

---

---

**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 June 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 64,971,096 shares of Common Stock, \$0.001 par value per share, outstanding as of August 4, 2021.

---

---

**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I – FINANCIAL INFORMATION</u></b>	<b>3</b>
<u>Item 1.</u> <u>Financial Statements (Unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets as of June 30, 2021 and December 31, 2020</u>	3
<u>Condensed Consolidated Statement of Operations and Comprehensive Loss for the three and six months ended June 30, 2021 and 2020</u>	4
<u>Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and six months ended June 30, 2021 and 2020</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2021 and 2020</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2.</u> <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	23
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	38
<u>Item 4.</u> <u>Controls and Procedures</u>	38
<b><u>PART II – OTHER INFORMATION</u></b>	<b>38</b>
<u>Item 1.</u> <u>Legal Proceedings</u>	38
<u>Item 1A.</u> <u>Risk Factors</u>	39
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	86
<u>Item 6.</u> <u>Exhibits</u>	87
<b><u>SIGNATURES</u></b>	<b>88</b>

**PART I – FINANCIAL INFORMATION****Item 1. Financial Statements.**

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

	<u>June 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 144,635	\$ 77,264
Short-term investments	5,000	76,276
Accounts receivable, net	11,859	9,604
Inventory	8,046	5,229
Prepaid expenses and other current assets	2,180	3,006
Total current assets	<u>171,720</u>	<u>171,379</u>
Non-current assets:		
Property and equipment, net	3,416	3,166
Long-term inventory	9,157	6,219
Right-of-use assets	27,953	27,853
Restricted cash and other long-term assets	3,218	12,989
Total assets	<u>\$ 215,464</u>	<u>\$ 221,606</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,844	\$ 1,724
Accrued expenses and other current liabilities	21,255	18,971
Current portion of lease liabilities	1,977	1,530
Total current liabilities	<u>26,076</u>	<u>22,225</u>
Long-term liabilities:		
Long-term lease liabilities	27,063	27,143
Long-term debt	78,055	72,243
Total long-term liabilities	<u>105,118</u>	<u>99,386</u>
Total liabilities	<u>131,194</u>	<u>121,611</u>
Commitments and Contingencies (Note 14)		
Stockholders' equity:		
Common stock, \$0.001 par value; 120,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 64,770,219 and 58,915,375 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	65	59
Additional paid-in capital	550,898	499,715
Accumulated other comprehensive income	—	4
Accumulated deficit	(466,693)	(399,783)
Total stockholders' equity	<u>84,270</u>	<u>99,995</u>
Total liabilities and stockholders' equity	<u>\$ 215,464</u>	<u>\$ 221,606</u>

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Product revenues, net	\$ 3,051	\$ 833	\$ 6,317	\$ 1,904
Costs and expenses:				
Cost of product revenues	1,016	759	1,771	1,113
Selling, general and administrative	27,986	15,301	55,685	30,709
Research and development	3,094	6,053	6,220	11,487
Total costs and expenses	32,096	22,113	63,676	43,309
Loss from operations	(29,045)	(21,280)	(57,359)	(41,405)
Other income (expense):				
Interest and other income	33	102	76	400
Interest and other expense	(2,091)	(2,134)	(4,232)	(4,262)
Loss on extinguishment of debt	(5,395)	—	(5,395)	—
Total interest and other expense	(7,453)	(2,032)	(9,551)	(3,862)
Net loss	\$ (36,498)	\$ (23,312)	\$ (66,910)	\$ (45,267)
Net loss per share—basic and diluted	\$ (0.57)	\$ (0.42)	\$ (1.06)	\$ (0.94)
Weighted average shares outstanding—basic and diluted	64,554,506	55,703,882	63,113,194	48,232,933
Net loss	\$ (36,498)	\$ (23,312)	\$ (66,910)	\$ (45,267)
Other comprehensive loss:				
Change in unrealized gains on investments	(3)	17	(4)	17
Total other comprehensive loss	(3)	17	(4)	17
Total comprehensive loss	\$ (36,501)	\$ (23,295)	\$ (66,914)	\$ (45,250)

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 June 30, 2021						
	Common Stock		Additional	Accumulated	Accumulated	Total	
	\$0.001 Par Value						Paid-In
	Shares	Amount	Capital	Comprehensive	Income	Equity	
<b>Balance as of March 31, 2021</b>	63,805,108	\$ 64	\$ 539,920	\$	3	\$ (430,195)	\$ 109,792
At the market offering, net of sales agent commission of \$170	837,257	1	6,020	—	—	—	6,021
Exercise of stock options	20,074	—	64	—	—	—	64
Issuance of vested restricted stock units	107,780	—	—	—	—	—	—
Stock-based compensation expense	—	—	4,894	—	—	—	4,894
Change in fair value of investments	—	—	—	(3)	—	—	(3)
Net loss	—	—	—	—	—	(36,498)	(36,498)
<b>Balance as of June 30, 2021</b>	<u>64,770,219</u>	<u>\$ 65</u>	<u>\$ 550,898</u>	<u>\$</u>	<u>—</u>	<u>\$ (466,693)</u>	<u>\$ 84,270</u>

	Three Months Ended June 30, 2020						
	Common Stock		Additional	Accumulated	Accumulated	Total	
	\$0.001 Par Value						Paid-In
	Shares	Amount	Capital	Comprehensive	Income	Equity	
<b>Balance as of March 31, 2020</b>	54,585,636	\$ 55	\$ 458,866	\$	—	\$ (317,411)	\$ 141,510
Exercise of stock options	249,870	—	772	—	—	—	772
Common stock offering, net of offering costs of \$464	979,371	1	7,215	—	—	—	7,216
Stock-based compensation expense	—	—	2,774	—	—	—	2,774
Warrant exercises	16,144	—	—	—	—	—	—
Change in fair value of investments	—	—	—	(17)	—	—	(17)
Net loss	—	—	—	—	—	(23,312)	(23,312)
<b>Balance as of June 30, 2020</b>	<u>55,831,021</u>	<u>\$ 56</u>	<u>\$ 469,627</u>	<u>\$</u>	<u>(17)</u>	<u>\$ (340,723)</u>	<u>\$ 128,943</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

	Six Months Ended June 30, 2021					
	Common Stock \$0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance as of December 31, 2020</b>	58,915,375	\$ 59	\$ 499,715	\$ 4	\$ (399,783)	\$ 99,995
At the market offering, net of offering costs \$1,161	5,583,329	6	40,724	—	—	40,730
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	74,847	—	431	—	—	431
Stock-based compensation expense	—	—	9,780	—	—	9,780
Change in fair value of investments	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	(66,910)	(66,910)
<b>Balance as of June 30, 2021</b>	<u>64,770,219</u>	<u>\$ 65</u>	<u>\$ 550,898</u>	<u>\$ —</u>	<u>\$ (466,693)</u>	<u>\$ 84,270</u>

	Six Months Ended June 30, 2020					
	Common Stock \$0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance as of December 31, 2019</b>	36,086,254	\$ 36	\$ 325,112	\$ —	\$ (295,456)	\$ 29,692
At the market offering, net of sales agent commission of \$388	2,352,671	3	12,543	—	—	12,546
Exercise of stock options	311,028	—	938	—	—	938
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	85,553	—	270	—	—	270
Stock-based compensation expense	—	—	5,358	—	—	5,358
Warrant exercises	16,144	—	—	—	—	—
Change in fair value of investments	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(45,267)	(45,267)
<b>Balance as of June 30, 2020</b>	<u>55,831,021</u>	<u>\$ 56</u>	<u>\$ 469,627</u>	<u>\$ (17)</u>	<u>\$ (340,723)</u>	<u>\$ 128,943</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2021	2020
<b>Cash flows from operating activities:</b>		
Net loss	\$ (66,910)	\$ (45,267)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	504	454
Non-cash operating lease cost	1,118	952
Loss on extinguishment of debt	5,395	—
Amortization of debt discount and other non-cash interest	645	513
Stock-based compensation	9,412	5,271
Amortization of discount on available-for-sale securities	22	—
Change in operating assets and liabilities:		
Accounts receivable	(2,255)	7,282
Prepaid expenses and other current assets	826	1,351
Inventory	(5,387)	(1,306)
Accounts payable	1,250	(973)
Accrued expenses and other current liabilities	1,966	(6,782)
Lease liabilities and other long-term liabilities	(834)	(629)
Net cash used in operating activities	<u>(54,248)</u>	<u>(39,134)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment and other assets	(545)	(915)
Purchases of short-term investments	—	(56,535)
Proceeds from sales or maturities of short-term investments	71,250	—
Net cash provided by (used in) investing activities	<u>70,705</u>	<u>(57,450)</u>
<b>Cash flows from financing activities:</b>		
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	40,730	137,969
Payment of principal on finance lease	(17)	(16)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	679	1,207
Net cash provided by financing activities	<u>41,164</u>	<u>139,160</u>
<b>Net increase in cash, cash equivalents and restricted cash:</b>	57,621	42,576
Cash, cash equivalents and restricted cash at beginning of period	89,756	98,031
Cash, cash equivalents and restricted cash at end of period	<u>\$ 147,377</u>	<u>\$ 140,607</u>
<b>Reconciliation of cash, cash equivalents and restricted cash:</b>		
Cash, cash equivalents, and restricted cash at end of period	\$ 147,377	\$ 140,607
Less restricted cash (Note 8)	(2,742)	(12,584)
Cash and cash equivalents at end of period	<u>\$ 144,635</u>	<u>\$ 128,023</u>
<b>Non-cash investing and financing activities:</b>		
Purchases of property and equipment in accrued expenses	\$ 318	\$ —
<b>Supplemental disclosure:</b>		
Cash paid for interest	\$ 3,030	\$ 3,749
Right-of-use assets obtained in exchange of operating lease obligations	1,218	—

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<sup>®</sup> 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<sup>®</sup> (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<sup>®</sup> (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, 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; 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; and its 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. 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 June 30, 2021, the Company had an accumulated deficit of \$466,693. 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, cash equivalents and short-term investments as of June 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. As a result, all office-based personnel are permitted to work from home, and the Company’s laboratory facilities that support its early-stage research activities are being utilized as necessary. In addition, 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. The Company’s sales force has since 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 our 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 six months ended June 30, 2021 and 2020.

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

As of June 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 10,043,748 and 8,573,573 shares of the Company's common stock, respectively, an aggregate of 1,282,830 and 957,097 unvested RSUs and PSUs, respectively, and an aggregate of 215,172 and 248,505 unexercised warrants, respectively.

**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 June 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 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.

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

- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company’s financial instruments consist 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 June 30, 2021 and December 31, 2020:

	June 30, 2021			
	Fair Value	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents	\$ 126,118	\$ 126,118	\$ —	\$ —
Short-term investments	5,000	5,000	—	—
<b>Total Assets</b>	<b>\$ 131,118</b>	<b>\$ 131,118</b>	<b>\$ —</b>	<b>\$ —</b>

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

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

**4. INVESTMENTS**

Investments by security type consisted of the following as of June 30, 2021 and December 31, 2020:

	June 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government agencies securities	\$ 5,000	\$ —	\$ —	\$ 5,000
<b>Total</b>	<b>\$ 5,000</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 5,000</b>

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

	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
<b>Total</b>	<b>\$ 76,272</b>	<b>\$ 4</b>	<b>\$ —</b>	<b>\$ 76,276</b>

As of June 30, 2021 and 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 Company also holds inventory at a third-party pharmacy on a consignment basis and records revenue when control of the product transfers to the customer upon sale to the end user. The amount of inventory held on a consignment basis as of June 30, 2021 and December 31, 2020 was immaterial.

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.

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

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

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

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.

The following tables summarize activity in each of the Company’s product revenue provision and allowance categories for the three and six months ended June 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	<u>\$ 1,538</u>	<u>\$ 456</u>	<u>\$ 7,214</u>
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	<u>\$ 1,411</u>	<u>\$ 701</u>	<u>\$ 8,253</u>

	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	<u>\$ 1,396</u>	<u>\$ 114</u>	<u>\$ 6,623</u>
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	<u>\$ 398</u>	<u>\$ 64</u>	<u>\$ 5,570</u>

- (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

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

time revenues are recognized and are included in accrued expenses and other current liabilities on the Company's condensed consolidated balance sheets.

**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 June 30, 2021 or December 31, 2020. The Company recorded an allowance of \$1,411 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 June 30, 2021 and December 31, 2020, respectively.

**6. INVENTORY**

Inventory consists of the following:

	<u>June 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Raw materials	\$ 1,485	\$ 801
Work in progress	9,580	6,437
Finished goods	6,138	4,210
Total inventory	<u>\$ 17,203</u>	<u>\$ 11,448</u>

As of June 30, 2021, the Company had \$8,046 of current inventory and \$9,157 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:

	<u>June 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Accrued revenue reserves (1)	\$ 8,261	\$ 5,224
Compensation and benefits	8,035	9,676
Commercial costs	2,121	2,103
Contract manufacturing	773	336
Professional services	605	926
Interest	533	—
Development costs	377	154
Other	550	552
Accrued expenses	<u>\$ 21,255</u>	<u>\$ 18,971</u>

(1) There were additional revenue reserves included in accounts payable of \$693 and \$280, as of June 30, 2021 and December 31, 2020, respectively.

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

**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 June 30, 2021 and December 31, 2020.

For the three and six months ended June 30, 2021, the variable lease expense for the Watertown Lease, which includes common area maintenance and real estate taxes, was \$334 and \$697, respectively. For the three and six months ended June 30, 2020, the variable lease expense for the Watertown Lease, which includes common area maintenance and real estate taxes, was \$611 and \$1,068, respectively. The remaining lease term was 10.3 years as of June 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 June 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 six months ended June 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
<b>Lease cost</b>				
Operating lease cost	\$ 1,268	\$ 1,185	\$ 2,484	\$ 2,371
Variable lease cost	584	658	1,093	1,068
<b>Total lease cost</b>	<u>\$ 1,852</u>	<u>\$ 1,843</u>	<u>\$ 3,577</u>	<u>\$ 3,439</u>
Operating cash outflows from operating leases	\$ 1,659	\$ 1,686	\$ 3,243	\$ 3,130

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

	June 30, 2021	December 31, 2020
Weighted average remaining lease term	9.9 years	10.3 years
Weighted average discount rate	9.6%	9.8%



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

**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.

*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 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.

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

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 June 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 June 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 June 30, 2021 and June 30, 2020, the Company recognized interest expense of \$1,860 and \$2,095, respectively, for the Loan Agreement and Athyrium Credit Facility. This consisted of amortization of debt discount of \$150 and \$223 for the periods ended June 30, 2021 and June 30, 2020, respectively, and the contractual coupon interest expense of \$1,710 and \$1,872 for the periods ended June 30, 2021 and June 30, 2020, respectively. During the six months ended June 30, 2021 and June 30, 2020, the Company recognized interest expense of \$3,952 and \$4,183, respectively. This consisted of amortization of debt discount of \$390 and \$439 for the periods ended June 30, 2021 and June 30, 2020, respectively, and the contractual coupon interest expense of \$3,562 and \$3,744 for the periods ended June 30, 2021 and June 30, 2020, respectively.

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

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

	June 30, 2021	December 31, 2020
Principal loan balance	\$ 80,000	\$ 75,000
Unamortized debt discount and issuance cost	(2,150)	(3,088)
Cumulative accretion of exit fee	205	331
Long-term debt, net	<u>\$ 78,055</u>	<u>\$ 72,243</u>

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

<b>Years Ending December 31,</b>	
2021 (remaining six months)	\$ —
2022	—
2023	—
2024	4,445
2025	53,333
Thereafter	22,222
Total	<u>\$ 80,000</u>

**10. WARRANTS**

The following table summarizes the common stock warrants outstanding as of June 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	
				June 30, 2021	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
				<u>215,172</u>	<u>248,505</u>

**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

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

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, the Company has issued an aggregate of 30,549,976 shares of common stock, including under the ATM Offering, resulting in aggregate gross proceeds of \$231,666. There was \$18,334 of securities available to be issued under the 2018 Shelf Registration as of June 30, 2021.

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 six months ended June 30, 2021, the Company issued and sold an additional 837,257 and 5,583,329 shares of its common stock under its ATM Offering, respectively, resulting in net proceeds of \$6,021 and \$40,730, respectively. As of June 30, 2021, there was \$11,859 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 six months ended June 30, 2021, the Company granted options for the purchase of 1,604,964 shares of common stock including 148,700 non-statutory stock options granted to new employees and 556,333 restricted stock units. In January 2021, employees of the Company purchased an aggregate of 74,847 shares under the ESPP. In July 2021, employees of the Company purchased an aggregate of 200,877 shares under the ESPP.

The assumptions used in determining fair value of the stock options granted during the six months ended June 30, 2021 are as follows:

	Six Months Ended June 30, 2021	
Expected volatility	72.9%	– 74.2%
Risk-free interest rate	0.50%	– 1.07%
Expected dividend yield	0%	
Expected term (in years)	6.03	– 6.10

During the six months ended June 30, 2021 the weighted average grant-date fair value of options granted was \$4.37.

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 June 30, 2021. As of June 30, 2021, a total of 1,370,830 RSUs and PSUs were outstanding, consisting of 1,282,830 unvested shares and 88,000 vested and deferred shares.

**KALA PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
(Unaudited)  
(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 six months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of product revenues	\$ 37	\$ 9	\$ 71	\$ 28
Research and development	986	551	1,952	1,274
Selling, general and administrative	3,687	1,933	7,389	3,686
Total	<u>\$ 4,710</u>	<u>\$ 2,493</u>	<u>\$ 9,412</u>	<u>\$ 4,988</u>

### 13. INCOME TAXES

The Company did not record a provision or benefit for income taxes during the three and six months ended June 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 June 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 six months ended June 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 June 30, 2021 and 2020, the Company paid JHU \$33 and \$11, respectively, in royalty payments associated with the sales of EYSUVIS and INVELTYS. During the six months ended June 30, 2021 and 2020, the Company paid JHU \$55 and \$23, respectively, in royalty payments associated with the sales of EYSUVIS and INVELTYS. The Company paid JHU a \$150 milestone payment during the six months ended June 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 \$21 and \$31 for the three months ended June 30, 2021 and 2020, respectively. The Company recorded a credit for other expenses related to the JHU agreement of \$30 and other expenses of \$76 for the six months ended June 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 minimum purchase obligations for EYSUVIS and INVELTYS as of June 30, 2021:

<b>Years Ending December 31,</b>	
2021 (remaining six months)	\$ 2,295
2022	5,390
2023	6,285
2024	7,875
2025	8,199
Thereafter	17,925
<b>Total minimum purchase commitments</b>	<b>\$ 47,969</b>

## 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.

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 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. We plan to further expand our sales force up to 125 TSMs by year-end, subject to continued growth in payor coverage and the status of the COVID-19 pandemic. Our sales representatives promote both EYSUVIS and INVELTYS. We expect to commercialize in the United States any of our 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 \$36.5 million and \$66.9 million for the three and six months ended June 30, 2021, respectively, and \$104.3 million for the year ended December 31, 2020. As of June 30, 2021, we had an accumulated deficit of \$466.7 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. 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. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

### **Business Impact of COVID-19 Pandemic**

In order to safeguard the health of our employees from the COVID-19 pandemic, we follow, 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. As a result, all office-based personnel are permitted to work from home, and our laboratory facilities that support our early-stage research activities are being utilized as necessary. In addition, we previously suspended our sales force from substantially all in-person interactions with physicians and were limited to conducting educational and promotional activities virtually. Our sales force has since resumed substantially all in-person interactions in the field, but to the extent we restrict, or are restricted from, in-person interactions with physicians in the future, 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. The extent of the impact of the COVID-19 pandemic on our commercialization efforts of EYSUVIS and INVELTYS 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 launch and commercialization of EYSUVIS 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, and INVELTYS prescriptions have returned to quarterly growth, 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 full promotional launch and commercialization of EYSUVIS.

### ***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 in the future as we continue to build our commercial infrastructure to support the full promotional launch and commercialization of EYSUVIS and the continued commercialization of INVELTYS or of any product candidates for which we obtain marketing approval. We also anticipate that our selling, general and administrative expenses will increase if and as we increase our administrative headcount to support our continued research activities and development of our product candidates. 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, or CROs, 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 in 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- Short Term Relief In Dry Eye), 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 if and as we continue to advance our preclinical development programs, identify product candidates and conduct preclinical studies and clinical trials. 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 our 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.

Our research and development programs are at the early stage of 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.

### **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 June 30, 2021 and 2020**

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

	Three Months Ended June 30,		Change
	2021	2020	
	(in thousands)		
Product revenues, net	\$ 3,051	\$ 833	\$ 2,218
Costs and expenses:			
Cost of product revenues	1,016	759	257
Selling, general and administrative	27,986	15,301	12,685
Research and development	3,094	6,053	(2,959)
Total operating expenses	32,096	22,113	9,983
Loss from operations	(29,045)	(21,280)	(7,765)
Other income (expense)			
Interest income	33	102	(69)
Interest expense	(2,091)	(2,134)	43
Loss on extinguishment of debt	(5,395)	—	(5,395)
Net loss	<u>\$ (36,498)</u>	<u>\$ (23,312)</u>	<u>\$ (13,186)</u>

*Product revenues, net*

Product revenues, net was \$3.1 million for the three months ended June 30, 2021, consisting of \$1.7 million from EYSUVIS sales and \$1.4 million from INVELTYS sales, compared to \$0.8 million from INVELTYS sales for the three months ended June 30, 2020. There were no sales of EYSUVIS in the three months ended June 30, 2020. The increase in product revenues, net of \$2.3 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 three months ended June 30, 2021 as well as a higher per unit gross selling price of INVELTYS as compared to those sold during the three months ended June 30, 2020. These increases in INVELTYS sales were partially offset by higher estimated reserves per unit during the three months ended June 30, 2021 as compared to those estimated during the three months ended June 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.

*Cost of product revenues*

Cost of product revenues was \$1.0 million for the three months ended June 30, 2021, compared to \$0.8 million for the three months ended June 30, 2020, an increase of \$0.2 million. Cost of product revenues increased \$0.5 million due to an increase in total INVELTYS units sold during the three months ended June 30, 2021, compared to the three months ended June 30, 2020 as well as a higher INVELTYS cost per unit as a result of the units sold during the three months ended June 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 June 30, 2021. Offsetting these increases was a reserve for excess inventory of \$0.5 million recorded during the three months ended June 30, 2020, which did not occur in the three months ended June 30, 2021. The cost of product revenues attributable to EYSUVIS was \$0.2 million for the three months ended June 30, 2021. There were no sales of EYSUVIS in the three months ended June 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 \$28.0 million for the three months ended June 30, 2021, compared to \$15.3 million for the three months ended June 30, 2020, which was an increase of \$12.7 million. Selling, general and administrative expenses for the three months ended June 30, 2021 included a \$4.8 million increase in external sales and marketing costs as compared to the three months ended June 30, 2020, primarily as a result of the launch of EYSUVIS. External sales and marketing costs incurred during the three months ended June 30, 2020 primarily related to commercial activities for INVELTYS. Also contributing to the increase in selling, general and administrative expenses for the three months ended June 30, 2021 was a \$5.7 million increase in employee-related expenses primarily due to an increase in employee headcount related to the launch of EYSUVIS and merit-based pay, a \$1.6 million increase in stock-based compensation costs and a \$0.9 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 \$0.3 million decrease in costs for administrative and professional service fees. We anticipate that our selling, general and administrative expenses will increase in the future as we continue to commercialize EYSUVIS and INVELTYS and if and as we increase our administrative headcount to support our continued research and development activities and seek marketing approval for our product candidates.

### Research and development expenses

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

	Three Months Ended June 30,		Change
	2021	2020	
	(in thousands)		
KPI-121 development costs	\$ 16	\$ 2,034	\$ (2,018)
Employee-related costs	2,106	3,357	(1,251)
Other research and development costs	972	662	310
Total research and development	<u>\$ 3,094</u>	<u>\$ 6,053</u>	<u>\$ (2,959)</u>

Research and development expenses were \$3.1 million for the three months ended June 30, 2021, compared to \$6.1 million for the three months ended June 30, 2020, a \$3.0 million decrease. The decrease was primarily the result of a \$2.0 million decrease in EYSUVIS development costs related to a decrease in external spend on STRIDE 3, our Phase 3 clinical trial of EYSUVIS, and a \$1.3 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 \$0.3 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 if and as we advance our development programs and conduct any necessary preclinical studies and clinical trials and other development activities for product candidates.

### Interest income

Interest income was less than \$0.1 million for the three months ended June 30, 2021, compared to \$0.1 million for the three months ended June 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. The decrease was attributable to lower interest rates during the three months ended June 30, 2021.

### Interest expense

We incurred interest expense of \$2.1 million for the three months ended June 30, 2021, which remained consistent with interest expense of \$2.1 million for the three months ended June 30, 2020. Interest expense 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. During the three months ended June 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 three months ended June 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 three months ended June 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 three months ended June 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 three months ended June 30, 2021. There was no loss on extinguishment of debt for the three months ended June 30, 2020.

**Comparison of the Six Months Ended June 30, 2021 and 2020**

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

	Six Months Ended June 30,		Change
	2021	2020	
	(in thousands)		
Product revenues, net	\$ 6,317	\$ 1,904	\$ 4,413
Costs and expenses:			
Cost of product revenues	1,771	1,113	658
Selling, general and administrative	55,685	30,709	24,976
Research and development	6,220	11,487	(5,267)
Total operating expenses	63,676	43,309	20,367
Loss from operations	(57,359)	(41,405)	(15,954)
Other income (expense)			
Interest income	76	400	(324)
Interest expense	(4,232)	(4,262)	30
Loss on extinguishment of debt	(5,395)	—	(5,395)
Net loss	<u>\$ (66,910)</u>	<u>\$ (45,267)</u>	<u>\$ (21,643)</u>

*Product revenues, net*

Product revenues, net was \$6.3 million for the six months ended June 30, 2021, consisting of \$3.3 million from EYSUVIS sales and \$3.0 million from INVELTYS sales, compared to \$1.9 million from INVELTYS sales for the six months ended June 30, 2020. There were no sales of EYSUVIS in the six months ended June 30, 2020. The increase in product revenues, net of \$4.4 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 six months ended June 30, 2021 as well as a higher per unit gross selling price of INVELTYS as compared to those sold during the six months ended June 30, 2020. These increases in INVELTYS sales were partially offset by higher estimated reserves per unit during the six months ended June 30, 2021 as compared to those estimated during the six months ended June 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.

*Cost of product revenues*

Cost of product revenues was \$1.8 million for the six months ended June 30, 2021, compared to \$1.1 million in the six months ended June 30, 2020, an increase of \$0.7 million. Cost of product revenues increased \$0.8 million due to an increase in total INVELTYS units sold during the six months ended June 30, 2021, compared to the six months ended June 30, 2020 as well as a higher INVELTYS cost per unit as a result of the units sold during the six months ended June 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 six months ended June 30, 2021. Partially offsetting these increases was a reserve for excess inventory of \$0.5 million recorded during the six months ended June 30, 2020, which did not occur in the six months ended June 30, 2021. The cost of product revenues attributable to EYSUVIS was \$0.4 million for the six months ended June 30, 2021. There were no sales of EYSUVIS in the six months ended June 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 \$55.7 million for the six months ended June 30, 2021, compared to \$30.7 million for the six months ended June 30, 2020, which was an increase of \$25.0 million. Selling, general and administrative expenses for the six months ended June 30, 2021 included a \$10.3 million increase in external

[Table of Contents](#)

sales and marketing costs as compared to the six months ended June 30, 2020, primarily as a result of the launch of EYSUVIS. External sales and marketing costs incurred during the six months ended June 30, 2020 primarily related to commercial activities for INVELTYS. Also contributing to the increase in selling, general and administrative expenses for the six months ended June 30, 2021 was a \$9.8 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 \$3.4 million increase in stock-based compensation costs and a \$1.5 million increase 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 in the future as we continue to commercialize EYSUVIS and INVELTYS and if and as we increase our administrative headcount to support our continued research and development activities and seek marketing approval for our product candidates.

#### *Research and development expenses*

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

	Six Months Ended June 30,		Change
	2021	2020	
	(in thousands)		
KPI-121 development costs	\$ 89	\$ 3,715	\$ (3,626)
Employee-related costs	4,311	6,234	(1,923)
Other research and development costs	1,820	1,538	282
Total research and development	<u>\$ 6,220</u>	<u>\$ 11,487</u>	<u>\$ (5,267)</u>

Research and development expenses were \$6.2 million for the six months ended June 30, 2021, compared to \$11.5 million for the six months ended June 30, 2020, a \$5.3 million decrease. The decrease was primarily the result of a \$3.6 million decrease in EYSUVIS development costs related to 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 \$0.2 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 if and as we advance our development programs and conduct any necessary preclinical studies and clinical trials and other development activities for product candidates.

#### *Interest income*

Interest income was \$0.1 million for the six months ended June 30, 2021, compared to \$0.4 million for the six months ended June 30, 2020, a decrease of \$0.3 million. Interest income consists of interest earned on our cash, cash equivalents and short-term investments. The decrease was attributable to lower interest rates during the six months ended June 30, 2021.

#### *Interest expense*

We incurred interest expense of \$4.2 million for the six months ended June 30, 2021, compared to \$4.3 million for the six months ended June 30, 2020, a \$0.1 million decrease. Interest expense 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. During the six months ended June 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 six months ended June 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 six months ended June 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 six months ended June 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 unaccrued exit fee were recorded as loss on extinguishment of debt for the six months ended June 30, 2021. There was no loss on extinguishment of debt for the six months ended June 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. Under the 2018 Shelf Registration, we may periodically offer one or more types of securities in amounts, at prices and on terms announced, if and when the securities are ever offered.

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 unaccrued 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, we have 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. There was \$18.3 million of securities available to be issued under the 2018 Shelf Registration as of June 30, 2021.

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 six months ended June 30, 2021, we issued and sold an additional 837,257 and 5,583,329 shares of our common stock under our ATM Offering, respectively, resulting in net proceeds to us of \$6.0 million and \$40.7 million, respectively. As of June 30, 2021, there was \$11.9 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 (in such capacity, the “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, 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.

### **Cash Flows**

As of June 30, 2021 and 2020, we had \$149.6 million and \$184.6 million, respectively, in cash, cash equivalents and short-term investments. As of June 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 June 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 six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (54,248)	\$ (39,134)
Net cash provided by (used in) investing activities	70,705	(57,450)
Net cash provided by financing activities	41,164	139,160
Increase in cash and restricted cash	<u>\$ 57,621</u>	<u>\$ 42,576</u>

#### *Operating Activities*

Net cash used in operating activities for the six months ended June 30, 2021 was \$54.2 million compared to \$39.1 million for the six months ended June 30, 2020, an increase of \$15.1 million, primarily due to an \$11.7 million increase in the net loss adjusted for non-cash charges and the timing of working capital fluctuations which accounted for \$3.4 million of the increase. Notable working capital fluctuations include an increase to accounts receivable in the six months ended June 30, 2021 of \$2.3 million driven by an increase in sales largely due to the launch of EYSUVIS, whereas accounts receivable had decreased by \$7.3 million in the six months ended June 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 six months ended June 30, 2021 due to an increase in manufacturing activity for EYSUVIS and INVELTYS. Offsetting these increases was an increase in accrued expenses and other current liabilities during the six months ended June 30, 2021 of \$2.0 million, as compared to a decrease in accrued expenses and other current liabilities in the six months ended June 30, 2020 of \$6.8 million.

#### *Investing Activities*

Net cash provided by investing activities for the six months ended June 30, 2021 was \$70.7 million compared to net cash used of \$57.5 million for the same period in 2020, an increase of \$128.2 million. Net cash provided by investing activities for the six months ended June 30, 2021 primarily related to the sales or maturities of short-term investments \$71.3 million. Net cash used in investing activities for the six months ended June 30, 2020 primarily related to the purchases of short-term investments of \$56.5 million.

#### *Financing Activities*

Net cash provided by financing activities for the six months ended June 30, 2021 was \$41.2 million, a decrease of \$98.0 million compared to \$139.2 million in the six months ended June 30, 2020. Net cash provided by financing activities for the six months ended June 30, 2021 included \$77.8 million of net proceeds from the tranche A term loan under our Loan Agreement, \$40.7 million of net proceeds from the sale of shares of our common stock under the ATM Offering and \$0.7 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 six months ended June 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,

\$12.6 million of net proceeds from the sale of shares of our common stock under the ATM Offering and \$1.2 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 expenses will increase substantially as compared to prior periods as we continue to commercialize INVELTYS in the United States and execute our commercial launch plans for EYSUVIS, as a result of increased headcount, including management personnel to support our clinical, manufacturing and commercialization activities, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and increased insurance premiums, among other factors. The increase in headcount includes the expansion of our sales force from 56 TSMs to 91 TSMs, which occurred in the fourth quarter of 2020, and from 91 TSMs to 105 TSMs, which occurred around the start of the third quarter 2021, with a subsequent expansion up to 125 TSMs expected by year-end, subject to continued growth in payor coverage and the status of the COVID-19 pandemic.

Our expenses will also increase if and as we:

- 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;
- continue to scale up our manufacturing processes and capabilities to support commercialization of EYSUVIS and INVELTYS;
- seek regulatory approval for EYSUVIS and INVELTYS outside of the United States;
- 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 future 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;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel;
- 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, cash equivalents and short-term investments as of June 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 for at least two years. 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.

## [Table of Contents](#)

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. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- successfully launching EYSUVIS and growing EYSUVIS revenues;
- successfully growing 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;
- manufacturing at commercial scale, marketing, selling and distributing EYSUVIS and INVELTYS;
- maintaining regulatory and marketing approvals for EYSUVIS and INVELTYS;
- discovering, developing and successfully seeking marketing approval and commercialization of 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.

In addition, our recent commercialization efforts have 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. Our sales force has since 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 INVELTYS and could adversely affect our ability to launch and market EYSUVIS. 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 COVID-19 on our 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 consist primarily of cash equivalents and short-term investments. Our cash equivalents as of June 30, 2021 consisted of money market accounts that have contractual maturities of less than 90 days from the date of acquisition. Our short-term investments as of June 30, 2021 consist of U.S. Government Agencies Securities. Due to the short-term maturities of our cash equivalents and short-term investments, 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 and short-term investments.

As of June 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 June 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 June 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 June 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 June 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 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 \$36.5 million and \$66.9 million for the three and six months ended June 30, 2021 and \$104.3 million for the year ended December 31, 2020. As of June 30, 2021, we had an accumulated deficit of \$466.7 million. 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. 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. 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 expenses will increase substantially as compared to prior periods as we continue to commercialize INVELTYS in the United States and execute our commercial launch plans for EYSUVIS, as a result of increased headcount, including management personnel to support our clinical, manufacturing and commercialization activities, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and increased insurance premiums, among other factors. The increase in headcount includes the expansion of our sales force from 56 territory sales managers, or TSMs, to 91 TSMs, which occurred in the fourth quarter of 2020, and from 91 TSMs to 105 TSMs, which occurred around the start of the third quarter 2021, with a subsequent expansion up to 125 TSMs expected by year-end, subject to continued growth in payor coverage and the status of the COVID-19 pandemic.

Our expenses will also increase if and as we:

- 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;
- continue to scale up our manufacturing processes and capabilities to support commercialization of EYSUVIS and INVELTYS;



## [Table of Contents](#)

- seek regulatory approval for EYSUVIS and INVELTYS outside of the United States;
- 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 future 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;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel;
- 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. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- successfully launching EYSUVIS and growing EYSUVIS revenues;
- successfully growing 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;
- manufacturing at commercial scale, marketing, selling and distributing EYSUVIS and INVELTYS;



- maintaining regulatory and marketing approvals for EYSUVIS and INVELTYS;
- discovering, developing and successfully seeking marketing approval and commercialization of 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.

In addition, our recent commercialization efforts have 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. Our sales force has since 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 INVELTYS and could adversely affect our ability to launch and market EYSUVIS. 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 COVID-19 on our 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 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 launch and commercialization of EYSUVIS. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had 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 as we advance our preclinical activities for our product candidates. We also expect to incur significant additional expenses if and as we conduct further research and development activities, and potentially initiate clinical trials of, and seek regulatory approval for, any product candidates that we identify and advance, including product candidates from our receptor Tyrosine Kinase Inhibitor, or rTKI, 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. For example, with the approval of EYSUVIS, we increased our sales force from 56 TSMs to 91 TSMs and from seven RSLs to 14 RSLs during the fourth quarter of 2020 and then to 105 TSMs around the start of the third quarter 2021, with a subsequent expansion up to 125 TSMs expected by year-end, subject to continued growth in payor coverage and the status of the COVID-19 pandemic. 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 costs and timing of commercialization activities for EYSUVIS and INVELTYS, including the costs and timing of expanding our sales force and establishing additional product sales, marketing, medical affairs, distribution and outsourced manufacturing capabilities;
- our ability to successfully commercialize and sell EYSUVIS and INVELTYS 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 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, cash equivalents, and short-term investments of

\$149.6 million as of June 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 for at least two years. 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, other than our approved products, EYSUVIS and INVELTYS, all of our other development efforts are in the early stages of preclinical development. 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 our preclinical development programs. Also, even if we successfully identify and develop product candidates from our preclinical development programs and 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 and INVELTYS, or any product candidates 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.

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 June 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 take certain 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 launch and commercialization of EYSUVIS 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. Our sales force has since 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 INVELTYS and could adversely affect our ability to launch and market EYSUVIS. Furthermore, while the majority of our day-to-day operations are continuing as our employees are permitted to work remotely, our laboratory facilities that support our early-stage research activities were partially limited, and may be limited again in the future, as a result of COVID-19.

Additionally, while we currently are not experiencing interruptions in our manufacturing of EYSUVIS or INVELTYS, 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 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 or any of our product candidates that receive 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 or any 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<sup>®</sup>, Xiidra<sup>®</sup>, Cequa<sup>™</sup>, off-label use of 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.

The market opportunity for EYSUVIS and INVELTYS 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. Our sales force has since 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 INVELTYS and could adversely affect our ability to successfully launch and market EYSUVIS.

Our assessment of the potential market opportunity for EYSUVIS, INVELTYS and our 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 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 or any of our product candidates 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 and INVELTYS.

If EYSUVIS, INVELTYS or any of our product candidates 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 or any product candidates 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;



## [Table of Contents](#)

- 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 or any 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 or any of our product candidates 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 or any 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 or any 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 or any 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 or our 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 or our 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 or any of our product candidates 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 TSMs, seven 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, increased our sales force from 91 TSMs to 105 TSMs by the start of the third quarter, with a subsequent expansion up to 125 TSMs expected by year-end subject to continued growth in payor coverage and the status of the COVID-19 pandemic. Our sales representatives promote both EYSUVIS and INVELTYS. There are risks involved with establishing, maintaining and expanding our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any future product launch. Further, we may underestimate the size of the sales force required for a successful product launch, including with respect to the launch of EYSUVIS, and may need to expand our sales force earlier and at a higher cost than we anticipated. If the commercial launch of any of our product candidates 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 or any product candidates 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 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 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 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 or any of our product candidates 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 or any of our product candidates 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 or any of our product candidates 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 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 any product candidates 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, 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. There are 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 Oyster Point Pharma's OC-01 nasal spray, for which an NDA was submitted in December 2020 and, if approved, could be launched as early as late 2021, 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<sup>®</sup> products and Durezol<sup>®</sup>. 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 Durezol lost its patent exclusivity in 2019, which could result in a potential generic launch of this product at any time.

There are also non-topical formulations of ocular steroids that have been recently approved and/or marketed. Eyepoint Pharmaceutical launched Dexycu<sup>®</sup>, an intraocular suspension of dexamethasone for the treatment of post-operative inflammation, in July 2019. Also in July 2019, Ocular Therapeutix launched Dextenza<sup>®</sup>, 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.

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.

***If our contracted manufacturing facilities experience production issues for any reason, we may be unable to manufacture commercial quantities of our products or product candidates for a substantial amount of time, which could have a material adverse effect on our business.***

We rely on third-party contract manufacturers to manufacture commercial supplies of EYSUVIS and INVELTYS. Specifically, we rely on the following: 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 for commercial use; 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 parties to manufacture clinical supplies of any other product candidates and commercial supplies of any other products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, serialization, storage, distribution and other production logistics. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture our products or our product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties, or if such parties are unable to expand capacities to support commercialization of our products or any of our product candidates for which we obtain marketing approval, we may not be able to compete, or may be delayed in producing sufficient product or product candidates to meet our supply requirements. These facilities, and suppliers to these facilities, may also be affected by natural disasters, such as floods or fire, epidemics or pandemics, such as COVID-19, or such facilities could face manufacturing issues, such as contamination or regulatory concerns following a regulatory inspection of such facility. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, or at all, which would cause additional delay and increased expense, including as a result of additional required FDA approvals, and may have a material adverse effect on our business.

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.

We or our third-party manufacturers may also 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.

***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. 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 if and as we commence commercialization of EYSUVIS or any product candidates 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**

***We are dependent on the success of EYSUVIS, INVELTYS and any product candidates for which we receive marketing approval. If we are unable to successfully commercialize our products and product candidates, our business will be materially harmed.***

We have devoted a significant portion of our financial resources and business efforts to the development of INVELTYS for the post-operative treatment of inflammation and pain following ocular surgery and EYSUVIS for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease. There is a significant risk that we will fail to successfully commercialize EYSUVIS and INVELTYS. Our ability to generate meaningful product revenues will depend on our successful commercialization of EYSUVIS and INVELTYS.

The success of our products EYSUVIS and INVELTYS and any product candidates for which we receive marketing approval will depend on many factors, including the following:

- successful commercialization of EYSUVIS and INVELTYS in the United States, including maintaining sales, marketing, manufacturing and distribution capabilities for EYSUVIS and INVELTYS;
- acceptance of EYSUVIS and INVELTYS and any product candidates 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;
- successfully developing and applying for and receiving marketing approvals from applicable regulatory authorities for any product candidates;
- maintaining regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities and maintaining adequate supply of our products;
- maintaining a workforce of experienced scientists and others with experience in eye diseases to continue to develop our product candidates;
- leveraging our sales, marketing and distribution capabilities for our current products and expanding upon these capabilities if and when appropriate;
- establishing additional sales, marketing and distribution capabilities for, and successfully launching commercial sales of any other product candidates for which we obtain marketing approval, whether alone or in collaboration with others;
- 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 EYSUVIS, INVELTYS or our product candidates, which would materially harm our business. In addition, other than our approved products, EYSUVIS and INVELTYS, all of our other development efforts are in the early stages of preclinical development. We may never identify any product candidates or advance any product candidates to clinical-stage development from these preclinical development programs. 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 product candidates from our preclinical development programs may never occur.

***If clinical trials of any 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.***

All of our current development efforts are in the early stages of preclinical development. 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. 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 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 any product candidates 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, 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 product candidates 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. 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 or any of our product candidates 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. 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 not be successful in our efforts to develop new product candidates based on our AMPPLIFY technology or expand the use of our AMPPLIFY technology for treating additional diseases and conditions.***

We are currently directing a portion of our development efforts towards applying our AMPPLIFY technology to develop new product candidates that are designed to diffuse through the mucus layer and enable the active drug substance to reach cells in the underlying target tissue. We have product candidates at various stages of development for treatment of eye diseases and may explore the potential use of our AMPPLIFY technology in other diseases. Our existing product candidates and any other potential product candidates that we identify may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize our product candidates that we develop based upon our AMPPLIFY technology, we will not be able to obtain substantial product revenues in future periods.

***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. 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.

***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.***

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

## Risks Related to Our Dependence on Third Parties

***We contract with third parties for the manufacture of EYSUVIS and INVELTYS and plan to contract with third parties for clinical and commercial supply of any future product candidates. 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 to manufacture and supply to us a minimum amount of EYSUVIS and INVELTYS bottles. We also rely on Altasciences for manufacturing bulk intermediates, and Chemo Iberica to manufacture and supply to us a bulk supply of LE. We expect to rely on third-party manufacturers to manufacture commercial supplies of all of our products and clinical supplies of any other product candidates if and when approved for marketing by applicable regulatory authorities. Our current and anticipated future dependence upon others for the manufacture of EYSUVIS, INVELTYS and any other product or product candidate that 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. In addition, 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. Any performance failure on the part of our existing or future manufacturers could delay clinical development, marketing approval or the supply and sale of any product of ours that has been approved for commercial use.

To date, we have obtained materials for our clinical trials and the commercialization of EYSUVIS and INVELTYS from third-party manufacturers, including Woodstock and Altasciences. We have supply agreements in place with these contract manufacturers to provide commercial supply. We obtain the API for EYSUVIS and INVELTYS from Chemo Iberica, a third-party API manufacturer. While we have long-term commercial supply agreements with these third-party manufacturers, if these suppliers do not perform as we expect, we may be required to replace one or more 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.

The FDA maintains strict requirements governing the manufacturing process. When a manufacturer seeks to modify or make even seemingly minor changes to that 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. The FDA has issued several rounds of guidance on this point. 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:

- EYSUVIS, INVELTYS and any other product that we develop may compete with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under current good manufacturing practices, or cGMP, regulations;
- 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 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.

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

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. Additionally, while we currently are not experiencing interruptions in our manufacturing of EYSUVIS or INVELTYS, quarantines, travel restrictions and bans and other governmental restrictions related to COVID-19 may significantly impact the ability of employees of our third-party suppliers to get to their places of work to manufacture and deliver future supply if and when needed.

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

***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 or any of our product candidates 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, or CROs, 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.

### **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. 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 AMPLIFY 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 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, that relate to our AMPPLIFY technology, JHU retains control of patent prosecution. Our rights with respect to in-licensed patents and patent applications may be lost if the applicable

license agreement expires or is terminated. 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 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 license agreement with JHU, under which we license certain of our patent rights and a significant portion of the technology for EYSUVIS, INVELTYS and our product candidates imposes royalty and other financial obligations on us and other substantial performance obligations. We also may enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or product candidate that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of 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 licensing agreement and might therefore terminate the agreement, thereby removing our ability to market products covered by our license agreement with JHU. If the JHU licensing 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 license agreement with JHU 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.

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. For example, 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.

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.

***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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively 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. 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. In addition, the Centers for Medicare & Medicaid Services has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

The costs of prescription pharmaceuticals in the United States 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. 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.

***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.

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 and may continue to expand our development, regulatory, commercial and manufacturing capabilities and are continuing to implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We have experienced and expect to continue experiencing 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. For example, in the fourth quarter of 2020, we increased our sales force from 56 TSMs to 91 TSMs, from seven RSLs to 14 RSLs and added two new area sales leaders. In 2021, we increased our sales force from 91 TSMs to 105 TSMs around the start of the third quarter, with a subsequent expansion up to 125 TSMs expected by year-end, subject to continued growth in payor coverage and the status of the COVID-19. To manage our recent, planned and potential future growth, we must continue to implement and improve our managerial, operational and financial systems, and may further expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such growth, we may not be able to effectively manage our recently expanded operations, planned sales force expansion 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, including our planned sales force expansion, 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.

### **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 June 30, 2021, our executive officers and directors and their affiliates in the aggregate, owned shares representing approximately 25.92% of our capital stock, based on the most recent institutional stockholder ownership filings with the SEC. 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 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 programs for any of our product candidates;
- 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 or our product candidates. 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 August 4, 2021, we had outstanding 64,971,096 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.

***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 May 14, 2021, we granted stock options to one new employee to purchase 27,500 shares of our common stock at an exercise price of \$5.06 per share and on June 15, 2021, we granted stock options to five new employees to purchase 64,500 shares of our common stock at an exercise price of \$5.70 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 10.1† - [Loan and Security Agreement, dated May 4, 2021, by and among the Registrant and Oxford Finance LLC, as collateral agent and lender \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K \(File No. 001-38150\) filed on May 5, 2021\).](#)
- EXHIBIT 10.2† - [Exclusive License Agreement, dated November 10, 2009, by and between the Registrant and The Johns Hopkins University, as amended by the First Amendment dated November 19, 2012, the Second Amendment dated May 23, 2014 and the Third Amendment dated August 26, 2014.](#)
- EXHIBIT 10.3† - [Settlement and License Agreement, dated October 24, 2014, by and between the Registrant and GrayBug, LLC.](#)
- 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: August 5, 2021

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

Dated: August 5, 2021

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



Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

**EXCLUSIVE LICENSE AGREEMENT**

**BETWEEN**

**THE JOHNS HOPKINS UNIVERSITY**

**&**

**HANES NEWCO, INC.**

**JHU Agreement: [\*\*]**

**LICENSE AGREEMENT**

THIS LICENSE AGREEMENT (the "Agreement") is entered into by and between THE JOHNS HOPKINS UNIVERSITY, a Maryland corporation having an address at 3400 N. Charles Street, Baltimore, Maryland, 21218-2695 ("JHU") and Hanes NewCo, Inc., a Delaware corporation having an address at c/o Jeff Wiesen, Mintz Levin Cohn Ferris Glovsky and Popeo PC, One Financial Center, Boston, MA 02111 ("Company"), with respect to the following:

**RECITALS**

WHEREAS, as a center for research and education, JHU is interested in licensing PATENT RIGHTS (hereinafter defined) in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes; and

WHEREAS, a valuable invention entitled [\*\*] was developed during the course of research conducted by [\*\*], and a valuable invention entitled [\*\*] was developed during the course of research conducted by [\*\*], and a valuable invention entitled [\*\*] was developed during the course of research conducted by [\*\*], and a valuable invention entitled [\*\*] was developed during the course of research conducted by [\*\*], and a valuable invention entitled [\*\*] was developed during the course of research conducted by [\*\*] (all hereinafter, "Inventors"); and

WHEREAS, JHU has acquired through assignment all rights, title and interest, with the exception of certain retained rights by the United States Government, in its interest in said valuable inventions; and

WHEREAS, Company desires obtain certain rights in such inventions as herein provided, and to commercially develop, manufacture, use and distribute products and processes based upon or embodying said valuable inventions throughout the world;

NOW THEREFORE, in consideration of the premises and the mutual promises and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

**ARTICLE 1  
DEFINITIONS**

All references to particular Exhibits, Articles or Paragraphs shall mean the Exhibits to, and Paragraphs and Articles of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

**1.1 "AFFILIATED COMPANY"** as used herein in either singular or plural shall mean any corporation, company, partnership, joint venture or other entity, which controls, is controlled by or is under common control with Company. For purposes of this Paragraph 1.1, control shall mean the direct or indirect ownership of at least fifty- percent (50%).

**1.2** “**EFFECTIVE DATE**” of this License Agreement shall mean the date the last party hereto has executed this Agreement.

**1.3** “**EXCLUSIVE LICENSE**” shall mean a grant by JHU to Company of its entire right and interest in the PATENT RIGHTS subject to rights retained by the United States Government, if any, in accordance with the Bayh-Dole Act of 1980 (established by P.L. 96-517 and amended by P.L. 98-620, codified at 35 USC § 200 et. seq. and implemented according to 37 CFR Part 401), and subject to the retained right of JHU to make, have made, provide and use for its and The Johns Hopkins Health Systems’ non-commercial academic research and teaching purposes LICENSED PRODUCT(S) and LICENSED SERVICE(S), including the ability to distribute any biological material disclosed and/or claimed in PATENT RIGHTS for nonprofit non-commercial academic research use to non-commercial entities as is customary in the scientific community.

**1.4** “**KNOW-HOW AND MATERIALS**” shall mean JHU’s interest in proprietary materials, information, records, and data developed by [\*\*] (including incidental information developed in his laboratory) and at his direction by his laboratory personnel, fellows, and students and that are directly related to the use of and practice of the PATENT RIGHTS, and are (a) subject to the Johns Hopkins Intellectual Property Policy and (b) owned by JHU as of the EFFECTIVE DATE or developed within [\*\*] years from the EFFECTIVE DATE and not subject to any third party rights, including without limitation the materials listed on Exhibit C. Know-How specifically excludes patentable inventions.

**1.5** “**LICENSED FIELD**” shall mean all fields of use.

**1.6** “**LICENSED PRODUCT(S)**” as used herein in either singular or plural shall mean any process or method, material, compositions, drug, or other product, the manufacture, use or sale of which would constitute, but for the license granted to Company pursuant to this Agreement, an infringement of a VALID CLAIM of PATENT RIGHTS (infringement shall include, but is not limited to, direct, contributory, or inducement to infringe) in the country of sale.

**1.7** “**LICENSED SERVICE(S)**” as used herein in either singular or plural shall mean the performance on behalf of a third party of any method or the manufacture of any product or the use of any product or composition which would constitute, but for the license granted to Company pursuant to this Agreement, an infringement of a VALID CLAIM of the PATENT RIGHTS, (infringement shall include, but not be limited to, direct, contributory or inducement to infringe) in the country of performance of the services.

**1.8** “**NET SALES**” shall mean gross sales revenues and fees billed by Company and AFFILIATED COMPANY from the sale of LICENSED PRODUCT(S) less (i) trade, quantity or cash discounts allowed, (ii) refunds, credits or allowances for returns, rejections and recalls; (iii) rebates and chargebacks, (iv) sales, use or other taxes and tariffs, duties or other charges levied by a governmental entity on the production, sale, delivery or use of LICENSED PRODUCT(S), and (iv) packing, freight, shipping and insurance charges.

In the event that Company or AFFILIATED COMPANY sells a LICENSED PRODUCT(S) as part of a combination, then:

(i) in the event that Company or AFFILIATED COMPANY sells in a particular country during a particular year a LICENSED PRODUCT(S) together with other non-therapeutic ingredients or substances or as part of a kit, and Company or AFFILIATED COMPANY also sells such LICENSED PRODUCT(S) in such country in such year separately the NET SALES for purposes of royalty payments shall be based on the sales revenues and fees that would be received from the separate sale of the same quantity of LICENSED PRODUCT as is contained in the combination.

(ii) in the event that Company or an AFFILIATED COMPANY sells, in a particular country during a particular year, a LICENSED PRODUCT for therapeutic purposes in combination with a therapeutically active ingredient which is not a LICENSED PRODUCT (“Other Items”), the NET SALES for purposes of royalty payments shall be calculated as follows:

(a) If all LICENSED PRODUCTS and Other Items contained in the combination are available separately in the particular country during such year, the NET SALES for purposes of royalty payments will be calculated by multiplying the NET SALES of the combination by the fraction  $A/A+B$ , where A is the separately available price of all LICENSED PRODUCTS in the combination in the particular country during such year, and B is the separately available price for all Other Items in the combination in the particular country during such year.

(b) If the combination includes Other Items which are not sold separately in the particular country during such year (but all LICENSED PRODUCTS contained in the combination are available separately in the particular country during such year), the NET SALES for purposes of royalty payments will be calculated by multiplying the NET SALES of the combination by  $A/C$ , where A is as defined above and C is the invoiced price of the combination.

(c) If the LICENSED PRODUCTS contained in the combination are not sold separately, the parties agree to negotiate a reduction in the royalty rate to reflect the fair value that the LICENSED PRODUCT attributed to the overall product sold.

The term “Other Items” does not include solvents, diluents, carriers, excipients, buffers or the like used in formulating a product.

(iii) In no event shall: (1) Company apply the credit in both paragraphs (i) and (ii) above to the same sale of a LICENSED PRODUCT, and (2) the royalty rates be reduced by greater than [\*\*] percent ([\*\*]%) when collectively applying the credits of paragraphs (i) above, (ii) above, and the offset of Paragraph 3 in EXHIBIT A.

**1.9 “NET SERVICE REVENUES”** shall mean gross service revenues and fees billed by Company and AFFILIATED COMPANY for the performance of LICENSED SERVICE(S) less (i) trade, quantity or cash discounts allowed, (ii) refunds, rebates, and chargebacks, (iii) sales or other taxes or charges levied by a governmental entity upon and with specific reference to the LICENSED SERVICE(S). In the event that Company or AFFILIATED COMPANY sells a LICENSED SERVICE(S) that is also sold separately in combination with other services, the NET SERVICE REVENUES for purposes of royalty payments shall be based on the sales revenues that

would be received from the separate sale of the same quantity of LICENSED SERVICE(S) as is contained in the combination.

**1.10 “PATENT RIGHTS”** shall mean the patents and applications listed in EXHIBIT D for JHU Ref # [\*\*] and JHU Ref # [\*\*], any patent applications hereafter filed for JHU Ref # [\*\*] and JHU Ref # [\*\*] (all such patent applications for JHU Ref # [\*\*], JHU Ref # [\*\*], JHU Ref # [\*\*] and JHU Ref # [\*\*] hereinafter referred to as “Patent Applications”) and all continuations, divisions, claims of continuations-in-part applications directed to subject matter specifically described in the Patent Applications, continued prosecution applications and reissues, reexaminations, extensions and supplemental protection certificates thereof, and any corresponding foreign patent applications, and any patents, or other equivalent foreign patent rights issuing, granted or registered thereon. “OPTION PATENT RIGHTS” shall mean the patents and applications listed in EXHIBIT D for JHU Ref # [\*\*] (hereinafter referred to as “Option Patent Applications”) and all continuations, divisions, claims of continuations-in-part applications directed to subject matter specifically described in the Option Patent Applications, continued prosecution applications and reissues, reexaminations, extensions and supplemental protection certificates thereof, and any corresponding foreign patent applications, and any patents, or other equivalent foreign patent rights issuing, granted or registered thereon. In the event of the exercise by Company of the option set forth in Section 2.5, the OPTION PATENT RIGHTS shall become PATENT RIGHTS for all purposes of this Agreement, except as set forth in Section 2.4.

**1.11 “SUBLICENSE CONSIDERATION”** shall mean consideration of any kind received by the Company or AFFILIATED COMPANIES from a SUBLICENSEE(S) for the grant of a sublicense under this Agreement, including upfront fees, running royalties on LICENSED PRODUCT(S) and LICENSED SERVICE(S), milestone fees based on SUBLICENSEE achievements, and any premium paid by the SUBLICENSEE(S) over Fair Market Value for stock of the Company or an AFFILIATED COMPANY in consideration for such sublicense; provided that **SUBLICENSE CONSIDERATION** shall not include amounts paid to the Company or an AFFILIATED COMPANY by the SUBLICENSEE(S) for milestone payments based on Company achievements (but only if (i) Company owes a milestone payment to JHU for that same achievement or (ii) the Company did not receive payments (other than the milestone payment) from the SUBLICENSEE for product development, research work, clinical studies or regulatory approvals performed by or for the Company or AFFILIATED COMPANIES to achieve the event resulting in the milestone payment), loans, equity investments at Fair Market Value, payments for product development, research work, clinical studies and regulatory approvals performed by or for the Company or AFFILIATED COMPANIES (including third parties on their behalf), each pursuant to a specific agreement providing for a work plan and reasonable budget. The term “Fair Market Value” shall mean (i) if the stock is publicly traded, the average price that the stock in question is publicly trading at for [\*\*] days prior to the announcement of its purchase by the SUBLICENSEE(S), (ii) if the stock is not publicly traded, and the Company or AFFILIATED COMPANY has had a private equity financing (including a financing with debt securities convertible to equity) within [\*\*], the value of such stock as determined by the most recent such private financing through a financial investor (an entity whose sole interest in the Company or AFFILIATED COMPANY is financial, including an investment entity owned or controlled by a pharmaceutical company or other operating company that makes an investment separate from a sublicense granted to its parent company) of the Company or AFFILIATED COMPANY that issued the shares, or (iii) if the stock is not publicly traded, and the

Company or AFFILIATED COMPANY has not had a private equity financing (including a financing with debt securities convertible to equity) through a financial investor (as defined above) within [\*\*], a value to be agreed upon by the Company and JHU, or if they fail to agree within [\*\*] days after the sale of the stock to the SUBLICENSEE, by an independent appraisal firm selected by the Company.

**1.12 “SUBLICENSEE(S)”** as used herein in either singular or plural shall mean any person or entity other than an AFFILIATED COMPANY to which Company or an AFFILIATED COMPANY has granted a sublicense under this Agreement.

**1.13 “VALID CLAIM”** shall mean either: (a) a claim of an issued and unexpired patent included within the PATENT RIGHTS which has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reexamination, reissue, disclaimer or otherwise; or (b) a claim of a pending patent application included within the PATENT RIGHTS, which claim has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application, and has been pending for less than [\*\*] years from the date such claim was filed in a first national filing non-provisional patent application in the country of interest and has not been (i) canceled, (ii) withdrawn from consideration, (iii) finally determined to be unallowable by the applicable governmental authority (and from which no appeal is or can be taken), or (iv) abandoned.

## **ARTICLE 2 LICENSE GRANT**

**2.1 Grant.** Subject to the terms and conditions of this Agreement, JHU hereby grants to Company

(i) a world-wide EXCLUSIVE LICENSE to research, develop, make, have made, use, have used, import, have imported, offer for sale, have offered for sale, sell and have sold the LICENSED PRODUCT(S) and to provide and have provided the LICENSED SERVICE(S) in the United States and worldwide under the PATENT RIGHTS in the LICENSED FIELD, and

(ii) a world-wide nonexclusive license to use the KNOW HOW AND MATERIALS in the LICENSED FIELD, provided that JHU will not grant a license to KNOW HOW AND MATERIALS to any other commercial entity.

This Grant shall apply to the Company and any AFFILIATED COMPANY. If any AFFILIATED COMPANY exercises rights under this Agreement, such AFFILIATED COMPANY shall be bound by all terms and conditions of this Agreement, including but not limited to indemnity and insurance provisions and royalty payments, which shall apply to the exercise of the rights, to the same extent as would apply had this Agreement been directly between JHU and the AFFILIATED COMPANY. In addition, Company shall remain fully liable to JHU for all acts and obligations of AFFILIATED COMPANY such that acts of the AFFILIATED COMPANY shall be considered acts of the Company.

KNOW HOW AND MATERIALS will be transferred from time-to-time by JHU's Inventor, [\*\*], at his discretion, and shall not be sold, invoiced, provided, or otherwise transferred, separately from PATENT RIGHTS.

**2.2 Sublicense.** Company may sublicense to others under this Agreement, subject to the terms and conditions of this Paragraph 2.2. As a condition to its validity and enforceability, each sublicense agreement shall: (a) incorporate by reference the terms and conditions of this Agreement, (b) be consistent with the terms, conditions and limitations of this Agreement, (c) name JHU as an intended third party beneficiary of the obligations of SUBLICENSEE without imposition of obligation or liability on the part of JHU or its Inventors to the SUBLICENSEE, and (d) specifically incorporate Paragraphs 6.2 "Representations by JHU", 7.1 "Indemnification", 10.1 "Use of Name", 10.4 "Product Liability" into the body of the sublicense agreement, and cause the terms used in therein to have the same meaning as in this Agreement.. Company shall provide to JHU a copy of each fully executed sublicense agreement, within [\*\*] days of execution by both Company and proposed SUBLICENSEE. To the extent that any terms, conditions or limitations of any sublicense agreement are inconsistent with this Agreement, those terms, conditions and limitations are null and void against JHU.

**2.3 Government Rights.** The United States Government may have acquired a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the inventions described in PATENT RIGHTS throughout the world. To the extent that the inventions claimed in the PATENT RIGHTS were funded by grants, awards or contracts with the United States government, the rights granted herein are additionally subject to: (i) the requirement that any LICENSED PRODUCT(S) produced for use or sale within the United States shall be substantially manufactured in the United States (unless a waiver under 35 USC § 204 or equivalent is granted by the appropriate United States government agency), (ii) the right of the United States government to require JHU, or its licensees, including Company, to grant sublicenses to responsible applicants on reasonable terms when necessary to fulfill health or safety needs, and, (iii) other rights acquired by the United States government under the laws and regulations applicable to the grant/contract award under which the inventions were made.

**2.4 Improvements.** Subject to any third party, including U.S. Government, obligations of JHU under any agreement under which any Improvement is made, JHU will notify Company in writing of any Improvement within [\*\*] days of disclosure to the JHU technology transfer office. Company will have a right of first negotiation for [\*\*] days to amend this Agreement to add the Improvement and related patent rights, know how and materials to this Agreement. JHU and Company will negotiate in good faith on reasonable terms for adding the Improvement to this Agreement. For purposes hereof, "Improvement" shall mean an invention (i) made in the laboratory of [\*\*], (ii) that would infringe the PATENT RIGHTS if made used, imported or sold without a license to PATENT RIGHTS, (iii) pertaining to mucosal delivery using mucus penetrating nanoparticles or microparticles, and (iv) reported to the JHU technology transfer office within [\*\*] from the EFFECTIVE DATE; provided, however, that if the OPTION PATENT RIGHTS become PATENT RIGHTS upon exercise of the option set forth in Section 2.5, the OPTION PATENT RIGHTS shall not be included in PATENT RIGHTS for purposes of this Section 2.4.

**2.5 Option for OPTION PATENT RIGHTS.** JHU hereby grants to Company an exclusive option for a period of [\*\*] months from the EFFECTIVE DATE to add the OPTION PATENT RIGHTS to the definition of PATENT RIGHTS hereunder. Such option may be exercised by written notice to JHU at any time during such [\*\*] month period, and upon the giving of such written notice, the OPTION PATENT RIGHTS shall become PATENT RIGHTS for all purposes of this Agreement, except as set forth in Section 2.4.

**ARTICLE 3  
FEES, ROYALTIES, & PAYMENTS**

**3.1 License Fee.** Company shall pay to JHU within [\*\*] days of the EFFECTIVE DATE of this Agreement a license fee as set forth in Exhibit A. JHU will not submit an invoice for the license fee, which is nonrefundable and shall not be credited against royalties or other fees.

**3.2 Minimum Annual Royalties.** Company shall pay to JHU minimum annual royalties as set forth in Exhibit A. These minimum annual royalties shall be due, without invoice from JHU, within [\*\*] days of [\*\*] of each year, commencing with [\*\*] Running royalties accrued under Paragraph 3.3 and percentage of SUBLICENSE CONSIDERATION accrued under Paragraph 3.4 and paid to JHU during the one year period preceding [\*\*] of each year, commencing with [\*\*] shall be credited against the minimum annual royalties due on that anniversary date.

**3.3 Running Royalties.** Company shall pay to JHU a running royalty as set forth in Exhibit A, for each LICENSED PRODUCT(S) sold, and for each LICENSED SERVICE(S) provided, by Company, AFFILIATED COMPANIES, based on NET SALES and NET SERVICE REVENUES for the term of this Agreement. Such payments shall be made quarterly, as set forth in Section 5.1(a). All non-US taxes related to LICENSED PRODUCT(S) or LICENSED SERVICE(S) sold under this Agreement shall be paid by Company and shall not be deducted from royalty or other payments due to JHU, but shall be deducted from gross sales revenues and fees and gross service revenues and fees in the calculation of NET SALES and NET SERVICE REVENUES to the extent such taxes have been included in gross sales revenues and fees and gross service revenues and fees. JHU shall be responsible for paying any and all taxes (other than withholding taxes or deduction of tax at source required by applicable law to be paid by Company) levied on it by account of its receipt of any payments it receives under this Agreement. If applicable laws require that taxes be withheld or deducted at source from any amounts due to JHU under this Agreement, the Company shall (a) deduct these taxes from the remittable amount, (b) pay the taxes to the proper taxing authority, and (c) deliver to JHU a statement including the amount of tax withheld and justification therefor, and such other information as may be necessary for tax credit purposes. Company shall cooperate with JHU in any action by JHU for a refund of such taxes withheld.

In order to insure JHU the full royalty payments contemplated hereunder, Company agrees that in the event any LICENSED PRODUCT(S) shall be sold by the Company to an AFFILIATED COMPANY, by an AFFILIATED COMPANY to the Company, or among AFFILIATED COMPANIES the royalties to be paid hereunder for such LICENSED PRODUCT(S) shall be based upon the greater of: 1) the NET SALES at which the purchaser of LICENSED PRODUCT(S) resells such product to the end user, 2) the NET SERVICE REVENUES received

from using the LICENSED PRODUCT(S) in providing a service, or 3) the NET SALES of LICENSED PRODUCT(S) paid by the purchaser.

In the event that consideration in lieu of money is received by Company or an AFFILIATED COMPANY from the sale of LICENSED PRODUCT(S), the fair market value of such consideration shall be included in the determination of NET SALES for such sale. Such fair market value shall be determined by the Company or AFFILIATED COMPANY, as applicable, in good faith.

**3.4 Sublicense Consideration.** In addition to the running royalty as set forth under Paragraph 3.3, Company shall pay to JHU a percentage of SUBLICENSE CONSIDERATION as set forth in Exhibit A. This percentage of SUBLICENSE CONSIDERATION shall be due, without the need for invoice from JHU, within [\*\*] days after the end of each calendar quarter in which sublicense consideration is received.

**3.5 Milestones.** Company shall pay to JHU milestones as set forth in Exhibit A. These milestones shall be due, without invoice from JHU, within [\*\*] days of achievement of such milestone.

**3.6 Patent Reimbursement.** Company will reimburse JHU for the costs of preparing, filing, maintaining and prosecuting PATENT RIGHTS incurred prior to the EFFECTIVE DATE ("PRIOR PATENT COSTS") (currently estimated at about \$ [\*\*]). In the event the OPTION PATENT RIGHTS become PATENT RIGHTS upon exercise of the option set forth in Section 2.5, the sum of \$[\*\*] shall be added to the PRIOR PATENT COSTS. Company shall pay without invoice from JHU \$[\*\*] per month until the sooner of (i) all PRIOR PATENT COSTS have been paid or (ii) Company has raised a total of \$[\*\*], at which time the balance of unpaid PRIOR PATENT COSTS shall be due within [\*\*] days.

In accordance with Paragraph 4.1 below, Company will reimburse JHU, within [\*\*] days of the receipt of an invoice from JHU, for all costs associated with the preparation, filing, maintenance, and prosecution of PATENT RIGHTS and the OPTION PATENT RIGHTS incurred by JHU subsequent to the EFFECTIVE DATE of this Agreement.

**3.7 Form of Payment.** All payments under this Agreement shall be made in U.S. Dollars by either check or wire transfer.

**3.8 Payment Information.** All check payments from Company to JHU shall be sent to:

Director  
Johns Hopkins Technology Transfer  
The Johns Hopkins University  
100 N. Charles Street, 5<sup>th</sup> Floor  
Baltimore, MD 21201

Attn: JHU Agrmt# [\*\*]



or such other addresses which JHU may designate in writing from time to time. Checks are to be made payable to “The Johns Hopkins University”. Wire transfers may be made through:

[\*\*]

[\*\*]

Transit/Routing/ABA number: [\*\*]

SWIFT code: [\*\*]

CHIPS ABA number: [\*\*]

Account Number: [\*\*]

Type of Account: Depository

Reference: [\*\*]

(JHU Agrmt. # [\*\*])

Attn: Financial Manager

Company shall be responsible for any and all costs associated with wire transfers.

Via ACH

[\*\*]

Transit/routing/ABA number: [\*\*]

Account number: [\*\*]

Type of account: depository

CTX format is preferred; CCD+ is also accepted

**3.9 Late Payments.** In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the tenth day following the due date thereof, calculated at the annual rate of the sum of (a) [\*\*] percent ([\*\*]%) plus (b) the prime interest rate quoted by The Wall Street Journal on the date said payment is due, the interest being compounded on the last day of each calendar quarter, provided however, that in no event shall said annual interest rate exceed the maximum legal interest rate for corporations. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of JHU to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment including, but not limited to termination of this Agreement as set forth in Paragraph 9.2, subject to the cure provisions set forth therein.

#### **ARTICLE 4 PATENT PROSECUTION, MAINTENANCE, & INFRINGEMENT**

**4.1 Prosecution & Maintenance.** JHU, at Company’s expense, shall file, prosecute and maintain all patents and patent applications specified under PATENT RIGHTS and, subject to the terms and conditions of this Agreement, Company shall be licensed thereunder. Title to all such patents and patent applications shall reside in JHU. JHU shall have full and complete control over all patent matters in connection therewith under the PATENT RIGHTS, provided however, that JHU shall (a) cause its patent counsel to timely copy Company on all official actions and written correspondence with any patent office, and (b) allow Company an opportunity to comment and advise JHU. JHU shall consider and reasonably incorporate all comments and advice unless

detrimental to JHU's intellectual property rights. By concurrent written notification to JHU and its patent counsel at least [\*\*] days in advance (or later at JHU's discretion) of any filing or response deadline, or fee due date, Company may elect not to have a patent application filed in any particular country or not to pay expenses associated with prosecuting or maintaining any patent application or patent, provided that Company pays for all costs incurred up to JHU's receipt of such notification. Failure to provide such notification can be considered by JHU to be Company's authorization to proceed at Company's expense. Upon such notification, JHU may file, prosecute, and/or maintain such patent applications or patent at its own expense and for its own benefit, and any rights or license granted hereunder held by Company, AFFILIATED COMPANIES or SUBLICENSEE(S) relating to the PATENT RIGHTS which comprise such patent applications or patent and/or apply to the particular country, shall terminate.

**4.2 Notification.** Each party will notify the other promptly in writing when any infringement by another is uncovered or suspected.

**4.3 Infringement.** Company shall have the first right to enforce any patent within PATENT RIGHTS against any infringement or alleged infringement thereof, and shall at all times keep JHU informed as to the status thereof. Before Company commences an action with respect to any infringement of such patents, Company shall give careful consideration to the views of JHU and to potential effects on the public interest in making its decision whether or not to sue. Thereafter, Company may, at its own expense, institute suit against any such infringer or alleged infringer and control and defend such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Paragraph 4.5. If required by law, JHU shall permit action under this Section to be brought in its name, including being joined as party-plaintiff. However, no settlement, consent judgment or other voluntary final disposition of the suit that concedes the invalidity or unenforceability of any patent within PATENT RIGHTS may be entered into without the prior written consent of JHU, which consent shall not be unreasonably withheld. This right to sue for infringement shall not be used in an arbitrary or capricious manner. JHU shall reasonably cooperate in any such litigation at Company's expense.

If Company elects not to enforce any patent within the PATENT RIGHTS, then it shall so notify JHU in writing within [\*\*] days of receiving notice that an infringement exists, and JHU may, in its sole judgment and at its own expense, take steps to enforce any patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover, for its own account, any damages, awards or settlements resulting therefrom. However, no settlement, consent judgment or other voluntary final disposition of the suit that concedes the invalidity or unenforceability of any patent within PATENT RIGHTS may be entered into without the prior written consent of Company, which consent shall not be unreasonably withheld.

**4.4 Patent Invalidity Suit.** If a declaratory judgment action is brought naming Company as a defendant and alleging invalidity of any of the PATENT RIGHTS, JHU may elect to take over the sole defense of the action at its own expense. Company shall cooperate fully with JHU in connection with any such action.

**4.5 Recovery.** Any recovery by Company under Paragraph 4.3 shall be deemed to reflect loss of commercial sales, and Company shall pay to JHU [\*\*] percent ([\*\*]%) of the

recovery, net of all reasonable costs and expenses associated with each suit or settlement. If the cost and expenses exceed the recovery, then [\*\*] of the excess shall be credited against royalties payable by Company to JHU hereunder in connection with sales of LICENSED PRODUCT covered in the PATENT RIGHTS which are the subject of the infringement suit, in the country of such legal proceedings, provided, however, that any such credit under this Paragraph shall not exceed [\*\*] percent ([\*\*]%) of the royalties otherwise payable to JHU with regard to sales in the country of such action in any one calendar year, with any excess credit being carried forward to future calendar years.

**4.6 Cooperation.** Each party agrees to cooperate in any action under this Article which is controlled by the other party, provided that the controlling party reimburses the cooperating party promptly for any costs and expenses incurred by the cooperating party in connection with providing such assistance.

**ARTICLE 5  
OBLIGATIONS OF THE PARTIES**

**5.1 Reports.** Company shall provide to JHU the following written reports according to the following schedules.

(a) Company shall provide quarterly Royalty Reports, substantially in the format of Exhibit B and due within [\*\*] days of the end of each calendar quarter following the first commercial sale of a LICENSED PRODUCT or LICENSED SERVICE by Company, an AFFILIATED COMPANY or a SUBLICENSEE(S). Royalty Reports shall disclose (i) the amount of LICENSED PRODUCT(S) and LICENSED SERVICE(S) sold, the total NET SALES and NET SERVICE REVENUES of such LICENSED PRODUCT(S) and LICENSED SERVICE(S), and the running royalties due to JHU as a result of NET SALES and NET SERVICE REVENUES by Company and AFFILIATED COMPANIES thereof and (ii) the amount of SUBLICENSE CONSIDERATION received and the percentage thereof payable to JHU pursuant to Section 3.4. Payment of any such royalties and percentage of SUBLICENSE CONSIDERATION due shall accompany such Royalty Reports.

(b) Until Company, an AFFILIATED COMPANY or a SUBLICENSEE(S) has achieved a first commercial sale of a LICENSED PRODUCT or LICENSED SERVICE, or received FDA market approval, Company shall provide [\*\*] Diligence Reports, due within [\*\*] days of the end of [\*\*] following the EFFECTIVE DATE of this Agreement. These Diligence Reports shall describe Company's, AFFILIATED COMPANIES or any SUBLICENSEE(S)'s technical efforts towards meeting its obligations under the terms of this Agreement.

(c) Company shall provide [\*\*] Reports within [\*\*] days of the end of [\*\*] following the EFFECTIVE DATE of this Agreement. [\*\*] Reports shall include:

- (i) evidence of insurance as required under Paragraph 10.4, or, a statement of why such insurance is not currently required, and
- (ii) identification of all AFFILIATED COMPANIES which have exercised rights pursuant to Paragraph 2.1, or, a statement that no AFFILIATED COMPANY has exercised such rights, and

(iii) notice of all FDA approvals of any LICENSED PRODUCT(S) or LICENSED SERVICE(S) obtained by COMPANY, AFFILIATED COMPANY or SUBLICENSEE, the patent(s) or patent application(s) licensed under this Agreement upon which such product or service is based, and the commercial name of such product or service, or, in the alternative, a statement that no FDA approvals have been obtained.

**5.2 Records.** Company shall make and retain, for a period of [\*\*] years following the period of each report required by Paragraph 5.1, true and accurate records, files and books of account containing all the data reasonably required for the full computation and verification of sales and other information required in Paragraph 5.1. Such books and records shall be in accordance with generally accepted accounting principles consistently applied. Company shall permit the inspection of such records, files and books of account by an independent certified public accountant selected by JHU and acceptable to Company in its reasonable judgment during regular business hours upon [\*\*] business days' written notice to Company. Such inspection shall not be made more than [\*\*]. All costs of such inspection shall be paid by JHU, provided that if any such inspection shall reveal that an error has been made in the amount of payments hereunder for any calendar year equal to [\*\*] percent ([\*\*]%) or more of such payments, such costs shall be borne by Company. As a condition to entering into any such agreement, Company shall include in any agreement with its AFFILIATED COMPANIES which permits such party to make, use, sell or import the LICENSED PRODUCT(S) or provide LICENSED SERVICE(S), a provision requiring such party to retain records of sales of LICENSED PRODUCT(S) and records of LICENSED SERVICE(S) and other information as required in Paragraph 5.1 and permit an independent certified public accountant selected by JHU and acceptable to Company in its reasonable judgment to inspect such records as required by this Paragraph.

**5.3 Commercially Reasonable Efforts.** Company shall exercise commercially reasonable efforts to develop and to introduce the LICENSED PRODUCT(S) and LICENSED SERVICE(S) into the commercial market, through itself, its AFFILIATED COMPANIES and/or its SUBLICENSEE(S), consistent with sound and reasonable business practice and judgment. Beginning on the EFFECTIVE DATE Company shall spend, at a minimum, a total of \$[\*\*] USD over a [\*\*] year period on research and development activities related to potential LICENSED PRODUCTS. In addition, Company shall have [\*\*] of a LICENSED PRODUCT prior to the [\*\*] of the EFFECTIVE DATE. Following the introduction of a LICENSED PRODUCT or LICENSED SERVICE into the commercial market, and until the expiration or termination of this Agreement, Company shall endeavor to keep LICENSED PRODUCT(S) and LICENSED SERVICE(S) reasonably available to the public consistent with sound and reasonable business practice and judgment. Company shall also exercise commercially reasonable efforts to develop LICENSED PRODUCT(S) suitable for different indications within the LICENSED FIELD, consistent with sound and reasonable business practice and judgment.

**5.4 Patent Acknowledgement.** Company agrees that all packaging containing individual LICENSED PRODUCT(S) sold by Company, AFFILIATED COMPANIES and SUBLICENSEE(S) of Company will be marked with the number of the applicable patent(s) licensed hereunder in accordance with each country's patent laws to the extent reasonably practical.

**ARTICLE 6  
REPRESENTATIONS**

**6.1 Duties of the Parties.** JHU is not a commercial organization. It is an institute of research and education. Therefore, JHU has no ability to evaluate the commercial potential of any PATENT RIGHTS or LICENSED PRODUCT or other license or rights granted in this Agreement. It is therefore incumbent upon Company to evaluate the rights and products in question, to examine the materials and information provided by JHU, and to determine for itself the validity of any PATENT RIGHTS, its freedom to operate, and the value of any LICENSED PRODUCTS or LICENSED SERVICES or other rights granted.

**6.2 Representations by JHU.** JHU warrants that it has good and marketable title to its interest in the inventions claimed under PATENT RIGHTS with the exception of certain retained rights of the United States Government, which may apply if any part of the JHU research was funded in whole or in part by the United States Government. JHU does not warrant the validity of any patents or that practice under such patents shall be free of infringement. EXCEPT AS EXPRESSLY SET FORTH IN THIS PARAGRAPH 6.2, COMPANY, AFFILIATED COMPANIES AND SUBLICENSEE(S) AGREE THAT THE PATENT RIGHTS ARE PROVIDED "AS IS", AND THAT JHU MAKES NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE PERFORMANCE OF LICENSED PRODUCT(S) AND LICENSED SERVICE(S) INCLUDING THEIR SAFETY, EFFECTIVENESS, OR COMMERCIAL VIABILITY. JHU DISCLAIMS ALL WARRANTIES WITH REGARD TO PRODUCT(S) AND SERVICE(S) LICENSED UNDER THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO, ALL WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, JHU ADDITIONALLY DISCLAIMS ALL OBLIGATIONS AND LIABILITIES ON THE PART OF JHU AND INVENTORS, FOR DAMAGES, INCLUDING, BUT NOT LIMITED TO, DIRECT, INDIRECT, SPECIAL, AND CONSEQUENTIAL DAMAGES, ATTORNEYS' AND EXPERTS' FEES, AND COURT COSTS (EVEN IF JHU HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, FEES OR COSTS), ARISING OUT OF OR IN CONNECTION WITH THE MANUFACTURE, USE, OR SALE OF THE PRODUCT(S) AND SERVICE(S) LICENSED UNDER THIS AGREEMENT. COMPANY, AFFILIATED COMPANIES AND SUBLICENSEE(S) ASSUME ALL RESPONSIBILITY AND LIABILITY FOR LOSS OR DAMAGE CAUSED BY A PRODUCT AND/OR SERVICE MANUFACTURED, USED, OR SOLD BY COMPANY, ITS SUBLICENSEE(S) AND AFFILIATED COMPANIES WHICH IS A LICENSED PRODUCT(S) OR LICENSED SERVICE(S) AS DEFINED IN THIS AGREEMENT.

**6.3 Prior Assignment of Rights.** The Parties acknowledge the Assignment of Rights Agreement dated December 8, 2005 among JHU, [\*\*] (the "Assignment Agreement"). JHU agrees (i) that as between JHU on the one hand and [\*\*] on the other hand, [\*\*] are the absolute owners of the patent rights that are the subject of the Assignment Agreement, and JHU will not exercise any right it may have to terminate said Assignment Agreement, (ii) JHU is not entitled to receive any part of any stock in the Company issued to [\*\*], and (iii) the Company will not be obligated to make any payment (including without limitation, royalties and milestones) to JHU with respect to the patent assigned under the Assignment Agreement.

**ARTICLE 7  
INDEMNIFICATION**

**7.1 Indemnification.** JHU and the Inventors would have no legal liability exposure to third parties if JHU did not license the LICENSED PRODUCT(S) and LICENSED SERVICE(S), and any royalties JHU and the Inventors may receive is not adequate compensation for such legal liability exposure. Therefore, JHU requires Company to protect JHU and Inventors from such exposure to the same manner and extent to which insurance, if available, would protect JHU and Inventors. Furthermore, JHU and the Inventors will not, under the provisions of this Agreement or otherwise, have control over the manner in which Company or its AFFILIATED COMPANIES or its SUBLICENSEE(S) or those operating for its account or third parties who purchase LICENSED PRODUCT(S) or LICENSED SERVICE(S) from any of the foregoing entities, develop, manufacture, market or practice the inventions of LICENSED PRODUCT(S) and LICENSED SERVICE(S). Therefore, Company, AFFILIATED COMPANY and SUBLICENSEE, each solely with respect to its own practice of such inventions, shall indemnify, defend with counsel reasonably acceptable to JHU, and hold JHU, The Johns Hopkins Health Systems, their present and former trustees, officers, Inventors of PATENT RIGHTS, agents, faculty, employees and students harmless as against any judgments, fees, expenses, or other costs arising from or incidental to any product liability or other lawsuit, claim, demand or other action brought as a consequence of its own practice of said inventions, whether or not JHU or said Inventors, either jointly or severally, is named as a party defendant in any such lawsuit and whether or not JHU or the Inventors are alleged to be negligent or otherwise responsible for any injuries to persons or property. Practice of the inventions covered by LICENSED PRODUCT(S) and LICENSED SERVICE(S), by an AFFILIATED COMPANY, SUBLICENSEE, or an agent or a third party on behalf of or for the account of Company or by a third party who purchases LICENSED PRODUCT(S) and LICENSED SERVICE(S) from Company, shall be considered Company's practice of said inventions for purposes of this Paragraph. The obligation of Company to defend and indemnify as set out in this Paragraph shall survive the termination of this Agreement, shall continue even after assignment of rights and responsibilities to an affiliate or sublicensee, and shall not be limited by any other limitation of liability elsewhere in this Agreement.

**ARTICLE 8  
CONFIDENTIALITY**

**8.1 Confidentiality.** If necessary, the parties will exchange information, which they consider to be confidential. The recipient of such information agrees to accept the disclosure of said information which is marked as confidential at the time it is sent to the recipient, and to employ all reasonable efforts to maintain the information secret and confidential, such efforts to be no less than the degree of care employed by the recipient to preserve and safeguard its own confidential information, and in any event no less than a reasonable degree of care. The information shall not be disclosed or revealed to anyone except employees, consultants, collaborators, investors and prospective investors of the recipient who have a need to know the information and who have entered into a secrecy agreement with the recipient under which such employees are required to maintain confidential the proprietary information of the recipient and such employees shall be advised by the recipient of the confidential nature of the information and that the information shall be treated accordingly.

The obligations of this Paragraph 8.1 shall also apply to AFFILIATED COMPANIES and/or SUBLICENSEE(S) provided such information of JHU by Company. JHU's, Company's, AFFILIATED COMPANIES, and SUBLICENSEES' obligations under this Paragraph 8.1 shall extend until [\*\*] years after the termination of this Agreement.

**8.2 Exceptions.** The recipient's obligations under Paragraph 8.1 shall not extend to any part of the information:

- a. that can be demonstrated to have been in the public domain or publicly known and readily available to the trade or the public prior to the date of the disclosure; or
- b. that can be demonstrated, from written records to have been in the recipient's possession or readily available to the recipient from another source not under obligation of secrecy to the disclosing party prior to the disclosure; or
- c. that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by the recipient; or
- d. that is demonstrated from written records to have been developed by or for the receiving party without reference to confidential information disclosed by the disclosing party.
- e. that is required to be disclosed by law, government regulation or court order.

**8.3 Right to Publish.** JHU may publish manuscripts, abstracts or the like describing the PATENT RIGHTS and inventions contained therein provided confidential information of Company as defined in Paragraph 8.1, is not included or without first obtaining approval from Company to include such confidential information. Otherwise, JHU and the Inventors shall be free to publish manuscripts and abstracts or the like directed to the work done at JHU related to the licensed technology without prior approval.

## **ARTICLE 9 TERM & TERMINATION**

**9.1 Term.** The term of this Agreement shall commence on the EFFECTIVE DATE and shall continue, in each country, until the date of expiration of the last to expire patent included within PATENT RIGHTS in that country or if no patents issue then for a term of twenty (20) years from the EFFECTIVE DATE of this Agreement.

**9.2 Termination By Either Party.** This Agreement may be terminated by either party, in the event that the other party (a) files or has filed against it a petition under the Bankruptcy Act that is not dismissed within [\*\*] days, makes an assignment for the benefit of creditors, has a receiver appointed for it or a substantial part of its assets and such receivership is not terminated within [\*\*] days, or otherwise takes advantage of any statute or law designed for relief of debtors or (b) fails to perform or otherwise breaches any of its obligations hereunder, if, following the giving of notice by the terminating party of its intent to terminate and stating the grounds therefor, the party receiving such notice shall not have cured the failure or breach within [\*\*] days; provided, however, that, except where the alleged breach is for failure to pay a fixed amount due

under this agreement (such as the License Fee, Minimum Annual Royalty or the \$[\*\*] monthly patent cost reimbursement payment set forth in Section 3.6), in the event the party receiving the notice disputes the alleged failure to perform or breach in good faith, such [\*\*] day cure period shall commence upon determination by a court of competent jurisdiction (or arbitrator if the parties agree to arbitrate the matter) that the alleged failure to perform or breach exists. In no event, however, shall such notice or intention to terminate be deemed to waive any rights to damages or any other remedy which the party giving notice of breach may have as a consequence of such failure or breach.

**9.3 Termination by Company.** Company may terminate this Agreement and the license granted herein, for any reason, upon giving JHU ninety (90) days written notice. Company may terminate its license with respect to any particular patent or patent application with 60 days' notice to JHU and Exhibit D shall be considered amended accordingly. Company will not be required to reimburse JHU for patent costs incurred after the 60-day notice period for such patents or patent applications.

**9.4 Obligations and Duties upon Termination.** If this Agreement is terminated, both parties shall be released from all obligations and duties imposed or assumed hereunder to the extent so terminated, except as expressly provided to the contrary in this Agreement. Upon termination, both parties shall cease any further use of the confidential information disclosed to the receiving party by the other party. Termination of this Agreement, for whatever reason, shall not affect the obligation of either party to make any payments for which it is liable prior to or upon such termination. Termination shall not affect JHU's right to recover unpaid royalties, fees, reimbursement for patent expenses, or other forms of financial compensation incurred prior to termination. Upon termination Company shall submit a final royalty report to JHU and any royalty payments, fees, unreimbursed patent expenses and other financial compensation due JHU shall become immediately payable. Furthermore, upon termination of this Agreement, all rights in and to the licensed technology shall revert immediately to JHU at no cost to JHU. Upon termination of this Agreement, any SUBLICENSEE(S) shall become a direct licensee of JHU, provided that JHU's obligations to SUBLICENSEE(S) are no greater than JHU's obligations to Company under this Agreement. Company shall provide written notice of such to each SUBLICENSEE(S) with a copy of such notice provided to JHU.

## **ARTICLE 10 MISCELLANEOUS**

**10.1 Use of Name.** Except as required by applicable law or regulations, Company, AFFILIATED COMPANIES and SUBLICENSEE(S) shall not use the name of The Johns Hopkins University or The Johns Hopkins Health System or any of its constituent parts, such as the Johns Hopkins Hospital or any contraction thereof or the name of Inventors in any advertising, promotional, sales literature or fundraising documents without prior written consent from an authorized representative of JHU, or, in the case of the name of an Inventor, from such Inventor; provided that the Company may disclose the existence of this Agreement and the terms hereof and the fact that [\*\*] is a founder of the Company and a faculty member of JHU without such consent. Company, AFFILIATED COMPANIES and SUBLICENSEE(S) shall allow at least [\*\*] days notice of any proposed public disclosure for JHU's review and comment or to provide written consent.



**10.2 No Partnership.** Nothing in this Agreement shall be construed to create any agency, employment, partnership, joint venture or similar relationship between the parties other than that of a licensor/licensee. Neither party shall have any right or authority whatsoever to incur any liability or obligation (express or implied) or otherwise act in any manner in the name or on the behalf of the other, or to make any promise, warranty or representation binding on the other.

**10.3 Notice of Claim.** Each party shall give the other or its representative immediate notice of any suit or action filed, or prompt notice of any claim made, against them arising out of the performance of this Agreement or arising out of the practice of the inventions licensed hereunder.

**10.4 Product Liability.** Prior to initial human testing or first commercial sale of any LICENSED PRODUCT(S) or LICENSED SERVICE(S) as the case may be in any particular country, Company shall establish and maintain, covering the Company's liability in each country in which Company, an AFFILIATED COMPANY or SUBLICENSEE(S) shall test or sell LICENSED PRODUCT(S) and LICENSED SERVICE(S), product liability or other appropriate insurance coverage in the minimum amount of [\*\*] dollars (\$[\*\*]) per claim and will annually present evidence to JHU that such coverage is being maintained. Upon JHU's request, Company will furnish JHU with a Certificate of Insurance of each product liability insurance policy obtained. JHU shall be listed as an additional insured in Company's said insurance policies. If such Product Liability insurance is underwritten on a 'claims made' basis, Company agrees that any change in underwriters during the term of this Agreement will require the purchase of 'prior acts' coverage to ensure that coverage will be continuous throughout the term of this Agreement.

**10.5 Governing Law.** This Agreement shall be construed, and legal relations between the parties hereto shall be determined, in accordance with the laws of the State of Maryland applicable to contracts solely executed and wholly to be performed within the State of Maryland without giving effect to the principles of conflicts of laws. Any disputes between the parties to this Agreement shall be brought in the state or federal courts of Maryland. Both parties agree to waive their right to a jury trial.

**10.6 Notice.** All notices or communication required or permitted to be given by either party hereunder shall be deemed sufficiently given if mailed by registered mail or certified mail, return receipt requested, or sent by overnight courier providing evidence of delivery, such as Federal Express, to the other party at its respective address set forth below or to such other address as one party shall give notice of to the other from time to time hereunder. Mailed notices shall be deemed to be received on the third business day following the date of mailing. Notices sent by overnight courier shall be deemed received the following business day.

If to Company:

Mintz, Levin, Cohn, Ferris,  
Glovsky and Popeo, P.C.  
One Financial Center  
Boston, MA 02111  
Attn: Jeffrey M. Wiesen, Esq.

With a Copy to: Mintz, Levin, Cohn, Ferris,  
Glovsky and Popeo, P.C.  
One Financial Center  
Boston, MA 02111  
Attn: Jeffrey M. Wiesen, Esq.

If to JHU: Director  
Technology Transfer  
Johns Hopkins University  
100 N. Charles Street  
5th Floor  
Baltimore, MD 21201  
Attn: Agrmt [\*\*]

**10.7 Compliance with All Laws.** In all activities undertaken pursuant to this Agreement, both JHU and Company covenant and agree that each will in all material respects comply with such Federal, state and local laws and statutes, as may be in effect at the time of performance and all valid rules, regulations and orders thereof regulating such activities.

**10.8 Successors and Assigns.** Neither this Agreement nor any of the rights or obligations created herein, except for the right to receive any remuneration hereunder, may be assigned by either party, in whole or in part, without the prior written consent of the other party, except that either party shall be free to assign this Agreement in connection with its merger or consolidation or any sale of substantially all of its assets without the consent of the other. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the parties hereto.

**10.9 No Waivers; Severability.** No waiver of any breach of this Agreement shall constitute a waiver of any other breach of the same or other provision of this Agreement, and no waiver shall be effective unless made in writing. Any provision hereof prohibited by or unenforceable under any applicable law of any jurisdiction shall as to such jurisdiction be deemed ineffective and deleted herefrom without affecting any other provision of this Agreement. It is the desire of the parties hereto that this Agreement be enforced to the maximum extent permitted by law, and should any provision contained herein be held by any governmental agency or court of competent jurisdiction to be void, illegal and unenforceable, the parties shall negotiate in good faith for a substitute term or provision which carries out the original intent of the parties.

**10.10 Entire Agreement; Amendment.** Company and JHU acknowledge that they have read this entire Agreement and that this Agreement, including the attached Exhibits constitutes the entire understanding and contract between the parties hereto and supersedes any and all prior or contemporaneous oral or written communications with respect to the subject matter hereof, all of which communications are merged herein. It is expressly understood and agreed that (i) there being no expectations to the contrary between the parties hereto, no usage of trade, verbal agreement or another regular practice or method dealing within any industry or between the parties hereto shall be used to modify, interpret, supplement or alter in any manner the express terms of this Agreement; and (ii) this Agreement shall not be modified, amended or in any way altered except by an instrument in writing signed by both of the parties hereto.

**10.11 Delays or Omissions.** Except as expressly provided herein, no delay or omission to exercise any right, power or remedy accruing to any party hereto, shall impair any such right, power or remedy to such party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or in any similar breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

**10.12 Force Majeure.** If either party fails to fulfill its obligations hereunder (other than an obligation for the payment of money), when such failure is due to an act of God, or other circumstances beyond its reasonable control, including but not limited to fire, flood, civil commotion, riot, war (declared and undeclared), revolution, or embargoes, then said failure shall be excused for the duration of such event and for such a time thereafter as is reasonable to enable the parties to resume performance under this Agreement, provided however, that in no event shall such time extend for a period of more than [\*\*] days.

**10.13 Further Assurances.** Each party shall, at any time, and from time to time, prior to or after the EFFECTIVE DATE of this Agreement, at reasonable request of the other party, execute and deliver to the other such instruments and documents and shall take such actions as may be required to more effectively carry out the terms of this Agreement.

**10.14 Survival.** All representations, warranties, covenants and agreements made herein and which by their express terms or by implication are to be performed after the execution and/or termination hereof, or are prospective in nature, shall survive such execution and/or termination, as the case may be. This shall include Paragraphs 3.7 (Late Payments), 5.2 (Records), and Articles 6, 7, 8, 9, and 10.

**10.15 No Third Party Beneficiaries.** Nothing in this Agreement shall be construed as giving any person, firm, corporation or other entity, other than the parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.

**10.16 Headings.** Article headings are for convenient reference and not a part of this Agreement. All Exhibits are incorporated herein by this reference.

**10.17 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which when taken together shall be deemed but one instrument.

IN WITNESS WHEREOF, this Agreement shall take effect as of the EFFECTIVE DATE when it has been executed below by the duly authorized representatives of the parties.

/s/ Wesley D. Blakeslee  
Wesley D. Blakeslee, J.D.  
Executive Director

/s/ Robert Paull  
Name: Robert Paull  
Title: CEO

Johns Hopkins Technology Transfer  
10 Nov. 2009  
(Date)

November 9th, 2009  
(Date)

I have read and agree to abide by the terms of this Agreement:

/s/ [\*\*]  
[\*\*]

11/11/09  
Date

EXHIBIT A. LICENSE FEE & ROYALTIES.  
EXHIBIT B. SALES & ROYALTY REPORT FORM.  
EXHIBIT C. MATERIALS.  
EXHIBIT D. PATENT APPLICATIONS.

LICENSE FEE & ROYALTIES

1. **License Fee:** The license fee due under Paragraph 3.1 is

- (i) [\*\*] dollars (\$[\*\*]), and
- (ii) shares of Company stock in such amounts that after issuance of those shares JHU shall own [\*\*] percent ([\*\*]%) of the total pre-financing outstanding shares of Company. After that, the JHU equity interest shall be diluted at the same rate as the founders’ shares through subsequent rounds of equity financing. JHU will become a party to Company’s Investor Rights Agreement on the same basis as Company’s founders.

2. **Minimum Annual Royalties:** The minimum annual royalties pursuant to Paragraph 3.2 are:

[**] year:	[**] dollars (\$[**]).
[**] year:	[**] dollars (\$[**]).
[**] year and each year thereafter until Launch Year:	Fifty thousand dollars (\$50,000).
Launch Year and each year thereafter:	One hundred thousand dollars (\$100,000).

“Launch Year” shall mean the year of the first commercial sale of a LICENSED PRODUCT in the U.S., EU or Japan.

3. **Royalties:** The running royalty rate payable under Paragraph 3.3 is:

Portion of Annual Sales	Royalty Rate
0-\$[**]	[**]%
\$[**]-\$[**]	[**]%
>\$[**]	[**]%

For those annual sales exceeding \$[\*\*]: In the event that Company is required to pay running royalties on any patent rights not licensed hereunder (“Other Payments”) in order to commercialize a LICENSED PRODUCT or LICENSED SERVICE, Company may offset [\*\*]% of such Other Payments actually paid against royalty payments owed to JHU, provided that that the royalty payment to JHU shall not fall below [\*\*]% of that which would otherwise be due JHU for that LICENSED PRODUCT or LICENSED SERVICE.

4. **Sublicense consideration:** The percent of SUBLICENSE CONSIDERATION payable under Paragraph 3.4 is:

[\*\*]% for any sublicense executed prior to [\*\*] months after the EFFECTIVE DATE;

[\*\*]% for any sublicense executed between [\*\*] months after the EFFECTIVE DATE and [\*\*] months after the EFFECTIVE DATE; and

[\*\*]% for any sublicense executed more than [\*\*] months after the EFFECTIVE DATE.

In the event that (i) Company sublicenses PATENT RIGHTS together with patent rights owned by Company and necessary to commercialize a LICENSED PRODUCT, the above percentages will be reduced by [\*\*]% and (ii) Company pays a portion of sublicensing revenue to a third party under a third-party license for patent rights necessary to commercialize a LICENSED PRODUCT, Company may offset [\*\*]% of such amounts actually paid against percentage of SUBLICENSE CONSIDERATION payments owed to JHU; provided that the percentage of SUBLICENSE CONSIDERATION payments to JHU shall not fall below [\*\*]%.

5. **Milestones:** The milestones payable under Paragraph 3.5 are:

- (i) [\*\*] upon [\*\*]
- (ii) \$[\*\*] upon [\*\*]
- (iii) \$[\*\*] upon [\*\*]
- (iv) \$[\*\*] upon [\*\*]
- (v) \$[\*\*] upon [\*\*]

Each milestone payment shall be paid for the first three LICENSED PRODUCTS to achieve such milestone and no milestone payments shall be required for subsequent LICENSED PRODUCTS. Milestone payments for the second and third LICENSED PRODUCTS shall be reduced by [\*\*]%.

**FIRST AMENDMENT  
TO EXCLUSIVE LICENSE AGREEMENT**

This First Amendment to Exclusive License Agreement is entered into by and between The Johns Hopkins University (“JHU”) and Kala Pharmaceuticals, Inc., formerly known as Hanes NewCo, Inc, a Delaware corporation (“Kala” or “Company”).

**WHEREAS**, Hanes NewCo, Inc. and JHU entered into an Exclusive License Agreement dated November 10, 2009 (“Agreement”) pursuant to which JHU licensed certain patent rights and know-how to Hanes NewCo, Inc.

**WHEREAS**, Hanes NewCo, Inc. changed its name to Kala Pharmaceuticals, Inc. on December 11, 2009.

**WHEREAS**, the parties wish to amend the Agreement on the terms set forth herein;

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements set forth below, the parties agree as follows:

1. Capitalized terms used herein and not defined herein shall have the respective meanings ascribed to such terms in the Agreement.
2. Each of the parties hereby agrees to amend the agreement to substitute Kala Pharmaceuticals, Inc. in place of Hanes NewCo, Inc. every place such name appears in the Agreement.
3. As of the First Amendment Date, Section 2.4 of the Agreement shall be superseded in its entirety by the following:

“Commencing on the First Amendment Date, Company may, within [\*\*] days following the end of a calendar quarter, by email to Director, Technology Licensing [email: [\*\*] or [\*\*]]. request information about any Improvements that were disclosed to the JHU technology transfer office during the previous calendar quarter. Within [\*\*] days after receipt of such email, JHU shall notify Company in writing of any such Improvements; provided, however, that if an invention disclosure describing an Improvement also contains disclosure for one or more additional inventions which are not Improvements (“Other Inventions”), then JHU may redact information on such Other Inventions. Subject to any third party, including U.S. Government, obligations of JHU under any agreement under which any Improvement is made, Company will have a right of first negotiation to amend this Agreement to add the Improvement and related patent rights, know how and materials to this Agreement; provided, that Company notifies JHU of Company’s interest in exercising such right of first negotiation within [\*\*] days after receipt of written notice from JHU of such Improvement. JHU and Company will negotiate in good faith on reasonable terms for adding the Improvement to this Agreement. For purposes hereof, “Improvement” shall mean an invention: (i) made in the laboratory of [\*\*]; (ii) that would infringe the PATENT RIGHTS if made, used, imported or sold without a license to PATENT RIGHTS; (iii) pertaining to mucosal delivery using mucus penetrating nanoparticles or microparticles; and (iv) reported to the JHU technology transfer office within [\*\*] years from the First Amendment Date.”
4. In Section 10.6, change the addresses for notices to the Company to the following:

“If to Company:   Kala Pharmaceuticals, Inc.  
                          135 Beaver Street #309  
                          Waltham, MA 02453  
                          Attn: Chief Executive Officer  
                          With a Copy to: General Counsel”
5. In all other respects the Agreement shall remain in full force and effect.
6. This First Amendment shall be effective as of the date the last party hereto has executed this First Amendment (the “First Amendment Date”).
7. For the convenience of the parties hereto, this Amendment may be executed in two counterparts, each of which shall be deemed to be an original, but both of which together shall constitute one and the same instrument, without necessity of production of the others. Signatures may be exchanged by facsimile or electronic transmission and each of the parties to this Amendment agrees that it will be bound by its own facsimile signature and that it accepts the facsimile signature of the other party.



8. Amendment Fee. Company shall pay to JHU within [\*\*] days of the First Amendment Date [\*\*] dollars (\$[\*\*]) as an amendment fee. JHU will not submit an invoice for the amendment fee, which is nonrefundable and shall not be credited against royalties or other fees.

This Agreement may be executed in one or more counterparts each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

**KALA PHARMAEUTICALS, INC.**

**THE JOHNS HOPKINS UNIVERSITY**

By: /s/ Guillaume Pfefer  
duly authorized

By: /s/ Wesley D. Blakeslee  
duly authorized

Guillaume Pfefer

Wesley D. Blakeslee, J.D.

CEO

Executive Director

Date:

Johns Hopkins Technology Transfer

Date: 11/19/2012

**SECOND AMENDMENT  
TO EXCLUSIVE LICENSE AGREEMENT**

This Second Amendment to Exclusive License Agreement (“Second Amendment”) is entered into by and between The Johns Hopkins University, a Maryland corporation having an address at 3400 N. Charles Street, Baltimore, MD 21218-2695 (“JHU”), and Kala Pharmaceuticals, Inc., formerly known as Hanes NewCo, Inc, a Delaware corporation having an address at 100 Beaver Street, Suite 201, Waltham, MA 02453 (“Kala” or “Company”).

**WHEREAS**, Kala and JHU entered into an Exclusive License Agreement dated November 10, 2009, as amended by a First Amendment (the “First Amendment”) dated November 19, 2012 (as so amended, the “Agreement”), pursuant to which JHU licensed certain patent rights and know-how to Kala;

**WHEREAS**, the Exclusive License Agreement provides for milestone payments to JHU upon the achievement by Company of certain clinical trial milestones with respect to Licensed Products;

**WHEREAS**, JHU, Company, and GrayBug LLC are discussing, as of the Second Amendment Date (as defined below), the proposed terms of a draft Settlement and License Agreement between JHU, Company, and GrayBug LLC (as may be modified by JHU, Company, and GrayBug, the “Proposed Settlement Terms”). (GrayBug LLC is hereinafter referred to as “GrayBug”).

**WHEREAS**, Company and JHU wish to amend the Agreement on the terms set forth herein;

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements set forth below, the Company and JHU agree as follows:

1. As of the Second Amendment Dale, Section 3.5 of the Agreement shall be superseded in its entirety by the following:  
  
“Company shall pay to JHU milestones as set forth in Exhibit A. These milestones shall be due, without invoice from JHU, within [\*\*] days of achievement of such milestone; provided however, if any of the milestones set forth in Exhibit A are achieved prior to [\*\*], the milestone payment for such milestone shall not be due until the earlier of (i) [\*\*] days after execution by JHU, Company, and GrayBug of the Proposed Settlement Terms and (ii) [\*\*]. Notwithstanding anything to the contrary in this Agreement or its exhibits, upon execution of the Proposed Settlement Terms by JHU, Company, and GrayBug, each milestone achieved prior to the execution of the Proposed Settlement Terms shall be subject to any payment reductions set forth in the executed Proposed Settlement Terms as if such milestones were achieved by Company after the execution of the Proposed Settlement Terms.”
2. This Second Amendment shall be effective as of May 22, 2014 (the “Second Amendment Date”).
3. In all other respects the Agreement shall remain in full force and effect.
4. Neither Company nor JHU is required to pay an amendment fee in connection with the execution of this Second Amendment.

This Agreement may be executed in one or more counterparts each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

**KALA PHARMACEUTICALS, INC.**

**THE JOHNS HOPKINS UNIVERSITY**

By: /s/ Guillaume Pfefer  
duly authorized

By: /s/ Steven L. Kousouris  
duly authorized

[Guillaume Pfefer]

~~[Wesley D. Blakeslee, J.D.]~~ Steven L. Kousouris

President &CEO

~~[Executive Director]~~ Sr. Director

Date: 5/23/2014

Johns Hopkins Technology Transfer

Date: 5/23/2014

**THIRD AMENDMENT  
TO EXCLUSIVE LICENSE AGREEMENT**

This Third Amendment to Exclusive License Agreement (“Third Amendment”) is entered into by and between The Johns Hopkins University, a Maryland corporation having an address at 3400 N. Charles Street, Baltimore, MD 21218-2695 (“JHU”), and Kala Pharmaceuticals, Inc., formerly known as Hanes NewCo, Inc., a Delaware corporation having an address at 100 Beaver Street, Suite 201, Waltham, MA 02453 (“Kala” or “Company”).

**WHEREAS**, Kala and JHU entered into an Exclusive License Agreement dated November 10, 2009, as amended by a First Amendment (the “First Amendment”) dated November 19, 2012 and a Second Amendment (the “Second Amendment”) effective as of May 22, 2014 (as so amended, the “Agreement”), pursuant to which JHU licensed certain patent rights and know-how to Kala and modified certain milestones, respectively;

**WHEREAS**, Paragraph 2.5 and certain other provisions of the Exclusive License Agreement reference “OPTION PATENT RIGHTS” and Company declined in 2010 to license such rights;

**WHEREAS**, the parties are joint owners of the patent rights relating to the invention entitled [\*\*] and the parties wish to amend the Agreement to add such jointly owned patent rights, and to amend the terms of the Agreement as set forth herein regarding each party’s rights with respect to the patent rights for such invention;

**WHEREAS**, JHU, Company, and GrayBug LLC (“GrayBug”) are discussing proposed terms for a Settlement and License Agreement between JHU, Company and GrayBug (as may be modified by JHU, Company and GrayBug, the “Settlement Agreement”);

**WHEREAS**, the parties wish to amend the Agreement on the terms set forth herein;

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements set forth below, the parties agree as follows:

1. Capitalized terms used herein and not defined herein shall have the respective meanings ascribed to such terms in the Agreement.
2. The parties agree that notwithstanding that no date is associated with Kala’s signature to the First Amendment, the parties agree that the “First Amendment Date” as defined in the First Amendment is November 19, 2012.
3. As of the Third Amendment Date, the second “Whereas” recital of the Agreement shall be superseded in its entirety by the following:

“WHEREAS, a valuable invention entitled [\*\*] was developed during the course of research conducted by [\*\*], and a valuable invention entitled [\*\*] was developed during the course of research conducted by [\*\*], and a valuable invention entitled [\*\*] was developed during the course of research conducted by [\*\*], and a valuable invention entitled [\*\*] was developed during the course of research conducted for

Company by [\*\*], and conducted for JHU by [\*\*] (all of the individuals in this paragraph who are officially affiliated with JHU, “Inventors”); and”

4. As of the Third Amendment Date, the third “Whereas” recital of the Agreement shall be superseded in its entirety by the following

“WHEREAS, JHU has acquired through assignment all rights, title and interest, with the exception of Kala’s ownership interest in connection with JHU Ref. # [\*\*] and certain retained rights by the United States Government, in its interest in said valuable inventions; and”

5. As of the Third Amendment Date, a new Section 1.14 shall be added to the Agreement as follows:

““KALA/JHU JOINTLY OWNED PATENT RIGHTS’ shall mean the issued patents and patent applications listed in EXHIBIT D for JHU Ref # [\*\*] (all such patent applications for JHU Ref # [\*\*] hereinafter referred to as “JOINT PATENT APPLICATIONS”) and all continuations, divisions, claims of continuations-in-part applications directed to subject matter specifically described in the Joint Patent Applications, continued prosecution applications and reissues, reexaminations, extensions and supplemental protection certificates thereof, and any corresponding foreign patent applications, and any patents, or other equivalent foreign patent rights issuing, granted or registered thereon.”

6. As of the Third Amendment Date, the definitions “LICENSED PRODUCTS” in Section 1.6 of the Agreement and “LICENSED SERVICES” in Section 1.7 of the Agreement are amended such that the phrase “the license granted to Company pursuant to this Agreement” in each definition shall include the addition of “or the Company’s ownership interest” as follows:

“but for the license granted to Company pursuant to this Agreement or the Company’s ownership interest,”

7. As of the Third Amendment Date, Section 1.10 of the Agreement shall be superseded in its entirety by the following:

““PATENT RIGHTS” shall mean the issued patents and patent applications listed in EXHIBIT D for JHU Ref # [\*\*] (including, without limitation, JHU Ref. # [\*\*]), JHU Ref # [\*\*], JHU Ref # [\*\*], JHU Ref # [\*\*], and KALA/JHU JOINTLY OWNED PATENT RIGHTS (all such patent applications for JHU Ref # [\*\*] (including, without limitation, JHU Ref. # [\*\*]), JHU Ref # [\*\*], JHU Ref # [\*\*], JHU Ref # [\*\*] and JOINT PATENT APPLICATIONS hereinafter referred to as “Patent Applications”) and all continuations, divisions, claims of continuations-in-part applications directed to subject matter specifically described in the Patent Applications, continued prosecution applications and reissues, reexaminations, extensions and supplemental protection certificates thereof, and any corresponding foreign patent applications, and any patents, or other equivalent foreign patent rights issuing, granted or registered thereon.”

8. As of the Third Amendment Date, the following sentence shall be added to the end of Section 2.2 of the Agreement:
- “The sublicensing restrictions set forth in this Section 2.2 shall not apply to Company’s right to sublicense Company’s interest in KALA/JHU JOINTLY OWNED PATENT RIGHTS.”
9. Section 4.1 of the Agreement shall not apply to KALA/JHU JOINTLY OWNED PATENT RIGHTS. Notwithstanding anything to the contrary in Section 4.1 of the Agreement, Company and JHU jointly own the KALA/JHU JOINTLY OWNED PATENT RIGHTS.
10. As of the Third Amendment Date, the following sentence shall be added to the end of Section 4.4 of the Agreement:
- “Notwithstanding anything to the contrary in this Section 4.4, if a declaratory judgment action is brought naming Company as a defendant and alleging invalidity of any of the KALA/JHU JOINTLY OWNED PATENT RIGHTS, Company shall have the first right to defend such action; provided that Company elects to take over the sole defense of the action at its own expense. JHU shall cooperate fully with Company in connection with any such action.”
11. As of the Third Amendment Date, the first sentence of Section 4.5 of the Agreement shall be amended to read:
- “Any recovery by Company under Paragraph 4.3 shall be deemed to reflect loss of commercial sales, and Company shall pay to JHU [\*\*] percent ([\*\*]%) of the recovery, net of all reasonable costs and expenses associated with each suit or settlement; provided, however, that, with respect to any recovery by Company under Paragraph 4.3 for infringement of KALA/JHU JOINTLY OWNED PATENT RIGHTS, but no PATENT RIGHTS other than KALA/JHU JOINTLY OWNED PATENT RIGHTS, Company shall pay to JHU [\*\*] percent ([\*\*]%) of the recovery, net of all reasonable costs and expenses associated with each suit or settlement.”
12. As of the Third Amendment Date, a new Section 4.7 shall be added to the Agreement as follows:
- “Prosecution and Maintenance of Kala/JHU Jointly Owned Patent Rights. Notwithstanding anything to the contrary in this Agreement, except as provided below, Company, at Company’s expense, shall file, prosecute and maintain all patents and patent applications specified under the KALA/JHU JOINTLY OWNED PATENT RIGHTS. Title to all such patents and patent applications shall reside in Company and JHU. Company shall have control over all patent matters in connection therewith under the KALA/JHU JOINTLY OWNED PATENT RIGHTS, provided however, that COMPANY shall (a) cause its patent counsel to timely copy JHU on all official actions and written correspondence with any patent office, and (b) allow JHU an opportunity to comment and advise Company.



“Notwithstanding anything to the contrary in this Agreement or its exhibits, if the only VALID CLAIMS of PATENT RIGHTS that cover the LICENSED PRODUCT or LICENSED SERVICE are VALID CLAIMS of KALA/JHU JOINTLY OWNED PATENT RIGHTS, then only [\*\*]% of the NET SALES or the NET SERVICE REVENUES of such LICENSED PRODUCT or LICENSED SERVICE shall apply for purposes of the royalty calculation as set forth in this Section 3.3 of the Agreement and Section 3 of this Exhibit A.”

18. As of the Third Amendment Date, the following paragraph shall be added to the end of Section 4 of Exhibit A of the Agreement:

“Notwithstanding anything to the contrary in this Agreement or its exhibits, the SUBLICENSE CONSIDERATION for any sublicense of only KALA/JHU JOINTLY OWNED PATENT RIGHTS, shall be reduced by [\*\*]% as applied to any obligations of Company under this Agreement. For clarity, the preceding paragraph regarding offsets for a third-party license shall apply after the reduction of SUBLICENSE CONSIDERATION set forth in this paragraph.”

19. As of the Third Amendment Date, the following paragraph shall be added to the end of Section 5 of Exhibit A of the Agreement:

“Notwithstanding anything to the contrary in this Agreement or its exhibits, each milestone payment in this Section 5 shall be reduced by [\*\*]% if the only VALID CLAIMS of PATENT RIGHTS that cover the LICENSED PRODUCT are VALID CLAIMS of KALA/JHU JOINTLY OWNED PATENT RIGHTS; such [\*\*]% reduction is in addition to any reductions that already apply to the second and third LICENSED PRODUCTS that achieve the applicable milestone.”

20. As of the Third Amendment Date, Exhibit D of the Agreement shall be superseded in its entirety by the updated Exhibit D (“Amended Exhibit D”) attached hereto.

21. As of the Third Amendment Date, (a) Paragraph 2.5 shall be deleted in its entirety, (b) the clause “provided, however, that if the OPTION PATENT RIGHTS become PATENT RIGHTS upon exercise of the option set forth in Section 2.5, the OPTION PATENT RIGHTS shall not be included in PATENT RIGHTS for purposes of this Section 2.4” in the last sentence of Section 2.4 of the Agreement shall be deleted in its entirety, (c) the second sentence of Section 3.6 of the Agreement shall be deleted in its entirety, and (d) the second paragraph of Section 3.6 of the Agreement shall be amended to read as follows:

“In accordance with Paragraph 4.1 below, Company will reimburse JHU, within [\*\*] days of the receipt of an invoice from JHU for all costs associated with the preparation, filing, maintenance, and prosecution of PATENT RIGHTS incurred by JHU subsequent to the EFFECTIVE DATE of this Agreement.”

22. In all other respects the Agreement shall remain in full force and effect.

23. This Third Amendment shall be effective as of the date the last party hereto has executed this Third Amendment (the “Third Amendment Date”).

24. For the convenience of the parties hereto, this Amendment may be executed in two counterparts, each of which shall be deemed to be an original, but both of which together shall constitute one and the same instrument, without necessity of production of the others. Signatures may be exchanged by facsimile or electronic transmission and each of the parties to this Amendment agrees that it will be bound by its own facsimile signature and that it accepts the facsimile signature of the other party.

25. Amendment Fee. Company shall pay to JHU within [\*\*] days of the Third Amendment Date [\*\*] dollars (\$[\*\*]) as an amendment fee (the "Third Amendment Fee"). JHU will not submit an invoice for the Third Amendment Fee, which shall not be credited against royalties or other fees. The Third Amendment Fee shall be refunded to Company in full if this Third Amendment is terminated according to Section 26.

26. Termination due to no Settlement. In the event the Settlement Agreement is not executed by JHU, Company, GrayBug, and any other required parties, on or before January I, 2015, each section of this Third Amendment, except for the last sentence of Section 25, shall terminate and the applicable sections in the Agreement shall revert to the language as of immediately prior to the Third Amendment Date; provided that (A) Exhibit D of the Agreement shall be superseded in its entirety by the Amended Exhibit D (but excluding JHU Ref [\*\*]) attached hereto, and (B) each party shall retain its rights as a co-owner in any patent rights jointly owned by Kala and JHU relating to JHU Ref [\*\*].



This Third Amendment may be executed in one or more counterparts each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

**KALA PHARMAEUTICALS, INC.**

**THE JOHNS HOPKINS UNIVERSITY**

By: /s/ Charles McDermott  
duly authorized

By: /s/ Steven L. Kousouris  
duly authorized

Charles McDermott  
Chief Business Officer and Interim President

Director **Steve Kousouris**  
**Sr. Director, Administration**  
**Johns Hopkins Technology Transfer**

Date:  
August 26, 2014

Johns Hopkins Technology Transfer  
Date: 8/26/2014

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

SUBJECT TO FED. R. EVID. 408  
CONFIDENTIAL

### Settlement and License Agreement

This Settlement and License Agreement (including its attachments, this "Agreement") is entered into as of October 24, 2014 ("Settlement Agreement Effective Date"), by and between GrayBug, LLC, a limited liability company organized and existing under the laws of the State of Maryland and having an address of P.O. Box 13043, Baltimore, MD 21203, on behalf of itself and its Affiliates (as defined below) (collectively, "GrayBug"), and Kala Pharmaceuticals, Inc., a corporation organized and existing under the laws of State of Delaware and having a place of business at 100 Beaver Street, Suite 201, Waltham, MA 02453, on behalf of itself and its Affiliates (collectively, "Kala").

WHEREAS, there is a dispute over the rights licensed to each Party under certain Patent Rights (as defined below) owned by JHU (as defined below);

WHEREAS, the Parties and JHU now wish to settle such dispute in an amicable manner which is intended to settle and clarify rights granted by JHU to each Party and to permit each Party to have the freedom to effectively develop pharmaceutical products that will benefit patients;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and other good and valuable consideration, the receipt of which is hereby acknowledged, upon approval of these terms by JHU (including acknowledgement by [\*\*]), GrayBug and Kala agree as follows:

1. Construction; Definitions.

1.A Construction. Each Party acknowledges that it has been advised by counsel during the course of negotiation of this Agreement, and, therefore, that this Agreement shall be interpreted without regard to any presumption or rule requiring construction against the Party causing this Agreement to be drafted. Any reference in this Agreement to a Section, subsection, paragraph or clause shall be deemed to be a reference to a Section, subsection, paragraph or clause of this Agreement. Except where the context otherwise requires, (a) wherever used, the use of any gender will be applicable to all genders; (b) the word "or" is used in the inclusive sense (and/or); (c) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restriction on such amendments, supplements or modifications set forth herein or therein); (d) any reference to any law refers to such law as from time to time enacted, repealed or amended and includes any regulations under such law; (e) the words "herein", "hereof" and hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; and (f) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation" or words of similar import.

1.B Definitions. Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

“Affiliate” means, with respect to a first Person, any second Person that directly or indirectly, through one or more intermediaries, is Controlled by, Controls, or is under Common Control with, such first Person, but only for so long as such Control shall continue. For purposes of this definition, “Controlling” (including, with correlative meanings, “Controlled by” and “under Common Control with”) means, with respect to a Person, possession, direct or indirect, of (a) at least fifty percent (50%) of the voting securities (whether directly or pursuant to any option, warrant, or other similar arrangement) or other comparable equity interests of such Person, or (b) the power to elect or appoint at least fifty percent (50%) of the Board of Directors of such Person or otherwise to direct or cause direction of the management and policies of such Person (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise).

“Business Day” means a day that is not a Saturday, a Sunday, nor a day on which banking institutions in Boston, Massachusetts and Baltimore, Maryland are authorized by law to remain closed.

“Confidential Information” means any proprietary information which is disclosed by one Party or JHU to the other Party in connection with this Agreement, and including any “Confidential Information” as defined in the Prior CDA. In addition, the terms of this Agreement and the Prior CDA shall be considered Confidential Information of each Party. Notwithstanding the foregoing, Confidential Information excludes information that, in each case as demonstrated by competent written documentation:

- i. is in the public domain or publicly known prior to the disclosure to the receiving Party;
- ii. is lawfully in the receiving Party’s possession prior to the disclosure;
- iii. becomes part of the public domain or publicly known by publication or otherwise through no unauthorized act or omission on the part of the receiving Party;
- iv. is provided to a receiving Party by a Third Party who has a lawful right to disclose it; or
- v. is independently discovered by a receiving Party without use of the disclosing Party’s Confidential Information.

“Counterpart” means, with respect to a patent application, (a) any patent applications (including provisional applications) from which such patent application claims priority, (b) all continuations, continuations-in-part, continued prosecution applications and divisionals of such patent application or any application described in clause (a), (c) any issued and unexpired letters patents issuing on such patent application or any application described in clauses (a) or (b), (d) any patent extensions, pediatric extensions, supplementary protection certificates, registrations, confirmations, reissues,

re-examinations, validations, revalidations, and renewals of any patent described in clause (c), and (e) with respect to clauses (a) through (d), any foreign counterparts thereof.

“Current Patent Rights” means (a) with respect to GrayBug as the licensing party or Kala as the sublicensed party, the GrayBug Current Patent Rights and (b) with respect to Kala as the licensing party or GrayBug as the sublicensed party, the Kala Current Patent Rights.

“Exclusive Field” means (a) with respect to GrayBug, the GrayBug Field of Use, and (b) with respect to Kala, the Kala Field of Use.

“Existing JHU License Agreement” means (a) with respect to GrayBug, the GrayBug/JHU Agreement, and (b) with respect to Kala, the Kala/JHU Agreement.

“Future Co-Licensed Patent Rights” means any Future Patent Right that is licensed to GrayBug and Kala pursuant to Section 2(c)(iii), until such time (if any) as such license has expired or been terminated with respect to either Party.

“Future Patent Rights” means (a) any Patent Right (other than GrayBug Current Patent Rights, Kala Current Patent Rights, Kala/JHU Jointly Owned Patent Rights, Other JHU Patent Rights, Transferred Patent Rights, and Jointly Owned Transferred Patent Rights) that, (i) is in whole owned by JHU, (ii) names solely [\*\*] as inventor, or, as co-inventors, limited to the following: [\*\*] and, subject to Section 2(c)(ix): [\*\*] (each of the foregoing, a “Co-Inventor”), or any other person (including laboratory personnel, fellows, and students) working, as of the relevant time, in the laboratory of [\*\*] who has authorized JHU in writing to license the relevant invention under this Settlement Agreement, (iii) is not subject to pre-existing Third Party rights granted by JHU or obligations of JHU to Third Parties (provided, however, that, to the extent such Third Party rights and obligations terminate during the Second Notice period of Section 2(c)(i), the relevant Patent Rights shall be considered Future Patent Rights), and (iv) relates to the GrayBug Field of Use or Kala Field of Use, and (b) any Counterparts of the foregoing.

“GrayBug Current Patent Rights” means [\*\*]; and any Counterparts of the foregoing.

“GrayBug Field of Use” means the use of a Particle for delivery of a biologically active material to the eye via injection, excluding such use of any Particle comprising or consisting of loteprednol etabonate. For the avoidance of doubt, GrayBug Field of Use includes without limitation injections to the eye that are intravitreal, intrastromal, intracameral, sub-tenon (including posterior and anterior), sub-retinal, retro-bulbar, peri-bulbar, suprachoroidal, conjunctival, subconjunctival, episcleral, posterior juxtasclear, scleral, circumcorneal, and tear duct injections, in each case, wherein a Particle does not go through mucus, mucin, or a mucosal barrier of the eye, but the injection means can pass through mucus, mucin, or a mucosal barrier of the eye to inject the Particle to a point of delivery that is not mucus, mucin, or a mucosal barrier of the eye.

“GrayBug/JHU Agreement” means the Exclusive License Agreement between GrayBug and JHU dated [\*\*], as amended on or before the Settlement Agreement Effective Date and as may be amended after the Settlement Agreement Effective Date in accordance with this Agreement.

“HSR Act” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

“JHU” means The Johns Hopkins University.

“JHU Patent Rights” means the GrayBug Current Patent Rights, the Kala Current Patent Rights, the Co-Licensed Other JHU Patent Rights, and the Future Co-Licensed Patent Rights.

“Jointly Owned Transferred Patent Rights” means JHU’s ownership interest in the Kala/JHU Jointly Owned Patent Rights transferred to GrayBug pursuant to Section 2(d)(iv).

“Kala/JHU Agreement” means the Exclusive License Agreement between Kala and JHU dated November 10, 2009, as amended on or before the Settlement Agreement Effective Date and as may be amended after the Settlement Agreement Effective Date in accordance with this Agreement.

“Kala/JHU Jointly Owned Patent Rights” means [\*\*], and any Counterparts thereof.

“Kala Current Patent Rights” means [\*\*]; and any Counterparts of the foregoing.

“Kala Field of Use” means the use of a Particle for delivery of a biologically active material through mucus, mucin, or a mucosal barrier; provided, however, that such delivery does not involve administration via injection to the eye. For the avoidance of doubt, Kala Field of Use includes without limitation topical administration to the eye.

“Licensed Product” means any process or method, material, compositions, drug, or other product, the manufacture, use or sale of which would constitute, but for the license granted to the relevant Party pursuant to this Agreement, an infringement of a Valid Claim of the relevant Patent Rights (where infringement includes direct, contributory, or inducement to infringe) in the country of sale.

“Licensed Service” means the performance on behalf of a Third Party of any method or the manufacture of any product or the use of any product or composition which would constitute, but for the license granted to the relevant Party pursuant to this Agreement, an infringement of a Valid Claim of the relevant Patent Rights (where infringement includes direct, contributory, or inducement to infringe) in the country of performance of the services.

“Losses” means claims, actions, causes of action, suits, defenses, judgments, debts, offsets, accounts, covenants, contracts, agreements, torts, damages, and any and all demands and liabilities whatsoever, including costs, expenses, and attorneys’ fees.

“Other JHU Patent Rights” means the Patent Rights listed in Schedule 1.24 and any Counterparts thereof, which shall be designated as (a) “Co-Licensed Other JHU Patent Rights” while both Parties retain licenses thereunder, pursuant to Section 2(b), (b) “GrayBug-Licensed Other JHU Patent Rights” while only GrayBug retains a license thereunder, pursuant to Section 2(b), and (c) “Kala-Licensed Other JHU Patent Rights” while only Kala retains a license thereunder, pursuant to Section 2(b).

“Particle” means a particle for delivery of a biologically active material, which particle has a [\*\*] or a [\*\*] (which may include a [\*\*] particle).

“Party” means each of GrayBug and Kala individually, and “Parties” means GrayBug and Kala collectively.

“Patent Rights” means patents, patent applications or provisional patent applications, utility models and utility model applications, petty patents, innovation patents, patents of addition, divisionals, continuations, continuation-in-part applications, continued prosecution applications, requests for continued examinations, reissues, renewals, registrations, confirmation, validations, revalidations, reexaminations, and extensions, pediatric extensions and supplementary protection certificates granted in relation thereto, in any country of the world.

“Person” means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship, or other business organization or a governmental agency or a political subdivision thereto.

“Potential Future Patent Right” means an invention (other than an invention covered by GrayBug Current Patent Rights, Kala Current Patent Rights, Other JHU Patent Rights, Kala/JHU Jointly-Owned Patent Rights or Future Patent Rights, as such Patent Rights exist as of the Settlement Agreement Effective Date), that (a) [\*\*] is an inventor of and (b) relates to the GrayBug Field of Use or the Kala Field of Use.

“Prior CDA” means the Confidentiality Agreement between Kala Pharmaceuticals, Inc. and GrayBug, LLC, made and entered into as of June 28, 2013.

“Prosecution and Maintenance” means, with regard to a Patent Right, the preparation, filing, and prosecution of the applicable patent application(s), the maintenance of applicable patent application(s) and patent(s), and the preparation, filing, prosecution, and control of appeals, post-grant reviews, defense of *inter partes* reexaminations, the prosecution of *ex parte* reexaminations, initiation or defense of interferences, derivation proceedings, requests for patent term adjustments, the defense of oppositions, and other similar proceedings with respect to such Patent Right, and any appeals therefrom. For clarity, “Prosecution and Maintenance” shall not include any other enforcement actions taken with respect to a Patent Right.

“Remaining Field” means any field outside the GrayBug Field of Use and the Kala Field of Use.

“Third Party” means a Person other than GrayBug, Kala, JHU and their respective Affiliates.

“Transferred Patent Rights” means (a) with respect to GrayBug, Kala Current Patent Rights transferred to GrayBug pursuant to Section 2(a)(v), and (b) with respect to Kala, GrayBug Current Patent Rights transferred to Kala pursuant to Section 2(a)(v).

“Valid Claim” means either: (a) a claim of an issued and unexpired patent included within the relevant Patent Rights which has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reexamination, reissue, disclaimer or otherwise; or (b) a claim of a pending patent application included within the relevant Patent Rights, which claim has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application, and has been pending for less than [\*\*] years from the date such claim was filed in a first national filing non-provisional patent application in the country of interest and has not been (i) canceled, (ii) withdrawn from consideration, (iii) finally determined to be unallowable by the applicable governmental authority (and from which no appeal is or can be taken), or (iv) abandoned.

2. License Grants.

a. Current Patent Rights.

- i. GrayBug Current Patent Rights. GrayBug hereby grants to Kala a worldwide, royalty-free, exclusive, sublicenseable (in accordance with Section 2(a)(iii)) sublicense, under the GrayBug Current Patent Rights, to research, develop, make, have made, use, have used, import, have imported, offer to sell, have offered for sale, sell and have sold Licensed Products in the Kala Field of Use, and to provide and have provided Licensed Services in the Kala Field of Use, in the United States and worldwide.
- ii. Kala Current Patent Rights. Kala hereby grants to GrayBug a worldwide, royalty-free, exclusive, sublicenseable (in accordance with Section 2(a)(iii)) sublicense, under the Kala Current Patent Rights, to research, develop, make, have made, use, have used, import, have imported, offer to sell, have offered for sale, sell and have sold Licensed Products in the GrayBug Field of Use, and to provide and have provided the Licensed Services in the GrayBug Field of Use, in the United States and worldwide.

- iii. Sublicensing. Each Party may sublicense the rights granted to it under the other Party's Current Patent Rights, including the right to further sublicense; provided that (A) any such sublicense must involve some aspect of collaboration, joint research, development, manufacture, partnership, or the like, and in any event, the grant of sublicenses beyond [\*\*] more tiers is not permitted without the original sublicensing Party's written consent, (B) all sublicensees (whether direct or through any tier) are bound by the applicable terms of this Agreement, and (C) the Party granting such sublicense (directly or through its sublicensees) provides the other Party notice of such sublicensee (1) within [\*\*] Business Days after the execution of such sublicense agreement for a direct sublicense or (2) within [\*\*] Business Days after execution of such sublicense agreement for a further sublicense granted through its sublicensee, and in any event of (C)(1) or (C)(2) of this Section 2(a)(iii), in each case to the extent permissible by law (including securities laws), prior to any public disclosure or press release for any such sublicense agreement.
- iv. Separation of Obligations. Neither Party granted a sublicense under the other Party's Current Patent Rights pursuant to Section 2(a)(i) or 2(a)(ii), or any Party's sublicensees under Section 2(a)(iii), shall be responsible for complying with the diligence, reporting, audit or other obligations under such other Party's Existing JHU License Agreement, except to the extent incorporated into this Agreement, and, except to the extent provided herein, such Party shall comply with the diligence, reporting, audit or other obligations to JHU under its own Existing JHU License Agreement with respect to such other Party's Current Patent Rights to the same extent as if such other Party's Current Patent Rights were "PATENT RIGHTS" under such Party's own Existing JHU License Agreement.
- v. Termination of Direct Licensee. Upon a termination, on a Current Patent Right-by-Current Patent Right and country-by-country basis, of the Existing JHU License Agreement with respect to a Party, which termination is not then being disputed by such Party, such terminated Current Patent Right shall be automatically licensed to the other Party under such other Party's Existing JHU License Agreement on a royalty-free, sublicenseable, exclusive basis (the "Transferred Patent Rights") with no rights thereunder retained by such terminated(ing) Party; provided that such license will be subject to any Third Party sublicenses that had been granted by such terminated(ing) Party that JHU continues to honor as a direct license. JHU shall provide the other Party written notice of the termination of a Party's rights with respect to such Current Patent Right under its Existing JHU License Agreement, and the other Party shall have [\*\*] Business Days from its receipt of the notice to send JHU a written notice that the Party declines to accept the automatic license described in this section.



The other Party shall not be obligated to pay any costs or fees related to the terminated(ing) Party's Current Patent Right unless and until such Party accepts the automatic license by not providing a notice to JHU declining such automatic license within the time period specified in the preceding sentence.

- vi. Termination of Sublicensee. If, pursuant to Section 9(c) or in accordance with the terms of its Existing JHU License Agreement, a Party sublicensed under any of the other Party's Current Patent Rights terminates (or JHU terminates, which termination is not then being disputed by the sublicensed Party) the sublicense to such sublicensed Party with respect to any of such directly licensed Party's Current Patent Rights, any Third Party sub-sublicenses, if any, that were granted by such terminated(ing) sublicensed Party under such directly licensed Party's Current Patent Rights shall be deemed direct sublicenses (each such Third Party, a "New Sublicensee") of such directly licensed Party under such Current Patent Rights, provided that such Third Party's sub-sublicense will automatically terminate if, at such time, the Third Party is not in good standing or in breach of any term of its sub-sublicense agreement. Such New Sublicensee shall remain subject to the terms of such New Sublicensee's agreement with the terminated(ing) sublicensed Party, a copy of which shall be promptly provided to the directly licensed Party; provided, however, that such directly licensed Party shall have no obligations to such New Sublicensee beyond respecting the sublicense.

b. Other JHU Patent Rights.

- i. License Grant. JHU hereby grants (A) to GrayBug a worldwide, royalty-bearing (in accordance with the terms and conditions of the GrayBug/JHU Agreement, as amended herein, and specifically as amended by Section 4), sublicenseable (in accordance with Section 2(b)(ii)), exclusive license, under Other JHU Patent Rights, to research, develop, make, have made, use, have used, import, have imported, offer to sell, have offered for sale, sell and have sold Licensed Products in the GrayBug Field of Use, and to provide and have provided Licensed Services in the GrayBug Field of Use, in the United States and worldwide, and (B) to Kala a worldwide, royalty-bearing (in accordance with the terms and conditions of the Kala/JHU Agreement, as amended herein, and specifically as amended by Section 4), sublicenseable (in accordance with Section 2(b)(ii)), exclusive license, under Other JHU Patent Rights, to research, develop, make, have made, use, have used, import, have imported, offer to sell, have offered for sale, sell and have sold Licensed Products in the Kala Field of Use, and to provide and have provided Licensed Services in the Kala Field of Use, in the United States and worldwide. If, pursuant to Section 9(c) or in

accordance with the terms of its Existing JHU Agreement, a Party terminates (or JHU terminates, which termination is not then being disputed by such Party) the license to such Party in such Party's Exclusive Field under this Section 2(b)(i) with respect to an Other JHU Patent Right, such Exclusive Field with respect to such Other JHU Patent Right shall be automatically licensed to the other Party under such other Party's Existing JHU License Agreement with no rights thereunder retained by such terminated(ing) Party, and all sublicensees receiving sublicenses granted by such terminating Party in such Exclusive Field under such Other JHU Patent Right shall be deemed sublicensees of JHU. JHU shall provide the other Party written notice of the termination of a Party's license in its Exclusive Field with respect to an Other JHU Patent Right, and the other Party shall have [\*\*] Business Days from its receipt of the notice to send JHU a written notice that the Party declines to accept the automatic license described in this section. The other Party shall not be obligated to pay the portion of any costs or fees attributable to or to be paid by the terminated(ing) Party for such Other JHU Patent Rights incurred after the termination unless and until such Party accepts the automatic license by not providing a notice to JHU declining such automatic license within the time period specified in the preceding sentence.

- ii. Sublicensing. Each Party may sublicense the exclusive rights granted to it under the Other JHU Patent Rights, including the right to further sublicense; provided that (A-) such further sublicense must involve some aspect of collaboration, joint research, development, manufacture, partnership, or the like, and in any event, the grant of sublicenses beyond [\*\*] more tiers is not permitted without the original sublicensing Party's written consent, (B) all sublicensees (whether direct or through any tier) are bound by the applicable terms of this Agreement, and (C) the Party granting such sublicense (directly or through its sublicensees) provides the other Party notice of such sublicensee (1) within [\*\*] Business Days after the execution of such sublicense agreement for a direct sublicense or (2) within [\*\*] Business Days after execution of such sublicense agreement for a further sublicense granted through its sublicensee, and in any event of (C)(1) or (C)(2) of this Section 2(b)(ii), in each case to the extent permissible by law (including securities laws), prior to any public disclosure or press release for any such sublicense agreement.

c. Future Patent Rights.

- i. Notice. Promptly after each of the following, JHU shall provide written notice concurrently to each of GrayBug and Kala, attaching a copy of the relevant invention disclosure, report, or patent application, as applicable: (1) JHU

Technology Transfer's receipt, within [\*\*] after the Settlement Agreement Effective Date, of an invention disclosure or other similar official report for an invention which, if patented, would be a Future Patent Right or the filing, within [\*\*] after the Settlement Agreement Effective Date, of the first patent application in a family for any Future Patent Right (a "First Notice"), and (2) the filing, within [\*\*] after the Settlement Agreement Effective Date, of the first non-provisional application (in any country or under the Patent Cooperation Treaty) in a family for any Future Patent Right or the filing, even if after the [\*\*] of the Settlement Agreement Effective Date, of the first non-provisional application (in any country or under the Patent Cooperation Treaty) in a family for any Future Patent Right which was, in whole or in part, the subject of an invention disclosure, report or patent application for which JHU provided, or was obligated to provide, a First Notice (a "Second Notice"). Except as provided in this Agreement, until such time as all notices under this paragraph and under Section 2(c)(vi) have been given to the Parties and the periods for the Parties to respond to such notices have expired, JHU shall not offer to license or license to any other Person any Future Patent Right or the subject matter of any invention disclosure or other similar report for an invention which, if patented, would be a Future Patent Right.

- ii. Exercise of Right. Subject to Section 2(c)(ii)(3), below, upon receiving a notice from JHU pursuant to Section 2(c)(i), each Party shall have [\*\*] Business Days thereafter to send written notice to JHU and to the other Party, to exercise its right to non-exclusively license such Future Patent Rights in its Exclusive Field in accordance with the provisions of Sections 2(c)(iii)-(v) below, as applicable.
  1. If, after receipt of the First Notice under Section 2(c)(i)(1) with respect to Patent Rights, only one Party exercises its right to license such Future Patent Rights (the "First Requesting Party"), then during the period between such exercise and the expiration of the period for the Parties' written notices in response to the Second Notice under Section 2(c)(i)(2) with respect to such Future Patent Rights, such Future Patent Rights shall be subject to either Section 2(c)(iv) or (v), as applicable, but the First Requesting Party may only grant sublicenses in the other Party's Exclusive Field if such sublicenses are subject to termination in such Exclusive Field if such other Party obtains an exclusive license in such other Party's Exclusive Field pursuant to Section 2(c)(vi). Thereafter, (A) if the other Party does not exercise its right to license such Future Patent Rights pursuant to the Second Notice, such Future Patent Rights shall remain subject to Section 2(c)(iv) or (v), as applicable, or (B) if the other Party, within [\*\*] Business Days after receipt of such Second

Notice, sends a written notice to JHU and the First Requesting Party requesting a license to such Future Patent Rights, then such Future Patent Rights will be subject to Section 2(c)(iii), and, per Section 2(c)(iv) or 2(c)(v), as applicable, such other Party shall reimburse the First Requesting Party for the pro rata portion of all patent costs the First Requesting Party has paid to JHU in connection with such Future Patent Rights up to that time, subject to the provision of an invoice with respect thereto and, to the extent requested by such other Party, any relevant supporting documentation.

2. If, after receipt of the First Notice under Section 2(c)(i)(1) with respect to Patent Rights, both Parties exercise their right to license such Future Patent Rights, then during the period between such exercise and the expiration of the period for the Parties' written notices in response to the Second Notice under Section 2(c)(i)(2) with respect to such Future Patent Rights, such Future Patent Rights shall be subject to Section 2(c)(iii). Thereafter, (A) if both Parties exercise their right to license such Future Patent Rights pursuant to the Second Notice, such Future Patent Rights shall remain subject to Section 2(c)(iii), or (B) if only one Party, within [\*\*] Business Days after receipt of such Second Notice, sends a written notice to JHU and the other Party requesting a license to such Future Patent Rights, then such Future Patent Rights will be subject to Section 2(c)(iv) or (v), as applicable, and the formerly-licensed Party shall not be entitled to any refund of any amounts it paid to JHU in connection with such Future Patent Rights up to that time and shall remain bound to pay the relevant amounts incurred by JHU in connection with such Future Patent Rights pursuant to Section 2(c)(iii) up to that time.
3. Notwithstanding Sections 2(c)(ii)(1) and 2(c)(ii)(2), if JHU establishes that a Future Patent Right is (A) based on research funded by a Party or (B) specifically designed for the use of one Party, then at the request of such Party, such Future Patent Right can be licensed non-exclusively to such Party in all fields and such Future Patent Right shall be added to such Party's Current Patent Rights but on a non-exclusive (but subject to Section 2(c)(iv)), sublicenseable basis, and shall otherwise be subject to the sublicenses granted by such Party under its Current Patent Rights to the other Party pursuant to this Agreement and, for the sake of clarity, shall be subject to Sections 3(a)(viii) and 4.

iii. Co-Licensed. This Section 2(c)(iii) is subject to Sections 2(c)(ii)(1) and (2) and Section 2(c)(vi).

1. If both GrayBug and Kala, within [\*\*] Business Days after receipt of a notice for Future Patent Rights from JHU pursuant to Section 2(c)(i) above, send a written notice to JHU and the other Party requesting a license under such Future Patent Rights, then JHU shall be deemed to have granted (A) to GrayBug a worldwide, royalty-bearing (in accordance with the terms of the GrayBug/JHU Agreement, as amended herein, and specifically as amended by Section 4), sublicenseable (in accordance with Section 2(c)(iii)(2)), non-exclusive license, under such Future Patent Rights, to research, develop, make, have made, use, have used, import, have imported, offer to sell, have offered for sale, sell and have sold Licensed Products in the GrayBug Field of Use, and to provide and have provided Licensed Services in the GrayBug Field of Use, in the United States and worldwide, and (B) to Kala a worldwide, royalty-bearing (in accordance with the terms of the Kala/JHU Agreement, as amended herein, and specifically as amended by Section 4), sublicenseable (in accordance with Section 2(c)(iii)(2)), non-exclusive license, under such Future Patent Rights, to research, develop, make, have made, use, have used, import, have imported, offer to sell, have offered for sale, sell and have sold Licensed Products in the Kala Field of Use, and to provide and have provided Licensed Services in the Kala Field of Use, in the United States and worldwide. If, pursuant to Section 9(c) or in accordance with the terms of its Existing JHU License Agreement, a Party terminates (or JHU terminates, which termination is not then being disputed by such Party) the license to such Party in its Exclusive Field under this Section 2(c)(iii)(1) with respect to a Future Patent Right, such Exclusive Field with respect to such Future Patent Right shall be automatically licensed to the other Party under such other Party's Existing JHU License Agreement with no rights thereunder retained by such terminated(ing) Party, and all sublicensees receiving sublicenses granted by such terminated(ing) Party in such Exclusive Field under such Future Patent Right shall be deemed sublicensees of JHU. JHU shall provide the other Party written notice of the termination of a Party's license in its Exclusive Field with respect to a Future Patent Right, and the other Party shall have [\*\*] Business Days from its receipt of the notice to send JHU a written notice that the Party declines to accept the automatic license described in this section. The other Party shall not be obligated to pay the portion of any costs or fees attributable to or to be paid by the terminated(ing) Party for such

Future Patent Rights incurred after the termination unless and until such Party accepts the automatic license by not providing a notice to JHU declining such automatic license within the time period specified in the preceding sentence.

2. Sublicensing. Each Party may sublicense the rights granted to it under the Future Co-Licensed Patent Rights, including the right to further sublicense; provided that (A) such further sublicense must involve some aspect of collaboration, joint research, development, manufacture, partnership, or the like, and in any event, the grant of sublicenses beyond [\*\*] more tiers is not permitted without the original sublicensing Party's written consent, (B) all sublicensees (whether direct or through any tier) are bound by the applicable terms of this Agreement, and (C) the Party granting such sublicense (directly or through its sublicensees) provides the other Party notice of such sublicensee (1) within [\*\*] Business Days after the execution of such sublicense agreement for a direct sublicense or (2) within [\*\*] Business Days after execution of such sublicense agreement for a further sublicense granted through its sublicensee, and in any event of (C)(1) or (C)(2) of this Section 2(c)(iii)(2), in each case to the extent permissible by law (including securities laws), prior to any public disclosure or press release for any such sublicense agreement.
  
- iv. GrayBug Only. Subject to Sections 2(c)(ii)(1) and (2) and Section 2(c)(vi), if GrayBug, but not Kala, within [\*\*] Business Days after receipt of a notice for Future Patent Rights from JHU pursuant to Section 2(c)(i) above, sends a written notice to JHU and Kala requesting a license under such Future Patent Rights, then such Future Patent Rights ("GrayBug-Licensed Future Patent Rights") shall be deemed licensed by JHU to GrayBug as if they were "PATENT RIGHTS" as defined in the GrayBug/JHU Agreement (as amended herein, and specifically as amended by Section 4), with the exception that (1) such license is non-exclusive and sublicenseable, (2) for clarity, no license, sublicense or other rights shall be deemed to have been granted to Kala in any field with respect to such Future Patent Rights pursuant to this Agreement, and (3) if JHU grants Kala or a Third Party a license under such GrayBug-Licensed Future Patent Rights, all patent costs incurred by JHU with respect to such GrayBug-Licensed Future Patent Rights, whether prior to or after the granting of such license to Kala or such Third Party(ies), shall be borne pro rata among GrayBug and all such licensees (based on the number of JHU-licensed licensees under such GrayBug-Licensed Future Patent Rights) and, with respect to any such patent costs with respect to such GrayBug-Licensed Future Patent Rights paid by GrayBug prior to JHU

granting such a license to Kala or any such Third Party, JHU shall ensure that Kala or such Third Party reimburses such prior patent costs to GrayBug so that GrayBug will only have borne its pro rata amount of such prior patent costs.

- v. Kala Only. Subject to Sections 2(c)(ii)(1) and (2) and Section 2(c)(vi), if Kala, but not GrayBug, within [\*\*] Business Days after receipt of a notice for Future Patent Rights from JHU pursuant to Section 2(c)(i) above, sends a written notice to JHU and GrayBug requesting a license under such Future Patent Rights, then such Future Patent Rights ("Kala-Licensed Future Patent Rights") shall be deemed licensed by JHU to Kala as if they were "PATENT RIGHTS" as defined in the Kala/JHU Agreement (as amended herein, and specifically as amended by Section 4), with the exception that (1) such license is non-exclusive and sublicenseable, (2) for clarity, no license, sublicense or other rights shall be deemed to have been granted to GrayBug in any field with respect to such Future Patent Rights pursuant to this Agreement, and (3) if JHU grants GrayBug or a Third Party a license under such Kala-Licensed Future Patent Rights, all patent costs incurred by JHU with respect to such Kala-Licensed Future Patent Rights, whether prior to or after the granting of such license to Kala or such Third Party(ies), shall be borne pro rata among Kala and all such licensees (based on the number of JHU-licensed licensees under such Kala-Licensed Future Patent Rights) and, with respect to any such patent costs with respect to such Kala-Licensed Future Patent Rights paid by Kala prior to JHU granting such a license to GrayBug or any such Third Party, JHU shall ensure that GrayBug or such Third Party reimburses such prior patent costs to Kala so that Kala will only have borne its pro rata amount of such prior patent costs.
- vi. Right of First Negotiation. Upon a Party's exercise of its right, pursuant to this Section 2(c), to obtain a non-exclusive license in its Exclusive Field with respect to Future Patent Rights, JHU shall automatically grant to such Party an exclusive right to negotiate an exclusive license under such Future Patent Rights in its Exclusive Field, which right such Party may exercise by providing written notice to JHU within [\*\*] days after such Party exercised its right pursuant to this Section 2(c) to obtain a non-exclusive license. If such Party exercises such right of negotiation, JHU and such Party shall negotiate in good faith (for a period not to exceed [\*\*] days after notice of exercise, extendable upon mutual agreement) on reasonable terms to make the license to such Party under such Future Patent Rights exclusive in such Party's Exclusive Field. In the event a particular Licensed Product or Licensed Service is covered by both such Party's Existing JHU License Agreement and any other agreement or amendment between such Party and JHU for the Future Patent Right(s), [\*\*] for a particular milestone payment will be due to JHU and JHU will apportion such revenue

amongst the relevant agreements according to JHU's internal policies. The failure of such Party to exercise such right to negotiate, or the failure of such Party and JHU to reach agreement on the terms on which the license to such Party under such Future Patent Rights shall be made exclusive in its Exclusive Field, shall not affect such Party's non-exclusive license under such Future Patent Rights in its Exclusive Field.

vii. Hart Scott Rodino Compliance. If required, each Party receiving a license under Future Patent Rights shall use commercially diligent efforts to satisfy any applicable requirements under the HSR Act, and the regulations promulgated thereunder or other applicable Federal Trade Commission or Department of Justice regulations, including by making an initial HSR Act filing as soon as practicable after the exercise of the option to obtain such a license pursuant to this Section 2(c). The licenses granted under this Section 2(c) with respect to such Future Patent Rights shall not be effective until the date of either (A) satisfaction of any such requirements and the expiration or termination of all applicable HSR Act waiting periods (including any extensions thereof) or (B) the mutual written agreement of JHU and each Party receiving a license under such Future Patent Rights that no HSR Act filings are required.

viii. Potential Future Patent Rights.

1. JHU hereby represents to each Party that (A) to JHU's knowledge as of the Settlement Agreement Effective Date, JHU Technology Transfer has not received an invention disclosure or other similar official report for a Potential Future Patent Right and no provisional or non-provisional patent application has been filed in any country or under the Patent Cooperation Treaty for any Potential Future Patent Right, other than those disclosed in writing by JHU Technology Transfer to GrayBug and Kala, (B) all the GrayBug Current Patent Rights existing on the Settlement Agreement Effective Date are listed in Schedule 1.21, (C) all the Kala/JHU Jointly Owned Patent Rights existing on the Settlement Agreement Effective Date are listed in Schedule 1.22, and (D) all the Kala Current Patent Rights existing on the Settlement Agreement Effective Date are listed in Schedule 1.23.
2. JHU shall provide written notice concurrently to each of GrayBug and Kala, promptly after JHU's receipt of an invention disclosure or other similar report, or JHU's knowledge of the filing of a provisional or non-provisional patent application, for a Potential Future Patent Right, if such receipt occurs or such knowledge is gained at any time prior to the [\*\*] of the Settlement Agreement Effective Date or thereafter with



respect to the filing of the first non-provisional application. Such notice from JHU shall initially be a non-confidential disclosure. If either GrayBug or Kala requests confidential information regarding the Potential Future Patent Right, JHU shall use reasonable efforts to comply with the request by seeking permission from any necessary Third Parties and providing such information if necessary under an appropriately tailored confidentiality agreement.

- ix. JHU represents that Schedule 2(c)(ix) lists each Co-Inventor from which JHU had not, as of the Settlement Agreement Effective Date, received authorization in writing to license the relevant invention under this Settlement Agreement (each such individual, a "Pending Co-Inventor"). JHU shall use reasonable efforts to obtain authorization in writing from each such Pending Co-Inventor to license the relevant invention under this Settlement Agreement as soon as possible after the Settlement Agreement Effective Date and shall notify each Party as it obtains such authorization from a Pending Co-Inventor. Authorization shall be at each Pending Co-inventor's personal discretion. In the event JHU does not secure an individual Pending Co-inventor's authorization after using reasonable efforts to obtain such by January 1, 2015, the individual will no longer be a Co-inventor under this Agreement and be deleted from the definition of "Future Patent Rights".

d. Kala/JHU Jointly Owned Patent Rights.

- i. Kala/JHU Jointly Owned Patent Rights. Kala hereby grants to GrayBug a worldwide, royalty-free, exclusive, sublicenseable (in accordance with Section 2(d)(ii)) (A) license, under Kala's ownership interest in the Kala/JHU Jointly Owned Patent Rights, and (B) sublicense, under JHU's ownership interest in the Kala/JHU Jointly Owned Patent Rights, in each case of (A) and (B) to research, develop, make, have made, use, have used, import, have imported, offer to sell, have offered for sale, sell and have sold Licensed Products in the GrayBug Field of Use, and to provide and have provided the Licensed Services in the GrayBug Field of Use, in the United States and worldwide.
- ii. Sublicensing. GrayBug may sublicense the rights granted to it under the Kala/JHU Jointly Owned Patent Rights, including the right to further sublicense; provided that (A) any such sublicense must involve some aspect of collaboration, joint research, development, manufacture, partnership, or the like, and in any event, the grant of sublicenses beyond [\*\*] more tiers is not permitted without Kala's written consent, (B) all sublicensees (whether direct or through any tier) are bound by the applicable terms of this Agreement, and (C) GrayBug (directly or through its sublicensees) provides Kala notice of such

sublicensee (1) within [\*\*] Business Days after the execution of such sublicense agreement for a direct sublicense or (2) within [\*\*] Business Days after execution of such sublicense agreement for a further sublicense granted through its sublicensee, and in any event of (C)(1) or (C)(2) of this Section 2(d)(ii), in each case to the extent permissible by law (including securities laws), prior to any public disclosure or press release for any such sublicense agreement.

- iii. Separation of Obligations. GrayBug shall not be responsible for complying with the diligence, reporting, audit or other obligations under the Kala/JHU Agreement, except to the extent incorporated into this Agreement, and Kala shall not be required to make GrayBug comply with such obligations, and, except to the extent provided herein, GrayBug shall comply with the diligence, reporting, audit or other obligations to JHU under the GrayBug/JHU Agreement with respect to the Kala/JHU Jointly Owned Patent Rights to the same extent as if such Kala/JHU Jointly Owned Patent Rights were "PATENT RIGHTS" under the GrayBug/JHU Agreement.
- iv. Termination of Direct Licensee. Upon a termination, in accordance with the terms of the Kala/JHU Agreement, of Kala's rights under JHU's ownership interest in any Kala/JHU Jointly Owned Patent Rights (which termination is not then being disputed by Kala), (A) the license granted by Kala to GrayBug under Kala's ownership interest in such Kala/JHU Jointly Owned Patent Rights shall terminate, and (B) JHU's ownership interest in such Kala/JHU Jointly Owned Patent Rights shall be automatically licensed to GrayBug under the GrayBug/JHU Agreement on a royalty-free, sublicenseable, exclusive basis (the "Jointly Owned Transferred Patent Rights"); provided that such license will be subject to any Third Party sublicenses that had been granted by Kala under JHU's ownership interest in such Kala/JHU Jointly Owned Patent Rights that JHU or Kala continues to honor as a direct license. JHU shall provide GrayBug written notice of the termination of Kala's rights under JHU's ownership interest in such Kala/JHU Jointly Owned Patent Rights, and GrayBug shall have [\*\*] Business Days from its receipt of the notice to send JHU a written notice that GrayBug declines to accept the automatic license described in this section. GrayBug shall not be obligated to pay any costs or fees related to the Kala/JHU Jointly Owned Patent Rights incurred after the termination unless and until GrayBug accepts the automatic license by not providing a notice to JHU declining such automatic license within the time period specified in the preceding sentence.
- v. Termination of Sublicensee. If, pursuant to Section 9(c), GrayBug terminates the license to GrayBug under Kala's ownership interest in any Kala/JHU Jointly

Owned Patent Rights, the license granted by Kala to GrayBug under Kala's ownership interest in such Kala/JHU Jointly Owned Patent Rights shall terminate, and any Third Party sublicenses, if any, that were granted by GrayBug under Kala's ownership interest in such Kala/JHU Jointly Owned Patent Rights shall terminate. If, pursuant to Section 9(c) or in accordance with the terms of its Existing JHU License Agreement, GrayBug terminates (or JHU terminates, which termination is not then being disputed by GrayBug) the sublicense to GrayBug with respect to any Kala/JHU Jointly Owned Patent Rights, (A) the license granted by Kala to GrayBug under Kala's ownership interest in such Kala/JHU Jointly Owned Patent Rights shall terminate, and any Third Party sublicenses, if any, that were granted by GrayBug under Kala's ownership interest in such Kala/JHU Jointly Owned Patent Rights shall terminate, and (B) any Third Party sub-sublicenses, if any, that were granted by GrayBug under JHU's ownership interest in such Kala/JHU Jointly Owned Patent Rights shall be deemed direct sublicenses (each such Third Party, a "New Direct Sublicensee") of Kala under such Kala/JHU Jointly Owned Patent Rights; provided that a Third Party sub-sublicense will automatically terminate if the Third Party is not in good standing or in breach of any term of its sub-sublicense agreement. Each New Direct Sublicensee shall remain subject to the terms of such New Direct Sublicensee's agreement with GrayBug, a copy of which shall be promptly provided to Kala; provided, however, that Kala shall have no obligations to such New Direct Sublicensee beyond respecting the sublicense.

- vi. Kala's Ownership Interest. For the avoidance of doubt, the terms of this Agreement do not in any way affect Kala's ownership interest in each of the Kala/JHU Jointly Owned Patent Rights.
- e. Government Rights. All exclusive rights granted to a Party hereunder are subject to rights retained by the United States Government, if any, in accordance with the Bayh-Dole Act of 1980 (established by P.L. 96-517 and amended by P.L. 98-620, codified at 35 USC § 200 et. seq. and implemented according to 37 CFR Part 401) (the "Bayh-Dole Act"), and subject to the retained right of JHU to make, have made, provide and use for its and The Johns Hopkins Health Systems' non-commercial academic research and teaching purposes Licensed Products and Licensed Services, including the ability to distribute any biological material disclosed and/or claimed in any of the JHU Patent Rights and Kala/JHU Jointly Owned Patent Rights licensed or sublicensed hereunder for nonprofit non-commercial academic research use to non-commercial entities as is customary in the scientific community.

f. Amendment to Know-how Grants.

- i. The GrayBug/JHU Agreement shall be amended by revising Paragraph 2.1(ii) by revising “provided that JHU will not grant a license to KNOW HOW AND MATERIALS to any other commercial entity” to read “provided that JHU will not grant a license to KNOW HOW AND MATERIALS to any commercial entity, other than Kala Pharmaceuticals, Inc. (its successors and assigns) (“Kala”) and any entity which controls, is controlled by or is under common control with Kala (where “control” means the direct or indirect ownership of at least fifty percent (50%)), without Company’s prior written approval; provided, however, that(i) JHU shall be free to transfer KNOW HOW AND MATERIALS to commercial entities for such entities’ non-commercial research purposes, and, (ii) nothing in this Paragraph shall prevent JHU from performing sponsored research using KNOW HOW AND MATERIALS for a commercial entity”. For the purpose of clarification, KNOW HOW AND MATERIALS is limited to materials, information, records and data licensed to GrayBug under the GrayBug/JHU Agreement prior to the Settlement Agreement Effective Date.
  - ii. The Kala/JHU Agreement shall be amended by revising Paragraph 2.1(ii) by revising “provided that JHU will not grant a license to KNOW HOW AND MATERIALS to any other commercial entity” to read “provided that JHU will not grant a license to KNOW HOW AND MATERIALS to any commercial entity, other than GrayBug, LLC (its successors and assigns) (“GrayBug”) and any entity which controls, is controlled by or is under common control with GrayBug (where “control” means the direct or indirect ownership of at least fifty percent (50%)), without Company’s prior written approval; provided, however(i) JHU shall be free to transfer KNOW HOW AND MATERIALS to commercial entities for such entities’ non-commercial research purposes, and, (ii) nothing in this Paragraph shall prevent JHU from performing sponsored research using KNOW HOW AND MATERIALS for a commercial entity”. For the purpose of clarification, KNOW HOW AND MATERIALS is limited to materials, information, records and data licensed to Kala under the Kala/JHU Agreement prior to the Settlement Agreement Effective Date.
- g. Covenant. On a Patent Right-by-Patent Right and country-by-country basis, Kala agrees that (i) it shall not exercise the applicable license or sublicense granted to it in the Kala Field of Use under JHU’s interest in the GrayBug Current Patent Rights, Kala Current Patent Rights, Other JHU Patent Rights, Kala/JHU Jointly Owned Patent Rights or Future Patent Rights where the use involves a Particle comprising or consisting of [\*\*], and (ii) with respect to any Kala/JHU Jointly Owned Patent Right, Kala shall not, prior to the termination of the license granted to Kala under JHU’s interest in such Kala/JHU Jointly

Owned Patent Right, exploit its rights under its ownership interest in such Kala/JHU Jointly Owned Patent Right to develop and commercialize a product in the Kala Field of Use where the Particle therein comprises or consists of [\*\*].

3. Prosecution and Enforcement.

a. Prosecution and Maintenance

- i. Except as set forth in this Section 3, (i) Co-Licensed Other JHU Patent Rights and Future Co-Licensed Patent Rights shall be treated as if they were "PATENT RIGHTS" as defined in each Existing JHU License Agreement for purposes of determining JHU's and each Party's respective rights and obligations with respect to the Prosecution and Maintenance thereof, and, following the termination of one Party's rights in its Exclusive Field with respect to any Co-Licensed Other JHU Patent Rights or Future Co-Licensed Patent Rights, such Patent Rights shall be treated as if they were "PATENT RIGHTS" as defined in the other Party's Existing JHU License Agreement for purposes of determining JHU's and such other Party's respective rights and obligations with respect to the Prosecution and Maintenance thereof, (ii), for clarity, JHU shall continue to have the primary responsibility for Prosecution and Maintenance of, (A) in accordance with the GrayBug/JHU Agreement, the GrayBug Current Patent Rights, the GrayBug-Licensed Other Patent Rights, any Transferred Patent Rights that are transferred to GrayBug and any GrayBug-Licensed Future Patent Rights, and (B) in accordance with the Kala/JHU Agreement, the Kala Current Patent Rights, the Kala-Licensed Other Patent Rights, any Transferred Patent Rights that are transferred to Kala and any Kala-Licensed Future Patent Rights, and (iii) Kala shall continue to have the primary responsibility for Prosecution and Maintenance of the Kala/JHU Jointly Owned Patent Rights in accordance with the Kala/JHU Agreement; provided, however, that:
  1. GrayBug shall have the primary interactions with JHU (as defined below) regarding Prosecution and Maintenance of the GrayBug Current Patent Rights in accordance with the GrayBug/JHU Agreement; provided, however, that JHU or GrayBug, as applicable, shall timely copy Kala on all correspondence that JHU or GrayBug, respectively, receives from or files with any patent office regarding the GrayBug Current Patent Rights and Kala may provide comments for consideration by JHU and GrayBug with respect thereto.
  2. Kala shall have the primary interactions with JHU (as defined below) regarding Prosecution and Maintenance of the Kala Current Patent Rights in accordance with the Kala/JHU Agreement; provided, however,

that JHU or Kala, as applicable, shall timely copy GrayBug on all correspondence that JHU or Kala, respectively, receives from or files with any patent office regarding the Kala Current Patent Rights and GrayBug may provide comments for consideration by JHU and Kala with respect thereto.

3. With regard to Prosecution and Maintenance of the Kala/JHU Jointly Owned Patent Rights, Kala shall timely copy JHU and GrayBug on all correspondence that Kala receives from or files with any patent office regarding the Kala/JHU Jointly Owned Patent Rights, and GrayBug and JHU may provide comments for consideration by Kala with respect thereto.
4. As used in this Section 3(a), “primary interaction with JHU” means that, to the extent that JHU receives conflicting input from each Party with respect to the relevant Current Patent Rights, JHU shall notify both Parties of such conflicting input but, unless the Parties subsequently agree with respect to their input to JHU, JHU shall weigh more heavily the input of the Party directly licensed by JHU under such Current Patent Rights.
5. JHU will select patent counsel (the “JHU Patent Counsel”) responsible for the Prosecution and Maintenance of the JHU Patent Rights that is acceptable to JHU and both Parties. Kala will select patent counsel (the “Other Patent Counsel”) responsible for Prosecution and Maintenance of the Kala/JHU Jointly Owned Patent Rights that is acceptable to JHU and both Parties. For the avoidance of doubt, this Agreement does not require JHU or Kala, respectively, to change any current JHU Patent Counsel or Other Patent Counsel.
6. If JHU or GrayBug elects not to have a patent application filed in any particular country or not to Prosecute and Maintain (or pay expenses associated with Prosecuting or Maintaining) any GrayBug Current Patent Right or claims therein and the other such party (GrayBug or JHU) does not, pursuant to its rights under the GrayBug/JHU Agreement, require such patent application to be filed, Prosecuted and Maintained or such expenses to be paid, then (A) JHU or GrayBug, respectively, shall within [\*\*] Business Days provide written notice thereof to GrayBug or JHU, as the case may be, and to Kala, (B) such Patent Right shall thereafter no longer be licensed by JHU to GrayBug and shall thereafter no longer be considered a GrayBug Current Patent Right hereunder, (C) Kala may elect (by written notice sent to JHU within [\*\*] Business Days after

receipt of the notice in clause (A)) to include such Patent Right as a “PATENT RIGHT” under the Kala/JHU Agreement, to be exclusively licensed to Kala in all fields, in which case such Patent Right shall not be licensed or sublicensed to GrayBug, with any sublicenses granted by GrayBug subject to Section 2(a)(v).

7. If JHU or Kala elects not to have a patent application filed in any particular country or not to Prosecute and Maintain (or pay expenses associated with Prosecuting and Maintaining) any Kala Current Patent Right or claims therein and the other such party (Kala or JHU) does not, pursuant to its rights under the Kala/JHU Agreement, require such patent application to be filed, Prosecuted and Maintained or such expenses to be paid, then (A) JHU or Kala, respectively, shall within [\*\*] Business Days provide notice thereof to Kala or JHU, as the case may be, and to GrayBug, (B) such Patent Right shall thereafter no longer be licensed by JHU to Kala and shall thereafter no longer be considered a Kala Current Patent Right hereunder, (C) GrayBug may elect (by written notice sent to JHU within [\*\*] Business Days after receipt of the notice in clause (A)) to include such Patent Right as a “PATENT RIGHT” under the GrayBug /JHU Agreement, to be exclusively licensed to GrayBug in all fields, in which case such Patent Right shall not be licensed or sublicensed to Kala, with any sublicenses granted by Kala subject to Section 2(a)(v).
- ii. At least [\*\*], one representative from each Party and JHU shall meet (in person or by tele-conference or video-conference) along with the JHU Patent Counsel to discuss the status, strategy, and any other relevant matters with respect to the Prosecution and Maintenance of the JHU Patent Rights in which both Parties retain a license or sublicense, provided that at least [\*\*] shall be in person. Each Party and JHU may replace its representative at any time upon written notice to the other Party(ies) and JHU, as applicable.
- iii. To the extent possible and legally permissible during Prosecution and Maintenance of JHU Patent Rights, at the request of either GrayBug or Kala, patent claims shall be split out in separate applications to facilitate each Party’s separate commercial purposes.
- iv. JHU shall give reasonable consideration to any comment, suggestion, recommendation or other request (a “Request”) of each Party regarding the Prosecution and Maintenance of the Co-Licensed Other JHU Patent Rights and Future Co-Licensed Patent Rights; provided that such Request is received by JHU in a reasonably sufficient time before the applicable filing date to consider such

Request. For Requests under this subsection, Kala and GrayBug shall work together to coordinate and compile their respective Requests into a joint Request (each a "Joint Request"), and for each Co-Licensed Other JHU Patent Right and Future Co-Licensed Patent Right, will designate which Party shall take the lead on conveying the Parties' Joint Request to JHU. If the Parties are unable to agree on a Joint Request for a matter, then the Parties shall jointly contact JHU to discuss their respective positions and JHU will in its sole discretion decide what to advise the JHU Patent Counsel with regard to that matter. For administrative purposes only, a "lead" Party will be nominated to coordinate the Parties' Joint Request for each Co-Licensed Other JHU Patent Right and Future Co-Licensed Patent Right, with the initial nominations decided at the first Prosecution and Maintenance meeting between the Parties after the Settlement Agreement Effective Date, and revised as necessary or appropriate at future meetings.

- v. With respect to Co-Licensed Other JHU Patent Right and the Future Co-Licensed Patent Rights, each Party (i.e., Kala and GrayBug) shall be responsible for [\*\*]percent (\*\*%) of JHU's costs (subject to clause (viii) below) incurred in the Prosecution and Maintenance thereof, and each Party shall reimburse JHU for such amount in accordance with the timelines and processes set forth in the Party's Existing JHU License Agreement, including for such patent costs with respect to such Patent Rights incurred prior to execution of this Agreement. From the point in time at which Other JHU Patent Rights or Future Co-Licensed Patent Rights are exclusively licensed to only one Party hereunder, such Party alone shall be solely responsible for JHU's costs incurred thereafter in the Prosecution and Maintenance of such Other JHU Patent Rights and Future Co-Licensed Patent Rights, in accordance with such Party's Existing JHU License Agreement. In the event a Party or a Third Party(ies) licenses from JHU any rights in the Remaining Field under the Co-Licensed Other JHU Patent Right, the patent costs incurred by JHU with respect to the Prosecution and Maintenance of such Patent Right, whether prior to or after the granting of such license to such Third Party(ies), shall be prorated amongst Kala, GrayBug, and such Third Party(ies), and the relevant Party ((the "Remaining Field Party") if one Party, but not both Parties, have been granted a license by JHU in the Remaining Field), based on the total number of licensees (counting such Remaining Field Party twice (once for its right in its Exclusive Field and once for its right in the Remaining Field) under such Patent Right and JHU shall refund to Kala and GrayBug the relevant amount received from such Third Party(ies) or such Remaining Field Party, as applicable.
- vi. The Parties and JHU each acknowledge the duties set forth in 37 C.F.R. § 1.56.



- vii. The Parties and JHU each acknowledge that patents falling within Patent Rights sublicensed or co-licensed under this Agreement may be eligible for patent term extension under 35 U.S.C. § 156, applications for which must be submitted by the owner of record or their agent. If a Party obtains approval of a New Drug Application (“NDA”) from the U.S. Food and Drug Administration (“FDA”) for a product and believes a patent falling within Patent Rights hereunder may be eligible for patent term extension, it shall notify JHU and the other Party, and JHU and the NDA-holding Party shall cooperate in connection with preparing and timely filing an application for patent term extension.
- viii. Notwithstanding anything to the contrary herein, a Party which has received, directly or indirectly, only non-exclusive rights in such Party’s Exclusive Field under a Future Patent Right in a country shall be responsible for [\*\*] percent ([\*\*]%) of the Prosecution and Maintenance costs such Party would otherwise be responsible for with respect to such Future Patent Right in such country; provided, however, that, in the event a Party or a Third Party(ies) licenses from JHU any rights in such Future Patent Right, the patent costs incurred by JHU with respect to the Prosecution and Maintenance of such Patent Right, whether prior to or after the granting of such license to such Party or Third Party(ies), shall be prorated amongst each Party with a license from JHU under such Future Patent Right and such Third Party(ies).

b. Enforcement.

i. Orange Book Listings & Hatch Waxman Litigation.

- 1. The Parties acknowledge that the owner of an NDA has a non-delegable duty to determine which patents should be listed in the U.S. FDA “Approved Drug Products with Therapeutic Equivalence Evaluations” (sometimes referred to as the “Orange Book”) and any foreign counterparts which require such, including the so-called “Patent Register” listings required in Canada. Prior to such listings and acts, the Parties will meet to evaluate and identify whether any patents falling within Patent Rights sublicensed or co-licensed to the non-NDA holding Party under this Agreement should be included, and the NDA-holding Party shall reach its own decision regarding which patents within such Patent Rights to list in the Orange Book or any foreign counterpart.
- 2. If an NDA-holding Party lists in the Orange Book or foreign counterpart a patent also licensed to the non-NDA holding Party, it shall give the non-NDA holding Party written notice within [\*\*] Business Days.

3. If the NDA-holding Party receives written notice from a generic company under 21 U.S.C. 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”) that it has filed an Abbreviated New Drug Application to sell a product covered by the NDA, and has certified that a patent listed in the Orange Book that falls within Patent Rights sublicensed or co-licensed to the non-NDA holding Party under this Agreement is either not infringed, invalid, or not enforceable, the NDA-holding Party shall give written notice to the non-NDA holding Party within [\*\*] Business Days, with a copy of the Paragraph IV Certification. The Parties acknowledge that time is of the essence in such matter given the statutory requirement that an NDA-holding Party bring a lawsuit within [\*\*] days of receiving the Paragraph IV Certification.
  
4. The NDA-holding Party shall promptly discuss with JHU and the non-NDA-holding Party the advisability of filing a lawsuit against the generic company under 21 U.S.C. § 355 (the “Hatch Waxman Act”). If GrayBug is the NDA-holding Party and the Patent Right challenged is a GrayBug Current Patent Right, then GrayBug shall control the litigation, and if it chooses not to litigate, then JHU shall have the secondary right of litigation. If Kala is the NDA-holding Party and the Patent Right challenged is a Kala Current Patent Right or a Kala/JHU Joint Patent Right, then Kala shall control the litigation, and if it chooses not to litigate, then JHU shall have the secondary right of litigation. If GrayBug or Kala is the NDA-holding Party and the Patent Right challenged is a Co-Licensed Other JHU Patent Right or a Future Co-Licensed Patent Right, then GrayBug and Kala shall meet to discuss terms under which the litigation shall take place, which terms shall include that the NDA-holding Party shall pay the cost of the litigation, the Non-NDA holding Party shall have the right of close communication and review of filed litigation documents (except to the extent marked highly business confidential), participation in (but not control over) litigation strategy, and if the NDA-holding Party receives an adverse judgment of invalidity from a court of final jurisdiction, the NDA-holding Party shall compensate the non-NDA-holding Party for all fees and costs it has invested in the litigated patent historically as well as its litigation attorney’s fees.

ii. Current Patent Rights (Other Than Hatch Waxman).

1. Each Party and JHU will notify the other Party(ies) and JHU, as applicable, promptly in writing when any infringement of any Current Patent Right by a Third Party is uncovered or suspected.
2. Except as otherwise provided in Section 3(b)(i), with respect to an actual or suspected infringement of a Current Patent Right in the Exclusive Field of the Party directly licensed by JHU under such Current Patent Right, the Party directly licensed by JHU under such Current Patent Right shall have the sole right, at its own expense, to institute and control suit against any Third Party with respect to such infringement and recover any damages, awards or settlements resulting therefrom (subject to any obligations to JHU with respect to such amounts pursuant to the applicable Existing JHU License Agreement). Such Party (or JHU, as applicable) shall keep the other Party and JHU reasonably informed of the status of any such enforcement action. Such other Party and JHU shall reasonably cooperate in any such litigation at the enforcing Party's request and expense. If required by applicable law, the other Party and JHU shall permit action under this Section 3(b)(ii) to be brought in its name, including being joined as party-plaintiff. To the extent permitted by applicable law, the other Party or JHU may join such suit at its own expense. No settlement, consent judgment or other voluntary final disposition of such suit that concedes the invalidity or unenforceability of any patent within Current Patent Rights may be entered into without the prior written consent of JHU, which consent shall not be unreasonably withheld.
3. With respect to an actual or suspected infringement of a Current Patent Right in the Exclusive Field of the Party sublicensed under such Current Patent Right, if such sublicensed Party desires to enforce such Current Patent Right against such infringement, such sublicensed Party shall send a written request for such enforcement right to the other Party and the Parties shall discuss in good faith the terms under which such sublicensed Party may enforce such Current Patent Right, including the allocation between the Parties of any damages, awards or settlements resulting therefrom (subject to any obligations to JHU with respect to such amounts pursuant to the applicable Existing JHU License Agreement). If the Parties agree on such enforcement terms, such terms shall be documented in writing and the Parties and JHU shall be bound thereby. If the Parties do not, within a reasonable period of time, agree on such enforcement terms, the Parties shall discuss such enforcement with JHU and any such enforcement action shall be

determined in the sole discretion of JHU, such determination to include a fair and reasonable allocation between the Parties of any damages, awards or settlements resulting therefrom, after taking into consideration litigation expenses and costs.

iii. Kala/JHU Joint Patent Rights (Other Than Hatch Waxman).

1. Each Party and JHU will notify the other Party(ies) and JHU, as applicable, promptly in writing when any infringement of any Kala/JHU Jointly Owned Patent Right by a Third Party is uncovered or suspected.
2. Except as otherwise provided in Section 3(b)(i), with respect to any actual or suspected infringement of a Kala/JHU Jointly Owned Patent Right, Kala shall have the sole right, at its own expense, to institute and control suit against any Third Party with respect to such infringement and recover any damages, awards or settlements resulting therefrom (subject to any obligations to JHU with respect to such amounts pursuant to the applicable Existing JHU License Agreement). Kala shall keep GrayBug and JHU reasonably informed of the status of any such enforcement action. GrayBug and JHU shall reasonably cooperate in any such litigation at Kala's request and expense. If required by applicable law, GrayBug and JHU shall permit action under this Section 3(b)(iii)(2) to be brought in its name, including being joined as party-plaintiff. To the extent permitted by applicable law, GrayBug or JHU may join such suit at its own expense. No settlement, consent judgment or other voluntary final disposition of such suit that concedes the invalidity or unenforceability of any patent within Kala/JHU Jointly Owned Patent Rights may be entered into without the prior written consent of JHU, which consent shall not be unreasonably withheld.
3. With respect to an actual or suspected infringement of a Kala/JHU Jointly Owned Patent Right in the GrayBug Field of Use, if GrayBug desires to enforce such Kala/JHU Jointly Owned Patent Right against such infringement, GrayBug shall send a written request for such enforcement right to Kala and the Parties shall discuss in good faith the terms under which GrayBug may enforce such Kala/JHU Jointly Owned Patent Right, including the allocation between the Parties of any damages, awards or settlements resulting therefrom (subject to any obligations to JHU with respect to such amounts pursuant to Kala's Existing JHU License Agreement). If the Parties agree on such enforcement terms, such terms shall be documented in writing and the Parties and JHU shall be bound thereby. If the Parties do not, within a

reasonable period of time, agree on such enforcement terms, the Parties shall discuss such enforcement with JHU and any such enforcement action shall be determined by Kala and JHU, such determination to include a fair and reasonable allocation between the Parties of any damages, awards or settlements resulting therefrom, after taking into consideration litigation expenses and costs.

iv. Co-Licensed Patent Rights (Other Than Hatch Waxman).

1. Each Party and JHU will notify the other Party(ies) and JHU, as applicable, promptly in writing when any infringement of any Co-Licensed Other JHU Patent Right or Future Co-Licensed Patent Right (each, a "Co-Licensed Patent Right") by a Third Party is uncovered or suspected.
  2. Except as otherwise provided in Section 3(b)(i), with respect to an actual or suspected infringement of a Co-Licensed Patent Right, the Parties shall discuss in good faith whether enforcement of such Co-Licensed Patent Right is appropriate and the terms under which a Party(ies) may enforce such Co-Licensed Patent Right, including the allocation between the Parties of any damages, awards or settlements resulting therefrom (subject to any obligations to JHU with respect to such amounts pursuant to the applicable Existing JHU License Agreement). If the Parties agree on such enforcement terms, such terms shall be documented in writing and the Parties and JHU shall be bound thereby. If the Parties do not, within a reasonable period of time, agree on such enforcement terms, the Parties shall discuss such enforcement with JHU and any such enforcement action shall be determined in the sole discretion of JHU, such determination to include a fair and reasonable allocation between the Parties of any damages, awards or settlements resulting therefrom, after taking into consideration litigation expenses and costs.
- c. Parallel Imports. For so long as a Party retains a license or sublicense to a Patent Right in one country but no longer has a license or sublicense of a related Patent Right in another country, the other Party covenants not to assert against the Party related Patent Rights in other countries for parallel imports into such other countries of otherwise infringing products sold by or on behalf of the Party in the Party's Exclusive Field.
- d. Declaratory Judgment. If a declaratory judgment action is brought naming a Party or JHU as a defendant and alleging invalidity of any of the JHU Patent Rights, the provisions

of the relevant Existing JHU License Agreement(s) shall apply, unless the action or claim arises in connection with a litigation under 21 U.S.C. § 355, the Hatch Waxman Act, or similar United States or foreign statutory provisions, in which case, Section 3(b)(i) shall apply.

4. Financial Terms.

- a. Kala and GrayBug acknowledge that the cross-licenses and releases provided in this Agreement constitute full consideration for the Agreement. Neither Kala nor GrayBug shall owe the other any royalties, milestone payments, or other payments with respect to the sublicenses granted to the other Party hereunder.
- b. JHU agrees that neither Party shall be responsible for paying to JHU any sublicense fees or other payments on Exhibit A of such Party's Existing JHU License Agreement (including milestone payments and royalties) that may otherwise have arisen under such Existing JHU License Agreement as a result of such Party's granting to the other Party any sublicenses under this Agreement (or such sublicensed Party granting any further sublicenses), or, with respect to any of the Kala/JHU Jointly Owned Patent Rights, Kala's granting to GrayBug any licenses under this Agreement under Kala's ownership interest in such Kala/JHU Jointly Owned Patent Rights (or GrayBug granting any sublicenses). For the avoidance of doubt, Kala and GrayBug shall each remain responsible to JHU for sublicense fees and other payments for any other sublicenses it grants under its Existing JHU License Agreements.
- c. Each Party acknowledges that, except as otherwise expressly set forth in this Agreement, any JHU Patent Rights sublicensed to such Party by the other Party pursuant to this Agreement shall be treated as if they were "PATENT RIGHTS" (as defined in the sublicensed Party's Existing JHU License Agreement) for purposes of payment obligations, including patent payments, and the royalty, sublicense income and milestone payments owed by such sublicensed Party to JHU under items 3, 4 and 5 of Exhibit A of such sublicensed Party's Existing JHU License Agreement; however, all such payments shall be subject to Section 4(d), below.
- d. JHU agrees that the milestones and minimum annual royalties (items 2 and 5 of Exhibit A) of each Existing JHU License Agreement are hereby amended such that all payments due to JHU thereunder during the term of this Agreement are reduced by twenty-five percent (25%). Furthermore, the following additional changes to the financial terms in each Existing JHU License Agreement shall apply (all other financial terms, such as running royalty, sublicensing consideration, and patent costs, shall be unaffected except as otherwise expressly provided herein):

- i. minimum annual royalties which would otherwise be due to JHU at any time between the Settlement Agreement Effective Date and the [\*\*] anniversary of the Settlement Agreement Effective Date are hereby eliminated, and, thereafter, if, at the time the minimum annual royalties are due to JHU, the only Patent Rights owned (in whole or in part) by JHU licensed to the paying Party are those with respect to which JHU's rights in such Patent Right are only non-exclusively licensed to such Party in its Exclusive Field or those which are jointly owned by such Party and JHU, then such minimum annual royalty payment shall be reduced by [\*\*] percent ([\*\*]%)
- ii. the development milestones in Section 5 of Exhibit A (e.g., those milestones which do not relate to first commercial sale) under such agreement shall not apply to the second and third "LICENSED PRODUCT(S)" (as defined in such agreement) to achieve such milestone, but the payments (after the application of the [\*\*] percent ([\*\*]%) reduction described above) applicable to the first "LICENSED PRODUCT" to achieve any such milestone shall apply, and the due date of payment for such milestone is extended [\*\*] months from the due date set forth in the applicable Existing JHU License Agreement as of the Settlement Agreement Effective Date; provided, however, that, if, during such [\*\*] month period, the relevant Party terminates the development of such first "LICENSED PRODUCT" which achieved such milestone, such milestone payment shall not be due unless such terminated development is reinitiated after the extended twelve months, under which circumstance the payment shall be reduced by [\*\*] percent and due [\*\*] months after reinitiation;
- iii. with respect to each "LICENSED PRODUCT", the milestone payments with respect to first commercial sale of such "LICENSED PRODUCT" in the United States shall be reduced by an additional [\*\*] percent ([\*\*]%), for a total reduction of [\*\*] percent ([\*\*]%) from the rates set forth in the applicable Existing JHU License Agreement prior to the Settlement Agreement Effective Date;
- iv. if the only "VALID CLAIMS" (as defined in such agreement) owned (in whole or in part) by JHU that cover the relevant "LICENSED PRODUCT" or "LICENSED SERVICE" (as defined in such agreement) are those with respect to which JHU's rights are only non-exclusively licensed to such Party or those which are jointly owned by such Party and JHU, then the milestone payments (including any development and first commercial sale milestone payments) and royalties due to JHU with respect to such "LICENSED PRODUCT" or "LICENSED SERVICE" shall be further reduced by [\*\*] percent ([\*\*]%), provided that by no operation(s)

(except Section 4(d)(ii) above) shall the payments to JHU be reduced by more than [\*\*] percent ([\*\*]%);

- v. if a payment of "SUBLICENSE CONSIDERATION" (as defined in such agreement) is received by a Party only as a result of a Patent Right owned (in whole or in part) by JHU with respect to which JHU's rights are only non-exclusively licensed to such Party or which Patent Right is jointly owned by such Party and JHU, then the percentage of such "SUBLICENSE CONSIDERATION" due to JHU shall be further reduced by [\*\*] percent ([\*\*]%), provided that by no operation(s) shall such payments to JHU fall below [\*\*] percent ([\*\*]%)
- vi. the following sales-based milestones shall be added to Exhibit A, as a new Section 6, of each Existing JHU License Agreement, with the terms which are included but not defined below having the meaning set forth in such Existing JHU License Agreement:

"6. Sales-Based Milestones: In addition to the milestones payable under item 5 of this Exhibit A, Company shall pay the following sales-based milestones:

i. with respect to the second LICENSED PRODUCT (other than the first LICENSED PRODUCT for which (y) the Company achieves NET SALES of at least [\*\*] dollars (\$[\*\*]) in a calendar year or (y) a SUBLICENSEE achieves royalty income from sales of such LICENSED PRODUCT and Company has received some form of consideration from such SUBLICENSEE (the "First Sold Licensed Product")) for which (A) the Company achieves NET SALES of at least [\*\*] dollars (\$[\*\*]) in a calendar year or (B) a SUBLICENSEE achieves royalty income from sales of such LICENSED PRODUCT and Company has received some form of consideration from such SUBLICENSEE (the "Second Sold Licensed Product"), Company shall pay JHU as follows:

- 1. if the event in clause (A) occurs before the event in clause (B): JHU shall be owed an amount equal to the sum of [\*\*] dollars (\$[\*\*]), plus the amount by which, pursuant to Section 4(d)(ii) of the Settlement and License Agreement entered into as of October 24, 2014, by and between GrayBug, LLC, Kala Pharmaceuticals, Inc. and The Johns Hopkins University (the "Settlement Agreement"), each of the development milestones in Section 5 of this Exhibit A for the second "LICENSED PRODUCT" to achieve such milestone was reduced, plus the amount by which, pursuant to Section 4(d)(iii) of the Settlement Agreement, the milestone payment with respect to first commercial sale of the second "LICENSED PRODUCT" in the United States was reduced (such sum, the "First Deferral Reimbursement Amount"); [\*\*]



of such amount to be paid to JHU by [\*\*] after which the Company obtained such NET SALES, and the remainder due by [\*\*]; or

2. if the event in clause (B) occurs before the event in clause (A): JHU shall be owed an amount equal to the First Deferral Reimbursement Amount, which shall be paid by increasing the applicable sublicensee royalty rates set forth in Section 4 of Exhibit A (as modified by the Settlement Agreement) due to JHU with respect to sales of the Second Sold Licensed Product by [\*\*]%, until the full amount of such First Deferral Reimbursement Amount has been paid to JHU.

ii. with respect to the third LICENSED PRODUCT (other than the First Sold Licensed Product and the Second Sold Licensed Product) for which (A) the Company achieves NET SALES of at least [\*\*] dollars (\$[\*\*]) in a calendar year or (B) a SUBLICENSEE achieves royalty income from sales of such LICENSED PRODUCT and Company has received some form of consideration from such SUBLICENSEE (the "Third Sold Licensed Product"), Company shall pay JHU as follows:

1. if the event in clause (A) occurs before the event in clause (B): JHU shall be owed an amount equal to [\*\*] dollars (\$[\*\*]), plus the amount by which, pursuant to Section 4(d)(ii) of the Settlement Agreement, each of the development milestones in Section 5 of this Exhibit A for the third "LICENSED PRODUCT" to achieve such milestone was reduced, plus the amount by which, pursuant to Section 4(d)(iii) of the Settlement Agreement, the milestone payment with respect to first commercial sale of the third "LICENSED PRODUCT" in the United States was reduced (such sum, the "Second Deferral Reimbursement Amount"); [\*\*] of such amount to be paid to JHU by [\*\*] after which the Company obtained such NET SALES, and the remainder due by [\*\*]; or

2. if the event in clause (B) occurs before the event in clause (A): JHU shall be owed an amount equal to the Second Deferral Reimbursement Amount, which shall be paid by increasing the applicable sublicensee royalty rates set forth in Section 4 of Exhibit A of (as modified by the Settlement Agreement) due to JHU with respect to sales of the Third Sold Licensed Product by [\*\*]%, until the full amount of such Second Deferral Reimbursement Amount has been paid to JHU.

iii. The parties agree and acknowledge that (i) the Second Sold Licensed Product may be a different LICENSED PRODUCT than the LICENSED PRODUCT to

be second to achieve one or more of the milestones described in Section 4(d)(ii) or 4(d)(iii) of the Settlement Agreement, and (ii) the Third Sold Licensed Product may be a different LICENSED PRODUCT than the LICENSED PRODUCT to be third to achieve one or more of the milestones described in Section 4(d)(ii) or 4(d)(iii) of the Settlement Agreement, and (iii) the First Sold Licensed Product may be a different LICENSED PRODUCT than the LICENSED PRODUCT to be first to achieve one or more of the milestones described in Section 4(d)(ii) or 4(d)(iii) of the Settlement Agreement.

5. Releases.

- a. Each Party, on behalf of itself and its predecessors, successors, assigns, employees, officers and directors (each, a "Releasor"), fully, finally and forever releases, relinquishes, acquits and discharges the other Party and each of its predecessors, successors, assigns, employees, officers and directors (each, a "Releasee"), of and from, and covenants not to sue, not to assign to any other Person a right to sue and not to authorize any other Person to sue any Releasee for, any and all Losses of every name and nature, both at law and in equity, accrued or unaccrued, that (i) any of such Party's Releasors is aware of as of the Settlement Agreement Effective Date, (ii) arise out of the actions of the Parties or JHU leading to the execution of this Agreement and (iii) relate to the subject matter hereof. This Section 5(a) shall not prevent or impair the right of a Releasor to bring a proceeding in court or any other forum to enforce its rights under this Agreement or its Existing JHU License Agreement (except as explicitly or implicitly amended by this Agreement).
- b. Each Party (on behalf of itself and its other Releasors) fully, finally and forever releases, relinquishes, acquits and discharges JHU, The Johns Hopkins Hospital, The Johns Hopkins Health System Corporation, and their affiliated entities, their present and former trustees, officers, INVENTORS (as defined in such Party's Existing JHU License Agreement), agents, faculty, employees and students (each, a "JHU Releasee") of and from, and covenants not to sue, not to assign to any other Person a right to sue and not to authorize any other Person to sue any JHU Releasee for, any and all Losses of every name and nature, both at law and in equity, accrued or unaccrued, that (i) any of such Releasors is aware of as of the Settlement Agreement Effective Date, (ii) arise out of the actions of the Parties or JHU Releasees leading to the execution of this Agreement and (iii) relate to the subject matter hereof. This Section 5(b) shall not prevent or impair the right of a Releasor to bring a proceeding in court or any other forum to enforce its rights under this Agreement or its Existing JHU License Agreement (except as explicitly or implicitly amended by this Agreement).
- c. Each Party and JHU acknowledges that the releases and other terms of this Agreement settle all known disputes as of the Settlement Agreement Effective Date relating to

subject matter licensed to a Party from JHU, and after the Settlement Agreement Effective Date, neither Party nor JHU may assert a claim that the other Party or JHU, or their respective predecessors, successors, assigns, directors, officers, employees, trustees, INVENTORS (as defined in each Party's Existing JHU License Agreement), faculty, students or agents released hereunder is in violation of any Existing JHU License Agreement in connection with such acts or omissions prior to the Settlement Agreement Effective Date.

6. Representations and Warranties.

- a. Each Party represents, warrants and covenants to the other Party that:
  - i. as of the Settlement Agreement Effective Date, it has the authority and right to enter into and perform this Agreement and grant the rights and licenses herein, and it is not aware of any legal impediment that could inhibit its ability to perform its obligations under this Agreement;
  - ii. as of the Settlement Agreement Effective Date, its execution, delivery and performance of this Agreement does not conflict with, or constitute a breach of, any order, judgment, agreement or instrument to which it is a party or is otherwise bound;
  - iii. as of the Settlement Agreement Effective Date, no consent of any third party (other than JHU) is required for such Party to grant the licenses and rights granted to the other Party under this Agreement or to perform its obligations hereunder; and
  - iv. it will not, after the Settlement Agreement Effective Date, enter into any written or oral contractual obligation with any third party (including JHU) that would be inconsistent with the obligations that arise on its part out of this Agreement or that would deprive the other Party of the benefits of or rights granted under this Agreement.
- b. GrayBug represents, warrants and covenants to Kala that the GrayBug Current Patent Rights are all the Patent Rights licensed to GrayBug by JHU as of the Settlement Agreement Effective Date. Kala represents, warrants and covenants to GrayBug that the Kala Current Patent Rights and the Kala/JHU Jointly Owned Patent Rights are all the Patent Rights licensed to Kala by JHU as of the Settlement Agreement Effective Date.
- C. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 6 OR AS EXPRESSLY PROVIDED BY JHU TO THE APPLICABLE PARTY UNDER AN EXISTING JHU LICENSE AGREEMENT, EACH PARTY AGREES THAT THE PATENT RIGHTS LICENSED HEREUNDER ARE PROVIDED "AS IS", AND THAT NEITHER JHU NOR THE OTHER PARTY MAKES ANY REPRESENTATION OR

WARRANTY WITH RESPECT TO THE PERFORMANCE OF LICENSED PRODUCTS AND LICENSED SERVICES, INCLUDING THEIR SAFETY, EFFECTIVENESS, OR COMMERCIAL VIABILITY. EACH PARTY AND JHU DISCLAIM ALL WARRANTIES WITH REGARD TO PRODUCTS AND SERVICES LICENSED UNDER THIS AGREEMENT, INCLUDING ALL WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE.

7. Confidentiality.

- a. The Parties agree that during the term of this Agreement, and for a period of [\*\*] years thereafter, each Party shall (i) maintain in confidence the Confidential Information of the other Party to the same extent such Party maintains its own confidential information, (ii) not disclose such Confidential Information to any Third Party without the prior written consent of the other Party, and (iii) not use such Confidential Information for any purpose except those permitted by this Agreement.
- b. Authorized Disclosure. Notwithstanding Section 7(b), a Party may disclose Confidential Information of the other Party to the extent such disclosure is reasonably necessary in the following instances:
  - i. disclosure to each applicable country's patent office to the extent necessary for the prosecution and maintenance of Patent Rights in accordance with this Agreement;
  - ii. making necessary filings with regulatory authorities with respect to Licensed Products or Licensed Services in the receiving Party's Exclusive Field;
  - iii. complying with applicable laws or submitting information to governmental authorities; provided that if a Party is required by law to make any public disclosure of Confidential Information of the other Party, to the extent it may legally do so, it will give reasonable advance notice to the other Party of such disclosure and will use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise); or
  - iv. to the extent mutually agreed to in writing by the Parties.
- c. Each Party may disclose the existence and terms of this Agreement to its Affiliates and to prospective and actual acquirers, licensors, collaborators, licensees, sublicensees, lenders, financing sources, investment bankers, employees, contractors, agents, accountants, lawyers, consultants, auditors, advisors and investors, on a need to know basis, each of whom prior to disclosure must be bound by written or professional ethical obligations of confidentiality and non-use equivalent in scope to those set forth in this

Section 7 and that are of reasonable duration in view of the circumstances of the disclosure.

- d. JHU agrees that any JHU Confidential Information may be disclosed by a Party in accordance with this Section 7.
  - e. Nothing herein grants JHU the right to disclose to a Party (i) the Existing JHU License Agreement of the other Party or (ii) any proprietary materials, information, records or data of the other Party.
  - f. Nothing herein requires either Party to disclose or produce its Existing JHU License Agreement to the other Party.
  - g. In no event shall this Section 7 (Confidentiality) limit JHU's ability to disclose or publish its own Confidential Information.
8. Indemnification.
- a. Each Party shall indemnify, hold harmless and defend the other Party, its Affiliates, and all of their respective officers, directors, employees, agents, licensors and shareholders (collectively, the "Indemnitees") from and against any and all losses, damages, liabilities, judgments, fines, amounts paid in settlement, expenses and costs of defense (including reasonable attorneys' fees and witness fees) resulting from any demand, claim, action or proceeding brought or initiated by a Third Party (each a "Third Party Claim") against any Indemnitee to the extent arising out of (a) the research, development, making, having made, use, having used, importation, having imported, offering to sell, having offered for sale, sale and having sold Licensed Products, and the provision and having provided Licensed Services, by or on behalf of the Indemnifying Party, in the United States and worldwide, (b) a breach of this Agreement by such Party, or (c) the gross negligence or willful misconduct of such Party.
  - b. As a condition to indemnification hereunder, (i) the indemnified Party shall provide the indemnifying Party with prompt notice of the Third Party Claim giving rise to the indemnification obligation under Section 8(a), (ii) the Indemnitees shall reasonably cooperate with the indemnifying Party, at the indemnifying Party's reasonable request and reasonable expense with respect to out-of-pocket costs, in the defense of such claim, and (iii) the Indemnitees shall permit the indemnifying Party to exclusively defend or settle any such claim; provided however that the indemnifying Party shall not enter into any settlement for damages, or that imposes upon any Indemnitee any obligation or liability, without such Indemnitee's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned. The Indemnitees shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the indemnifying Party.

- c. Each Party shall indemnify JHU with respect to that Party's research, development, making, having made, use, having used, importation, having imported, offering to sell, having offered for sale, sale and having sold Licensed Products in the indemnifying Party's Exclusive Field, and the provision and having provided Licensed Services in the indemnifying Party's Exclusive Field, in the United States and worldwide, in accordance with the indemnification procedures set forth in such Party's Existing JHU License Agreement, *mutatis mutandis*.

9. Termination.

- a. This Agreement shall remain in effect until the expiration of all JHU Patent Rights, Other JHU Patent Rights, Future Patent Rights and Kala/JHU Jointly Owned Patent Rights unless earlier terminated in accordance with this Section 9.
- b. If a Party (the "Disparaging Party"), or its employees, officers, directors, agents or representatives, Disparages a Current Patent Right or Kala/JHU Jointly Owned Patent Right directly licensed by JHU to the other Party (the "Disparaged Party"), then the Disparaged Party may, upon written notice to the Disparaging Party, immediately terminate one or more of its sublicenses granted to the Disparaging Party under this Agreement, including any further sublicenses granted by the Disparaging Party. "Disparagement" (including, with correlative meanings, "Disparage") means, with respect to a Patent Right, offensively opposing (including filing an opposition or declaration judgment action) or taking an independent action to attempt to invalidate, or formal steps prevent from issuing, such Patent Right, including by making written statements that such Patent Right is unpatentable; provided, however, that Disparagement shall not include any comments or arguments made by patent counsel for a Party before a patent office during the course of prosecution of any patent application owned by or licensed to such Party anywhere in the world. Notwithstanding the foregoing, each Party shall have the right to defend itself, including in a litigation brought by the other Party, using any applicable position. For example, if a Party sues the other Party for infringement, the purported infringer can defend itself with a position that the patentee's asserted claim is invalid.
- c. Each Party may terminate any of the rights and licenses granted to it under this Agreement or under such Party's Existing JHU License Agreement, on a Patent Right-by-Patent Right and country-by-country basis, by providing thirty (30) calendar days prior written notice thereof to the other Party and JHU, following which, but subject to Section 9(d), the terminating Party's rights and obligations hereunder and under its Existing JHU License Agreement shall terminate with respect to such Patent Right in such country. For clarity, termination of a Party's rights and licenses under a Patent Right in a country shall not be deemed to have occurred merely because a particular

patent application has been abandoned if such patent application continues to be Prosecuted and Maintained, or issues, through a Counterpart.

- d. Expiration or termination of this Agreement, or of any of the licenses under this Agreement, shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Termination of such licenses shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief with respect to any Disparagement.
- e. All remaining applicable provisions of this Agreement shall survive its expiration or termination.

10. Miscellaneous.

- a. Affirmative Amendment; Inconsistent Terms. This Agreement affirmatively amends each Party's Existing JHU License Agreement as necessary to reflect the terms of this Agreement.
- b. Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred by any Party without the consent of the other Party; provided, however, that any Party may, without such consent, assign this Agreement, in whole or in part: (a) to any of its Affiliates; provided that the assigning Party shall remain jointly and severally liable with such Affiliate(s) in respect of all obligations so assigned unless such Affiliate(s) are fully capable of fulfilling all the assigning Party's obligations under this Agreement; or (b) to any successor in interest by way of merger, acquisition or sale of all or substantially all of its assets to which this Agreement relates. Any assignment not in accordance with the foregoing shall be void.
- c. No Waivers; Severability. No waiver of any breach of this Agreement shall constitute a waiver of any other breach of the same or other provision of this Agreement, and no waiver shall be effective unless made in writing. Any provision hereof prohibited by or unenforceable under any applicable law of any jurisdiction shall as to such jurisdiction be deemed ineffective and deleted herefrom without affecting any other provision of this Agreement. Should any provision contained herein be held by any governmental agency or court of competent jurisdiction to be void, illegal and unenforceable, the Parties shall negotiate in good faith for a substitute term or provision which carries out the original intent of the Parties.
- d. Entire Agreement; Amendment. The Parties acknowledge that they have read this entire Agreement and that this Agreement constitutes the entire understanding and contract between the Parties with respect to the subject matter hereof and supersedes any and all prior or contemporaneous oral or written communications with respect to the subject matter hereof (including the Prior CDA). It is expressly understood and

agreed that there being no expectations to the contrary between the Parties, no usage of trade, verbal agreement or another regular practice or method of dealing within any industry or between the Parties shall be used to modify, interpret, supplement or alter in any manner the express terms of this Agreement. This Agreement shall not be modified, amended or in any way altered except by an instrument in writing signed by both of the Parties and, with respect to any provision applicable to JHU's rights, JHU.

- e. No Inconsistent Amendments. Neither Party shall amend its Existing JHU License Agreement in a manner that is inconsistent with its or JHU's obligations to the other Party under this Agreement.
- f. No Partnership. Nothing in this Agreement shall be construed to create any agency, employment, partnership, joint venture or similar relationship between the Parties other than that of a licensor/licensee. Neither Party shall have any right or authority whatsoever to incur any liability or obligation (express or implied) or otherwise act in any manner in the name or on the behalf of the other, or to make any promise, warranty or representation binding on the other.
- g. Governing Law. This Agreement shall be construed, and legal relations between the parties hereto shall be determined, in accordance with the laws of the State of New York applicable to contracts solely executed and wholly to be performed within the State of New York without giving effect to the principles of conflicts of laws.
- h. Dispute Resolution. Each Party will appoint one representative (each a "Representative") to serve as the main point of contact for activities relating to this Agreement. Neither Party will file suit against the other Party with respect to a dispute arising in connection with this Agreement except as permitted under this Section 10(h). In the event that any dispute arises between the Parties in connection with this Agreement, the Parties will, upon written notice from either Party to the other Party (the "First Notice"), first attempt to resolve it through good faith negotiations among the Representatives. If the Representatives fail to resolve the dispute within [\*\*] days of the First Notice, then upon written notice from one Party to the other (the "Second Notice"), the Parties will escalate the dispute to their respective CEOs who will also attempt to resolve the dispute by good faith negotiations. In the event the Parties are unable to resolve such dispute within [\*\*] days of the Second Notice, either Party may, subject to Section 10(g), proceed to file suit regarding the dispute without further obligations under this Section 10(h) with respect to such dispute (including any claims and counterclaims which may be subsequently added or modified). Notwithstanding the foregoing, a Party may at any time seek or obtain preliminary, interim, or conservatory measures from a court.



- i. Notice. All notices or communication required or permitted to be given by either Party hereunder shall be deemed sufficiently given if sent by overnight courier providing evidence of delivery, such as Federal Express or United States Postal Service (USPS) overnight, to the other Party at its respective address set forth below or to such other address as one Party shall give notice of to the other from time to time hereunder, and a courtesy copy shall be sent by email to the email address(es) shown below or to such other email address(es) as one Party shall give notice of to the other from time to time hereunder. Notices shall be deemed received the following Business Day.

If to GrayBug:                    GrayBug, LLC  
  [\*\*]  
  Baltimore, MD 21203  
  Attn: Chief Executive Office (currently Michael O'Rourke)  
  Email: [\*\*]

With a Copy to:                 [\*\*]  
If to Kala:                         Kala Pharmaceuticals, Inc.  
  100 Beaver Street  
  Suite 201  
  Waltham, MA 02453

  Attn: President (currently Charlie McDermott, Interim President)  
  Email: [\*\*]

With a Copy to:                 Chief IP Counsel (*at the same address*)  
  Email: [\*\*]

Notices to JHU shall be provided by the relevant Party in accordance with the provisions of its Existing JHU License Agreement.

- j. Compliance with All Laws. In all activities undertaken pursuant to this Agreement, both Parties covenant and agree that each will in all material respects comply with such federal, state and local laws and statutes, as may be in effect at the time of performance and all valid rules, regulations and orders thereof regulating such activities. Each Party has confirmed that it is not required to make a filing under the HSR Act with respect to the rights granted to it as of the Settlement Agreement Effective Date under this Agreement.
- k. Delays or Omissions. Except as expressly provided herein, no delay or omission to exercise any right, power or remedy accruing to any Party shall impair any such right, power or remedy to such Party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or in any similar breach or default be

deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any Party of any breach or default under this Agreement, or any waiver on the part of any Party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies either under this Agreement or by law or otherwise afforded to any Party, shall be cumulative and not alternative.

- l. No Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any Person, other than the Parties, JHU (to the extent set forth herein) and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.
- m. Headings. Section headings are for convenient reference and not a part of this Agreement.
- n. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which when taken together shall be deemed but one instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, this Agreement shall take effect as of the Settlement Agreement Effective Date when it has been executed below by the duly authorized representatives of the Parties.

**GrayBug, LLC**

**Kala Pharmaceuticals, Inc.**

BY: /s/ Michael O'Rourke

BY: /s/ Charles McDermott

NAME: Michael O'Rourke

NAME: Charles McDermott

TITLE: President and Chief Executive Officer

TITLE: Chief Business Officer and Interim President

[JHU Signature Page Attached]

WHEREAS, there is a dispute over the rights licensed to each Party under certain Patent Rights owned by JHU;

WHEREAS, the Parties and JHU now wish to settle such dispute in an amicable manner which is intended to settle and clarify rights granted by JHU to each Party and to permit each Party to have the freedom to effectively develop pharmaceutical products that will benefit patients;

WHEREAS, at JHU's request, GrayBug and Kala have undertaken extensive time and effort to work cooperatively to negotiate the terms of the Settlement and License Agreement to which this JHU Signature Page is attached (the "Settlement Agreement") that sets forth the terms and conditions for settling all currently outstanding disputes between JHU and the Parties, and each of their respective directors, officers, employees, and agents; and

WHEREAS, the Settlement Agreement provides for resolution of all known disputes as of the Settlement Agreement Effective Date relating to the scope of subject matter licensed to a Party from JHU, including releases of the Parties and JHU, and their respective predecessors, successors, assigns, employees, officers and directors, as set forth in Section 5 of the Settlement Agreement, which include releasing JHU in connection with any allegations of breach of contract or other potential causes of action with respect to such subject matter.

JHU acknowledges, accepts, and agrees with GrayBug and Kala that:

- The capitalized terms used but not defined in on this JHU Signature Page have the meaning ascribed to them in the Settlement Agreement.
- Kala, GrayBug and JHU each agrees to, and shall comply with, all the terms and conditions of the Settlement Agreement to the extent relevant or applicable to such Party or JHU, as applicable. Without limitation, it is confirmed that the provisions of Sections 1-7 and 10 of the Settlement Agreement shall apply to JHU and to the paragraphs set forth on this JHU Signature Page to the same extent as they apply to either Party.
- Each Existing JHU License Agreement is hereby amended to reflect the terms set forth in the Settlement Agreement, to the extent necessary to implement the intent, terms, and provisions of the Settlement Agreement, including Sections 2, 3, 4, 7, and 9 of the Settlement Agreement.
- As set forth in more detail and in accordance with Section 5(b) of the Settlement Agreement, Kala (on behalf of itself and its other Releasors (as defined in Section 5(a) of the Settlement Agreement)) fully, finally and forever releases, relinquishes, acquits and discharges the JHU Releasees (as defined in Section 5(b) of the Settlement Agreement) of and from, and covenants not to sue, not to assign to any other Person a right to sue and not to authorize any other Person to sue the JHU Releasees for, any and all Losses of every name and nature, both at law

and in equity, accrued or unaccrued, that (i) any of such Releasors is aware of as of the Settlement Agreement Effective Date, (ii) arise out of the actions of the Parties or JHU Releasees leading to the execution of this Agreement and (iii) relate to the subject matter hereof.

- As set forth in more detail and in accordance with Section 5(b) of the Settlement Agreement, GrayBug (on behalf of itself and its other Releasors (as defined in Section 5(a) of the Settlement Agreement)) fully, finally and forever releases, relinquishes, acquits and discharges the JHU Releasees (as defined in Section 5(b) of the Settlement Agreement) of and from, and covenants not to sue, not to assign to any other Person a right to sue and not to authorize any other Person to sue the JHU Releasees for, any and all Losses of every name and nature, both at law and in equity, accrued or unaccrued, that (i) any of such Releasors is aware of as of the Settlement Agreement Effective Date, (ii) arise out of the actions of the Parties or JHU Releasees leading to the execution of this Agreement and (iii) relate to the subject matter hereof.
- JHU (on behalf of itself and the JHU Releasees (as defined on Section 5(b) of the Settlement Agreement)) fully, finally and forever releases, relinquishes, acquits and discharges each Party and each of its predecessors, successors, assigns, employees, officers and directors (each, a "Party Releasee"), of and from, and covenants not to sue, not to assign to any other Person a right to sue and not to authorize any other Person to sue any Party Releasee for, any and all Losses of every name and nature, both at law and in equity, accrued or unaccrued, that (i) any of such JHU Releasees is aware of as of the Settlement Agreement Effective Date, (ii) arise out of the actions of the Parties or JHU Releasees leading to the execution of the Settlement Agreement and (iii) relate to the subject matter thereof. This paragraph shall not prevent or impair the right of JHU to bring a proceeding in court or any other forum to enforce its rights under this Agreement or its Existing JHU License Agreement with a Party (except as explicitly or implicitly amended by the Settlement Agreement).
- JHU acknowledges that the releases and amendments provided in the Settlement Agreement and continued consideration under the Parties' Existing JHU License Agreements constitute full consideration for the Settlement Agreement and this JHU Signature Page. Notwithstanding any obligation that either Party may have to JHU regarding responsibility for sublicensees under an Existing JHU License Agreement, neither Party shall have any liability to JHU for the acts or omissions of the other Party, whether as a "Sublicensee" as defined under an Existing JHU License Agreement or otherwise.
- JHU represents and that: (i) it has good and marketable title to its interest in each of the inventions claimed under any PATENT RIGHTS (as defined in each of the Existing JHU License Agreements), GrayBug Current Patent Rights, Kala Current Patent Rights, Other JHU Patent Rights, Kala/JHU Jointly Owned Patent Rights (all such patent rights, collectively, the "LICENSED PATENT RIGHTS"), including by acquiring, through written assignment, the rights of the relevant inventors in such inventions and patent rights therein and having taken all necessary actions in accordance with the Bayh-Dole Act to elect to retain title to such inventions, subject to certain

retained rights (other than ownership) of the United States Government which may apply to such JHU-owned inventions and LICENSED PATENT RIGHTS if any part of the JHU research was funded in whole or in part by the United States Government; (ii) as of the Settlement Agreement Effective Date, it has not entered any contract, license or similar agreement with a third party that restricts, contradicts, interferes with or otherwise limits the grant of rights under this Settlement Agreement; (iii) it has proper authority to enter into this Settlement Agreement and to grant the rights set forth herein; (iv) it has not granted any rights or licenses that may conflict with this Settlement Agreement or the rights and licenses granted herein; (v) to its knowledge, neither JHU nor any assignee of or inventor listed in any of the LICENSED PATENT RIGHTS has received any notice from any third party that the exercise of the LICENSED PATENT RIGHTS infringes or reasonably could be expected to infringe the rights of any third party; and (vi) to its knowledge, all inventors have been named in the LICENSED PATENT RIGHTS.

ACKNOWLEDGED, ACCEPTED, AND AGREED:

THE JOHNS HOPKINS UNIVERSITY

BY: /s/ Jill E. Uhl  
NAME: Jill E. Uhl  
TITLE: Interim Executive Director

KALA PHARMACEUTICALS, INC.

BY: /s/ Charles McDermott  
NAME: Charles McDermott  
TITLE: Interim President & CEO

GRAYBUG, LLC

BY: /s/ Michael O'Rourke  
NAME: Michael O'Rourke  
TITLE: President & CEO

**Johns Hopkins Technology Transfer**

100 N. Charles Street, 5th Floor  
Baltimore MD 21201  
410-516-8300 / Fax 410-516-4411  
www.jhtt.jhu.edu

January 8, 2015

MEMORADUM: CO-INVENTORS

To Whom It May Concern,

As of the Settlement and License Agreement date, October 24, 2014, all potential Co-Inventors listed in the definition of Future Patent Rights were additionally identified as "Pending Co-Inventors" on Schedule 2c(ix). This letter is to inform that [\*\*]Pending Co-Inventors have agreed in writing to become Co-Inventors and subject to the relevant provisions of the Settlement and License Agreement. These Co-Inventors are as follows:

[\*\*]

Sincerely,

/s/ Jill E. Uhl

---

Jill Uhl

Interim Executive Director

Johns Hopkins Technology Transfer



*JHIT – Bringing the Benefits of Discovery to the World*

---

## 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: August 5, 2021

By: /s/ Mark Iwicki

---

Mark Iwicki  
President and Chief Executive Officer  
(Principal Executive Officer)

---



## 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: August 5, 2021

By: /s/ Mary Reumuth

---

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

---

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 June 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: August 5, 2021

/s/ Mark Iwicki

Mark Iwicki

President and Chief Executive Officer

(Principal Executive Officer)

---

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 June 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: August 5, 2021

/s/ Mary Reumuth

\_\_\_\_\_  
Mary Reumuth

Chief Financial Officer

(Principal Financial and Accounting Officer)

---