Closing Date 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 prepay all, but not less than all, of the outstanding loans, subject to a prepayment fee equal to the following percentage of the principal amount being prepaid: 3.00% if an advance is prepaid during the first 12 months following the applicable advance date, 2.00% if an advance is prepaid after 12 months but prior to 24 months following the

(In thousands, except share and per share amounts)

applicable advance date, and 1.00% if an advance is prepaid any time after 24 months following the applicable advance date but prior to the Maturity Date.

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. 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, 2021. 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.

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 were amortized using the effective interest method over the term of the Loan Agreement. The amortization of debt discount and debt issuance cost is included in interest expense within the condensed consolidated statements of operations and comprehensive loss. As of September 30, 2021, the effective interest rate was 10.41%, 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, 2021, the Company recognized interest expense of $1,746 for the Loan Agreement and during the three months ended September 30, 2020, the Company recognized interest expense of $2,125 for the Athyrium Credit Facility. This consisted of amortization of debt discount of $110 and $232 for the periods ended September 30, 2021 and September 30, 2020, respectively, and the contractual coupon interest expense of $1,636 and $1,893 for the periods ended September 30, 2021 and September 30, 2020, respectively. During the nine months ended September 30, 2021 and September 30, 2020, the Company recognized interest expense of $5,698 and $6,308, respectively, for the Loan Agreement and the Athyrium Credit Facility. This consisted of amortization of debt discount of $501 and $671 for the periods ended September 30, 2021 and September 30, 2020, respectively, and the contractual coupon interest expense of $5,197 and $5,637 for the periods ended September 30, 2021 and September 30, 2020, respectively.

The components of the carrying value of the debt as of September 30, 2021 and December 31, 2020 are detailed below:

	September 30, 2021	December 31, 2020
Principal loan balance	$ 80,000	$ 75,000
Unamortized debt discount and issuance cost	(2,039)	(3,088)
Cumulative accretion of exit fee	530	331
Long-term debt, net	$ 78,491	$ 72,243

(In thousands, except share and per share amounts)

The annual principal payments due under the Loan Agreement as of September 30, 2021 were as follows:

Years Ending December 31,	
2021 (remaining three months)	$ —
2022	—
2023	—
2024	4,445
2025	53,333
Thereafter	22,222
Total	$ 80,000

10. WARRANTS

The following table summarizes the common stock warrants outstanding as of September 30, 2021 and December 31, 2020, each exercisable into the number of shares of common stock set forth below as of the specified dates:

Issued	Exercise Price	Expiration Date	Exercisable From	Shares Exercisable at September 30, 2021	Shares Exercisable at December 31, 2020
2013	$ 7.50	April 2021	July 2017	—	33,333
2014	$ 7.50	November 2024	July 2017	16,000	16,000
2016	$ 8.27	October 2026	September 2017	14,512	14,512
2018	$ 12.18	October 2025	October 2018	184,660	184,660
				215,172	248,505

11. EQUITY FINANCINGS

On August 9, 2018, the Company filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on August 27, 2018 (the “2018 Shelf Registration”). Under the 2018 Shelf Registration, the Company could initially offer and sell up to $250,000 of a variety of securities including common stock, preferred stock, warrants, depositary shares, debt securities, purchase contracts, purchase units or any combination of such securities during the three-year period that commenced upon the 2018 Shelf Registration becoming effective.

In connection with the filing of the 2018 Shelf Registration, the Company entered into a sales agreement (the “2018 Sales Agreement”) with Jefferies, LLC (“Jefferies”) pursuant to which the Company may issue and sell, from time to time, up to an aggregate of $50,000 of its common stock in an ATM Offering through Jefferies, as sales agent. Through the first quarter of 2020, the Company issued an aggregate of 4,945,605 shares of its common stock under the ATM Offering, resulting in net proceeds to the Company of $25,605. On March 10, 2020, the Company notified Jefferies that it was suspending and terminating the prospectus related to the 2018 Sales Agreement.

On March 11, 2020, the Company sold 16,000,000 shares of its common stock (the “2020 Offering Shares”) in an underwritten offering (the “2020 Offering”), pursuant to the 2018 Shelf Registration, at a public offering price of $7.89 per share, resulting in net proceeds of $118,207, after underwriting discounts, commissions, and offering expenses. In addition, the underwriters of the 2020 Offering were granted the option for a period of 30 days to purchase up to an additional 2,400,000 shares of common stock offered in the public offering at the public offering price, less underwriting discounts, commissions and offering expenses. On April 3, 2020, the underwriters exercised their option and purchased an additional 979,371 shares of common stock at $7.89 per share, resulting in net proceeds to the Company of $7,216, after underwriting discounts, commissions, and offering expenses. The total number of shares sold by the Company in the 2020 Offering was 16,979,371, resulting in total net proceeds to the Company, after underwriting discounts, commissions, and offering expenses, of $125,423. Under the 2018 Shelf Registration, which expired in

(In thousands, except share and per share amounts)

August 2021, the Company issued an aggregate of 30,549,976 shares of common stock, including under the ATM Offering, resulting in aggregate gross proceeds of $231,666.

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 with Jefferies pursuant to which it may issue and sell, from time to time, up to an aggregate of $75,000 of its common stock under its ATM Offering through Jefferies, as a sales agent. During the fourth quarter of 2020, the Company issued an aggregate of 2,821,059 shares of its common stock under the ATM Offering, resulting in net proceeds of $20,612. During the three and nine months ended September 30, 2021, the Company issued and sold an additional 114,128 and 5,697,457 shares of its common stock under its ATM Offering, respectively, resulting in net proceeds of $332 and $41,063, respectively. As of September 30, 2021, there was $11,517 of shares of common stock remaining under the ATM Offering and, excluding the shares of common stock that may be offered under the ATM Offering, there was approximately $275,000 of securities available to be issued under the 2020 Shelf Registration.

12. STOCK-BASED COMPENSATION

During the nine months ended September 30, 2021, the Company granted options for the purchase of 1,936,964 shares of common stock including 430,700 non-statutory stock options granted to new employees and 556,333 restricted stock units. In January 2021 and July 2021, employees of the Company purchased an aggregate of 74,847 and 200,877 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, 2021 are as follows:

	Nine Months Ended September 30, 2021
Expected volatility	72.7% – 74.2%
Risk-free interest rate	0.50% – 1.07%
Expected dividend yield	0%
Expected term (in years)	5.13 – 6.10

During the nine months ended September 30, 2021, the weighted average grant-date fair value of options granted was $3.98.

In June 2020, the Company issued 693,537 PSUs to certain executives and other employees tied to certain performance criteria, which will vest, if at all, as to 50% on the first anniversary of satisfying the performance criteria and the remaining 50% vesting upon the second anniversary of satisfying the performance criteria. The Company has determined that the performance criteria for these awards has been achieved but not all of the awards have vested as of September 30, 2021. As of September 30, 2021, a total of 1,340,737 RSUs and PSUs were outstanding, consisting of 1,252,737 unvested shares and 88,000 vested and deferred shares.

(In thousands, except share and per share amounts)

Stock-based compensation expense was classified in the condensed consolidated statements of operations and comprehensive loss as follows for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of product revenues	$ 38	$ 32	$ 109	$ 60
Research and development	869	985	2,821	2,259
Selling, general and administrative	3,021	3,244	10,410	6,930
Total	$ 3,928	$ 4,261	$ 13,340	$ 9,249

13. INCOME TAXES

The Company did not record a provision or benefit for income taxes during the three and nine months ended September 30, 2021 and 2020. 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 has materially limited the net operating loss carryforwards and research and development tax credits available to offset future tax liabilities. The Company may be further limited by any changes that may have occurred or may occur subsequent to December 31, 2020.

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, 2021 and December 31, 2020, 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, 2021 and 2020.

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

14. COMMITMENTS AND CONTINGENCIES

License Agreement—In 2009, the Company entered into an exclusive license agreement with The Johns Hopkins University ("JHU"), as amended in November 2012, May 2014, August 2014, October 2014, June 2018 and July 2020, which licensed to the Company a portfolio of specified patent rights and remains in full force and effect. Pursuant to the terms of the agreement, as amended, the Company agreed to pay an initial license fee, minimum annual payments beginning in 2017, certain development and commercial milestone payments, royalties on product sales and reimburse all or a portion of the costs associated with the preparation, filing, prosecution and maintenance of the agreed-upon patents and patent applications to JHU.

After 2016 and until the first commercial sale of product, which occurred in January 2019, the minimum annual payment was $38. Upon the first commercial sale of INVELTYS, the annual minimum payment increased to $113. The Company is obligated to pay JHU low single-digit running royalties based upon a percentage of net sales of the licensed products, which is applied to the annual minimum payment. The Company also has an obligation to pay JHU certain one-time development and commercial milestone payments. During the three months ended September 30, 2021 and 2020, the Company paid JHU $31 and $8, respectively, in royalty payments associated with the sales of EYSUVIS and INVELTYS. During the nine months ended September 30, 2021 and 2020, the Company paid JHU $86 and $44, respectively, in royalty payments associated with the sales of EYSUVIS and INVELTYS. The Company paid JHU a $150 milestone payment during the nine months ended September 30, 2021, which was triggered by the first commercial sale of EYSUVIS in the United States in December 2020.

The Company recorded other expenses related to the JHU agreement of $6 and $44 for the three months ended September 30, 2021 and 2020, respectively. The Company recorded a credit for other expenses related to the JHU agreement of $23 and other expenses of $121 for the nine months ended September 30, 2021 and 2020, respectively.

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

Other Commitments — The Company entered into a commercial supply agreement with Woodstock Sterile Solutions, Inc. (formerly known as Catalent Pharma Solutions, LLC) to manufacture commercial supplies of EYSUVIS and INVELTYS.

The Company has the following remaining minimum purchase obligations for EYSUVIS and INVELTYS as of September 30, 2021:

Years Ending December 31,	
2021 (remaining three months)	$ 1,090
2022	5,276
2023	6,285
2024	7,875
2025 (1)	8,199
Thereafter (1)	17,925
Total minimum purchase commitments	$ 46,650

(1) The minimum contract amount for the years included here are 75% of the actual dollar value of the units ordered for EYSUVIS and INVELTYS, in the aggregate, in the minimum requirement year immediately prior to the applicable minimum requirement year. The table above assumes actual units are consistent with the purchase commitments for these years.

15. SUBSEQUENT EVENTS

Combangio Acquisition

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 "Acquisition"). Combangio is a clinical-stage biotechnology company focused on developing regenerative biotherapeutics for severe ocular diseases based on mesenchymal stem cell ("MSCs") secretomes, including, its lead product candidate, CMB-012 for the treatment of persistent corneal epithelial defects ("PCED"). Following the Acquisition, the Company refers to CMB-012 as KPI-012.

In connection with the closing of the Acquisition on November 15, 2021 (the "Closing"), the Company made an upfront payment of an aggregate of $5,000 in cash to former Combangio stockholders and other equityholders (the "Combangio Equityholders"), subject to customary adjustments, and agreed to issue an aggregate of 7,788,667 shares (the "Post-Closing Stock Consideration") of the Company's common stock, $0.001 par value per share (the "Common Stock"), to the Combangio Equityholders with an aggregate value of approximately $16,123, consisting of (i) an aggregate of 6,815,129 shares of Common Stock to be issued on January 3, 2022 and (ii) an aggregate of 973,538 shares of Common Stock that will be held back by the Company and will be issuable subject to the terms of the Merger Agreement to the Combangio Equityholders on the Escrow Release Date (as defined below) (the "Initial Holdback Shares"). The aggregate value of the Post-Closing Stock Consideration was calculated using the closing price of the Company's Common Stock on the Nasdaq Global Select Market on November 12, 2021, the last trading day prior to the Closing.

In addition, pursuant to the Merger Agreement, the Combangio Equityholders, in the aggregate and subject to the terms and conditions of the Merger Agreement, will also be entitled to receive from the Company the following contingent consideration (the "Contingent Consideration"):

- up to $105,000 in contingent milestone consideration, of which (i) $2,300 would become payable in cash and $2,700 would be payable in shares of the Company's Common Stock upon the first patient dosed with any product candidate whose active ingredient comprises one or more biological factors secreted by MSCs or their progenitors, including KPI-012 (the "Product Candidate") in a Phase 2 clinical trial (the "Dosing Milestone"), (ii) $2,300 would become payable in cash and $2,700 would be payable in shares of the Company's Common Stock upon the first patient dosed with a Product Candidate in a pivotal clinical trial, (iii) $12,500 would become payable in cash (with up to $6,250 payable, at the option of the Company, in shares of the Company's Common Stock and the remainder in cash) upon regulatory approval by the U.S. Food and Drug Administration (the "FDA") of marketing and sale of a Product Candidate in the United States, subject to certain specified reductions (the "BLA Approval Milestone"); (iv) $17,500 would become payable in cash (with up to $8,750 payable, at the option of the Company, in shares of the Company's Common Stock and the remainder in cash) upon the first commercial sale of a Product Candidate in the United States, subject to certain specified reductions (the "Commercialization Milestone"), and (v) an aggregate of up to $65,000 would become payable in cash upon the achievement of specified sales milestones;
- tiered cash royalties at percentage rates in the mid-to-high single digits payable on annual net sales of all Product Candidates; and
- a cash payment at a percentage rate in the high single digits of all income, including earnout payments, received by the Company or any of its affiliates from a product license granted by the Company to a third party to sell or otherwise commercialize the Product Candidate in countries where neither the Company nor its affiliates conduct sales of such Product Candidate, subject to certain exceptions set forth in the Merger Agreement.

The portion of any payment of Contingent Consideration payable in shares of the Company's Common Stock is referred to herein as "Contingent Stock Consideration" and the portion of any payment of Contingent Consideration payable in cash is referred to herein as "Contingent Cash Consideration".

If the issuance of the Post-Closing Stock Consideration or any Contingent Stock Consideration would result in the aggregate number of shares of the Company's Common Stock issued under the Merger Agreement equaling or exceeding 19.9% of the total number of shares of the Company's Common Stock issued and outstanding immediately prior to the Closing (the "Share Cap"), then the Company will be required to pay the portion of the Post-Closing Stock Consideration or any Contingent Stock Consideration in excess of the Share Cap in cash. If the aggregate amount of Contingent Cash Consideration payable in any calendar year (after giving effect to the Share Cap) exceeds $2,500 (the "Excess Cash Cap"), such excess portion ("Carry Forward Contingent Cash Consideration") will be carried forward and, subject to application of the Excess Cash Cap in the following calendar year, become payable on the first business day of the following calendar year. Any Carry Forward Contingent Cash Consideration outstanding on June 1, 2026 is payable in full on June 1, 2026.

The Company is currently evaluating the initial accounting for this acquisition.

Watertown Lease Termination

In November 2021, the Company entered into a Lease Termination Agreement to accelerate the lease termination date for the Company's corporate headquarters in Watertown, Massachusetts to December 31, 2021 (the "Lease Termination Date"). Under the terms of the Lease Termination Agreement, subject to the landlord entering into a new lease amendment with a new tenant on terms and conditions acceptable to the landlord, the Company will receive a payment of $2,000 from its landlord. The Company is obligated to make rent payments outlined in the existing lease agreement until the Lease Termination Date.

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, 2020, which was filed with the Securities and Exchange Commission on February 25, 2021.

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.

We are a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for diseases of the eye. We have worldwide rights to a portfolio of innovative products and product candidates that include two marketed therapies utilizing our proprietary mucus-penetrating particle, or MPP, drug delivery technology, which we refer to as our AMPPLIFY® technology, to address medical needs for the front of the eye, and a pipeline of proprietary new chemical entities, or NCEs, targeted to address front and back of the eye diseases.

Our two marketed products are 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 apply our AMPPLIFY technology to loteprednol etabonate, or LE, a corticosteroid designed for ocular applications. The AMPPLIFY technology uses selectively-sized nanoparticles that each have a proprietary coating. We believe that these two key attributes enable even distribution of drug particles on mucosal surfaces and significantly increase drug delivery to target tissues by enhancing mobility of drug particles through mucus and preventing drug particles from becoming trapped and eliminated by mucus. We commercially launched INVELTYS in January 2019 and began shipping EYSUVIS to wholesalers in the U.S. in late December 2020. Full promotional launch of EYSUVIS began in January 2021.

Upon the consummation of our acquisition of Combangio, Inc., or Combangio, on November 15, 2021, we acquired Combangio's lead product candidate, CMB-012, which we now refer to as KPI-012. KPI-012, our lead product candidate, is currently in clinical development for the treatment of persistent corneal epithelial defects, or PCED, a rare disease of impaired corneal healing. For a further description of KPI-012, our acquisition of Combangio and PCED, see "Recent Developments" below.

We are also progressing our pipeline of proprietary preclinical development programs targeted to address front and back of the eye diseases. These preclinical development programs, all of which are new chemical entities, include our receptor Tyrosine Kinase Inhibitor program, that is designed to inhibit the vascular endothelial growth factor pathway, for the treatment of retinal diseases, including wet age-related macular degeneration; our selective glucocorticoid receptor modulators, which are a novel class of therapies designed to modify the downstream activity of the receptors to exhibit the anti-inflammatory and immunomodulatory properties of the corticosteroid class of therapies without their associated side effects; and our novel surface targeting steroid designed to target the ocular surface and thus have the potential to have fewer side effects compared to traditional topical steroids. We own all intellectual property and worldwide rights to these pipeline preclinical development programs.

We have retained worldwide commercial rights for EYSUVIS, INVELTYS, KPI-012 and our preclinical development programs. Starting with FDA approval of INVELTYS, we have built a commercial infrastructure with our own focused, specialty sales force which now includes 105 territory sales managers, or TSMs, 14 regional sales leaders, two area sales leaders and four directors of national accounts. Our sales representatives promote both EYSUVIS and INVELTYS. We have determined to delay our plans to further expand our specialty sales force, pending growth in payor coverage for EYSUVIS and the status of the COVID-19 pandemic.

We expect to commercialize in the United States any of our other product candidates that receive marketing approval as well. We also expect to explore commercialization of EYSUVIS for the treatment of dry eye disease in certain markets outside the United States, including the European Union, or EU, utilizing a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

Since inception, we have incurred significant losses from operations and negative cash flows from operations. Our net losses were $28.1 million and $95.0 million for the three and nine months ended September 30, 2021, respectively, and $104.3 million for the year ended December 31, 2020. As of September 30, 2021, we had an accumulated deficit of $494.8 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 have had only limited revenues to date from product sales and have financed our operations primarily through proceeds from 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, or ATM Offerings, private placements of preferred stock, borrowings under credit facilities and the Loan and Security Agreement, or Loan Agreement, with Oxford Finance LLC, or Oxford Finance, convertible promissory notes and warrants. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and engaging in activities to commercialize EYSUVIS and INVELTYS. As a result of the acquisition of Combangio, we expect to devote substantial financial resources to the research and development and potential commercialization of KPI-012. Although we expect to continue to generate revenue from sales of EYSUVIS and INVELTYS, there can be no assurance as to the amount or timing of any such revenue, and we expect to continue to incur significant expenses and operating losses for at least the next several years, including in connection with our continued development, regulatory approval efforts and commercialization, if any, of KPI-012. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

Recent Developments

Acquisition of Combangio, Inc.

On November 15, 2021, we and our newly formed, direct wholly owned subsidiary, Ceres Merger Sub, Inc., or the Merger Subsidiary, entered into an Agreement and Plan of Merger, or the Merger Agreement, with 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 our direct wholly owned subsidiary, or the Acquisition. Combangio is a clinical-stage biotechnology company focused on developing regenerative biotherapeutics for severe ocular diseases based on mesenchymal stem cell, or MSCs, secretomes, including, its lead product candidate, CMB-012 for the treatment of persistent corneal epithelial defects, or PCED. Following the Acquisition, we refer to CMB-012 as KPI-012.

In connection with the closing of the Acquisition on November 15, 2021, or the Closing, we made an upfront payment of an aggregate of $5.0 million in cash to former Combangio stockholders and other equityholders, or the Combangio Equityholders, subject to customary adjustments, and agreed to issue an aggregate of 7,788,667 shares, or the Post-Closing Stock Consideration, of our common stock, $0.001 par value per share, or the Common Stock, to the Combangio Equityholders with an aggregate value of approximately $16,122,541, consisting of (i) an aggregate of 6,815,129 shares of Common Stock to be issued on January 3, 2022 and (ii) an aggregate of 973,538 shares of Common Stock that will be held back by us and will be issuable subject to the terms of the Merger Agreement to the Combangio Equityholders on the Escrow Release Date (as defined below), or the Initial Holdback Shares. The aggregate value of the Post-Closing Stock Consideration was calculated using the closing price of our Common Stock on the Nasdaq Global

Select Market on November 12, 2021, the last trading day prior to the Closing. The Post-Closing Stock Consideration constitutes approximately 11.9% of our Common Stock outstanding as of immediately prior to the Closing.

In addition, pursuant to the Merger Agreement, the Combangio Equityholders, in the aggregate and subject to the terms and conditions of the Merger Agreement, will also be entitled to receive from us the following contingent consideration, or the Contingent Consideration:

- up to $105.0 million in contingent milestone consideration, of which (i) $2.3 million would become payable in cash and $2.7 million would be payable in shares of our common stock upon the first patient dosed with any product candidate whose active ingredient comprises one or more biological factors secreted by MSCs or their progenitors, including KPI-012, or the Product Candidate, in a Phase 2 clinical trial, or the Dosing Milestone, (ii) $2.3 million would become payable in cash and $2.7 million would be payable in shares of our common stock upon the first patient dosed with a Product Candidate in a pivotal clinical trial, (iii) $12.5 million would become payable in cash (with up to $6.25 million payable, at our option, in shares of our common stock and the remainder in cash) upon regulatory approval by the FDA of marketing and sale of a Product Candidate in the United States, subject to certain specified reductions, or the BLA Approval Milestone; (iv) $17.5 million would become payable in cash (with up to $8.75 million payable, at our option, in shares of our common stock and the remainder in cash) upon the first commercial sale of a Product Candidate in the United States, subject to certain specified reductions, or the Commercialization Milestone, and (v) an aggregate of up to $65.0 million would become payable in cash upon the achievement of specified sales milestones, or the Net Sales Milestone Payments;

- tiered cash royalties at percentage rates in the mid-to-high single digits payable on annual net sales of all Product Candidates; and

- a cash payment at a percentage rate in the high single digits of all income, including earnout payments, received by us or any of our affiliates from a product license granted by us to a third party to sell or otherwise commercialize the Product Candidate in countries where neither we nor our affiliates conduct sales of such Product Candidate, subject to certain exceptions set forth in the Merger Agreement.

The portion of any payment of Contingent Consideration payable in shares of our common stock is referred to herein as “Contingent Stock Consideration” and the portion of any payment of Contingent Consideration payable in cash is referred to herein as “Contingent Cash Consideration”.

If the issuance of the Post-Closing Stock Consideration or any Contingent Stock Consideration would result in the aggregate number of shares of our common stock issued under the Merger Agreement equaling or exceeding 19.9% of the total number of shares of our common stock issued and outstanding immediately prior to the Closing, or the Share Cap, then we will be required to pay the portion of the Post-Closing Stock Consideration or any Contingent Stock Consideration in excess of the Share Cap in cash. If the aggregate amount of Contingent Cash Consideration payable in any calendar year (after giving effect to the Share Cap) exceeds $2,500,000, or the Excess Cash Cap, such excess portion, or the Carry Forward Contingent Cash Consideration, will be carried forward and, subject to application of the Excess Cash Cap in the following calendar year, become payable on the first business day of the following calendar year. Any Carry Forward Contingent Cash Consideration outstanding on June 1, 2026 is payable in full on June 1, 2026.

Former Combangio Equityholders who are non-accredited investors will receive cash in lieu of any of our common stock that otherwise would be issuable to them pursuant to the Merger Agreement.

The Merger Agreement contains customary representations, warranties and covenants of Combangio and us. The representations and warranties of Combangio generally will survive until the date that is fifteen months following the Closing, with certain specified representations and warranties surviving until the earlier of seven years following the Closing or the date that is 60 days after the expiration of the longest applicable statute of limitations applicable and other specified representations and warranties surviving to the date that is 60 days after the expiration of the longest applicable statute of limitations.

The Merger Agreement also contains customary indemnification provisions whereby the Combangio Equityholders will indemnify us and certain affiliated parties for any losses arising out of breaches of the representations, warranties and covenants of Combangio under the Merger Agreement; pre-Closing tax matters; appraisal claims of former Combangio stockholders; any pre-closing indebtedness or expenses not previously adjusted for at the Closing; fraud by Combangio with respect to the transactions contemplated by the Merger Agreement; any knowing misrepresentation by Combangio of the representations and warranties of Combangio; any willful breach by Combangio of the provisions of the Merger Agreement; any inaccuracy in or claim related to the Closing allocation schedule and certain other matters.

In connection with the Closing, we are placing $625,000 of the cash purchase price in an escrow account, or the Escrow Account, to be disbursed in accordance with an escrow agreement with Computershare Corporate Trust Company, N.A., or the Escrow Agreement, as escrow agent, and subject to the terms of the Merger Agreement, we will place 12.5% of any Contingent Cash Consideration that becomes payable prior to the date that is fifteen months after the Closing, or the Escrow Release Date, into such Escrow Account to be disbursed in accordance with the Escrow Agreement. Subject to the terms of the Merger Agreement, 12.5% of any Contingent Stock Consideration that becomes payable in common stock prior to the Escrow Release Date will be held back by us, or the Contingent Holdback Shares, and, together with the Initial Holdback Shares, which we collectively referred to herein as the Holdback Shares, will serve as partial security for the satisfaction of indemnification obligations and other payment obligations of the Combangio Equityholders and, subject to reduction in respect of these obligations, the Holdback Shares will be issued to the Combangio Equityholders on the Escrow Release Date.

Description of Combangio Acquired Business and KPI-012

Combangio Acquired Business and CMB-012 (now KPI-012)

On November 15, 2021 we acquired Combangio, including its lead product candidate, CMB-012, which we now refer to as KPI-012. Combangio is a clinical-stage biotechnology company focused on developing novel biotherapeutics based on bone marrow derived mesenchymal stem cell, or MSC, secretomes. KPI-012 is currently in clinical development for the treatment of persistent corneal epithelial defects, or PCED. A PCED is a persistent non-healing corneal defect or wound that is refractory to conventional treatments. PCED is a disease of impaired corneal healing. Normal healing is a highly regulated multifactorial process that involves numerous biologic pathways and molecules, including growth factors, cell signaling, proliferation, migration and extracellular matrix remodeling. In PCED, the normal healing process is impaired due to an imbalance of the key biomolecules that orchestrate the normal wound healing process. We believe that effective treatment of PCED requires a multifactorial mechanism of action to address the impaired healing that is responsible for the disease.

PCED is a rare disease with an estimated incidence of 100,000 cases per year in the United States and 238,000 cases per year in the United States, European Union and Japan combined. Clinical symptoms of PCED include pain, foreign body sensation, redness, photophobia and tearing. Clinical signs include non-healing epithelial defects, stromal scarring and stomal thinning. The etiology of a PCED can be due to various underlying conditions, including neurotrophic keratitis, or NK, surgical epithelial debridement, microbial/viral keratitis, corneal transplant, limbal stem cell deficiency, mechanical trauma and exposure keratopathy. A PCED may lead to infection, corneal ulceration, corneal perforation, scarring, opacification and significant vision loss. There is currently a significant unmet need for therapies to effectively treat PCED. Conventional therapies, which include bandage contact lenses, autologous serum and surgery, are usually ineffective in overcoming the dysregulation present in multiple cellular pathways that may need to be addressed to heal a PCED. Surgical procedures used in the treatment of PCED include tarsorrhaphy, corneal epithelial stem cell transplants and corneal transplants which are used to aid in restoration and maintenance of vision capabilities. The only currently approved product in the PCED space is OXERVATEÔ, indicated for the treatment of NK, which we believe to be the primary etiology for approximately one-third of PCED cases. OXERVATE contains a single growth factor – nerve growth factor (NGF) – and has been demonstrated to be effective in only the subgroup of PCED cases whose underlying etiology is neurotrophic disease.

CMB-012 (now KPI-012)

KPI-012 is a novel, bone-marrow derived MSC secretome composed of biologically active components secreted from the MSCs, such as growth factors, protease inhibitors, matrix proteins and neurotropic factors, that have been shown in preclinical studies by Combangio and others to facilitate corneal healing. KPI-012 is cell-free and produced from a proprietary cell bank. The drug substance for KPI-012 is produced as a chemically-defined cell-free solution followed by formulation and filling of the drug product in non-preserved single dose units. We believe that KPI-012's multi-factorial mechanism of action has the potential to normalize the impaired healing in PCED and other ocular surface diseases driven by impaired corneal healing. As such, KPI-012 offers a potentially promising approach for the treatment of PCED and other ocular surface diseases across multiple etiologies. Key biological factors contained in KPI-012 and their potential wound healing functions are shown below:

Key KPI-012 Components	Ocular Surface Wound-Healing Function
Protease Inhibitors (TIMP-1, TIMP-2, Serpin E)	Inhibit destructive proteases that degrade matrix in the wound bed
Matrix Proteins (Collagen)	Build a molecular scaffold in the wound bed for cells to migrate and adhere to
Growth Factors (HGF)	Suppress inflammation and promote corneal epithelium repair
Neurotrophic Factors (PEDF)	Promote maintenance of neurons to support corneal health

The multifactorial mechanism of action of KPI-012 is thought to be responsible for the significant wound healing activity observed in Combangio's preclinical animal models and in the Phase 1b clinical trial. KPI-012 has received orphan drug designation from the U.S. Food and Drug Administration, or the FDA, for the treatment of PCED and we believe KPI-012 should meet the criteria for fast-track and breakthrough designations.

Preliminary Clinical Development Plan for KPI-012

We will be initially developing KPI-012 for the treatment of PCED. Combangio completed a Phase 1b clinical trial in 12 patients with PCED in Mexico City. Based on the results of this Phase 1b clinical trial, we plan to submit an investigational new drug, or IND, application to the FDA for KPI-012 in the third quarter of 2022 and subject to regulatory clearance, commence a Phase 2/3 clinical trial of KPI-012 for PCED in the United States. Our planned Phase 2/3 randomized, placebo-controlled clinical trial of KPI-012 will evaluate the safety and efficacy of various dosing regimens of KPI-012 in patients diagnosed with PCED. If the results of our planned Phase 2/3 clinical trial of KPI-012 are positive, and subject to discussions with regulatory authorities, we believe this trial can serve as the first of two required pivotal trials. If so, we plan to conduct an additional Phase 3 pivotal trial in PCED patients to support the potential submission of a biologics license application, or BLA, to the FDA.

Clinical Development of KPI-012

Phase 1b Clinical Trial Results

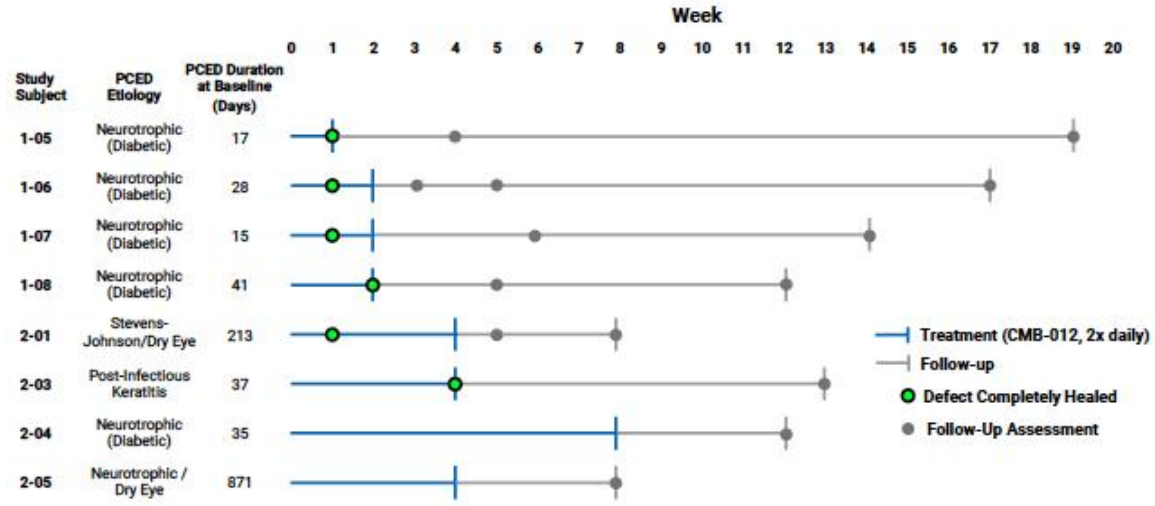
Combangio conducted a 12 patient Phase 1b clinical trial of KPI-012 in Mexico City during 2020 and 2021. Of the 12 patients evaluated, three patients who did not have PCED or active corneal disease were enrolled in the safety cohort and nine patients with PCED were enrolled in the PCED cohort. Key inclusion criteria for the PCED cohort included:

- Subjects with PCED of at least 10 days without improvement from one or more conventional non-surgical treatments in study eye due to any of the following:
  - NK, provided there was no active herpetic infection of the eye in the prior three months
  - Corneal Burns (alkali, acid and thermal)

- Post-photorefractive Keratectomy (Post-PRK)
- Post-corneal Transplant Surgery
- Corneal epithelial debridement resulting from Diabetic Vitrectomy Surgery
- Trauma
- Keratoconjunctivtis sicca
- Sjogren's Syndrome
- Corneal cross-linking

- Subjects with bilateral corneal burns could only have one eye entered into the clinical trial
- Any previous treatment was stopped except for the study medication

Patients were treated with KPI-012 topically twice a day, with the patients in the safety cohort treated for one week and patients in the PCED cohort treated between one to eight weeks. One subject in the PCED cohort had to withdraw from the trial after several days due to a protocol screening violation. KPI-012 was shown to be well-tolerated with no treatment-related safety issues observed. As depicted in Figure 1 below, six of eight patients in the PCED cohort (75%) achieved complete healing of the lesion after four weeks of treatment, with one additional patient experiencing some clinical improvement but not complete healing. Four of eight patients in the PCED cohort (50%) achieved complete healing of the lesion after one week of treatment and the other two patients achieved complete healing within two to four weeks of initiation of treatment with KPI-012. All six of the patients who achieved complete healing remained healed through the follow-up period of the trial, which ranged between eight to 19 weeks. Of the two patients who did not show complete healing in the trial, clinical investigators noted some clinical improvement in one of the patients (Patient 2-05), but the corneal staining images did not show complete healing of the defect. Patient 2-04 had a PCED in a blind eye which was perhaps too severe to respond to a pharmaceutical intervention. Patient 2-05 had a PCED that had existed for 871 days before treatment; corneal specialists have advised that it is rare for a PCED to have persisted for this duration and that it could be indicative of systemic disease.



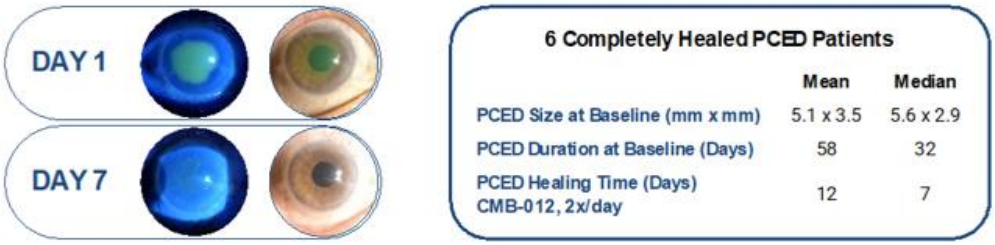


Figure 1. Summary of Phase 1b clinical trial of KPI-012 for PCED, including representative images for a healed patient study eye. The Day 1 images were taken on the first day of treatment, prior to first KPI-012 administration, with the fluorescein (green) stain demarking the corneal wound boundary of the study eye image. The Day 7 images were taken on the last day of KPI-012 treatment showing the PCED completely healed. The images on the left depict the study eye viewed under blue light to visualize the PCED with fluorescein stain.

Significant pain relief was reported by patients in the PCED cohort within one week of treatment with KPI-012, as shown in Figure 2 below. Of the six patients who reported pain at the baseline, all six patients reported a reduction in pain after one week of treatment, four patients reported a pain score of zero after one week of treatment and all six patients reported a pain score of zero after three weeks of treatment.

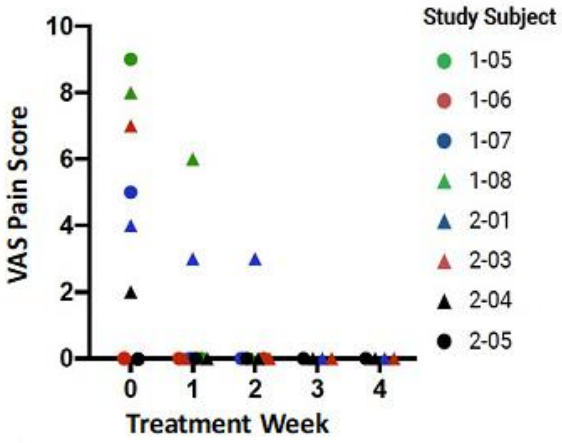


Figure 2. PCED cohort patient-reported score of pain level due to defect using a visual analogue scale, or VAS, which is a subjective rating of pain levels on a scale of 0 to 10 where a score of 0 represents no pain at all and a score of 10 represents the worst possible pain.

Preclinical Studies and Results

KPI-012 has been evaluated by Combangio in a number of preclinical studies. In these studies, KPI-012 promoted rapid ocular re-epithelialization and mitigated scarring and neovascularization in a number of well-established animal models.

In vitro Human Corneal Epithelial Wound Closure Assay

The therapeutic mechanism of action of KPI-012 involves stimulating corneal re-epithelialization and ocular surface healing. Combangio evaluated KPI-012 in an *in vitro* wound gap assay developed using human corneal epithelial cells. In this assay, a mechanical defect (cell-free region) was introduced into a two-dimensional monolayer of epithelial cells to create a wound. The 'injured' monolayer was then treated with the KPI-012 and the cell free region was monitored for wound closure as show in Figure 3 below. In this assay, KPI-012 exhibited a dose-dependent and potent wound closure response.

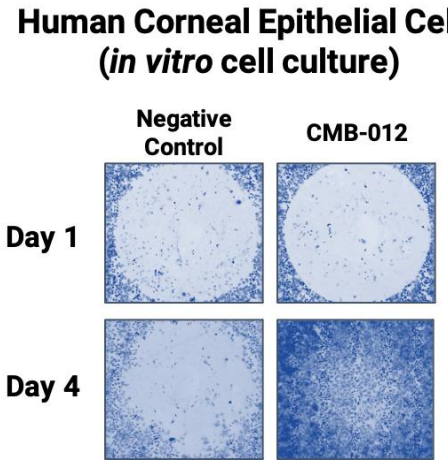


Figure 3. Representative images from an *in vitro* human corneal epithelial wound closure assay. A mechanical wound instilled to a corneal epithelial cell monolayer on Day 1 healed after treatment with KPI-012 (Day 4 of treatment), but not negative control (vehicle). Depicted images are wounded cell monolayers stained with Gentian Violet.

In vivo Mechanical Wound Studies of Activity

Combangio also evaluated the activity of KPI-012 in a mechanical corneal injury mouse model. In this model, a circular area on the surface of the cornea was debrided (mechanically scraped) to remove the epithelial layer and create a circular wound.

Topical formulations of vehicle or KPI-012 were administered twice daily to the wounded eyes. As shown in Figure 4 below, mice treated with KPI-012 exhibited prominent wound healing at day four of the treatment period, while the vehicle-treated wounded eyes remained largely unhealed. Further, treatment with KPI-012 resulted in reduced corneal haze and scarring relative to treatment with vehicle. Results of this mouse model suggested that at day 4 of treatment KPI-012 promoted *in vivo* closure of cornea mechanical wounds relative to vehicle control.

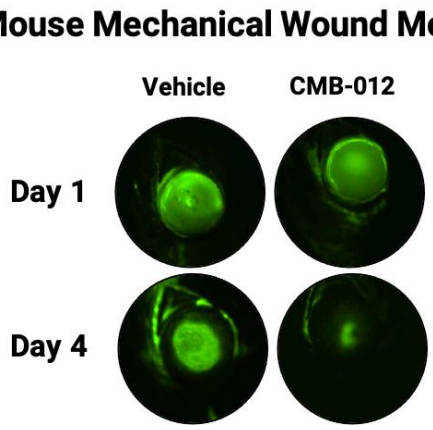


Figure 4. Representative images of wounded mouse corneas after mechanical injury (Day 1). Depicted is the fluorescein (green) stain, which demarks the corneal wound boundary. Treatment with KPI-012 rapidly healed the wound size (as indicated by the disappearance of the green stain by Day 4) relative to vehicle control-treated eyes.

A second confirmatory mechanical corneal injury mouse model study was performed according to the method described above using a different lot of KPI-012. The study yielded similar results, with KPI-012 promoting wound healing relative to vehicle as well as exhibiting dose-dependent potency dynamics. After four days of treatment, KPI-012 treated eyes exhibited more pronounced reduction in wound staining relative to vehicle-treated eyes, as shown in Figure 5A below, and after five days most KPI-012 treated eyes completely healed, as shown in Figure 5B below. Further, a KPI-012 formulation lacking key biologic factors known to mediate wound healing exhibited reduced healing capacity in the study, supporting the selection of KPI-012's critical quality attributes.

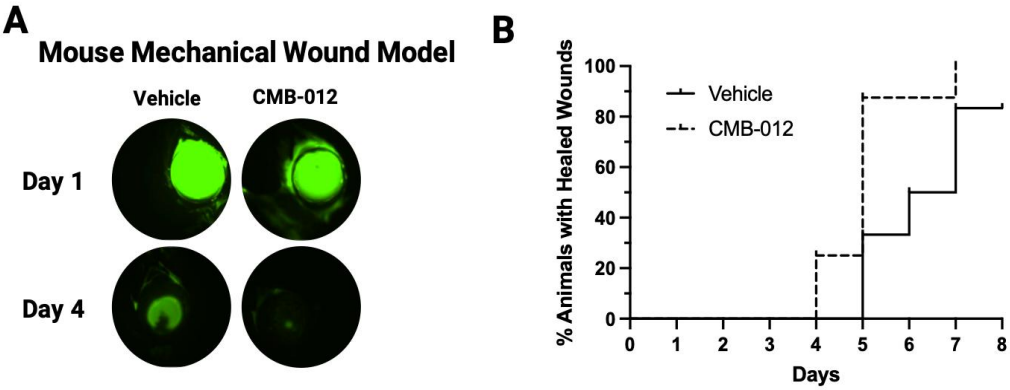


Figure 5. Summary of second mouse corneal mechanical study. (A) Representative images of wounded mouse corneas after mechanical injury (Day 1) and after four days of treatment with KPI-012 or vehicle (Day 4). Depicted is the fluorescein (green) stain, which demarks the corneal wound boundary. Treatment with KPI-012 rapidly healed the wound size (as indicated by the disappearance of the green stain by Day 4) relative to vehicle control-treated eyes; (B) Treatment with KPI-012 resulted in more rapid complete healing and a greater percentage of completely healed eyes (dashed line), relative to vehicle-treated eyes (solid line).

Rabbit Tolerability Study

To evaluate tolerability of KPI-012, Combangio conducted a 15-day good laboratory practice toxicology study following ocular instillation of KPI-012 in rabbits. The purpose of the study was to determine the ocular and systemic toxicity of KPI-012 following repeated topical ocular instillation for 15 days. One group of rabbits was administered

KPI-012 three times a day via topical ocular instillation to the right eye (the low dose) and another group was administered KPI-012 six times a day via topical ocular instillation to the right eye (the high dose), in each case with a one-week recovery period. The left eye served as a contralateral control and received vehicle at the same frequency as the KPI-012-treated right eye. All rabbits survived to the end of the study, and no gross lesions and abnormalities were recorded. There were no observed test article-related findings on body weight, intraocular pressure, clinical pathology, gross pathology, organ weights, ophthalmologic examination or ocular histopathology. The data of the toxicology study supported that repeated daily topical administration of KPI-012, at both three times a day and six times a day for 15 days, was well-tolerated and resulted in no overt toxicities in rabbits.

Competition

There is one approved prescription pharmaceutical product in the PCED space. OXERVATE™ (cenegermin-bkbj), which was approved in August 2018 for the treatment of NK, a degenerative disease characterized by decreased corneal sensitivity and poor corneal healing, which we believe to be the primary underlying etiology of 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 is currently only one product candidate in active clinical development for the treatment of a broad PCED population. ST266, an eye drop, is currently being studied in a Phase 2b clinical trial in patients with PCED and is being developed by Noveome Biotherapeutics Inc, or Noveome. ST266 is a secretome produced from amnion-derived epithelial cells from donated full-term placentas.

A number of companies are pursuing development of product candidates for the treatment of NK.

Other Potential Indications for KPI-012

We believe the multifactorial nature of KPI-012 also makes it a platform technology, and we are evaluating KPI-012 for potential expansion areas in indications such as corneal ulcers, corneal burns, ocular chronic graft vs host disease and Stevens-Johnson Syndrome disease. The wound-healing mechanism of action of KPI-012 also potentially enables partnering opportunities in chronic and/or severe indications outside of the eye such as diabetic foot ulcer.

Intellectual Property

As part of our acquisition of Combangio, we acquired a patent portfolio consisting of U.S. patents and patent applications, including original filings, continuations and divisional applications, as well as numerous related foreign patent applications. We now own three U.S. granted patents and a U.S. patent application and multiple related foreign patent applications, which are directed to MSC secretome compositions and formulations, and methods of treatment thereof for an ocular condition (e.g. PCED), and, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, are expected to expire in 2040.

As part of our acquisition of Combangio, we acquired Combangio’s exclusively in-licensed patent portfolio from Stanford University consisting of a U.S. patent application and multiple related foreign patent applications, which are directed to stem cell secretome compositions in biocompatible polymer carriers and methods of treatment thereof for damaged tissues, and, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, are expected to expire in 2038.

In addition to patent portfolios, we also hold trade secrets and know-how related to the manufacture, assays, and analytical methods of KPI-012 to develop and protect its competitive position.

Manufacturing and Supply

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 drug

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. 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 drug product for KPI-012 on a purchase order basis and do not have long term committed supply arrangements with respect to KPI-012.

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 mesenchymal stem cell secretome 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 plan to implement 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.

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.

Commercialization

We have not yet established our own commercial organization or distribution capabilities specific to KPI-012. 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. We may explore the use of a variety of types of collaboration, co-promotion, distribution and other marketing arrangements with one or more third parties to commercialize KPI-012 in markets outside the United States.

Combangio's License Agreement with Stanford University

In October 2019, Combangio entered into a license agreement with The Board of Trustees of The Leland Stanford Junior University, or Stanford, which was amended in February 2020. Pursuant to the license agreement with Stanford, or the Stanford Agreement, Combangio obtained from Stanford a worldwide, exclusive, sublicensable license under certain patent rights, or licensed patents, directed to methods to promote eye wound healing, to make, have made, use, import, offer to sell and sell products that are covered by the licensed patents, or licensed products, for use in all fields. Under the Stanford Agreement, Combangio agreed to pay Stanford annual license maintenance fees and milestone payments upon the achievement of specified development, regulatory and sales milestone, as well as tiered royalties on net sales of licensed products that are covered by a valid claim of a licensed patent. Stanford retains the right, on behalf of itself, Stanford Health Care, Lucile Packard Children's Hospital at Stanford, and all other non-profit research institutions, to practice the licensed patents for any non-profit purpose. In addition, the United States government retains nonexclusive rights under the licensed patents to practice or have practiced the licensed patents by or on behalf of the United States government or on behalf of any foreign government or international organization pursuant to treaty or agreement. Under the Stanford Agreement, Combangio agreed to diligently develop, manufacture and sell licensed product, diligently develop markets for licensed product, and use commercially reasonable efforts to achieve certain funding and development milestones by specified dates. Unless earlier terminated, Combangio's exclusive license under the Stanford Agreement will continue until the expiration of the licensed patents. Combangio may terminate the Stanford Agreement at any time for any reason by providing at least 30 days' written notice to Stanford. Stanford may terminate the agreement if Combangio breaches certain provisions of the agreement and fails to remedy such breach within 60 days after written notice of such breach by Stanford.

Government Regulation: Licensure and Regulation of Biological Products

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Licensure and Regulation of Biologics in the United States

In the United States, biological products, or biologics, are regulated under the Public Health Service Act, or PHSA, and the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations and guidances. The regulatory framework governing biologic products is substantially similar to the FDA's regulation of new drug products. However, while the vehicle through which the FDA approves a new drug product for sale and marketing in the United States is a New Drug Application, a Biologics License Application, or "BLA" is filed for biologic products under the PHSA. For a further discussion of the U.S. regulatory framework and requirements that apply to drug products, see "Business-Government Regulation" in our Annual Report on Form 10-K for the year ended December 31, 2020.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practice regulations;
- completion of the manufacture, under current Good Manufacturing Practices, or cGMP, conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency, and purity of the product candidate for each proposed indication, in accordance with current Good Clinical Practices, or GCP;
- preparation and submission to the FDA of a Biologic License Application, or BLA, for a biologic product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods, and controls are adequate to preserve the product's identity, strength, quality, and purity, and, if applicable, the FDA's current good tissue practice, or GTP, for the use of human cellular and tissue products;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GCPs and the integrity of clinical data in support of the BLA;
- payment of user Prescription Drug User Free Act, or PDUFA, securing FDA approval of the BLA and licensure of the new biologic product; and

- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy and any post-approval studies required by the FDA.

Compliance with cGMP and GTP Requirements

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

For a biologic, the FDA also will not approve the product if the manufacturer is not in compliance with GTP. These standards are found in FDA regulations and guidances that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission, and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a “risk-based schedule” that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Concurrent with clinical trials, companies usually complete additional preclinical studies and must also develop additional information about the physical characteristics of the biologic product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents or of causing other adverse events with the use of biologic products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biologic product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biologic product candidate does not undergo unacceptable deterioration over its shelf life.

Breakthrough Therapy Designation

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. One such program is breakthrough therapy designation. A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or 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.

The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review

team; and taking other steps to design the clinical trials in an efficient manner. Moreover, FDA will consider an Expedited Review for each marketing application for a candidate product that has been designated as a breakthrough therapy. For products expedited in this manner, FDA may take action on the application at least one month prior to the PDUFA goal date for a decision.

Breakthrough therapy designation does not change the standards for approval but it may help expedite the development or approval process of product candidates.

Fast Track, Priority Review and Regenerative Advanced Therapy Designations

In addition, the FDA is authorized to designate certain products for expedited review pursuant to other programs. These programs are referred to as fast track designation, priority review and regenerative advanced therapy designation.

Specifically, the FDA may 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 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 product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Finally, with passage of the 21st Century Cures Act, or the Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

As with breakthrough therapy designation, none of these expedited programs change the standards for approval but they may help expedite the development or approval process of product candidates.

Review and Approval of a BLA

The results of product candidate development, preclinical testing, and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting license to market the product. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure, and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. Under federal law, the submission of most BLAs is

subject to an application user fee, which for federal fiscal year 2021 is $2,875,842 for an application requiring clinical data. The sponsor of a licensed BLA is also subject to an annual program fee, which for fiscal year 2021 is $336,432.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of non-clinical and clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA.

Orphan Drug Designation and Exclusivity

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the biologic for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same product for seven years, except in certain limited circumstances. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and has historically been interpreted by FDA to apply to the indication for which the product has been designated. In September 2021, however, the Court of Appeals for the 11th Circuit held 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 concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." It is unclear how this court decision will be implemented by FDA.

Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product with the same drug for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan drug exclusivity regardless of a showing of

clinical superiority. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to drug products that received orphan drug designation before enactment of FDARA in 2017 but have not yet been approved by FDA.

Biosimilars and Exclusivity

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, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the FDA must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. Since the passage of the BPCIA, many states have passed laws or amendments to laws, including laws governing pharmacy practices, which are state-regulated, to regulate the use of biosimilars.

Patent Term Restoration and Extension

A patent claiming a new biologic product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States, although the European regulatory authorities do not generally distinguish between drug products and biological products.

PRIME Designation in the EU

In March 2016, the European Medicines Agency, or EMA, launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and rapporteur from the Committee for Human Medicinal Products or Committee for Advanced Therapies are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Orphan Drug Designation and Exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Business Impact of COVID-19 Pandemic

In order to safeguard the health of our employees from the ongoing COVID-19 pandemic, we are following and will continue to follow, recommendations from the U.S. Centers for Disease Control and Prevention, as well as federal, state, and local governments, regarding working-from-home practices for non-essential employees. We previously suspended our sales force from substantially all in-person interactions with physicians and were limited to conducting educational and promotional activities virtually. Commencing in the fourth quarter of 2020, our sales force resumed substantially all in-person interactions in the field, but if we suspend all or some in-person interactions with physicians in the future, or to the extent physicians limit in-person interactions, we may be limited to conducting educational and promotional activities virtually, which may continue to hamper our ability to market and commercialize EYSUVIS and INVELTYS.

In addition, government restrictions have at times led to moratoria on elective ocular surgeries in many jurisdictions, which had significantly reduced, and may in the future continue to significantly reduce, the demand for INVELTYS, which is indicated for the treatment of inflammation and pain following ocular surgery. We do not know the extent to which the COVID-19 pandemic will impact our development of KPI-012. The extent of the impact of the

COVID-19 pandemic on our commercialization efforts of EYSUVIS and INVELTYS, our development efforts for KPI-012 and our operational and financial performance will depend on certain developments, including the length and severity of this pandemic, the timing and extent of any resurgence of the COVID-19 virus or any variant strains of the virus, the availability and effectiveness of vaccines, and the full extent of the impact on our customers, employees and vendors and government agencies, all of which are uncertain and cannot be predicted.

Management is actively monitoring the COVID-19 pandemic and its effects on our financial condition, liquidity, operations, customers, sales force, contractors, and workforce. For additional information on risks posed by the COVID-19 pandemic, please see Part II, Item 1A – "Risk Factors" of this Quarterly Report on Form 10-Q, including the risk factor entitled "The ongoing novel coronavirus pandemic and the efforts to prevent its spread have adversely impacted our operations and the market for INVELTYS, could impact the ongoing commercialization of EYSUVIS and the development of KPI-012 and may continue to adversely affect our business, results of operations and financial condition."

Financial Operations Overview

Product Revenues, Net

We commenced generating product revenues from sales of INVELTYS in January 2019 and commenced generating revenue from EYSUVIS upon the shipment to wholesalers in the United States in late December 2020. Full promotional launch of EYSUVIS began in early January 2021. Our product revenues 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. Beginning in March 2020 and continuing through most of the second quarter of 2020, prescriptions of INVELTYS and revenue had been adversely affected by the ongoing COVID-19 pandemic as federal, state and local governments implemented restrictions on elective procedures, which included most ocular surgeries. While many deferred ocular surgeries have been rescheduled as individual states have released restrictions on elective procedures, we are unable to project the specific timing or potential impact on future revenues given the continued uncertainty around the impact and duration of the restrictions related to the COVID-19 pandemic. We also cannot project the full extent of the impact that the COVID-19 pandemic may have on the commercialization of EYSUVIS. Moreover, KPI-012 is in the early stages of clinical development and, accordingly, we do not expect it to generate revenue from KPI-012 for several years, if at all.

Cost of Product Revenues

Cost of product revenues consists 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 and losses on inventory purchase commitments and other manufacturing overhead costs. We expensed cost of product revenues related to INVELTYS as research and development expenses prior to U.S. regulatory approval, which we received on August 22, 2018. We expensed cost of product revenues related to EYSUVIS as research and development expenses prior to the determination that FDA approval was probable and before the future economic benefit was expected to be realized. With respect to the ongoing COVID-19 pandemic, we expect that the cost of product revenues will be impacted consistent with the negative impact to product revenues, net. However, we are unable to predict the specific timing or specific impact on cost of product revenues given the continued uncertainty around the impact and duration of the restrictions related to the COVID-19 pandemic.

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, information technology and business development functions. Selling, general and administrative expenses also

include external selling and marketing costs, 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 anticipate that our selling, general and administrative expenses will increase for the year ending December 31, 2021 as compared to the year ended December 31, 2020 as a result of the full promotional launch of EYSUVIS in January 2021. We further expect that our selling, general and administrative expenses will decrease in 2022 as compared to the year ending December 31, 2021 as we have built our commercial infrastructure to support the commercialization of INVELTYS, have incurred launch-related expenses during 2021 that we do not expect to incur again in the future related to EYSUVIS or INVELTYS and have terminated the lease for our corporate headquarters, effective December 31, 2021, subject to the satisfaction of specific conditions. Until we pursue the commercialization of KPI-012, if approved, we anticipate that our selling, general and administrative expenses will remain largely consistent beyond 2022 and for the foreseeable future as we continue to commercialize EYSUVIS and INVELTYS and as we support our continued research and development activities and seek marketing approval for our product candidates, including KPI-012. Our sales force has resumed substantially all in-person interactions in the field with physicians, which were previously suspended due to the restrictions with respect to the ongoing COVID-19 pandemic. If we are forced to suspend all or some in-person sales force interactions again in the future as a result of the COVID-19 pandemic, selling, general and administrative expenses could be favorably impacted by a reduction in certain expenses associated with the restriction in activities for our sales force and other employees. We are unable to predict the specific amount of this impact if we are forced to resume such restrictions.

Research and Development Expenses

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

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

We expense research and development costs as they are incurred. We expense costs relating to the production of inventory for our product candidates, as research and development expenses within our condensed consolidated statements of operations and comprehensive loss in the period incurred, unless we believe regulatory approval and subsequent commercialization of the product candidate is probable and we expect the future economic benefit from sales of the drug to be realized. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense until incurred. We track outsourced development costs by development program but do not allocate personnel costs, payments made under our 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 total research and development costs will decrease for the year ending December 31, 2021 as compared to the year ended December 31, 2020 as a result of the completion of our Phase 3 clinical trial of EYSUVIS, which we refer to as STRIDE 3 (STRIDE- **S**hort **T**erm **R**elief **I**n **D**ry **E**ye), and as a result of the capitalization of EYSUVIS manufacturing costs as inventory beginning in the third quarter of 2020. We expect that research and development costs will increase as we continue to advance our development programs and conduct any necessary preclinical studies and clinical trials and other development activities for product candidates, including KPI-012. 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. With respect to the ongoing COVID-19 pandemic, we may incur reduced research and development costs resulting from any limitations that may be placed on any laboratory facilities that support our early-stage research. However, we are unable to predict the specific amount of this impact, nor are we able to predict the additional costs, if any, associated with personnel safely resuming their full activities.

KPI-012 is in the early stages of clinical development and all of our other research and development programs are at the early stages of 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 may need to raise additional capital and may seek collaborations in the future to advance our various product candidates. 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.

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 facility.

Loss on Extinguishment of Debt

Loss on extinguishment of debt primarily consists of unamortized debt discount and issuance costs, a prepayment premium and unaccreted exit fees on the Athyrium Credit Facility.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table summarizes the results of our operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Product revenues, net	$ 3,067	$ 2,220	$ 847
Costs and expenses:			
Cost of product revenues	908	701	207
Selling, general and administrative	25,349	23,893	1,456
Research and development	2,881	3,468	(587)
Total operating expenses	29,138	28,062	1,076
Loss from operations	(26,071)	(25,842)	(229)
Other income (expense)			
Interest income	16	51	(35)
Interest expense	(2,072)	(2,157)	85
Net loss	$ (28,127)	$ (27,948)	$ (179)

Product revenues, net

Product revenues, net was $3.1 million for the three months ended September 30, 2021, consisting of $1.83 million from EYSUVIS sales and $1.24 million from INVELTYS sales, compared to $2.2 million from INVELTYS sales for the three months ended September 30, 2020. There were no sales of EYSUVIS in the three months ended September 30, 2020. The increase in product revenues, net of $0.9 million was driven primarily by sales of EYSUVIS, which we began shipping to wholesalers in the United States in late December 2020 and a higher per unit gross selling price of INVELTYS as compared to those sold during the three months ended September 30, 2020. These increases in INVELTYS sales were offset by higher estimated reserves per unit as well as a decrease in the total units of INVELTYS sold during the three months ended September 30, 2021 as compared to those sold during the three months ended September 30, 2020. We expect product revenues to increase if and as we increase our market share and obtain and maintain coverage and adequate reimbursement for EYSUVIS and INVELTYS from third-party payors; however, revenues could continue to be negatively impacted in 2021 as a result of the COVID-19 pandemic. Moreover, KPI-012 is in the early stages of clinical development and, accordingly, we do not expect it to generate revenue from KPI-012 for several years, if at all.

Cost of product revenues

Cost of product revenues was $0.9 million for the three months ended September 30, 2021, compared to $0.7 million for the three months ended September 30, 2020, an increase of $0.2 million. The cost of product revenues attributable to EYSUVIS was $0.2 million for the three months ended September 30, 2021, while there were no sales of EYSUVIS in the three months ended September 30, 2020. Cost of product revenues decreased $0.1 million as a result of the decrease in INVELTYS units sold during the three months September 30, 2021 compared to the three months ended September 30, 2020 but was offset by a $0.1 million increase due to a higher INVELTYS cost per unit as a result of the units sold during the three months ended September 30, 2020 being partially manufactured prior to FDA approval and for which costs were expensed as research and development prior to FDA approval as compared to those units sold during the three months ended September 30, 2021. We expect aggregate cost of product revenues to increase as we continue to commercialize INVELTYS and as a result of the launch of EYSUVIS, which we began shipping to wholesalers in the United States in late December 2020 and for which we commenced a full promotional launch in early January 2021.

Selling, general and administrative expenses

Selling, general and administrative expenses were $25.3 million for the three months ended September 30, 2021, compared to $23.9 million for the three months ended September 30, 2020, which was an increase of $1.4 million. Selling, general and administrative expenses for the three months ended September 30, 2021 included a $4.7 million increase in employee-related expenses primarily due to an increase in employee headcount related to the launch of EYSUVIS and merit-based pay. This increase, as compared to the three months ended September 30, 2020, was partially offset by a $2.1 million decrease in external sales and marketing costs, a $0.7 million decrease in costs for administrative and professional service fees, a $0.1 million decrease in stock-based compensation costs and a $0.4 million decrease in other selling, general and administrative expenses, which included facility related costs and certain medical affairs costs attributable to our commercial products. We anticipate that our selling, general and administrative expenses will increase for the year ending December 31, 2021 as compared to 2020 due to the full promotional launch of EYSUVIS in January 2021. We further expect our selling, general and administrative expenses to decrease in 2022 as compared to the year ending December 31, 2021 as we have built our commercial infrastructure to support the commercialization of INVELTYS, have incurred launch-related expenses in 2021 that we do not expect to incur again in the future related to EYSUVIS or INVELTYS and have terminated the lease for our corporate headquarters, effective December 31, 2021, subject to the landlord entering into a new lease amendment with a new tenant on terms and conditions acceptable to the landlord. Until we pursue the commercialization of KPI-012, if approved, we anticipate that our selling, general and administrative expenses will remain largely consistent beyond 2022 and for the foreseeable future as we continue to commercialize EYSUVIS and INVELTYS and as we support our continued research and development activities and seek marketing approval for our product candidates, including KPI-012.

Research and development expenses

The following table summarizes the research and development expenses incurred during the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
KPI-121 development costs	$ 169	$ 953	$ (784)
Employee-related costs	1,859	1,820	39
Other research and development costs	853	695	158
Total research and development	$ 2,881	$ 3,468	$ (587)

Research and development expenses were $2.9 million for the three months ended September 30, 2021, compared to $3.5 million for the three months ended September 30, 2020, a $0.6 million decrease. The decrease was primarily the result of a $0.8 million decrease in EYSUVIS development costs including a decrease in external spend on STRIDE 3, our Phase 3 clinical trial of EYSUVIS, partially offset by a $0.2 million increase in other research and development costs, which included preclinical studies and other facility related costs. We expect research and development costs to increase as we advance our development programs and conduct any necessary preclinical studies and clinical trials and other development activities for product candidates, including KPI-012.

Interest income

Interest income was less than $0.1 million for the three months ended September 30, 2021, compared to $0.1 million for the three months ended September 30, 2020, a decrease of less than $0.1 million. Interest income consists of interest earned on our cash, cash equivalents and short-term investments, if any. The decrease was attributable to lower interest rates during the three months ended September 30, 2021.

Interest expense

We incurred interest expense of $2.1 million for the three months ended September 30, 2021, compared to $2.2 million for the three months ended September 30, 2020, a $0.1 million decrease. Interest expense for the three months

ended September 30, 2021 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 LLC. Interest expense for the three months ended September 30, 2020 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 Athyrium Credit Facility. During the three months ended September 30, 2021, $80.0 million of indebtedness was outstanding under our Loan Agreement. During the three months ended September 30, 2020, $75.0 million of indebtedness was outstanding under the Athyrium Credit Facility.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes the results of our operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Product revenues, net	$ 9,384	$ 4,124	$ 5,260
Costs and expenses:			
Cost of product revenues	2,679	1,814	865
Selling, general and administrative	81,034	54,602	26,432
Research and development	9,101	14,955	(5,854)
Total operating expenses	92,814	71,371	21,443
Loss from operations	(83,430)	(67,247)	(16,183)
Other income (expense)			
Interest income	92	451	(359)
Interest expense	(6,304)	(6,419)	115
Loss on extinguishment of debt	(5,395)	—	(5,395)
Net loss	$ (95,037)	$ (73,215)	$ (21,822)

Product revenues, net

Product revenues, net was $9.4 million for the nine months ended September 30, 2021, consisting of $5.1 million from EYSUVIS sales and $4.3 million from INVELTYS sales, compared to $4.1 million from INVELTYS sales for the nine months ended September 30, 2020. There were no sales of EYSUVIS in the nine months ended September 30, 2020. The increase in product revenues, net of $5.3 million was driven primarily by sales of EYSUVIS, which we began shipping to wholesalers in the United States in late December 2020, an increase in the total units of INVELTYS sold in the nine months ended September 30, 2021 as well as a higher per unit gross selling price of INVELTYS as compared to those sold during the nine months ended September 30, 2020. These increases in INVELTYS sales were offset by higher estimated reserves per unit during the nine months ended September 30, 2021 as compared to those reserves per unit during the nine months ended September 30, 2020. We expect product revenues to increase if and as we increase our market share and obtain and maintain coverage and adequate reimbursement for EYSUVIS and INVELTYS from third-party payors; however, revenues could continue to be negatively impacted in 2021 as a result of the COVID-19 pandemic. Moreover, KPI-012 is in the early stages of clinical development and, accordingly, we do not expect it to generate revenue from KPI-012 for several years, if at all.

Cost of product revenues

Cost of product revenues was $2.7 million for the nine months ended September 30, 2021, compared to $1.8 million in the nine months ended September 30, 2020, an increase of $0.9 million. Cost of product revenues increased $0.8 million due to an increase in total INVELTYS units sold during the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020 as well as a higher INVELTYS cost per unit as a result of the units sold during the nine months ended September 30, 2020 being partially manufactured prior to FDA approval and for which costs were expensed as research and development prior to FDA approval as compared to those units sold during the nine months ended September 30, 2021. Partially offsetting these increases was a reserve for excess inventory of

$0.5 million recorded during the nine months ended September 30, 2020, which did not occur in the nine months ended September 30, 2021. The cost of product revenues attributable to EYSUVIS was $0.6 million for the nine months ended September 30, 2021. There were no sales of EYSUVIS in the nine months ended September 30, 2020. We expect aggregate cost of product revenues to increase as we continue to commercialize INVELTYS and as a result of the launch of EYSUVIS, which we began shipping to wholesalers in the United States in late December 2020 and for which we commenced a full promotional launch in early January 2021.

Selling, general and administrative expenses

Selling, general and administrative expenses were $81.0 million for the nine months ended September 30, 2021, compared to $54.6 million for the nine months ended September 30, 2020, which was an increase of $26.4 million. Selling, general and administrative expenses for the nine months ended September 30, 2021 included a $8.2 million increase in external sales and marketing costs as compared to the nine months ended September 30, 2020, primarily as a result of the launch of EYSUVIS. External sales and marketing costs incurred during the nine months ended September 30, 2020 primarily related to commercial activities for INVELTYS. Also contributing to the increase in selling, general and administrative expenses for the nine months ended September 30, 2021 was a $14.6 million increase in employee-related expenses primarily due to an increase in employee headcount related to the launch of EYSUVIS and merit-based pay, a $3.3 million increase in stock-based compensation costs and a $1.0 million increase in other selling, general and administrative expenses, which included facility related costs and certain medical affairs costs attributable to our commercial products. These increases were partially offset by a $0.7 million decrease in costs for administrative and professional service fees. We anticipate that our selling, general and administrative expenses will increase for the year ending December 31, 2021 as compared to 2020 due to the full promotional launch of EYSUVIS in January 2021. We further expect our selling, general and administrative expenses to decrease in 2022 as compared to the year ending December 31, 2021 as we have built our commercial infrastructure to support the commercialization of INVELTYS, have incurred launch-related expenses in 2021 that we do not expect to incur again in the future related to EYSUVIS or INVELTYS and have terminated the lease for our corporate headquarters, effective December 31, 2021, subject to the landlord entering into a new lease amendment with a new tenant on terms and conditions acceptable to the landlord. Until we pursue the commercialization of KPI-012, if approved, we anticipate that our selling, general and administrative expenses will remain largely consistent beyond 2022 and for the foreseeable future as we continue to commercialize EYSUVIS and INVELTYS and as we support our continued research and development activities and seek marketing approval for our product candidates, including KPI-012.

Research and development expenses

The following table summarizes the research and development expenses incurred during the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
KPI-121 development costs	$ 258	$ 4,668	$ (4,410)
Employee-related costs	6,170	8,054	(1,884)
Other research and development costs	2,673	2,233	440
Total research and development	$ 9,101	$ 14,955	$ (5,854)

Research and development expenses were $9.1 million for the nine months ended September 30, 2021, compared to $15.0 million for the nine months ended September 30, 2020, a $5.9 million decrease. The decrease was primarily the result of a $4.4 million decrease in EYSUVIS development costs including a decrease in external spend on STRIDE 3, our Phase 3 clinical trial of EYSUVIS, and a $1.9 million decrease in employee-related costs largely due to the decrease in the allocation of employee time dedicated to research and development, partially offset by a $0.4 million increase in other research and development costs, which included preclinical studies and other facility related costs. We expect research and development costs to increase as we advance our development programs and conduct any necessary preclinical studies and clinical trials and other development activities for product candidates, including KPI-012.

Interest income

Interest income was $0.1 million for the nine months ended September 30, 2021, compared to $0.5 million for the nine months ended September 30, 2020, a decrease of $0.4 million. Interest income consists of interest earned on our cash, cash equivalents and short-term investments, if any. The decrease was attributable to lower interest rates during the nine months ended September 30, 2021.

Interest expense

We incurred interest expense of $6.3 million for the nine months ended September 30, 2021, compared to $6.4 million for the nine months ended September 30, 2020, a $0.1 million decrease. Interest expense for the nine months ended September 30, 2021 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 LLC and our Athyrium Credit Facility. Interest expense for the nine months ended September 30, 2020 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 Athyrium Credit Facility. During the nine months ended September 30, 2021, $75.0 million of indebtedness was outstanding under the Athyrium Credit Facility until we repaid such indebtedness in full on May 4, 2021. During the nine months ended September 30, 2021, $80.0 million of indebtedness was outstanding under our Loan Agreement after we drew down the tranche A term loan on May 4, 2021. During the nine months ended September 30, 2020, $75.0 million of indebtedness was outstanding under the Athyrium Credit Facility.

Loss on extinguishment of debt

The loss of extinguishment of debt was $5.4 million for the nine months ended September 30, 2021. Upon the repayment in full of all amounts owed under the Athyrium Credit Facility, the unamortized debt discount and issuance costs, prepayment premium and unaccreted exit fee were recorded as loss on extinguishment of debt for the nine months ended September 30, 2021. There was no loss on extinguishment of debt for the nine months ended September 30, 2020.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. As we commercially launched our first product, INVELTYS, in January 2019, and commenced a full promotional launch of our second product, EYSUVIS, in early January 2021, we have had limited revenues to date from product sales and have financed our operations primarily through proceeds from our IPO, follow-on public common stock offerings and sales of our common stock under our ATM Offerings, private placements of preferred stock, borrowings under credit facilities and the Loan Agreement, convertible promissory notes and warrants.

In July 2017, we completed an IPO pursuant to which we issued and sold 6,900,000 shares of our common stock, which included 900,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares, at a price of $15.00 per share. We received net proceeds of $94.0 million after deducting underwriting discounts and commission of $7.3 million and offering costs of $2.2 million.

On August 9, 2018, we filed our shelf registration statement on Form S-3 that was declared effective by the SEC on August 27, 2018, or the 2018 Shelf Registration, under which we could initially offer and sell up to $250.0 million of a variety of securities including common stock, preferred stock, warrants, depositary shares, debt securities, purchase contracts, purchase units or any combination of such securities during the three-year period that commenced upon the 2018 Shelf Registration becoming effective. The 2018 Shelf Registration is now expired.

On October 1, 2018, we entered into the Athyrium Credit Facility with Athyrium for up to $110.0 million. The Athyrium Credit Facility provided for a Term Loan A in the aggregate principal amount of $75.0 million, and a Term Loan B in the aggregate principal amount of $35.0 million which we did not draw down on. On May 4, 2021, concurrently with the closing of the Loan Agreement with Oxford Finance LLC and the initial borrowing of the tranche A loan, we utilized substantially all of the proceeds from the tranche A term loan to repay in full all outstanding amounts owed under our Athyrium Credit Facility, under which we had an aggregate principal amount of $75.0 million of indebtedness outstanding. We terminated all commitments by Athyrium to extend further credit under the Athyrium

Credit Facility and all guarantees and security interests granted by us thereunder. In connection with the termination of the Athyrium Credit Facility, we paid to the lenders a prepayment premium of $2.25 million and an exit fee of $0.8 million. The transaction resulted in a loss on extinguishment of debt of $5.4 million, consisting of the prepayment premium, the unamortized debt discount and the unaccreted exit fee.

On October 5, 2018, we sold 7,500,000 shares of common stock in an underwritten offering pursuant to the 2018 Shelf Registration at a public offering price of $8.25 per share, before underwriting discounts and commissions. In addition, the underwriters were granted an overallotment option to purchase an additional 1,125,000 shares of the common stock at the same public offering price, less underwriting discounts and commissions. On October 11, 2018, the underwriters exercised in full their option to purchase the overallotment shares. The total number of shares sold by us in the offering was 8,625,000 shares, resulting in net proceeds to us, after underwriting discounts and offering expenses, of $66.1 million. In connection with the filing of the 2018 Shelf Registration, we entered into a sales agreement with Jefferies, pursuant to which we could issue and sell, from time to time, up to an aggregate of $50.0 million of our common stock in an ATM Offering, through Jefferies, as sales agent. Through the first quarter of 2020, we issued an aggregate of 4,945,605 shares of our common stock under the ATM Offering, resulting in net proceeds to us of $25.6 million. On March 10, 2020, we suspended and terminated the prospectus related to the ATM Offering.

On March 11, 2020, we sold 16,000,000 shares of our common stock in an underwritten offering pursuant to the 2018 Shelf Registration at a public offering price of $7.89 per share, resulting in net proceeds of $118.2 million, after underwriting discounts, commissions, and offering expenses. In addition, the underwriters of the offering were granted the option for a period of 30 days to purchase up to an additional 2,400,000 shares of common stock offered in the public offering at the public offering price, less underwriting discounts, commissions and offering expenses. On April 3, 2020, the underwriters exercised their option and purchased an additional 979,371 shares of common stock at $7.89 per share, resulting in net proceeds to us of $7.2 million, after underwriting discounts, commissions, and offering expenses. The total number of shares sold by us in the offering was 16,979,371, resulting in total net proceeds to us, after underwriting discounts, commissions and offering expenses, of $125.4 million.

Under the 2018 Shelf Registration, which has now expired, we issued an aggregate of 30,549,976 shares of common stock, including under the ATM Offering, resulting in aggregate gross proceeds to us of $231.7 million.

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, pursuant to which we may issue and sell, from time to time, up to an aggregate of $75.0 million of our common stock under our ATM Offering. During the fourth quarter of 2020, we issued an aggregate of 2,821,059 shares of our common stock under the ATM Offering, resulting in net proceeds to us of $20.6 million. In the three and nine months ended September 30, 2021, we issued and sold an additional 114,128 and 5,697,457 shares of our common stock under our ATM Offering, respectively, resulting in net proceeds to us of $0.3 million and $41.1 million, respectively. As of September 30, 2021, there was $11.5 million of shares of common stock remaining under the ATM Offering that we may issue and sell in the future and, excluding the shares of common stock that may be offered under our ATM Offering, there was $275.0 million of securities available to be issued under the 2020 Shelf Registration.

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, pursuant to which a term loan of up to an aggregate principal amount of $125.0 million is available to us, consisting of (i) 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; (ii) a contingent tranche B term loan in the aggregate principal amount of $20.0 million available to us through June 30, 2023 and within 90 days of our achieving trailing 6-month product revenue equal to or greater than $75.0 million, subject to certain other terms and conditions; and (iii) a contingent tranche C term loan in the aggregate principal amount of $25.0 million available to us through December 31, 2023 and within 90 days of our achieving trailing 6-month product revenue equal to or greater than $100 million, subject to certain other terms and conditions. The term loans bear interest at a floating rate equal to the greater of 30-day LIBOR and 0.11%, plus 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. The Loan Agreement provides 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, or the Amortization Date. The aggregate outstanding principal balance of the term loans are 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 is due and payable in full on May 1, 2026, or the Maturity Date.

We paid a facility fee of $400,000 on the closing date of the Loan Agreement and have agreed to pay a facility fee of $100,000 upon closing of the tranche B term loan and a $125,000 facility fee upon the closing of the tranche C term loan. 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, the we may elect to prepay all, but not less than all, of the outstanding loans, subject to a prepayment fee equal to the following percentage of the principal amount being prepaid: 3.00% if an advance is prepaid during the first 12 months following the applicable advance date, 2.00% if an advance is prepaid after 12 months but prior to 24 months following the applicable advance date, and 1.00% if an advance is prepaid any time after 24 months following the applicable advance date but prior to the Maturity Date.

Following the Closing of the Acquisition, 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 Cash Consideration and Contingent Stock 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 more fully described above under "Recent Developments". At our option and subject to Nasdaq rules, we may satisfy a portion of certain of the milestone payments through either the payment of cash or the issuance of additional shares of our common stock. If the issuance of the Post-Closing Stock Consideration or any Contingent Stock Consideration would result in us equaling or exceeding the Share Cap, then we will be required to pay the portion of the Post-Closing Stock Consideration or any Contingent Stock Consideration in excess of the Share Cap in cash. If the aggregate amount of Contingent Cash Consideration payable in any calendar year (after giving effect to the Share Cap) exceeds the Excess Cash Cap, such Carry Forward Contingent Cash Consideration will be carried forward and, subject to application of the Excess Cash Cap in the following calendar year, become payable on the first business day of the following calendar year. Any Carry Forward Contingent Cash Consideration outstanding on June 1, 2026 is payable in full on June 1, 2026. For a full description of the consideration payable as a result of the Acquisition of Combangio, see "Recent Developments" above.

Cash Flows

As of September 30, 2021, we had $124.5 million in cash and cash equivalents and as of September 30, 2020, we had $159.1 million in cash, cash equivalents and short-term investments. As of September 30, 2021, we had $80.0 million in indebtedness, which represented the aggregate principal amount that was outstanding under the Loan Agreement with Oxford Finance LLC. As of September 30, 2020, we had $75.0 million in indebtedness, which represented the aggregate principal amount that was outstanding under the Athyrium Credit Facility.

The following table summarizes our sources and uses of cash for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (80,331)	$ (64,775)
Net cash provided by (used in) investing activities	75,426	(115,051)
Net cash provided by financing activities	42,394	139,906
Increase in cash and restricted cash	$ 37,489	$ (39,920)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2021 was $80.3 million compared to $64.8 million for the nine months ended September 30, 2020, an increase of $15.5 million, primarily due to a $11.6 million increase in the net loss adjusted for non-cash charges and the timing of working capital fluctuations which accounted for $3.9 million of the increase. Notable working capital fluctuations include an increase to accounts receivable in the nine months ended September 30, 2021 of $3.0 million driven by an increase in sales largely due to the launch of EYSUVIS, whereas accounts receivable had decreased by $4.1 million in the nine months ended September 30, 2020 driven by a decrease in sales of INVELTYS primarily as a result of the COVID-19 pandemic. Inventory increased by a greater amount during the nine months ended September 30, 2021 due to an increase in manufacturing activity for EYSUVIS and INVELTYS. Partially offsetting these increases was an increase in accounts payable, accrued expenses and other current liabilities during the nine months ended September 30, 2021 of $4.7 million, as compared to a decrease in accounts payable, accrued expenses and other current liabilities in the nine months ended September 30, 2020 of $5.2 million.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2021 was $75.4 million compared to net cash used in investing activities of $115.1 million for the same period in 2020, an increase of $190.5 million. Net cash provided by investing activities for the nine months ended September 30, 2021 primarily related to the sales or maturities of short-term investments of $76.3 million, partially offset by purchases of property and equipment and other assets of $0.9 million. Net cash used in investing activities for the nine months ended September 30, 2020 consisted of the purchases of short-term investments of $113.6 million and purchases of property and equipment and other assets of $1.5 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2021 was $42.4 million, a decrease of $97.5 million compared to $139.9 million in the nine months ended September 30, 2020. Net cash provided by financing activities for the nine months ended September 30, 2021 included $77.8 million of net proceeds from the tranche A term loan under our Loan Agreement, $41.1 million of net proceeds from the sale of shares of our common stock under the ATM Offering and $1.5 million of proceeds from the exercise of stock options and the issuance of common stock under our employee stock purchase plan, partially offset by the repayment of indebtedness under our Athyrium Credit Facility of $78.0 million. Net cash provided by financing activities for the nine months ended September 30, 2020 consisted of $125.4 million of net proceeds from the sale of shares of our underwritten offering

pursuant to the 2018 Shelf Registration, $12.5 million of net proceeds from the sale of shares of our common stock under the ATM Offering and $2.0 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 substantially in the future as we advance our development programs and conduct any necessary preclinical studies and clinical trials and other development activities for product candidates. We continue to commercialize EYSUVIS and INVELTYS in the United States and we expect our selling, general and administrative expenses will increase substantially when we pursue the commercialization of KPI-012, if approved, and support commercialization of any other product candidate.

Our expenses will also increase if and as we:

- submit an IND for, and continue the clinical development of, KPI-012 for PCED;
- initiate and continue the research and development of KPI-012 for additional indications;
- grow our sales, marketing and distribution capabilities in connection with the commercialization of EYSUVIS, INVELTYS and any product candidates for which we may submit for and obtain marketing approval;
- scale up our manufacturing processes and capabilities to manufacture the clinical supply of KPI-012;
- seek regulatory approval for EYSUVIS and INVELTYS outside of the United States;
- seek regulatory approval for KPI-012 in the United States and other jurisdictions;
- progress our current and any future preclinical development programs;
- in-license or acquire the rights to other products, product candidates or technologies;
- conduct clinical trials and other development activities and/or seek marketing approval for KPI-012 and any other product candidates;
- leverage our proprietary AMPPLIFY technology to seek to advance additional therapeutics into preclinical and clinical development;
- maintain, expand and protect our intellectual property portfolio;
- integrate employees of Combangio following the Acquisition;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel including to support our operations following the Acquisition;
- expand our operational, financial and management systems; and
- increase our product liability insurance coverage as we expand our commercialization efforts for EYSUVIS and INVELTYS.

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, 2021, along with anticipated revenue from EYSUVIS and INVELTYS, will enable us to fund our operations, lease and debt service obligations, and capital expenditure requirements until the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. 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. While we began to generate revenue from the sales of EYSUVIS and INVELTYS in late December 2020 and January 2019, respectively, there can be no assurance as to the amount or timing of any future revenue from these products, and we may not achieve profitability. Our lead product candidate, KPI-012, is in the early stages of clinical development and, accordingly, we do not expect it to generate revenue from KPI-012 for several years, if at all. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- successfully commercializing and growing EYSUVIS and INVELTYS revenues;
- achieving an adequate level of market acceptance, and obtaining and maintaining coverage and adequate reimbursement from third-party payors for EYSUVIS, INVELTYS and any other products we commercialize;
- successfully integrating Combangio into our business;
- timely filing an IND for, and completing the clinical development of, KPI-012 for PCED and any other indications we determine to pursue;
- subject to obtaining favorable results from our planned clinical trials of KPI-012, applying for and obtaining marketing approval of KPI-012;
- successfully commercializing KPI-012, if approved;
- manufacturing at commercial scale, marketing, selling and distributing EYSUVIS, INVELTYS and, if approved, KPI-012;
- maintaining regulatory and marketing approvals for EYSUVIS and INVELTYS;
- discovering, developing and successfully seeking marketing approval and commercialization of any additional product candidates;

- hiring and building a full commercial organization required for marketing, selling and distributing those products for which we obtain marketing approval;
- obtaining, maintaining and protecting our intellectual property rights; and
- adapting our business in response to the current pandemic health event resulting from COVID-19 and its collateral consequences.

EYSUVIS and INVELTYS are our only products that have been approved for sale, and they have only been approved in the United States. We plan to seek approval in other jurisdictions, but may not do so successfully, or at all. Further, the successful commercialization of EYSUVIS and INVELTYS in the United States is subject to many risks. As a company, we have limited experience commercializing products, and we may not be able to do so successfully. 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. Our revenue from sales of EYSUVIS and INVELTYS alone may not be sufficient for us to become profitable in the near future, if at all. Moreover, KPI-012 is in the early stages of clinical development and, accordingly, we do not expect it to generate revenue from KPI-012 for several years, if at all.

In addition, our commercialization efforts were hampered by the operational restrictions on our sales force from quarantines, travel restrictions and bans and other governmental restrictions related to the COVID-19 pandemic. As a result of these restrictions, we previously suspended our sales force from substantially all in-person interactions with physicians and were limited to conducting educational and promotional activities virtually. Commencing in the fourth quarter of 2020, our sales force resumed substantially all in-person interactions in the field, but to the extent we restrict, or are restricted from, in-person interactions with physicians, we may be limited to conducting educational and promotional activities virtually, which may continue to hamper our ability to market EYSUVIS and INVELTYS. In addition, government restrictions have at times led to moratoria on elective ocular surgeries in many jurisdictions, which had significantly reduced, and may in the future continue to significantly reduce, the demand for INVELTYS, which is indicated for the treatment of post-operative inflammation and pain following ocular surgery. We do not know the extent to which the COVID-19 pandemic will impact our development of KPI-012. The extent of the impact of COVID-19 on our development and commercialization efforts will depend on the length and severity of this pandemic, including the extent there is any resurgence of the COVID-19 virus or any variant strains of the virus, the availability and effectiveness of vaccines, and the impact of the foregoing on our customers, employees and vendors and government agencies, which is uncertain and cannot be predicted.

We may never succeed in these activities and 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.

We may 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. Additionally, the COVID-19 pandemic has already caused significant disruptions in the financial markets, and may again cause such disruptions, which could impact our ability to raise additional funds. The COVID-19 pandemic has also impacted, and may continue to impact, the volatility of our stock price and trading in our stock. Even after the COVID-19 pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future.

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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our financial instruments as of September 30, 2021 consisted primarily of cash equivalents which consisted of money market accounts 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, 2021, the aggregate principal amount outstanding under the Loan Agreement was $80.0 million, which bears interest at a floating rate equal to the greater of 30-day LIBOR and 0.11%, plus 7.89% per annum. An immediate 10% change in the 30-day LIBOR rate would not have a material impact on our operating results or cash flows. As of September 30, 2020, the aggregate principal amount outstanding under the Athyrium Credit Facility was $75.0 million, which bore interest at a fixed rate of 9.875% per annum. On May 4, 2021, we utilized substantially all of the proceeds from the tranche A term loan under the Loan Agreement to repay in full all outstanding amounts under the Athyrium Credit Facility.

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, 2021. 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, 2021, 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, 2021 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 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 Recent Acquisition of Combangio

We may fail to realize the anticipated benefits of our acquisition of Combangio, those benefits may take longer to realize than expected, and we may encounter significant integration difficulties.

On November 15, 2021, we completed our acquisition, or the Acquisition, of Combangio, Inc., or Combangio, a clinical-stage biotechnology company focused on developing regenerative biotherapeutics based on mesenchymal stem cell secretomes, pursuant to an Agreement and Plan of Merger, or the Merger Agreement, dated November 15, 2021. Our ability to realize the anticipated benefits of the Acquisition will depend, to a large extent, on our ability to integrate Combangio and KPI-012 (previously known as CMB-012), a product candidate in clinical development for the treatment of persistent corneal epithelial defects, or PCED, into our business and business strategy and realize anticipated growth opportunities and synergies. We expect that the integration process will be complex, costly and time-consuming. As a result, we will be required to devote significant management attention and resources to integrating Combangio into our business and KPI-012 into our business strategy. The integration process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of the Acquisition could cause an interruption of, or a loss of momentum in, our commercialization efforts for EYSUVIS and INVELTYS and could adversely affect our business, financial condition and results of operations.

Our ability to realize the anticipated benefits of the Acquisition is expected to entail numerous additional material potential difficulties, risks and uncertainties, including, among others:

- any delay in or failure in filing an investigational new drug, or IND, application for KPI-012 with the U.S. Food and Drug Administration, or FDA, for KPI-012;
- if filed, the FDA may not clear our IND submission for KPI-012 and may not permit us to commence clinical trials in the United States of KPI-012 on the timeline we expect or at all;

- any clinical trials of KPI-012 that we commence in the future may fail to provide sufficient evidence that KPI-012 is both safe and effective for use;
- any delay or failure in obtaining marketing approvals for KPI-012, or any delay or failure to commercialize KPI-012 in the United States or other jurisdictions thereafter;
- increased scrutiny from third parties, including regulators, legislative bodies and enforcement agencies, including with respect to product pricing and commercialization matters;
- changes in laws or regulations that adversely impact the anticipated benefits of the Acquisition;
- challenges related to the perception by patients, the medical community and third-party payors of KPI-012 for the treatment of persistent corneal epithelial defects, PCED;
- challenges related to the reliance on third-party manufacturers;
- challenges related to the complex manufacturing process for KPI-012 and the reliance on manufacturing arrangements with third-party manufacturers;
- difficulties in managing the expanded operations of a more complex company following the Acquisition;
- the diversion of management attention to integration matters;
- difficulties in achieving the anticipated business opportunities and growth prospects from the Acquisition;
- the size of the treatable patient population for PCED may be smaller than we believe it is;
- difficulties in assimilating Combangio employees in our business, in maintaining employee morale and in attracting and retaining key personnel; and
- potential unknown liabilities, adverse consequences, unforeseen increased expenses or other unanticipated problems associated with the Acquisition.

Many of these factors are outside of our control, and any one of them could result in increased costs, decreased expected revenues and further diversion of management time and energy, which could materially adversely impact our business, financial condition and results of operations.

Also, following the Acquisition, we now possess certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by us upon closing of the Acquisition. Further, it is possible that undisclosed, contingent, or other liabilities, problems or obligations may arise in the future of which we were previously unaware. These disclosed and undisclosed liabilities could have an adverse effect on our business, financial condition and results of operations.

In addition, we expect to incur expenses related to the continued development, regulatory approval process and commercialization with respect to KPI-012. As a company, we have no prior experience developing biological product candidates. Because we have limited financial resources, by investing in the Acquisition and focusing on the development of KPI-012, we may forgo or delay pursuit of other opportunities that may have proven to have greater commercial potential.

Any or all of these factors could decrease or delay the expected accretive effect of the Acquisition and negatively impact our stock price. As a result, it cannot be assured that we will be successful in the integration of Combangio with our business or that we will realize the benefits anticipated from the Acquisition or in the anticipated time frames or at all.

Our existing stockholders will experience dilution upon any future issuance of shares of our common stock to former equityholders of Combangio pursuant to the terms of the Merger Agreement.

In connection with the closing of the Acquisition, we agreed to issue on January 3, 2022 an aggregate of 6,815,129 shares of our common stock to the former Combangio equityholders. Such shares, together with 973,538 shares of our common stock that will be held back by us and will be issuable subject to the terms of the Merger Agreement to the Combangio equityholders on the escrow release date, constitute approximately 11.9% of our common stock as of immediately prior to the Closing. In addition, former Combangio equityholders are entitled to receive from us, subject to the terms and conditions of the Merger Agreement, contingent consideration of up to $5.4 million payable in shares of our common stock upon our achievement of various development and regulatory milestones, and, we may elect, subject to the Nasdaq rules, to satisfy a portion of certain milestone payments that are payable to Combangio equityholders in cash through the issuance of up to $15 million of our common stock. Our existing stockholders will experience dilution upon any future issuance of shares of our common stock to former Combangio equityholders pursuant to the Merger Agreement.

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 $28.1 million and $95.0 million for the three and nine months ended September 30, 2021 and $104.3 million for the year ended December 31, 2020. As of September 30, 2021, we had an accumulated deficit of $494.8 million. Combangio has also incurred net operating losses since its inception. Combangio's net losses were $1.2 million for the nine months ended September 30, 2021 and $1.6 million for the year ended December 31, 2020. In January 2019, we launched our first product, INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% for the treatment of post-operative inflammation and pain following ocular surgery. On October 26, 2020, the U.S. Food and Drug Administration, or FDA, approved our second product, 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. We began shipping EYSUVIS to wholesalers in the United States in late December 2020 and commenced a full promotional launch in early January 2021. We have had limited revenues to date from product sales. We have financed our operations primarily through proceeds from our initial public offering, or IPO, follow-on public offerings of common stock and sales under our at-the-market offering facility, or the ATM Offering, private placements of 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. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials, and engaging in activities to launch and commercialize EYSUVIS and INVELTYS. As of result of the acquisition of Combangio, we expect to devote substantial financial resources to the research and development and potential commercialization of KPI-012. Although we expect to continue to generate revenue from sales of EYSUVIS and INVELTYS, there can be no assurance as to the amount or timing of any such revenue, and we expect to continue to incur significant expenses and operating losses for at least the next several years, 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 substantially in the future as we advance our development programs and conduct any necessary preclinical studies and clinical trials and other development activities for product candidates. We continue to commercialize EYSUVIS and INVELTYS in the United States and expect that our selling, general and administrative expenses will increase substantially when we pursue the commercialization of KPI-012, if approved, and support commercialization of any other product candidate.

Our expenses will also increase if and as we:

- submit an IND for, and continue the clinical development of, KPI-012 for PCED;
- initiate and continue the research and development of KPI-012 for additional indications;
- continue to grow our sales, marketing and distribution capabilities in connection with the commercialization of EYSUVIS, INVELTYS and any product candidates for which we may submit for and obtain marketing approval;
- scale up our manufacturing processes and capabilities to manufacture the clinical supply of KPI-012;
- seek regulatory approval for EYSUVIS and INVELTYS outside of the United States;
- seek regulatory approval for KPI-012 in the United States and other jurisdictions;
- progress our current and any future preclinical development programs;
- in license or acquire the rights to other products, product candidates or technologies;
- conduct clinical trials and other development activities and/or seek marketing approval for KPI-012 and any other product candidates;
- leverage our proprietary AMPPLIFY technology to seek to advance additional therapeutics into preclinical and clinical development;
- maintain, expand and protect our intellectual property portfolio;
- integrate employees of Combangio following the Acquisition;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel, including to support our operations following the Acquisition;
- expand our operational, financial and management systems; and
- increase our product liability insurance coverage as we expand our commercialization efforts for EYSUVIS and INVELTYS.

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. While we began to generate revenue from the sales of EYSUVIS and INVELTYS in late December 2020 and January 2019, respectively, there can be no assurance as to the amount or timing of any future revenue from these products, and we may not achieve profitability. Our lead product candidate, KPI-012, is in the early stages of clinical development and, accordingly, we do not except it to generate revenue from KPI-012 for several years, if at all. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- successfully commercializing and growing EYSUVIS and INVELTYS revenues;
- achieving an adequate level of market acceptance, and obtaining and maintaining coverage and adequate reimbursement from third-party payors for EYSUVIS, INVELTYS and any other products we commercialize;
- successfully integrating Combangio into our business;
- timely filing of an IND for, and completing the clinical development of, KPI-012 for PCED and any other indications we determine to pursue;
- subject to obtaining favorable results from our planned clinical trials of KPI-012, applying for and obtaining marketing approval of KPI-012;
- successfully commercializing KPI-012, if approved;
- manufacturing at commercial scale, marketing, selling and distributing EYSUVIS, INVELTYS and, if approved, KPI-012;
- maintaining regulatory and marketing approvals for EYSUVIS and INVELTYS;
- discovering, developing and successfully seeking marketing approval and commercialization of any additional product candidates;
- hiring and building a full commercial organization required for marketing, selling and distributing those products for which we obtain marketing approval;
- obtaining, maintaining and protecting our intellectual property rights; and
- adapting our business in response to the current pandemic health event resulting from COVID-19 and its collateral consequences.

EYSUVIS and INVELTYS are our only products that have been approved for sale, and they have only been approved in the United States. We plan to seek approval in other jurisdictions, but may not do so successfully, or at all. Further, the successful commercialization of EYSUVIS and INVELTYS in the United States is subject to many risks. As a company, we have limited experience commercializing products, and we may not be able to do so successfully. 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. Our revenue from sales of EYSUVIS and INVELTYS alone may not be sufficient for us to become profitable in the near future, if at all. Moreover, KPI-012 is in the early stages of clinical development and, accordingly, we do not expect it to generate revenue from KPI-012 for several years, if at all.

In addition, our commercialization efforts have previously been hampered by the operational restrictions on our sales force from quarantines, travel restrictions and bans and other governmental restrictions related to the COVID-19 pandemic. As a result of these restrictions, we previously suspended our sales force from substantially all in-person interactions with physicians and were limited to conducting educational and promotional activities virtually.

Commencing in the fourth quarter of 2020, our sales force resumed substantially all in-person interactions in the field, but to the extent we restrict, or are restricted from, in-person interactions with physicians, we may be limited to conducting educational and promotional activities virtually, which may continue to hamper our ability to market EYSUVIS and INVELTYS. In addition, government restrictions have at times led to moratoria on elective ocular surgeries in many jurisdictions, which had significantly reduced, and may in the future continue to significantly reduce, the demand for INVELTYS, which is indicated for the treatment of post-operative inflammation and pain following ocular surgery. We do not know the extent to which the COVID-19 pandemic will impact our development of KPI-012. The extent of the impact of COVID-19 on our development and commercialization efforts will depend on the length and severity of this pandemic, including the extent there is any resurgence of the COVID-19 virus or any variant strains of the virus, the availability and effectiveness of vaccines, and the impact of the foregoing on our customers, employees and vendors and government agencies, which is uncertain and cannot be predicted.

We may never succeed in these activities and 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 as a commercial company and 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 are an early-stage commercial company. Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing EYSUVIS and INVELTYS and conducting other research and development activities, and commercially launching EYSUVIS and INVELTYS. We are in the process of transitioning from a company solely with a research and development focus to a company engaging in commercial activities. We may not be successful in such a transition. We only launched INVELTYS in January 2019 and are still in the process of executing our commercial launch plan for EYSUVIS, have no prior history of commercializing products, and, to date, have generated limited revenue from the sale of EYSUVIS and INVELTYS. In addition, our commercial operations and INVELTYS sales have been and continue to be negatively impacted by COVID-19 and its collateral consequences. The effects of COVID-19 may also disrupt the commercialization of EYSUVIS. Moreover, following our acquisition of Combangio, we plan to develop KPI-012 for the treatment of PCED. As a company, we have no prior experience developing biological product candidates. We may also encounter delays or difficulties in our efforts to, or fail to, successfully integrate the operations of Combangio into our business and KPI-012 into our business strategy. 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, integrating acquired businesses into our existing business 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 may 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 programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we commercialize EYSUVIS and INVELTYS and integrate the operations of Combangio into our business. We also expect to incur significant additional expenses if and as we conduct further research and development activities, and initiate clinical trials of, and seek regulatory approval for, KPI-012 and any other product candidate that we identify and advance, including product candidates from our receptor Tyrosine Kinase Inhibitor program, novel surface targeting steroid program and novel selective glucocorticoid receptor modulators, or SEGRM, program.

Our expenses have increased relative to prior periods in connection with our launch and commercialization of EYSUVIS and INVELTYS, including costs associated with the addition and subsequent expansion of our specialty sales

force and increased marketing, distribution and manufacturing capabilities. Accordingly, we may 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 current or future commercialization efforts.

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

- the progress, costs and results of integrating Combangio operations into our business and our 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 timing and amount of future milestone payments under the Merger Agreement;
- the costs and timing of commercialization activities for EYSUVIS, INVELTYS and, if approved, KPI-012, including establishing additional product sales, marketing, medical affairs, distribution and outsourced manufacturing capabilities;
- our ability to successfully commercialize and sell EYSUVIS, INVELTYS and, if approved, KPI-012 in the United States and the amount of revenue received from commercial sales;
- the progress, costs and results of any clinical activities for regulatory review of, and our success seeking approval and/or commercializing, EYSUVIS and INVELTYS outside of the United States;
- 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 any other product candidates that we may develop;
- 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 $124.5 million as of September 30, 2021, along with anticipated revenue from EYSUVIS and INVELTYS, will enable us to fund our operations, lease and debt service obligations, and capital expenditure requirements until the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our available capital resources sooner than we currently expect.

Commercializing products is a time-consuming, expensive and uncertain process. Although we commercially launched INVELTYS in early 2019, began shipping EYSUVIS to wholesalers in the United States in late December 2020 and commenced a full promotional launch of EYSUVIS in early January 2021, our revenue from product sales of EYSUVIS and INVELTYS may not be sufficient for us to become profitable in the near future, if at all. In addition, 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. 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 need to rely on the commercial success of EYSUVIS and INVELTYS to generate product revenue for the foreseeable future.

We may 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 EYSUVIS, INVELTYS, KPI-012 or any other 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 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 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 connection with the closing of the Acquisition, we agreed to issue on January 3, 2022 an aggregate of 6,815,129 shares of our common stock to the former Combangio equityholders. Such shares, together with 973,538 shares of our common stock that will be held back by us and will be issuable subject to the terms of the Merger Agreement to the Combangio equityholders on the escrow release date, constitute approximately 11.9% of our common stock as of immediately prior to the Closing. In addition, former Combangio equityholders are entitled to receive from us, subject to the terms and conditions of the Merger Agreement, contingent consideration of up to $5.4 million payable in shares of our common stock upon our achievement of various development and regulatory milestones, and we may elect, subject to the Nasdaq rules, to satisfy a portion of certain milestone payments that are payable to Combangio equityholders in cash through the issuance of up to $15 million of our common stock. Our existing stockholders will experience dilution upon any future issuance of shares of our common stock to former Combangio equityholders pursuant to the Merger Agreement.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.

We have a substantial amount of indebtedness. As of September 30, 2021, we had $80.0 million of outstanding borrowings under the tranche A term loan under the Loan Agreement, bearing interest at a floating rate equal to the greater of 30-day LIBOR and 0.11%, plus 7.89%. The Loan Agreement provides 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, or the Amortization Date. Beginning on the Amortization Date, we are required to repay the outstanding principal in monthly installments over a period of (i) 18 months if neither the tranche B term loan nor the tranche C term loan is made or (ii) 12 months if either the tranche B term loan or the tranche C term loan is made. All unpaid principal and interest is due in full on May 1, 2026, the date of maturity.

Our obligations under the Loan Agreement are secured by substantially all of our assets. We could in the future incur additional indebtedness beyond our borrowings under our Loan Agreement.

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 intend to satisfy our current and future debt service obligations with our existing cash and anticipated product revenue. Nonetheless, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt and funds from external sources may not be available on 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. If an event of default occurs and the lender accelerates the amounts due under our Loan Agreement, we may not be able to make accelerated payments, and the lender could seek to enforce security interests in the collateral securing such indebtedness.

Fluctuations in interest rates could materially affect the interest expense on our Loan Agreement.

Because our debt under the Loan Agreement bears interest at floating interest rates, increases in interest rates could materially increase our interest expense.

Further, our Loan Agreement uses LIBOR as a reference rate. On July 27, 2017, the United Kingdom’s Financial Conduct Authority, or the FCA, which regulates LIBOR, announced that it intends to stop encouraging or compelling banks to submit rates for the calibration of LIBOR by the end of 2021. On November 30, 2020, ICE Benchmark Administration, the administrator of LIBOR, with the support of the United States Federal Reserve and the FCA, announced plans to consult on ceasing publication of LIBOR on December 31, 2021 for only the one week and two month LIBOR tenors, and on June 30, 2023 for all other LIBOR tenors. While this announcement extends the transition period to June 2023, the United States Federal Reserve concurrently issued a statement advising banks to stop new LIBOR issuances by the end of 2021. In light of these recent announcements, the future of LIBOR at this time is uncertain and any changes in the methods by which LIBOR is determined or regulatory activity related to LIBOR's phaseout could cause LIBOR to perform differently than in the past or cease to exist. In June 2017, the Alternative Reference Rates Committee selected the Secured Overnight Financing Rate, or SOFR, a new index calculated by reference to short-term repurchase agreements backed by Treasury securities, as its preferred replacement for U.S. dollar LIBOR. Whether or not SOFR attains market acceptance as a LIBOR replacement tool remains in question. As such, the future of LIBOR and the potential alternatives at this time is uncertain. If the method for calculation of LIBOR changes, if LIBOR is no longer available or if lenders have increased costs due to changes in LIBOR or changes in law, we may

suffer from potential increases in interest rate costs on our floating debt rate. Further, we may need to renegotiate our Loan Agreement and the floating loans thereunder to replace the interest rate calculated by reference to LIBOR with an interest rate calculated by reference to a new standard that is established.

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 these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include 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 and the recoverability of our net deferred tax assets and related valuation allowance. We base our estimates and judgments on historical experience, expected future experience and on various other assumptions that we believe to be reasonable under the circumstances. In addition, from time to time, we may rely on projections regarding our expected future performance that represent our management's then-current estimates. However, any of these estimates, judgments or projections, or the assumptions underlying them, may change over time or may otherwise prove to be inaccurate. Our results of operations may be adversely affected if our estimates, assumptions or projections change or if actual circumstances differ from those in our estimates or assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock.

For example, we rely on third-party data providers to collect and report estimates of prescription information and pipeline inventory levels as components of our estimations for revenue recognition. There is a limited amount of information available to such data providers to determine the actual number of total prescriptions for prescription products during such periods. Their estimates are based on a combination of data received from pharmacies and other distributors, and historical data when actual data is unavailable. Their calculations of changes in prescription levels between periods can be significantly affected by lags in data reporting from various sources or by changes in pharmacies and other distributors providing data. Such methods can from time to time result in significant inaccuracies in information when ultimately compared with actual results. Further, data for a single and limited period may not be representative of a trend or otherwise predictive of future results.

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 profit.

Risks Related to the Commercialization of EYSUVIS, INVELTYS and our Product Candidates

The ongoing novel coronavirus pandemic and the efforts to prevent its spread have adversely impacted our operations and the market for INVELTYS, could impact the commercialization of EYSUVIS and the development of KPI-012 and may continue to adversely affect our business, results of operations and financial condition.

The outbreak of the COVID-19 pandemic and government measures taken in response to it, including from time to time quarantines, strict travel restrictions and bans, heightened border scrutiny and other measures, have had a significant impact, both direct and indirect, on businesses and commerce; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen significantly.

In particular, from time to time moratoria have been put in place on routine medical appointments and elective surgeries in many jurisdictions, including ocular surgeries, which have adversely affected, and may adversely affect in the future, the market for INVELTYS, which is indicated for the treatment of inflammation and pain following ocular surgery, resulting in a significant reduction in the demand for INVELTYS. The COVID-19 pandemic has negatively impacted revenues from INVELTYS and we expect it to continue to do so until surgeries return to and remain at historical levels. In light of shelter-in-place orders and other mandated local travel and social interaction prohibitions, we previously suspended substantially all in-person interactions with physicians and were limited to conducting educational and promotional activities virtually. Commencing in the fourth quarter of 2020, our sales force resumed substantially all in-person interactions in the field, but to the extent we restrict, or are restricted from, in-person interactions with physicians, we may be limited to conducting educational and promotional activities virtually, which may continue to hamper our ability to market EYSUVIS and INVELTYS.

We and any of our contract manufacturing organizations and contract research organizations may face disruptions that may affect our ability to initiate and complete clinical trials, 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. We may face impediments to regulatory meetings and clearance and approvals due to measures intended to limit in-person interactions. We plan to submit an IND application to the FDA for KPI-012 in the third quarter of 2022 and subject to regulatory clearance, commence a Phase 2/3 clinical trial of KPI-012 for PCED in the United States. The COVID-19 pandemic may delay our planned IND filing and/or the initiation and conduct of our planned clinical trial.

Additionally, while we currently are not experiencing interruptions in our manufacturing of EYSUVIS, INVELTYS or KPI-012, any reinstatement of quarantines, travel restrictions and other measures 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 has already caused significant disruptions in the financial markets, and may again cause such disruptions, 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 significant ongoing impact of the pandemic on economies worldwide could result in more extensive adverse effects on our business and operations. The full extent of the impact of COVID-19 on our development and commercialization efforts will depend on the length and severity of this pandemic, the timing and extent of any resurgence of the COVID-19 virus or any variant strains of the virus, the availability and effectiveness of vaccines, and the impact of the foregoing on our customers, employees and vendors and government agencies, which is uncertain and cannot be predicted. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to significantly and adversely affect our business, financial condition, results of operations and prospects.

EYSUVIS, INVELTYS, KPI-012 or any other product candidate that receives marketing approval 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.

EYSUVIS, INVELTYS, KPI-012 or any other product candidate that we develop that receives marketing approval may fail to gain sufficient market acceptance by clinicians, patients, third-party payors and others in the medical community. While there are no drugs other than EYSUVIS currently approved in the United States for the short-term treatment of the signs and symptoms of dry eye disease, current treatments that are used in the United States for dry eye disease include over-the-counter artificial tears, Restasis®, Xiidra®, Cequa™, Tyrvaya™, off-label use of branded or generic corticosteroids and various drugs that are produced by compounding pharmacies. Generic versions of Restasis are also expected to become available in the United States in the near future. Our current expectations regarding market potential for EYSUVIS are based, in part, on market research data we have commissioned, which indicated that interest in prescribing EYSUVIS is high among surveyed eye care professionals, or ECPs. However, it is possible that ECPs may continue to rely on other existing treatments rather than EYSUVIS. In addition, generic versions of any products that compete with any of our products or product candidates would likely be offered at a substantially lower price than we

offer our products and 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 products or product candidates.

Common treatments in the United States for inflammation and pain following ocular surgery include corticosteroids. Our current estimates of potential future revenue from sales of INVELTYS are based, in part, on market research data we have commissioned, which indicated that a majority of surveyed ophthalmologists were likely to prescribe INVELTYS. However, doctors may continue to rely on ocular steroids other than INVELTYS and other treatments rather than INVELTYS. In addition, there are also non-topical formulations of ocular steroids that are available to patients. It is also possible that other therapeutics will be approved for treatment of inflammation and pain following ocular surgery with twice a day or less frequent dosing.

In addition, 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.

The market opportunity for EYSUVIS, INVELTYS and KPI-012 may be further impacted by extraordinary events such as the current pandemic health event resulting from COVID-19 and its collateral consequences. For example, from time to time moratoria have been put in place on routine medical appointments and elective surgeries in many jurisdictions, including ocular surgeries such as cataract and refractive, which have adversely affected, and may adversely affect in the future, the market for INVELTYS, which is indicated for the treatment of post-operative inflammation and pain following ocular surgery, resulting in a significant reduction in the demand for INVELTYS. In light of shelter-in-place orders and other mandated local travel prohibitions, we previously suspended substantially all in-person interactions with physicians and were limited to conducting educational and promotional activities virtually. Commencing in the fourth quarter of 2020, our sales force resumed substantially all in-person interactions in the field, but to the extent we restrict, or are restricted from, in-person interactions with physicians, we may be limited to conducting educational and promotional activities virtually, which may continue to hamper our ability to market EYSUVIS and INVELTYS.

Our assessment of the potential market opportunity for EYSUVIS, INVELTYS, KPI-012 and our other product candidates is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, some of which we commissioned. 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 dry eye disease and PCED in particular is difficult to precisely estimate. The results from our physician and patient surveys may be less reflective of the dry eye disease population as a whole than a survey conducted with a larger sample size. Our estimates of the potential market opportunities for our product candidates 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 EYSUVIS, INVELTYS, KPI-012 or any other product candidate may be smaller than we expect, and as a result our 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 EYSUVIS, INVELTYS and KPI-012.

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

- the efficacy and potential advantages of our product or 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, particularly by Medicare in light of the prevalence of dry eye disease and cataracts in persons over age 55;
- the clinical indications for which the product is 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 EYSUVIS, INVELTYS, KPI-012 or any other product candidate that we may develop, 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 EYSUVIS, INVELTYS, KPI-012 or any other product candidate that we may develop successfully 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 drug 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 EYSUVIS, INVELTYS, KPI-012 or any other product candidate that we 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, EYSUVIS, INVELTYS, 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 EYSUVIS, INVELTYS, KPI-012 or any other product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, such as EYSUVIS, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug 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 drugs, if applicable, may also not be sufficient to

cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and 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 drug 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 drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the 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.

There can be no assurance that EYSUVIS, INVELTYS, KPI-012 or our other product candidates, even if such product candidates are approved for sale in the United States or in other countries, 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 EYSUVIS, INVELTYS, KPI-012 or our other product candidates profitably.

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

We established our sales and marketing infrastructure for the commercial launch of INVELTYS, our first product, and EYSUVIS, and, as a company, we have limited experience in the sales, marketing and distribution of therapeutic products. To achieve commercial success for any product for which we obtained marketing approval, we may need to establish additional sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties.

In 2019, we completed the initial buildout of our specialty sales, marketing and distribution infrastructure in the United States to commercialize INVELTYS, which included a sales force of 57 territory sales managers, or TSMs, seven regional sales leaders, or RSLs, and three directors of national accounts. During the fourth quarter of 2020, we expanded our sales force to include 91 TSMs, 14 RSLs, and two new area sales leaders. In 2021, we increased our sales force from 91 TSMs to 105 TSMs by the start of the third quarter. Our sales representatives promote both EYSUVIS and INVELTYS.

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. Maintaining a recently expanded sales force requires us to continue to implement and improve our managerial, operational and financial systems, which we may not do effectively. Any inability to manage growth 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, including with respect to the ongoing launch of EYSUVIS. We have

determined to delay any further specialty sales force expansions, pending growth in payor coverage for EYSUVIS and the status of the COVID-19 pandemic. In addition, 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 to expand our sales force and at a higher cost than previously anticipated. If the commercial launch of KPI-012, if approved, any other product candidate for which we establish additional commercial infrastructure is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize EYSUVIS, INVELTYS, KPI-012 or any other product candidate for which we receive marketing approval on our own 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, including as a result of limitation on office visits as a result of COVID-19 or other health concerns, 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 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 EYSUVIS and KPI-012 in certain markets outside the United States, including the European Union, utilizing a variety of collaboration, distribution 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 EYSUVIS and KPI-012 ourselves. We may also consider seeking marketing approval outside the United States for other product candidates 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 EYSUVIS, INVELTYS, KPI-012 or any other product candidate 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 EYSUVIS, INVELTYS, KPI-012 or any other product candidate for which we obtain marketing approval. If we do not maintain our sales, marketing and distribution capabilities successfully, or do not establish additional capabilities if and when needed successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing EYSUVIS, INVELTYS, KPI-012 or any other 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. EYSUVIS, INVELTYS, KPI-012 and our product candidates 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 EYSUVIS, INVELTYS and will face competition with respect to KPI-012 and 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.

Our products and product candidates target markets that are already served by a variety of competing products. Many of these existing products have achieved widespread acceptance among clinicians, patients and payors. In addition, many of these products are available on a generic basis, and our products or 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 generic products.

The current disease management approaches for dry eye disease in the United States includes non-pharmaceutical therapies and pharmaceutical therapies. Non-pharmaceutical therapies include over the counter artificial tear eye drops, which are palliative and used on an intermittent or chronic basis to provide short-term symptomatic relief of dryness and irritation; hot compresses for the eye and lid hygiene management; and devices, such as punctal plugs that are inserted into the tear ducts to inhibit tear drainage, resulting in more moisture on the surface of the eye.

Pharmaceutical therapies for dry eye disease include on label prescription drugs, including Restasis, Xiidra, Tyrvaya and Cequa, which are the only prescription pharmaceutical products other than EYSUVIS that are approved in the United States for use in patients with dry eye disease; and off label prescription drugs, including topical steroid drops and/or other similar products, which are sometimes prescribed for treatment of dry eye disease. Generic versions of Restasis are expected to become available in the United States in the near future. Restasis and Cequa are both topical cyclosporine formulations that are approved for increasing tear production in patients whose tear production is presumed to be suppressed due to ocular keratoconjunctivitis sicca. Xiidra is a topical anti-inflammatory therapy approved for treatment of the signs and symptoms of dry eye disease.

EYSUVIS is indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease, which includes dry eye flares. Any product that is developed for the treatment of the signs and/or symptoms of dry eye disease could directly compete with EYSUVIS, such as Oyster Point Pharma's Tyrvaya™ (varenicline solution) Nasal Spray 0.03 mg, which received FDA approval in October 2021 and is now available with a prescription in November 2021. There are also several product candidates in preclinical and clinical development in the United States for the treatment of dry eye disease. If any of these product candidates is approved and such product candidate either treats the signs and/or symptoms of dry eye disease or reduces the frequency of flares in dry eye patients, it could reduce the overall market opportunity for EYSUVIS. These product candidates are being developed by pharmaceutical, biotechnology, specialty pharmaceutical and generic drug companies of various sizes, such as Aldeyra Therapeutics' reproxalap ophthalmic solution, Novaliq's CyclAsol and NOV03, which have been licensed to Bausch Health Companies Inc., and others.

Following ocular surgery, topical steroids are commonly prescribed to manage and prevent complications from post-operative inflammation. Topical steroid drops are the main competition to INVELTYS for the treatment of inflammation and pain following ocular surgery. The current branded market leaders for topical steroids in the United States, based on revenue, are Lotemax® products and Durezol®. Generic topical steroid formulations consist mainly of products containing prednisolone, fluorometholone or dexamethasone. In addition, the first generic formulations of loteprednol suspension 0.5% (Lotemax suspension) and loteprednol ophthalmic gel 0.5% (Lotemax Gel) were launched in May 2019 and February 2021, respectively, and the first generic version of Durezol was launched in September 2021.

There are also non-topical formulations of ocular steroids that have been approved and/or marketed. Eyepoint Pharmaceutical launched Dexycu®, an intraocular suspension of dexamethasone for the treatment of post-operative inflammation, in July 2019. Also in July 2019, Ocular Therapeutix launched Dextenza®, an intracanalicular insert of dexamethasone, for the treatment of ocular pain following ophthalmic surgery. There are also a number of companies in the United States developing products and therapies in preclinical research and clinical development for the treatment of inflammation and pain following ocular surgery. In addition, there are various formulations of steroids that are produced by compounding pharmacies and that are in drop form or are injected into the eye following ocular surgery.

If approved, we expect KPI-012 to compete with OXERVATE™, which is the one 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. In addition, to our knowledge, there is currently only one product candidate in active clinical development for the treatment of a broad PCED population. ST266, an eye drop, is currently being studied in a Phase 2b clinical trial in patients with PCED and is being developed by Noveome Biotherapeutics Inc, or Noveome. ST266 is a secretome produced from amnion-derived epithelial cells from donated full-term placentas. A number of companies are pursuing development of product candidates for the treatment of NK.

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.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of generic products. Generic products are currently being used for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years.

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. Given that EYSUVIS and INVELTYS utilize a known FDA-approved corticosteroid, these products and any similar product candidates, if approved, may face competition from generic and branded versions of existing drugs based on corticosteroids that are administered in a different manner.

Product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and limit commercialization of EYSUVIS, INVELTYS and any other 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 as we commercialize EYSUVIS, INVELTYS or any other 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 EYSUVIS, INVELTYS and any other 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 EYSUVIS, INVELTYS and any other products that we may develop.

We currently hold $15 million in product liability insurance coverage in the aggregate, with a per incident limit of $15 million, which may not be adequate to cover all liabilities that we may incur. We may need to 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 Product Development

If we are unable to successfully complete the clinical development of KPI-012 and obtain marketing approval, or experience significant delays in doing so, or if, after obtaining marketing approvals, we fail to commercialize our products and product candidates, our business will be materially harmed.

As a result of the acquisition of Combangio, we expect to devote a significant portion of our research and development resources and business efforts to the development of KPI-012, a clinical-stage product candidate for the treatment of PCED.

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

- timely submission and clearance of our planned IND submission for KPI-012 and for any other product candidates we develop;
- completing and obtaining favorable results from our planned clinical trials of KPI-012 and any other product candidate 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;
- receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities for KPI-012 and any other product candidate we develop;
- if approved, successful launch and commercialization of 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 or leveraging our existing sales, marketing, manufacturing and distribution capabilities if and when appropriate;
- 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 our 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 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, which would materially harm our business. In addition, KPI-012 is still in the early stages of clinical development, and all of our other development efforts are in the early stages of preclinical development. We may never generate the necessary data or results required to obtain regulatory approval of KPI-012 or any other product candidate we develop. Therefore, our ability to generate product revenue will depend heavily on the successful commercialization of EYSUVIS and INVELTYS, as the development and eventual commercialization of KPI-012 or any other product candidate may never occur.

If clinical trials of KPI-012 or any other product candidate that we develop fail to demonstrate safety and efficacy 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 safety and efficacy of our product candidates 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 planned Phase 2/3 clinical trial. 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 safety and efficacy 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, we previously conducted a Phase 2 clinical trial of EYSUVIS for the treatment of meibomian gland dysfunction which did not achieve its primary endpoint. The failure of this trial may have an adverse impact on the perceived safety or efficacy of EYSUVIS in treating dry eye disease or other indications or of INVELTYS.

In January 2018, we announced that we had completed two Phase 3 clinical trials evaluating EYSUVIS, STRIDE 1 and STRIDE 2, evaluating the safety and efficacy of EYSUVIS versus placebo in patients with dry eye disease. In STRIDE 1, statistical significance was achieved for both primary endpoints. However, in STRIDE 2 we did not achieve statistical significance for the primary symptom endpoint of ocular discomfort severity. In August 2019, we announced that we received a complete response letter, or CRL, from the FDA indicating that positive efficacy data from an additional clinical trial will be needed to support a resubmission of our new drug application, or NDA. On March 9, 2020, we announced that our Phase 3 clinical trial of EYSUVIS, which we refer to as STRIDE 3, met both of its primary symptom endpoints and its key secondary sign endpoint, and on April 30, 2020, we resubmitted our NDA with the positive data from STRIDE 3. On October 26, 2020, we received approval from the FDA to market EYSUVIS in the United States. Our Phase 3 clinical trials of EYSUVIS may not be sufficient to support an application for marketing approval outside the United States. Further, if regulatory authorities outside the United States do not accept the data from any trial we conduct in the United States, in particular if the European Union does not allow us to utilize the results from our Phase 3 clinical trials of EYSUVIS pursuant to the Article 10(3) submission pathway or otherwise, we will likely need to conduct additional trials to obtain marketing approval in such jurisdiction, which would be costly and time-consuming and could delay or permanently halt our ability to commercialize the applicable product candidates in the applicable jurisdictions.

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;
- ongoing or future restrictions resulting from the COVID-19 pandemic and its 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 dry eye disease or 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 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 the ongoing COVID-19 pandemic; and
- the lack of adequate compensation for prospective patients.

For example, we experienced a delay in patient enrollment for STRIDE 3, which evaluated EYSUVIS for the short-term treatment of the signs and symptoms of dry eye disease. There were a number of factors that may have impacted the delay, including increased competition for eligible patients from competitors that were developing product candidates to treat similar indications and the limited number of patients who fit the eligibility criteria for STRIDE 3. In addition, 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 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 products or product candidates, we may need to abandon or limit our commercialization efforts for our products or development of such product candidates.

If EYSUVIS, INVELTYS, 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 our products or 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. The most common adverse effects to date in trials evaluating the safety and efficacy of EYSUVIS and INVELTYS have been eye pain, instillation site pain, blurred vision and photophobia, which is discomfort or pain due to exposure to light. There have been no serious adverse events related to the administration of EYSUVIS and INVELTYS reported in any of our clinical trials and serious adverse events reported to date following approval and commercialization have been very rare. Increases in IOP and cataract formation are additional adverse effects associated with the use of corticosteroids in general. We have no clinical safety data on or patient exposure to either EYSUVIS or INVELTYS for longer than 28 days. Our understanding of the relationship between our products and these adverse effects may change as we gather more information, and additional unexpected adverse effects may occur. In addition, while KPI-012 was generally well-tolerated in Combangio's Phase 1b clinical trial, it was only administered in 12 subjects. Compounds that initially show promise in clinical or earlier stage testing for treating ophthalmic 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 our products or our product candidates (including use of EYSUVIS or INVELTYS more frequently than is prescribed) by patients could cause increases in IOP and may result in additional unexpected side effects or adverse events. There can be no assurance that our products or our product candidates will be used correctly, and if used incorrectly, such misuse could hamper commercial adoption or market acceptance of our 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. We may never realize the anticipated benefits of the acquisition of Combangio and by investing our limited resources in the acquisition of Combangio and the development of KPI-012, 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 product candidates 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 only been evaluated in a clinical trial outside of the United States. We may in the future conduct clinical trials for product candidates at sites outside the United States, and 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. KPI-012 has only been evaluated in clinical trials outside of the United States. Based on the results of the Phase 1b clinical trial conducted in Mexico, we plan to submit an IND application to the FDA for KPI-012 in the third quarter of 2022 and subject to regulatory clearance, commence a Phase 2/3 clinical trial of KPI-012 for PCED in the United States. However, if the FDA does not accept the data from Combangio's Phase 1b clinical trial of KPI-012 or any trial that we conduct in the future 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.

Risks Related to Our Dependence on Third Parties

We contract with third parties for the manufacture of EYSUVIS, INVELTYS and KPI-012 and plan to contract with third parties for 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 products and 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 commercial quantities of EYSUVIS, INVELTYS or any product candidates. We rely on Woodstock Sterile Solutions Inc. (formerly known as Catalent Pharma Solutions, LLC), or Woodstock, to manufacture and supply to us a minimum amount of EYSUVIS and INVELTYS bottles. We also rely on Altasciences company, or Altasciences, for manufacturing bulk intermediates, and Chemo Iberica SA, or Chemo Iberica, to manufacture and supply to us a bulk supply of loteprednol etabonate, or LE. We expect to rely on third-party manufacturers to manufacture clinical supplies of KPI-012 and any other product candidates we develop and commercial supplies of all of our products if and when approved for marketing by applicable regulatory authorities, as well as for packaging, serialization, storage, distribution and other production logistics. We do not currently have arrangements in place for redundant supply for bulk drug substances.

Certain of our third-party manufacturers have in the past, and may in the future, experience performance issues that result in lower than expected yields. Our third party manufacturers may encounter shortages in the raw materials or

active pharmaceutical ingredient, or API, necessary to produce our product candidates in the quantities needed for our clinical trials, or our products 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 or API, including shortages caused by the purchase of such raw materials or API 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 or API necessary to manufacture sufficient quantities of our products or product candidates, may have a material adverse effect on our business.

While we have long-term commercial supply agreements with third-party manufacturers, if these suppliers do not perform as we expect, we may be required to replace one or more suppliers for EYSUVIS and INVELTYS. These manufacturers, and suppliers to these manufacturers, may also be affected by natural disasters, such as floods or fire, epidemics or pandemics, such as COVID-19, or such manufacturers could face manufacturing issues, such as contamination or regulatory concerns following a regulatory inspection of such facility, requiring us to seek replacement suppliers. Although we believe that there are a number of potential long-term replacements to our suppliers, we may incur added costs and delays in identifying and qualifying any such replacements, including as a result of additional required FDA approvals. Replacements may not be readily available or on acceptable terms, or at all. In addition, 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 drug 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. 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 drug 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 conclude agreements for commercial supply of KPI-012 on acceptable terms or at all.

Following our acquisition of Combangio, we became subject to additional risks related to our reliance on third-party manufacturers for the manufacture of the drug substance and drug 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 mesenchymal stem cell secretome 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 plan to implement 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.

The FDA maintains strict requirements governing the manufacturing process and our third-party manufacturers are subject to inspection and approval by the FDA before we can commence the manufacture and sale of any of our products or product candidates, and thereafter subject to FDA inspection from time to time. Failure by our third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our 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 products and harm our business and results of operations.

EYSUVIS, INVELTYS, 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 planned clinical trials or development timeline.

Our current and anticipated future dependence upon others for the manufacture of EYSUVIS, INVELTYS, 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.

Our commitment to purchase from Woodstock a minimum amount of EYSUVIS and INVELTYS for commercial use may result in us paying for product in excess of our needs if we are not able to successfully commercialize our products and/or successfully estimate our supply needs.

Under our long-term supply agreement with Woodstock, we have agreed to purchase an annual combined minimum amount of EYSUVIS and INVELTYS for commercial use through the expiration of the initial term of the agreement in 2030. We cannot be certain that at any given point our future supply needs will meet or exceed such minimum purchase commitments. If demand for our products falls short of such minimum purchase requirements, our business, results of operation and financial condition may be adversely affected.

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

We expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to develop and commercialize EYSUVIS, INVELTYS, 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 to enhance our own sales, marketing and distribution capabilities in the United States 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 K006, KPI-333 or any other product candidates we develop, including our SEGRMs. 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 products and 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 products or 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 products or 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 products or product candidates 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.

We rely, 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 rely 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 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 our products, producing additional losses and depriving us of potential product revenue.

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 and the commercialization of our products 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 or 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 commercialization of a product or 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.

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 good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for KPI-012 or any future product candidates, 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.

Risks Related to Our Intellectual Property

We may be unable to obtain and maintain patent protection for our technology, products and 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, products 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, products and product candidates, including those acquired in connection with our acquisition of Combangio. We have sought to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our novel technologies, products 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, products 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, products 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, products 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. In particular, a competitor may develop an approach to deliver drugs through the mucus layer to the underlying target tissue that uses a different approach than our AMPPLIFY technology, and therefore may not infringe on our patent rights.

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, products 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 products or 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. We do not expect the U.S. patents covering EYSUVIS and INVELTYS to be eligible for patent term extension due to this limitation. 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 products or one of 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.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, with respect to the patent, a manufacturer of generic drugs would not have to provide advance notice to us of any Abbreviated New Drug Application filed with the FDA to obtain permission to sell a generic version of such product candidate.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, 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. 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, products 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.

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 EYSUVIS, INVELTYS and our product candidates and 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 products, 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 as our product candidates commence commercialization and as we gain the greater visibility associated with being a public company. 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 products or product candidates and their uses. Thus, we do not know with certainty that

EYSUVIS, INVELTYS or 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 our products, 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 products or 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 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.

EYSUVIS, INVELTYS, KPI-012 and certain aspects of our AMPPLIFY technology are protected by patents 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 approved products will be harmed.

A substantial 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 exclusive licenses for patent families relating to EYSUVIS, INVELTYS and our product candidates and some aspects of our AMPPLIFY technology. While we control patent prosecution of the licensed patent families relating to EYSUVIS and INVELTYS, for the remainder of the patent families subject to our exclusive license agreement with The Johns Hopkins University, or JHU, or the JHU License Agreement, that relate to our AMPPLIFY technology, JHU retains control of patent prosecution. In addition, 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 JHU License Agreement and 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 products or 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, our AMPPLIFY technology as well as certain aspects of our patents that use LE as an active ingredient were developed using United States government funds. As a result, the United States government may have certain rights to intellectual property embodied in our current or future products and product candidates based on our AMPPLIFY technology or that use LE as an active ingredient 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 JHU License Agreement, under which we license certain of our patent rights and a significant portion of the technology for EYSUVIS, INVELTYS and certain of our product candidates imposes royalty and other financial obligations on us and other substantial performance obligations. We are subject to similar obligations under the Stanford University License Agreement, pursuant to which we license certain patent rights related to KPI-012. 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 our products or product candidates. 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 JHU may conclude that we have materially breached the JHU License Agreement and might therefore terminate the agreement, thereby removing our ability to market products covered by our license agreement with JHU. If the JHU 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 JHU License Agreement is terminated, JHU 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 JHU license agreement will revert to JHU at no cost to JHU. This could have a material adverse effect on our competitive business position, our financial condition, our results of operations and our business prospects. Similar risks apply to the Stanford University License Agreement, pursuant to which we license intellectual property rights related to KPI-012.

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 the affected products or product candidates, 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 products and 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, our products and 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.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, 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, 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 any other products 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 the product candidate's safety and efficacy. 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 any product candidate that we develop is not effective, is only moderately effective, is not safe 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 drugs 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 drugs 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, 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.

In addition, the COVID-19 pandemic has led to disruptions at the FDA and has prolonged the time necessary for certain new drugs to be reviewed and/or approved. The FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. However, as of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily postponed. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. There can be no assurance that the FDA timely reviews applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

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 EYSUVIS, INVELTYS or our product candidates 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. Our Phase 3 clinical trials of EYSUVIS, INVELTYS or any product candidate 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.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom withdrew from the European Union, effective December 31, 2020. On December 24, 2020, the United Kingdom and European Union entered into a trade and cooperation agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for EYSUVIS, INVELTYS or our product candidates, 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 EYSUVIS, INVELTYS or for any of our products for which we obtain marketing approval. Promotional communications with respect to drug 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, we are limited to promoting EYSUVIS and INVELTYS in accordance with their approved labels and 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 drugs to ensure drugs 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 relating to the promotion of prescription drugs or the promotion or manufacturing of drug products or medical devices may lead to investigations 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.

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 drug 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 EMA from approving other competing products. Additionally, if another company with a competing product candidate were to obtain orphan drug exclusivity for its competing product candidate before we do, we may be barred from marketing our product candidate for the same indication as the competing product candidate during the exclusivity period.

Under the Orphan Drug Act, the FDA may designate a product 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.” 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.

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 a new drug application 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, 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 play a primary role in the recommendation and prescription and use of EYSUVIS and INVELTYS, and will play a primary role in the recommendation and prescription and use of any product candidates for which we obtain marketing approval. Our 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 EYSUVIS and INVELTYS and 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; 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.

Recently enacted and future legislation may affect our ability to commercialize our products and product candidates and the prices we obtain for any products that are approved in the United States or foreign jurisdictions.

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 EYSUVIS, INVELTYS or 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 drugs 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 drug 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 ACA. 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 to the statute, will stay in effect through 2029 unless additional congressional action is taken. 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. 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 EYSUVIS, INVELTYS and for any of our product candidates for which we may obtain regulatory approval or the frequency with which EYSUVIS, INVELTYS or any product candidate is prescribed or used.

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 EYSUVIS, INVELTYS or any other approved product 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 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. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. 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 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.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. 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 candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

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.

Reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

As a condition of reimbursement by various federal and state health insurance programs, pharmaceutical companies are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various

government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such assumptions involve subjective decisions and estimates. Pharmaceutical companies are required to report any revisions to their calculation, price reporting and payment obligations previously reported or paid. Such revisions could affect liability to federal and state payers and also adversely impact reported financial results of operations in the period of such restatement.

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If a company becomes subject to investigations, restatements, or other inquiries concerning compliance with price reporting laws and regulations, it could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on the business, financial condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in increased pressure on pricing and reimbursement of products and thus have an adverse impact on financial position or business operations.

Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in a company having to carry a liability on its consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, the company's financial position and results of operations could be adversely affected.

In addition to retroactive rebates and the potential for 340B Program refunds, if a pharmaceutical firm is found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to the Centers for Medicare & Medicaid Services, or CMS, it may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate the Medicaid drug rebate agreement, pursuant to which companies participate in the Medicaid program. In the event that CMS terminates a rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for covered outpatient drugs.

Additionally, if a pharmaceutical company overcharges the government in connection with the FSS program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price or otherwise, it is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against a company under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we or any third-party manufacturers we engage 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 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. We hold $3.0 million of environmental liability insurance for claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. These limits, both in the aggregate and per incident, may not be adequate to cover all liabilities that we may incur.

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 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, 2020, we had federal net operating loss, or NOL, carryforwards of $243.2 million, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030. As of December 31, 2020, we also had state NOL carryforwards of $215.0 million, which may be available to offset future state income tax liabilities and expire at various dates beginning in 2030, and federal and state research and development credit carryforwards of approximately $2.4 million, which begin to expire in 2039 (federal) and 2034 (state). These 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. We may be further limited by any changes that may have occurred or may occur subsequent to December 31, 2020. 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 may significantly impact 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 may be unable to use a material portion of our NOLs and other tax attributes.

Risks Related to Employee Matters and Managing Growth

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 President and Chief Executive Officer, Todd Bazemore, our Chief Operating Officer, Mary Reumuth, our Chief Financial Officer, Kim Brazzell, Ph.D., our Chief Medical Officer, Hongming Chen, Sc.D., our Chief Scientific Officer, and Eric Trachtenberg, our General Counsel, Chief Compliance Officer and Corporate Secretary, as well as the other principal members of our management, scientific, clinical and commercial 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, following the acquisition of Combangio, we will be highly dependent on the employees who joined us in connection with the Acquisition and their expertise developing biologics.

Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing 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. In addition, we rely on consultants and advisors, including scientific and clinical 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 pursue our growth strategy will be limited.

We have expanded our development, regulatory, commercial and manufacturing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We have experienced significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs, manufacturing, sales, marketing and distribution. To manage growth, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. In addition, the change in our business in connection with the Acquisition, including the addition of a biological product candidate and employees who joined us in connection with the Acquisition, will impose added responsibilities on members of our management, including the need to recruit, hire, retain, motivate and integrate additional employees and business operations, including employees with experience developing biologics should KPI-012 advance through the various stages of development.

Due to our limited financial resources and our limited experience in managing such growth, we may not be able to effectively integrate Combangio into our business and KPI-012 into our business strategy, manage our recently expanded operations, or any future expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Furthermore, operational and other restrictions related to COVID-19 may further hamper our ability to grow as needed and/or to manage our growth. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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 and commercialization of our products.

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, the commercialization of our products 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.

On November 12, 2021, we entered into a lease termination agreement with the landlord for our office and laboratory space at our corporate headquarters in Watertown, Massachusetts, which requires us to vacate the premises by December 31, 2021, subject to the satisfaction of specified conditions. While we have retained a nominal amount of office space on a short-term basis to conduct in-person meetings from time-to-time and have acquired a sublease in Menlo Park, California in connection with our acquisition of Combangio, the vast majority of our employees will not have individual offices or access to dedicated laboratory space after December 31, 2021. We plan to outsource all laboratory activities until such time, if ever, that we maintain our own dedicated laboratory space. 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 partially remote workplace will increase our reliance on third parties to conduct all aspects 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

Our executive officers and directors and their affiliates, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

As of September 30, 2021, our executive officers and directors and their affiliates in the aggregate, owned shares representing approximately 25.80% of our capital stock, based on the most recent institutional stockholder ownership filings with the SEC. Following the closing of the Acquisition, Mark Blumenkranz, a former director and former stockholder of Combangio, joined our board of directors, and Darius Kharabi, the former President and Chief Executive Officer and stockholder of Combangio, joined our company as the Chief Business Officer. As of September 30, 2021, our executive officers and directors, including Dr. Blumenkranz and Mr. Kharabi, and their affiliates in the aggregate, owned shares representing approximately 30.18% of our capital stock, after giving effect to the closing of the Acquisition and the issuance of an aggregate of 6,815,129 shares of our common stock that we expect to issue to the former Combangio stockholders on January 3, 2022 pursuant to the Merger Agreement. As a result, if these stockholders were to choose to act together, they may be able to significantly influence all matters submitted to our stockholders for

approval, as well as our management and affairs. For example, these persons, if they choose to act together, could significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of voting power may delay, defer or prevent a change in control, entrench our management and our board of directors, or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire.

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

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

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

Our shares of common stock began trading on The Nasdaq Global Select Market on July 20, 2017. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be

sustained, which could put downward pressure on the market price for our common stock and thereby affect your ability to sell your shares. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. 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:

- our ability to achieve the anticipated benefits of the Acquisition and to successfully implement our proposed business strategy following the Acquisition;
- market reaction to the Acquisition;
- our success in commercializing EYSUVIS, INVELTYS and other product candidates;
- results of clinical trials of any of our product candidates;
- 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 commercialization of EYSUVIS, INVELTYS and clinical development of KPI-012 and for 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;
- 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 ongoing COVID-19 pandemic;
- general economic, industry and market conditions; and
- 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 fail to successfully commercialize EYSUVIS, INVELTYS, 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 into the market 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 in the public market, 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 12, 2021, we had outstanding 65,500,275 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. Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons 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. Moreover, holders of a substantial number of shares of our common stock, including shares of our common stock issuable upon exercise of outstanding warrants and options, have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. 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 connection with the closing of the Acquisition, we agreed to issue on January 3, 2022 an aggregate of 6,815,129 shares of our common stock to the former Combangio equityholders, and we held back 973,538 shares of our common stock that will be issuable subject to the terms of the Merger Agreement to the Combangio equityholders on the escrow release date. In addition, former Combangio equityholders are entitled to receive from us, subject to the terms and conditions of the Merger Agreement, contingent consideration of up to $5.4 million payable in shares of our common stock upon our achievement of various development and regulatory milestones, and we may elect, subject to the Nasdaq rules, to satisfy a portion of certain milestone payments that are payable to Combangio equityholders in cash through the issuance of up to $15 million of our common stock. While the shares of common stock issued to former Combangio equityholders will be restricted as a result of securities laws, following expiration of applicable holding periods, these shares will be able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act.

In addition, the Merger Agreement obligates us to file a registration statement with respect to public resale of our shares of common stock that may become issuable upon the achievement of certain of the milestones.

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.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2022, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th or if we have annual gross revenues of $1.07 billion or more in any fiscal year, we would cease to be an emerging growth company as of

December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1 billion of non-convertible debt over a three-year period.

We are also 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 an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition to the above reduced disclosure requirements applicable to emerging growth companies, 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:

- 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;
- not being required to furnish a contractual obligations table in "Management's Discussion and Analysis of Financial Condition and Results of Operations"; 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 after we are no longer an emerging growth company, we will 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 Global Select 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 an emerging growth company or a smaller reporting company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies or smaller reporting companies 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 an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with 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 preclude us from paying dividends without the lenders' consent, and 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. On December 22, 2017, President Trump signed into law the 2017 Tax Act, which significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The 2017 Tax Act, among other things, 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%, the limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), the limitation of the deduction for net operating losses arising in taxable years ending after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, the CARES Act was enacted on March 27, 2020 and COVID relief provisions were included in the Consolidated Appropriations Act, 2021, or CAA, which was enacted on December 27, 2020. All contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of net operating losses, which was enacted as part of the 2017 Tax Act. It also provides that net operating losses arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the 2017 Tax Act, the FFCR Act, the CARES Act and the CAA is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also possible that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the 2017 Tax Act, the FFCR Act, the CARES Act or the CAA.

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 15, 2021, we granted stock options to 16 new employees to purchase a total of 92,000 shares of our common stock at an exercise price of $4.01 per share, on August 13, 2021, we granted stock options to eight new employees to purchase a total of 78,000 shares of our common stock at an exercise price of $3.03 per share and on September 15, 2021, we granted stock options to 11 new employees to purchase a total of 112,000 shares of our common stock at an exercise price of $3.08 per share. These options were inducement grants made outside of our 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 award 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 employee's continued service with our company through the applicable vesting date. 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 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.

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 2.1†	-	Agreement and Plan of Merger, dated as of November 15, 2021, by and among Kala Pharmaceuticals, Inc., Ceres Merger Sub, Inc., Combangio, Inc. and, solely in its capacity as Combangio Equityholder Representative, Fortis Advisors LLC. (incorporated by reference to Exhibit 2.1 to Registrant's Current Report on Form 8-K filed with the SEC on November 15, 2021)
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, President and 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
†Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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 PHARMACEUTICALS, INC.

Dated: November 15, 2021

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

Dated: November 15, 2021

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 Pharmaceuticals, 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 15, 2021

By: /s/ Mark Iwicki
Mark Iwicki
President and 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 Pharmaceuticals, 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 15, 2021

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 Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark Iwicki, President and 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 15, 2021

/s/ Mark Iwicki
Mark Iwicki
President and 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 Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2021 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 15, 2021

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