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: 001-36399

ADAMAS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**42-1560076**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1900 Powell Street, Suite 1000, Emeryville, CA, 94608
(Address of principal executive offices) (Zip Code)

(510) 450-3500
(Registrant's telephone number, including area code)

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

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, par value $0.001 per share	**ADMS**	**The Nasdaq Global 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 x 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No x

Number of shares outstanding of the issuer's common stock, par value $0.001 per share, as of July 31, 2020, was 28,281,840.

ADAMAS PHARMACEUTICALS, INC.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ADAMAS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share data)

	June 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 30,538	$ 65,774
Available-for-sale securities	72,876	66,833
Accounts receivable, net	6,608	5,770
Inventory	5,851	5,267
Prepaid expenses and other current assets	7,814	6,676
Total current assets	123,687	150,320
Property and equipment, net	1,989	2,449
Operating lease right-of-use assets	7,351	8,048
Prepaid expenses and other non-current assets	38	1,341
Total assets	$ 133,065	$ 162,158
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable	$ 2,469	$ 6,932
Accrued liabilities	13,694	16,117
Current portion of long-term debt	3,232	2,041
Other current liabilities	1,820	1,858
Total current liabilities	21,215	26,948
Long-term debt	126,300	125,674
Long-term portion of operating lease liabilities	7,364	8,272
Other non-current liabilities	2,595	2,157
Total liabilities	157,474	163,051
Commitments and Contingencies (Note 7)		
Stockholders' deficit		
Preferred stock, $0.001 par value — 5,000,000 shares authorized, and zero shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value — 100,000,000 shares authorized, 28,281,840 and 27,964,778 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	33	33
Additional paid-in capital	450,536	446,942
Accumulated other comprehensive gain	120	16
Accumulated deficit	(475,098)	(447,884)
Total stockholders' deficit	(24,409)	(893)
Total liabilities and stockholders' deficit	$ 133,065	$ 162,158

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ADAMAS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Product sales	$ 17,954	$ 12,691	$ 32,435	$ 24,356
Royalty revenue	840	—	840	—
Total revenues	18,794	12,691	33,275	24,356
Costs and operating expenses:				
Cost of product sales	381	685	953	1,098
Research and development	2,550	8,598	5,015	18,812
Selling, general and administrative, net	23,177	25,216	47,729	52,904
Total costs and operating expenses	26,108	34,499	53,697	72,814
Loss from operations	(7,314)	(21,808)	(20,422)	(48,458)
Interest and other income, net	215	734	299	1,457
Interest expense	(3,467)	(3,797)	(7,091)	(7,528)
Net loss	$ (10,566)	$ (24,871)	$ (27,214)	$ (54,529)
Net loss per share, basic and diluted	$ (0.37)	$ (0.90)	$ (0.97)	$ (1.98)
Weighted average shares used in computing net loss per share, basic and diluted	28,194	27,579	28,112	27,516

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ADAMAS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (10,566)	$ (24,871)	$ (27,214)	$ (54,529)
Other comprehensive income				
Reclassification of realized gain on available-for-sale securities recognized in interest and other income, net	(34)	—	(34)	—
Unrealized gain on available-for-sale securities	81	137	138	367
Total other comprehensive income	47	137	104	367
Comprehensive loss	$ (10,519)	$ (24,734)	$ (27,110)	$ (54,162)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ADAMAS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(unaudited)
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2018	27,434,358	$ 32	$ 432,815	$ (264)	$ (342,698)	$ 89,885
Exercise of stock options	18,230	—	49	—	—	49
Restricted stock units vested	67,391	—	—	—	—	—
Other comprehensive income	—	—	—	230	—	230
Stock-based compensation	—	—	3,410	—	—	3,410
Net loss	—	—	—	—	(29,658)	(29,658)
Balances at March 31, 2019	27,519,979	32	436,274	(34)	(372,356)	63,916
Exercise of stock options	65,064	—	99	—	—	99
Restricted stock units vested	12,860	—	—	—	—	—
Stock issued under employee stock purchase plan	112,304	—	449	—	—	449
Other comprehensive income	—	—	—	137	—	137
Stock-based compensation	—	—	2,973	—	—	2,973
Net loss	—	—	—	—	(24,871)	(24,871)
Balances at June 30, 2019	27,710,207	$ 32	$ 439,795	$ 103	$ (397,227)	$ 42,703

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balances at December 31, 2019	27,964,778	$ 33	$ 446,942	$ 16	$ (447,884)	$ (893)
Exercise of stock options	61,766	—	42	—	—	42
Restricted stock units vested	131,661	—	—	—	—	—
Other comprehensive income	—	—	—	57	—	57
Stock-based compensation	—	—	1,589	—	—	1,589
Net loss	—	—	—	—	(16,648)	(16,648)
Balances at March 31, 2020	28,158,205	33	448,573	73	(464,532)	(15,853)
Restricted stock units vested	28,541	—	—	—	—	—
Stock issued under employee stock purchase plan	95,094	—	223	—	—	223
Other comprehensive income	—	—	—	47	—	47
Stock-based compensation	—	—	1,740	—	—	1,740
Net loss	—	—	—	—	(10,566)	(10,566)
Balances at June 30, 2020	28,281,840	$ 33	$ 450,536	$ 120	$ (475,098)	$ (24,409)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ADAMAS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (27,214)	$ (54,529)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	460	692
Stock-based compensation	3,176	6,323
Accretion of interest expense	7,091	7,528
Change in fair value of embedded derivative liability	438	149
Net accretion of discounts and amortization of premiums of available-for-sale securities	(147)	(675)
Realized gain on available-for-sale securities	(55)	—
Provision for write-down of inventory	340	—
Changes in assets and liabilities		
Accrued interest of available-for-sale securities	236	54
Accounts receivable, net	(838)	(900)
Inventory	(666)	(524)
Prepaid expenses and other assets	165	619
Operating lease right-of-use assets	697	413
Accounts payable	(4,436)	(253)
Current portion of long-term debt	(5,274)	(3,121)
Long-term portion of operating lease liabilities	(810)	(482)
Accrued liabilities and other liabilities	(2,691)	899
Net cash used in operating activities	(29,528)	(43,807)
Cash flows from investing activities		
Purchases of property and equipment		(18)
Purchases of available-for-sale securities	(63,939)	(38,657)
Maturities of available-for-sale securities	40,900	88,000
Sales of available-for-sale securities	17,066	—
Net cash provided by (used in) investing activities	(5,973)	49,325
Cash flows from financing activities		
Proceeds from Paycheck Protection Program Loan	2,650	—
Repayment of Paycheck Protection Program Loan	(2,650)	—
Proceeds from issuance of common stock upon exercise of stock options	42	165
Proceeds from employee stock purchase plan	223	449
Net cash provided by financing activities	265	614
Net increase (decrease) in cash and cash equivalents	(35,236)	6,132
Cash and cash equivalents at beginning of period	65,774	56,605
Cash and cash equivalents at end of period	$ 30,538	$ 62,737
Supplemental disclosure of noncash activities		
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 8,005
Stock-based compensation capitalized in inventory	$ 153	$ 60

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ADAMAS PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. DESCRIPTION OF BUSINESS

Adamas Pharmaceuticals, Inc. (the "Company") is a commercial-stage pharmaceutical company focused on supporting its patient community and growing a portfolio of therapies to reduce the burden of neurological diseases on patients, caregivers, and society. In August 2017, the U.S. Food and Drug Administration (FDA) approved GOCOVRI® (amantadine) extended release capsules, the first and only FDA-approved medication indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

The Company was incorporated in the State of Delaware on November 15, 2000, and operates as one segment. The Company's headquarters and operations are located in Emeryville, California.

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, these financial statements include all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair statement of the Company's condensed consolidated financial statements for the periods presented. The condensed consolidated balance sheet at December 31, 2019 was derived from the audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP.

These interim financial results are not necessarily indicative of results to be expected for the full fiscal year ending December 31, 2020, or any other future period. Readers should read these interim unaudited condensed consolidated financial statements in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2019, included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC. The Company's critical accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2019. The Company's critical accounting policies have not changed materially from December 31, 2019.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in the consolidated financial statements and the accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition and variable consideration, lease assets and liabilities, clinical trial accruals, fair value of assets and liabilities including short-term and long-term classification, embedded derivatives, income taxes, inventory, and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results may differ from those estimates.

Risks and Uncertainties

The outbreak of the novel Coronavirus ("COVID-19"), which is understood to have begun in December 2019, continues to grow both within the U.S. and globally. The World Health Organization has declared the outbreak of COVID-19 to be a pandemic, and the U.S. federal government has declared it a national emergency. The Company is subject to risks and uncertainties as a result of the outbreak of COVID-19. Despite disruptions to the Company's business operations, the COVID-19 pandemic did not significantly impact GOCOVRI prescription refill rates for the three and six months ended June 30, 2020, and thus far management has observed no disruptions to its inventory on hand

or planned manufacturing schedule. However, new prescription rates have slowed due to several factors, including: many healthcare providers have temporarily closed their offices or are restricting patient visits; patients are postponing visits to healthcare provider facilities; and the sales force has moved to conducting activities virtually with healthcare providers. While management believes this decline in new prescriptions to be temporary, the duration and severity is dependent on future developments, including new information that may emerge concerning the actions taken to contain or prevent further spread, all of which are highly uncertain and cannot be predicted with confidence.

As of the date of issuance of these condensed consolidated financial statements, due to the numerous uncertainties surrounding the COVID-19 pandemic, the Company is unable to predict the extent to which the COVID-19 pandemic may materially adversely affect the Company's future business, financial results, liquidity and cash flows.

Liquidity

Since January 1, 2017, the Company has funded its operations primarily through a royalty-backed loan agreement ("Royalty-Backed Loan") with HealthCare Royalty Partners III, L.P., ("HCRP"), sales of GOCOVRI, and sales of its common stock. In 2017, the Company entered into a Royalty-Backed Loan with HCRP, whereby the Company borrowed a total of $100.0 million. The Company made GOCOVRI available for physician and patient use in the fourth quarter of 2017, with a full commercial launch in January 2018. In January 2018, the Company completed a follow-on public offering of its common stock from which proceeds raised were approximately $134.3 million, net of underwriting discounts, commissions, and offering-related transaction costs. Prior to the generation of revenue from GOCOVRI, the Company had not generated any commercial revenue from the sale of its products.

In November 2019, the Company entered into a sales agreement with Cowen and Company, LLC, pursuant to which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50.0 million. As of June 30, 2020, no shares had been sold under the sales agreement.

As of June 30, 2020, the Company had $103.4 million of cash, cash equivalents, and investments, which management believes will be sufficient to fund its projected operating requirements, including commercialization of GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease and operations related to activities for ADS-5102 for MSW, for at least 12 months from the issuance of this quarterly report on Form 10-Q. However, it is possible that the Company will not achieve the progress it expects, because revenues from GOCOVRI may be less than anticipated, especially in light of the current COVID-19 pandemic.

Recent Accounting Pronouncements

Accounting Pronouncements Adopted in 2020

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value measurements. The Company adopted the new guidance effective January 1, 2020, and determined the adoption did not have a material impact on its consolidated financial statements. Disclosures are updated in Note 3 "Fair Value Measurements".

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which amends ASC 808 to clarify ASC 606 should apply in entirety to certain transactions between collaborative arrangement participants. The Company adopted the new guidance effective January 1, 2020, and determined the adoption did not have a material impact on its consolidated financial statements.

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments;* in November 2018 the FASB issued a subsequent amendment ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*; in April 2019 the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*; in May 2019 the FASB issued ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief*; and in November 2019 the FASB issued ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*. The new guidance changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are

recorded. In November 2019 the FASB issued ASU No. 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)—Effective Dates*, which defers the effective date of ASU 2016-13 for all entities except SEC reporting companies that are not smaller reporting companies. As a smaller reporting company, this guidance is effective for fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company is currently evaluating the timing and effect the new guidance will have on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes*, which is intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating but does not expect the new guidance to have a material impact on its consolidated financial statements.

3. FAIR VALUE MEASUREMENTS

In accordance with ASC 820-10, Fair Value Measurements and Disclosures, the Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1 inputs, which include quoted prices in active markets for identical assets or liabilities;
- Level 2 inputs, which include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability. For available-for-sale securities, the Company reviews trading activity and pricing as of the measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data; and
- Level 3 inputs, which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies, or similar valuation techniques, as well as significant management judgment or estimation.

The following table represents the fair value hierarchy for the Company's financial assets and liabilities which require fair value measurement on a recurring basis (in thousands):

	June 30, 2020			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market	$ 10,954	$ 10,954	$ —	$ —
Corporate debt	13,792	—	13,792	—
U.S. Treasury securities	59,084	—	59,084	—
Commercial paper	—	—	—	—
Total assets measured at fair value	$ 83,830	$ 10,954	$ 72,876	$ —
Liabilities:				
Embedded derivative liability	$ 2,595	$ —	$ —	$ 2,595
Total liabilities measured at fair value	$ 2,595	$ —	$ —	$ 2,595

	December 31, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market	$ 27,720	$ 27,720	$ —	$ —
Corporate debt	22,576	—	22,576	—
U.S. Treasury securities	37,811	—	37,811	—
Commercial paper	10,928	—	10,928	—
Total assets measured at fair value	$ 99,035	$ 27,720	$ 71,315	$ —
Liabilities:				
Embedded derivative liability	$ 2,157	$ —	$ —	$ 2,157
Total liabilities measured at fair value	$ 2,157	$ —	$ —	$ 2,157

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

Corporate debt, U.S. Treasury securities, and commercial paper are measured at fair value using Level 2 inputs. The Company reviews trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy. In certain cases where there is limited activity or less transparency around inputs to valuation, the related assets or liabilities are classified as Level 3. The Company classified an embedded derivative related to the Company's Royalty-Backed Loan with HCRP as a Level 3 liability.

The fair value of the embedded derivative as a result of a change in control was calculated using a probability-weighted discounted cash flow model. The model used in valuing this embedded derivative requires the use of significant estimates and assumptions including but not limited to: 1) expected cash flows the Company expects to receive on U.S. net sales of GOCOVRI and on royalties from Allergan on U.S. net sales of Namzaric; 2) the Company's risk adjusted discount rates; and 3) the probability of a change in control occurring during the term of the note based on the percentage of similar companies that were acquired over the previous five year period. Changes in the estimated fair value of the bifurcated embedded derivative are reported as gains or losses in interest and other income, net, in the condensed consolidated statement of operations. In the periods presented, the Company evaluated the embedded derivative value as a result of an event of default and the value as a result of increased costs due to a regulatory change and considered both to have no material value based on current assessment of probability, but could become material in future periods if a specified event of default or regulatory change became more probable than is currently estimated. See Note 8 "Long-Term Debt" for further description.

At June 30, 2020, the embedded derivative related to the Royalty-Backed Loan was the only recurring fair value measurement with Level 3 unobservable inputs. A risk-adjusted discount rate of 19.6% and a probability of a change in control of 3.0% were applied to calculate the value of the embedded derivative. Significant increases (or decreases) in the discount rate, and significant increases (or decreases) in the probability of a change in control would result in a significantly higher (or lower) fair value measurement.

The following table sets forth changes in Level 3 liabilities measured at fair value on a recurring basis 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
Beginning balance	$ 2,498	$ 1,453	$ 2,157	$ 1,352
Change in fair value included in interest and other income, net	97	48	438	149
Ending balance	$ 2,595	$ 1,501	$ 2,595	$ 1,501

There were no transfers into or out of Level 3 during the three and six months ended June 30, 2020 and 2019.

4. INVESTMENTS

The Company's investments consist of corporate debt, U.S. Treasury securities, and commercial paper classified as available-for-sale securities.

The Company limits the amount of investment exposure as to institution, maturity, and investment type. To mitigate credit risk, the Company invests in investment grade corporate debt, U.S. Treasury securities, and commercial paper. Such securities are reported at fair value, with unrealized gains and losses excluded from earnings and shown separately as a component of accumulated other comprehensive loss within stockholders' equity. Realized gains and losses are reclassified from other comprehensive loss to other income on the condensed consolidated statements of operations when incurred. The Company may pay a premium or receive a discount upon the purchase of available-for-sale securities. Interest earned and gains realized on available-for-sale securities and amortization of discounts received and accretion of premiums paid on the purchase of available-for-sale securities are included in investment income.

The following table is a summary of amortized cost, unrealized gain and loss, and the fair value of available-for-sale securities as of June 30, 2020 and December 31, 2019 (in thousands):

	June 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Investments:				
Corporate debt	$ 13,718	$ 74	$ —	$ 13,792
U.S. Treasury securities	59,038	47	(1)	59,084
Commercial paper				—
Total	$ 72,756	$ 121	$ (1)	$ 72,876
Reported as:				
Short-term investments	$ 72,756	$ 121	$ (1)	$ 72,876
Total	$ 72,756	$ 121	$ (1)	$ 72,876

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Investments:				
Corporate debt	$ 22,582	$ 3	$ (9)	$ 22,576
U.S. Treasury securities	37,789	22	—	37,811
Commercial paper	6,446	—	—	6,446
Total	$ 66,817	$ 25	$ (9)	$ 66,833
Reported as:				
Short-term investments	$ 66,817	$ 25	$ (9)	$ 66,833
Total	$ 66,817	$ 25	$ (9)	$ 66,833

Short-term investments include accrued interest of $0.2 million and $0.4 million as of June 30, 2020 and December 31, 2019, respectively. For both the three and six months ended June 30, 2020, there were gross realized gains on investments of $55,000 and no gross realized losses. There were no gross realized gains or losses on investments for the three and six months ended June 30, 2019. Realized gains are reflected in interest and other income, net, in the condensed consolidated statements of operations, using the specific-identification method. Investments are classified as short-term or long-term depending on the underlying investment's maturity date. The Company had no investments with a maturity date greater than 12 months as of June 30, 2020 and December 31, 2019. All investments with unrealized losses at June 30, 2020 have been in a loss position for less than twelve months or the loss is not material and were temporary in nature. The Company does not intend to sell the investments that are in an unrealized loss position before recovery of their amortized cost basis.

5. INVENTORY

If the Company identifies excess, obsolete or unsalable product, the Company will write down its inventory to net realizable value in the period it is identified. During the six months ended June 30, 2020, the Company recorded a $0.3 million provision for the write-down of inventory to cost of sales. There was no write-down of inventory during the six months ended June 30, 2019. Inventory consists of the following (in thousands):

	June 30, 2020	December 31, 2019
Raw materials	$ 804	$ 1,057
Work-in-process	3,229	1,925
Finished goods	1,818	2,285
Total inventory	$ 5,851	$ 5,267

6. LICENSE AGREEMENTS

In November 2012, the Company granted Forest Laboratories Holdings Limited “Forest”, an indirect wholly-owned subsidiary of Allergan plc (collectively “Allergan”) an exclusive license, with right to sublicense, certain of the Company’s intellectual property rights relating to human therapeutics containing memantine in the United States. In connection with these rights, Allergan markets and sells Namzaric® and Namenda XR® for the treatment of moderate to severe dementia related to Alzheimer’s disease.

Pursuant to the agreement, Allergan made an upfront payment of $65.0 million. The Company earned and received additional cash payments totaling $95.0 million upon achievement by Allergan of certain development and regulatory milestones. Under the agreement, external costs incurred related to the prosecution and litigation of intellectual property rights are reimbursable. Reimbursable external costs are recorded as a reduction to selling, general and administrative, net. For the three and six months ended June 30, 2020 and 2019, there were no reimbursable external costs for prosecution or litigation of intellectual property rights.

In addition, the Company may earn tiered royalty payments based on net sales of Namzaric and Namenda XR. Beginning in May 2020, the Company became entitled to receive royalties at rates in the low double digits to mid-teens from Allergan for sales of Namzaric in the United States. The Company recognized $0.8 million in Namzaric royalty revenue for both the three and six months ended June 30, 2020, and recognized no royalty revenue for the three and six months ended June 30, 2019. Accrued revenue related to Namzaric royalties is recorded in prepaid expenses and other current assets on the Condensed Consolidated Balance Sheets. Allergan’s obligation to pay royalties with respect to fixed-dose memantine-donepezil products, including Namzaric, continues until the later of (i) 15 years after the commercial launch of the first fixed-dose memantine-donepezil product by Allergan in the United States or (ii) the expiration of the Orange Book listed patents for which Allergan obtained rights from the Company covering such product, but is eliminated in any quarter where there is significant competition from generics. Based on Allergan’s and the Company’s current settlement agreements with the Namzaric ANDA filers to date, the earliest date on which any of these agreements grant a license to market a Namzaric ANDA filer’s generic version of Namzaric is January 1, 2025 (or earlier in certain circumstances). Alternatively, the Namzaric ANDA filers with the earliest license date have the option to launch an authorized generic version of Namzaric beginning on January 1, 2026 instead of launching their own generic version of Namzaric on January 1, 2025. For further discussion of Namzaric ANDA filers, see *Litigation and Other Legal Proceedings* in “Note 7 – Commitments and Contingencies”. Beginning in June 2018, the Company was entitled to receive royalties at rates in the low to mid-single digits for sales of Namenda XR in the United States. The Company does not expect to receive royalties on net sales of Namenda XR, due to the entry of generic versions of Namenda XR. Royalties under the license agreement will be recognized when the related sales occur, in accordance with the sales-based royalty exception.

7. COMMITMENTS AND CONTINGENCIES

Purchase Commitments

The Company has entered into agreements for the supply of API and the manufacture of commercial supply of GOCOVRI, with Moehs Ibérica, S.L. and Catalent Pharma Solutions, LLC, respectively. Under the terms of the agreements, the Company will supply the vendors with non-cancelable firm commitment purchase orders. The Company

has also entered into other agreements with certain vendors for the provision of services, including services related to data access and packaging, under which the Company is contractually obligated to make certain payments to the vendors.

The Company enters into contracts in the normal course of business that include, among others, arrangements with CROs for clinical trials, vendors for preclinical research, and vendors for manufacturing. These contracts generally provide for termination upon notice, and therefore the Company believes that its obligations under these agreements are not material.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown, because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Indemnification

In accordance with the Company's amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. The Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for claims. In addition, in the normal course of business, the Company enters into contracts and agreements that may contain a variety of representations and warranties and provide for general indemnifications. For example, the Company provided certain indemnifications to its agents and underwriters as part of the Company's January 2018 underwritten secondary public offering of common stock. Underwriters have now made a claim to such indemnifications in conjunction with the ongoing litigation involving that transaction.

Litigation and Other Legal Proceedings

In November 2012, the Company granted Forest an exclusive license to certain of the Company's intellectual property rights relating to human therapeutics containing memantine in the United States. Under the terms of that license agreement, Forest has the right to enforce such intellectual property rights which are related to its right to market and sell Namzaric and Namenda XR for the treatment of moderate to severe dementia related to Alzheimer's disease. The Company has a right to participate in, but not control, such enforcement actions by Forest.

In 2018 and as of the date of this filing, multiple generic companies have launched generic versions of Namenda XR.

As of the date of this filing, a number of companies have submitted ANDAs including one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv) to the FDA requesting approval to manufacture and market generic versions of Namzaric, on which the Company is entitled to receive royalties from Forest beginning in May 2020.

As of the date of this filing, the Company and Forest have settled with all such Namzaric ANDA filers, including all first filers on all the available dosage forms of Namzaric. Subject to those agreements, the earliest date on which any of these agreements grant a license to market a Namzaric ANDA filer's generic version of Namzaric is January 1, 2025 (or earlier in certain circumstances). Alternatively, the Namzaric ANDA filers with the earliest date have the option to launch an authorized generic version of Namzaric beginning on January 1, 2026 instead of launching their own generic version of Namzaric on January 1, 2025. The Company and Forest intend to continue to enforce the patents associated with Namzaric.

On February 16, 2018, Osmotica Pharmaceuticals LLC and Vertical Pharmaceuticals LLC ("Osmotica") filed an action against the Company in U.S. District Court for the state of Delaware, requesting a declaratory judgment that Osmotica's newly-approved product Osmolex ER™ (amantadine) extended release tablets do not infringe certain of the Company's patents. On September 20, 2018, the Company filed its first amended answer including infringement counterclaims against Osmotica asserting Osmotica has infringed nine Company patents under 35 U.S.C. §§ 271(a), (b), and/or (c) and 35 U.S.C. § 271(e)(2)(A) and seeking various forms of relief, including damages, treble damages, injunctive relief, and an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Osmotica's

NDA for Osmolex ER™ be a date that is not earlier than the latest expiration date of the Company patents involved in the lawsuit. This action is ongoing, but was stayed on May 23, 2019 at the parties' joint request.

On July 1, 2020, the Company received a letter dated June 29, 2020, notifying the Company that Zydus Worldwide DMCC ("Zydus") submitted to the FDA an ANDA for Amantadine Extended-Release Capsules, 68.5 mg and 137 mg that contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Company's U.S. Patent Nos. 8,389,578; 8,741,343; 8,796,337; 8,889,740; 8,895,614; 8,895,615; 8,895,616; 8,895,617; 8,895,618; 9,867,791; 9,867,792; 9,867,793; 9,877,933; and 10,154,971, that these patents are invalid or will not be infringed by the manufacture, use or sale of Zydus's Amantadine Extended-Release Capsules, 68.5 mg and 137 mg.

On April 1, 2019, the Company was served with a complaint filed in the United States District Court for the Northern District of California (Case No. 3:18-cv-03018-JCS) against the Company and several Allergan entities alleging violations of Federal and state false claims acts ("FCA") in connection with the commercialization of Namenda XR and Namzaric by Allergan. The lawsuit is a *qui tam* complaint brought by a named individual, Zachary Silbersher, asserting rights of the Federal government and various state governments. The lawsuit was originally filed in May 2018 under seal, and the Company became aware of the lawsuit when it was served. The complaint alleges that patents held by Allergan and the Company covering Namenda XR and Namzaric were procured through fraud on the United States Patent and Trademark Office and that these patents were asserted against potential generic manufacturers of Namenda XR and Namzaric to prevent the generic manufacturers from entering the market, thereby wrongfully excluding generic competition resulting in an artificially high price being charged to government payors. The Company's patents in question were licensed exclusively to Forest. The complaint includes a claim for damages of "potentially more than $2.5 billion dollars," treble damages "under the federal FCA and most of the State FCAs," and "statutory penalties that can be assessed for each false claim." This action is ongoing. The federal and state governments have declined to intervene in this action. To the Company's knowledge, the individual plaintiff is pursuing the lawsuit in his individual capacity. The Company believes it has strong factual and legal defenses and intends to defend itself vigorously. The Company is in the early stages of this litigation.

On May 13, 2019, a putative class action lawsuit alleging violations of the federal securities laws was filed in California Superior Court for the County of Alameda (Case No. RG1901875). The lawsuit alleges violations of the Securities Act of 1933 by the Company and certain of the Company's current and former directors and officers for allegedly making false statements and omissions in the registration statement and prospectus filed by the Company in connection with our January 24, 2018, secondary public offering of common stock. On December 10, 2019, another putative class action lawsuit alleging violations of the federal securities laws was filed in federal court in the Northern District of California (Case No. 4:19-cv-08051). This lawsuit alleges violations of the Securities Act of 1934 by the Company and certain of the Company's current and former officers. On March 16, 2020, a shareholder derivative lawsuit was filed in federal court in the Northern District of California (Case No. 4:20-cv-01815). This lawsuit alleges breaches of fiduciary duty and violations of the Securities Act of 1934 by certain of the Company's current and former directors and officers. The Company is named as a nominal defendant only. On April 6, 2020, another, virtually identical, shareholder derivative lawsuit was filed in federal court in the Northern District of California (Case No. 4:20-cv-02320). This lawsuit contains the same allegations, claims, and defendants as the first derivative action. Other similar cases may be filed in the future. In all of these actions, Plaintiffs seek unspecified monetary damages and other relief. These actions are ongoing. The Company believes it has strong factual and legal defenses to all actions and intends to defend itself vigorously.

From time to time, the Company may be party to legal proceedings, investigations, and claims in the ordinary course of its business. Other than the matters described above, the Company is not currently party to any material legal proceedings.

8. LONG-TERM DEBT

Royalty-Backed Loan Agreement

In May 2017, the Company, through a new wholly-owned subsidiary, Adamas Pharma, LLC, entered into a Royalty-Backed Loan with HCRP, whereby the Company initially borrowed $35 million, followed by an additional $65 million received in the fourth quarter 2017 upon FDA's recognition in the Orange Book of seven-year orphan drug exclusivity, which GOCOVRI earned upon approval on August 24, 2017. Principal and interest will be payable quarterly from the proceeds of a 12.5% royalty on U.S. net sales of GOCOVRI and up to $15 million of the Company's annual

royalties from Allergan on U.S. net sales of Namzaric starting in May 2020, pursuant to the Company's license agreement with Allergan. The royalty rate on net sales of GOCOVRI will drop to 6.25% after the principal amount of the loan has been repaid in full, until the Company has made total payments of 200% of the funded amounts. The Company may elect to voluntarily prepay the loan at any time, or may be required to prepay subject to specified prepayment trigger events as described below, in which case the amount due will be 200% of the funded amounts, less total payments made to date. Royalty rates are subject to increase to 17.5% and 22.5% if total principal and interest payments have not reached minimum specified levels at measurement dates on December 2021 and December 2022, respectively. Under the terms of the loan, HCRP has recourse to Adamas Pharma, LLC, not the Company. The loan agreement matures in December 2026 but as the repayment of the loan amount is contingent upon the sales volumes of GOCOVRI and royalties from Allergan, the repayment term may be shortened depending on the actual sales of GOCOVRI and actual royalties received from Allergan.

The loans bear interest at an annual rate of 11% on the outstanding principal amount and includes an interest-only period until the interest payment date following the ninth full calendar quarter after the $65 million additional loan received in the fourth quarter 2017. To the extent that royalties were insufficient to pay interest in full during the first nine quarters of the loan, any unpaid portion of the quarterly interest payment was added to the principal amount of the loans. This payment-in-kind period ended in the first quarter of 2020.

In connection with the Royalty-Backed Loan, in 2017 the Company paid HCRP a lender expense amount of $0.4 million and incurred additional debt issuance costs totaling $0.8 million. The lender expense and additional debt issuance costs have been recorded as a debt discount and are being amortized and recorded as interest expense over the estimated term of the loan using the effective interest method. The Company recorded interest expense, including amortization of the debt discount, related to the Royalty-Backed Loan, of $3.5 million and $7.1 million for the three and six months ended June 30, 2020, respectively, and $3.8 million and $7.5 million for the three and six months ended June 30, 2019, respectively. Interest expense over the life of the Royalty-Backed Loan includes an annual interest rate of 11% on the outstanding principal, a royalty rate of 6.25% on net sales of GOCOVRI after the principal amount is paid, and amortization of the debt discount. The effective interest rate as of June 30, 2020 on the amounts borrowed under the Royalty-Backed Loan, including the amortization of the debt discount, was 13.0%.

The assumptions used in determining the expected repayment term of the loan and amortization period of the debt discount require that the Company make estimates that could impact the short and long-term classification of these costs, as well as the period over which these costs will be amortized and the effective interest rate.

The Company may be required to make mandatory prepayments of the borrowings under the Royalty-Backed Loan upon the occurrence of specified prepayment trigger events, including: (1) the occurrence of any event of default or (2) the occurrence of a change in control. Upon the prepayment of all or any of the outstanding principal balance, the Company shall pay, in addition to such prepayment, a prepayment premium. As HCRP, as the holder of the loans, may exercise the option to require prepayment by the Company, the prepayment premium is considered to be an embedded derivative which is required to be bifurcated from its host contract and accounted for as a separate financial instrument. The valuation of the embedded derivative is described further in Note 3.

Payment obligations under the Royalty-Backed Loan are as follows (in thousands):

	June 30, 2020	December 31, 2019
Total repayment obligation	$ 200,000	$ 200,000
Less: Interest to be accreted in future periods	(56,126)	(63,217)
Less: Payments made	(14,342)	(9,068)
Carrying value of loans payable	$ 129,532	$ 127,715
Less: Current portion of long-term debt	(3,232)	(2,041)
Non-current portion of long-term debt	$ 126,300	$ 125,674

The estimated fair value of the long-term debt, as measured using Level 3 inputs, approximates $100.8 million as of June 30, 2020. The estimated fair value was calculated in the same methodology as the valuation of the embedded derivative as described further in Note 3.

There are no contractual minimum principal payments due until the loan matures in December 2026 as the repayment of the loan amount is contingent upon the sales volumes of GOCOVRI and royalties from Allergan on U.S. net sales of Namzaric.

Paycheck Protection Program

On April 15, 2020, the Company received proceeds from a loan in the amount of $2.7 million (the "PPP Loan") from JPMorgan Chase Bank, N.A. (the "Lender"), pursuant to the Small Business Association ("SBA") Paycheck Protection Program (or "PPP") of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). At the time the Company applied for the PPP loan, the Company believed it qualified to receive the funds pursuant to the then published qualification requirements. On April 23, 2020, the SBA, in consultation with the Department of Treasury, issued new guidance regarding qualification requirements for public companies. Based on the Company's assessment of the new guidance, on April 29, 2020, the Company repaid the principal and interest on the PPP loan.

9. STOCKHOLDERS' EQUITY

Common Stock

The amended and restated certificate of incorporation authorizes the Company to issue 100,000,000 shares of common stock. Common stockholders are entitled to dividends as and when declared by the board of directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. Each share of common stock is entitled to one vote.

Sales Agreement

In November 2019, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC ("Cowen"), as sales agent, pursuant to which the Company may, from time to time, issue and sell at its option, shares of the Company's common stock for an aggregate offering price of up to $50.0 million under an at-the-market offering ("ATM Offering"). Sales of the common stock, if any, will be made pursuant to a shelf registration statement that was declared effective by the Securities and Exchange Commission ("SEC") on December 2, 2019. Cowen is acting as sole sales agent for any sales made under the Sales Agreement and the Company will pay Cowen a commission of up to 3% of the gross proceeds. The Company's common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary.

The Company is not obligated to make any sales of shares of common stock under the Sales Agreement. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. As of June 30, 2020, no shares have been sold under the Sales Agreement.

Shares Reserved for Future Issuance

Shares of the Company's common stock reserved for future issuance are as follows:

	June 30, 2020	December 31, 2019
Common stock awards issued and outstanding	7,076,844	6,874,633
Authorized for future issuance under 2014 Equity Incentive Plan	3,262,732	2,376,613
Authorized for future issuance under 2016 Inducement Plan	494,562	236,269
Employee stock purchase plan	1,111,497	926,943
Total	11,945,635	10,414,458

10. STOCK-BASED COMPENSATION

Stock Compensation Plans

In January 2020, the common stock available for issuance under the 2014 Equity Incentive Plan (the "2014 Plan") automatically increased by 4% of the total number of shares of the Company's capital stock outstanding on December 31, 2019, or 1,118,591 shares.

In February 2020, the Company's board of directors approved an amendment to the 2016 Inducement Plan (the "Inducement Plan") to increase the number of shares available for issuance by an additional 450,000.

Employee Stock Purchase Plan

In January 2020, the common stock available for issuance under the 2014 Employee Stock Purchase Plan (the "ESPP") automatically increased by 1% of the total number of shares of the Company's capital stock outstanding on December 31, 2019, or 279,648 shares.

Stock-Based Compensation Expense

The following table reflects stock-based compensation expense recognized 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
Research and development	$ 134	$ 563	$ 220	$ 1,153
Selling, general and administrative	1,561	2,376	2,956	5,170
Total stock-based compensation expense	$ 1,695	$ 2,939	$ 3,176	$ 6,323

Stock-based compensation of $45,000 and $153,000 was capitalized into inventory for the three and six months ended June 30, 2020, respectively, and $34,000 and $60,000 for the three and six months ended June 30, 2019, respectively. Stock-based compensation capitalized into inventory is recognized as cost of sales when the related product is sold.

11. NET LOSS PER SHARE

For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position. The following total outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented, because including them would have been anti-dilutive (in thousands):

	Three and Six Months Ended June 30,	
	2020	2019
Options to purchase common stock	5,450	5,716
Restricted stock units	1,627	900
Total	7,077	6,616

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes included elsewhere in this report, and with the consolidated financial statements and management's discussion and analysis of our financial condition and results of operations in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on February 25, 2020. This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions, and the expected impact that the COVID-19 pandemic will continue to have on our business. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report titled "Risk factors."

Overview

At Adamas Pharmaceuticals, Inc., our purpose is to make everyday life significantly better for people affected by neurological diseases. We strive to turn this purpose into reality by combining our proven expertise in discovery, development and commercialization with our passion for improving lives. We believe our medicines should be differentiated and provide a meaningful benefit to patients. With one partnered product and a commercial medicine, we are focused on supporting our patient community and growing a portfolio of therapies to reduce the burden of neurological diseases on patients, caregivers, and society.

Our portfolio includes:

Approved Product:

- GOCOVRI® (amantadine) extended release capsules, is the first and only FDA-approved medication indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. It is also the only medicine clinically proven to reduce both dyskinesia and OFF time in that population. GOCOVRI was approved for marketing by the U.S. Food and Drug Administration, or FDA, on August 24, 2017, with seven years of orphan exclusivity and additional patent protections out to 2034. On January 2, 2020, we announced we had granted Sandoz Inc. a license for its generic version of GOCOVRI as of March 4, 2030, or earlier in certain circumstances typical for such agreements. On June 4, 2020, we announced the FDA had accepted for review our supplemental New Drug Application (sNDA) for GOCOVRI as a treatment for OFF episodes in Parkinson's disease patients receiving levodopa-based therapy. The anticipated PDUFA action date is February 1, 2021.

Potential Additional Indication for GOCOVRI (amantadine) Extended Release Capsules (ADS-5102):

- ADS-5102 in development for the treatment of walking impairment in patients with multiple sclerosis ("MSW"). We announced topline results from INROADS Phase III trial of ADS-5102 on December 17, 2019. The study met its primary endpoint, showing a potential benefit for patients with walking impairment. Following a comprehensive evaluation of the INROADS Phase III data, including evaluating the ongoing, open label extension study, and engaging with the FDA, the revised product profile and potential path to submission reconfirmed our decision not to initiate further Phase 3 development on June 17, 2020.

Product Candidate (paused):

- ADS-4101 (lacosamide) modified release capsules in development for the treatment of partial onset seizures in patients with epilepsy. In 2019, we placed the development program on hold to focus on other priorities and are currently evaluating the potential value and options for a path forward.

Partnered Product:

- Namzaric® (memantine hydrochloride extended release and donepezil hydrochloride) capsules for the treatment of moderate to severe dementia of an Alzheimer's type, marketed in the United States by Allergan plc under an exclusive license agreement between us and Forest Laboratories Holdings Limited

("Forest"), an indirect, wholly-owned subsidiary of Allergan plc (collectively, "Allergan"). We began recognizing royalty revenue on net sales of Namzaric in May 2020.

Products in our wholly-owned, non-partnered portfolio, potential additional indications for these products, and our product candidate, are protected by an array of intellectual property, including robust and diversified patent claims, and regulatory exclusivities.

Impact of the COVID-19 pandemic on our company

The outbreak of the novel Coronavirus ("COVID-19"), which is understood to have begun in December 2019, continues to grow both within the U.S. and globally. The World Health Organization has declared the outbreak of COVID-19 to be a pandemic, and the U.S. federal government has declared it a national emergency.

How we are operating in the current COVID-19 shutdown

We are committed to the health and safety of our employees and their families and doing our part to slow the community spread of COVID-19. In mid-March, we implemented a number of actions, including a work-from-home policy for all our employees, allowing for flexible work schedules, and restrictions on in-person meetings. We are very proud of our entire team as we transitioned swiftly to working remotely. We are following the guidelines of the Centers for Disease Control and other federal, state and local authorities and will continue to assess when it is appropriate for our team to return to normal work practices.

Impact on our ability to sell GOCOVRI

We continue to see stable GOCOVRI prescription refill rates due to our continued strong patient persistence, adequate supply of GOCOVRI, and patient access to GOCOVRI through distribution from our specialty pharmacy directly to a patient's home. However, we have seen that new prescription rates have slowed due to several factors, including: many healthcare providers have temporarily closed their offices or are restricting patient visits; patients are postponing visits to healthcare provider facilities; and our sales force has moved to conducting activities virtually with healthcare providers. While we believe this decline in new prescriptions to be temporary, the duration and severity is dependent on future developments, which are highly uncertain and cannot be predicted with confidence.

Impact on our supply chain

Our GOCOVRI supply chain remains robust and thus far we have observed no disruptions to our inventory on hand or our planned manufacturing schedule. We have an adequate supply of GOCOVRI to address patients' needs into late 2021. Based on current information, we believe that our partners in our supply chain have been and will continue to operate during the current COVID-19 outbreak.

Impact on our financial condition and capital resources

The extent of the impact of COVID-19 on our business, financial results, liquidity and cash flows will depend largely on future developments, including new information that may emerge concerning the severity and duration of actions taken to contain or prevent further spread. With already imposed shelter-at-home orders in place, we have observed widespread closure of clinics, and cancellation or rescheduling of patient appointments have been combined with restriction of access to sales representatives in some institutions and a marked increase in telemedicine consultations that may result in further sales reductions. In light of restrictions on travel and in-person meetings, we have also experienced cost reductions related to the transition to virtual formats and other travel related costs, in addition to other certain cost management activities. As of June 30, 2020, we had cash, cash equivalents, and investments of $103.4 million.

Financial operations overview

Summary

As of June 30, 2020, we had cash, cash equivalents, and available-for-sale securities of $103.4 million. We are commercializing GOCOVRI through our deployed sales force targeting neurologists and movement disorder specialists in the United States. As of June 30, 2020, we had an accumulated deficit of $475.1 million.

In November 2019, we entered into a sales agreement with Cowen and Company, LLC, pursuant to which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50.0 million. As of June 30, 2020, we have not sold any shares under the sales agreement.

Revenue

Product sales consist of sales of GOCOVRI, which was approved by the FDA on August 24, 2017. We began commercial sales of GOCOVRI in the fourth quarter of 2017, and initiated the full commercial launch via the deployment of our sales team in January 2018.

Royalty revenue consists of royalties from Allergan for sales of Namzaric in the United States, which we began to receive in May 2020.

Prior to the generation of product sales from GOCOVRI, our revenue had been generated primarily from payments under our license agreement with Allergan for non-refundable upfront license payments, milestone payments and reimbursements for research and development expenses for full-time equivalent employees assigned to the license agreement. There are no further milestone payments to be earned under our license agreement with Allergan, and we expect reimbursements for full-time equivalents assigned to the license agreement to be inconsequential in future periods. Beginning in May 2020, we began to receive tiered royalties from Allergan in the low double digits to mid-teens, as a percent of net sales of Namzaric in the United States. Based on recent trends of Namzaric net sales, we expect the tiered royalty to be in the low double digits through the term of the agreement, but is eliminated in any quarter where there is significant competition from generics. Based on Allergan's and our current settlement agreements with the Namzaric ANDA filers to date, the earliest date on which any of these agreements grant a license to market a Namzaric ANDA filer's generic version of Namzaric is January 1, 2025 (or earlier in certain circumstances). Alternatively, the Namzaric ANDA filers with the earliest license date have the option to launch an authorized generic version of Namzaric beginning on January 1, 2026 instead of launching their own generic version of Namzaric on January 1, 2025. For further discussion of Namzaric ANDA filers, see *Litigation and Other Legal Proceedings* in "Note 7 – Commitments and Contingencies".

Cost of product sales

Cost of product sales consists primarily of direct and indirect costs related to the manufacturing of GOCOVRI products sold, including third-party manufacturing costs, packaging services, freight, allocation of overhead costs, and inventory adjustment charges. We began capitalizing inventory manufactured at the FDA approved locations upon FDA approval of GOCOVRI and upon FDA approval of a supplemental NDA for a second manufacturing site with our current third-party manufacturer. We recorded inventory acquired prior to the regulatory approvals as research and development expense.

Research and development expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our wholly-owned product candidates. We recognize all research and development costs as they are incurred.

Research and development expenses consist of:

- fees paid to clinical investigators, clinical trial sites, consultants, and vendors, including contract research organizations, or CROs, in conjunction with implementing, conducting, and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as for investigator grants, patient screening fees, laboratory work, and statistical compilation and analysis;
- expenses related to production of clinical supplies, including fees paid to contract manufacturing organizations, or CMOs;
- expenses related to establishment and validation of manufacturing capabilities for commercial supply;
- expenses related to the buildup of commercial supply to support commercial launch, prior to FDA approval;
- expenses related to compliance with regulatory requirements;
- other consulting fees paid to third parties; and

- employee-related expenses, which include salaries, benefits, and stock-based compensation.

The following table summarizes our research and development expenses incurred during the three and six months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Increase (Decrease)	Six Months Ended June 30,		Increase (Decrease)
	2020	2019		2020	2019	
GOCOVRI(1)	$ 2,167	$ 6,234	$ (4,067)	$ 4,152	$ 13,276	$ (9,124)
ADS-4101(2)	—	1,001	(1,001)	—	2,459	(2,459)
Other research and development expenses	383	1,363	(980)	863	3,077	(2,214)
Total research and development expenses	$ 2,550	$ 8,598	$ (6,048)	$ 5,015	$ 18,812	$ (13,797)

(1) Includes program costs we incurred for GOCOVRI (formerly referred to as ADS-5102) for the treatment of dyskinesia in patients with Parkinson's disease, and ADS-5102 (GOCOVRI) for additional potential CNS indications, including for the treatment of walking impairment in patients with multiple sclerosis.

(2) We reduced investments in ADS-4101 in the quarter ended June 30, 2019.

The program-specific expenses summarized in the table above include costs directly attributable to our product candidates. Other research and development expenses include costs for early stage programs and costs not allocated to a specific program. We allocate benefits, stock-based compensation, and indirect costs to our product candidates on a program-specific basis, and we include these costs in the program-specific expenses. We begin to track and report program-specific expenses for early stage programs once they have been nominated and selected for further development and clinical-stage work has commenced.

Our investment in research and development activities, including the clinical development of our product candidates, has historically represented a significant portion of our total operating expenses. We have concluded the two-year Phase 3 open-label study of GOCOVRI, suspended investment in the development of ADS-4101, and completed additional analyses of the data from the INROADS trial for ADS-5102 for MSW and will not initiate further Phase 3 development. Our research and development efforts are focused on completing activities for ADS-5102 for MSW, primarily continuing the open-label extension study through the end of 2020 and publishing the data from the INROADS trial. As a result, we expect research and development costs to decrease from 2019 levels for the foreseeable future, based on this focused strategy.

The process of conducting the necessary clinical research to obtain FDA approval is costly and time consuming. The actual probability of success for each product candidate and clinical program may be affected by a variety of factors, including but not limited to, the quality of the product candidate, early clinical data, investment in the program, competition, manufacturing capability, and commercial viability. Furthermore, in the past we have entered into licensing arrangements with other pharmaceutical companies to develop and commercialize our product candidates, and we may enter into additional licensing arrangements or collaborations in the future. In situations in which third parties have control over the clinical development of a product candidate, the estimated completion dates are largely under the control of such third parties and not under our control. We cannot forecast with any degree of certainty which of our product candidates, if any, will be subject to future licensing or collaboration arrangements or how such arrangements would affect our development plans or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Selling, general and administrative expenses, net

Selling, general and administrative expenses, net, consist primarily of personnel and related benefit costs, including stock-based compensation, facilities, professional services, insurance, public company related expenses, charitable contribution expenses, as well as the costs associated with supporting the commercialization of GOCOVRI, reduced to a small degree in certain periods by reimbursement from Allergan for external costs related to supporting prosecution and litigation of intellectual property rights under our license agreement. We anticipate our selling, general and administrative expenses will remain significant and may increase as we continue to support the commercialization of GOCOVRI.

Interest and other income, net

Interest and other income, net, consists of changes in fair value of the embedded derivative liability related to our royalty-backed loan agreement ("Royalty-Backed Loan") with HealthCare Royalty Partners III, L.P., ("HCRP"), in addition to interest received on our investments.

Interest expense

Interest expense consists of accrued interest pursuant to our Royalty-Backed Loan and amortization of debt issuance costs. Interest expense accrues using the effective interest rate method over the estimated period the debt is expected to be repaid. Interest expense over the life of the Royalty-Backed Loan includes an annual interest rate of 11% on the outstanding principal, a royalty rate of 6.25% on net sales of GOCOVRI after the principal amount is paid, and amortization of the debt discount, until a maximum aggregate repayment amount has been reached.

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 have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. We base our estimates on our historical experience and on various other factors that we believe are 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 significant and material changes in our critical accounting policies from those as reflected in "Management's Discussion and Analysis of Financial Condition and Results of Operations," in our Annual Report on Form 10-K for the year ended December 31, 2019.

Results of operations

Fluctuations in Operating Results

Our results of operations have fluctuated from period to period in the past and, especially in light of the COVID-19 pandemic, are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the impact on our operations as a result of the COVID-19 pandemic, fluctuations in product sales due to variances in the number of paid prescriptions from period to period, conversions from our free drug trial program to paid prescriptions, and fluctuations in our Medicare Part D Coverage Gap liability and the volume of purchases eligible for government mandated discounts and rebates, as well as changes in discount percentages that may be impacted by potential future price increases and other factors. Further, we expect the timing of expenditures related to our commercial activities associated with GOCOVRI to vary from period to period, including those associated with the potential label revision for GOCOVRI to include OFF episodes, and potential development of additional product candidates. Due to these fluctuations, we believe that the period to period comparisons of our operating results are not necessarily a good indication of our future performance.

Comparison of the three and six months ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three and six months ended June 30, 2020 and 2019 (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	Increase (Decrease)	% Increase (Decrease)	2020	2019	Increase (Decrease)	% Increase (Decrease)
Product sales	$ 17,954	$ 12,691	$ 5,263	41 %	$ 32,435	$ 24,356	$ 8,079	33 %
Royalty revenue	840	—	840	NM	840	—	840	NM
Cost of product sales	381	685	(304)	(44)%	953	1,098	(145)	(13)%
Research and development expenses	2,550	8,598	(6,048)	(70)%	5,015	18,812	(13,797)	(73)%
Selling, general and administrative expenses, net	23,177	25,216	(2,039)	(8)%	47,729	52,904	(5,175)	(10)%
Interest and other income, net	215	734	(519)	(71)%	299	1,457	(1,158)	(79)%
Interest expense	3,467	3,797	(330)	(9)%	7,091	7,528	(437)	(6)%

NM – Not meaningful.

The following table summarizes the approximate number of total GOCOVRI paid prescriptions for the three and six months ended June 30, 2020 and 2019:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	Increase (Decrease)	% Increase (Decrease)	2020	2019	Increase (Decrease)	% Increase (Decrease)
GOCOVRI Paid Prescriptions	8,150	6,160	1,990	32 %	15,360	11,980	3,380	28 %

Product sales

Product sales increased by $5.3 million, or 41%, to $18.0 million for the three months ended June 30, 2020, from $12.7 million for the three months ended June 30, 2019, and increased by $8.1 million, or 33%, to $32.4 million for the six months ended June 30, 2020, from $24.4 million for the six months ended June 30, 2019. The increase in both periods was due to growth in sales of GOCOVRI since its launch, in addition to a 3% price increase that went into effect in January 2020. The approximate number of total paid prescriptions increased by 1,990, or 32%, to 8,150 for the three months ended June 30, 2020, from 6,160 for the three months June 30, 2019, and increased by 3,380, or 28%, to 15,360 for the six months ended June 30, 2020, from 11,980 for the six months ended June 30, 2019.

The approximate number of total paid prescriptions in the first quarter of 2019 was 5,820, in the second quarter of 2019 was 6,160, in the third quarter of 2019 was 6,640, in the fourth quarter of 2019 was 7,160, in the first quarter of 2020 was 7,210, and in the second quarter of 2020 was 8,150. In addition to total paid prescriptions, we monitor new paid prescriptions as a key performance indicator for our business and starting with the first quarter of 2020 are reporting this metric. The approximate number of new paid prescriptions in the first quarter of 2020 was 500 and in the second quarter of 2020 was 370.

Royalty revenue

Royalty revenue was $0.8 million for both the three and six month periods ended June 30, 2020. We began recognizing royalty revenue on net sales of Namzaric in May 2020 and accordingly had no royalty revenue for the three and six months ended June 30, 2019.

Cost of product sales

Cost of product sales decreased by $0.3 million to $0.4 million, or 2% of product sales, for the three months ended June 30, 2020, from $0.7 million, or 5% of product sales, for the three months ended June 30, 2019, and decreased by $0.1 million to $1.0 million, or 3% of product sales, for the six months ended June 30, 2020, from $1.1 million, or 5% of product sales, for the six months ended June 30, 2019. Cost of product sales for the six months ended June 30, 2019 included a one-time charge related to amending our agreement with our CMO. Prior to receiving FDA approval in August 2017, we recorded all inventory costs incurred in the manufacture of GOCOVRI to be sold upon commercialization as research and development expense. As of June 30, 2020, substantially all the inventory that was

previously expensed to research and development had been sold to customers. We do not expect our cost of product sales of GOCOVRI as a percentage of product sales to exceed 6% for the foreseeable future, excluding potential unknown one-time charges.

Research and development expenses

Research and development expenses decreased by $6.0 million, or 70%, to $2.6 million for the three months ended June 30, 2020, from $8.6 million for the three months ended June 30, 2019; and decreased by $13.8 million, or 73%, to $5.0 million for the six months ended June 30, 2020, from $18.8 million for the six months ended June 30, 2019. The decrease in research and development expenses for both periods was mainly attributable to: decreased costs related to clinical activity for our Phase 3 study in support of ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis mainly due to completion of the Phase 3 INROADS trial at the end of 2019; and decreased costs related to the decision during the second quarter of 2019 to defer additional investment in the development of our product candidate ADS-4101 for the treatment of partial onset seizures in patients with epilepsy. Included in research and development expenses was stock-based compensation expense, which was $0.1 million and $0.2 million for the three and six months ended June 30, 2020, respectively, compared to $0.6 million and $1.2 million for the three and six months ended June 30, 2019, respectively.

Selling, general and administrative expenses, net

Selling, general and administrative expenses, net, decreased by $2.0 million, or 8%, to $23.2 million for the three months ended June 30, 2020, from $25.2 million for the three months ended June 30, 2019; and decreased by $5.2 million, or 10%, to $47.7 million for the six months ended June 30, 2020, from $52.9 million for the six months ended June 30, 2019. The decrease in selling, general and administrative expenses for both the three and six months ended June 30, 2020, was primarily due to: decreased costs of $1.8 million and $3.4 million, respectively, in personnel related costs including stock-based compensation and other costs due to lower headcount, cost management activities, and certain one-time charges during the three and six months ended June 30, 2019; decreased costs of $2.7 million and $3.6 million, respectively, for GOCOVRI related promotional costs, market research, professional services and other external service costs including legal fees, partially related to the effects associated with COVID-19 and other cost management activities. The decrease in both periods was offset in part by increased costs of $2.5 million and $2.0 million, respectively, for other general corporate expense. Included in selling, general and administrative expenses was stock-based compensation expense, which was $1.6 million and $3.0 million for the three and six months ended June 30, 2020, respectively, compared to $2.4 million and $5.2 million for the three and six months ended June 30, 2019.

Interest and other income, net

Interest and other income, net, for the three and six months ended June 30, 2020 was $0.2 million and $0.3 million, respectively, compared to $0.7 million and $1.5 million for the three and six months ended June 30, 2019. The decrease in interest and other income, net, for both the three and six months ended June 30, 2020, was primarily driven by lower interest income earned on lower cash and investment balances.

Interest expense

Interest expense was $3.5 million and $7.1 million for the three and six months ended June 30, 2020, compared to $3.8 million and $7.5 million for the three and six months ended June 30, 2019. The decrease in interest expense for both the three and six months ended June 30, 2020, was mainly related to a lower estimated effective interest rate on our Royalty-Backed Loan with HCRP, offset in part by a higher principal balance.

Liquidity and Capital Resources

Since January 1, 2017, we have funded our operations primarily through sales of our common stock and sales of GOCOVRI, as well as we borrowed $100 million under our Royalty-Backed Loan with HCRP.

In November 2019, we entered into a sales agreement with Cowen and Company, LLC, pursuant to which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50.0 million. As of June 30, 2020, no shares had been sold under the sales agreement.

We made GOCOVRI available for physician and patient use in the fourth quarter of 2017, with a full commercial launch via the deployment of our sales team in January 2018. Prior to the generation of revenue from

GOCOVRI, we had not generated any commercial revenue from the sale of our products. Our principal sources of liquidity are our cash, cash equivalents, and investments, which totaled $103.4 million and $132.6 million at June 30, 2020 and December 31, 2019, respectively.

We believe our existing cash, cash equivalents, and investments at June 30, 2020 will be sufficient to fund our projected operating requirements, including commercialization of GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease and operations related to the open label study for ADS-5102 in MSW, for at least 12 months from the issuance of this quarterly report on Form 10-Q. However, it is possible that we will not achieve the progress that we expect, because revenues from GOCOVRI may be less than anticipated, especially in light of the current COVID-19 pandemic, and the actual costs and timing of drug development, particularly clinical studies, and regulatory approvals are difficult to predict, subject to substantial risks and delays, and often vary depending on the particular indication and development strategy. The duration and severity of the COVID-19 pandemic is unknown and makes projecting the outcome of future developments highly uncertain and cannot be predicted with confidence. Moreover, the costs associated with commercializing drugs are high and market acceptance is uncertain.

We expect to incur substantial expenses and operating losses for the foreseeable future. We expect to continue significant spending in connection with the commercialization of GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease, as well as the potential label revision to include OFF episodes, and potential development of additional product candidates. To continue these activities, we may decide to raise additional funds through a combination of public equity offerings, debt financings, royalty financings, collaborations, strategic alliances, licensing arrangements, asset sales, and other marketing and distribution arrangements. Sufficient additional funding may not be available on acceptable terms, or at all, especially as a result of the economic downturn occurring and expected to continue as a result of the actions taken to contain the spread of COVID-19. If adequate funds are not available in the future, we may need to delay, reduce the scope of, or put on hold our clinical studies, research and development programs, or commercialization efforts.

The following table summarizes our cash flows for the periods indicated (in thousands):

	Six Months Ended June 30,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	$ (29,528)	$ (43,807)
Investing activities	(5,973)	49,325
Financing activities	265	614
Net increase (decrease) in cash and cash equivalents	$ (35,236)	$ 6,132

Net Cash Used In Operating Activities

Net cash used in operating activities was $29.5 million for the six months ended June 30, 2020 and consisted primarily of our net loss of $27.2 million less non-cash adjustments of $11.3 million, mainly for accretion of interest expense of $7.1 million and stock-based compensation of $3.2 million, in addition to payments related to our Royalty-Backed Loan with HCRP of $5.3 million, coupled with paying down accounts payable and accrued liabilities of $7.1 million.

Net Cash Used In Investing Activities

Net cash used in investing activities was $6.0 million for the six months ended June 30, 2020, mainly as a result of net purchases of available-for-sale securities.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $0.3 million for the six months ended June 30, 2020, as a result of cash proceeds related to the exercise of stock options and purchases of common stock under the Employee Stock Purchase Plan.

Off-balance sheet arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities, or variable interest entities.

Contractual obligations

Our future non-cancelable contractual obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2019 that was filed with the SEC on February 25, 2020. There have been no material changes outside the ordinary course of our business to our future non-cancelable contractual obligations during the six months ended June 30, 2020.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2020. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2020, 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 identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended June 30, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For information regarding legal proceedings, refer to *Litigation and Other Legal Proceedings* in "Note 7 – Commitments and Contingencies" in the accompanying "Notes to Condensed Consolidated Financial Statements (unaudited)," which information is incorporated by reference here.

ITEM 1A. RISK FACTORS

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations, and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes.

The outbreak of the novel Coronavirus ("COVID-19") has negatively impacted our business, including the commercialization strategy and sales of GOCOVRI® (amantadine) extended release capsules.

The outbreak of the novel Coronavirus ("COVID-19"), which is understood to have begun in December 2019, continues to grow both within the U.S. and globally. The World Health Organization has declared the outbreak of COVID-19 to be a pandemic, and the U.S. federal government has declared it a national emergency. Efforts to contain the spread of COVID-19 have intensified and the U.S. has implemented severe travel restrictions, enforced social distancing, shelter-in-place orders and delays or cancellations of physician visits. These circumstances have negatively impacted our business and the commercialization strategy of GOCOVRI, including patients postponing visits to healthcare provider facilities, healthcare providers temporarily closing their offices or restricting patient visits, and limiting the ability of our sales force to travel and meet with healthcare providers and resulting in sales and marketing being conducted virtually. In particular, we have observed a decrease in our new prescription rate, which we attribute to the effects of the restrictive actions taken.

We have implemented a work-from-home policy for all our employees, including allowing for flexible work schedules. The effects of our work-from-home policy may negatively impact productivity and disrupt our business.

These disruptions in our operations have negatively impacted, and we expect will continue to negatively impact, our business, operating results and financial condition. The COVID-19 pandemic continues to rapidly evolve. The ultimate cumulative impact of the COVID-19 pandemic on our business operations is highly uncertain, the duration and severity of which will depend on future developments, and cannot be predicted with confidence. We will continue to monitor the situation closely. The COVID-19 pandemic may also exacerbate a number of the risks discussed below.

Risks related to the commercialization of GOCOVRI® (amantadine) extended release capsules

Our success depends heavily on the success of GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. To the extent GOCOVRI is not commercially successful, our business, financial condition and results of operations will be materially harmed.

We have invested and continue to invest a significant portion of our efforts and financial resources in the development, approval and commercialization of GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The success of GOCOVRI will depend on numerous factors, including:

- GOCOVRI's efficacy and safety profile;
- our success in the marketing, sales, and distribution of GOCOVRI, especially in light of the COVID-19 pandemic;
- the duration of the COVID-19 pandemic and the stay-at-home restrictions;

- acceptance of GOCOVRI by physicians, hospital administrators, patients, third-party payers, and others in the healthcare community;
- coverage and adequate reimbursement of GOCOVRI by third-party payers;
- willingness and ability of patients to pay out of pocket for GOCOVRI;
- successfully establishing and maintaining commercial manufacturing with third parties;
- effectively competing with other approved or used medicines and future compounds in development;
- continued demonstration of an acceptable safety profile of GOCOVRI; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we are not successful in addressing these issues, or one or more of these factors negatively affect us, we could experience significant delays or an inability to further commercialize GOCOVRI, which would materially harm our business.

If we are unable to recruit and retain qualified personnel and third-party distributors, our business will be substantially harmed.

Competition for biotechnology and pharmaceutical employees, sales personnel and other key personnel is intense. We have experienced and may in the future experience difficulty attracting and retaining qualified candidates to fill open positions and may be required to expend significant financial resources in our employee recruitment and retention efforts. We are required to expend significant time and resources to market, sell, and distribute GOCOVRI to neurologists and movement disorder specialists in a credible, persuasive, and compliant manner consistent with applicable laws. Our business could be harmed if we are unable to recruit, employ, appropriately train, and retain experienced sales professionals to successfully execute our commercialization strategies and tactics, including educating potential customers about the benefits and risks of GOCOVRI and its proper administration.

Moreover, there is no guarantee that the strategies, tactics and marketing messages, or the distribution and reimbursement capabilities that we have established will be successful. Specifically, for distribution of GOCOVRI, we are heavily dependent on third-party logistics, pharmacy and distribution partners. If they are unable to perform effectively, including due to the impact of the COVID-19 pandemic on their operations, or if they do not provide efficient distribution of the medicine to patients, our business will suffer.

Failure to successfully obtain coverage and reimbursement for GOCOVRI in the United States, or the availability of coverage and reimbursement only at limited levels, would diminish our ability to generate product revenue.

Our ability to commercialize GOCOVRI successfully in the United States will depend in part on the extent to which we obtain and maintain coverage and reimbursement for GOCOVRI from third-party payers, including government health administration authorities, such as those that administer the Medicare and Medicaid programs, and private health insurers. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from both governmental healthcare programs, such as Medicare and Medicaid, and commercial payers are critical to GOCOVRI's commercial success. Coverage and reimbursement decisions may depend upon clinical and economic standards that disfavor newer drug products when more established or cheaper therapeutic alternatives are already available or subsequently become available. For example, even though other versions of amantadine are not approved for dyskinesia, some payers have asked physicians if patients have had prior experience with such versions or required that physicians actually prescribe such versions prior to providing reimbursement for GOCOVRI.

For some patients, coverage and reimbursement may not be available for GOCOVRI. Even if we obtain coverage for GOCOVRI, the resulting reimbursement rates might not be adequate or may require co-payments or co-insurance payments that patients find unacceptably high. Coverage and reimbursement determinations by third-party payers can impact the demand for GOCOVRI and therefore our revenues. Patients may choose not to use GOCOVRI if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost. If coverage and reimbursement are not available or are available only to limited levels, our business could be harmed.

Our inability to obtain and maintain coverage and adequate reimbursement rates from both government-funded and private third-party payers for GOCOVRI could have a material adverse effect on our operating results, and our overall financial condition.

We face substantial competition in the commercialization of GOCOVRI.

The commercialization of pharmaceutical products is highly competitive, and we face substantial competition with respect to GOCOVRI. For example, although GOCOVRI is the first and only FDA-approved medicine for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, we face competition from various branded and generic drugs approved for the treatment of Parkinson's disease that physicians either have historically used or may use in attempt to manage dyskinesia. If approved, we will also face competition from investigational drugs in late stage development for the treatment of Parkinson's disease, and may also face competition from drugs currently in development for dyskinesia in Parkinson's disease or for Parkinson's disease from a number of pharmaceutical companies.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, have significantly greater financial resources commercializing approved products than we do. Also, many of our competitors are large pharmaceutical companies that will have a greater ability to reduce prices for their competing drugs in an effort to gain market share and undermine the value proposition that we might otherwise be able to offer to payers.

Unforeseen safety issues could emerge with GOCOVRI that could require us to change the prescribing information to add warnings, limit use of the product, and/or result in litigation. Any of these events could have a negative impact on our business.

Discovery of unforeseen safety problems or increased focus on a known problem could impact our ability to commercialize GOCOVRI and could result in restrictions on its permissible uses, including withdrawal of the medicine from the market.

If we or others identify additional undesirable side effects caused by GOCOVRI after approval:

- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications, or field alerts to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the product and require us to take our approved drugs off the market;
- we may be required to change the way the product is administered, conduct additional clinical trials, change the labeling of the product, or implement a Risk Evaluation and Mitigation Strategy, or REMS;
- we may have limitations on how we promote our drugs;
- third-party payers may limit coverage or reimbursement for GOCOVRI;
- sales of GOCOVRI may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of GOCOVRI and could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from its sale.

Further, GOCOVRI may also be affected by the safety and tolerability of its parent drug or drugs with similar mechanisms of action. Although amantadine, which is a component of GOCOVRI, has been used in patients for many years, problems identified with other approved amantadine products or amantadine products being studied in clinical trials could result in increased regulatory scrutiny of our products and/or adversely affect the commercialization of GOCOVRI.

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers, their patients or payers. Product liability claims could divert management's attention from our core business,

be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. If we cannot successfully defend ourselves against claims that GOCOVRI caused injuries, we will incur substantial liabilities.

We currently hold $15.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to obtain insurance coverage at a reasonable cost or in amounts adequate to satisfy any liability or associated costs that may arise in the future. These events could harm our business and results of operations and cause our stock price to decline.

If manufacturers obtain approval for generic versions of GOCOVRI, or of products with which we compete, our business may suffer.

Under the U.S. Food, Drug and Cosmetic Act, or FDCA, the FDA can approve an Abbreviated New Drug Application, or ANDA, for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form, route of administration and that it is bioequivalent to the branded product. We have recently settled an ANDA litigation with a generic filer. See *Litigation and Other Legal Proceedings* in “Note 7 – Commitments and Contingencies” in the accompanying “Notes to Condensed Consolidated Financial Statements (unaudited)” for more information. However, other filers could submit an ANDA to the FDA requesting permission to manufacture and market another generic version of GOCOVRI, which could result in our expending significant time and incurring significant expenses in challenging the submissions. Further, if one or more of these filers is successful, the introduction of a generic version of GOCOVRI could harm our business and results of operations and cause our stock price to decline.

The marketing and promotion of GOCOVRI must be limited to the approved indication for use and the information and clinical data included in or consistent with the approved prescribing information. If we want to expand the marketing and promotion of GOCOVRI beyond the approved indication or with information not consistent with the approved prescribing information, we will need to obtain additional regulatory approvals, which may not be granted.

With the August 2017 approval of GOCOVRI for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, we currently are permitted to market or promote it, consistent with the information and data in its approved prescribing information, only for the treatment of dyskinesia and not for other uses. Our current marketing and promotional efforts is limited to the use of information included in or deemed to be consistent with the approved prescribing information for GOCOVRI for the treatment of dyskinesia, including the clinical data and results reflected in the prescribing information. The FDA will need to approve supplemental NDAs for GOCOVRI before we can market the drug for other indications, such as the treatment of OFF episodes in Parkinson’s disease patients receiving levodopa therapy.

If we are found to have improperly promoted GOCOVRI, or if physicians misuse it, we may be subject to restrictions on the sale or marketing of GOCOVRI and significant fines, penalties, sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies, including regulatory authorities outside the United States, strictly regulate the marketing and promotional claims that are made about drug products, such as GOCOVRI. In particular, promotion of a product must be consistent with its labeling approved by the FDA or by regulatory agencies in other countries. For example, in the case of GOCOVRI, for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, we cannot prevent physicians from prescribing GOCOVRI for indications or uses that are inconsistent with the approved label. If, however, we are found to have promoted such unapproved uses prior to the FDA’s approval for an additional indication, we may, among other consequences, receive untitled or warning letters and become subject to significant liability, which would materially harm our business. Both the U.S. federal government and foreign regulatory authorities have levied significant civil and criminal fines against companies and individuals for alleged improper promotion and have entered into settlement agreements with pharmaceutical companies to limit inappropriate promotional activities. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management’s attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged.

Physicians prescribing of our products for unapproved uses may also subject us to product liability claims, to the extent such uses lead to adverse events, side effects, or injury.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by the Centers for Medicare and Medicaid Services, or CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries/recipients of these programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional enforcement and administrative bodies have increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price, or AMP, and best price, or BP, for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payers. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in significant civil monetary penalties for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

GOCOVRI is complex to manufacture, and manufacturing disruptions may occur that could cause us to experience disruptions in the supply of GOCOVRI.

GOCOVRI is a high-dose, extended release amantadine taken once-daily at bedtime that delivers high levels of amantadine in the morning upon waking and throughout the day. The manufacture of extended release versions of drugs is more complex than the manufacture of the immediate release versions of drugs. Notwithstanding the fact that we have validated our process, manufacturing disruptions may occur, including disruptions related to the impact or uncertainties of the duration of the COVID-19 pandemic. Such problems may prevent the production of lots that meet the specifications required for sale of the product and may be difficult and expensive to resolve. Although we have an adequate supply of GOCOVRI to address patient needs into late 2021 and have not observed disruptions in our supply chain to date as a result of COVID-19, there is no guarantee that will we not experience interruption of, or delays in receiving, supply due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems in the future. If any such issues were to arise with respect to GOCOVRI, our business, financial results, or stock price could be adversely affected.

If we are unable to maintain orphan exclusivity for GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, our business may be substantially harmed.

When GOCOVRI was approved for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, GOCOVRI earned seven years of orphan drug exclusivity under the Orphan Drug Act. Even so, the FDA could still subsequently approve the same drug with the same active moiety for the same indication if the FDA concludes that the later drug is safer or more effective or makes a major contribution to patient care, or if we are unable to assure that sufficient quantities of medicine are available to meet patient needs. If we are unable to maintain orphan drug exclusivity for GOCOVRI for the treatment of

dyskinesia, our business would be substantially harmed.

Risks related to clinical development of potential future product candidates

If we resume development of ADS-4101, or seek to develop additional product candidates that we may develop or acquire, we will face regulatory and development risks.

Although we have placed the development program for ADS-4101 (lacosamide) modified release capsules for the treatment of partial onset seizures in patients with epilepsy on hold, if we determine to resume development of ADS-4101, or develop or acquire other potential product candidates and seek to develop them, we will face regulatory and other development risks. There are risks associated with pursuing clinical trials for potential future product candidates, as we may experience numerous unforeseen events during, or as a result, of clinical studies that could harm our ability to commercialize such products or to receive regulatory approval, including that:

- clinical studies may produce negative or inconclusive results or raise significant safety concerns, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- even if clinical studies demonstrate statistically significant efficacy and acceptable safety, the FDA or similar authorities outside the United States may not consider the results of our studies to be sufficient for approval or we may not receive approval in a timely manner, especially in light of the COVID-19 pandemic;
- our clinical sites and clinical investigators may fail to comply with, or inconsistently apply, the trial protocols, regulatory requirements including Good Clinical Practices, contractual obligations, and the rating assessments;
- our third-party vendors, including our Contract Research Organizations, or CROs, and contract manufacturing organizations, or CMOs, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies for various reasons, including a finding that our products have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the supply or quality of materials necessary to conduct clinical studies may be insufficient or inadequate, especially in light of the COVID-19 pandemic;
- our new product discovery or research program may not be successful or warrant clinical development;
- successfully completing the development program in a timely manner, especially in light of the COVID-19 pandemic;
- commercializing our products, if approved, including marketing, sales, and distribution of the product independently or in partnership with another company;
- acceptance by the medical community and patients of the approved product;
- coverage and adequate reimbursement by third party payers;
- willingness and ability of patients to pay out of pocket for the products;
- effectively competing with other approved or used medicines and future compounds in development;
- continued demonstration of an acceptable safety profile following approval; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we are forced to delay or abandon development of our products, especially in light of the COVID-19 pandemic, our business, results of operations, and financial condition will be materially and adversely harmed.

We may expend our limited resources to pursue a particular product or indication and fail to capitalize on products 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 may choose to focus on research programs and products for specific indications. As a result, we may forego or delay pursuit of opportunities with our product candidate or 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 investment in current and future research and development programs and product candidates for specific indications may not yield any commercially viable products for us or future partners.

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 advantageous for us to retain sole development and commercialization rights.

We may in the future seek to acquire additional product candidates, which may subject us to additional risks and expense.

In the future in seeking to diversify our product candidate portfolio we may seek to identify and acquire or in-license novel product candidates. We may fail to identify and acquire or in-license product candidates, including for reasons discussed in these risk factors, and also:

- the process by which we identify and decide to acquire product candidates may not be successful;
- the competition to acquire or in-license promising product candidates is fierce and many of our competitors are large, multinational pharmaceutical, biotechnology and medical device companies with considerably more financial, development and commercialization resources and experience than we have;
- potential product candidates may, upon further study during or after the acquisition process, fail to demonstrate clinical efficacy, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance; and
- potential product candidates may not be effective in treating their targeted diseases.

In addition, if we do acquire additional product candidates and they prove to be unsuccessful, we will have spent significant amounts of resources in acquiring and pursuing these product candidates, and not receive any return on our investments. Further, time and resources spent searching for, identifying, acquiring, and developing potential product candidates may distract management’s attention from our existing business.

Risks related to our reliance on third parties

We rely on third-party organizations to manufacture, supply, and distribute GOCOVRI. If one of these organizations fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new third party vendors and/or face delays in the commercialization and supply of GOCOVRI.

We do not own facilities for clinical and commercial manufacturing of GOCOVRI, and we rely upon third-party contract manufacturing organizations to manufacture, serialize and supply drug product for our clinical studies and to meet commercial demand. If our manufacturers were to encounter difficulties with production costs and yields, quality control, including stability of GOCOVRI and quality assurance testing, shortages of qualified personnel, especially in light of the COVID-19 pandemic, or fail to comply with strictly enforced cGMP requirements, other federal and state regulatory requirements, our commercial supply of GOCOVRI could be jeopardized. We have little control over our manufacturers’ operations or their compliance with applicable regulations and standards. Any delay or interruption in the supply of clinical study materials or commercial product could cause delays in our clinical programs, harm our ability to gain approval from regulatory authorities, and potentially disrupt patient access to our approved products. These events would substantially harm our business, reputation and stock price.

We also rely on a single specialty pharmacy to distribute and provide access to GOCOVRI for the vast majority of our patients. Accordingly, this specialty pharmacy is our largest customer representing approximately 96% of our product revenue. If this specialty pharmacy fails to perform, it could materially harm our business.

All third-party manufacturers of our products and ingredients thereof must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging, or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical studies, regulatory submissions, approvals, commercialization or supply of our products, entail higher costs, impair our reputation, and potentially disrupt patient access or our approved products.

We rely on a single source third-party contract manufacturing organization for the manufacture and supply of our drug substances and drug product for GOCOVRI.

Although we have supply agreements with two drug substance suppliers, only one is currently manufacturing at commercial scales required for GOCOVRI. In addition, we also currently rely on a single drug product manufacturer for GOCOVRI. We continue to seek additional long-term supply agreements with suppliers and supplier qualifications. A failure of our single source manufacturer or drug substance supplier or our failure to qualify at least one other manufacturer organization on a timely basis, especially in light of the current COVID-19 pandemic, and validate the manufacturing process employed at that manufacturer or supplier could delay or harm commercialization of GOCOVRI. Although we believe alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange and negotiate acceptable long-term contracts and obtain regulatory approvals and qualifications, which would adversely affect our business. New suppliers of any drug substance would be required to be qualified under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs, which may be passed on to us. Qualifying and negotiating long-term contracts with manufacturers and providers of packaging services is a lengthy process. If at any time, one or more of our qualified contract manufacturing organizations were not able to manufacture our drug substance or drug product or provide the requisite services, our business and financial condition would be materially adversely affected.

We 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 these trials.

We do not independently conduct clinical studies of our products. Instead, we rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators to perform this function. 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, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practice, for conducting, recording, and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of patients in clinical studies are protected, even though we are not in control of these processes. These third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our products and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

We also rely on other third parties to store and distribute supplies for our clinical studies. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our products or commercialization of our products, producing additional losses and depriving us of potential product revenue.

Risks related to government regulation

Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payer cost-containment initiatives and current societal pressures regarding pharmaceutical product pricing, may negatively impact our ability to generate revenues from or could limit or prevent our products' commercial success.

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, the Patient Protection and Affordable Care Act ("PPACA") was passed, which has substantially changed how healthcare is financed by both governmental and private insurers, and has significantly impacted the U.S. pharmaceutical industry. Details of healthcare regulations, including changes under the PPACA, are discussed in the business heading "Other healthcare regulations" in Part I, Item 1, of our 2019 Annual Report on Form 10-K.

We expect that the PPACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products.

The continuing efforts of the government, insurance companies, managed care organizations, other payers of healthcare services, and patient and political groups to contain or reduce costs of healthcare may, among other things, adversely affect:

- our ability to set a price we believe is fair for our products;
- the reputation of our company;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Our ability to commercialize our products successfully, and to attract commercialization partners for our products, will depend in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the United States, governmental payers such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Details of these considerations are discussed in the business heading "Other healthcare regulations" in Part I, Item 1, of our 2019 Annual Report on Form 10-K.

We are subject to ongoing regulatory obligations and regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

The manufacturing, marketing, and further development of GOCOVRI are subject to continual review by the FDA and/or analogous non-U.S. regulatory authorities. In addition, we are and will be subject to extensive and ongoing regulatory requirements with regard to the labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion, tracking, recordkeeping, and periodic reporting for our products. Further, we and our contract manufacturers of our drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance and maintenance of records and documentation. Regulatory authorities must approve manufacturing facilities before they can be used to manufacture our drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. Certain changes to the manufacturing processes would also be subject to pre-approval by regulatory authorities. In addition, if we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, its manufacturer, or us, including but not limited to requiring withdrawal of the product from the market or suspension of manufacturing. If we, our products or the manufacturing facilities for our products fail to comply with regulatory requirements of the FDA and/or applicable non-U.S. regulatory authorities, we could be subject to administrative or other sanctions, including:

- warning letters or untitled letters;

- civil or criminal penalties and fines;
- injunctions;
- suspension, variation, or withdrawal of regulatory approval;
- suspension of ongoing clinical studies;
- voluntary or mandatory product recalls;
- requirements for dissemination of corrective information or modifications to promotional materials;
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications filed by us;
- refusal to permit import or export of our products;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products.

Regulatory requirements and policies may change, and we may need to comply with additional laws and regulations that are enacted. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market, or continue to market, our future products and our business may suffer.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations, and financial condition could be adversely affected.

Healthcare providers, physicians, distributors, and third-party payers play a primary role in the distribution, recommendation, and prescription of any pharmaceutical product for which we obtain marketing approval. Our arrangements with third-party payers and customers expose us to broadly applicable federal and state fraud and abuse and other laws and regulations that may constrain the business or financial arrangements through which we market, sell and distribute GOCOVRI and other products for which we may obtain marketing approval. The laws and regulations that may affect our ability to operate include: the federal healthcare program Anti-Kickback Statute, the federal civil and criminal false claims laws, including the federal civil False Claims Act and civil monetary penalties laws, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, including as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, the federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, and analogous state laws and regulations, such as anti-kickback, and false claims laws, which may be broader in scope and apply to items or services reimbursed by any third-party payer, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these or other laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, and fraud laws may prove costly. In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. Moreover, the requirements governing drug pricing and reimbursement vary widely from country to country.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures, and most European Union member states now have an HTA system. The HTA process in the European Union member states is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is

conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the national healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA may influence the pricing and reimbursement status for specific medicinal products within individual European Union member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of a specific medicinal product vary between the European Union member states.

In 2011, Directive 2011/24/EU was adopted at European Union level. This Directive concerns the application of patients' rights in cross-border healthcare. The Directive is intended to establish rules for facilitating access to safe and high-quality cross-border healthcare in the European Union. Pursuant to Directive 2011/24/EU, a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states was established. The purpose of the network is to facilitate and support the cooperation between national authorities or bodies and the exchange of information concerning HTAs. This could lead to greater harmonization between European Union member states of the criteria taken into account in the conduct of HTA in pricing and reimbursement decisions.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs that we may join if we successfully commercialize any of our product candidates, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs.

Under the Medicaid Drug Rebate program, a manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

The PPACA made significant changes to the Medicaid Drug Rebate program, as discussed under the heading "Other healthcare regulations" in Part I, Item 1, of our 2019 Annual Report on Form 10-K. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the PPACA. These regulations became effective on April 1, 2016. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program may increase our costs and the complexity of compliance and could have a material adverse effect on our results of operations if we participate in the Medicaid Drug Rebate Program if and when we successfully commercialize any of our product candidates.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The PPACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's final regulations implementing those changes also could affect the 340B ceiling price calculations for any of our product candidates that we successfully commercialize and could negatively impact our results of operations.

The PPACA obligates the Secretary of the HHS to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer

makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration, or HRSA, recently initiated the process of updating the agreement with participating manufacturers. The PPACA also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program. After implementation delays directed by the Trump Administration, on November 30, 2018, HRSA published its final rule regarding the calculation of 340B ceiling price and imposition of civil monetary penalties on manufacturers for knowingly and intentionally overcharging covered entities, which became effective on January 1, 2019. The issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate, if and when we successfully commercialize any of our product candidates and if we participate in the 340B program. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by the reporting manufacturer, governmental or regulatory agencies and the courts. In the case of Medicaid pricing data, if we join the Medicaid Drug Rebate Program and become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we will be obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations would increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we would be required to offer any of our product candidates that we successfully commercialize under the 340B drug discount program.

We will be liable for errors associated with any submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted any false price information to the government, we may be liable for significant civil monetary penalties per item of false information. Our failure to submit the required price data on a timely basis could result in significant civil monetary penalties for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we will participate in the Medicaid program if we join the program if and when we successfully commercialize any of our product candidates. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for any of our product candidates that we successfully commercialize.

CMS and the OIG have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions, if we participate in the federal programs if and when we successfully commercialize any of our product candidates, will not be found by CMS to be incomplete or incorrect.

In order to be eligible to have any of our product candidates that we successfully commercialize paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs, or VA, Department of Defense, Public Health Service, and Coast Guard, referred to collectively as the Big Four agencies, and certain federal grantees, we are required to participate in the VA Federal Supply Schedule, or FSS, pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make any of our product candidates that we successfully commercialize that meet the statutory definition of “covered drug” (biologics and single and innovator multiple source drugs) available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price, or FCP, which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the “non-federal average manufacturer price,” or Non-FAMP, which we will be required to calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements.

Under Section 703 of the National Defense Authorization Act for FY 2008, we will be required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. If we overcharge the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated

FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects if we successfully commercialize any of our product candidates.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation, increased compliance costs and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us, including civil and/or criminal penalties, private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Although we are not directly subject to HIPAA—other than potentially with respect to providing certain employee benefits—we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

On June 28, 2018, California enacted the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

In the EU, the General Data Protection Regulation (GDPR) took effect on May 25, 2018, introducing sweeping new data protection requirements that carry potential fines of up to the greater of 20 million Euros or 4% of annual global revenue. The GDPR will increase our responsibility and potential liability in relation to personal data that we process, expose us to substantial potential fines in the event of violations, increase our compliance costs and could restrict our operations in Europe.

The regulatory approval process is expensive, time consuming, and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates.

The research, development, manufacturing, quality control, labeling, approval, safety, effectiveness, storage, record keeping, reporting, selling, import, export, advertising, promotion, marketing, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, and by regulatory authorities in other countries, with different regulations from country to country. We are not permitted to market our products in the United States or other countries until we receive regulatory approvals. In August 2017, GOCOVRI was FDA-approved for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The FDA will need to approve supplemental NDAs for GOCOVRI before we can market the drug for other indications, such as the treatment of OFF episodes in Parkinson's disease patients receiving levodopa therapy.

To receive approval to commercialize any of our product candidates in the United States, we must demonstrate with substantial evidence from adequate and well-controlled clinical studies, and to the satisfaction of the FDA, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA. Administering any of our product candidates to humans may produce undesirable side effects, which could interrupt, delay, or cause suspension of clinical studies of our product candidates and result in the denial of approval of our product candidates for any or all targeted indications.

FDA approval of an NDA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense we invest, failure can occur at any stage, and we could encounter problems that require us to repeat clinical studies, perform additional preclinical studies and clinical studies, or abandon development and commercialization of a product candidate altogether. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on, among other factors, the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. The FDA can delay, limit, or deny approval of a product candidate for many reasons, including, but not limited to:

- disagreement with the design or implementation of our clinical trials;
- failure of clinical trials to show the level of statistical significance or clinical meaningfulness needed for approval;
- failure to demonstrate that a product candidate is safe or effective;
- insufficient data from preclinical and clinical studies to support an application;
- a finding by an institutional review board, or IRB, Data Safety Monitoring Board, or DSMB, Data Monitoring Committee, or DMC, or the FDA that the clinical trial exposes subjects or patients to an unacceptable health risk;
- disapproval of our or our third-party manufacturer’s processes or facilities; or
- changes to FDA’s approval policies or regulations.

If any of our product candidates fails to demonstrate safety and efficacy in clinical studies or does not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

Risks related to intellectual property

Our ability to successfully commercialize GOCOVRI and any product candidates may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our products and product candidates.

Our success depends in large part on our ability to obtain and maintain exclusivity, patent(s), and other intellectual property protection in the United States and in other countries with respect to GOCOVRI, our product candidates, and any in- and out-licensed programs. We have sought to protect GOCOVRI and our product candidate(s) by filing patent applications in the United States and abroad related to our novel discoveries, technologies, and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our discoveries or technologies or from developing competing products and technologies.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant 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 not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. 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. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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 that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the United States Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights is highly uncertain.

The United States has enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

From time to time, we may become involved in opposition, interference, derivation, *inter partes* review, post-grant review, or other proceedings challenging our patent rights or the patent rights of others, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us or Allergan, without payment to us.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, 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 or products in a non-infringing manner. The issuance of a patent is not conclusive as to its 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 the patent claims of our owned or licensed patents being narrowed, invalidated, or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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 or otherwise provide us with a competitive advantage.

For our partnered assets, like Namzaric, we may not have the right to control the prosecution of patent applications, or to maintain or enforce the patent, covering our products or product candidates that we license to third parties or that we may license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us or from us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

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

Filing, prosecuting, and defending patents on all of our products and product candidates throughout the world would be prohibitively expensive. 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 but where enforcement is not as strong as in the United States. These products may compete with our products and product candidates in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so 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 and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Obtaining and maintaining our patent protection depends upon 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.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent prosecution process and following the issuance of a patent. Our failure to comply with such requirements could result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case if our patent were in force.

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

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property for GOCOVRI, our partnered products, any product candidates, and any in- and out-licensed programs. To counter infringement or unauthorized use, we or our licensees may be required to file infringement claims, which can be expensive and time-consuming. For example, on February 16, 2018, Osmotica Pharmaceuticals LLC and Vertical Pharmaceuticals LLC (“Osmotica”) filed an action against us in U.S. District Court for the state of Delaware, requesting a declaratory judgment that Osmotica’s newly-approved product Osmolex ER™ (amantadine) extended release tablets does not infringe certain of our patents. For further information, see *Litigation and Other Legal Proceedings* in “Note 7 – Commitments and Contingencies” in the accompanying “Notes to Condensed Consolidated Financial Statements (unaudited)”.

We anticipate that the prosecution of any lawsuits related to our partnered products and any lawsuits related to GOCOVRI may require a significant amount of time and attention from our senior executives and management. In addition, in a patent infringement proceeding, a court may decide that a patent of ours (or a patent we license) is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the product in question. An adverse result in any litigations or proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Such a result could limit our ability to prevent others from using or commercializing similar or identical products, limit our ability to prevent others from launching generic versions of our products and could limit the duration of patent protection for our products, all of which could have a material adverse effect on our business. Also, a successful challenge to our patents could reduce or eliminate our right to receive royalties from Allergan under our license agreement with Allergan. 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 could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we or our partners are infringing 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 and the ability of our partners to develop, manufacture, market, and sell our products and product candidates and to use our proprietary discoveries and technologies without infringing, misappropriating, or otherwise violating the proprietary rights or intellectual property of third parties. We or our partners may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, re-examination, *inter partes* review, post-grant review, opposition, or similar proceedings before the USPTO and its foreign counterparts. The costs of these proceedings could be substantial, and the proceedings may result in a loss of such intellectual property rights. Some of our competitors may be able to sustain the costs of complex patent disputes and litigation more effectively than we can, because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any disputes or litigation could adversely affect our ability to raise the funds necessary to continue our operations. Third parties may assert infringement claims against us or our partners based

on existing patents or patents that may be granted in the future. Under our license agreement with Allergan we are obliged to indemnify Allergan under certain circumstances and our royalty entitlements may also be reduced. Our indemnification obligation to Allergan, while subject to customary limitations, has no monetary cap, and our right to receive royalties from Allergan may be eliminated in any calendar quarter in which certain third party generic competition exists. If we or our partners are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products 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. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our products and product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be unable to protect the confidentiality of our trade secrets, thus harming our business and competitive position.

In addition to our patented technology and products, we rely upon trade secrets, including unpatented know-how, technology, and other proprietary information, to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees, our partners, and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. However, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute such agreements, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. In addition, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement.

While to our knowledge the confidentiality of our trade secrets has not been compromised, if the employees, consultants or partners that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated, or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect our intellectual property to the same extent as the laws of the United States. If our trade secrets are disclosed or misappropriated, it would harm our ability to protect our rights and adversely affect our business.

Risks related to Namzaric®

Under our license agreement with Allergan, if Allergan fails to successfully commercialize Namzaric for any reason or if the license agreement with Allergan is terminated, the royalties we are eligible to receive under our license agreement with Allergan may not occur or may be minimal, and would have a negative impact on our revenue potential and harm our business.

In November 2012, we entered into a license agreement with Allergan pursuant to which we granted Allergan a right to develop and commercialize Namzaric in the United States. Under that agreement, we began to receive royalties from Allergan on the net sales of Namzaric, starting in May 2020. If for any reason Allergan fails to successfully commercialize Namzaric, on which we are eligible to receive royalties in the low double digits to mid-teens, we may not receive such future royalties or receive minimal amounts, and our business may be harmed. Even if we do receive royalties, based on recent trends of Namzaric net sales, we expect the tiered royalty to be in the low double digits through the term of the agreement.

We are the subject of litigation claiming violation of Federal and state false claims acts in connection with the commercialization of Namenda XR and Namzaric by Allergan, which may have a material and negative impact on our business.

On April 1, 2019, we were served with a complaint against us and several Allergan entities alleging violations of Federal and state false claims acts ("FCA") in connection with the commercialization of Namenda XR and Namzaric by Allergan, as further described in *Litigation and Other Legal Proceedings* in "Note 7 – Commitments and Contingencies" in the accompanying "Notes to Condensed Consolidated Financial Statements (unaudited)". The

complaint alleges that patents held by Allergan and us covering Namenda XR and Namzaric were procured through fraud on the United States Patent and Trademark Office and that these patents were asserted against potential generic manufacturers of Namenda XR and Namzaric to prevent the generic manufacturers from entering the market, thereby wrongfully excluding generic competition resulting in artificially high price being charged to government payors. The complaint includes a claim for damages of "potentially more than $2.5 billion dollars," treble damages and statutory penalties. We are in the early stages of this litigation. Defending this litigation may be costly, divert time and attention of our management from the conduct of our business, and if we are unable to prevail in this litigation it may result in substantial damages, each of which could have a material and negative impact on our business.

Risks related to our financial condition and need for additional capital

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results have fluctuated significantly, and we expect may fluctuate significantly in the future, particularly in light of the COVID-19 pandemic and the effect that it is having on patient demand and the economy as a whole, which makes it difficult for us to predict our future operating results. Any future revenue will depend on our ability to market and sell GOCOVRI, ADS-5102 and our product candidate, the payment of royalties to us from Allergan under terms of our licensing agreement regarding Namzaric, or the establishment of potential future collaboration and license agreements, if any, and the achievement of any upfront or milestone payments provided thereunder. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including:

- uncertainties related to, and the duration of, the COVID-19 pandemic;
- the level of demand for our products, which may vary significantly as they are launched and compete for position in the marketplace;
- pricing and reimbursement policies with respect to GOCOVRI and our product candidate, if approved, and the competitive response from existing and potential future therapeutic approaches that compete with our products and product candidate;
- the cost of manufacturing our products and product candidate, which may vary due to a number of factors, including the terms of our agreements with contract manufacturing organizations, or CMOs;
- the timing, cost, level of investment, and success or failure of research and development activities relating to our products and product candidate, which may change from time to time;
- expenditures that we may incur to acquire and develop additional product candidates and technologies;
- the timing and success or failure of clinical studies for competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing and magnitude of upfront and milestone payments under any potential future collaboration and licensing agreements;
- future accounting pronouncements or changes in our accounting policies; and
- changing or volatile U.S., European, and global economic environments, especially as a result of the COVID-19 pandemic.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated operating results and/or earnings guidance that we may provide.

If we do not have adequate funds to cover all of our development and commercial activities, we may have to raise additional capital or curtail or cease operations.

We began to commercialize GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, in January 2018, and it will require substantial funds to continue to commercialize GOCOVRI. In addition, funds are required for the continued operation of our business. We have entered into a Sales Agreement with Cowen and Company, LLC under which we may offer and sell our common stock having aggregate sales proceeds of up to $50 million from time to time through Cowen and Company, LLC as our sales agent. As of June 30, 2020, we have not made any sales under this facility. As of June 30, 2020, we had approximately $103.4 million in cash, cash equivalents, and investments. We believe that our available cash, cash equivalents, and investments will be sufficient to fund our anticipated level of operations for at least the next 12 months, but there can be no assurance that this will be the case, especially in light of the uncertainties related to, and the duration of, the COVID-19 pandemic.

We have financed our operations primarily through proceeds from our license agreement with Allergan, public and private equity offerings, our royalty-backed loan agreement ("Royalty-Backed Loan") with HealthCare Royalty Partners III, L.P., ("HCRP"), since 2017 with sales of GOCOVRI, and, to a lesser extent, government grants, venture debt, and benefits from tax credits made available under a federal stimulus program supporting drug development. We anticipate that our cash requirements will be substantial as we:

- commercialize GOCOVRI, including distribution, marketing, and sales capabilities;
- manufacture GOCOVRI for commercial use;
- investigate ADS-5102 in preclinical and clinical trials for potentially other indications;
- seek regulatory approvals for our products and any product candidates that successfully complete clinical studies;
- continue the research, development, and manufacture of our current products and product candidate; and
- seek to discover or in-license additional product candidates.

If we do not have adequate funds to support these activities, our business opportunities could be hindered.

If we need additional funds to operate our business and if we cannot raise additional capital when needed, or if additional capital is not available to us on favorable terms, our stockholders may be adversely affected or our business may be harmed.

If we need additional funds to support our business and additional funding is not available on favorable terms or at all, we may need to delay or reduce the scope of our research and clinical development programs or commercialization efforts. We do not have any committed external source of funds or other support for our development efforts. We expect to finance future cash needs through a combination of public or private equity offerings, debt financings, royalty financings, collaborations, strategic alliances, licensing arrangements, asset sales, and other marketing and distribution arrangements. The trading prices for our common stock, as well as the broader equity and debt markets, have been highly volatile since the advent of the COVID-19 pandemic. Additional financing may not be available to us when we need it or it may not be available on favorable terms. If we raise additional capital through debt financings, royalty financings, collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our products and product candidate, technologies, future revenue streams, or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, in addition to the repayment of principal and interest on negotiated terms, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

We have outstanding debt backed by two of our principal assets, GOCOVRI and royalties we may receive on Namzaric, and failure by us or our royalty subsidiary to fulfill our obligations under the applicable loan agreements may cause the repayment obligations to accelerate.

In May 2017, we, through a newly formed wholly-owned subsidiary, entered into a Royalty-Backed Loan with HCRP, pursuant to which we initially borrowed $35 million and then borrowed an additional $65 million upon FDA approval and FDA's recognition in the Orange Book of the seven-year orphan drug exclusivity that GOCOVRI earned upon approval in August 2017, for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

Interest and principal on the loan will be payable from the proceeds of royalty on U.S. net sales of GOCOVRI and up to $15 million of our annual royalties from Allergan on U.S. net sales of Namzaric. The HCRP notes mature in December 2026, if not earlier repaid.

We secured the loan with rights to GOCOVRI (ADS-5102) and rights to certain payment amounts on Namzaric and the loan documents further provide for assignment into our subsidiary holding these rights to any future intellectual property, licenses, assets and agreements with respect to the manufacture, development, supply, distribution, sale and commercialization of GOCOVRI. The loan documents contain customary events of default permitting HCRP to accelerate and require mandatory prepayment of outstanding principal and interest, including: failure to timely pay principal and interest when due and payable; failure to perform specified covenants with respect to maintenance of the collateral and prohibitions on liens with respect to the collateral; limitations on payments of dividends, additional loans, acquisition or merger transactions not in accordance with the arrangement. Upon the occurrence, an event of default under the loan documents, we could be required to prepay the entire loan and, if we are not able to do so, we may lose control over certain rights and payments to GOCOVRI and royalty payments with respect to Namzaric, either of which would seriously harm our business.

We are and in the future may be subject to securities litigation, which may be expensive and could divert management attention.

Our share price is volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We have become the target of this type of litigation and in May 2019 a putative class action lawsuit alleging violations of the federal securities laws was filed against us and certain of our current and former directors and officers alleging violations of the securities laws by us and certain of our current and former directors and officers in connection with our January 2018 secondary public offering of common stock. In addition, in December 2019, another putative class action lawsuit was filed against us and certain former officers alleging violations of the Securities Act of 1934. For more information, please see *Litigation and Other Legal Proceedings* in "Note 7 – Commitments and Contingencies" in the accompanying "Notes to Condensed Consolidated Financial Statements (unaudited)". Lawsuits such as this one can be expensive to defend and could divert our management's attention from the conduct of our business, which could have an adverse effect on our business.

Risks related to ownership of our common stock

Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has fluctuated in the past and may be volatile in the future. The stock market in general and the market for securities of pharmaceutical and biotechnology 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, investors may experience losses on their investments in our stock.

In addition, the clinical development stage of our operations may make it difficult for investors to evaluate the success of our business to date and to assess our future viability. The market price for our common stock may be influenced by many factors, including:

- uncertainties related to, and the duration of, the COVID-19 pandemic;
- our success in commercializing GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease;
- the availability of reimbursement by third-party payers at acceptable levels, or at all, for GOCOVRI;

- the success of competitive products or technologies;
- results of clinical studies of product candidates we may choose to develop or those of our competitors;
- introductions and announcements of new products and product candidates by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our or our competitors' products, product candidates, clinical studies, manufacturing process, or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be comparable to us;
- our revenue performance, both in absolute terms and relative to analyst and shareholder expectations;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing and our commercialization partners;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our current or future products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare reimbursement systems;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our current or future products;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in revenue forecasts, earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry, and market conditions; and
- the other risks described in this "Risk Factors" section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Additionally, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations, and growth prospects.

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

Provisions in our corporate charter and our bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their 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, 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. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include that:

- our board of directors is divided into three classes with staggered three-year terms, which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to change the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders may not act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors or the chairman of the board and chief executive officer;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may issue, without stockholder approval, shares of undesignated preferred stock, and the ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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.

Other Risks

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2019, we had federal and, subject to the recent California franchise tax law change affecting California state net operating losses mentioned below, state net operating loss carryforwards of $354.4 million and $325.8 million, respectively. Portions of the federal net operating loss carryforwards will begin to expire, if not utilized, beginning in 2025, and the state net operating loss carryforward begins expiring in 2028. Portions of these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the current federal income tax law, federal net operating losses incurred in taxable years beginning after December 31, 2017, and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020, is limited. It is still uncertain if and to what extent various states will conform to the changes in federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. It is possible that we have experienced an ownership change. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, including a recent California franchise tax law change limiting the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023.

We are a "smaller reporting company" and we cannot be certain whether the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a "smaller reporting company" and, as such, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely 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 suffer or be more volatile.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations have been affected by the COVID-19 pandemic and could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, fires, extreme weather conditions, other medical epidemics, and other natural or manmade disasters or business interruptions. The duration of the COVID-19 pandemic and the occurrence of any of these other business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our corporate headquarters is located in California and certain clinical sites for our product candidates, operations of our existing and future partners, and suppliers are or will be located near major earthquake faults and fire zones. The ultimate impact on us, our significant partners, suppliers, and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire, or other natural or manmade disaster.

Any future operations or business arrangements with entities outside the United States present risks that could materially adversely affect our business.

If we obtain approval to commercialize any approved products or utilize CMOs outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. If any product or product candidates that we may develop are approved for commercialization outside the United States, we will be subject to additional risks related to entering into international business relationships, including:

- impacts of the COVID-19 pandemic;
- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- different payer reimbursement regimes, governmental payers or patient self-pay systems and price controls;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- difficulties in assuring compliance with foreign corrupt practices laws;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- compliance with privacy laws;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes or typhoons, floods, and fires.

Our internal computer systems, or those of our CROs, CMOs, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our business.

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, specialty pharmacy, distributors, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we are not aware of any material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs or commercialization efforts. For example, the loss of clinical study data from completed or ongoing clinical studies for any of our products or product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. While we back-up our internal computer systems periodically and store such data off-site or in the cloud, we can offer no assurance that such off-site storage of data will allow us to continue our business without interruptions to our operations, which could result in a material disruption of our drug development programs or commercialization efforts. 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 or proprietary information, we could incur liability and the further development of our products and product candidates could be delayed.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation By Reference				Filed / Furnished Herewith
		Form	SEC File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Adamas Pharmaceuticals, Inc.	8-K	001-36399	3.1	4/15/2014	
3.2	Amended and Restated Bylaws of Adamas Pharmaceuticals, Inc.	S-1	333-194342	3.4	3/5/2014	
4.1	Reference is made to Exhibits 3.1 through 3.2.					
4.2	Form of Common Stock Certificate of Adamas Pharmaceuticals, Inc.	S-1	333-194342	4.1	3/26/2014	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(1)					X
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					X

(1) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

** The confidential portions of this Exhibit have been omitted and are marked by an asterisk.

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.

Adamas Pharmaceuticals, Inc.
(Registrant)

Date: August 6, 2020

/s/ Neil F. McFarlane
Neil F. McFarlane
Chief Executive Officer
(Principal Executive Officer)

Date: August 6, 2020

/s/ Christopher B. Prentiss
Christopher B. Prentiss
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Neil F. McFarlane, hereby certify that:

1. I have reviewed this quarterly report on Form 10-Q of Adamas 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 registrant's most recent fiscal quarter (the registrant's fourth 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.

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 registrant's board of directors (or persons performing the equivalent functions):

    a) all significant deficiencies and material weakness 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

/s/ Neil F. McFarlane

Neil F. McFarlane
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Christopher B. Prentiss, hereby certify that:

1. I have reviewed this quarterly report on Form 10-Q of Adamas 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 registrant's most recent fiscal quarter (the registrant's fourth 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.

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 registrant's board of directors (or persons performing the equivalent functions):

    a) all significant deficiencies and material weakness 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

/s/ Christopher B. Prentiss

Christopher B. Prentiss
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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Neil F. McFarlane, Chief Executive Officer of Adamas Pharmaceuticals, Inc. (the "Company"), and Christopher B. Prentiss, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 6th day of August, 2020.

/s/ Neil F. McFarlane	/s/ Christopher B. Prentiss
Neil F. McFarlane	Christopher B. Prentiss
Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.