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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2020
OR

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

For the transition period from to
Commission file number 001-38150

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 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 56,059,865 shares of Common Stock, $0.001 par value per share, outstanding as of August 3, 2020.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

KALA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share and per share amounts)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 128,023	$ 85,449
Short-term investments	56,536	—
Accounts receivable, net	4,281	11,563
Inventory	5,711	4,648
Prepaid expenses and other current assets	2,473	3,824
Total current assets	197,024	105,484
Non-current assets:		
Property and equipment, net	2,964	2,698
Long-term inventory	4,109	3,778
Right-of-use assets	28,829	29,781
Restricted cash	12,584	12,582
Total assets	$ 245,510	$ 154,323
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,548	$ 2,518
Accrued expenses and other current liabilities	13,967	20,929
Current portion of lease liabilities	1,425	1,327
Total current liabilities	16,940	24,774
Long-term liabilities:		
Long-term lease liabilities - less current portion	27,930	28,673
Long-term debt	71,697	71,184
Total long-term liabilities	99,627	99,857
Total liabilities	116,567	124,631
Commitments and Contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.001 par value; 120,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 55,831,021 and 36,086,254 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	56	36
Additional paid-in capital	469,627	325,112
Accumulated other comprehensive income	(17)	—
Accumulated deficit	(340,723)	(295,456)
Total stockholders' equity	128,943	29,692
Total liabilities and stockholders' equity	$ 245,510	$ 154,323

See accompanying notes to these unaudited condensed consolidated financial statements.

KALA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Product revenues, net	$ 833	$ 2,057	$ 1,904	$ 3,443
Costs and expenses:				
Cost of product revenues	759	352	1,113	593
Selling, general and administrative	15,301	17,007	30,709	35,243
Research and development	6,053	7,108	11,487	14,067
Total costs and expenses	22,113	24,467	43,309	49,903
Loss from operations	(21,280)	(22,410)	(41,405)	(46,460)
Other income (expense):				
Interest and other income	102	646	400	1,402
Interest and other expense	(2,134)	(2,061)	(4,262)	(4,155)
Total interest and other expense	(2,032)	(1,415)	(3,862)	(2,753)
Net loss	$ (23,312)	$ (23,825)	$ (45,267)	$ (49,213)
Net loss per share—basic and diluted	$ (0.42)	$ (0.70)	$ (0.94)	$ (1.45)
Weighted average shares outstanding—basic and diluted	55,703,882	33,882,939	48,232,933	33,880,494
Net loss	$ (23,312)	$ (23,825)	$ (45,267)	$ (49,213)
Other comprehensive income:				
Change in unrealized gains/losses on investments:				
Change in fair value of investments, net of tax	17	—	17	—
Total change in unrealized gains/losses on investments, net of tax	17	—	17	—
Total other comprehensive income	17	—	17	—
Total comprehensive loss	$ (23,295)	$ (23,825)	$ (45,250)	$ (49,213)

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 data)

	Three Months Ended June 30,					
	Common Stock $0.001 Par Value		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balance as of March 31, 2019	33,882,857	$ 34	$ 308,830	$ —	$ (226,497)	$ 82,367
Exercise of stock options	110	—	—	—	—	—
Stock-based compensation expense	—	—	2,524	—	—	2,524
Net loss	—	—	—	—	(23,825)	(23,825)
Balance as of June 30, 2019	33,882,967	$ 34	$ 311,354	$ —	$ (250,322)	$ 61,066
Balance as of March 31, 2020	54,585,636	$ 55	$ 458,866	$ —	$ (317,411)	$ 141,510
Exercise of stock options	249,870	—	772	—	—	772
Common stock offering, net of issuance cost and underwriting fees of $0.5 million	979,371	1	7,215	—	—	7,216
Stock-based compensation expense	—	—	2,774	—	—	2,774
Warrant exercises	16,144	—	—	—	—	—
Accumulated other comprehensive income	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(23,312)	(23,312)
Balance as of June 30, 2020	55,831,021	$ 56	$ 469,627	$ (17)	$ (340,723)	$ 128,943

See accompanying notes to these unaudited condensed consolidated financial statements

	Six Months Ended June 30,					
	Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2018	33,863,077	$ 34	$ 306,053	$ —	$ (201,109)	$ 104,978
Exercise of stock options	19,890	—	39	—	—	39
Stock-based compensation expense	—	—	5,262	—	—	5,262
Net loss	—	—	—	—	(49,213)	(49,213)
Balance as of June 30, 2019	33,882,967	$ 34	$ 311,354	$ —	$ (250,322)	$ 61,066
Balance as of December 31, 2019	36,086,254	$ 36	$ 325,112	$ —	$ (295,456)	$ 29,692
At the market offering, net of sales agent commission of $0.4 million	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 $8.1 million	16,979,371	17	125,406	—	—	125,423
Issuance under employee stock purchase plan	85,553	—	270	—	—	270
Stock-based compensation expense	—	—	5,358	—	—	5,358
Warrant exercises	16,144	—	—	—	—	—
Accumulated other comprehensive income	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(45,267)	(45,267)
Balance as of June 30, 2020	55,831,021	$ 56	$ 469,627	$ (17)	$ (340,723)	$ 128,943

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, 2020	Six Months Ended June 30, 2019
Cash flows from operating activities:		
Net loss	$ (45,267)	$ (49,213)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	454	388
Non-cash operating lease cost	952	840
Amortization of debt discount and other non-cash interest	513	466
Stock-based compensation	5,271	5,094
Change in operating assets and liabilities:		
Accounts receivable	7,282	(5,648)
Prepaid expenses and other current assets	1,351	1,106
Inventory	(1,306)	(3,955)
Accounts payable	(973)	(2,249)
Accrued expenses and other current liabilities	(6,782)	1,776
Lease liabilities and other long-term liabilities	(629)	(201)
Net cash used in operating activities	(39,134)	(51,596)
Cash flows from investing activities:		
Purchases of property and equipment	(915)	(943)
Purchases of short-term investments	(56,535)	—
Net cash used in investing activities	(57,450)	(943)
Cash flows from financing activities:		
Proceeds from common stock offerings, net of underwriters' discounts and offering cost	137,969	—
Payment of principal on finance lease	(16)	(20)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	1,207	39
Net cash provided by financing activities	139,160	19
Net increase/(decrease) in cash and restricted cash:	42,576	(52,520)
Cash and restricted cash at beginning of period	98,031	183,104
Cash and restricted cash at end of period	140,607	130,584
Reconciliation of cash and restricted cash:		
Cash, cash equivalents, and restricted cash at end of period	140,607	130,584
Less restricted cash	(12,584)	(12,578)
Cash and cash equivalents at end of period	$ 128,023	$ 118,006
Non-cash investing and financing activities:		
Right-of-use asset obtained in exchange for finance lease obligation	$ —	$ 136
Supplemental disclosure:		
Cash paid for interest	$ 3,749	$ 3,683
Right-of-use assets obtained in exchange of operating lease obligations	—	1,852

See accompanying notes to these unaudited condensed consolidated financial statements.

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Nature of Business— Kala Pharmaceuticals, Inc. (the "Company") was incorporated on July 7, 2009, and is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for diseases of the eye. The Company has applied its AMPPLIFY® mucus-penetrating particle ("MPP") Drug Delivery Technology to loteprednol etabonate ("LE"), a corticosteroid designed for ocular applications, resulting in the U.S. Food and Drug Administration's (the "FDA") approval of INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% as the first and only topical twice-daily ocular corticosteroid for treatment of post-operative inflammation and pain following ocular surgery, and the development of its lead product candidate, KPI-121 0.25%, which if approved it plans to commercialize under the brand name EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25%, for the short-term treatment of the signs and symptoms of dry eye disease.

In October 2018, the Company submitted a New Drug Application ("NDA") to the FDA for EYSUVIS. In August 2019, the Company announced that it received a complete response letter ("CRL") from the FDA indicating that positive efficacy data from an additional clinical trial would be needed to support a resubmission of the NDA. Based upon the previous recommendation of the FDA, the Company initiated an additional Phase 3 clinical trial ("STRIDE 3") (STRIDE- **S**hort **T**erm **R**elief **I**n **D**ry **E**ye), in July 2018. On March 9, 2020, the Company announced that STRIDE 3 met both of its primary symptom endpoints and its key secondary sign endpoint and on April 30, 2020, the Company resubmitted its NDA with the positive data from STRIDE 3. The Company believes that the data from STRIDE 3 replicates the positive efficacy data from previous clinical trials for both signs and symptoms of dry eye disease and will satisfy the recommendation in the CRL for an additional positive trial. On May 26, 2020, the Company announced that the FDA stated that our NDA resubmission was a complete, Class 2 response to the CRL and set a Prescription Drug User Fee Act ("PDUFA") goal date of October 30, 2020 for the completion of its review of the NDA.

In January 2019, the Company launched its first commercial product, INVELTYS, in the United States. The Company is engaged in the commercialization of INVELTYS, pursuing FDA approval of, and preparing to launch, EYSUVIS, 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 obtain regulatory approval of EYSUVIS, the success of commercializing its products, the success of its research and development efforts, its ability to obtain regulatory approval of its other product candidates, its ability to raise additional capital when needed and, ultimately, attain profitable operations.

The Company is also evaluating other opportunities for MPP nanosuspensions of LE, compounds in its receptor Tyrosine Kinase Inhibitor program (the "rTKI program"), that inhibit the vascular endothelial growth factor ("VEGF"), pathway, for the potential treatment of a number of retinal diseases, and novel next-generation anti-inflammatories designed to exhibit steroid-like anti-inflammatory action for eye disease with the goal of eliminating the risk of interocular pressure ("IOP") increase and cataract formation.

Liquidity— Since inception, the Company has incurred significant losses from operations and negative cash flows from operations. As of June 30, 2020, the Company had an accumulated deficit of $340.7 million. The Company has generated only limited revenues to date from product sales and has financed operations primarily through proceeds from its initial public offering of common stock ("IPO"), public common stock offerings and sales of its common stock under its at-the-market offering facility, private placements of preferred stock, convertible debt financings, borrowings under credit facilities 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 launch and commercialize INVELTYS. The Company 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 believes that its existing cash, cash equivalents and short-term investments as of June 30, 2020, will enable it to fund its planned 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.

COVID-19 – The ongoing novel coronavirus pandemic, commonly referred to as COVID-19, which was declared a global pandemic by the World Health Organization on March 11, 2020, has caused federal, state, and local governments to implement measures to slow the spread of the outbreak through quarantines, strict travel restriction and bans, heightened border scrutiny and other measures. 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, the Company previously suspended substantially all in-person interactions with customers, including visits to physician offices, clinics, and hospitals, and was limited to conducting educational and promotional activities virtually, and the Company may be forced to suspend all or some in-person interactions again in the future. In addition, all office-based personnel have been instructed to work from home and the Company’s laboratory facilities, that support our early-stage research activities, are being utilized as necessary. The moratoria on routine medical appointments and elective surgeries that have occurred at times in many jurisdictions, including ocular surgeries, has adversely affected 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 extent of the impact of COVID-19 on the Company’s operational and financial performance will depend on certain developments, including the length and severity of this pandemic, impact on its customers, employees, 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 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 sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants.

The 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 and warrants. 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 the three and six months ended June 30, 2020 and 2019.

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, 2019 (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 period ended June 30, 2020, other than the addition of the Investments section below.

Investments — The Company determines the appropriate classification of its investments at the time of purchase. The Company's investments are classified as available-for-sale in accordance with Accounting Standards Codification ("ASC") Topic 320. The Company classifies investments available to fund current operations as current assets on its condensed consolidated balance sheets. Investments are classified as long-term assets on the condensed consolidated balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in comprehensive loss on the condensed consolidated statements of operations and in accumulated other comprehensive loss on the condensed consolidated balance sheets. Realized gains and losses, interest income earned on the Company's cash, cash equivalents and investments, and amortization or accretion of discounts and premiums on investments are included within other income (expense).

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time.

Recent Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). ASU 2018-13 is intended to improve the effectiveness of disclosures in the notes to financial statements related to fair value measurements in Topic 820. This ASU will become effective for annual periods beginning after December 15, 2019, including interim periods within that period, and early adoption is permitted. The ASU was effective on January 1, 2020 and the adoption of ASU 2018-13 did not have a material effect on the Company's condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software - Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). ASU 2018-15 aligns the accounting for implementation costs incurred in a hosting arrangement that is a service contract with the guidance on capitalizing costs associated with developing or obtaining internal-use software. This ASU became effective for annual periods beginning after December 15, 2019, including interim periods within that period, and early adoption is permitted. The ASU was effective on January 1, 2020 and the adoption of ASU 2018-15 did not have a material effect on the Company's condensed consolidated financial statements.

In June 2016, the FASB issued 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 public business entities that meet the definition of an SEC filer, excluding entities eligible to be Smaller Reporting Companies ("SRCs") as defined by the SEC, for fiscal years beginning after December 15, 2019, including interim period within those fiscal years and for all other entities, including SRCs, for fiscal years beginning 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 our own assumptions (unobservable inputs). The hierarchy consists of three levels:

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

Our financial instruments consist primarily of cash, cash equivalents, and short-term investments in money market funds and short-term securities. Cash, cash equivalents and short-term investments are reported at their respective fair values on our Condensed Consolidated Balance Sheets. See Note 4 (Investments) for additional information.

The following table sets forth the fair value of the Company's financial assets by level within the fair value hierarchy at June 30, 2020:

	Carrying Amount	Fair Value	Level 1	Level 2	Level 3
Assets:					
Cash and cash equivalents	$ 128,023	$ 128,023	$ 128,023	$ -	$ -
Short-term investments	56,536	56,536	56,536	-	-
Total Assets	$ 184,559	$ 184,559	$ 184,559	$ -	$ -

During the three and six months ended June 30, 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, 2020:

	June 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 27,980	$ -	$ (8)	$ 27,972
U.S. government agencies securities	28,573	-	(9)	28,564
Total	$ 56,553	$ -	$ (17)	$ 56,536

As of June 30, 2020, all of our investments had a contractual maturity within one year. The fair value of all our investments are classified as short-term on our 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 INVELTYS to wholesalers and/or specialty distributors 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 payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts for the purchase of the Company’s products.

The goods promised in the Company’s product sales contracts represent a single performance obligation; as the promise to transfer the individual products to the Customer is not separately identifiable from other promises in the contracts and, therefore, not distinct. 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 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, 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 in the net sales price to the extent it is determined probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved.

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

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 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 estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Centers for Medicaid and Medicare Services. The Company's liability for these rebates consists of estimates of claims for the current period and estimated future claims that will be made for product that has been recognized as revenue but remains in the distribution channel at the end of each reporting period. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Co-pay Assistance Program

The Company offers a co-pay assistance program (the “co-pay program”), which is intended to provide financial assistance to patients who may or may not be covered by commercial insurance or who opt out of Medicare Part D programs. The calculation of accruals for the co-pay program 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 table summarizes activity in each of the Company’s product revenue provision and allowance categories for the six months ended June 30, 2020:

	Trade Discounts, Allowances and Chargebacks (1)	Product Returns (2)	Rebates and Incentives (3)
Balance at 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 at March 31, 2020	$ 1,396	$ 114	$ 6,623
Provision related to current period sales	335	—	2,194
Changes in estimate related to prior period sales	3	(51)	(234)
Credit/payments made	(1,336)	1	(3,013)
Balance at June 30, 2020	$ 398	$ 64	$ 5,570

(1) Trade discounts, allowances and chargebacks include fees for distribution service fees, prompt pay discounts, and chargebacks. 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 in the Company’s Condensed Consolidated Balance Sheets.
(2) 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 in the Company’s Condensed Consolidated Balance Sheets.
(3) Rebates and incentives includes managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances. Provisions for rebates and discounts are deducted from gross revenues at the time revenues are recognized and are included in accrued expenses and other current liabilities in 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 contractual fees for service arrangements 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, 2020 or June 30, 2019. The Company recorded an allowance of $0.4 million and $0.9 million for expected sales discounts, related to prompt pay discounts and contractual fee for service arrangements, to wholesalers and distributors as of June 30, 2020 and June 30, 2019, respectively.

6. INVENTORY

Current inventory and long-term inventory consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Raw materials	$ 1,025	$ 1,387
Work in progress	4,589	4,166
Finished goods	4,206	2,873
Total inventory	$ 9,820	$ 8,426

As of June 30, 2020, the Company had $5.7 million of current inventory and $4.1 million of long-term inventory. As of December 31, 2019, the Company had $4.6 million of current inventory and $3.8 million of long-term inventory.

7. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Compensation and benefits	$ 5,347	$ 6,502
Accrued revenue reserves (1)	5,061	9,482
Development costs	179	1,600
Professional services	938	760
Commercial cost	800	930
Contract manufacturing	1,462	630
Other	180	1,025
Accrued expenses	$ 13,967	$ 20,929

(1) There were additional revenue reserves included in accounts payable of $0.6 million and $0.7 million, as of June 30, 2020 and December 31, 2019, respectively.

8. LEASES

Operating leases

On February 28, 2018, the Company entered into a lease agreement for the lease of a portion of the building located at 490 Arsenal Way, Watertown, Massachusetts (the “Watertown Lease”) to be used as the Company’s corporate headquarters. The Company recognized the right-of-use asset and corresponding lease liability on November 15, 2018, by calculating the present value of lease payments, discounted at 9.9%, the Company’s estimated incremental borrowing rate, over the 13-year expected term.

In connection with the Watertown Lease, the Company issued a letter of credit to the landlord for $2.0 million. The Company secured the letter of credit for the full amount of the letter with cash on deposit, which is reported as restricted cash as of June 30, 2020 and December 31, 2019.

For the six months ended June 30, 2020 and 2019, the variable lease expense for the Watertown Lease, which includes common area maintenance and real estate taxes, was $1.1 million and $0.5 million, respectively. The remaining lease term was 11.3 years as of June 30, 2020.

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 currently leases approximately 65 vehicles. In connection with the Vehicle Fleet Lease, the Company issued a letter of credit for $0.5 million, which was reported as restricted cash on the balance sheet. The lease has an expected term of three years, which commenced upon the delivery of the vehicles in March 2019. As of June 30, 2020, the remaining lease term was 1.7 years.

The components of lease expense and related cash flows were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Lease cost				
Operating lease cost	$ 1,185	$ 1,187	$ 2,371	$ 2,243
Variable lease cost	658	383	1,068	507
Total lease cost	$ 1,843	$ 1,570	$ 3,439	$ 2,750
Operating cash outflows from operating leases	$ 1,686	$ 911	$ 3,130	$ 1,654

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 $110.0 million. The Athyrium Credit Facility provided for a Term Loan A in the aggregate principal amount of $75.0 million (the "Term Loan A"), and a Term Loan B in the aggregate principal amount of $35.0 million (the "Term Loan B"). On October 1, 2018, the Company borrowed the entire principal amount of the Term Loan A. The Company did not satisfy the conditions to draw down any of the Term Loan B funds, and as a result, the Term Loan B funds are no longer available. The maturity date of the Athyrium Credit Facility is October 1, 2024, the six-year anniversary of the close.

The Term Loan A bears interest at a rate of 9.875% per annum, with quarterly, interest-only payments until the fourth anniversary of the Term Loan A. The unpaid principal amount of the Term Loan A is due and payable in quarterly installments starting on the fourth anniversary of the loan. The Company may make voluntary prepayments, in whole or in part, and subject to certain exceptions, is required to make mandatory prepayments upon the occurrence of certain events of default as defined in the agreement, including but not limited to, the occurrence of a change of control. In addition, upon payment or repayment of any outstanding balance under the Athyrium Credit Facility, the Company will have to pay a 1% exit fee of the total principal payments (whether mandatory, voluntary, or at maturity) made throughout the term. The exit fee of $0.7 million based on the $75.0 million principal amount outstanding, will be accreted to the carrying amount of the debt using the effective interest method over the term of the loan.

All mandatory and voluntary prepayments of the Athyrium Credit Facility are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the second anniversary of the applicable date of issuance, an amount equal to the amount by which (a) the present value of 105% of the principal prepaid plus all interest that would have accrued on such principal through such second anniversary exceeds (b) the amount of principal prepaid, (ii) if prepayment occurs on or after the second anniversary of the applicable date of issuance but prior to the third anniversary of such issuance, an amount equal to 3% of the principal prepaid, and (iii) if prepayment occurs on or after the third anniversary of the applicable date of issuance but prior to the fourth anniversary of such issuance, an amount equal to 2% of the principal prepaid. No prepayment premium is due on any principal prepaid after the fourth anniversary of the applicable date of issuance.

The Athyrium Credit Facility includes features requiring (1) additional interest rate upon an event of default accrued at an additional 3%, or a total interest rate of 12.875%, and (2) 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, 2020. 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.

The Athyrium Credit Facility is secured by a pledge of substantially all of the Company's assets and contains affirmative and negative covenants customary for financings of this type, including limitations on the Company's and its subsidiaries' ability to, among other things, incur and prepay additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, change in the nature of business, enter into sale and leaseback transactions, make distributions, and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the Athyrium Credit Facility also contains a financial covenant requiring the Company to maintain at least $10.0 million of cash and cash equivalents. As a result of this financial covenant, the Company has recorded $10.0 million as restricted cash as of June 30, 2020 and December 31, 2019.

In connection with the Athyrium Credit Facility, the Company issued a warrant ("Warrant"), to purchase up to 270,835 shares of the Company's common stock, at an exercise price per share of $12.18456. The Warrant is immediately exercisable as to 184,660 shares. The remaining 86,175 shares under the Warrant were exercisable only upon the Company's draw of the Term Loan B and, as a result, the remaining 86,175 shares under the Warrant are no longer exercisable. The Warrant is exercisable through October 1, 2025 and is classified as an equity instrument. The Company allocated the proceeds from the Term Loan A to the Warrant using the relative fair value method. The fair value of the Warrant of $1.9 million was recognized as equity and a corresponding debt discount.

In addition, the Company paid certain fees to Athyrium and other third-party service providers. These fees paid to Athyrium were recorded as a debt discount while the fees paid to other third-party service providers were recorded as debt issuance cost. These costs, along with the fair value of the Warrant of $1.9 million are being amortized using the effective interest method over the term of the Athyrium Credit Facility. The amortization of debt discount and debt issuance cost is included in interest expense within the Condensed Consolidated Statements of Operations. As of June 30, 2020 and June 30, 2019, the effective interest rate was 11.63%, which takes into consideration the non-cash accretion of the exit fee and the amortization of the debt discount and issuance costs. During each of the three months ended June 30, 2020 and June 30, 2019, the Company recognized interest expense of $2.1 million, which consisted of amortization of the debt discount of $0.2 million, and the contractual coupon interest expense of $1.9 million. During the six months ended June 30, 2020, and June 30, 2019, the Company recognized interest expense of $4.2 million and $4.1 million, respectively. This consisted of amortization of debt discount of $0.4 million for the periods ended June 30, 2020 and June 30, 2019, and the contractual coupon interest expense of $3.8 million and $3.7 million as of June 30, 2020 and June 30, 2019, respectively.

The components of the carrying value of the debt as of June 30, 2020, and December 31, 2019 are detailed below (in thousands):

	June 30, 2020	December 31, 2019
Principal loan balance	$ 75,000	$ 75,000
Unamortized debt discount and issuance cost	(3,559)	(3,999)
Cumulative accretion of exit fee	256	183
Long-term debt, net	$ 71,697	$ 71,184

The annual principal payments due under the Athyrium Credit Facility as of June 30, 2020 were as follows (in thousands):

Years Ending December 31,		
2020 (remaining six months)	$	—
2021		—
2022		16,665
2023		33,330
2024		25,005
Total	$	75,000

10. WARRANTS

The Company issued warrants in connection with debt transactions that were completed prior to 2017. Upon the completion of the IPO, the Company's then outstanding warrants to purchase preferred stock converted into warrants to purchase common stock. The Company also issued the Warrant to purchase common stock in connection with the Athyrium Credit Facility, described further in Note 9.

The following table summarizes the common stock warrants outstanding as of June 30, 2020 and December 31, 2019, each exercisable into the number of shares of common stock set forth below as of the specified dates:

				Shares Exercisable at	
Issued	Exercise Price	Expiration Date	Exercisable From	June 30, 2020	December 31, 2019
2013	$ 7.50	April 2021	July 2017	33,333	82,816
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
2018	$ 12.18	October 2025	(1)	—	—
				248,505	297,988

(1) As of June 30, 2020, and December 31, 2019, the warrant outstanding to acquire 86,175 shares of common stock was not exercisable. As of June 30, 2020, the Company did not satisfy the conditions to draw down the Term Loan B, and as a result, the warrant to acquire 86,175 shares of common stock expired.

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 may 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.

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 could issue and sell, from time to time, up to an aggregate of $50.0 million of its common stock in an at-the-market equity offering ("ATM Offering") through Jefferies, as sales agent. As of December 31, 2019, the Company issued 2,592,934 shares of its common stock under the ATM Offering, resulting in net proceeds to the Company of $13.1 million. During the first quarter of 2020, the Company issued an aggregate of 2,352,671 shares of its common stock under the ATM Offering, resulting in net proceeds to the Company of $12.5 million. 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 the Company's 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, before underwriting discounts, commissions, and offering expenses, resulting in net proceeds of $118.2 million. 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, before underwriting discounts, commissions, and offering expenses, resulting in net proceeds to the Company of $7.2 million. 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 $125.4 million. As of June 30, 2020, there was $18.3 million of securities available to be issued under the 2018 Shelf Registration.

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 $350.0 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, the Company entered into an amended and restated sales agreement with Jefferies pursuant to which the Company may issue and sell, from time to time, up to an aggregate of $75.0 million of its common stock under its ATM Offering through Jefferies, as a sales agent.

12. STOCK-BASED COMPENSATION

Stock Incentive Plans—In December 2009, the Board of Directors (the “Board”) adopted the 2009 Employee, Director and Consultant Equity Incentive Plan (the “2009 Plan”) for the issuance of common stock and stock options to employees, officers, directors, consultants, and advisors.

In July 2017, the Company’s 2017 Equity Incentive Plan (the “2017 Plan”) became effective. The 2017 Plan was established to provide equity-based ownership opportunities for employees, officers, directors, consultants, and advisors. On June 25, 2020, the 2017 Plan was amended to increase the number of shares of common stock authorized for issuance thereunder by 2,000,000 shares. As of June 30, 2020, there were 1,181,416 shares of common stock available for grant under the 2017 Plan. In addition, any shares of common stock subject to awards under the 2009 Plan that expire, are forfeited, or are otherwise surrendered, without having been fully exercised or resulting in any common stock being issued will become available for issuance under the prior plan, up to an additional 2,262,070 shares, which is the number of shares issuable pursuant to outstanding awards granted under the prior plan.

Also approved under the 2017 Plan is an annual increase for each of the years through December 31, 2027, equal to the least of (i) 3,573,766 shares of common stock, (ii) 4% of the shares of common stock outstanding on December 31 of the prior year and (iii) an amount determined by the Board.

Under the plans, the Board determines the number of shares of common stock to be granted pursuant to the awards, as well as the exercise price and terms of such awards. The exercise price of incentive stock options cannot be less than the fair value of the common stock on the date of grant. Stock options awarded under the plans expire 10 years after the grant date, unless the Board sets a shorter term. Options granted under the plans generally vest over a four-year period. A portion of the unvested stock options will vest upon the sale of all or substantially all of the stock or assets of the Company.

In the past, the Company had granted stock options which contain performance-based vesting criteria. These criteria were milestone events that were specific to the Company’s corporate goals. Stock-based compensation expense associated with performance-based stock options is recognized if the achievement of the performance condition is considered probable using management’s best estimates. As of June 30, 2020, there were no performance-based stock option awards outstanding.

Inducement Stock Option Awards—During the six months ended June 30, 2020 and 2019, the Company granted non-statutory stock options to purchase an aggregate of 12,000 shares and 63,000 shares of the Company's common stock, respectively. These stock options will vest over a four-year period, with 25% of the shares underlying each option award vesting on the one-year anniversary of the applicable employees' new hire date and the remaining 75% of the shares underlying each award vesting monthly thereafter for three-years. Vesting of each option is subject to such employee's continued service with the Company through the applicable vesting dates. These stock options were granted outside of the 2017 Plan as an inducement material to each employee's acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

A summary of option activity for employee awards under the 2009 Plan, the 2017 Plan and inducement grants for the six months ended June 30, 2020 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2020	7,453,076	$ 7.46	7.7	$ 1,313
Granted	1,477,422	3.88		
Exercised	(311,028)	3.02		
Forfeited	(45,897)	6.26		
Outstanding at June 30, 2020	8,573,573	$ 7.01	7.7	$ 40,475
Vested or expected to vest at June 30, 2020	8,573,573	$ 7.01	7.7	$ 40,475
Options exercisable at June 30, 2020	4,656,466	$ 7.39	6.8	$ 21,417

The Company records stock-based compensation related to stock options granted at fair value. The Company utilizes the Black-Scholes option-pricing model to estimate the fair value of stock option grants and to determine the related compensation expense. The assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates. The assumptions used in determining fair value of the stock options granted during the six months ended June 30, 2020 and 2019, are as follows:

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Expected volatility	80% – 81%	61% – 82%
Risk-free interest rate	0.42% – 1.73%	1.87% – 2.58%
Expected dividend yield	0%	0%
Expected term (in years)	5.91 – 6.08	0.5 – 6.63

The Company derived the risk-free interest rate assumption from the U.S. Treasury rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the awards being valued. The Company based the assumed dividend yield on its expectation of not paying dividends in the foreseeable future. The Company calculated the weighted-average expected term of options using the simplified method, as the Company lacks relevant historical data due to the Company's limited operating experience. The estimated volatility is based upon the historical volatility of comparable companies with publicly available share prices. The impact of forfeitures on compensation expense is recorded as they occur.

During the three months June 30, 2020 and 2019, the weighted average grant-date fair value of options granted was $9.35 and $3.71, respectively. During the six months ended June 30, 2020 and 2019, the weighted average grant-date fair value of options granted was $3.88 and $3.71, respectively. The fair value is being expensed over the vesting period of the options on a straight-line basis as the services are being provided. As of June 30, 2020 and 2019, there was

$19.1 million and $23.0 million, respectively, of unrecognized compensation cost related to the stock options granted, which is expected to be expensed over a weighted-average period of 2.59 years and 2.67 years, respectively.

Stock-based compensation costs for the Company's manufacturing employees related to INVELTYS manufactured since FDA approval totaled $0.01 million for the three months ended June 30, 2020 and 2019, and has been capitalized into inventory as a component of overhead expense. Stock-based compensation costs for the Company's manufacturing employees related to INVELTYS manufactured since FDA approval totaled $0.03 million and $0.3 million for the six months ended June 30, 2020 and 2019, respectively, and has been capitalized into inventory as a component of overhead expense. Capitalized stock-based compensation is recognized as an expense when the related product is sold or expensed to selling, general and administrative expense when the related sample is issued.

Restricted Stock Units—In June 2020, the Company issued restricted stock units ("RSUs") to certain executives and board members, as well as performance-based restricted stock units ("PSUs") to certain executives and other employees. The Company granted 135,560 RSUs to certain executives which vest 50% on the first anniversary of the grant date, and 50% on the second anniversary of the grant date. Additionally, the Company issued 128,000 RSUs to members of the board which will vest upon the earlier of the first anniversary of the 2020 Annual Meeting of Stockholders or the date of the 2021 Annual Meeting of Stockholders. 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. For the three and six months ended June 30, 2020, stock-based compensation costs associated with these RSUs and PSUs are immaterial.

A summary of the outstanding RSUs and PSUs as of June 30, 2020 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested and outstanding balance at December 31, 2019	-	$ -
Changes during the period:		
RSUs granted	263,560	11.70
PSUs granted	693,537	11.70
Non-vested and outstanding balance at June 30, 2020	957,097	$ 11.70

Employee Stock Purchase Plan—In 2017, the Company approved the 2017 Employee Stock Purchase Plan, which was amended and restated in December 2018 (as amended, the "ESPP"). The ESPP reserved an aggregate of 223,341 shares of common stock and provides for an annual increase on the first day of each fiscal year, beginning on January 1, 2019 and ending on December 31, 2029, in an amount equal to the lowest of: (1) 893,441 shares of the Company's common stock; (2) 1% of the total number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year; and (3) an amount determined by the Company's board of directors.

The ESPP provides for two six-month offering periods each year; the first offering period begins on the first trading day on or after each January 1; the second offering period begins on the first trading day on or after each July 1. Under the ESPP, participating employees can authorize the Company to withhold a portion of their base pay during consecutive six-month payment periods for the purchase of shares of the Company's common stock. At the conclusion of the period, participating employees can purchase shares of the Company's common stock at 85% of the lesser of the closing price of the common stock on (i) the first business day of the plan period or (ii) the exercise date. The fair value of the purchase rights granted under the ESPP was estimated on the date of grant, using the Black-Scholes option-pricing model. In January 2020, employees of the Company purchased an aggregate of 85,553 shares under the ESPP. In July 2020, employees of the Company purchased an aggregate of 228,844 shares under the ESPP.

Stock-based compensation expense was classified in the condensed consolidated statements of operations as follows for the three and six months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of product revenues	$ 9	$ 39	$ 28	$ 41
Research and development	551	795	1,274	1,402
Selling, general and administrative	1,933	1,787	3,686	3,651
Total	$ 2,493	$ 2,621	$ 4,988	$ 5,094

Reserved Shares—As of June 30, 2020 and December 31, 2019, the Company had reserved the following shares of common stock issuable upon exercise of rights under equity compensation plans, inducement stock option awards, and warrant rights to acquire common stock:

	June 30, 2020	December 31, 2019
Warrant rights to acquire Common Stock	334,680	384,163
ESPP	523,860	438,307
Outstanding inducement stock option awards	717,500	705,500
2009 Plan	2,262,070	2,530,586
2017 Plan	7,836,141	4,429,849
Total	11,674,251	8,488,405

13. INCOME TAXES

The Company did not record a provision or benefit for income taxes during the three months ended June 30, 2020 and 2019. 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 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 recently completed an analysis and determined that an ownership change had occurred prior to December 31, 2019 and that such 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, 2019.

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, 2020, and 2019, 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, 2020 and 2019.

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 and June 2018, 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 $37,500. Upon the first commercial sale of INVELTYS, the annual minimum payment increased to $0.1 million. 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, 2020 and 2019, the Company paid JHU $0.01 million and $0.3 million, respectively, in royalty payments associated with the sale of INVELTYS. During the six months ended June 30, 2020 and 2019, the Company paid JHU $0.02 million and $0.3 million, respectively, in royalty payments associated with the sale of INVELTYS.

The Company recorded other expenses related to the JHU agreement of $0.03 million and $0.1 million for the three months ended June 30, 2020 and 2019, respectively. The Company recorded other expenses related to the JHU agreement of $0.1 million and $0.1 million for the six months ended June 30, 2020 and 2019, respectively.

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

Other Commitments — The Company entered into a commercial supply agreement with Catalent Pharma Solutions, LLC to manufacture commercial supplies of INVELTYS and EYSUVIS, with annual minimum purchase requirements. The Company is only subject to the minimum purchase requirements for EYSUVIS upon receiving FDA approval for the product.

15. SUBSEQUENT EVENTS

The Company has evaluated all events and transactions that occurred after the balance sheet date through the date of this filing. During this period, the Company did not have any material subsequent events that impacted its condensed consolidated financial statements or disclosures.

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, 2019, which was filed with the Securities and Exchange Commission on February 12, 2020.

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. Our innovative mucus-penetrating particle, or MPP, drug delivery technology, which we refer to as our 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 have applied the AMPPLIFY technology to loteprednol etabonate, or LE, a corticosteroid designed for ocular applications, resulting in the August 2018 approval of INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%, our topical twice-a-day ocular steroid for the treatment of inflammation and pain following ocular surgery, by the U.S. Food and Drug Administration, or the FDA, and the development of our lead product candidate, KPI-121 0.25%, which if approved we plan to commercialize under the brand name EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25%, for the short-term treatment of the signs and symptoms of dry eye disease. We commercially launched INVELTYS in January 2019.

EYSUVIS is our product candidate for patients with dry eye disease utilizing a two-week course of therapy. In January 2018, we announced topline results from two completed Phase 3 clinical trials, which we refer to as STRIDE 1 and STRIDE 2 (STRIDE - **S** hort **T** erm **R** elief **I** n **D** ry **E** ye), evaluating the safety and efficacy of EYSUVIS versus vehicle (placebo) in patients with dry eye disease. In STRIDE 1, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia and the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the intent-to-treat, or ITT population, in addition, statistical significance was also achieved in STRIDE 1 for a second pre-specified primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in patients with more severe baseline ocular discomfort. In STRIDE 2, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia, but statistical significance was not achieved for the primary symptom endpoint of ocular discomfort severity. EYSUVIS was generally well tolerated in both STRIDE 1 and STRIDE 2, with no clinically significant treatment-related adverse events observed during the course of either trial, and with elevations in interocular pressure, or IOP, in both trials similar to placebo. Based upon the previous recommendation of the FDA, we initiated an additional Phase 3 clinical trial, STRIDE 3, in July 2018. In October 2018, we submitted a New Drug Application, or NDA, to the FDA for EYSUVIS. 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 would be needed to support a resubmission of the NDA.

On March 9, 2020, we announced that STRIDE 3 achieved both of its independent primary endpoints, demonstrating a statistically significant reduction in the symptom endpoint of ocular discomfort severity, or ODS, from baseline to day 15 compared to vehicle control in both the overall ITT population ($p=0.0002$) and in a pre-defined subgroup of ITT patients with more severe baseline ocular discomfort (p=0.0007), defined as patients who scored greater than or equal to 68 mm in baseline ocular discomfort. These data replicate the achievement of both primary symptom endpoints of STRIDE 1 (p<0.0001 in the overall ITT population and p=0.0008 in the pre-defined ITT subgroup with more severe ocular discomfort at baseline). Statistical significance was also achieved in the key secondary endpoint of conjunctival hyperemia at day 15 in the ITT population (p<0.0001). We believe this result replicates the achievement of the positive results of STRIDE 1 and STRIDE 2, where statistical significance was demonstrated for conjunctival hyperemia at day 15 in the ITT population as a prespecified primary endpoint in each of those trials. Statistical significance was also achieved for the key secondary endpoint of ODS at day 8 in the ITT population (p=0.0282), which was consistent with STRIDE 1 (p=0.0011) and STRIDE 2 (p=0.0408). Significant improvement was also observed for corneal staining in the ITT population (p=0.0042), consistent with the result in STRIDE 2 (p=0.0314). Consistent with STRIDE 1 and STRIDE 2, EYSUVIS was generally well tolerated in STRIDE 3, with no clinically significant treatment related adverse events observed during the course of either trial, and with elevations in interocular pressure, or IOP, in both trials similar to placebo. On April 30, 2020, we resubmitted our NDA with the positive data from STRIDE 3 and on May 26, 2020 we announced that the FDA stated that our NDA resubmission was a complete, Class 2 response to the CRL and set the Prescription Drug User Fee Act, or PDUFA, goal date of October 30, 2020 for the completion of its review of the NDA. If approved, we believe EYSUVIS could become the preferred first-line prescription therapy for the short-term treatment of the signs and symptoms of dry eye disease, which will include treatment of dry eye flares that affect the vast majority of dry eye patients.

INVELTYS is the first and only FDA-approved ocular corticosteroid product with a twice-a-day dosing regimen for the treatment of post-operative inflammation and pain. Other approved topical ocular corticosteroid products for this indication are dosed three or four times a day. In clinical trials, INVELTYS showed statistical significance in the primary efficacy endpoints of complete resolution of inflammation at day eight maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day eight maintained through day 15 with no need for rescue medications compared to placebo.

We are also evaluating other opportunities for MPP nanosuspensions of LE, compounds in our receptor Tyrosine Kinase Inhibitor program, or rTKI program, that inhibit the vascular endothelial growth factor, or VEGF, pathway, for the potential treatment of a number of retinal diseases and novel next-generation anti-inflammatories designed to exhibit steroid-like anti-inflammatory action with the goal of eliminating the risk of IOP increase and cataract formation.

INVELTYS received FDA approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, which is the pathway we are pursuing for the approval of EYSUVIS as well. We have retained worldwide commercial rights for INVELTYS and our current product candidates, including EYSUVIS. Since the FDA approval of INVELTYS, we have built a commercial infrastructure with our own focused, specialty sales force which includes 56 territory sales managers, 7 regional sales leaders, and 3 directors of national accounts. If EYSUVIS is approved by the FDA, we plan to increase, pending the status of the COVID-19 pandemic, our sales force from 56 sales representatives to a total of approximately 100 to 125 sales representatives, who will promote both EYSUVIS and INVELTYS. We expect to commercialize in the United States any of our other product candidates that receive marketing approval as well. We also expect to explore commercialization of EYSUVIS for the treatment of dry eye disease in certain markets outside the United States, including the European Union, or EU, utilizing a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

Since the initial public offering of our common stock, or IPO, we have financed our operations primarily through common stock offerings pursuant to a shelf registration statement on Form S-3 that was declared effective by the SEC on August 27, 2018, or the 2018 Shelf Registration, and sales of our common stock pursuant to a sales agreement, or the 2018 Sales Agreement, with Jefferies, LLC, or Jefferies, under which we were able to issue and sell, from time to time, common stock in at-the-market offerings, or the ATM Offering, through Jefferies, as a sales agent. On March 10, 2020, we notified Jefferies that we were suspending and terminating the prospectus related to the 2018 Sales Agreement. Through June 30, 2020, we have issued an aggregate of 30,549,976 shares of common stock under our 2018 Shelf Registration, including the ATM Offering, resulting in aggregate gross proceeds to us of $231.7 million.

On May 7, 2020, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on May 19, 2020, or 2020 Shelf Registration. Under the 2020 Shelf Registration, we may offer and sell up to $350.0 million of a variety of securities including common stock, preferred stock, warrants, depositary shares, debt securities or units during the three-year period the 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 through Jefferies, as a sales agent. Through June 30, 2020, we have no issued any shares of common stock under our 2020 Shelf Registration.

We also have an aggregate amount of $75.0 million of indebtedness outstanding under our credit facility, or the Athyrium Credit Facility, with Athyrium Opportunities III Acquisition LP, or Athyrium.

Since inception, we have incurred significant losses from operations and negative cash flows from operations. Our net losses were $45.3 million for the six months ended June 30, 2020 and $94.3 million for the year ended December 31, 2019. As of June 30, 2020, we had an accumulated deficit of $340.7 million. As we 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 IPO, public common stock offerings and sales of our common stock under our ATM Offering, private placements of preferred stock, convertible debt financings, borrowings under credit facilities 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 INVELTYS. Although we expect to continue to generate revenue from sales of 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

The ongoing COVID-19 pandemic, which began in December 2019, has spread worldwide, causing federal, state and local governments to implement measures to slow the spread of the pandemic through quarantines, strict travel restrictions and bans, heightened border scrutiny and other measures. In order to safeguard the health of our employees, 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 have been instructed 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 customers and were limited to conducting educational and promotional activities virtually. If we suspend all or some in-person interactions with physicians and customers in the future, we will again be limited to conducting educational and promotional activities virtually, which has hampered, and may continue to hamper, our ability to market INVELTYS and could adversely affect our ability to launch and market EYSUVIS, if and when approved.

In addition, government restrictions have at times led to moratoria on elective ocular surgeries in many jurisdictions, which has 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 COVID-19 on our commercialization efforts and our operational and financial performance will depend on certain developments, including the length and severity of this pandemic, impact on our customers, employees, vendors, and government agencies, all of which are uncertain and cannot be predicted.

While we believe FDA review of our resubmitted NDA for EYSUVIS remains on track to be finalized by the PDUFA goal date of October 30, 2020, it is unknown whether the demands and operational restrictions placed on the FDA by COVID-19 will delay this review. The effects of COVID-19 may also disrupt the commercialization of EYSUVIS, if approved.

Management is actively monitoring the COVID-19 pandemic and its possible 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, 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 and may continue to adversely affect our business, results of operations and financial condition.”

Financial Operations Overview

Product Revenues, Net

As a result of the commercial launch of INVELTYS in the United States in early January 2019, we commenced generating product revenues from sales of INVELTYS. Our product revenues are recorded net of provisions relating to estimates for (i) trade discounts and allowances, such as discounts for prompt payment and distributor fees, (ii) estimated rebates, chargebacks and co-pay assistance program, 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 have been adversely affected by the ongoing COVID-19 pandemic as federal, state and local governments implemented restrictions on elective procedures, which include most ocular surgeries during the second quarter. While many deferred ocular surgeries have been rescheduled as individual states have released restrictions on elective procedures, and INVELTYS prescriptions have returned to 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 COVID-19.

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 other manufacturing overhead costs. We expensed cost of product revenues related to INVELTYS as research and development expenses prior to regulatory approval which we received on August 22, 2018. 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 COVID-19.

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 includes external costs related to marketing, samples 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 commercialization of INVELTYS or of any product candidates for which we obtain marketing approval, and if and as we increase our administrative headcount to support our continued research activities and development of our product candidates or additional product candidates, including EYSUVIS. In addition, we anticipate increased expenses related to supporting a larger organization and increase in selling expense related to EYSUVIS, if approved. With respect to the ongoing COVID-19 pandemic, selling, general and administrative expenses were favorably impacted during the three and six months ended June 30, 2020 by a reduction in certain expenses associated with the restriction in the activities of our sales force, which had previously suspended substantially all in-person interactions with physicians and customers. Our sales force has resumed in-person interactions in the field. 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. 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, payments to universities under our license agreements and other 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 receipt of regulatory approval;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and supplies; and
- payments made under our third-party licensing agreements, including the annual minimum royalty and reimbursable expenses for defense of agreed upon patents under a license agreement with Johns Hopkins University, or JHU.

We expense research and development costs as they are incurred. 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 research and development costs in 2020 will remain consistent as compared to the year ended December 31, 2019 as a result of the completion of STRIDE 3, which will largely be offset by costs to manufacture EYSUVIS included in research and development. We expect that such costs will increase if and as we continue to advance our product candidates and conduct additional late-stage 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, including EYSUVIS. 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 continuing limitations 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 various stages of development. Successful development and completion of 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 balance held in a deposit account.

Interest Expense

Interest expense primarily consists of contractual coupon interest expense, amortization of debt discounts and debt issuance costs recognized on our debt 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, 2019.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

The following table summarizes the results of our operations for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Product revenues, net	$ 833	$ 2,057	$ (1,224)
Costs and expenses:			
Cost of product revenues	759	352	407
Selling, general and administrative	15,301	17,007	(1,706)
Research and development	6,053	7,108	(1,055)
Total operating expenses	22,113	24,467	(2,354)
Loss from operations	(21,280)	(22,410)	1,130
Other income (expense)			
Interest income	102	646	(544)
Interest expense	(2,134)	(2,061)	(73)
Net loss	$ (23,312)	$ (23,825)	$ 513

Product revenues, net

Product revenues, net was $0.8 million for the three months ended June 30, 2020 compared to $2.1 million for the three months ended June 30, 2019. The decrease in net revenue of $1.3 million was driven primarily by a decrease in total units sold in the three months ended June 30, 2020 as compared to those sold during the three months ended June 30, 2019, which we attribute to the reductions in elective surgeries as a result of the restrictions related to COVID-19.

INVELTYS is our first product to receive regulatory approval, which we launched in the United States in January 2019. We expect product revenues to increase if and as we increase our market share, and obtain and maintain coverage and adequate reimbursement for INVELTYS from third-party payors; however, we expect full-year product revenues to be negatively impacted for 2020 as a result of the COVID-19 pandemic.

Cost of product revenues

Cost of product revenues was $0.8 million for the three months ended June 30, 2020 compared to $0.4 million for the three months ended June 30, 2019, an increase of $0.4 million. The primary driver of this increase was a reserve for excess inventory of $0.5 million, recorded during the three months ended June 30, 2020. Also contributing to the increase was a $0.1 million write-off of INVELTYS inventory as a result of certain inventory units that did not pass quality inspection. The increase was primarily offset by a $0.2 million decrease in cost of product revenues as a result of a decrease in units sold compared to the three months ended June 30, 2019.

Selling, general and administrative expenses

Selling, general and administrative expenses were $15.3 million for the three months ended June 30, 2020 compared to $17.0 million for the three months ended June 30, 2019, which was a decrease of $1.7 million. The decrease was driven by lower employee-related expenses of $1.9 million for the three months ended June 30, 2020 as a result of lower overall headcount, reduced travel due to COVID-19 and reduced variable compensation associated with lower unit sales of INVELTYS due to COVID-19. Also contributing to the decrease in costs was a reduction in external sales and marketing costs of $0.7 million due primarily to COVID-19 as well as launch-related costs for INVELTYS incurred during the three months ended June 30, 2019 that were not incurred during the same period in 2020. The decreases were partially offset by an increase in costs for insurance and professional services of $0.6 million and an increase in stock compensation of $0.3 million. We anticipate that our selling, general and administrative expenses will increase in the future as we plan for the launch of EYSUVIS, if approved, and if and as we increase our administrative headcount to support our continued research 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, 2020 and 2019:

	Three Months Ended June 30,		
	2020	**2019**	**Change**
	(in thousands)		
KPI-121 development costs	$ 2,034	$ 3,298	$ (1,264)
Employee-related costs	3,357	3,279	78
Other research and development costs	662	531	131
Total research and development	$ 6,053	$ 7,108	$ (1,055)

Research and development expenses were $6.1 million for the three months ended June 30, 2020 compared to $7.1 million for the three months ended June 30, 2019, a $1.0 million decrease. The decrease was primarily the result of a $1.9 million decrease in external spend on Stride 3, our clinical trial for EYSUVIS for which we announced topline data in March 2020. Offsetting the decrease was a $0.7 million increase in EYSUVIS related manufacturing activities, a $0.1 million increase in employee-related costs as a result of manufacturing employees allocating more time to research and development for EYSUVIS related activities, and a $0.1 million increase in other research and development costs, which include facility related costs, pre-clinical studies, certain medical affairs and associated regulatory costs.

Interest income

Interest income decreased by $0.5 million to $0.1 million for the three months ended June 30, 2020 compared to $0.6 million for the three months ended June 30, 2019. Interest income consists of interest earned on our cash balance held in an interest-bearing deposit account. The decrease was attributable to a lower interest rate during the three months ended June 30, 2020.

Interest expense

We incurred interest expense of $2.1 million for the three months ended June 30, 2020, which remained consistent with interest expense of $2.1 million for the three months ended June 30, 2019. Interest expense is comprised of the contractual coupon interest expense and the amortization of the debt discount associated with our Athyrium Credit Facility during the three months ended June 30, 2020 and 2019. During the three months ended June 30, 2019, $75.0 million under the Athyrium Credit Facility was outstanding, and remained outstanding during the three months ended June 30, 2020.

Comparison of the Six Months Ended June 30, 2020 and 2019

The following table summarizes the results of our operations for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Product revenues, net	$ 1,904	$ 3,443	$ (1,539)
Costs and expenses:			
Cost of product revenues	1,113	593	520
Selling, general and administrative	30,709	35,243	(4,534)
Research and development	11,487	14,067	(2,580)
Total costs and expenses	43,309	49,903	(6,594)
Loss from operations	(41,405)	(46,460)	5,055
Other income (expense)			
Interest income	400	1,402	(1,002)
Interest expense	(4,262)	(4,155)	(107)
Net loss	$ (45,267)	$ (49,213)	$ 3,946

Product revenues, net

Product revenues, net was $1.9 million for the six months ended June 30, 2020 compared to $3.4 million for the six months ended June 30, 2019. The decrease in product revenues, net of $1.5 million was driven by a decrease in the total units sold in the six months ended June 30, 2020 as compared to those sold during the six months ended June, 30 2019, which we attribute to the reductions in elective surgeries as a result of the restrictions related to COVID-19. INVELTYS is our first product to receive regulatory approval, which we launched in the United States in January 2019. We expect product revenues to increase if and as we increase our market share, and obtain and maintain coverage and adequate reimbursement for INVELTYS from third-party payors.

Cost of product revenues

Cost of product revenues was $1.1 million for the six months ended June 30, 2020, a $0.5 million increase compared to $0.6 million for the six months ended June 30, 2019. The primary driver of this increase was a reserve for excess inventory of $0.5 million, recorded during the six months ended June 30, 2020. Also contributing to the increase was a $0.1 million write-off of INVELTYS inventory as a result of certain inventory units that did not pass quality inspection. The increase was primarily offset by a $0.1 million decrease in cost of product revenues as a result of a decrease in units sold compared to the six months ended June 30, 2019.

Selling, general and administrative expenses

Selling, general and administrative expenses were $30.7 million for the six months ended June 30, 2020 compared to $35.2 million for the six months ended June 30, 2019, which was a decrease of $4.5 million. The decrease was driven by lower employee-related expenses of $2.6 million for the six months ended June 30, 2020 primarily attributable to lower overall headcount, reduced travel due to COVID-19 and reduced variable compensation associated with lower unit sales of INVELTYS due to COVID-19. Also contributing to the decrease in selling, general and administrative expenses was a reduction in external sales and marketing costs of $2.6 million due to COVID-19 as well as launch-related expenses incurred during the six months ended June 30, 2019 but were not incurred during the six months ended June 30, 2020. Facilities costs allocated to selling, general and administrative were lower by $0.3 million during the six months ended June 30, 2020, which was offset by an increase in costs for insurance and professional service fees of $1.0 million. We anticipate that our selling, general and administrative expenses will increase in the future as we plan for the launch of EYSUVIS, if approved, and if and as we increase our administrative headcount to support our continued research 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, 2020 and 2019:

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
KPI-121 development costs	$ 3,715	$ 6,649	$ (2,934)
Employee-related costs	6,234	5,765	469
Other research and development costs	1,538	1,653	(115)
Total research and development	$ 11,487	$ 14,067	$ (2,580)

Research and development expenses were $11.5 million for the six months ended June 30, 2020 compared to $14.1 million for the six months ended June 30, 2019, a $2.6 million decrease. The decrease was primarily the result of a $3.3 million decrease in external spend on the Stride 3, our clinical trial for EYSUVIS for which we announced topline data in March 2020. Offsetting the decrease was a $0.4 million increase in EYSUVIS related manufacturing activities and a $0.4 million increase in employee-related costs as a result of manufacturing employees allocating more time to research and development for EYSUVIS related activities. Also contributing to the overall decrease was a $0.1 million reduction in other research and development costs.

Interest income

Interest income decreased by $1.0 million to $0.4 million for the six months ended June 30, 2020 compared to $1.4 million for the six months ended June 30, 2019. Interest income consists of interest earned on our cash balance held in an interest-bearing deposit account. The decrease was attributable to a lower interest rate during the six months ended June 30, 2020.

Interest expense

We incurred interest expense of $4.3 million for the six months ended June 30, 2020, compared to $4.2 million for the six months ended June 30, 2019. Interest expense is comprised of the contractual coupon interest expense and the amortization of the debt discount associated with our Athyrium Credit Facility during the three months ended June 30, 2020 and 2019. During the six months ended June 30, 2019, $75.0 million under the Athyrium Credit Facility was outstanding, and remained outstanding during 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, we have had limited revenues to date from product sales and have financed our operations primarily through proceeds from our IPO, public common stock offerings and sales of our common stock under our ATM Offering, private placements of preferred stock, convertible debt financings, borrowings under credit facilities, 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 incurred in 2017 of $2.2 million.

On August 9, 2018, we filed our 2018 Shelf Registration, under which we may 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. We initially designated $50.0 million of our 2018 Shelf Registration to be offered under our ATM Offering. There was $18.3 million of securities available to be issued under the 2018 Shelf Registration as of June 30, 2020.

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. On October 1, 2018, we borrowed the entire principal amount of the Term Loan A. We did not satisfy the conditions to draw down any of the Athyrium Term Loan B funds, and as a result, the Term Loan B funds are no longer available. The maturity date of the Athyrium Credit Facility is October 1, 2024, the six-year anniversary of the close. The Term Loan A bears interest at a rate of 9.875% per annum, with quarterly, interest-only payments until the fourth anniversary of the Term Loan A. The unpaid principal amount of the Term Loan A is due and payable in quarterly installments starting at the end of the fourth anniversary of the loan.

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.

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, before underwriting discounts, commissions, and offering expenses, resulting in net proceeds of $118.2 million. 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 and commissions. On April 3, 2020, the underwriters exercised their option and purchased an additional 979,371 shares of common stock at $7.89 per share, before underwriting discounts, commissions, and offering expenses, resulting in net proceeds to us of $7.2 million. 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 and offering expenses, of $125.4 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. As of December 31, 2019, we had issued an aggregate of

2,592,934 shares of our common stock under the ATM Offering, resulting in net proceeds to us of $13.1 million. During the first quarter of 2020, we issued an aggregate of 2,352,671 shares of our common stock under the ATM Offering, resulting in net proceeds to us of $12.5 million. On March 10, 2020, we suspended and terminated the prospectus related to the ATM Offering.

On May 7, 2020, we filed our 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.

Cash Flows

As of June 30, 2020, we had $128.0 million in cash on hand and $75.0 million in indebtedness. The following table summarizes our sources and uses of cash for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (39,134)	$ (51,596)
Net cash used in investing activities	(57,450)	(943)
Net cash provided by financing activities	139,160	19
Increase / (decrease) in cash and restricted cash	$ 42,576	$ (52,520)

Net Cash Used in Operating Activities

During the six months ended June 30, 2019, our cash used in operating activities was primarily due to our net loss of $49.2 million primarily consisting of $35.2 million of selling, general and administrative costs and $14.0 million of research and development costs, partially offset by non-cash charges of $6.8 million, consisting primarily of $5.1 million in stock-based compensation. Net cash used by changes in our operating assets and liabilities primarily consisted of a $5.6 million increase in accounts receivable driven by sales of INVELTYS and a $4.0 million increase in inventory due to increase in manufacturing activity for INVELTYS, which were offset by a $0.4 million decrease in other prepaid and accounts payable balances.

During the six months ended June 30, 2020, our cash used in operating activities was primarily due to our net loss of $45.3 million primarily consisting of $30.7 million of selling, general and administrative costs and $11.5 million of research and development costs, partially offset by non-cash charges of $7.2 million, consisting primarily of $5.3 million in stock-based compensation. Net cash used by changes in our operating assets and liabilities primarily consisted of a $7.3 million decrease in accounts receivable driven by a decrease in sales of INVELTYS when compared to the six months ended June 30, 2019, offset by a $7.8 million decrease in accounts payable and accrued expenses, mainly driven by a decrease in accrued revenue reserves, and accrued compensation, as a result of bonus payments during the six months ended June 30, 2020.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0.9 million for the six months ended June 30, 2019, consisting primarily of purchases of furniture and fixtures.

Net cash used in investing activities was $57.4 million for the six months ended June 30, 2020, consisting primarily of $56.5 million of purchases of short-term investments and $0.9 million of purchases of laboratory and manufacturing equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $19,000 for the six months ended June 30, 2019, consisting of $39,000 of proceeds from the exercise of stock options, offset by $20,000 of principal payments on our finance lease obligation.

Net cash provided by financing activities was $139.2 million for the six months ended June 30, 2020, consisting of $125.4 million of net proceeds from the sale of shares of our common stock in an underwritten offering under 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 engage in activities to prepare for commercialization of our lead product candidate, EYSUVIS, for the short-term treatment of the signs and symptoms of dry eye disease, as a result of increased headcount, including our plan to increase, pending the status of the COVID-19 pandemic, our sales force from 56 sales representatives to a total of approximately 100 to 125 sales representatives if EYSUVIS is approved by the FDA, as well as 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.

Our expenses will also increase if and as we:

- continue to grow our sales, marketing and distribution capabilities in connection with the commercialization of INVELTYS and any product candidates, including EYSUVIS, for which our NDA is under review by the FDA with a goal date under PDUFA set for October 30, 2020 for the completion of its review of our NDA;

- conduct any necessary clinical trials and other development activities and/or seek marketing approvals for EYSUVIS and any other product candidates;

- in-license or acquire the rights to other products, product candidates or technologies;

- pursue the clinical development of KPI-121 for the treatment of other additional indications or for use in other patient populations;

- pursue the preclinical and clinical development of product candidates, including our rTKI program, for use in the treatment of retinal diseases, and novel next-generation anti-inflammatories designed to exhibit steroid-like anti-inflammatory action with the goal of eliminating the risk of IOP increase and cataract formation;

- seek regulatory approval for EYSUVIS, INVELTYS or any other product candidate outside of the United States;

- continue to scale up our manufacturing processes and capabilities to support commercialization of INVELTYS, and any of our product candidates, including EYSUVIS, for which we seek and/or obtain marketing approval;

- leverage our proprietary AMPPLIFY technology to advance additional potential high-value 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 personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability insurance coverage as we expand our commercialization efforts, including increased coverage for EYSUVIS, if approved.

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 existing cash, cash equivalents, and short-term investments as of June 30, 2020, will enable us to fund our operations, lease and debt service obligations, and capital expenditure requirements into at least the second quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our available capital resources sooner or later than we currently expect.

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

- we elect or are required by the FDA or non-U.S. regulatory agencies to perform clinical trials or studies in addition to those expected;
- there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates; 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 INVELTYS in January 2019, there can be no assurance as to the amount or timing of any such revenue, and we may not achieve profitability. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- successfully growing INVELTYS revenues;
- obtaining marketing approval of EYSUVIS or any other product candidates;
- achieving an adequate level of market acceptance and obtaining and maintaining coverage and adequate reimbursement from third-party payors for INVELTYS and EYSUVIS, if approved, and any other products we commercialize;
- manufacturing at commercial scale, marketing, selling and distributing INVELTYS or any product candidates for which we obtain marketing approval, including EYSUVIS;
- maintaining regulatory and marketing approvals for INVELTYS and for any other product candidates for which we obtain approval, including EYSUVIS;

- hiring and building a full commercial organization required for marketing, selling and distributing those products for which we obtain marketing approval, including EYSUVIS;
- 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.

INVELTYS is our only product that has been approved for sale and it has only been approved in the United States. Our ability to generate revenue from operations will depend, in part, on the success of commercial sales of INVELTYS, which we commercially launched in the United States in January 2019. However, the successful commercialization of INVELTYS in the United States is subject to many risks. We are currently undertaking our first commercial launch with INVELTYS, 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. We do not anticipate our revenue from sales of INVELTYS alone will be sufficient for us to become profitable for several years, 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 COVID-19. As a result of these restrictions, we previously suspended our sales force from substantially all in-person interactions with physicians and customers and were limited to conducting educational and promotional activities virtually, and we may be forced to suspend all or some in-person interactions again in the future. To the extent we restrict in-person interactions with physicians and customers, we will again be limited to conducting educational and promotional activities virtually, which has hampered, and may continue to hamper, our ability to market INVELTYS and could adversely affect our ability to launch and market EYSUVIS, if and when approved. In addition, government restrictions have at times led to moratoria on elective ocular surgeries in many jurisdictions, which has 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 COVID-19 on our commercialization efforts will depend on the length and severity of this pandemic, 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 Athyrium Credit Facility may limit our ability to obtain additional debt financing. Under our Athyrium Credit Facility, we are also restricted from paying dividends on our common stock and limited with respect to certain other uses of our cash without the lenders' consent.

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 continue to 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 cash, cash equivalents, and short-term investments of $184.6 million as of June 30, 2020 consist of U.S. Government Agency and Treasury 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, 2020, the aggregate principal amount outstanding under the Athyrium Credit Facility was $75.0 million, which bears interest at a fixed rate of 9.875% per annum.

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, 2020. 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, 2020, 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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As a result of the COVID-19 pandemic, the majority of our workforce began working remotely in March 2020. These changes to the working environment did not have a material effect on our internal controls over financial reporting during the most recent quarter.

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. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

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 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 $23.3 million and $45.3 million for the three and six months ended June 30, 2020, respectively, and $94.3 million for the year ended December 31, 2019. As of June 30, 2020, we had an accumulated deficit of $340.7 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, and have had limited revenues to date from product sales. We have financed our operations primarily through proceeds from public offerings of common stock, private placements of preferred stock, convertible debt financings, borrowings under credit facilities, warrants, and sales under our at-the-market offering facility, or the ATM Offering. 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 INVELTYS. Although we expect to continue to generate revenue from sales of 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 engage in activities to prepare for commercialization of our lead product candidate, KPI-121 0.25%, which if approved we plan to commercialize under the brand name EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25%, for the short-term treatment of the signs and symptoms of dry eye disease, as a result of increased headcount, including our plan to increase, pending the status of the COVID-19 pandemic, our sales force from 56 sales representatives to a total of approximately 100 to 125 sales representatives if EYSUVIS is approved by the U.S. Food and Drug Administration, or FDA, as well as 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.

Our expenses will also increase if and as we:

- continue to grow our sales, marketing and distribution capabilities in connection with the commercialization of INVELTYS and any product candidates, including EYSUVIS, for which a new drug application, or NDA, is under review by the FDA with a goal date under the Prescription Drug User Fee Act, or PDUFA, set for October 30, 2020 for the completion of its review of our NDA;

- conduct any necessary clinical trials and other development activities and/or seek marketing approvals for EYSUVIS and any other product candidates;

- in license or acquire the rights to other products, product candidates or technologies;

- pursue the clinical development of KPI-121 for the treatment of other additional indications or for use in other patient populations;

- pursue the preclinical and clinical development of product candidates, including our receptor Tyrosine Kinase Inhibitor program, or rTKI program, for use in the treatment of retinal diseases, and novel next generation anti-inflammatories designed to exhibit steroid-like anti-inflammatory action with the goal of eliminating the risk of interocular pressure, or IOP, increase and cataract formation;

- seek regulatory approval for EYSUVIS, INVELTYS or any other product candidate outside of the United States;

- continue to scale up our manufacturing processes and capabilities to support commercialization of INVELTYS, and any of our product candidates, including EYSUVIS, for which we seek and/or obtain marketing approval;

- leverage our proprietary AMPPLIFY technology to advance additional potential high value 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 personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and

- increase our product liability insurance coverage as we expand our commercialization efforts, including increased coverage for EYSUVIS, if approved.

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; 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 INVELTYS in January 2019, there can be no assurance as to the amount or timing of any such revenue, and we may not achieve profitability. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- successfully growing INVELTYS revenues;

- obtaining marketing approval for EYSUVIS or any other product candidates;

- achieving an adequate level of market acceptance, and obtaining and maintaining coverage and adequate reimbursement from third-party payors for INVELTYS and EYSUVIS, if approved, and any other products we commercialize;

- manufacturing at commercial scale, marketing, selling and distributing INVELTYS or any product candidates for which we obtain marketing approval, including EYSUVIS;
- maintaining regulatory and marketing approvals for INVELTYS and for any other product candidates for which we obtain approval, including EYSUVIS;
- hiring and building a full commercial organization required for marketing, selling and distributing those products for which we obtain marketing approval, including EYSUVIS;
- 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.

INVELTYS is our only product that has been approved for sale and it has only been approved in the United States. Our ability to generate revenue from operations will depend, in part, on the success of commercial sales of INVELTYS, which we commercially launched in the United States in January 2019. However, the successful commercialization of INVELTYS in the United States is subject to many risks. We are currently undertaking our first commercial launch with INVELTYS, 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. We do not anticipate our revenue from sales of INVELTYS alone will be sufficient for us to become profitable for several years, 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 COVID-19. As a result of these restrictions, we previously suspended our sales force from substantially all in-person interactions with physicians and customers and were limited to conducting educational and promotional activities virtually, and we may be forced to suspend all or some in-person interactions again in the future. To the extent we restrict in-person interactions with physicians and customers, we will again be limited to conducting educational and promotional activities virtually, which has hampered, and may continue to hamper, our ability to market INVELTYS and could adversely affect our ability to launch and market EYSUVIS, if and when approved. In addition, government restrictions have at times led to moratoria on elective ocular surgeries in many jurisdictions, which has 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 COVID-19 on our commercialization efforts will depend on the length and severity of this pandemic, 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 INVELTYS and our product candidates, including EYSUVIS, commercially launching INVELTYS and preparing to commercially launch EYSUVIS, if approved. We are in the early stages of 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, have no history of commercializing products, and, to date, have generated limited revenue from the sale of INVELTYS. In addition, our commercial operations and INVELTYS sales have been and continue to be negatively impacted by the current pandemic health event resulting from the novel coronavirus (COVID-19) and its collateral consequences. 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 INVELTYS, seek marketing approval for EYSUVIS, and continue the development of and potentially seek marketing approval for other product candidates. Our expenses may increase substantially in connection with our ongoing activities, particularly as we commercialize INVELTYS and EYSUVIS, if and when approved, and as we advance our preclinical activities and clinical trials for our product candidates. In addition, our expenses will further increase if we elect to or are required to conduct any further trials for EYSUVIS. We also expect to devote additional financial resources to conducting research and development, and potentially initiating clinical trials of, and seeking regulatory approval for, other potential product candidates, including product candidates that we may develop using our rTKI program and novel next-generation anti-inflammatories.

Our expenses have increased relative to prior periods in connection with our launch and commercialization of INVELTYS, including costs associated with the addition of our specialty sales force and increased marketing, distribution and manufacturing capabilities. If we obtain marketing approval for any product candidate that we develop, we may incur significant additional commercialization expenses for such product candidate. For example, if EYSUVIS is approved, we plan to increase, pending the status of the COVID-19 pandemic, our sales force from 56 sales representatives to a total of approximately 100 to 125 sales representatives, who will promote both EYSUVIS and INVELTYS. Furthermore, we incur additional costs associated with operating as a public company, hiring additional personnel and expanding our facilities. 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, timing and outcome of regulatory review of EYSUVIS, including whether any additional clinical trials or other activities are required for approval or label expansion;
- the costs and timing of commercialization activities for INVELTYS and EYSUVIS, if we receive marketing approval, 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 INVELTYS in the United States;
- the amount of revenue received from commercial sales of INVELTYS and, if approved, EYSUVIS or any other product candidates;
- the costs and timing of process development and manufacturing scale up activities associated with INVELTYS and EYSUVIS, if approved;
- the progress, costs and results of any clinical activities for regulatory review of INVELTYS and EYSUVIS 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 derive from any other product candidates that we may develop;

- the extent to which we 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 existing cash, cash equivalents, and short-term investments of $184.6 million as of June 30, 2020, will enable us to fund our planned operations, lease and debt service obligations, and capital expenditure requirements into at least the second quarter of 2022. 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.

Conducting preclinical testing and clinical trials, seeking market approvals and commercializing products are time-consuming, expensive and uncertain processes that take years to complete. Although we commercially launched INVELTYS in early 2019, we do not anticipate that our revenue from product sales of INVELTYS will be sufficient for us to become profitable for several years, if at all. Additionally, in August 2019, we announced that we received a complete response letter, or CRL, from the FDA regarding our NDA for EYSUVIS for the short-term treatment of the signs and symptoms of dry eye disease. In the CRL, the FDA indicated that positive efficacy data from an additional clinical trial would be needed to support a resubmission of the NDA. On March 9, 2020, we announced positive top-line results for our STRIDE 3 clinical trial, which served as the basis of our response to the CRL along with data from the three previous trials. On May 26, 2020, we announced that the FDA stated that our NDA resubmission was a complete, Class 2 response to the CRL and set a PDUFA goal date of October 30, 2020 for the completion of its review of the NDA. While we believe our clinical trials of EYSUVIS to date have generated sufficient data to support regulatory approval of EYSUVIS, the FDA may determine otherwise, and we may need to conduct additional clinical trials to support approval of EYSUVIS.

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 INVELTYS and EYSUVIS, if approved, or any other 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 credit facility with Athyrium Opportunities III Acquisition LP, or Athyrium Credit Facility, may limit our ability to obtain additional debt financing. Under the Athyrium Credit Facility, we are also restricted from paying dividends on our common stock and limited with respect to certain other uses of our cash without the lenders' consent.

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 significant amount of indebtedness. As of June 30, 2020, we had $75.0 million of outstanding borrowings under the Athyrium Credit Facility. Amounts outstanding under the Athyrium Credit Facility bear interest at a rate of 9.875% per annum. The Athyrium Credit Facility provides for quarterly interest-only payments for 48 months. Beginning on September 30, 2022, we will be required to make principal and interest payments through October 1, 2024, the date of maturity. Our obligations under the Athyrium Credit Facility are secured by substantially all of our assets. We could in the future incur additional indebtedness beyond our borrowings under our Athyrium Credit Facility.

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 Athyrium Credit Facility 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 Athyrium Credit Facility, we may not be able to make accelerated payments, and the lender could seek to enforce security interests in the collateral securing such indebtedness.

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, or U.S. GAAP, requires management to make estimates and assumptions that affect the amounts reported in the condensed 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 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 Product Development

We are dependent on the success of INVELTYS and our lead product candidate, EYSUVIS. If we are unable to successfully commercialize INVELTYS or obtain marketing approval for EYSUVIS, or if we experience significant delays in doing so, or if, after obtaining marketing approval for EYSUVIS, we fail to successfully commercialize EYSUVIS, 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 treatment of the signs and symptoms of dry eye disease. There is a significant risk that we will fail to successfully commercialize INVELTYS and to successfully obtain marketing approval for and commercialize EYSUVIS. 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 October 2018, we submitted an NDA to the FDA for EYSUVIS. In August 2019, we announced that we received a CRL from the FDA indicating that positive efficacy data from an additional clinical trial would be needed to support a resubmission of the NDA. On March 9, 2020, we announced that 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 May 26, 2020, we announced that the FDA stated that our NDA resubmission was a complete, Class 2 response to the CRL and set a PDUFA goal date of October 30, 2020 for the completion of its review of the NDA. The FDA may still determine that we need to conduct additional clinical trials to support approval of EYSUVIS. Moreover, the FDA has announced that in order to bring new therapies to patients sick with COVID-19 as quickly as possible, it has redeployed medical and regulatory staff from other areas to work on COVID-19 therapies. Although the FDA has set a PDUFA goal date of October 30, 2020 for the completion of its review of our NDA, it is unknown whether the demands and operational restrictions placed on the FDA by COVID-19 will delay the FDA's review of the NDA for EYSUVIS. We cannot accurately predict when or if EYSUVIS will receive marketing approval. Our ability to generate meaningful product revenues will depend on our successful commercialization of INVELTYS and our obtaining marketing approval for, and successfully commercializing, EYSUVIS.

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

- successful commercialization of INVELTYS in the United States, including maintaining sales, marketing, manufacturing and distribution capabilities for INVELTYS;
- acceptance of INVELTYS and, if and when approved, EYSUVIS and our other product candidates by patients, the medical community and third-party payors;
- obtaining and maintaining coverage, adequate pricing, and adequate reimbursement from third-party payors, including government payors, for INVELTYS and our product candidates, including EYSUVIS;
- successfully developing and applying for and receiving marketing approvals from applicable regulatory authorities for EYSUVIS and other product candidates;
- receiving 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 AMPPLIFY technology and eye diseases to continue to develop our product candidates;
- leveraging our sales, marketing and distribution capabilities for EYSUVIS 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.

Successful development of KPI-121 for additional indications, if any, or for use in broader patient populations will depend on similar factors.

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 INVELTYS or our product candidates, including EYSUVIS, which would materially harm our business.

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

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 CRL from the FDA indicating that positive efficacy data from an additional clinical trial will be needed to support a resubmission of the NDA. On March 9, 2020, we announced that 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 May 26, 2020, we announced that the FDA stated that our NDA resubmission was a complete, Class 2 response to the CRL and set a PDUFA goal date of October 30, 2020 for the completion of its review of the NDA. The FDA may still determine that we need to conduct additional clinical trials to support approval of EYSUVIS. If we conduct additional clinical trials of EYSUVIS, our expenses will significantly increase and could delay or halt our ability to obtain marketing approval. Our Phase 3 clinical trials of EYSUVIS may not be sufficient to support an application for marketing approval outside the United States. Further, if regulatory authorities outside the United States do not accept the data from any trial we conduct in the United States, in particular if the European Union does not allow us to utilize the results from our Phase 3 clinical trials of EYSUVIS pursuant to the Article 10(3) submission pathway or otherwise, we will likely need to conduct additional trials to obtain marketing approval in such jurisdiction, which would be costly and time-consuming and could delay or permanently halt our ability to commercialize the applicable product candidates in the applicable jurisdictions.

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

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

- have the product removed from the market after obtaining marketing approval.

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

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize 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; and
- the lack of adequate compensation for prospective patients.

For example, we experienced a delay in patient enrollment for our Phase 3 clinical trial, STRIDE 3, evaluating 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 are 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 product or product candidates, we may need to abandon or limit our development of such product or product candidates.

If INVELTYS or any of our product candidates, including EYSUVIS, are associated with serious adverse events or undesirable side effects in clinical trials or following approval and/or commercialization, or if our product 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 INVELTYS and EYSUVIS 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 KPI-121 reported in any of our clinical trials to date. 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 KPI-121 concentration 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 product or our product candidates (including use of INVELTYS or EYSUVIS, if approved, 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 product or our product candidates will be used correctly, and if used incorrectly, such misuse could hamper commercial adoption or market acceptance of our product 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 the Commercialization of INVELTYS and our Product Candidates, Including EYSUVIS

The ongoing novel coronavirus pandemic and the efforts to prevent its spread have adversely impacted our operations and the market for INVELTYS and may continue to adversely affect our business, results of operations and financial condition.

The ongoing novel coronavirus pandemic, commonly referred to as COVID-19, which began in December 2019, has spread worldwide, causing federal, state and local governments to implement measures to slow the spread of the outbreak through quarantines, strict travel restrictions and bans, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also 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 historical levels. Shelter-in-place orders and other mandated local travel and social interaction prohibitions have also restricted the activities of our sales force. We previously suspended substantially all in-person interactions with physicians and customers and were limited to conducting educational and promotional activities virtually, and we may be forced to suspend all or some in-person interactions again in the future. To the extent we restrict in-person interactions with physicians and customers, we will again be limited to conducting educational and promotional activities virtually, which has hampered, and may continue to hamper, our ability to market INVELTYS and could adversely affect our ability to launch and market EYSUVIS, if and when approved. Furthermore, while the majority of our day-to-day operations are continuing as our employees are working 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.

The effects of COVID-19 may also disrupt the review of our resubmitted NDA for EYSUVIS and the timing of its review by the FDA and, if approved, the commercialization of EYSUVIS. Moreover, the FDA has announced that in order to bring new therapies to patients sick with COVID-19 as quickly as possible, it has redeployed medical and regulatory staff from other areas to work on COVID-19 therapies. Although the FDA has set a PDUFA goal date of October 30, 2020 for the completion of its review of our NDA for EYSUVIS, it is unknown whether the demands and operational restrictions placed on the FDA by COVID-19 will delay the FDA's review of the NDA.

Additionally, while we currently are not experiencing interruptions in our manufacturing of INVELTYS or EYSUVIS, 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 continue to 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. 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.

INVELTYS or any of our product candidates that receive marketing approval, including EYSUVIS, 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.

INVELTYS or any product candidate that we develop that receives marketing approval, including EYSUVIS, may fail to gain sufficient market acceptance by clinicians, patients, third-party payors and others in the medical community. 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. For example, based on a market survey we commissioned in 2018 of 100 ophthalmologists, we believe INVELTYS offers advantages over existing post-surgical treatment options due to its AMPPLIFY technology and being the first and only topical twice-daily dosing, two-week course of treatment and safety data, including low incidence of reported IOP spikes, and efficacy data from our clinical trials. In this market survey, a majority of surveyed ophthalmologists indicated they were likely to prescribe INVELTYS. We also conducted an Attitudes, Trial and Usage Study (ATU) in August 2019 with approximately 200 eye care professionals, which indicated that many current INVELTYS prescribers intend to increase their usage of 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 have been recently approved and/or marketed. 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.

While there are no drugs currently approved in the United States for the short-term relief of the signs and symptoms of dry eye disease, current treatments that are used in the United States for dry eye disease include over-the-counter artificial tears, Restasis®, Xiidra®, Cequa™, 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 2020. Our current expectations regarding market potential for EYSUVIS are based, in part, on market research data we have commissioned. For example, based on two surveys we commissioned of 503 and 297 dry eye disease patients in 2017 and 2018, respectively, which we refer to as our patient surveys, 80% to 90% of surveyed patients reported experiencing dry eye flares, with the majority experiencing four to six times per year, and the most common reason given by patients for discontinuing the two leading branded dry eye treatments were insufficient efficacy and side effects. However, it is possible that doctors may continue to rely on other existing treatments rather than EYSUVIS, if and when it is approved by the FDA. In addition, if generic versions of any products that compete with any of our product candidates are approved for marketing by the FDA, they would likely be offered at a substantially lower price than we expect to offer for our product candidates, if approved. As a result, clinicians, patients and third-party payors may choose to rely on such products rather than our product candidates.

The market opportunity for INVELTYS may be further impacted and, if approved, the market opportunity for EYSUVIS may also be adversely 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 inflammation and pain following ocular surgery, resulting in a significant reduction in the demand for INVELTYS. Shelter-in-place orders and other mandated local travel prohibitions have also restricted the activities of our sales force. We previously suspended substantially all in-person interactions with physicians and customers and were limited to conducting educational and promotional activities virtually, and we may be forced to suspend all or some in-person interactions again in the future. To the extent we restrict in-person interactions with physicians and customers, we will again be limited to conducting educational and promotional activities virtually, which has hampered, and may continue to hamper, our ability to market INVELTYS and could adversely affect our ability to launch and market EYSUVIS, if and when approved.

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

If INVELTYS or any of our product candidates for which we obtain marketing approval, including EYSUVIS, 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 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;
- 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 INVELTYS or any product candidate that we may develop, including EYSUVIS, 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 INVELTYS or any of our product candidates, including EYSUVIS, 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 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, INVELTYS or any product candidate, including EYSUVIS, 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 INVELTYS or any product candidate for which we obtain marketing approval, including EYSUVIS.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, 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 INVELTYS or our product candidates, including EYSUVIS, 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 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 INVELTYS or any of our product candidates, including EYSUVIS, that we may develop if and when they are approved.

We have only recently established our sales and marketing infrastructure for our commercial launch of INVELTYS, our first product, and have no prior experience in the sales, marketing or 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 buildout of our specialty sales, marketing and distribution infrastructure in the United States to commercialize INVELTYS and may need to expand that infrastructure to market any of our product candidates that we develop in the United States, if and when such product candidates are approved. For example, if EYSUVIS is approved, we plan to increase, pending the status of the COVID-19 pandemic, our sales force from 56 sales representatives to a total of approximately 100 to 125 sales representatives, who will 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 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 INVELTYS or any product candidates for which we receive marketing approval, including EYSUVIS, on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our ability 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 plan to 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 INVELTYS or any of our product candidates, including EYSUVIS, 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 INVELTYS or any of our product candidates for which we obtain marketing approval, including EYSUVIS, effectively. 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 INVELTYS, or any of our product candidates for which we obtain marketing approval, including EYSUVIS.

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. INVELTYS, and our product candidates, including EYSUVIS, if approved, will also compete with existing branded, generic and off-label products.

The development and commercialization of new drug products is highly competitive. We face competition with respect to INVELTYS and our product candidates, including EYSUVIS, and will face competition with respect to any other 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 product and our product candidates will 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 product 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.

Following ocular surgery, topical steroids are commonly prescribed to manage and prevent complications from post-operative inflammation. Topical steroid drops are the main competition to INVELTYS for the treatment of inflammation and pain following ocular surgery. The current branded market leaders for topical steroids in the United States, based on revenue, are Lotemax® products and Durezol®. Generic topical steroid formulations consist mainly of products containing prednisolone, fluorometholone or dexamethasone. In addition, the first generic formulation of loteprednol suspension 0.05% (Lotemax suspension) was launched in May 2019 and Durezol lost its patent exclusivity in 2019, which could result in a potential generic launch of this product in 2020.

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

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; 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; and TrueTear® Intranasal Tear Neurostimulator, a neurostimulator that received marketing approval from the FDA in April 2017, which provides electrical pulses within the nasal cavity to stimulate tear production.

Pharmaceutical therapies for dry eye disease include on label prescription drugs, including Restasis, Xiidra, and Cequa, which are the only prescription pharmaceutical products 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 prescribed on occasion for treatment of dry eye disease. Generic versions of Restasis are expected to become available in the U.S. in 2020. 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.

We are developing EYSUVIS for the short-term 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 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 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 companies, biotechnology companies, and specialty pharmaceutical and generic drug companies of various sizes, such as Oyster Point Pharma’s OC-01 nasal spray, Aldeyra Therapeutics’ reproxalap ophthalmic solution, Aurinia Pharmaceuticals’ voclosporin ophthalmic solution, Novaliq’s Cyclasol candidate as well as its NOV03 candidate, which has been licensed to Bausch Health Companies Inc., Silk Technologies’ SDP-4 ophthalmic solution, and others.

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 INVELTYS and EYSUVIS 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 product 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 INVELTYS and expect to rely on third party contract manufacturers to manufacture commercial supplies of EYSUVIS, if approved. Specifically, we rely on the following: Catalent Pharma Solutions, LLC, or Catalent, to manufacture and supply to us a minimum amount of INVELTYS and EYSUVIS bottles for commercial use; Alliance Contract Pharma, LLC, or Alliance, for manufacturing bulk KPI-121 concentrates; 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 product 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 product 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 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 product 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 product 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 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 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 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 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 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 other 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 Our Dependence on Third Parties

We contract with third parties for the manufacture of INVELTYS and EYSUVIS 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 INVELTYS, EYSUVIS or any other product candidates. We rely on Catalent to manufacture and supply to us a minimum amount of INVELTYS bottles and expect to rely on Catalent to manufacture and supply to us a minimum amount EYSUVIS bottles for commercial use, if approved. We also rely on Alliance for manufacturing bulk KPI-121 concentrates, 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 INVELTYS, EYSUVIS 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 KPI-121 for our clinical trials and the commercialization of INVELTYS from third-party manufacturers, including Catalent and Alliance. We have supply agreements in place with these contract manufacturers to provide commercial supply. We obtain the API for KPI-121 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 EYSUVIS or other 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:

- INVELTYS, EYSUVIS 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 INVELTYS or EYSUVIS, 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 INVELTYS, EYSUVIS or our other 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 INVELTYS or any of our product candidates, including EYSUVIS, 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 KPI-285, our lead rTKI compound, or any other product candidates we develop, including our novel next-generation anti-inflammatories. 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 AMPPLIFY technology, and therefore may not infringe on our patent rights.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology, products or product candidates, or limit the duration of the patent protection of our technology, products and product candidates. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Patent reform legislation under Leahy-Smith America Invests 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.

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 INVELTYS and EYSUVIS 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 INVELTYS and our product candidates, including EYSUVIS, 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 near 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 INVELTYS or any of our product candidates, including EYSUVIS, 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.

INVELTYS, EYSUVIS 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 INVELTYS and our product candidates, including EYSUVIS, and some aspects of our AMPPLIFY technology. While we control patent prosecution of the licensed patent families relating to INVELTYS and EYSUVIS, 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-licensed 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 INVELTYS and our product candidates, including EYSUVIS, 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 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. The marketing approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain marketing approval to commercialize our product candidates.

Our product candidates, including EYSUVIS, 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.

On August 22, 2018, we received approval from the FDA to market INVELTYS in the United States, which is our first and only product candidate to receive marketing approval. We have not received approval to market EYSUVIS or any other product candidate from regulatory authorities in any jurisdiction. In August 2019, we announced that we received a CRL from the FDA regarding our NDA for EYSUVIS for the short-term treatment of the signs and symptoms of dry eye disease. In the CRL, the FDA indicated that positive efficacy data from an additional clinical trial would be needed to support a resubmission of the NDA. On March 9, 2020, we announced that 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 May 26, 2020, we announced that the FDA stated that our NDA resubmission was a complete, Class 2 response to the CRL and set a PDUFA goal date of October 30, 2020 for the completion of its review of the NDA. The FDA may still determine that we need to conduct additional clinical trials to support approval of EYSUVIS. In addition, 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. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. In the United States, the FDA also approves the proprietary brand name used to market an approved drug. The FDA has not yet approved our use of the brand name "EYSUVIS", which we plan to use to market KPI-121 0.25%. If the FDA does not approve the brand name "EYSUVIS" or any other brand name or trademark we propose to use in connection with the sale of any product that receives regulatory approval, we would need to adopt and seek approval for a new name and our marketing efforts may be adversely effected.

Although the FDA has set a PDUFA goal date of October 30, 2020 for the completion of its review of our NDA for EYSUVIS, it is unknown whether the demands and operational restrictions placed on the FDA by COVID-19 will delay the FDA's review of the NDA for EYSUVIS. If we experience delays in obtaining approval or if we fail to obtain approval of EYSUVIS or any other 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.

If the FDA does not conclude that EYSUVIS satisfies the approval requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act, or if the requirements for EYSUVIS under Section 505(b)(2) are not as we expect, the approval for EYSUVIS may take longer, cost more and entail greater complications and risks than anticipated, and may not be achieved.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from findings of safety and efficacy based on studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference, which could expedite the development program for EYSUVIS by potentially decreasing the amount of preclinical and clinical data that we would need to generate in order to obtain FDA approval.

We are seeking FDA approval of EYSUVIS through the Section 505(b)(2) regulatory pathway. The FDA previously approved INVELTYS through the Section 505(b)(2) regulatory pathway. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional non-clinical and clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for EYSUVIS, and complications and risks associated with approval of EYSUVIS, would likely substantially increase. Even if we are allowed to pursue the Section 505(b)(2) pathway to FDA approval, we cannot assure you that EYSUVIS will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), certain competitors and others have objected to the FDA’s interpretation of Section 505(b)(2). If the FDA’s interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2), including our NDA for EYSUVIS. In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and to mandatory delays in approval of our NDAs for up to 30 months, depending on the outcome of any litigation. In addition, it is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may in certain cases substantially delay approval while it considers and responds to the petition. Thus, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval of EYSUVIS.

Even if EYSUVIS is approved under Section 505(b)(2), its approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell INVELTYS or our product candidates, including EYSUVIS, 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 or any other 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, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister of the United Kingdom has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption..

Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. 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 INVELTYS or our product candidates, including EYSUVIS, 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 INVELTYS or for any of our products for which we or our collaborators 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 INVELTYS in accordance with its approved label 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 FDCA 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.

Under the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which required that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency must identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order included a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, the administration indicated that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations. More recently, on October 9, 2019, the President issued another executive order ("Executive Order on Promoting the Rule of Law Through Improved Agency Guidance Documents"). The order is meant to ensure that agency guidance documents do not establish legally binding requirements and it directs each agency to rescind guidance documents that it determines should no longer be in effect. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Inadequate funding for the FDA, the Securities and Exchange Commission and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission, or the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, the FDA has announced that in order to bring new therapies to patients sick with COVID-19 as quickly as possible, it has redeployed medical and regulatory staff from other areas to work on COVID-19 therapies. Although the FDA has set a PDUFA goal date of October 30, 2020 for the completion of its review of our NDA for EYSUVIS, it is unknown whether the demands and operational restrictions placed on the FDA by COVID-19 will delay the FDA's review of the NDA. Additionally, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government 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.

Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 INVELTYS, and will play a primary role in the recommendation and prescription and use of any product candidates for which we obtain marketing approval, including EYSUVIS. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute INVELTYS and any products for which we obtain marketing approval, including EYSUVIS. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. 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 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 INVELTYS or any product candidate, including EYSUVIS, 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. Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- a new Medicare Part D coverage gap discount program, in which participating manufacturers must agree to offer 70% point-of-sale discounts off negotiated drug prices during the coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs; and
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, 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 new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for INVELTYS and for any of our product candidates for which we may obtain regulatory approval or the frequency with which INVELTYS or any product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for 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, which was signed by the President 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. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provision. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, the Centers for Medicare & Medicaid Services, or CMS, has recently 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. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On April 27, 2020, however, the United States Supreme Court reversed the federal circuit decision upholding Congress' denial of such risk corridor funding.

Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. The Trump Administration represented to the Court of Appeals considering this judgment that it does not oppose the lower court's ruling. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. In those arguments, the Trump administration argued in support of upholding the lower court decision. On December 18, 2019, that court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. On March 3, 2020, the U.S. Supreme Court agreed to hear the case. On June 25, 2020, the Trump Administration and a coalition of 18 states asked the court to strike down the entirety of the ACA. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

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 Trump 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. Finally, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our products and product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent product labeling and post-marketing testing and other requirements with respect to INVELTYS or any other product candidate for which we obtain approval.

Specifically, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services (HHS) will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases. In addition, on December 23, 2019, the Trump Administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to the FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, the FDA issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products). Finally, the current presidential administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs.

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.

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

Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or 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, and the CARES Act was enacted on March 27, 2020. Both 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 and the CARES Act 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 or the CARES Act.

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, 2019, we had federal net operating loss, or NOL, carryforwards of $168.8 million, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030. At December 31, 2019, we also had state NOL carryforwards of $171.8 million, which may be available to offset future state income tax liabilities and expire at various dates beginning in 2030. These NOL carryforwards could expire unused and be unavailable to offset our future income tax liabilities.

In general, under Section 382 of the Code, the amount of benefits from our NOL carryforwards 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 may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of federal NOL carryforwards could be limited. State NOL carryforwards may be similarly limited. 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 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 could expire or otherwise become unavailable to offset future income tax liabilities. As described above 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. To manage our recent 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 or any future expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Furthermore, operational and other restrictions related to COVID-19 may further hamper our ability to grow as needed and/or to manage our growth. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

Despite the implementation of security measures, our internal computer systems and those of our current and any future vendors, contractors or consultants, including any collaborator, are vulnerable to damage from cyber-attacks, computer viruses, worms and other destructive or disruptive software, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber incidents or attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber incidents also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. System failures, accidents, cyberattacks or security breaches could cause interruptions in our operations, it could result in a material disruption of our development programs, the commercialization of our products and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential, personal or proprietary information, we could incur liability, including civil fines and penalties under the General Data Protection Regulation (EU) 2016/679, or GDPR, HIPAA and other relevant state and federal privacy laws in the United States and abroad, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. In addition, we may not have adequate insurance coverage to provide compensation for any losses associated with such events.

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

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders, 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, 2020, our executive officers and directors and principal stockholders in the aggregate, owned shares representing approximately 39.50% of our capital stock, based on the most recent institutional shareholder 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 obtaining FDA approval of EYSUVIS;
- our success in commercializing INVELTYS and, if approved, EYSUVIS and other product candidates;
- results of clinical trials of any of our product candidates, including EYSUVIS;
- 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 INVELTYS, EYSUVIS, if approved, 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 INVELTYS, or if we cannot obtain regulatory approvals for or otherwise fail to successfully develop or commercialize EYSUVIS or our other 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 3, 2020, we had outstanding 56,059,865 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 now required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will 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 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 Athyrium Credit Facility 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.

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

Sales of Unregistered Securities

On April 15, 2020, we granted stock options to two new employees to purchase 8,000 shares of our common stock at an exercise price of $9.35 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	-	Amended and Restated Sales Agreement, dated May 7, 2020, by and between the Registrant and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 (File No. 333-238087) filed on May 7, 2020).
EXHIBIT 10.2*+	-	Fifth Amendment to Exclusive License Agreement, date July 6, 2020, by and between the Johns Hopkins University and the Registrant.
EXHIBIT 10.3+	-	Form of Employee Restricted Stock Unit Award under 2017 Equity Incentive Plan
EXHIBIT 10.4	-	2017 Equity Inventive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-38150) filed on June 26, 2020).
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).

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* Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
+ Filed herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KALA PHARMACEUTICALS, INC.

Dated: August 6, 2020	By: /s/ Mark Iwicki Mark Iwicki Chairman of the Board, Chief Executive Officer and President (Principal Executive Officer)
Dated: August 6, 2020	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) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

Exhibit 10.2

FIFTH AMENDMENT
TO EXCLUSIVE LICENSE AGREEMENT

This Fifth Amendment to Exclusive License Agreement (the "Fifth Amendment") is entered into by and between The Johns Hopkins University, a Maryland corporation having an address at 1812 Ashland Avenue, Suite 100, Baltimore, MD 21205 ("JHU") and Kala Pharmaceuticals, Inc., a Delaware corporation having an address at 490 Arsenal Way, Suite 120, Watertown, MA 02472 ("Kala" or "Company").

WHEREAS, Kala and JHU entered into an Exclusive License Agreement dated November 10, 2009 (JHU Agmt No. [**]), as amended by a first amendment (JHU Agmt. No. [**]) dated November 19, 2012 (the "First Amendment"), a second amendment (JHU Agmt. No. [**]) effective May 22, 2014 (the "Second Amendment"), a third amendment (JHU Agmt. No. [**]) effective August 26, 2014 (the "Third Amendment"), a Settlement and License Agreement between JHU, Kala and Graybug Vision, Inc. (formerly known as GrayBug, LLC and GrayBug, Inc.) ("Graybug") that provided certain further amendments (JHU Agmt. No. [**]) effective October 24, 2014 (the "S&L Agreement"), a Side Agreement between JHU, Kala and Graybug dated October 24, 2014 (JHU Agmt. No. [**]) to further clarify the S&L Agreement (the "Side Agreement"), and a fourth amendment (JHU Agmt. No. [**]) effective June 22, 2018 (the "Fourth Amendment") (as so amended, the "Agreement"); and

WHEREAS, in 2015, Graybug obtained rights in JHU Ref. [**] as a Side Patent Right through the Side Agreement as a Rights Holding Party, and such rights were deemed to be Current Patent Rights under the S&L Agreement and simultaneously granting rights to Kala as a Sublicensee Party under the S&L Agreement; and

WHEREAS, Graybug provided notice to JHU to terminate its rights in the Current Patent Rights under JHU Ref. [**] and on December 6, 2017 Graybug's rights in the Current Patent Rights under JHU Ref. [**] were terminated and pursuant to the S&L Agreement, such Graybug Current Patent Rights under JHU Ref. [**] were automatically licensed to Kala exclusively on a royalty-free, sublicensable basis, and such Patent Rights are now Kala Current Patent Rights under the Agreement; and

WHEREAS, pursuant to the S&L Agreement, JHU co-licensed Kala and Graybug under all the patent rights arising from JHU Ref # [**] ("Other JHU Patent Rights"), granting Kala an exclusive, sublicensable, worldwide license in the field of use of a Particle for delivery of a biologically active material through mucus, mucin, or a mucosal barrier where such delivery does not involve administration via injection to the eye ("Kala Field"), and granting Graybug an exclusive, sublicensable, worldwide license in the field of use of a particle for delivery of a biologically active material to the eye via injection, excluding any particle comprising or consisting of loteprednol etabonate ("Graybug Field");

WHEREAS, Graybug terminated its license under each of the Other JHU Patent Rights, such that since August 5, 2017, only Kala retains a license to each of the Other JHU Patent Rights and pursuant to Section 2(b) of the S&L Agreement, and each of the Other JHU Patent Rights becomes Kala-Licensed Other JHU Patent Right to which Kala currently has an exclusive, sublicensable, worldwide license in both the Kala Field and the Graybug Field, and Kala currently pays all patent costs associated therewith;

WHEREAS, Kala obtained rights in JHU Ref. # [**] as NEW PATENT RIGHTS (hereinafter defined) through the Fourth Amendment to the Agreement, and such NEW PATENT RIGHTS are not subject to the S&L Agreement; and

WHEREAS, a valuable invention entitled [**] (JHU Ref. # [**]) was developed during the course of research conducted by [**] (all hereinafter, "Inventors"), such invention to be added to the Agreement as NEW PATENT RIGHTS; 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 said valuable invention; and

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

WHEREAS, the parties wish to amend the Agreement to add the invention and update the patents and patent applications listed on Exhibit D 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. **Terms.** Capitalized terms in this Fifth Amendment shall have the same meaning as those in the Agreement, unless specifically defined in this Fifth Amendment. All section and paragraph references refer to sections or paragraphs as applicable, in the Agreement. References to the term "Agreement" in the Agreement shall be deemed to include the Fifth Amendment.

2. **Effective Date**. This Fifth Amendment shall be effective as of the date the last party hereto has executed this Fifth Amendment (the "Fifth Amendment Date").

3. **Agreement Second Whereas Recital.** As of the Fifth Amendment Date, the second "Whereas" recital of the Agreement shall be superseded in its entirety by the following:

   "WHEREAS, a valuable invention entitled [**] (JHU Ref. # [**]) was developed during the course of research conducted by [**], and a valuable invention entitled [**] (JHU Ref. # [**]) was developed during the course of research conducted by [**], and a valuable invention entitled [**] (JHU Ref. [**]) was developed during the course of research conducted by [**], and a valuable invention entitled [**] (JHU Ref. #[**]) was developed during the course of research conducted by [**], and a valuable invention entitled [**] (JHU Ref. #[**]) was developed during the course of research conducted by [**], and a valuable invention entitled [**] (JHU Ref. #[**]) was developed during the course of research conducted by [**], and a valuable invention entitled [**] (JHU Ref. #[**]) was developed during the course of research conducted by [**], and a valuable invention entitled [**] (JHU Ref. # [**]) was developed during the course of research by [**], and a valuable invention entitled [**] (JHU Ref. #[**]) was developed during the course of research conducted for Company by: [**]; and conducted for JHU by: [**], and a valuable invention entitled [**] (JHU Ref. #[**]) was developed during the course of research by [**], and a valuable invention entitled [**] (JHU Ref. # [**]) was developed during the course of research by [**] (all inventors officially affiliated with JHU hereinafter, "Inventors"); and"

4. **Agreement Section 1.10**. As of the Fifth 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 KALA CURRENT PATENT RIGHT (JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref# [**]), and for KALA/JHU JOINTLY OWNED PATENT RIGHTS (JHU Ref # [**]), and for NEW PATENT RIGHTS (JHU Ref # [**], and JHU Ref. # [**]) (all such patent applications for JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref # [**], JHU Ref. # [**], JHU Ref # [**], 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.

5. **Agreement Section 1.15**. As of the Fifth Amendment Date, Section 1.15 shall be added to the Agreement as follows:

   1.15 "**NEW PATENT RIGHTS**" shall mean the patent applications and issued patents listed on EXHIBIT D for JHU Refs. # [**] and # [**] and all continuations, divisions, claims of continuations-in-part applications directed to subject matter specifically described in the patent applications listed on EXHIBIT D for JHU Refs. # [**] and # [**], continued prosecution applications, reissues, reexaminations, extensions and supplemental protection certificates thereof, for which the financial terms and considerations remain subject to the provisions of the Agreement and its Amendments, expressly excluding the provisions of Amendment 2 and the S&L Agreement.

6. **Amendment of Exhibit A; Change to Milestone Provision**. As of the Fifth Amendment Date, the first sentence of the paragraph at the end of Section 5 of Exhibit A of the Agreement shall be superseded in its entirety by the following:

Each milestone payment shall be paid for the first four (4) LICENSED PRODUCTS to achieve such milestone and no milestone payments shall be required for subsequent LICENSED PRODUCTS. For clarity, milestone payments for LICENSED PRODUCTS developed solely under NEW PATENT RIGHTS shall not be subject to the provisions of Amendment 2 and the S&L Agreement, provided however that LICENSED PRODUCTS that are developed under a combination of KALA CURRENT PATENT RIGHTS, KALA/JHU JOINTLY OWNED PATENT RIGHTS and NEW PATENT RIGHTS shall be subject to the provisions of Amendment 2 and the S&L Agreement. Milestone payments for the second, third and fourth LICENSED PRODUCTS shall be reduced by [**]%.

7. **Amendment of Exhibit A; Addition of Diligence Timelines for Milestones.** As of the Fifth Amendment Date, a Section 6 entitled "Diligence Timelines for Milestones for JHU Ref. [**]" shall be added to Exhibit A of the Agreement as follows:

"6. **Diligence Timelines for Milestones for JHU Ref. [**]**. Company shall have completed the following milestones of Section 5 of Exhibit A targeting the specified time from the Fifth Amendment Date of this Agreement (each a "DILIGENCE TIMELINE").

Diligence Timelines for JHU Ref. [**]

Achieved	Milestone for JHU Ref. [**]
[**] from the Fifth Amendment Date	[**]
[**] from the Fifth Amendment Date	[**]
[**] from the Fifth Amendment Date	[**]
[**] from the Fifth Amendment Date	[**]

Company shall achieve the milestones as set forth above in the Diligence Timelines for JHU Ref. [**] and shall notify JHU of the achievement of each milestone within [**] of achieving them.

(i) **Extension of Diligence Timelines.** Company may request, in writing, an extension of the period for achieving a milestone set forth in the Diligence Timelines for JHU Ref. [**] by up to [**] unless the parties agree otherwise. JHU will grant the requested extension provided (i) Company has diligently pursued achievement of the milestone; and (ii) Company remits with the request the milestone payment amount due upon achievement of the delayed milestone, if any. The extension of a milestone shall automatically extend the deadline for subsequent milestones of the Diligence Timelines for JHU Ref. [**] respecting the same subject matter by like amount. Company may seek extensions for a milestone no more than [**] during the term of this Agreement.

(ii) **Failure to Achieve Diligence Milestone.** Failure to achieve a milestone within the timeline as set forth in the Diligence Timelines for JHU Ref. [**], with any extensions thereof, is considered a material breach of this Agreement with respect to JHU Ref. No. [**], and JHU may terminate Company's PATENT RIGHTS with respect to JHU Ref.

[**], upon [**] written notice, provided that Company does not cure such breach prior to expiration of such [**] period."

8. **Amendment of Exhibit D; PATENT RIGHTS.** As of the Fifth Amendment Date, Exhibit D of the Agreement shall be superseded in its entirety by the updated Exhibit D attached hereto and shall include the following additional NEW PATENT RIGHTS and associated PATENT RIGHTS:

    - JHU Ref. # [**], entitled, [**] (the "NEW PATENT RIGHTS").

9. **Patent Reimbursement.** In accordance with Paragraph 3.6 of the Agreement, Company will reimburse JHU for the costs of preparing, filing, maintaining and prosecuting the NEW PATENT RIGHTS added to the Agreement pursuant to this Fifth Amendment incurred prior to the Fifth Amendment Date ("Prior New Patent Costs"). Promptly after the Fifth Amendment Date, JHU will send Company an invoice for Prior New Patent Costs, and Company will pay said invoice within [**] of Company's receipt of the invoice. Company will reimburse JHU, within [**] of the receipt of an invoice from JHU, for all costs incurred after the Fifth Amendment Date associated with the ongoing preparation, filing, maintenance, and prosecution of PATENT RIGHTS.

10. **Amendment and License Fee.** Company shall pay to JHU, [**] dollars ($[**]) as an amendment and license fee (the "Fifth Amendment Fee") within [**] of the Fifth Amendment Date. JHU is not required to submit an invoice for the Fifth Amendment Fee, which shall not be credited against royalties or other fees.

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

12. **Counterparts.** Signatures to this Fifth Amendment may be executed by way of facsimile or electronic signature, and such signatures shall be considered original. Signatures transmitted by email, portable document format (.pdf), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Fifth Amendment shall have the same effect as the physical delivery of a paper document bearing the original signatures. All facsimile or electronic copies of this Fifth Amendment will be deemed to be duplicate originals. This Fifth Amendment may be executed simultaneously in any number of counterparts, any one of which need not contain the signature of more than one Party, but all of which shall be deemed an original and all such counterparts taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, this Fifth Amendment shall take effect as of the Fifth Amendment Date when it has been executed below by the duly authorized representatives of both parties.

THE JOHNS HOPKINS UNIVERSITY	**KALA PHARMACEUTICALS, INC**.
By: /s/ Steven L. Kousouris ___________	By : /s/ Eric Trachtenberg _______________
Name: Steven L. Kousouris	Name: Eric Trachtenberg
Title: Executive Director	Title: General Counsel, Chief Compliance Officer & Corporate Secretary
Date: July 6, 2020 ______________________	Date: July 6, 2020 __________________

Exhibit 10.3

KALA PHARMACEUTICALS, INC.
RESTRICTED STOCK UNIT AWARD

Kala Pharmaceuticals, Inc. (the "***Company***") hereby grants the following Restricted Stock Units pursuant to its 2017 Equity Incentive Plan (the "***Plan***"). The terms of the grant are set forth in the attached Restricted Stock Unit Award Agreement (the "***Agreement***").

<u>NOTICE OF GRANT</u>

Participant:	[____]
Date of Grant:	[____]
Number of Restricted Stock Units:	[____]
Vesting Commencement Date:	**[____]**
Vesting:	[____]

All vesting is dependent on the Participant continuing to be employed by, or provide services to, the Company, as provided herein, through the relevant vesting date.

The above is a summary description of certain provisions of the Agreement and is not intended to be complete. In the event any aspect of this summary conflicts with the terms of the Agreement, the terms of the Agreement shall govern.

Kala Pharmaceuticals, Inc.

By:___________________________
Title:_________________________

I hereby accept the Restricted Stock Units described in the Agreement, and I agree to be bound by the terms of the Plan and the Agreement. I hereby further agree that all the decisions and determinations of the Committee shall be final and binding.

Participant:___________________________

Date:______________________________

KALA PHARMACEUTICALS, INC.

2017 EQUITY INCENTIVE PLAN

RESTRICTED STOCK UNIT AWARD AGREEMENT

This **RESTRICTED STOCK UNIT AWARD AGREEMENT** (the "***Agreement***"), dated as of date set forth on the Notice of Grant attached hereto (the "***Date of Grant***"), is delivered by Kala Pharmaceuticals, Inc. (the "***Company***") to the individual named on the Notice of Grant attached hereto (the "***Participant***").

RECITALS

A. The Kala Pharmaceuticals Inc. 2017 Equity Incentive Plan (the "***Plan***") provides for the grant of stock-based awards with respect to shares of Common Stock of the Company, in accordance with the terms and conditions of the Plan. The Company has decided to make a Restricted Stock Unit award as an inducement for the Participant to promote the best interests of the Company and its stockholders.

B. The terms and conditions of the Restricted Stock Units should be construed and interpreted in accordance with the terms and conditions of this Agreement and the Plan. The Plan is administered and interpreted by the Compensation Committee of the Board of Directors of the Company (the "***Board***") (or a subcommittee thereof), or such other committee of the Board (including, without limitation, the full Board) to which the Board has delegated power to act under or pursuant to the provisions of the Plan (the "***Committee***"). The Committee may delegate authority to one or more subcommittees as it deems appropriate. If a subcommittee is appointed, all references in this Agreement to the "Committee" shall be deemed to refer to the committee. Capitalized terms that are used but not defined herein shall have the respective meanings accorded to such terms in the Plan. For purposes of this Agreement, "Company" shall mean the Company and any of its Subsidiaries where applicable.

NOW, THEREFORE, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1. **Grant of Restricted Stock Units**. Subject to the terms and conditions set forth in this Agreement and the Plan, the Company hereby awards to the Participant the number of Restricted Stock Units (as defined in the Plan) under the Plan as set forth on the Notice of Grant attached hereto. The Participant accepts the Restricted Stock Units and agrees to be bound by the terms and conditions of this Agreement and the Plan with respect to the award. Each vested Restricted Stock Unit entitles the Participant to receive the one share of Common Stock, as described in Paragraph 2 below.

2. **<u>Vesting of Award/Payment of Shares</u>.**

(a) The Restricted Stock Units shall vest according to the following vesting schedule, if the Participant continues to be employed by, or provide service to, the Company (or one of its Subsidiaries) until the applicable vesting date (each, a "***Vesting Date***"):

<u>Number of Restricted Stock Units Subject to Vesting Condition</u>	**<u>Vesting Commencement Date</u>**	**<u>Vesting Condition/Date</u>**	**<u>% of Restricted Stock Units Subject to Condition Vested</u>**

(b) If and when the Restricted Stock Units vest, the Company will issue to the Participant one share of Company Common Stock for each whole Restricted Stock Unit that has vested, subject to satisfaction of the Participant's tax withholding obligations as described in Section 5 below. In the event that the percentage listed above would result in the vesting of partial shares, the number of Restricted Stock Units that vest on the applicable Vesting Date shall be rounded down to the nearest share. The shares of Common Stock will be issued to the Participant as soon as practicable following the Vesting Date, but in any event within 30 days of such date. The Restricted Stock Units shall cease to be outstanding upon such issuance of shares.

(c) Unless otherwise provided in a Company-sponsored plan, policy or arrangement, or any agreement to which the Company is a party, the Participant shall forfeit the unvested Restricted Stock Units in the event the Participant ceases to be employed by, or provide service to, the Company (or one of its Subsidiaries) prior to the Vesting Date.

(d) [Notwithstanding the foregoing, upon the consummation of a Change in Control Event (as defined below) prior to a Vesting Date, the Restricted Stock Units shall immediately vest.][1]

(e) [For purposes of this Agreement a "***<u>Change in Control Event</u>***" is the occurrence of any of the following events: (i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934 (the "***<u>Exchange Act</u>***")) (a "***<u>Person</u>***") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) fifty percent (50%) or more of either (x) the then-outstanding shares of common stock of the Company (the "***<u>Outstanding Company Common Stock</u>***") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors

[1] Include only in RSU agreement for executive officers

(the "***Outstanding Company Voting Securities***"); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control Event: (1) any acquisition directly from the Company or (2) any acquisition by any entity pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (iii) of this definition; or (ii) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "***Continuing Director***" means at any date a member of the Board (x) who was a member of the Board on the date of the initial adoption of the Plan by the Board or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; provided, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or (iii) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company, or a sale or other disposition of all or substantially all of the assets of the Company (a "***Business Combination***"), unless, immediately following such Business Combination, each of the following two (2) conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one (1) or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "***Acquiring Corporation***") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, fifty percent (50%) or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or (iv) the liquidation or dissolution of the Company.][2]

3. **No Stockholder Rights Prior to Settlement; Issuance of Certificates**. The Participant shall have no rights as a stockholder with respect to any shares of Common Stock represented by the Restricted Stock Units until the date of issuance of the shares of Common Stock (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), if applicable. Except as otherwise required by the Plan, no adjustment shall be made for dividends, distributions, or other rights for which the record date is prior to the date, if any, that shares of Common Stock are issued.

[2] Include only in RSU agreement for executive officers

4. **Withholding**. All obligations of the Company under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for any taxes, if applicable. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other taxes of any kind required by law to be withheld which arise in connection with the Participant's Restricted Stock Units (the "***Withholding Taxes***"). [ALTERNATIVE 1: Additionally, (a) the Company may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to the Participant's Restricted Stock Units by requiring the Participant to tender a cash payment, and (b) unless otherwise determined by the Board or Committee, the Participant may elect to satisfy all or any portion of the Withholding Taxes obligation by (i) entering into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby the Participant irrevocably elects to sell a portion of the shares to be delivered under the Agreement to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company; or (ii) electing to have shares of Common Stock withheld by the Company from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Restricted Stock Units with a fair market value (valued in the manner determined by (or in a manner approved by) the Company) equal to the amount of such Withholding Taxes; provided, however, that the number of such shares of Common Stock so withheld shall not exceed the amount necessary to satisfy the Company's required tax withholding obligations up to the maximum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income.] [ALTERNATIVE 2: At such such time as the Participant is not aware of any material nonpublic information about the Company or the Common Stock and is not prohibited from doing so by the Company's insider trading policy or otherwise, the Participant shall execute the instructions set forth in Schedule A attached hereto (the "***Automatic Sale Instructions***") as the means of satisfying the Withholding Taxes. If the Participant does not execute the Automatic Sale Instructions prior to an applicable vesting date, then the Participant agrees that if under applicable law the Participant will owe taxes at such vesting date on the portion of the award then vested the Company shall be entitled to immediate payment from the Participant of the amount of any tax required to be withheld by the Company.] [ALTERNATIVE 3: The Participant acknowledges and agrees that the withholding shall be satisfied by the Company retaining from the number of shares of Common Stock otherwise issuable to the Participant on the applicable vesting date or event a number of shares of Common Stock having a fair market value (valued in the manner determined by (or in a manner approved by) the Company) equal to the amount of such Withholding Taxes; provided, however, that the number of such shares of Common Stock so withheld shall not exceed the amount necessary to satisfy the Company's required tax withholding obligations up to the maximum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income.] Unless the tax withholding obligations of the Company are satisfied, the Company shall have no obligation to deliver to the Participant any Common Stock. In the event the Company's obligation to withhold arises prior to the delivery to the Participant of Common Stock or it is determined after the delivery of Common Stock to the Participant that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, the Participant agrees to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

5. **<u>Adjustments or Reorganization Event</u>**. The provisions of the Plan applicable to adjustments or a Reorganization Event (as described in Section 9 of the Plan) or other corporate transaction, shall apply to the Restricted Stock Units. Notwithstanding anything in the Plan to the contrary, in no event shall the Committee exercise its discretion to accelerate the payment or settlement of the Restricted Stock Units where such payment or settlement constitutes deferred compensation within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***") unless, and solely to the extent that, such accelerated payment or settlement is permissible under Treasury Regulation section 1.409A-3(j)(4) or any successor provision.

6. **<u>Grant Subject to Plan Provisions</u>**. This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The Restricted Stock Units are subject to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan. The Committee shall have the authority to interpret and construe the Restricted Stock Units pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

7. **<u>No Employment or Other Rights</u>**. The grant of the Restricted Stock Units shall not confer upon the Participant any right to be retained by or in the employ or service of the Company (or any of its Subsidiaries) and shall not interfere in any way with the right of the Company (or any of its Subsidiaries) to terminate the Participant's employment or service at any time. The right of the Company (or any of its Subsidiaries) to terminate at will the Participant's employment or service at any time for any reason is specifically reserved.

8. **<u>Delivery Subject to Legal Requirements</u>**. The obligation of the Company to deliver stock shall be subject to the condition that if at any time the Board shall determine in its discretion that the listing, registration or qualification of the shares upon any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the issue of shares, the shares may not be issued in whole or in part unless such listing, registration, qualification, consent or approval shall have been effected or obtained free of any conditions not acceptable to the Board. The issuance of shares to the Participant pursuant to this Agreement is subject to any applicable taxes and other laws or regulations of the United States or of any state having jurisdiction thereof.

9. **<u>Clawback</u>**. In accepting the grant of Restricted Stock Units, the Participant agrees to be bound by any clawback policy that the Company may currently have in place or may adopt in the future.

10. **<u>Assignment and Transfers</u>**. The rights and interests of the Participant under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Participant, by will or by the laws of descent and distribution. In the event of any attempt by the Participant to alienate, assign, pledge, hypothecate, or otherwise dispose of the Restricted Stock Units or any right hereunder, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Restricted Stock Units by notice to the Participant, and the Restricted Stock Units and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the

Company's parents, Subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Participant's consent.

11. **Applicable Law**. The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflict of laws provisions thereof.

12. **Notice**. Any notice to the Company provided for in this Agreement shall be addressed to the Company in care of the Committee, and any notice to the Participant shall be addressed to such Participant at the current address shown on the payroll of the Company, or to such other address as the Participant may designate to the Company in writing. Any notice shall be delivered by hand, sent by telecopy or enclosed in a properly sealed envelope addressed as stated above, deposited, postage prepaid, in a post office regularly maintained by the United States Postal Service.

13. **Section 409A**. This Agreement and the Restricted Stock Units granted hereunder are intended to fit within the "short-term deferral" exemption from Section 409A of the Code, as set forth in Treasury Regulation Section 1.409A-1(b)(4) or any successor provision, or to comply with, or otherwise be exempt from, Section 409A of the Code. This Agreement and the Restricted Stock Units shall be administered, interpreted and construed in a manner consistent with Section 409A of the Code. Each amount payable under this Agreement is designated as a separate identified payment for purposes of Section 409A of the Code.

14. **Counterparts**. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement. Facsimile or other electronic transmission of any signed original document or retransmission of any signed facsimile or other electronic transmission will be deemed the same as delivery of an original.

15. **Complete Agreement**. Except as otherwise provided for herein, this Agreement and those agreements and documents expressly referred to herein embody the complete agreement and understanding among the parties and supersede and preempt any prior understandings, agreements or representations by or among the parties, written or oral, which may have related to the subject matter hereof in any way. The terms of this Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of the Participant.

16. **Committee Authority**. By entering into this Agreement the Participant agrees and acknowledges that all decisions and determinations of the Committee shall be final and binding on the Participant, his or her beneficiaries and any other person having or claiming an interest in the Award.

Schedule A

Automatic Sale Instructions[3]

[3] To be included solely if Alternative 2 in Section 4 is selected.

The undersigned hereby consents and agrees that any taxes due on a vesting date as a result of the vesting of Restricted Stock Units on such date shall be paid through an automatic sale of shares as follows:

(a) Upon any vesting of Restricted Stock Units pursuant to Section 2 hereof, the Company shall arrange for the sale of such number of shares of Common Stock issuable with respect to the Restricted Stock Units that vest pursuant to Section 2 as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by the Participant upon the vesting of the RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the net proceeds of such sale shall be delivered to the Company in satisfaction of such tax withholding obligations.

(b) The Participant hereby appoints the Chief Executive Officer, the Chief Financial Officer and the Chief Legal Officer, and any of them acting alone and with full power of substitution, to serve as his or her attorneys in fact to arrange for the sale of the Participant's Common Stock in accordance with this Schedule A. The Participant agrees to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the shares pursuant to this Schedule A.

(c) The Participant represents to the Company that, as of the date hereof, he or she is not aware of any material nonpublic information about the Company or the Common Stock and is not prohibited from entering into these Automatic Sale Instructions by the Company's insider trading policy or otherwise. The Participant and the Company have structured this Agreement, including this Schedule A, to constitute a "binding contract" relating to the sale of Common Stock, consistent with the affirmative defense to liability under Section 10(b) of the Securities Exchange Act of 1934 under Rule 10b5-1(c) promulgated under such Act.

The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

____

Participant Name: ______________________________

Date: ____

Exhibit 31.1

CERTIFICATIONS

I, Mark Iwicki, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kala Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2020

By: /s/ Mark Iwicki

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

Exhibit 31.2

CERTIFICATIONS

I, Mary Reumuth, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kala Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2020

By: /s/ Mary Reumuth

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

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Kala Pharmaceuticals, Inc. (the “Company”) for the period ended June 30, 2020 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 6, 2020

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

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Kala Pharmaceuticals, Inc. (the “Company”) for the period ended June 30, 2020 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 6, 2020	/s/ Mary Reumuth
	Mary Reumuth
	Chief Financial Officer
	(Principal Financial and Accounting Officer)