

# ADAMAS PHARMACEUTICALS INC

## FORM 10-Q (Quarterly Report)

Filed 11/02/17 for the Period Ending 09/30/17

Address	1900 POWELL ST., SUITE 750 EMERYVILLE, CA, 94608
Telephone	510-450-3554
CIK	0001328143
Symbol	ADMS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-Q**

---

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

For the quarterly period ended **September 30, 2017**

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 No. **001-36399**

---

**ADAMAS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

---

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**42-1560076**

(I.R.S. Employer  
Identification Number)

**1900 Powell Street, Suite 750**

**Emeryville, CA**

(Address of Principal Executive Offices)

**94608**

(Zip Code)

Registrant's Telephone Number, Including Area Code: **(510) 450-3500**

---

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

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

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of October 31, 2017 was 22,778,880 .

---

---

**ADAMAS PHARMACEUTICALS, INC.  
QUARTERLY REPORT ON FORM 10-Q  
INDEX**

		<b>Page</b>
<b><u>PART I.</u></b>	<b><u>FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	<u>Financial Statements</u>	
	<u>Condensed Consolidated Balance Sheets at September 30, 2017 (unaudited) and December 31, 2016</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2017 and 2016 (unaudited)</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2017 and 2016 (unaudited)</u>	<u>5</u>
	<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and 2016 (unaudited)</u>	<u>6</u>
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>7</u>
<u>Item 2.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>21</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>30</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>30</u>
 <u>PART II.</u>	 <u>OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u>	<u>31</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>31</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>63</u>
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	<u>63</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>63</u>
<u>Item 5.</u>	<u>Other Information</u>	<u>63</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>64</u>
<u>SIGNATURES</u>		<u>65</u>

**PART I. FINANCIAL INFORMATION**  
**ITEM 1. FINANCIAL STATEMENTS**  
**ADAMAS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(unaudited)**  
**(in thousands, except share and per share data)**

	September 30, 2017	December 31, 2016
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 22,121	\$ 23,735
Available-for-sale securities	101,605	89,917
Accounts receivable	3	794
Inventory	425	—
Prepaid expenses and other current assets	2,806	2,541
Total current assets	126,960	116,987
Property and equipment, net	3,110	3,156
Available-for-sale securities, non-current	7,004	22,292
Other assets	38	38
Total assets	\$ 137,112	\$ 142,473
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable	\$ 5,380	\$ 3,589
Accrued liabilities	9,539	5,867
Other current liabilities	292	287
Total current liabilities	15,211	9,743
Long-term debt	35,408	—
Other non-current liabilities	615	547
Total liabilities	51,234	10,290
Commitments and Contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.001 par value — 5,000,000 shares authorized, and zero shares issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value — 100,000,000 shares authorized, 22,716,277 and 22,013,644 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	27	27
Additional paid-in capital	268,305	254,558
Accumulated other comprehensive loss	(112)	(193)
Accumulated deficit	(182,342)	(122,209)
Total stockholders' equity	85,878	132,183
Total liabilities and stockholders' equity	\$ 137,112	\$ 142,473

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
<b>License and grant revenue</b>	\$ 1	\$ 138	\$ 3	\$ 535
<b>Operating expenses</b>				
Research and development	6,459	7,437	20,723	24,183
Selling, general and administrative, net	16,064	7,344	38,323	22,043
Total operating expenses	22,523	14,781	59,046	46,226
Loss from operations	(22,522)	(14,643)	(59,043)	(45,691)
Interest and other income, net	839	249	1,265	593
Interest expense	(1,677)	—	(2,406)	—
Loss before income taxes	(23,360)	(14,394)	(60,184)	(45,098)
Benefit for income taxes	—	—	(51)	—
Net loss	\$ (23,360)	\$ (14,394)	\$ (60,133)	\$ (45,098)
Net loss per share, basic and diluted	\$ (1.04)	\$ (0.66)	\$ (2.69)	\$ (2.09)
Weighted average shares used in computing net loss per share, basic and diluted	22,569	21,941	22,390	21,616

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)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Net loss	\$ (23,360)	\$ (14,394)	\$ (60,133)	\$ (45,098)
Unrealized gain (loss) on available-for-sale securities	71	(96)	81	94
Comprehensive loss	<u>\$ (23,289)</u>	<u>\$ (14,490)</u>	<u>\$ (60,052)</u>	<u>\$ (45,004)</u>

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)**

	Nine Months Ended September 30,	
	2017	2016
<b>Cash flows from operating activities</b>		
Net loss	\$ (60,133)	\$ (45,098)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	884	562
Stock-based compensation	9,911	7,782
Non-cash interest expense	2,406	—
Change in fair value of embedded derivative liability	(531)	—
Net accretion of discounts and amortization of premiums of available-for-sale securities	216	(332)
Changes in assets and liabilities		
Accrued interest of available-for-sale securities	(261)	(119)
Inventory	(75)	—
Prepaid expenses and other assets	356	(2,325)
Accounts receivable	791	515
Accounts payable	924	3,007
Accrued liabilities and other liabilities	3,509	(2,431)
Net cash used in operating activities	(42,003)	(38,439)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(936)	(1,222)
Purchases of available-for-sale securities	(56,524)	(95,528)
Maturities of available-for-sale securities	60,250	46,795
Net cash provided by (used in) investing activities	2,790	(49,955)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of long-term debt	34,600	—
Proceeds from public offerings, net of offering costs	—	61,822
Payment of debt issuance costs	(623)	—
Proceeds from issuance of common stock upon exercise of stock options	3,192	2,918
Proceeds from employee stock purchase plan	430	326
Net cash provided by financing activities	37,599	65,066
Net decrease in cash and cash equivalents	(1,614)	(23,328)
Cash and cash equivalents at beginning of period	23,735	33,104
Cash and cash equivalents at end of period	\$ 22,121	\$ 9,776
<b>Supplemental disclosure of noncash investing and financing activities</b>		
Purchases of inventory in accounts payable and accrued expenses	\$ 337	\$ —
Debt issuance costs in accounts payable and accrued expense	\$ 10	\$ —
Purchases of property and equipment in accounts payable and accrued expense	\$ 51	\$ 227
Stock-based compensation capitalized in inventory	\$ 13	\$ —

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”) discovers, develops, and commercializes new medicines to treat chronic neurologic disorders. The Company’s portfolio includes:

- GOCOVRI™ (amantadine) extended release capsules, formerly referred to as ADS-5102, for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications;
- ADS-5102 (amantadine) extended release capsules (GOCOVRI) in development for the treatment of walking impairment in patients with multiple sclerosis;
- ADS-4101 (lacosamide) modified release capsules in development for the treatment of partial onset seizures in patients with epilepsy; and
- Namzaric® (memantine hydrochloride extended release and donepezil hydrochloride) capsules and Namenda XR® (memantine hydrochloride) extended release capsules for the treatment of moderate to severe Alzheimer’s disease.

*GOCOVRI (formerly referred to as ADS-5102) for the Treatment of Dyskinesia in Patients with Parkinson’s Disease*

On August 24, 2017, the U.S. Food and Drug Administration (“FDA”) approved the Company’s New Drug Application (“NDA”) for GOCOVRI (amantadine) extended release capsules for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications (“dyskinesia”). The Company made GOCOVRI available for physician and patient use in the fourth quarter of 2017, with plans for a full commercial launch via the deployment of the Company’s sales team in January 2018. GOCOVRI has orphan drug exclusivity until August 24, 2024.

*ADS-5102 (GOCOVRI) in Development for the Treatment of Walking Impairment in Patients with Multiple Sclerosis*

ADS-5102 is an investigational high-dose, extended release amantadine capsule, taken once-daily at bedtime. The Company completed a Phase 2 proof-of-concept study designed to evaluate ADS-5102 in patients with multiple sclerosis who have walking impairment and plans to initiate a Phase 3 clinical program in the first quarter of 2018.

*ADS-4101 in Development for the Treatment of Partial Onset Seizures in Patients with Epilepsy*

ADS-4101 is an investigational high-dose, modified release lacosamide capsule, taken once -daily at bedtime. Lacosamide is an anti-epilepsy active ingredient previously approved by the FDA and currently marketed by UCB SA/NV as VIMPAT® (lacosamide). The Company completed two Phase 1 studies of ADS-4101 in healthy volunteers and expects to meet with the FDA at an End-of-Phase 2 Meeting regarding a planned Phase 3 clinical development program for ADS-4101 in the first quarter of 2018.

*Namzaric and Namenda XR for the Treatment of Moderate to Severe Alzheimer’s Disease*

Namzaric (memantine hydrochloride extended release and donepezil hydrochloride) capsules and Namenda XR (memantine hydrochloride) extended release capsules are two commercially available medicines, which are currently marketed by Forest Laboratories Holdings Limited (“Forest”), an indirect wholly-owned subsidiary of Allergan plc (“Allergan”), in the United States for the treatment of moderate to severe Alzheimer’s disease. The Company is eligible to receive royalties on net sales of Namenda XR and Namzaric beginning in June of 2018 and May of 2020, respectively.

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. 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. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the Company believes are necessary for a fair presentation of the periods presented. The condensed consolidated balance sheet at December 31, 2016 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 or any other future period and should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2016, included in the Company’s Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC.

### **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, clinical trial accruals, fair value of assets and liabilities including short-term and long-term classification, embedded derivatives, income taxes, 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.

### **Liquidity and Financial Condition**

To date, a significant portion of the Company’s resources have been dedicated to the research and development of its products. The Company has not generated any commercial revenue from the sale of its products through September 30, 2017; however, the Company received approval for GOCOVRI on August 24, 2017. The Company made GOCOVRI available for physician and patient use in the fourth quarter of 2017, with plans for a full commercial launch via the deployment of the Company’s sales team in January 2018.

Based upon the current status of, and plans for, its product development and commercialization, the Company believes that the existing cash, cash equivalents, and investments of \$130.7 million as of September 30, 2017 will be adequate to satisfy the Company’s capital needs through at least the next twelve months from the issuance of this Quarterly Report on Form 10-Q. However, the process of developing and commercializing products requires significant research and development, preclinical testing and clinical trials, manufacturing arrangements, as well as regulatory approvals. These activities, together with the Company’s selling, general and administrative expenses, are expected to result in significant operating losses until the commercialization of the Company’s products or license agreements generate sufficient revenue to offset expenses. While the Company had net income during 2014, 2013, and 2012, it has not generated any commercial revenue from sales of its products. Under its license agreement with Allergan, the Company received the final milestone payment in 2014, and is not entitled to receive any royalties for net sales of Namzaric<sup>®</sup> until mid-2020 and Namenda XR<sup>®</sup> until mid-2018. To achieve sustained profitability, the Company, alone or with others, must successfully develop its product candidates, obtain required regulatory approvals, and successfully manufacture and market its products.

### **Inventory**

Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first-in first-out method. Inventory consists of raw materials, work-in-process, and GOCOVRI finished goods. Raw materials and work-in-process that may be utilized for both commercial and clinical programs are included in inventory and charged to research and development expense when the product enters the research and development process and can no longer be used for commercial purposes. Costs include active pharmaceutical ingredient (API), third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process,

and indirect overhead costs. If the Company identifies excess, obsolete or unsalable product, the Company will write down its inventory to its net realizable value in the period it is identified.

The Company begins capitalizing costs as inventory when the product candidate receives regulatory approval. Prior to regulatory approval, inventory costs related to product candidates are recorded as research and development expense. The Company received FDA approval for GOCOVRI on August 24, 2017, and began capitalizing inventory manufactured at the FDA approved location, after FDA approval.

### **Revenue Recognition**

The Company recognizes revenue when all four of the following criteria have been met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable, and (iv) collectability is reasonably assured. Revenue under license arrangements is recognized based on the performance requirements of the contract. Determinations of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments regarding the fixed nature of the fees charged for deliverables and the collectability of those fees. Should changes in conditions cause management to determine that these criteria are not met for any new or modified transactions, revenue recognized could be adversely affected.

The Company generates revenue from collaboration and license agreements for the development and commercialization of products. Collaboration and license agreements may include non-refundable upfront license fees, partial or complete reimbursement of research and development costs, contingent consideration payments based on the achievement of defined objectives, and royalties on sales of commercialized products. The Company's performance obligations under the collaboration and license agreements may include the license or transfer of intellectual property rights, obligations to provide research and development services and related materials, and obligations to participate on certain development and/or commercialization committees with the partners.

For revenue agreements with multiple-element arrangements, the Company allocates revenue to each non-contingent element based on the relative-selling-price of each element in an arrangement. When applying the relative-selling-price method, the Company determines the selling price for each deliverable using the following estimation hierarchy: (i) vendor-specific objective evidence of fair value of the deliverable, if it exists, (ii) third-party evidence of selling price, if vendor-specific objective evidence is not available, or (iii) the vendor's best estimate of selling price, if neither vendor-specific nor third-party evidence is available. Revenue allocated is then recognized when the four basic revenue recognition criteria, mentioned above, are met for each element.

The Company recognizes payments that are contingent upon achievement of a substantive milestone in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can only be achieved based on the Company's performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones subject to this guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms within the agreement and commensurate with the Company's performance to achieve the milestone after commencement of the agreement.

Amounts related to research and development funding and full-time equivalent employees assigned to the license agreement are recognized as the related services or activities are performed, in accordance with the contract terms.

### **Accounts Receivable**

The Company's accounts receivable balance consists of amounts due from Allergan, in accordance with the contract terms of the license agreement, for research and development funding and full-time equivalent employees assigned to the Allergan license agreement, as well as for reimbursement of external costs, recorded as contra-expense, associated with supporting prosecution and litigation of intellectual property rights.

### **Clinical Trial Accruals**

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple

research institutions and contract research organizations (“CROs”) that conduct and manage clinical trials on the Company’s behalf.

The Company estimates clinical trial expenses based on the services performed pursuant to contracts with research institutions and CROs that conduct and manage clinical trials on its behalf. In accruing service fees, the Company obtains the reported level of patient enrollment at each site and estimates the time period over which services are to be performed and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

### **Research and Development**

Research and development (“R&D”) expenses include salaries and related compensation, contractor and consultant fees, external clinical trial expenses performed by CROs, licensing fees, acquired intellectual property with no alternative future use, and facility and administrative expense allocations. In addition, the Company funds R&D at research institutions under agreements that are generally cancelable at its option. Research costs typically consist of applied research and preclinical and toxicology work. Pharmaceutical manufacturing development costs consist of pre-approval inventory purchases, product formulation, chemical analysis, and the transfer and scale-up of manufacturing at facilities operated by the Company’s contract manufacturers. Clinical development costs include the costs of Phase 1, Phase 2, and Phase 3 clinical trials. These costs are a significant component of the Company’s research and development expenses.

The Company accrues costs for clinical trial activities performed by CROs and other third parties based upon the estimated amount of work completed on each study as provided by the CRO. These estimates are reviewed for reasonableness by the Company’s internal clinical personnel, and the Company aims to match the accrual to actual services performed by the organizations as determined by patient enrollment levels and related activities. The Company monitors patient enrollment levels and related activities using available information; however, if the Company underestimates activity levels associated with various studies at a given point in time, the Company could be required to record significant additional R&D expenses in future periods when the actual activity level becomes known. The Company charges all such costs to R&D expenses. Non-refundable advance payments are capitalized and expensed as the related goods are delivered or services are performed.

### **Long-Term Debt**

Long-term debt consists of the Company’s loan agreement with HealthCare Royalty Partners (“HCRP”). The Company accounted for the loan agreement as a debt financing arrangement. Interest expense is accrued using the effective interest rate method over the estimated period the debt will be repaid. Debt issuance costs have been recorded as a debt discount in the Company’s consolidated balance sheets and are being amortized and recorded as interest expense throughout the life of the loan using the effective interest rate method. The Company must make certain assumptions and estimates, including future royalties and net product sales, in determining the expected repayment term and amortization period of the debt discount, as well as the classification between current and long-term portions. The Company periodically assesses these assumptions and estimates, and adjusts the liabilities accordingly.

### **Embedded Derivatives Related to Debt Instruments**

Embedded derivatives that are required to be bifurcated from their host contract are evaluated and valued separately from the debt instrument. Under the Company’s loan agreement with HCRP, upon the occurrence of a default or a change in control, the Company may be required to make mandatory prepayments of the borrowings. The prepayment premium is considered an embedded derivative, as the holder of the loans may exercise the option to require prepayment by the Company. Further, in the event of a regulatory change that results in a material adverse effect on HCRP’s rate of return, the Company shall pay directly to HCRP an amount that compensates HCRP for such reduction. The embedded derivative is presented as a component of other non-current liabilities. The Company will remeasure the embedded derivatives each reporting period and report changes in the estimated fair value as gains or losses in interest and other income, net, in the condensed consolidated statement of operations.

### **Basic and Diluted Net Loss Per Share**

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net loss per share is based upon the weighted average number of common shares outstanding and dilutive common stock equivalents outstanding during the period. Common stock equivalents are options granted under the Company's stock awards plans and are calculated under the treasury stock method. Common equivalent shares from unexercised stock options and unvested restricted stock units are excluded from the computation when there is a loss as their effect is anti-dilutive, or if the exercise price of such options is greater than the average market price of the stock for the period. The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. For the three and nine months ended September 30, 2017, approximately 6,206,000 and 6,002,000, respectively, shares of potentially dilutive securities were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive. For the three and nine months ended September 30, 2016, approximately 5,523,000 and 5,535,000, respectively, shares of potentially dilutive securities were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive.

### **Stock-Based Compensation**

The Company accounts for stock-based compensation of stock options granted to employees and directors and for employee stock purchase plan shares by estimating the fair value of stock-based awards using the Black-Scholes option-pricing model. The Company accounts for stock-based compensation of restricted stock units granted to employees based on the closing price of the Company's common stock on the date of grant. The fair value of stock-based awards is recognized and amortized over the applicable vesting period. All stock options awarded to non-employees are accounted for at the fair value of the consideration received or the fair value of the equity instrument issued, as calculated using the Black-Scholes model. Stock options granted to non-employees are subject to periodic revaluation at each reporting date as the underlying equity instruments vest.

In order to estimate the value of share-based awards, the Company uses the Black-Scholes model, which requires the use of certain subjective assumptions. The most significant subjective assumptions are management's estimates of the expected volatility and the expected term of the award. In addition, judgment is also required in estimating the amount of share-based awards that are expected to be forfeited. If actual results differ significantly from any of these estimates, stock-based compensation expense and the Company's results of operations could be materially impacted.

### **Recent Accounting Pronouncements**

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*. The amendment in this ASU provides guidance on the revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The core principle of this update provides guidance to identify the performance obligations under the contract(s) with a customer and how to allocate the transaction price to the performance obligations in the contract. It further provides guidance to recognize revenue when (or as) the entity satisfies a performance obligation. This standard will replace most existing revenue recognition guidance. On July 9, 2015, the FASB approved a one-year deferral of the effective date of this standard to 2018 for public companies, with an option that would permit companies to adopt the standard as early as the original effective date of 2017. Early adoption prior to the original effective date is not permitted. Since the issuance of ASU 2014-09, the FASB has issued several amendments which clarify certain points, including ASU 2016-08, *Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, ASU 2016-10, *Identifying Performance Obligations and Licensing*, ASU 2016-11, *Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting*, ASU 2016-12, *Narrow-Scope Improvements and Practical Expedients*, and ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*. The Company plans to adopt the new standard in the first quarter of fiscal year 2018 using the full retrospective method to restate each prior reporting period presented in its consolidated financial statements. The Company is currently evaluating the effect the new guidance will have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The authoritative guidance significantly amends the current accounting for leases. Under the new provisions, all lessees will report a right-of-use asset and a liability for the obligation to make payments for all leases with the exception of those leases with a term of 12 months or less. All other leases will fall into one of two categories: (i) a financing lease or (ii) an operating lease. Lessor accounting remains

substantially unchanged with the exception that no leases entered into after the effective date will be classified as leveraged leases. For sale leaseback transactions, a sale will only be recognized if the criteria in the new revenue recognition standard are met. For public business entities, this guidance is effective for fiscal periods beginning after December 15, 2018 and interim periods thereafter. Early adoption is permitted. The Company is currently evaluating the effect the new guidance will have on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments*. The new guidance changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. This guidance is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the effect the new guidance will have on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718) – Scope of Modification Accounting*. The new guidance clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. This guidance is effective for fiscal years beginning after December 15, 2017. Early adoption is permitted. The Company does not expect the adoption of 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):

	September 30, 2017			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market	\$ 11,043	\$ 11,043	\$ —	\$ —
Corporate debt	37,913	—	37,913	—
U.S. Treasury notes	70,696	—	70,696	—
Total assets measured at fair value	<u>\$ 119,652</u>	<u>\$ 11,043</u>	<u>\$ 108,609</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Embedded derivative liability	\$ 233	\$ —	\$ —	\$ 233
Total liabilities measured at fair value	<u>\$ 233</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 233</u>

	December 31, 2016			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market	\$ 192	\$ 192	\$ —	\$ —
Corporate debt	51,233	—	51,233	—
U.S. Treasury notes	60,976	—	60,976	—
Total assets measured at fair value	<u>\$ 112,401</u>	<u>\$ 192</u>	<u>\$ 112,209</u>	<u>\$ —</u>

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 and U.S. Treasury notes 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 Royalty-Backed Loan 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<sup>®</sup>; 2) the Company's risk adjusted discount rates; 3) the probability of receipt of orphan drug exclusivity for GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease; and 4) 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 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 are both not material, 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.

The following table sets forth a summary of the changes in the estimated fair value of the Company's embedded derivative, which is measured at fair value as a Level 3 liability on a recurring basis (in thousands):

Balance as of December 31, 2016	\$	—
Issuance of long-term debt with embedded derivative		764
Change in fair value included in interest and other income, net		(531)
Balance as of September 30, 2017	\$	233

There were no transfers between any of the levels of the fair value hierarchy during the three and nine months ended September 30, 2017.

#### 4. INVESTMENTS

The Company's investments consist of corporate debt and U.S. Treasury notes 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 and United States Treasury notes. 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 (expense) 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 September 30, 2017 and December 31, 2016 (in thousands):

	September 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>Investments:</b>				
Corporate debt	\$ 37,948	\$ —	\$ (35)	\$ 37,913
U.S. Treasury notes	70,773	—	(77)	70,696
Total	\$ 108,721	\$ —	\$ (112)	\$ 108,609
<b>Reported as:</b>				
Short-term investments	\$ 101,709	\$ —	\$ (104)	\$ 101,605
Long-term investments	7,012	—	(8)	7,004
Total	\$ 108,721	\$ —	\$ (112)	\$ 108,609
	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>Investments:</b>				
Corporate debt	\$ 51,354	\$ —	\$ (121)	\$ 51,233
U.S. Treasury notes	61,048	5	(77)	60,976
Total	\$ 112,402	\$ 5	\$ (198)	\$ 112,209
<b>Reported as:</b>				
Short-term investments	\$ 90,050	\$ 1	\$ (134)	\$ 89,917
Long-term investments	22,352	4	(64)	22,292
Total	\$ 112,402	\$ 5	\$ (198)	\$ 112,209

Short-term and long-term investments include accrued interest of \$0.6 million and \$30,000, respectively, as of September 30, 2017. Short-term and long-term investments includes accrued interest of \$0.3 million and \$0.1 million, respectively, as of December 31, 2016. The Company has not incurred any realized gains or losses on investments for the three and nine months ended September 30, 2017 and 2016. Investments are classified as short-term or long-term depending on the underlying investment's maturity date. Long-term investments held by the Company have a maturity date range of greater than 12 months and a maximum of 14 months as of September 30, 2017.

## 5. INVENTORY

The Company began capitalizing inventory in August 2017 once the FDA approved GOCOVRI. Inventory consists of the following (in thousands):

	September 30, 2017	December 31, 2016
Raw materials	\$ 326	\$ —
Work-in-process	72	—
Finished goods	27	—
Total inventory	\$ 425	\$ —

## 6. LICENSE AGREEMENTS

In November 2012, the Company granted 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<sup>®</sup> and Namenda XR<sup>®</sup> 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. For the nine months ended September 30, 2017 and 2016, reimbursed expenses amounting to zero and \$2.4 million, respectively, are reflected as a reduction to selling, general and administrative, net. In addition, the Company may earn tiered royalty payments based on future net sales of Namzaric<sup>®</sup> and Namenda XR<sup>®</sup>.

The Company is entitled to receive royalties on net sales in the United States by Allergan, its affiliates, or any of its sublicensees of controlled release versions of memantine products covered by the terms of the license agreement. Beginning in May 2020, the Company will be entitled to receive royalties in the low to mid-teens from Allergan for sales of Namzaric<sup>®</sup> in the United States. Beginning in June 2018, the Company will be entitled to receive royalties in the low to mid-single digits for sales of Namenda XR<sup>®</sup> in the United States. Allergan's obligation to pay royalties with respect to fixed-dose memantine-donepezil products, including Namzaric<sup>®</sup>, 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. Allergan's obligation to pay royalties with respect to Namenda XR<sup>®</sup> continues until the expiration of the Orange Book listed patents covering such products. However, Allergan's obligation to pay royalties for any product covered by the license is eliminated in any quarter where there is significant competition from generics.

## 7. COMMITMENTS AND CONTINGENCIES

### Lease Commitments

The Company leases approximately 18,500 square feet of office space in Emeryville, California under an operating lease that expires April 30, 2020. The lease provides for periods of escalating rent. The total cash payments over the life of the lease are divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period.

### Purchase Commitments

The Company has entered into agreements for the supply of API and the manufacture of commercial supply of GOCOVRI, with Moebs 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 pre-clinical 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.

As of September 30, 2017, future minimum lease payments under the non-cancelable facility operating lease and non-cancelable purchase commitments were as follows (in thousands):

	September 30, 2017
2017 (remaining)	\$ 2,144
2018	1,918
2019	1,925
2020	592
2021	—
Thereafter	—
Total	\$ 6,579

### 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. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

### 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<sup>®</sup> and Namenda XR<sup>®</sup> 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.

As of the date of this filing, several companies have submitted Abbreviated New Drug Applications, or 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 Namenda XR<sup>®</sup>, on which the Company is entitled to receive royalties from Forest beginning in June 2018. In the notices, these companies allege that the patents associated with Namenda XR<sup>®</sup>, some of which are owned by Forest or licensed by Forest from Merz Pharma GmbH & Co. KGaA, and others of which are owned by the Company and licensed by the Company exclusively to Forest in the United States, are invalid, unenforceable, and/or will not be infringed by the companies' manufacture, use, or sale of generic versions of Namenda XR<sup>®</sup>. The Company, Forest, Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (together Merz) filed

lawsuits in the U.S. District Court for the District of Delaware for infringement of the relevant patents against all of these companies. The Company and Forest will continue to enforce the patents associated with Namenda XR®.

The Company and Forest have entered into a series of settlement agreements with all Namenda XR® ANDA filers, except for one ANDA filer. Entry dates for generic Namenda XR® are governed by the settlement agreements in that action. Subject to those agreements, the earliest date on which any of these agreements grants a license to market generic version of Namenda XR® is January 31, 2020 or in the alternative, an option to launch an authorized generic version of Namenda XR® beginning on January 31, 2021.

In January 2016, the Delaware District Court issued a claim construction (Markman) ruling in the Namenda XR® litigation that includes findings of indefiniteness as to certain claim terms in the asserted patents licensed by the Company to Forest. On July 26, 2016, the District Court issued a final judgment of invalidity on those patents based upon the Markman ruling. The Company and Forest filed the notice of appeal of that final judgment to the United States Court of Appeals for the Federal Circuit. The appeal is ongoing. If the appeal is unsuccessful, generic entry of Namenda XR® could occur prior to January 31, 2020.

On June 2, 2017, the Company and Forest filed a lawsuit against the remaining ANDA filer in the U.S. District Court for the District of Delaware for infringement of certain patents based on that filer's filing of an ANDA seeking FDA approval to manufacture and market generic versions of Namenda XR® that included one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv). This action is ongoing and in a very early stage.

On July 24, 2017, an ANDA filer that previously entered into a settlement agreement with Forrest and Adamas filed a complaint against the Company and Forest in the Court of Chancery of the State of Delaware alleging that Forest and the Company breached the license agreement and settlement agreement entered into with that filer to settle the litigation related to its ANDA referencing Namenda XR® as the reference listed drug. As of the date of this filing, this action has been settled by the parties.

Additionally, 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. The Company and Forest have filed lawsuits alleging infringement of the relevant patents against Namzaric® ANDA filers, who are seeking to launch generic versions of Namzaric®, in the same court as heard the Namenda XR® litigation. As of the date of this filing, the Company and Forest have settled with all but one of the ANDA filers, including all first filers on all the available dosage forms of Namzaric®. Entry dates for generic Namzaric® are governed by the settlement agreements in those actions. Subject to those agreements, the earliest date on which any of these agreements grants a license to market generic version of Namzaric® is January 1, 2025 or in the alternative, an option to launch an authorized generic version of Namzaric® beginning on January 1, 2026. The Company and Forest intend to continue to enforce the patents associated with Namzaric®.

On June 2, 2017, the Company and Forest filed a lawsuit against the remaining ANDA filer in the U.S. District Court for the District of Delaware for infringement of certain patents based on its filing of an ANDA seeking FDA approval to manufacture and market generic versions of Namzaric® that included one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv). This action is ongoing and in a very early stage.

On April 20, 2017, an opposition was filed against Adamas' European Patent EP 2 506 709 B1, which relates to extended release compositions comprising amantadine or a pharmaceutically acceptable salt thereof. On May 26, 2017, the Company received a Communication of Notices of Opposition (R. 79(1) EPC) from the European Patent Office that requested the Company file its observations in response to the opposition within a period of four months from May 26, 2017. The Company filed its response to the opposition on October 5, 2017.

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 \$35.0 million and will borrow an additional \$65.0 million upon FDA approval and when the FDA's Orange Book is updated to recognize the 7-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 \$15.0 million of the Company's annual royalties from Allergan on U.S. net sales of Namzaric<sup>®</sup> 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 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 earlier of the \$65.0 million additional loan or October 2018. To the extent that royalties are insufficient to pay interest in full during the first nine quarters of the loan, any unpaid portion of the quarterly interest payment will be added to the principal amount of the loans. For the three and nine months ended September 30, 2017, accrued interest in the amount of \$1.6 million and \$ 2.3 million was added to the principal balance of the loan.

In connection with the Royalty-Backed Loan, 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 \$1.7 million and \$ 2.4 million for the three and nine months ended September 30, 2017. The effective interest rate as of September 30, 2017 on the amounts borrowed under the Royalty-Backed Loan, including the amortization of the debt discount, was 20.6%.

The assumptions used in determining the expected repayment term of the loan and amortization period of the debt discount require that we 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, subject to 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 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.

Long-term debt and unamortized debt discount balances are as follows (in thousands):

	<b>September 30, 2017</b>
Loans payable, gross	\$ 35,000
Less: Unamortized debt discount and issuance costs	(1,879)
Plus: Unpaid portion of quarterly interest payment	2,287
Carrying value of loans payable	\$ 35,408
Less: Current portion of long-term debt	—
Non-current portion of long-term debt	\$ 35,408

The estimated fair value of the long-term debt, as measured using Level 3 inputs, approximates \$42.5 million as of September 30, 2017. The estimated fair value was calculated in the same manner 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.

## 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.

### Public Offering

In January 2016, the Company completed a follow-on public offering of 2,875,000 shares of common stock, which includes the exercise in full by the underwriters of their option to purchase 375,000 shares of common stock, at an offering price of \$23.00 per share. Proceeds from the follow-on public offering were approximately \$61.8 million, net of underwriting discounts and offering-related transaction costs.

### Shares Reserved for Future Issuance

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

	September 30, 2017	December 31, 2016
Common stock awards issued and outstanding	5,926,814	5,483,557
Authorized for future issuance under 2014 Equity Incentive Plan	1,700,824	1,576,926
Authorized for future issuance under 2016 Inducement Plan	429,365	334,062
Employee stock purchase plan	718,210	532,849
<b>Total</b>	<b>8,775,213</b>	<b>7,927,394</b>

### Sales Agreement

In May 2017, 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 November 21, 2016. 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 September 30, 2017, no shares have been sold under the Sales Agreement.

## 10. STOCK-BASED COMPENSATION

### Stock Compensation Plans

In January 2017, 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, 2016, or 880,362 shares.

In March 2016, the Company's board of directors approved the 2016 Inducement Plan (the "Inducement Plan") under which 450,000 shares of the Company's common stock were made available for issuance. In January 2017, an amendment to the Inducement Plan was approved to increase the number of shares available for issuance an additional 450,000 shares for a total of 900,000 shares.

#### Employee Stock Purchase Plan

In January 2017, 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, 2016, or 220,090 shares.

#### Stock-Based Compensation Expense

The following table reflects stock-based compensation expense recognized for the three and nine months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	\$ 837	\$ 738	\$ 2,553	\$ 2,136
Selling, general and administrative	2,425	1,860	7,358	5,646
Total stock-based compensation expense	\$ 3,262	\$ 2,598	\$ 9,911	\$ 7,782

Stock-based compensation of \$13,000 was capitalized into inventory for the three and nine months ended September 30, 2017. Stock-based compensation capitalized into inventory is recognized as cost of sales when the related product is sold.

#### 11. SUBSEQUENT EVENTS

In October 2017, the FDA recognized GOCOVRI's orphan drug exclusivity by letter to the Company and on its Orphan Drug Designation and Approvals database listing. Under the Company's Royalty-Backed Loan agreement with HRCF, the Company will borrow an additional \$65.0 million when the FDA's Orange Book is updated to recognize the 7-year orphan drug exclusivity. The Company expects to receive the \$65.0 million during the fourth quarter of 2017.

## 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. 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. 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 entitled "Risk factors."*

### Overview

At Adamas, we believe in the power and the promise of medicines derived from a deep understanding of time-dependent biology. All biological processes, including the body's responses to disease and drug interventions, are governed by complex timing patterns. When the timing of disease and drug responses are out of sync, patient outcomes can be compromised.

Our expertise lies in uncovering and mapping the relationship between disease and drug activity timing patterns. From there, we strive to create medicines with therapeutic profiles that match the pattern of disease to drive a significant and durable clinical effect. As a result, our medicines are designed to provide patients with what they need, when they need it - the right level of drug at the right place and time to enhance efficacy - and then lower levels of drug when they don't need it. Our goal is to develop medicines that are timed for the benefit of patients.

Our understanding of time-dependent biological processes informs our every innovation, targeting advancement in treatment of chronic neurologic disorders. Our portfolio includes:

- GOCOVRI™ (amantadine) extended release capsules, formerly referred to as ADS-5102, for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications;
- ADS-5102 (amantadine) extended release capsules (GOCOVRI) in development for the treatment of walking impairment in patients with multiple sclerosis;
- ADS-4101 (lacosamide) modified release capsules in development for the treatment of partial onset seizures in patients with epilepsy; and
- Namzaric® (memantine hydrochloride extended release and donepezil hydrochloride) capsules and Namenda XR® (memantine hydrochloride) extended release capsules for the treatment of moderate to severe Alzheimer's disease.

Individual products in Adamas' portfolio and their proposed indications are protected by an array of intellectual property, including robust and diversified patent claims, and regulatory exclusivities. For example, GOCOVRI is protected by 7-year orphan drug exclusivity, 3-year new product exclusivity, and issued patents and pending patent applications out to at least 2035.

#### *GOCOVRI (formerly referred to as ADS-5102) for the Treatment of Dyskinesia in Patients with Parkinson's Disease*

On August 24, 2017, the U.S. Food and Drug Administration ("FDA") approved our new drug application ("NDA") for GOCOVRI (amantadine) extended release capsules for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications ("dyskinesia"). GOCOVRI is the first and only FDA-approved medicine for this indication, and GOCOVRI earned 7-years of orphan exclusivity upon its approval. GOCOVRI is a high-dose 274-mg amantadine taken once-daily at bedtime that delivers high levels of amantadine in the morning and throughout the day when dyskinesia occurs. We made GOCOVRI available for physician and patient use in the fourth quarter of 2017, with plans for a full commercial launch via the deployment of our sales team in January 2018.

Parkinson's disease is a chronic neurodegenerative disorder affecting close to 1 million people in the United States. Levodopa, which replaces lost dopamine, is considered the "gold standard" and the most effective therapy for Parkinson's disease. Over time, people with Parkinson's disease require increasingly higher or more frequent doses of levodopa to avoid recurrent periods of OFF time - characterized by slowness of movement, rigidity, impaired walking, tremor, and postural instability - when the underlying symptoms of Parkinson's disease return. At this stage, Parkinson's disease is characterized by an over-activated glutamate system, which may contribute to motor complications (dyskinesia and OFF). As Parkinson's disease progresses, approximately 90 percent of people on levodopa therapy will experience dyskinesia, which is characterized by involuntary movements that are non-rhythmic, purposeless, and unpredictable, impacting peoples' daily lives. Approximately 150,000 to 200,000 Parkinson's disease patients in the United States suffer with dyskinesia.

In a robust clinical program consisting of three randomized placebo-controlled studies and a two-year, ongoing, open label safety study, GOCOVRI demonstrated a durable reduction in both dyskinesia and OFF time in people with Parkinson's disease.

*ADS-5102 (GOCOVRI) in Development for the Treatment of Walking Impairment in Patients with Multiple Sclerosis*

ADS-5102 is an investigational high-dose, extended release amantadine taken once-daily at bedtime. We completed a Phase 2 proof-of-concept study designed to evaluate ADS-5102 in multiple sclerosis patients with walking impairment. A 17% improvement in walking speed versus placebo was observed in the timed 24 foot walk. The results for timed-up-and-go and 2-minute walking test also suggested benefit on other aspects of mobility and walking.

We plan to initiate a Phase 3 clinical program of ADS-5102 for multiple sclerosis patients with walking impairment in the first quarter of 2018, based on the data from the Phase 2 trial and feedback we received from our End-of-Phase 2 meeting with the FDA.

*Additional Indications for GOCOVRI*

We intend to continue to review the results of preclinical studies, clinical trials, and case reports published in peer reviewed medical journals to evaluate additional potential CNS indications for GOCOVRI, including upstream indications in Parkinson's disease and other hyperkinetic movement disorders.

*ADS-4101 in Development for the Treatment of Partial Onset Seizures in Patients with Epilepsy*

ADS-4101 is an investigational high-dose, modified release lacosamide capsule, taken once-daily at bedtime. Lacosamide is an anti-epilepsy active ingredient previously approved by the FDA and currently marketed by UCB SA/NV as VIMPAT® (lacosamide). ADS-4101 was designed to temper the initial rate-of-rise in lacosamide concentrations, potentially improving the adverse event profile and dose limitations due to dizziness following administration of VIMPAT. The slow initial rise may enable a higher once-daily dose at bedtime, which results in a higher daytime concentration that may be more effective for patients than VIMPAT.

We have completed two Phase 1 studies of ADS-4101 in healthy volunteers. The Phase 1a study showed that a single 400 mg dose of ADS-4101 was better tolerated compared to the equivalent dose of VIMPAT immediate release tablets. The data also demonstrated that ADS-4101 exhibited the desired pharmacokinetic properties, namely a reduced rate of initial rise and delayed time to maximum drug concentration (T<sub>max</sub>) appropriate for bedtime dosing. The recently completed and reported results of a multi-dose Phase 1b study demonstrated that a 600 mg dose of ADS-4101, taken once-nightly, provided a 1.5 to 2.5-fold increase in average lacosamide concentrations throughout the day compared to the maximum approved daily dose of 400 mg, taken as 200 mg twice-daily (BID), of VIMPAT immediate release tablets in healthy volunteers, with comparable tolerability.

We expect to meet with the FDA at an End-of-Phase 2 meeting regarding our planned Phase 3 clinical development program for ADS-4101 in 2018.

*Namzaric and Namenda XR for the Treatment of Moderate to Severe Alzheimer's Disease*

Namzaric (memantine hydrochloride extended release and donepezil hydrochloride) capsules and Namenda XR (memantine hydrochloride) extended release capsules are two commercially available medicines, which are currently

marketed by Forest Laboratories Holdings Limited (“Forest”), an indirect wholly-owned subsidiary of Allergan plc (“Allergan”), in the United States for the treatment of moderate to severe Alzheimer’s disease. We are eligible to receive royalties on sales of Namenda XR<sup>®</sup> and Namzaric<sup>®</sup> beginning in June of 2018 and May of 2020, respectively.

## **Financial operations overview**

### **Summary**

Our revenue through September 30, 2017, has been generated primarily from license, milestone, and development revenue pursuant to our license agreement with Allergan. We have not generated any commercial product revenue through September 30, 2017; however, we received approval for GOCOVRI on August 24, 2017. We made GOCOVRI available for physician and patient use in the fourth quarter of 2017, with plans for a full commercial launch via the deployment of our sales team in January 2018. As of September 30, 2017, we had an accumulated deficit of \$182.3 million. Although we reported net income in each of the years ended December 31, 2014, 2013, and 2012, this was primarily due to the recognition of revenue pursuant to our license agreement with Allergan. There are no further milestone payments to be earned under our license agreement with Allergan. We incurred significant losses in the nine months ended September 30, 2017, and in the years 2016, 2015, and prior to 2012, and expect to continue to incur significant losses as we support the commercialization of GOCOVRI and advance our product candidates into later stages of development and commercialization.

We plan to commercialize GOCOVRI through our own sales force targeting neurologists and movement disorder specialists in the United States, and possibly through partnership agreements with pharmaceutical companies outside the United States. Consequently, we expect selling, general and administrative expenses to increase as we approach full product commercialization of GOCOVRI in January 2018. In addition, we expect to continue to incur significant research and development expenses as we continue to advance our product candidates through clinical development. Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to predict the timing or amount of expenses incurred or when, or if, we will be able to achieve or maintain profitability.

Under our agreement with Allergan, beginning in May 2020, we are entitled to receive tiered royalties in the low to mid-teens for net sales of Namzaric<sup>®</sup> in the United States. In addition, we are also entitled to receive tiered royalties in the low to mid-single digits from Allergan for net sales of Namenda XR<sup>®</sup> in the United States beginning in June 2018; however, we do not expect the Namenda XR<sup>®</sup> royalties will make a significant financial contribution to our business. Pursuant to the agreement, we received a non-refundable upfront license fee of \$65.0 million in 2012, which we recognized on a straight-line basis from November 2012 to February 2013. We also earned and received additional cash payments totaling \$95.0 million upon achievement by Allergan of certain development and regulatory milestones, which we recognized in 2013 and 2014.

Prior to our initial public offering of our common stock, or IPO, in April 2014, we had raised an aggregate of approximately \$87.2 million through the sale of convertible preferred stock and \$1.0 million through the exercise of preferred stock warrants. In 2014, we issued and sold 3,081,371 shares of common stock in our IPO and received net proceeds of approximately \$42.6 million, which included partial exercise of the underwriters’ option to purchase additional shares and after deducting underwriting discounts and offering expenses. In connection with the completion of our IPO, all convertible preferred stock converted into common stock. In June 2015, we entered into a Controlled Equity Offering Sales Agreement, pursuant to which we were able to issue and sell shares of common stock having an aggregate offering value of up to \$25.0 million, which was terminated in November 2016. During the term of the agreement, we issued 509,741 shares of common stock and raised net proceeds of \$9.7 million. In January 2016, we raised \$61.8 million from the sale of 2,875,000 shares of common stock in a follow-on public offering. In May 2017, 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 the \$50.0 million. As of September 30, 2017, no shares have been sold under the sales agreement. Also in May 2017, we entered into a royalty-backed loan agreement (“Royalty-Backed Loan”) with HealthCare Royalty Partners (“HCRP”), whereby we borrowed \$35.0 million and will borrow an additional \$65.0 million upon FDA approval and FDA’s recognition in the Orange Book of the 7-year orphan drug exclusivity that GOCOVRI earned upon approval on August 24, 2017, for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The FDA has already recognized GOCOVRI’s orphan drug exclusivity by letter to us and on its Orphan Drug Designation and Approvals database listing.

As of September 30, 2017, we had cash, cash equivalents, and available-for-sale securities of \$130.7 million.

**Revenue**

We have not generated any revenue from commercial product sales to date. Our revenue to date has been generated primarily from non-refundable upfront license payments, milestone payments, reimbursements for research and development expenses and full-time equivalents assigned under our license agreement with Allergan, and to a lesser degree reimbursement for research and development expenses from NIH grants and government contracts. We do not expect to recognize any further milestone payments 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 will be entitled to receive royalties in the low to mid-teens from Allergan for net sales of Namzaric<sup>®</sup> in the United States, and in June 2018 we will be entitled to receive royalties in the low to mid-single digits for net sales of Namenda XR<sup>®</sup> in the United States; however, we do not expect the Namenda XR<sup>®</sup> royalties will make a significant financial contribution to our business. We were also awarded a continuation of an NIH grant for \$1.0 million in August 2014 that terminated in July 2016, which we administered, but conducted through subcontractors.

**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 and, to a lesser degree, the development of product candidates pursuant to our agreement with Allergan. 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 nine months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Increase (Decrease)	2017	2016	Increase (Decrease)
ADS-5102(1)	\$ 4,921	\$ 5,748	\$ (827)	\$ 15,467	\$ 19,985	\$ (4,518)
ADS-4101	1,080	—	1,080	4,056	—	4,056
Other research and development expenses	458	1,689	(1,231)	1,200	4,198	(2,998)
Total research and development expenses	\$ 6,459	\$ 7,437	\$ (978)	\$ 20,723	\$ 24,183	\$ (3,460)

(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.

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 research and development salaries, 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 anticipate incurring significant research and development expenses as we continue to support: clinical trials for ADS-5102 (GOCOVRI) in indications beyond dyskinesia in patients with Parkinson's disease, including but not limited to walking impairment in multiple sclerosis patients and other Parkinson's disease indications earlier in the Parkinson's disease treatment journey; ADS-4101 for treatment of epilepsy; and potentially additional clinical-stage programs in more indications or for future product candidates. The process of conducting the necessary clinical research to obtain FDA approval is costly and time consuming. We consider the active management and development of our clinical pipeline to be crucial to our long-term success. 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, facilities, professional services, insurance, and public company related expenses, as well as increasingly the costs associated with establishing commercial capabilities in support of the commercialization of GOCOVRI, reduced to a small degree 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 increase significantly as we continue to establish our commercial capabilities and support our potential commercial-stage programs. We plan to market and sell GOCOVRI through our own sales force with support from a contract sales organization for certain functions, targeting neurologists and movement disorder specialists in the United States.

***Interest and other income (expense), net***

Interest and other income (expense), net, consists primarily of a change in fair value of the embedded derivative liability related to our royalty-backed loan agreement with HCRP, in addition to interest received on our investments.

***Interest expense***

Interest expense consists of accrued interest pursuant to our Royalty-Based Loan and amortization of debt issuance costs.

**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. Our estimates are based 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. We have discussed the development, selection, and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates under different assumptions or conditions. Refer to "Note 2 - Summary of Significant Accounting Policies" in the accompanying "Notes to Condensed Consolidated Financial Statements (unaudited)," which information is incorporated

by reference here, for changes to our critical accounting policies during the nine months ended September 30, 2017, as compared to those disclosed 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, 2016.

**Results of operations**

**Comparison of the three and nine months ended September 30, 2017 and 2016**

The following table summarizes our results of operations for the three and nine months ended September 30, 2017 and 2016 (in thousands, except percentages):

	Three Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)	Nine Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2017	2016			2017	2016		
Revenue	\$ 1	\$ 138	\$ (137)	(99)%	\$ 3	\$ 535	\$ (532)	(99)%
Research and development expenses	6,459	7,437	(978)	(13)%	20,723	24,183	(3,460)	(14)%
Selling, general and administrative expenses, net	16,064	7,344	8,720	119 %	38,323	22,043	16,280	74 %
Interest and other income, net	839	249	590	237 %	1,265	593	672	113 %
Interest expense	1,677	—	1,677	100 %	2,406	—	2,406	100 %

**Revenue**

Revenue for the three and nine months ended September 30, 2017 was \$1,000 and \$3,000, respectively, compared to \$0.1 million and \$0.5 million for the three and nine months ended September 30, 2016, respectively. Revenue for all periods presented was primarily related to reimbursement of certain expenses as provided for in our license agreement with Allergan, as well as from government contracts in 2016.

**Research and development expenses**

Research and development expenses decreased by \$1.0 million, or 13%, to \$6.5 million for the three months ended September 30, 2017 from \$7.4 million for the three months ended September 30, 2016. The decrease in research and development expenses was mainly attributable to costs associated with the clinical development of GOCOVRI for the treatment of dyskinesia in patients with Parkinson’s disease due to the conclusion of two Phase 3 clinical trials, in addition to decreased costs associated with the ongoing open-label safety study and decreased volume of pre-commercial manufacturing activities. The decrease was offset in part by increased activity related to clinical work associated with 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 \$0.8 million compared to \$0.7 million for the three months ended September 30, 2017 and 2016, respectively.

Research and development expenses decreased by \$3.5 million, or 14%, to \$20.7 million for the nine months ended September 30, 2017 from \$24.2 million for the nine months ended September 30, 2016. The decrease in research and development expenses was mainly attributable to costs associated with the clinical development of GOCOVRI for the treatment of dyskinesia in patients with Parkinson’s disease due to the conclusion of two Phase 3 clinical trials, in addition to costs associated with the ongoing open-label safety study which also decreased from the prior year. The decrease was offset by increased activity related to clinical work associated with 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 \$2.6 million compared to \$2.1 million for the nine months ended September 30, 2017 and 2016, respectively.

We began capitalizing inventory manufactured at the FDA approved location upon FDA approval of GOCOVRI in August 2017. Inventory acquired prior to the regulatory approval was recorded as research and development expense. We expect to use inventory expensed to research and development over approximately the next two years, and accordingly we would expect our cost of GOCOVRI product sales to increase as a percentage of net sales of GOCOVRI in future periods.

***Selling, general and administrative expenses, net***

Selling, general and administrative expenses, net, increased by \$8.7 million , or 119% , to \$16.1 million for the three months ended September 30, 2017 from \$7.3 million for the three months ended September 30, 2016 . The increase in selling, general and administrative expenses was primarily due to increased costs associated with establishing commercial capabilities in anticipation of the commercialization of GOCOVRI, including an increase in headcount-related expenses and commercial activities. Selling, general and administrative expenses also included stock-based compensation expense of \$2.4 million compared to \$1.9 million for the three months ended September 30, 2017 and 2016 , respectively.

Selling, general and administrative expenses, net, increased by \$16.3 million , or 74% , to \$38.3 million for the nine months ended September 30, 2017 from \$22.0 million for the nine months ended September 30, 2016 . The increase in general and administrative expenses was primarily due to increased costs associated with establishing commercial capabilities in anticipation of the commercialization of GOCOVRI, including an increase in headcount-related expenses and commercial activities. General and administrative expenses also included stock-based compensation expense of \$7.4 million compared to \$5.6 million for the nine months ended September 30, 2017 and 2016 , respectively.

***Interest and other income, net***

Interest and other income, net, for the three and nine months ended September 30, 2017 was \$0.8 million and \$1.3 million , respectively, compared to \$0.2 million and \$0.6 million for the three and nine months ended September 30, 2016 , respectively. The increase in interest and other income, net, was primarily due to a change in fair value of the embedded derivative liability related to our Royalty-Backed Loan with HCRP. Also included in interest and other income, net is interest income earned on investments.

***Interest expense***

The increase in interest expense to \$1.7 million and \$2.4 million for the three and nine months ended September 30, 2017 , compared to zero in the three and nine months ended September 30, 2016 , was due to the new Royalty-Backed Loan entered into in May 2017.

**Liquidity, capital resources and plan of operation**

We have funded our operations primarily through \$160.0 million of payments received pursuant to our license agreement with Allergan, \$88.2 million sales of convertible preferred stock and warrants, \$114.1 million pursuant to sales of our common stock, and \$35.0 million pursuant to our Royalty-Backed Loan with HCRP. In April 2014, we completed our IPO and raised net proceeds of \$42.6 million, including the underwriters' partial exercise of their option to purchase additional shares. In June 2015, we entered into a Controlled Equity Offering Sales Agreement, pursuant to which we were able to, from time to time, issue and sell shares of common stock having an aggregate offering value of up to \$25.0 million, which was terminated in November 2016. During the term of the agreement we issued 509,741 shares of common stock and raised net proceeds of \$9.7 million. In January 2016, we completed a follow-on public offering of 2,875,000 shares of common stock, which includes the exercise in full by the underwriters of their option to purchase 375,000 shares of common stock, at an offering price of \$23.00 per share. Proceeds from the follow-on public offering were approximately \$61.8 million, net of underwriting discounts and offering-related transaction costs. In May 2017, we entered into a Royalty-Backed Loan with HCRP, whereby we initially borrowed \$35.0 million and will borrow an additional \$65.0 million upon FDA approval and FDA's recognition in the Orange Book of the 7-year orphan drug exclusivity that GOCOVRI earned upon approval on August 24, 2017, for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The FDA has already recognized GOCOVRI's orphan drug exclusivity by letter to us and on its Orphan Drug Designation and Approvals database listing.

We have not generated any revenue from the sale of products. We incurred losses and generated negative cash flows from operations since inception through the year ended December 31, 2011. Although we recognized a profit and positive cash flow from operations in 2014, 2013, and 2012 as a result of payments received pursuant to our license agreement with Allergan, we received our final milestone payment from Allergan in December 2014. We do not currently receive any royalties from Allergan, nor do we have other license agreements or collaborations from which we might expect milestone or royalty revenue. Consequently, we expect to continue to incur substantial and increasing losses for

the foreseeable future. Our principal sources of liquidity were our cash, cash equivalents, and investments, which totaled \$130.7 million as of September 30, 2017, compared to \$ 135.9 million at December 31, 2016 .

We believe our existing cash, cash equivalents, and investments will be sufficient to fund our projected operating requirements, including operations related to the continued development of our product candidates and commercialization of GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease, for at least the next 12 months. However, it is possible that we will not achieve the progress that we expect, because revenues from GOCOVRI may be less than anticipated 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. Moreover, the costs associated with commercializing drugs are high and market acceptance is uncertain.

We expect to continue significant spending in connection with the development and commercialization of our product candidates, particularly for the commercialization of GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease, as well as the development of ADS-5102 for other indications, and also for ADS-4101 for indications in epilepsy, for which Phase 3 clinical trials may be initiated in 2018. To continue these activities, we may decide to raise additional funds 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. Sufficient additional funding may not be available on acceptable terms, or at all. 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):

	Nine Months Ended September 30,	
	2017	2016
Net cash (used in) provided by:		
Operating activities	\$ (42,003)	\$ (38,439)
Investing activities	2,790	(49,955)
Financing activities	37,599	65,066
Net decrease in cash and cash equivalents	\$ (1,614)	\$ (23,328)

Net cash used in operating activities was \$42.0 million for the nine months ended September 30, 2017 compared to \$38.4 million for the same period in the prior year. Net loss of \$60.1 million for the nine months ended September 30, 2017 included net non-cash adjustments of \$12.9 million, which consisted primarily of stock-based compensation of \$9.9 million and non-cash interest expense of \$2.4 million. Net loss of \$45.1 million for the nine months ended September 30, 2016 included non-cash adjustments of \$8.0 million, primarily related to \$7.8 million in stock-based compensation. The primary use of cash for the nine months ended September 30, 2017 was to fund activities in support of the NDA and pre-commercial activities in preparation for the commercialization of GOCOVRI. Additionally, cash was used to fund development of ADS-4101 for indications in epilepsy.

Net cash provided by investing activities was \$2.8 million for the nine months ended September 30, 2017, compared to net cash used in investing activities of \$50.0 million for the same period in the prior year. In the nine months ended September 30, 2017, we received \$3.7 million as a result of net maturities of available-for-sale securities, offset by \$0.9 million in purchases of property and equipment. Net cash used in investing activities for the nine months ended September 30, 2016 was a result of \$48.7 million in net purchases of available-for-sale securities as a result of investing the cash from our follow-on public offering that occurred in January 2016, and \$1.2 million in purchases of property and equipment.

Net cash provided by financing activities was \$37.6 million for the nine months ended September 30, 2017, compared to \$65.1 million for the nine months ended September 30, 2016. In the period ended September 30, 2017, we received net proceeds of \$34.6 million from long-term debt and received cash proceeds of \$3.6 million related to the exercise of stock options and purchases of common stock under the Employee Stock Purchase Plan. In the nine months ended September 30, 2016, we received net cash proceeds of \$61.8 million related to the sale of common stock under a

follow-on public offering, coupled with \$3.2 million 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 contractual obligations at September 30, 2017, were not materially different than at December 31, 2016, except for commitments resulting from our Royalty-Backed Loan with HCRP and purchase commitments entered into for the supply of API, the manufacture of commercial supply of GOCOVRI, and other agreements with certain vendors for the provision of services. For further discussion of the Royalty-Backed Loan agreement and purchase commitments, see “Note 8 - Long-Term Debt” and *Purchase Commitments* in “Note 7 - Commitments and Contingencies”, respectively, in the accompanying “Notes to Condensed Consolidated Financial Statements (unaudited)”.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. As of September 30, 2017, we had cash, cash equivalents, and investments of \$130.7 million, compared to \$135.9 million at December 31, 2016, consisting of cash and cash equivalents, as well as short and long-term investment grade available-for-sale securities. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration and our holdings in US government bonds and corporate debt securities mature prior to our expected need for liquidity, we believe that our exposure to interest rate risk is not significant and, as a consequence, a one percentage point movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

### **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 September 30, 2017. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2017, our disclosure controls and procedures were effective.

#### **Changes in Internal Control Over Financial Reporting**

During the quarter ended September 30, 2017, we implemented processes and internal controls to record inventory as a result of the FDA approval of GOCOVRI. The implementation of these processes resulted in changes to internal controls over financial reporting, which we believe were material. There were no other changes in our internal control over financial reporting during the quarter ended September 30, 2017 identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act 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* 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.*

#### **Risks related to the commercialization of GOCOVRI, and the development, regulatory approval, and commercialization of our current and future product candidates**

***Our success depends heavily on successful commercialization of GOCOVRI, which received approval on August 24, 2017, from the U.S. Food and Drug Administration, or FDA, 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 into the development, approval and now commercialization of GOCOVRI for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, (“dyskinesia”). The success of GOCOVRI will depend on numerous factors, including:

- our success in commercializing GOCOVRI, including the marketing, sales, and distribution of the product;
- successfully establishing and maintaining commercial manufacturing with third parties;
- acceptance of GOCOVRI by the physicians, patients and the healthcare community;
- the acceptance of pricing and placement of GOCOVRI on payers’ formulary tiers and the reimbursement rates established for GOCOVRI;
- effectively competing with other approved or used medicines and future compounds in development;
- continued demonstration of an acceptable safety profile of GOCOVRI following approval; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize GOCOVRI, which would materially harm our business.

***GOCOVRI may fail to achieve the degree of market acceptance by physicians, patients, healthcare payers, and others in the medical community necessary for commercial success, negatively impacting our business.***

GOCOVRI may fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payers, and others in the healthcare community. The degree of market acceptance of GOCOVRI will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- efficacy, duration of response, and potential advantages compared to alternative treatments;
- the price;
- the willingness of physicians to change their current treatment practices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of marketing, promotion, selling, and distribution support; and
- the availability of third-party insurance coverage or reimbursement.

The failure of GOCOVRI to achieve market acceptance would negatively impact our business.

***We currently have only limited commercial experience and capabilities with limited sales personnel. If we are unable to obtain or further develop commercial capabilities, including sales, marketing and market access personnel, we will not be successful in commercializing GOCOVRI.***

We have only a limited commercial infrastructure and have limited experience in the commercialization, sale, marketing, or distribution of pharmaceutical products, like GOCOVRI. To achieve commercial success of GOCOVRI, we must either develop a commercial organization, including sales, marketing and market access personnel or outsource these functions to third parties. We expect that the primary focus of our commercialization efforts will be in the United States. We intend to commercialize GOCOVRI through our own sales force personnel with support from a contract sales organization (“CSO”) in certain functions. Commercialization of GOCOVRI (and other future product candidates) outside of the United States, to the extent pursued, is likely to require collaboration with one or more third parties.

There are risks involved with both establishing our own commercial capabilities and relying on third parties to perform these services. For example, recruiting and building a marketing organization and/or field sales representatives are expensive and time-consuming, and if GOCOVRI is not commercially successful, our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

***If we are unable to effectively build, train and equip our sales force, our ability to successfully commercialize GOCOVRI will be harmed.***

GOCOVRI will be a newly marketed drug and, therefore, none of the members of our sales force has ever promoted GOCOVRI prior to its launch. In addition, GOCOVRI is the first and only drug approved by the FDA for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. As a result, we will be required to expend significant time and resources to train our sales force to be credible, persuasive, and compliant with applicable laws in marketing GOCOVRI to neurologists, movement disorder specialists, and pharmacists. In addition, we must train our sales force to ensure that we deliver a consistent and appropriate message about GOCOVRI to our customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of GOCOVRI and its proper administration, our efforts to successfully commercialize GOCOVRI could be put in jeopardy, which would negatively impact our ability to generate product revenues.

***Failure to successfully obtain coverage and reimbursement for GOCOVRI, or if coverage and reimbursement is only available at limited levels in the United States, will diminish our ability to generate product revenue.***

Our ability to commercialize GOCOVRI or any products successfully in the United States will depend in part on the extent to which coverage and reimbursement for these products becomes available 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 governmental healthcare programs, such as Medicare and Medicaid, and

commercial payers is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Coverage and reimbursement may not be available for products that we commercialize and, if reimbursement is available, we cannot guarantee what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, distribution, marketing, and sale. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product, the clinical setting in which it is used, and generic competitor availability, and may be based on initial payments for generic competitors or payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs, e.g., the federal 340B Drug Pricing Program, or private third-party payers and by any future relaxation of laws that currently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the United States, private third-party payers often rely upon Medicare coverage and reimbursement policies and payment limitations in setting their own coverage and reimbursement policies. Our inability to promptly obtain coverage, reimbursement, and profitable payment rates from both government funded and private third-party payers for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Also, even if we obtain coverage for GOCOVRI, the resulting reimbursement payment rates might not be adequate or may require co-payments or co-insurance payments that patients find unacceptably high. Patients may not use GOCOVRI if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize GOCOVRI.

***We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.***

The development and commercialization of new pharmaceutical products is highly competitive. We face competition with respect to our current product and product candidates, including GOCOVRI, and will face competition with respect to any future products that we may seek to develop or commercialize from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. For example, GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, may face competition from various drugs approved for treatment of Parkinson's disease, though not dyskinesia, such as Azilect (Teva Pharmaceuticals Industries, Ltd.), Requip XL (GlaxoSmithKline plc), Mirapex ER (Boehringer Ingelheim Pharmaceuticals Inc.), Neupro Patch (UCB SA/NV), Sinemet (Merck & Co., Inc.), Parcopa (Jazz Pharmaceuticals, Inc.), Rytary (Impax), Duopa (AbbVie), Xadago (safinamide) (Newron Pharmaceuticals S.p.A.) and immediate release amantadine. GOCOVRI 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, such as Merck, Novartis, Osmotica Pharmaceuticals Corp., Avanir Pharmaceuticals, Neurolix, Amaranthus BioScience, Addex Pharma, and Neurim Pharmaceuticals Ltd. Other products in late stage development for Parkinson's disease includes product candidates from Kyowa Hakko, Acorda, Neuroderm, Bial-Portela CSA, Genervon Biopharmaceuticals, Pharma Two B, and Depomed.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals, and commercializing approved products than we do. These third parties will compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites, and patient registration for clinical studies, as well as in acquiring technologies and products complementary to, or necessary for, our programs. Finally, 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.

GOCOVRI will face competition from generic versions of immediate release amantadine and potentially from other extended release versions of amantadine that may be in development. For example, while immediate release amantadine is not approved for use in Parkinson's disease for the treatment of dyskinesia, some physicians may still prescribe it for such conditions. In addition, a competitor has registered two Phase 3 clinical trials of extended release amantadine for dyskinesia on [clinicaltrials.gov](http://clinicaltrials.gov).

***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 would be substantially harmed.***

Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. Generally, if a drug product with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the drug product is entitled to a period of marketing exclusivity, which may preclude the FDA from approving another marketing application for the same drug product for the same therapeutic indication. The applicable period of exclusivity is up to seven (7) years in the United States. GOCOVRI received orphan designation for the treatment of levodopa-induced dyskinesia in 2015. When it 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 7-years of orphan drug exclusivity. The FDA has recognized GOCOVRI's orphan drug exclusivity by letter to us and on its Orphan Drug Designation and Approvals database listing.

Although we have obtained marketing approval for GOCOVRI for the treatment of dyskinesia, the FDA could still subsequently approve the same drug with the same active moiety for the same condition, if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. If we are unable to maintain orphan drug exclusivity for GOCOVRI for the treatment of dyskinesia, our business would be substantially harmed.

***There is an ongoing open label safety study with GOCOVRI in Parkinson's disease patients with dyskinesia; therefore, there could be new safety findings regarding GOCOVRI.***

There is an ongoing safety study with GOCOVRI. If any new safety concerns emerge from our ongoing clinical study, we may:

- have the product removed from the market;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed, marketed, or used.

Any of these unforeseen events could impair our ability to commercialize GOCOVRI and harm our business and results of operations.

***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 (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 the affected product 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, newly observed toxicities or worsening of known toxicities in preclinical studies or in subjects in clinical studies receiving amantadine, or reconsideration of known toxicities of compounds in the setting of new indications, could result in increased regulatory scrutiny of our products and product candidates.

In addition, problems with approved products marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as amantadine could 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 or their patients. 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 our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- the inability to commercialize any products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation;
- substantial monetary awards to patients; and
- loss of revenue.

We currently hold \$10.0 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.

***We will face risks in the development of ADS-5102 (GOCOVRI) for additional indications and other product candidates.***

There are risks associated with pursuing clinical trials in other indications for ADS-5102 (GOCOVRI), as we may experience numerous unforeseen events during, or as a result of clinical studies that could harm our ability to commercialize or to receive regulatory approval for other indications of ADS-5102, 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;

- 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 (“CROs”) 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 product candidates 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; and
- the supply or quality of ADS-5102 or other materials necessary to conduct clinical studies may be insufficient or inadequate.

Although the safety profile of amantadine, the active pharmaceutical ingredient in GOCOVRI, is already characterized in the approved label for amantadine (i.e., Symmetrel®) and in the GOCOVRI clinical trial data in the dyskinesia population, there can be no assurance that our clinical development program for ADS-5102 (GOCOVRI) for multiple sclerosis walking impairment or future studies in other indications, will not reveal additional safety or tolerability issues. In such an event, our ability to commercialize GOCOVRI for dyskinesia and/or expand our business could be compromised.

If we are forced to delay or abandon development of our product candidates, our business, results of operations, and financial condition will be materially and adversely harmed.

***The marketing and promotion of GOCOVRI will 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 24, 2017, approval of GOCOVRI (formerly ADS-5102) for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, we will be permitted to market or promote it only for the treatment of dyskinesia and not for other uses. We are developing GOCOVRI for at least one additional indication, treatment of walking impairment in patients with multiple sclerosis, and potentially others. In order to market and promote GOCOVRI for these additional indications, we will need to conduct additional clinical trials that will likely be time-consuming and expensive, and to obtain regulatory approval for such uses. Additionally, our marketing and promotional efforts will be 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. To use information not consistent with the approved prescribing information will require additional regulatory approvals.

***If we are found to have improperly promoted unapproved uses of our products, or if physicians misuse our products, we may be subject to restrictions on the sale or marketing of our products, significant fines, penalties, and sanctions, 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 for 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. 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. Furthermore, the use of our products for indications other than those approved by the FDA or regulatory authorities outside the United States may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Any of these events could harm our business and results of operations and cause our stock price to decline.

***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 will participate in the Medicaid Drug Rebate Program, as administered by 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. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the 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. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. 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 recently 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 a civil monetary penalty of \$10,000 per day 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 the 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 or our product candidates.***

GOCOVRI is an extended release version of amantadine. 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. 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. If any such issues were to arise with respect to GOCOVRI or our future product candidates, our business, financial results, or stock price could be adversely affected.

***Our success depends on the timely development, approval and successful commercialization of our product candidates. If we are unable to do any of these with our product candidates or if we experience significant delays in doing so, our business will be materially harmed.***

We have invested a significant portion of our efforts and financial resources into the development and potential commercialization of our product candidates, including ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis, and potentially other indications, as well as ADS-4101 for the treatment of partial onset seizures in epilepsy. Our ability to generate product revenue will depend heavily on the successful development, regulatory approval, and commercialization of our other product candidates. The success of our product candidates will depend on numerous factors, including:

- successfully completing the development program for our product candidates in a timely manner;
- receiving marketing approval for our product candidates from the FDA in a timely manner;
- successfully establishing and maintaining commercial manufacturing with third parties;
- commercializing our product candidates, 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;
- the pricing and placement of our product candidates on payers' formulary tiers and the reimbursement rates established for the approved products;
- effectively competing with other approved or used medicines and future compounds in development;
- continued demonstration of an acceptable safety profile of the approved products following approval; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we have chosen to focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates 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.

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.

***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.

The FDCA requires that an applicant for approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book, or that those patents are not

enforceable. This process is known as a paragraph IV challenge. Upon receipt of the paragraph IV notice, the owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. The discovery, trial, and appeals process in such suits can take several years. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. This type of litigation is often time-consuming and costly and may result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. Such litigation has been commenced by Forest Laboratories Holdings Limited ("Forest"), an indirect wholly-owned subsidiary of Allergan plc (collectively, "Allergan") and us to enforce certain patents related to Namenda XR<sup>®</sup> and Namzaric<sup>®</sup>. See *Litigation* in "Note 7 - Commitments and Contingencies" in the accompanying "Notes to Condensed Consolidated Financial Statements (unaudited)" for more information.

If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs. Once an ANDA is approved by the FDA, the generic manufacturer may market and sell the generic form of the branded drug in competition with the branded medicine.

#### **Risks related to our financial condition and need for additional capital**

*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 expect to begin to launch GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, in 2018, and it will require substantial funds to be successful. In addition, funds are required for the continued operation of our business, as we seek to advance additional product candidates through the research and clinical development to regulatory approval and commercialization. On May 11, 2017, we 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 September 30, 2017, we have not made any sales under this facility. As of September 30, 2017, we had approximately \$130.7 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.

We have financed our operations primarily through proceeds from our license agreement with Allergan, public and private equity offerings, and, to a lesser extent, our Royalty-Backed Loan with HCRP, government grants, venture debt, and benefits from tax credits made available under a federal stimulus program supporting drug development. We have devoted substantially all of our efforts to research and development, including clinical studies, of our product candidates, including GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease. We anticipate that our cash requirements will increase substantially as we:

- enhance operational, financial, and information management systems and hire more personnel, including personnel to support development of our product candidates and, our commercial operations;
- commercialize GOCOVRI, including establishing distribution, marketing, and sales capabilities;
- manufacture GOCOVRI for commercial use;
- investigate ADS-5102 (GOCOVRI) in preclinical and clinical trials for the treatment of walking impairment in patients with MS, and potentially other indications;
- conduct preclinical and clinical trials of ADS-4101 for the treatment of epilepsy (partial onset seizures);
- seek regulatory approvals for our product candidates that successfully complete clinical studies;
- continue the research, development, and manufacture of our current product candidates; 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 under our Royalty-Backed Loan with HCRP, or from new funding sources 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 other than under our Royalty-Backed Loan with HCRP, or from new funding sources or under our license agreement with Allergan, which may be terminated by Allergan upon delivery of notice. 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. 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 product candidates, 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 note arrangement with HealthCare Royalty Partners III, L.P. ("HCRP") pursuant to which we initially borrowed \$35 million and will borrow an additional \$65 million upon FDA approval and FDA's recognition in the Orange Book of the 7-year orphan drug exclusivity that GOCOVRI earned upon approval on August 24, 2017, for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The FDA has already recognized GOCOVRI's orphan drug exclusivity by letter to us and on its Orphan Drug Designation and Approvals database listing.

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<sup>®</sup> starting in May 2020. The HCRP notes mature in December 2026, if not earlier prepaid.

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.

***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 may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Any future revenue will depend on the successful commercialization and sales of GOCOVRI and our product candidates, the payment of royalties to us from Allergan under terms of our licensing agreement regarding Namenda XR<sup>®</sup> and Namzaric<sup>®</sup>, 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:

- 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 product candidates, if approved, and the competitive response from existing and potential future therapeutic approaches that compete with our product candidates;
- the cost of manufacturing our product candidates, 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 preclinical and clinical-stage product candidates, 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.

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.

#### **Risks related to our reliance on third parties**

*We rely on third-party contract manufacturing organizations to manufacture, serialize and supply GOCOVRI and our product candidates. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers and qualify them. We may also face delays in the development, commercialization, and supply of GOCOVRI or our product candidates.*

We currently have limited experience in, and we do not own facilities for, clinical and commercial manufacturing of GOCOVRI or our product candidates, and we rely upon third-party contract manufacturing organizations to manufacture, serialize and supply drug product for our clinical studies and to meet potential commercial demand. The manufacture of pharmaceutical products in compliance with the FDA's current Good Manufacturing Practices, or cGMPs, requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements, and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our commercial supply of GOCOVRI or product candidates in our clinical trials could be jeopardized. 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.

All third-party manufacturers of our products, product candidates 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 and product candidates 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 or product candidates 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 or product candidates, entail higher costs, impair our reputation, and potentially disrupt patient access to our approved products.

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

We currently rely on single source suppliers for our drug substances for GOCOVRI and our other product candidates. 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 and validate the manufacturing process employed at that manufacturer or supplier could delay or harm commercialization of GOCOVRI or our product candidates. 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 product candidate would be required to be qualified under applicable regulatory requirements, including demonstration of bioequivalence of the product made at the new supplier, and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. 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.

***In our existing or any future potential collaborations or partnerships, we will likely not be able to control all aspects of the development and commercialization of our products or product candidates. This lack of control could subject us to additional risks that could harm our business.***

Collaborations or license agreements involving our current or future products are subject to numerous risks, which may include that:

- partners have significant discretion in determining the efforts and resources that they will apply to collaborations;
- partners may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical study results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- partners may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a product candidate, repeat or conduct new clinical studies, or require a new formulation of a product candidate for clinical testing;

- partners could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a partner with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our partners that would prevent us from collaborating with others;
- Allergan and future partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- Allergan and future partners may not aggressively or adequately pursue litigation against ANDA filers or may settle such litigation on unfavorable terms, and as Allergan substantially controls the current ANDA litigation and terms of settlement and has different economic interests than ours, Allergan may grant licenses to generic manufacturers that permit them to make and sell generic versions of Namenda XR<sup>®</sup> and Namzaric<sup>®</sup>, which would negatively impact the royalties we receive under our license with Allergan;
- disputes may arise between us and a partner that causes the delay or termination of the research, development, or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- agreements may be terminated, sometimes at-will, without penalty, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- partners may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- a partner's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

***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 product candidates. 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 product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

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 product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

## Risks related to Namenda XR<sup>®</sup> and Namzatic<sup>®</sup>

***Under our license agreement with Allergan, if Allergan fails to successfully commercialize Namenda XR<sup>®</sup> and Namzatic<sup>®</sup> for any reason or if the license agreement with Allergan is terminated, the potential royalties we are eligible to receive under our license agreement with Allergan may not occur or 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 Namenda XR<sup>®</sup> and Namzatic<sup>®</sup> in the United States. Under that agreement, we expect to receive future royalties from Allergan on the net sales of Namenda XR<sup>®</sup> and Namzatic<sup>®</sup>, starting in 2018 and 2020, respectively. If Allergan fails to successfully commercialize Namenda XR<sup>®</sup> and, more importantly, Namzatic<sup>®</sup>, on which we are eligible to receive double digits percentage royalties for any reason, we may not receive such future royalties or receive minimal amounts, and our business will be harmed.

Under the license agreement, we are reliant on Allergan to commercialize Namenda XR<sup>®</sup> and Namzatic<sup>®</sup> and in that capacity Allergan has the discretion to:

- determine the efforts and resources that they apply towards commercialization;
- market, manufacture, and distribute the licensed products or to otherwise not perform satisfactorily in carrying out these activities; and
- to terminate the agreement without penalty and, such termination, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products.

***Under the license agreement, Allergan substantially controls the intellectual property rights subject to the agreement and the current ANDA litigation and potential settlement thereof, and has economic interests different from ours. Accordingly, Allergan may manage the litigation and settlements on terms which may have a material and negative impact on our business.***

We and Allergan are currently involved in ANDA litigation to enforce our intellectual property rights against generic manufacturers, who are seeking to bring generic versions of Namenda XR<sup>®</sup> and Namzatic<sup>®</sup> to the market. See *Litigation* in “Note 7 - Commitments and Contingencies” in the accompanying “Notes to Condensed Consolidated Financial Statements (unaudited)”. Under the terms of that license agreement, Allergan has the right to enforce such intellectual property rights and control such litigation. Specifically, Allergan has the discretion to:

- maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; and
- not adequately pursue litigation against ANDA filers or settle such litigation on unfavorable terms, and as Allergan substantially controls the current ANDA litigation and terms of settlement and has different economic interests than ours, Allergan may grant licenses to generic manufacturers that permit them to make and sell generic versions of Namenda XR<sup>®</sup> and Namzatic<sup>®</sup>, which would negatively impact the royalties we receive under our license with Allergan.

We have a right to participate in, but not control, such litigations. If Allergan decides not to enforce the intellectual property rights licensed under the agreement or the litigation is resolved in favor of the generic manufacturers or if the FDA approves the ANDA filed by the generic manufacturers, such manufacturers may be able to market and sell the generic form of the branded drug in competition with Namenda XR<sup>®</sup> and Namzatic<sup>®</sup>. This could harm our business.

***The post-marketing safety risks relating to Namzatic<sup>®</sup> and Namenda XR<sup>®</sup> are the same as those facing GOCOVRI.***

The post-marketing safety risks relating to Namzatic<sup>®</sup> and Namenda XR<sup>®</sup> are the same as those facing GOCOVRI, which are described in the risk factor captioned “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.” These things could lead us to experience

failure to receive regulatory approval or receive approval with unexpected safety information in the prescribing information that could limit physician and patient acceptance of the product.

### **Risks related to government regulation**

***The regulatory approval process is expensive, time consuming, and uncertain and may prevent us or our collaboration partners 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. Neither we nor our collaboration partners are permitted to market our product candidates in the United States or other countries until we receive FDA approval of an NDA. On August 24, 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 multiple sclerosis walking impairment.

To receive approval to commercialize any of our product candidates in the United States, we and our collaboration partners 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 and our collaboration partners 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 (IRB), Data Safety Monitoring Board (DSMB), Data Monitoring Committee (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.

***If the FDA concludes that our product candidates do not satisfy the requirements for approval under the Section 505(b)(2) regulatory approval pathway, or if the requirements for approval under Section 505(b)(2) are not as we expect, the approval pathway for our products will likely take significantly longer, cost significantly more, and entail significantly greater complications and risks than anticipated, and in any case may not be successful. Similar obstacles may arise in other countries.***

Similar to the approval pathway for GOCOVRI, we are developing our current and future product candidates, with the expectation that they will be eligible for approval through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the FDCA allows an NDA to rely in part on the FDA's prior conclusions regarding the safety and effectiveness of an approved drug product, or reference listed drug (RLD). Use of the Section 505(b)(2) regulatory pathway could reduce the time required for the development programs of our product candidates by, for example, potentially decreasing the amount of preclinical and/or clinical data specific to a product candidate that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for product approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and the complications and risks associated with regulatory approval would likely substantially increase. Moreover, our inability to pursue the Section 505(b)(2) regulatory pathway may result in competitive products reaching the market more quickly than our product candidates, which would adversely impact our competitive position and prospects. Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee that utilizing this pathway will ultimately lead to faster product development or earlier approval for any product candidate that we may attempt to develop and commercialize.

An NDA submitted through the Section 505(b)(2) regulatory pathway for a drug product with an active moiety that has been previously approved in another product (e.g., amantadine) may be entitled to three years of regulatory exclusivity if the NDA contains data from clinical investigations (other than bioavailability or bioequivalence studies) conducted by or for the sponsor and deemed essential to FDA's approval of the NDA. This regulatory exclusivity precludes, among other things, approval of another 505(b)(2) NDA for a product with the same conditions of approval. Although obtaining such exclusivity for our product candidates could provide a competitive benefit for us, the availability of such exclusivity to competitors, if their products were to be approved before our product candidates, presents a risk. If a competing product were approved in our target indication and granted three years of exclusivity, and if the FDA were to find that our product candidate does not differ with respect to the relevant conditions of approval of the approved competing product, then approval of the 505(b)(2) NDA for our product candidate in the target indication may be delayed for as long as the competitor has exclusivity.

With a Section 505(b)(2) NDA, we also must certify to the FDA concerning any patents listed for the RLD in the Orange Book. A certification that our product candidate does not infringe the RLD's Orange Book-listed patents, or that such patents are invalid (known as a paragraph iv certification) would require providing notice of that certification to the patent holder and the sponsor of the RLD NDA, and we could then be challenged in court by the patent owner or the holder of the approved NDA for the RLD. If such a lawsuit were to be filed within a specified timeframe, it would lead to a 30-month period during which FDA would be precluded from approving our NDA.

***With the approval of GOCOVRI, we will continue to be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.***

With the approval of GOCOVRI, the manufacturing, marketing, and further development of the approved product are subject to continual review by the FDA and/or analogous non-U.S. regulatory authorities. Any regulatory approval that we or our collaboration partners receive for our product candidates will be subject to limitations on the indicated uses for which the product may be marketed, and may be subject to requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. In addition, if the FDA and/or analogous non-U.S. regulatory authorities approve any of our product candidates, we 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 for our product candidates, if approved, 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 product candidates or the manufacturing facilities for our product candidates 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.

***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 product candidates' 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 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 changes under the PPACA are discussed in the business heading "Other healthcare regulations" in Part I, Item 1, of our 2016 Annual Report on Form 10-K.

Legislative and regulatory changes to the PPACA remain possible and appear likely in the 115th United States Congress and under the Trump Administration. 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. There have also been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries.

If any of these proposals are adopted, they could result in our owing additional rebates, which could have a negative impact on revenues from sales of our 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 U.S., 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 2016 Annual Report on Form 10-K.

***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 intend to participate in and then will 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 the Centers for Medicare and Medicaid Services, or 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 2016 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. In 2015, HRSA issued proposed omnibus guidance that addresses many aspects of the 340B program, and in August 2016, HRSA issued a proposed regulation regarding an administrative dispute resolution process for the 340B program. It is unclear when or whether the guidance or regulation will be released in final form under the Trump Administration. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The March 6, 2017 effective date of this regulation is subject to a temporary delay directed by the Trump Administration, and the regulation could be subject to further delay or other modification by the Trump Administration. Implementation of this final rule and 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 civil monetary penalties in the amount of \$178,156 per item of false information. Our failure to submit the required price data on a timely basis could result in a civil monetary penalty of \$17,816 per day 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 (“VA”), Department of Defense, Public Health Service, and Coast Guard (the “Big Four agencies”), and certain federal grantees, we are required to participate in the VA Federal Supply Schedule (“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 (“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” (“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 penalties of \$178,156 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 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 any products for which we have obtained or may obtain marketing approval. The laws and regulations that may affect our ability to operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, lease, arrangement or recommendation of, any good, facility, item, or service for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs. Liability under the Anti-Kickback Statute may be established without a person or entity having actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- the federal civil False Claims Act, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds, or knowingly using false records or statements, to obtain payment from the federal government. In recent years, several pharmaceutical and other health care companies have faced enforcement actions under the False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government healthcare programs, providing free product to customers with the expectation that the customers would bill federal programs, product and patient assistance programs, including reimbursement services, and marketing products for off-label or unapproved uses;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. HIPAA also imposes obligations on certain entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, also governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to the federal government information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members; 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. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-relating activities, including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

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 civil, criminal and/or administrative penalties, damages, fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, 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. For example, in the European Union the sole legal instrument at the European Union level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC (the Price Transparency Directive). The aim of the Price Transparency Directive is to ensure that pricing and reimbursement mechanisms established in European Union member states are transparent and objective, do not hinder the free movement and trade of medicinal products in the European Union, and do not hinder, prevent or distort competition on the market. The Price Transparency Directive does not, however, provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual European Union member states. The national authorities of the individual European Union member states are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some individual European Union member states adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other European Union member states adopt a system of reference pricing, basing the price or reimbursement level in their territory either, on the pricing and reimbursement levels in other countries, or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Furthermore, some European Union member states impose direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some European Union member states. These countries include the United Kingdom, France, Germany, and Sweden. 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 exchange of scientific information concerning HTAs. This could lead to harmonization between European Union member states of the criteria taken into account in the conduct of HTA in pricing and reimbursement decisions and negatively impact price in at least some European Union member states.

***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 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 U.S., 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 FTC 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 (which could include 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 the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"). 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.

EU member states and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland has adopted similar restrictions. Data protection authorities from the different EU member states may interpret the applicable laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. Although there are legal mechanisms to allow for the transfer of personal data from the EU to the U.S., the decision of the European Court of Justice in the *Schrems* case (Case C-362/14 Maximilian Schrems v. Data Protection Commissioner) invalidated the Safe Harbor framework and increased uncertainty around compliance with European Union restrictions on cross-border data transfers. As a result of the decision, it was no longer possible to rely on safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the U.S. On February 29, 2016, however, the European Commission announced an agreement with the United States Department of Commerce ("DOC") to replace the invalidated Safe Harbor framework with a new EU-U.S. "Privacy Shield." On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. U.S. companies have been able to certify to the U.S. DOC their compliance with the privacy principles of the Privacy Shield since August 1, 2016. On September 16, 2016, the Irish privacy advocacy group Digital Rights Ireland brought an action for annulment of the European Commission decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). Case T-670/16 is still pending. If, however, the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the European Union to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. U.S.-based

companies are permitted to rely either on their adherence to the EU-US Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the EU Data Protection Directive.

In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, introducing new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules, was agreed between the European Parliament, the Council of the European Union, and the European Commission. The EU General Data Protection Regulation entered into force on May 24, 2016 and will apply from May 25, 2018. The EU Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process and we will also face substantial fines for breaches of the data protection rules. We may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. Furthermore, there is a growth towards the public disclosure of clinical trial data in the European Union which adds to the complexity of processing health data from clinical trials.

If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EU or Switzerland to the U.S. (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the European Union or Switzerland is restricted.

***Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.***

We may decide to seek marketing authorizations to commercialize GOCOVRI, ADS-4101, and other future product candidates outside of the United States. To market our future products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically, in the EU, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

Before granting an MA, the European Medicines Agency or the competent authorities of the member states of the EU make an assessment of the risk-benefit balance of the product on the basis of a Common Technical Document including, among other information, scientific criteria concerning its quality, safety, and efficacy.

Similar to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU member states both before and after grant of the manufacturing and Marketing Authorizations. This includes control of compliance with cGMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures. We and our third-party manufacturers are required to ensure that all of our processes, methods, and equipment are compliant with cGMP. Failure by us or by any of our third-party partners, including suppliers, manufacturers, and distributors to comply with EU laws and the related national laws of individual EU member states governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products, both before and after grant of marketing authorization, and marketing of such products following grant of authorization may result in administrative, civil, or criminal penalties. These penalties could include delays in or refusal to authorize the conduct of clinical trials or to grant Marketing Authorization, product withdrawals and recalls, product seizures, suspension, or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties.

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from and be longer than that required to obtain FDA approval. Clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval as well as additional, different risks.

There is no assurance that we will be able to obtain marketing authorizations in foreign countries on a timely basis, if at all. We may not be able to file for foreign regulatory approvals, and even if we file we may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain non-U.S. regulatory

approval to market our product candidates in other countries, we may not be able to achieve the financial results we project and our stock price could decline.

## **Risks related to the operation of our business**

### ***Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain, and motivate qualified personnel.***

We are highly dependent on our chief executive officer and the other members of our executive and scientific teams. Our executives may terminate their employment with us at any time. The loss of the services of any of these people could impede the achievement of our research, development, and commercialization objectives. We maintain “key person” insurance for our chief executive officer, but not for any other executives or employees. Any insurance proceeds we may receive under this “key person” insurance would not adequately compensate us for the loss of our chief executive officer’s services.

Recruiting and retaining qualified scientific, clinical, manufacturing, and commercial personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

### ***We expect to expand our development and sales and marketing capabilities, and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

As of September 30, 2017, we had 84 full-time equivalent employees. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, informational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

### ***We are an “emerging growth company,” and we cannot be certain whether the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. 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 could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, fires, extreme weather conditions, medical epidemics, and other natural or manmade disasters or business interruptions. The occurrence of any of these 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 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:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- 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;
- 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, CSO, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.***

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, 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 such 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 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 product candidates could be delayed.

***Risks generally associated with a company-wide implementation of information systems, including an enterprise resource planning (ERP) system, may adversely affect our business and results of operations or the effectiveness of our internal controls over financial reporting.***

In support of our anticipated growth and future commercial-stage operations, we intend to select and implement a number of company-wide information systems, including adding new functionality to our enterprise resource planning (“ERP”), and other similar systems. Many of these systems are complex and their successful and timely implementation is not assured, requires significant capital expenditures, and can be disruptive to our business operations. We recently implemented a new ERP system in addition to a new human resource information system (“HRIS”). These projects required and may continue to require investment of capital and human resources and the attention of many employees who would otherwise be focused on other aspects of our business. Any deficiencies in the design and implementation of the new ERP and HRIS system could result in potentially much higher costs than we had incurred and could adversely affect our ability to develop and launch solutions, provide services, fulfill contractual obligations, file reports with the SEC in a timely manner, operate our business, or otherwise affect our controls environment. Any of these consequences could have an adverse effect on our results of operations and financial condition.

#### **Risks related to intellectual property**

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

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain or enforce the patents, covering technology or products 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 have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel 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 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.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In March 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a “first to invent” to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear, as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the “first-to-file” provisions, only became effective in March 2013. In addition, the courts have only recently started to address these provisions such that the law is still developing, and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

From time to time, we may become involved in opposition, interference, derivation, *inter partes* 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.

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

Filing, prosecuting, and defending patents on all of our 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 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 unsuccessful.***

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. 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, we, Forest, Forest Laboratories, Inc., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH filed patent infringement lawsuits under Forest's patents and patents owned by us and licensed to Forest, against several manufacturers of generic pharmaceuticals that have filed ANDAs with the FDA seeking approval to manufacture and sell generic versions of Namzaric<sup>®</sup> and Namenda XR<sup>®</sup>. We anticipate that the prosecution of the lawsuits will require a significant amount of time and attention of our chief executive officer and other senior executives. In addition, in a patent infringement proceeding, a court may decide that a patent of ours 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 technology in question. An adverse result in any of the Forest litigations or any other litigation 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 technology and 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. A successful challenge to our patents could reduce or eliminate our right to receive royalties from Forest. 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 product candidates and to use our proprietary 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 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 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:

- our success in commercializing GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease;
- the availability of reimbursement by payers at acceptable levels, or at all, for GOCOVRI;
- the success of competitive products or technologies;
- results of clinical studies of our product candidates 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.

***Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

***Concentration of ownership of our common stock among our existing executive officers, directors, and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own a significant percentage of our outstanding common stock. These persons, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

***We will continue to incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, and we could fail to successfully improve our systems, procedures, and controls, which could affect our operating results.***

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as well as new rules implemented by the SEC and the NASDAQ Stock Market LLC. We expect that we will need to continue to improve existing, and implement new operational, financial, and information management systems, procedures, and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures,

or controls may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective.

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

Our stock is currently traded on NASDAQ, but we can provide no assurance that we will be able to maintain an active trading market on NASDAQ or any other exchange in the future or that the daily trading volume will be adequate to allow orderly purchases or sales of our common stock without significantly impacting the price per share. If an active market for our common stock is not maintained, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about us or our business, our stock price and trading volume could decline.***

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may cease to publish research on our company at any time in their discretion. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. In addition, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If our operating results fail to meet the forecast of analysts, our stock price will likely decline.

***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 acquiror from conducting a solicitation of proxies to elect the acquiror'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.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.***

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

**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	
<a href="#">3.1</a>	Amended and Restated Certificate of Incorporation of Adamas Pharmaceuticals, Inc.	8-K	001-36399	3.1	4/15/2014	
<a href="#">3.2</a>	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.					
<a href="#">4.2</a>	Form of Common Stock Certificate of Adamas Pharmaceuticals, Inc.	S-1	333-194342	4.1	3/26/2014	
<a href="#">4.3</a>	Fourth Amended and Restated Investor Rights Agreement, dated as of June 30, 2011, by and among the registrant and certain of its stockholders.	S-1	333-194342	10.5	3/5/2014	
<a href="#">10.1*</a>	Amended and Restated Commercial Supply Agreement by and between Adamas Pharmaceuticals, Inc. and Catalent Pharma Solutions, LLC.					X
<a href="#">10.2*</a>	Amended and Restated API Supply Agreement by and between Adamas Pharma, LLC and Moehs Ibérica, S.L.					X
<a href="#">10.3</a>	Change in Compensation for Christopher B. Prentiss, Chief Accounting Officer.	8-K	001-36399	Item 5.02	9/21/2017	
<a href="#">31.1</a>	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
<a href="#">31.2</a>	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
<a href="#">32.1</a>	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	XBRL Instance Document					
101.SCH	XBRL Taxonomy Extension Schema Document					
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					

\* Confidential Treatment Requested for certain portions of this exhibit

(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.

**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: November 2, 2017

/s/ Gregory T. Went, Ph.D.

Gregory T. Went, Ph.D.

Chief Executive Officer

(Principal Executive Officer)

Date: November 2, 2017

/s/ Alfred G. Merriweather

Alfred G. Merriweather

Chief Financial Officer

(Principal Financial Officer)

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**EXECUTION COPY**

**AMENDED AND RESTATED COMMERCIAL SUPPLY AGREEMENT**  
(Amantadine HCl extended release capsules)

This Amended and Restated Commercial Supply Agreement (“ **Amended and Restated Agreement** ”) is effective as of February 16, 2017 (“ **Restatement Effective Date** ”), by and between Adamas Pharmaceuticals, Inc., a Delaware corporation, with a place of business at 1900 Powell St., Suite 750, Emeryville, CA 94608 (“ **Client** ”), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, with a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA (“ **Catalent** ”).

**RECITALS**

- A. Client is a specialty pharmaceutical company that develops and plans to market and sell pharmaceutical products;
- B. Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services for pharmaceutical, biotechnology and consumer healthcare companies;
- C. Client desires to engage Catalent to provide certain services to Client in connection with the processing and manufacture of Client’s Product, ADS-5102, a proprietary controlled-released version of amantadine HCl that is in development for the treatment of levodopa induced dyskinesia, or LID, a complication associated with the treatment of Parkinson’s disease, and potentially as a treatment for one or more additional disorders of the central nervous system, and Catalent desires to provide such services, all pursuant to the terms and conditions set forth in this Agreement;
- D. Effective as of June 29, 2015 (“ **Effective Date** ”) Client and Catalent entered into that certain Commercial Supply Agreement (“ **Original Agreement** ”) and the Parties now desire to amend certain terms of the Original Agreement and restate the Original Agreement in its entirety on the terms and conditions set forth in this this Amended and Restated Agreement.

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

**ARTICLE 1**  
**DEFINITIONS**

The following terms have the following meanings in this Agreement:

- 1.1 “ **Acknowledgement** ” has the meaning set forth in Section 4.3.
-

1.2 “ **Affiliate(s)** ” means, with respect to Client or any third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity; and with respect to Catalent, Catalent Pharma Solutions, Inc. and any corporation, firm, partnership or other entity controlled by it. For the purposes of this definition, “ **control** ” means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.

1.3 “ **Agreement** ” means the Original Agreement (including all its Attachments and other appendices) as in effect from the Effective Date until the Restatement Effective Date, together with the Amended and Restated Agreement, which pursuant to Section 18.1 below replaces the Original Agreement in its entirety as of the Restatement Effective Date, including with respect to this Amended and Restated Agreement its Attachments and other appendices (all of which are incorporated herein by reference) and any amendments to any of the foregoing made as provided herein or therein.

1.4 “ **API** ” means the compound Amantadine HCl, as further described in the Specifications, that has been provided on behalf of Client to Catalent along with a certificate of analysis as provided in this Agreement and in accordance with Section 3.1 (b).

1.5 “[\*]” has the meaning set forth in [\*].

1.6 “ **Applicable Laws** ” means, with respect to Client, all laws, ordinances, rules and regulations, as amended from time to time, of each jurisdiction in which API or Product is produced, marketed, distributed, used or sold, together with the FDA’s Guidance, Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination.; and with respect to Catalent, all laws, ordinances, rules and regulations, as amended from time to time, of the jurisdiction in which Catalent Processes Product, including cGMP.

1.7 “ **Batch** ” means a defined quantity of Product that has been or is being Processed in accordance with the Specifications and in conformity with the terms of this Agreement. Notwithstanding the foregoing, upon tender of delivery of Product by Catalent to Client, the Batch shall have completed Processing, including encapsulation into either the 170 mg or 85 mg dosage form, and released in accordance with Section 5.1 and the Quality Agreement. For purposes of clarity, as of the Restatement Effective Date, the estimated quantity of Product is approximately such number of capsules as set forth on Attachment C, which may increase over time for a variety of reasons, including but not limited to, increased yields or efficiencies in the Process.

1.8 “ **Catalent** ” has the meaning set forth in the introductory paragraph, or any successor or permitted assign. As permitted and in conformity with the provisions of Section 18.7, Catalent shall have the right to cause any of its Affiliates to perform any of its obligations hereunder, and Client shall accept such performance as if it were performance by Catalent to the extent set forth in Section 18.7.

1.9 “ **Catalent Commitment** ” has the meaning set forth in Section 4.3B.

- 1.10 “ **Catalent Defective Processing** ” has the meaning set forth in Section 5.2.
- 1.11 “ **Catalent Indemnitees** ” has the meaning set forth in Section 13.2.
- 1.12 “ **Catalent IP** ” has the meaning set forth in Article 11.
- 1.13 “ **cGMP** ” means current good manufacturing practice and standards as provided for (and as amended from time to time) in the current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations Title 21 (21 C.F.R. §§210 and 211), in the European Community Directive 2003/94/EC (Principles and guidelines of good manufacturing practice for medicinal products) in relation to the production of finished pharmaceutical products, as interpreted by ICH Harmonised Tripartite Guideline, Good Manufacturing Practice Guides for Active Pharmaceutical Ingredients (Q7a), and Pharmaceutical Quality System (Q10), and in the Territory, as applicable, and subject to any arrangements, additions or clarifications, and the respective roles and responsibilities, agreed from time to time between the Parties.
- 1.14 “ **Client** ” has the meaning set forth in the introductory paragraph, or any successor or permitted assign.
- 1.15 “ **Client Indemnitees** ” has the meaning set forth in Section 13.1.
- 1.16 “ **Client IP** ” has the meaning set forth in Article 11.
- 1.17 “ **Client-supplied Materials** ” means any materials to be supplied by or on behalf of Client to Catalent for Processing, as provided in Attachment B, including API and certain specified reference standards listed thereon, if any.
- 1.18 “ **Commencement Date** ” means the first date upon which a Regulatory Authority approves Catalent as a manufacturer of any Product.
- 1.19 “ **Confidential Information** ” has the meaning set forth in Section 10.1.
- 1.20 “ **Contract Year** ” means each consecutive 12 month period beginning on the Commencement Date or anniversary thereof, as applicable, provided that Contract Year 1 shall start on the Restatement Effective Date and end after the 12 month period beginning on the Commencement Date.
- 1.21 “ **Defective Product** ” has the meaning set forth in Section 5.2.
- 1.22 “ **Discloser** ” has the meaning set forth in Section 10.1.
- 1.23 “ **Effective Date** ” has the meaning set forth in the Recitals.
- 1.24 “ **Exception Notice** ” has the meaning set forth in Section 5.2.
- 1.25 “ **Facility** ” means Catalent’s facilities located in (a) [\*], as each is determined acceptable by the Client from time to time, and (b) such other location as mutually agreed by the parties. Catalent

shall only Process Product at a Facility in accordance with the foregoing and the terms of this Agreement.

1.26 “ **Firm Commitment** ” has the meaning set forth in Section 4.2.

1.27 “ **Initial Forecast** ” has the meaning set forth in Section 4.2.

1.28 “ **Invention** ” has the meaning set forth in Article 11.

1.29 “ **Joint Steering Committee** ” or “ **JSC** ” has the meaning set forth in Section 4.10.

1.30 “ **Losses** ” has the meaning set forth in Section 13.1.

1.31 “ **Minimum Requirement** ” has the meaning set forth in Section 4.1.

1.32 “ **Pellet Batch** ” means a Batch that remains in Process after (a) completion of manufacture, blending and lubrication of the pellets, and prior to (b) encapsulation. For purposes of clarity, the parties reference Pellet Batches in Section 4.7 for purposes of determining quantities of Raw Material Safety Stock regardless of dosage form but are not intending for delivery of Product at such stage of Processing.

1.33 “ **Process** ” or “ **Processing** ” means the compounding, filling or pressing, producing, manufacture and bulk packaging (but not secondary or retail packaging) of Client-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement.

1.34 “ **Processing Date** ” means the day on which the first step of physical Processing is scheduled to occur, as identified in an Acknowledgement.

1.35 “[\*]” has the meaning set forth in [\*].

1.36 “ **Product** ” means the bulk pharmaceutical product containing the API, as more specifically described in the Specifications.

1.37 “ **Product Maintenance Services** ” has the meaning set forth in Section 2.3.

1.38 “ **Purchase Order** ” has the meaning set forth in Section 4.3.

1.39 “ **Quality Agreement** ” has the meaning set forth in Section 9.6.

1.40 “ **Raw Materials** ” means all raw materials, supplies, components and packaging necessary to manufacture and ship Product in accordance with the Specifications, as provided in Attachment B, but excluding Client-supplied Materials.

1.41 “ **Raw Material Safety Stock** ” has the meaning set forth in Section 4.7.

1.42 “ **Recall** ” has the meaning set forth in Section 9.5.

1.43 “ **Recipient** ” has the meaning set forth in Section 10.1.

1.44 “ **Regulatory Approval** ” means any approvals, permits, product and/or establishment licenses, registrations or authorizations, including approvals pursuant to U.S. Investigational New Drug applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of any Regulatory Authorities that are necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product in the Territory.

1.45 “ **Regulatory Authority** ” means the international, federal, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities in the Territory that are responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally. In the United States, this includes the United States Food and Drug Administration (the “ **FDA** ”); and in the European Union, this includes the European Medicines Agency.

1.46 “ **Representatives** ” of an entity means such entity’s duly-authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.47 “ **Review Period** ” has the meaning set forth in Section 5.2.

1.48 “ **Rolling Forecast** ” has the meaning set forth in Section 4.2.

1.49 “ **Shortfall Payment** ” and “ **Shortfall Percentage** ” have the meanings set forth in Section 4.1.

1.50 “ **Specifications** ” means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment B, as modified from time to time in accordance with Article 8.

1.51 “ **Supply Failure** ” has the meaning set forth in Section 4.8.

1.52 “ **Term** ” has the meaning set forth in Section 16.1.

1.53 “ **Territory** ” means those countries set forth in Schedule 1.51, as modified and agreed to by the parties from time to time in an amendment to this Agreement. Catalent shall make commercially reasonable efforts to accommodate additional countries, but shall not be obliged to Process Products for sale in any of such countries if it is prevented from doing so, or would be required to obtain or apply for special permission to do so with an unreasonable or significant level of effort, due to any restrictions (such as embargoes) imposed on it by any governmental authorities, including without limitation, those imposed by the U.S. Office of Foreign Assets Control.

1.54 “ **Unit Pricing** ” has the meaning set forth in Section 7.1(B).

1.55 “ **Validation Services** ” has the meaning set forth in Section 2.1.

1.56 “ **Vendor** ” has the meaning set forth in Section 3.2(B).

## ARTICLE 2 VALIDATION, PROCESSING & RELATED SERVICES

2.1 Validation Services. Catalent shall perform the Product qualification, validation and stability services described in Attachment A (the “ **Validation Services** ”) in accordance with the timelines specified in Attachment A.

2.2 Product Processing and Supply of Product.

2.2.1 Catalent shall Process Product in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.2.2 Personnel: Catalent shall provide an adequate number of properly trained operators and technicians to conduct all Product Processing, and such training shall be documented and promptly available to Client for review upon request. Catalent Quality Assurance personnel shall document and maintain a routine manufacturing room presence during all Product Processing activities, observing Product Processing at least one time per Catalent work shift. Quality Assurance documentation shall be promptly available to Client for review, upon request.

2.2.3 Equipment: Catalent shall ensure that all equipment required for Product Processing is validated and calibrated, as necessary, and available prior to Product Processing. Catalent shall ensure equipment redundancies, as requested by Client, in the event that equipment malfunctions prior to or during Product Processing, for example, [\*]. To the extent that [\*] such equipment in order to [\*], Client agrees to [\*] such equipment [\*], and Catalent agrees to [\*] such equipment [\*], and to [\*] such equipment [\*] determined by the parties.

2.2.4 Catalent shall provide to Client a detailed Processing plan and schedule at least [\*] prior to start of Product Processing for each Client Product Batch or Campaign, specifying and confirming all preparatory and Processing steps, the equipment to be utilized in Product Processing, the raw materials to be utilized, and the raw material release dates, which dates shall be at least [\*] prior to start of Product Processing,

2.2.5 Client and its Affiliates shall purchase from Catalent their requirements of Product, subject to Section 4.1, and in accordance with the terms and conditions of this Agreement; provided, however, that nothing herein shall be construed to preclude Client from purchasing Product from one or more other manufacturers. Catalent shall provide an adequate number of properly trained operators and technicians to conduct all Product Processing, and such training shall be documented and promptly available to Client for review upon request.

2.3 Product Maintenance Services. Catalent shall provide the following product maintenance services on a timely basis and in accordance with the Specifications, Applicable Laws and the terms of this Agreement (the “**Product Maintenance Services**”): [\*], if applicable; [\*], including [\*], as applicable. For avoidance of doubt, the following services and items are not included in Product Maintenance Services: [\*], as applicable.

2.4 Other Related Services. Catalent shall provide such Product-related services, other than Validation Services, Processing or Product Maintenance Services, including but not limited to, services to [\*], and such other services as agreed to in writing by the parties from time to time. Such writing shall include the scope and reasonable fees for any such services and be appended to this Agreement in the form of the attached work order as set forth on Exhibit I (the “**Work Order**”). The terms and conditions of this Agreement shall govern and apply to such services.

### ARTICLE 3 MATERIALS

#### 3.1 Client-supplied Materials.

A. Client shall supply to Catalent for Processing, at Client’s cost, all Client-supplied Materials, in quantities sufficient to meet Client’s requirements for Product. Client shall deliver such items and associated certificates of analysis to the Facility no later than [\*] (but not earlier than [\*]) before the Processing Date. Client shall be responsible at its expense for securing any necessary export or import, or similar clearances or permits required in respect of such supply. Catalent shall use such items solely for Processing. Prior to delivery of any such items, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information, and shall promptly provide any updates thereto.

B. Following receipt of Client-supplied Materials, Catalent shall (i) promptly inspect such items to verify their identity and (ii) with respect to API, Catalent shall be responsible for release of the API, in accordance with the Specification, including identification test, visual inspection for appearance and review of the certificate of analysis. Unless otherwise set forth in this Agreement, including the Specifications, Catalent shall have no additional obligation to test such items to confirm that they meet the associated specifications or certificate of analysis or otherwise; but in the event that Catalent detects a nonconformity with Specifications, Catalent shall give Client prompt notice of such nonconformity pursuant to the requirements in the Quality Agreement. Catalent shall not be liable for any defects in Client-supplied Materials, or in Product as a result of defective Client-supplied Materials, unless Catalent failed to properly perform the foregoing obligations. Catalent shall follow Client’s reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client’s cost.

C. Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss thereof.

#### 3.2 Raw Materials.

A. Catalent shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed to by the parties in writing. Catalent shall not be liable for any delay in delivery of Product if (i) Catalent is unable to obtain, in a timely manner, a particular Raw Material necessary for Processing after having made commercially reasonable efforts to secure such Raw Material, (ii) Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the parties will negotiate in good faith an appropriate amendment to this Agreement, including Section 4.2.

B. In certain instances, Client may require a specific supplier, manufacturer or vendor (" **Vendor** ") to be used for Raw Material. In such an event, (i) such Vendor will be identified in the Specifications and (ii) if the Vendor was not previously qualified by Catalent, then (a) the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of this Agreement, as set forth on Attachment B and (b) if the cost of the Raw Materials from any such Vendor is greater than Catalent's costs for the same raw material of equal quality from other vendors, Catalent shall add the difference between Catalent's cost of the Raw Material and the Vendor's cost of the Raw Material to the Unit Pricing. Client will be responsible for all costs associated with qualification of any such Vendor who has not been previously qualified by Catalent. For purposes of clarity, a list of Vendors that have already been qualified are set forth on Attachment B. In the event of (i) a Specification change for any reason (other than Catalent's own business needs), which shall be subject to Client's approval as set forth in the Quality Agreement, (ii) obsolescence of any Raw Material or (iii) termination (other than by Client pursuant to Section 16.2(A) or (B)) or expiration of this Agreement, Client shall bear the cost of any unused Raw Materials (including packaging), so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Firm Commitment or for purposes of Raw Material Safety Stock.

3.3 Artwork and Labeling. Client shall provide or approve, prior to the procurement of applicable Raw Material, all artwork, advertising and labeling information necessary for Processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder.

3.4 Inventory. Within three (3) business days after the end of each calendar month, Catalent shall provide to Client an inventory report reporting the quantity of Client-supplied Materials, Raw Materials, Products and work-in-progress in Catalent's inventory.

#### **ARTICLE 4**

#### **MINIMUM REQUIREMENT, PURCHASE ORDERS & FORECASTS**

4.1 Minimum Requirement.

- A. Subject to Section 4.8 (Failure to Supply) and Section 4.1.B and after the Commencement Date, Client shall purchase and accept delivery of Product in a Contract Year such that the sum of all purchases of such Product, in aggregate, is equal to or greater than the minimum requirement for such Contract Year set forth in Section II of Attachment C (the “ **Minimum Requirement** ”). For clarity, any Product purchased by Client in the entirety of Contract Year 1, regardless of whether before the Commencement Date, shall be credited towards Client’s obligation to purchase the Minimum Requirements for Contract Year 1.

For purposes of clarity, the parties shall consider those Batches of Product delivered in a Contract Year for purposes of calculating Client’s satisfaction of the Minimum Requirement and Firm Commitment relative to the Rolling Forecast in Section 4.2 below.

- B. Shortfall Payment. If Client does not purchase such Minimum Requirement during a Contract Year, then within [\*] after the end of such Contract Year, Client shall pay Catalent the amount calculated as follows (the “ **Shortfall Payment** ”):

[\*]

Shortfall Payments payable on the Minimum Requirement for any particular Contract Year shall be reduced by any Firm Commitment Payments previously made or made at the same time by Client with respect to any quarterly Firm Commitment during that same Contract Year. For clarity, payments made in accordance with this Section 4.1.B shall cure the applicable failure by Client to purchase Minimum Requirements, in full, and Catalent shall have no further right to seek damages or terminate this Agreement as a result of such failure.

4.2 Forecast. On or before [\*] each calendar quarter, beginning at least [\*] prior to the anticipated Commencement Date, Client shall furnish to Catalent a written rolling forecast of the quantities of Product that Client intends to purchase from Catalent during subsequent [\*], beginning with the [\*] (“ **Rolling Forecast** ”). For purposes of clarity, the initial Rolling Forecast shall cover the timeframe from the Commencement Date to [\*] thereafter (i.e. [\*] period). An example of the mechanics of the Rolling Forecast and the Batches delivered pursuant to the issuance of Purchase Orders is set forth on Attachment D. For (i) the initial Rolling Forecast and each Rolling Forecast delivered prior to the actual Commencement Date, the first [\*] of the Rolling Forecast that includes the anticipated Commencement Date shall constitute a binding order (the “ **Firm Commitment** ”), and the following [\*] shall be non-binding, good faith estimates, and (ii) each Rolling Forecast delivered on or after the actual Commencement Date, the first [\*] of such Rolling Forecast shall be the Firm Commitment and [\*] of the Rolling Forecast shall be non-binding, good faith estimates. In the event of a delay in the anticipated Commencement Date, the parties agree that the Minimum Requirement and the Firm Commitment shall be adjusted accordingly.

#### 4.3 Purchase Orders.

A. From time to time as provided in this Section 4.3(A), Client shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the specified delivery date for each Batch (“**Purchase Order**”) in accordance with Attachment C and in the form attached hereto as Exhibit II. Purchase Orders for quantities of Product shall be submitted by Client at least [\*] in advance of the delivery date requested in the Purchase Order, unless otherwise agreed by Catalent.

B. Promptly (and within [\*]) following receipt of a Purchase Order, Catalent shall issue a written acknowledgement (“**Acknowledgement**”) that it accepts or rejects such Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date consistent with Catalent’s obligations hereunder, and shall include the Processing Date. Catalent shall accept any Purchase Order (i) for [\*], as long as it is [\*] of the Firm Commitment for such period, and (ii) for Contract Year 3 and each Contract Year thereafter, as long as it is [\*] of the Firm Commitment for such Period, in each case rounded up to the nearest whole number of Batches (the “**Catalent Commitment**”). Catalent may reject any Purchase Order in excess of the Catalent Commitment (subject to Section 4.3(C)), or otherwise not given in accordance with this Agreement. Catalent shall be required to accept an otherwise conforming Purchase Order and shall Process and deliver Product in conformity with Purchase Order and this Agreement.

C. Notwithstanding Section 4.3(B), Catalent shall use commercially-reasonable efforts to supply Client with the specified quantity of Product in excess of the Catalent Commitment, subject to Catalent’s other supply commitments and manufacturing, packaging and equipment capacity.

D. In the event of a conflict between the terms of any Purchase Order, Work Order or Acknowledgement, Quality Agreement and this Agreement, the terms of this Agreement shall control except to the extent set forth in Section 9.6.

4.4 Catalent’s Cancellation of Purchase Orders. Notwithstanding Section 4.5, Catalent reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Client, and Catalent shall have no further obligations or liability with respect to such Purchase Order, if Client refuses or fails to timely supply conforming Client-supplied Materials in accordance with Section 3.1. Any such cancellation of Purchase Orders shall not constitute a breach of this Agreement by Catalent nor shall it absolve Client of its obligation in respect of the Minimum Requirement.

#### 4.5 Client’s Modification or Cancellation of Purchase Orders.

A. Client may modify the delivery date or quantity of Product in a Purchase Order only by submitting a written change order to Catalent at least [\*] in advance of the earliest Processing Date covered by such change order. Such change order shall be effective and binding against

Catalent only upon the written approval of Catalent, and notwithstanding the foregoing, Client shall remain responsible for the Firm Commitment.

B. Notwithstanding any amounts due to Catalent under Section 4.4 or Section 4.1, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Client shall pay to Catalent an amount equal to [\*] (the “**Firm Commitment Payment**”). For clarity, payments made in accordance with this Section 4.5.B shall cure the applicable failure by Client to place Purchase Orders sufficient to satisfy the Firm Commitment, in full, and Catalent shall have no further right to seek damages or terminate this Agreement as a result of such failure.

C. Neither changes to nor postponement of any Batch of Product, nor the payment of the fees described in this Section 4.5, will reduce or in any way affect Client’s Minimum Requirement obligations set forth in Section 4.1, except as expressly set forth in Section 4.1.

4.6 Unplanned Delay or Elimination of Processing. Catalent shall meet the Purchase Orders, subject to the terms and conditions of this Agreement. Catalent shall provide Client with as much advance notice as practicable if Catalent determines that any Processing will be delayed or eliminated for any reason.

4.7 Raw Material Safety Stock. Promptly following the Restatement Effective Date, Catalent shall establish and maintain at its cost but for the benefit of Client, a minimum quantity of Raw Materials to Process [\*] and [\*] (the “Raw Material Safety Stock”). The Raw Materials Safety Stock shall be maintained and stored in accordance with the terms of this Agreement, and Catalent will fulfill Purchase Orders for Product submitted by Client out of such inventory of Raw Materials on a “first in, first out” basis (and will accordingly replace the consumed inventory on a timely basis). Catalent shall promptly provide to Client full details relating to such quantities of Raw Materials Safety Stock, upon Client’s written request.

4.8 Failure to Supply.

4.8.1 In the First Contract Year. Except in the event of force majeure under Section 18.14, if Catalent is unable, or anticipates that it will not be able, or otherwise fails due to its gross negligence or deviation to meet the Specifications or its obligations under this Agreement, to deliver Batches, including Batches resulting from Validation Services, Catalent shall:

- (a) notify Client in writing as agreed in the Quality Agreement;
- (b) shall within [\*] such failure, commence the Processing of replacement product for the failed Batches [\*]; and
- (c) shall pay all manufacturing costs necessary for Client to replace such Batch(es).

Catalent and Client shall cooperate in good faith to resolve any problems causing the out-of Specification Batch.

4.8.2 After the First Contract Year: Except in the event of force majeure under Section 18.14, if Catalent is unable, or anticipates that it will not be able, or fails due to Catalent's failure to meet the Specifications or its obligations under this Agreement, to deliver Product, in the quantities and within [\*] of (i) the time periods specified in the Firm Commitment of any Rolling Forecast or (ii) the delivery date specified in any Purchase Order accepted in accordance with this Agreement (the “ **Supply Failure** ”), Catalent shall immediately notify Client in writing of the same with its best estimate of the duration of the delay. In such event, Catalent shall make best efforts during any period in which Client's Product is being Processed [\*] to cure such Supply Failure or cause and keep Client fully informed of such efforts including provide frequent updates. In the event of notice of such Supply Failure, Client may require that:

(a) Catalent shall remedy, at its own cost, any Supply Failure and use best efforts, in each case to Process Product, including from another Client-approved site (not to be unreasonably withheld or delayed), as soon as possible and as close to the original delivery date as possible;

(b) Catalent shall pay the excess of the replacement costs necessary for Client to replace the supply for the Product over the cost of the Product hereunder; provided, that [\*]; and

(c) Client be relieved from its obligations to purchase any quantities of Product identified in any then-existing Purchase Order and may cancel such quantities effective upon notice to Catalent.

In the event of a Supply Failure, the parties agree that (i) the Minimum Requirement and the Firm Commitment shall be adjusted accordingly, and (ii) Catalent shall resume supplying Product meeting the requirements of this Agreement as soon as the circumstances causing the Supply Failure have been resolved.

#### 4.9 Observation of Processing.

4.9.1 In addition to Client's audit right pursuant to Section 9.4, Client may (i) send up to [\*] Representatives to the Facility to observe Processing of Client's Product during any period in which Client's Product is being Processed until and unless the Client and Catalent agree otherwise, and (ii) send up to [\*] Representatives to the Facility to audit Client's inventory of API, Client-supplied Materials, or Product, upon at least [\*] prior notice, at reasonable times during regular business hours. Such Representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance. Client shall indemnify and hold harmless Catalent for any action, omission or other activity of such Representatives while on Catalent's premises. Client's Representatives shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility. Client observation of Processing does not relieve Catalent of any obligation, responsibility, representation or warranty under this Agreement.

4.9.2 Client will observe all Product Processing, and Catalent may not process Product without the presence of Client Representatives, unless otherwise authorized by Client in writing. However,

if the Client Representative is not present when they are scheduled to be present, and such absence solely and directly causes a delay in the commencement of any batch processing or manufacturing campaign, [\*]; except that [\*] if [\*].

4.10 Governance. After the Effective Date, Catalent and Client shall establish a joint steering committee (the “ **Joint Steering Committee** ” or “ **JSC** ”) consisting of at least 2 members appointed by each party. The JSC shall be responsible for reviewing the ongoing relationship of the parties, considering and attempting to achieve resolution of any disputes referred to it pursuant to Section 18.10 hereof and addressing such other matters as the parties may mutually agree. For the avoidance of doubt, the JSC is not authorized to amend this Agreement.

## ARTICLE 5 TESTING; SAMPLES; RELEASE

5.1 Batch Records and Data; Release. Unless otherwise agreed to by the parties, after Catalent completes a unit operation step in the Processing of a Batch and no later than [\*] thereof, Catalent shall provide Client with copies of Batch records for such step prepared in accordance with the Specifications; *provided*, that if testing reveals an out-ofSpecification result, Catalent shall provide such Batch records and any other documentation as reasonably requested promptly (and no later than [\*]) following resolution of the out-of-Specification result. If for any reason Catalent is unable to send final copies of Batch records for Processing steps to Client within [\*] of Processing, Catalent will immediately scan and electronically send to Client draft copies of such Batch records, [\*], so as to allow Client to review the draft Batch records in parallel with Catalent’s review of such records. After Catalent completes Processing of a Batch and no later than [\*] thereof, Catalent shall also provide Client or its designee with a certificate of analysis, certificates of compliance and conformance with cGMP, and TSE/BSE certificate in forms mutually acceptable to the parties for such Batch. Issuance of certificates of analysis, conformance and TSE/BSE certificates constitute release of the Batch by Catalent to Client. Client shall be responsible at its cost for final release of Product to the market.

5.2 Testing; Rejection. Following Client’s receipt of a shipment of a Batch, Client or Client’s designee may test samples of such Batch to confirm that the Specifications have been met. Unless within [\*] after Client’s receipt of a Batch and all documents listed in the Specifications (“ **Review Period** ”), Client or its designee notifies Catalent in writing (an “ **Exception Notice** ”) that such Batch does not meet the warranty set forth in Section 12.1 (“ **Defective Product** ”), and provides a sample of the alleged Defective Product, the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch, except as set forth in Section 5.6. Upon timely receipt of an Exception Notice from Client, Catalent shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with Client that Product is Defective Product and to determine the cause of any nonconformity. If Catalent agrees (or if the independent party determines pursuant to Section 5.3) that Product is Defective Product and determines that the cause of nonconformity

is attributable to Catalent's negligence or willful misconduct (" **Catalent Defective Processing** "), then Section 5.4 shall apply.

5.3 Discrepant Results. If the parties disagree as to whether Product is Defective Product and/or whether the cause of the nonconformity is Catalent Defective Processing, and this is not resolved within [\*] of the Exception Notice date, the parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed to by the parties in writing, the costs associated with such testing and review shall be borne by Catalent if Product is Defective Product attributable to Catalent Defective Processing, and by Client in all other circumstances.

5.4 Defective Processing. Catalent shall, at Client's option, either (A) re-Process (or if re Processing is not permissible under cGMPs, then replace), at its cost any Batch of Defective Product attributable to Catalent Defective Processing (and Client shall be liable to pay for either the rejected Batch (es) or the replacement Batch (es), but not both), or (B) credit any payments made by Client for such Batch. THE OBLIGATION OF CATALENT TO REPLACE CATALENT DEFECTIVE PROCESSING IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT PAYMENTS MADE BY CLIENT FOR DEFECTIVE PRODUCT ATTRIBUTABLE TO CATALENT DEFECTIVE PROCESSING SHALL BE, CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED. NOTWITHSTANDING THE FOREGOING, IF THERE ARE MORE THAN [\*] OF CATALENT DEFECTIVE PROCESSING IN A [\*] PERIOD CLIENT SHALL HAVE SUCH ADDITIONAL RIGHTS AS IN THE EVENT OF A SUPPLY FAILURE UNDER SECTION 4.8 HEREOF FOR ANY SUCH CATALENT DEFECTIVE PROCESSING THAT RESULTS IN A SUPPLY FAILURE.

5.5 Supply of Material for Defective Product. In the event Catalent reprocesses Defective Product pursuant to Section 5.4, Client shall supply, at its cost (except in the case of Defective Product attributable to Catalent's Defective Processing in which case such supply shall be, subject to Section 14.1, at Catalent's cost), Catalent with sufficient quantities of Client-supplied Materials in order for Catalent to complete such reprocessing.

5.6 Latent Defects. Notwithstanding anything to the contrary in this Agreement, if, within [\*] of the date of delivery pursuant to Section 5.2 of Product manufactured by Catalent, Client becomes aware of any defect in any Batch of Product that existed at the time of delivery and would not have been discoverable upon reasonable inspection or quality assurance testing as set forth in the Specifications, Client shall immediately notify Catalent in writing (identifying the batch(es) involved), and Section 5.2 above shall apply as if such notice was provided by Client within the [\*] period specified in Section 5.2 above.

**ARTICLE 6**  
**DELIVERY**

6.1 Delivery. Catalent shall deliver Product [\*] promptly following Catalent's release of Product to Client pursuant to Section 5.1. Catalent shall segregate and store all Product until tender of delivery. Title to Product shall transfer to Client upon [\*]. Client shall qualify at least 3 carriers to ship Product and then designate the priority of such qualified carriers to Catalent.

6.2 Storage Fees. If Client fails to take delivery of any Product on any scheduled delivery date, Catalent shall store such Product for [\*] and Client shall be invoiced on the first day of each month thereafter for reasonable administration and storage costs in accordance with Attachment C.

**ARTICLE 7**  
**PAYMENTS**

7.1 Fees. In consideration for Catalent performing services hereunder:

A. Client shall pay to Catalent the fees for Validation Services set forth on Attachment A. Catalent shall submit an invoice to Client for such fees upon the completion of the relevant phase of the Validation Services.

B. Client shall pay Catalent the unit pricing for Product set forth on Attachment C (“**Unit Pricing**”). Catalent shall submit an invoice to Client for such fees upon tender of delivery of Product as provided in Section 6.1.

C. Catalent shall submit an invoice to Client for the annual fees and Client shall pay Catalent such fees for Product Maintenance Services set forth on Attachment C.

D. Other Fees. Client shall pay Catalent for all other fees and expenses of Catalent owing in accordance with the terms of this Agreement, including pursuant to Sections 2.4, 4.1, 6.2 and 16.3. Catalent shall submit an invoice to Client for such fees as and when appropriate.

7.2 Unit Pricing. Unit Pricing is set forth in Attachment C, and shall be valid during the term of this Agreement, except as set forth in this Section 7.2. The Unit Pricing will be adjusted on an annual basis, effective on the first day of each calendar year after [\*], upon [\*] prior written notice from Catalent for (a) an annual increase or decrease in the processing and analytical components of the Unit Pricing, which shall not exceed the increase (or in the case of a decrease, equal to the change) in the Producer Price Index (PPI) for Pharmaceutical Preparations (PCU325412325412) for the prior 12 month period and (b) notwithstanding the foregoing or any change in the PPI, with reasonable supporting documentation, price increases or decreases for Raw Materials shall be passed through to Client, at the time of such increase or decrease, via an increase or decrease in the Unit Pricing.

7.3 Payment Terms. Payment of all Catalent invoices shall be due [\*] after the date of invoice, subject to amounts disputed in good faith by the Client. Client shall make payment in U.S. dollars,

and otherwise as directed in the applicable invoice. If any payment is not received by Catalent by its due date, then Catalent may, in addition to any other remedies available at equity or in law, charge interest on the outstanding sum from the due date (both before and after any judgment) at [\*] until paid in full (or, if less, the maximum amount permitted by Applicable Laws).

7.4 {RESERVED}

7.5 Taxes. All taxes, duties and other amounts assessed (excluding tax based on net income and franchise taxes) on Client-supplied Materials, services or Product prior to or upon provision or sale to Catalent or Client, as the case may be, are the responsibility of Client, and Client shall reimburse Catalent for all such taxes, duties or other expenses paid by Catalent or such sums will be added to invoices directed at Client, where applicable.

7.6 Client and Third Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, Client shall be responsible for 100% of its own and all third-party expenses associated with the development, Regulatory Approvals and commercialization of Product, including regulatory filings and post-approval marketing studies.

7.7 Development Batches. Each Batch produced under this Agreement, including those Processed as part of the Validation Services and necessary to support the validation portion of Client's submissions for Regulatory Approvals, will be considered to be a "development batch" unless and until Processing has been validated (as defined by the FDA) and in accordance with the Validation Services. Client shall be responsible for the cost of each such Batch, even if such Batch fails to meet the Specifications, unless such Batch of Product was not Processed in accordance with the mutually agreed batch records for such Batch or Catalent was grossly negligent in the Processing of the out-of-Specification Batch.

## ARTICLE 8 CHANGES TO SPECIFICATIONS

All Specifications and any changes thereto agreed to by the parties from time to time shall be in writing, dated and signed by the parties. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing). Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. As soon as possible after a request is made for any change in Specifications, Catalent shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with such agreed upon changes except to the extent such change is primarily attributable to Catalent's own business needs. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. Catalent reserves the

---

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the required written amendment; provided, however, Catalent agrees to effectuate such changes promptly after such amendment.

## ARTICLE 9 RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. Catalent shall maintain complete and accurate Batch, laboratory data, reports and other technical records relating to Processing in accordance with Catalent standard operating procedures. Such information shall be maintained for a period of at least [\*] or longer if required under Applicable Laws or the Quality Agreement.

9.2 Regulatory Compliance. Catalent shall obtain and maintain all permits and licenses with respect to general Facility operations required by Applicable Laws and any Regulatory Authority in the jurisdiction in which Catalent Processes Product. Client shall obtain and maintain all other Regulatory Approvals, including those necessary for Catalent to commence Processing. Client shall reimburse Catalent for any payments Catalent is required to make to any Regulatory Authority pursuant to changes in Applicable Laws resulting from and specific to Catalent's formulation, development, manufacturing, processing, filling, packaging or testing of Client's Product at the Facility (for example, such as [\*]); provided, however, that the foregoing shall not entitle Catalent to reimbursement for any establishment fees payable to any Regulatory Authority or for any fees or costs associated with general Facility operation as required by Applicable Laws. Client shall not identify Catalent in any regulatory filing or submission without Catalent's prior written consent, unless Catalent fails to meet the Warranty in Sections 12.1(G) of this Agreement. If consent is required, such consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized representatives of both Parties. Upon written request, Client shall provide Catalent with a copy of any Regulatory Approvals required to distribute, market and sell Product in the Territory, as applicable, and only to the extent that Client is unable to provide such information, Catalent shall have no obligation to deliver Product to Client if Catalent determines that such delivery would violate Applicable Laws. In no event shall the foregoing modify Catalent's obligation to timely deliver the development or validation batches as referenced in Section 7.7 for further packaging and in accordance with Client's Purchase Order prior to and in anticipation of Regulatory Approval. During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client's request and expense, unless such expense is related to Catalent's failure to meet the Warranty in Section 12.1 (A) and (G) of this Agreement. The parties intend and commit to cooperate to allow each party to satisfy its obligations under Applicable Laws relating to Processing under this Agreement.

9.3 Governmental Inspections and Requests. Catalent shall promptly advise Client if an authorized agent of any Regulatory Authority notifies Catalent that it intends to or does visit the Facility for the purpose of reviewing the Processing or for the purpose of reviewing Catalent's adherence with Applicable Laws. Catalent agrees that a Client representative may be onsite at the

Facility during any inspection directly related to ADS-5102, including but not limited to, any pre-approval inspections and other visits related to the Product which shall be further addressed in the Quality Agreement. Upon request, Catalent shall provide Client with a copy of any report issued by such Regulatory Authority received by Catalent following such visit, redacted as appropriate to protect any confidential information of Catalent and Catalent's other customers and in accordance with the procedures and other terms as set forth in the Quality Agreement. Client acknowledges that it may not direct the manner in which Catalent fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities; provided, however, that the foregoing should not be construed to modify or alter any obligation to Client unless directly in conflict. Client shall reimburse Catalent for all reasonable and documented costs associated with inspections by Regulatory Authorities directly attributable to Product; provided, that such inspection was not in connection with or as a result of Catalent's willful misconduct, negligence or non-compliance with Applicable Laws.

9.4 Client Facility Audits. During the Term, Client's Representatives shall be granted access upon at least [\*] prior notice, at reasonable times during regular business hours to (A) the portion of the Facility where Catalent performs Processing, (B) relevant personnel involved in Processing and (C) Processing records described in Section 9.2, in each case solely for the purpose of verifying that Catalent is Processing in accordance with cGMPs, the Specifications and the Product master Batch records. Client may not conduct an audit under this Section more than [\*] during any [\*] period; *provided*, that additional inspections may be conducted in the event there is a quality or compliance issue concerning Product or its Processing. Client's Quality Assurance Manager will arrange Client audits with Catalent Quality Management. Audits shall be designed to minimize disruption of operations at the Facility. Client's Representatives shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility. Such Representatives shall comply with the Facility's rules and regulations. Client shall indemnify and hold harmless Catalent for any action or activity of such Representatives while on Catalent's premises.

9.5 Recall. If Catalent believes a recall, field alert, Product withdrawal or field correction (“**Recall**”) may be necessary with respect to any Product supplied under this Agreement, Catalent shall promptly notify Client. Catalent will not act to initiate a Recall without the express prior written approval of Client, unless otherwise required by Applicable Laws. If Client believes a Recall may be necessary with respect to any Product supplied under this Agreement, Client shall promptly notify Catalent and Catalent shall provide all necessary cooperation and assistance to Client. To the extent appropriate and to be further set forth in the Quality Agreement, Client may provide Catalent opportunity to review and comment any relevant submissions to a Regulatory Authority in respect of any Recall. The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for expenses incurred in connection with any Recall, in each case unless such Recall is caused by Catalent's breach of its obligations under this Agreement, violation of Applicable Laws or its negligence or willful misconduct, then such cost shall be borne by Catalent. For purposes

hereof, such cost shall be limited to reasonable, actual and documented administrative costs incurred by Client for such Recall and replacement of the Product subject to Recall in accordance with Article 5.

9.6 Quality Agreement. Concurrent with or immediately after the Effective Date, and in any event prior to the first Processing of Product hereunder, the parties shall negotiate in good faith and enter into a quality agreement on Catalent's standard template (the "**Quality Agreement**"). The Quality Agreement shall be incorporated by reference in this Agreement. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

## ARTICLE 10 CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term "**Confidential Information**" includes all information furnished by or on behalf of Catalent or Client (the "**Discloser**"), its Affiliates or any of its or their respective Representatives, to the other party (the "**Recipient**"), its Affiliates or any of its or their respective Representatives, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any information furnished by the Discloser, its Affiliates or any of its or their respective Representatives. Notwithstanding the foregoing, Client's Confidential Information shall include: (i) the medical, clinical, toxicological or other scientific data or information relating to the Product (including, without limitation, pre clinical and clinical data, process condition data, notes, reports, models, analyses, and samples), (ii) the manufacture, production, procedures and processes, as well as analytical methodology, used in the testing, assaying, analysis, production, and packaging of the Product (in each case to the extent specifically related to the Product); (iii) Client's provided materials and substances for the Product; (ii) all Specifications, Client IP and [\*] Inventions; and (iii) Client's other information and non-patented proprietary rights (to the extent not already included in this definition of Confidential Information) with respect to the Product. Confidential Information also includes the existence of this Agreement and its terms.

10.2 Exclusions. Notwithstanding Section 10.1, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known

---

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

by the Recipient at the time of disclosure as evidenced by the Recipient's written records, (C) becomes available to the Recipient on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for the Recipient without reference to the Confidential Information of the Discloser as evidenced by the Recipient's written records.

10.3 Mutual Obligation. The Recipient agrees that it will keep confidential and not use the Discloser's Confidential Information except in connection with the performance of its obligations hereunder and will not disclose, without the prior written consent of the Discloser, Confidential Information of the Discloser to any third party, except that the Recipient may disclose the Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this Article and (C) are bound to the Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives.

10.4 Permitted Disclosure. The Recipient may disclose the Discloser's Confidential Information to the extent required by law or regulation; *provided*, that prior to making any such legally required disclosure, the Recipient shall give the Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. In addition, with written notice to Catalent, disclosure of Catalent's Confidential Information may be made by Client hereunder: (i) to governmental agencies to the extent required to secure Regulatory Approval, and (ii) to clinical investigators where necessary or desirable for their information to the extent normal and usual in the custom of the trade and under confidentiality obligations no less restrictive than those contained in this Agreement. Any such disclosure, however, shall not relieve the Recipient of its obligations contained herein. Either party may disclose the terms of this Agreement if and as required by (a) law, including, without limitation, SEC reporting requirements, or by the rules or regulations of any stock exchange that a Party is subject to; (b) the FDA as may be necessary or useful in obtaining and maintaining final approval of the Product; (c) outside counsel, accountants or bankers to a Party; and (d) the outside counsel, accountants or bankers to a third party (except in the case of other contract manufacturing organizations) in connection with a bona fide corporate transaction, financing or acquisition, in each case under obligations of confidentiality no less restrictive than those under this Agreement.

10.5 No Implied License. Except as expressly set forth in Section 10.1, the Recipient will obtain no right of any kind or license under any Confidential Information of the Discloser, including any patent application or patent, by reason of this Agreement. All Confidential Information will remain the sole property of the Discloser, subject to Article 11.

10.6 Return of Confidential Information. Upon expiration or termination of this Agreement, the Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within 30 days either return or destroy (and certify as to such destruction) all Confidential Information of the Discloser, including any copies thereof, except for

a single copy which may be retained for the sole purpose of ensuring compliance with its obligations under this Agreement.

10.7 Survival. The obligations of this Article will terminate [\*] from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under Applicable Laws.

## ARTICLE 11 INTELLECTUAL PROPERTY

11.1 Intellectual Property. For purposes hereof, “ **Client IP** ” means all intellectual property and embodiments thereof owned by or licensed to Client as of the date hereof or acquired or developed by Client other than in connection with this Agreement (including “Sponsor Intellectual Property” as defined in Section 6.1 of the June 13, 2013 Master Services Agreement between the parties (the “2013 MSA”)); “ **Catalent IP** ” means all intellectual property and embodiments thereof owned by or licensed to Catalent as of the date hereof or developed by Catalent other than in connection with this Agreement.

11.2 Inventions. “ **Invention** ” means any intellectual property developed by either party or jointly by the parties in connection with this Agreement; “[\*] **Inventions** ” means any Invention that [\*] or [\*]; and “[\*] **Inventions** ” means any Invention, other than [\*] Invention, that [\*]; and “ **Joint Inventions** ” means any Invention developed jointly by the parties, other than [\*] Inventions and [\*] Inventions.

11.3 Licenses.

(a) All Client IP and [\*] Inventions shall be owned solely by Client and no right therein is granted to Catalent under this Agreement, except that Catalent shall have a non-exclusive, royalty-free license to such items solely to the extent necessary to perform its obligations under this Agreement. Catalent shall, and does hereby assign, and shall cause its Affiliates to assign to Client all right, title and interest in and to [\*] Inventions. Catalent shall, if so requested by Client and at Client’s sole cost and expense, execute all such documents and do all such other acts and things as may be reasonably required to comply with this Section 11.3(a) to vest in Client all rights in the [\*] Inventions and shall make reasonable efforts to procure execution by the named inventor of all such documents as may reasonably be required by Client in connection with any related patent application.

(b) All Catalent IP and [\*] Inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement, except that Catalent hereby grants to Client the following licenses:

(i) a perpetual, royalty-free, non-exclusive, sublicensable license to use any Catalent IP or [\*] Invention (x) incorporated into a Product or (y) incorporated into or contained in any Client IP (including without limitation, any batch records or analytical methods relating to a Product), in each

case, solely for the purpose of using, making, having made, selling, offering for sale, importing, packaging and/or otherwise exploiting Products; and

(ii) a perpetual, royalty-free, exclusive, sublicensable license to use any [\*] Inventions incorporated into a Product or utilized in the manufacture or packaging of a Product for the purposes of using, making, having made, selling, offering for sale, importing, packaging and/or otherwise exploiting any Product.

11.4 Joint Inventions. The parties shall jointly own the Joint Inventions, each with the right to practice and enforce such rights without any approval or accounting of the other party; provided, however that Catalent shall not use the Joint Inventions to enable any third party to make use or sell any Product.

11.5 Cooperation. The parties shall cooperate to achieve the allocation of rights to Inventions anticipated herein and each party shall be solely responsible for costs associated with the protection of its intellectual property.

## **ARTICLE 12 REPRESENTATIONS AND WARRANTIES**

12.1 Catalent. Catalent represents, warrants and undertakes to Client that (A) at the time of delivery by Catalent as provided in Section 6.1, Product shall have been Processed in a professional workman-like manner in accordance with cGMP, Applicable Laws and the terms and conditions of this Agreement, and in conformance with the Specifications and shall not be adulterated, misbranded, or mislabeled within the meaning of Applicable Laws; provided, that Catalent shall not be liable for defects attributable to Client-supplied Materials (including artwork, advertising and labeling); (B) it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b); (C) that none of Catalent's services hereunder or any part of this Agreement is or will be inconsistent with any obligation Catalent may have to others; (D) all work under this Agreement will be Catalent's original work and, to the best of its knowledge, none of the Processing or any development, use, production, distribution or exploitation thereof will infringe, misappropriate or violate any intellectual property or other right of any person or entity (including, without limitation Catalent or any of its Affiliates); (E) no [\*] shall be employed or utilized in the performance of any Services hereunder, nor incorporated into any Product or other deliverables generated by Catalent under this Agreement (including any Client IP); (F) at the time of execution of this Agreement, no [\*] shall be employed or utilized in the performance of any Services hereunder, nor incorporated into any Product or other deliverables generated by Catalent under this Agreement or under the 2013 MSA and; (G) Catalent does not, and will not during the term of this Agreement, knowingly manufacture, process or house in inventory penicillin or non-penicillin beta lactam products or products that result in beta lactam-containing derivatives, degradation products or other compounds, unless with prior written approval by Client; and (H) Catalent has the full right and authority to provide Client with the assignments, licenses and other rights provided for herein.

12.2 Client. Client represents, warrants and undertakes to Catalent that:

A. all Client-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

B. the content of all artwork provided to Catalent shall comply with all Applicable Laws;

C. all Product delivered to Client by Catalent shall be held, used and disposed of by or on behalf of the Client in accordance with all Applicable Laws, and Client will otherwise comply with all laws, rules, regulations and guidelines applicable to Client's performance under this Agreement;

D. Client will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Client does not hold all necessary Regulatory Approvals to market and sell the Product (except to the extent such consumption occurs in the course of clinical studies that expressly permit such use and that have been conducted in accordance with Applicable Laws);

E. Client has all necessary authority to use and to permit Catalent to use pursuant to this Agreement all intellectual property related to Product or Client-supplied Materials (including artwork), and to its knowledge, the Processing of the foregoing, including any copyrights, trademarks, trade secrets, patents, inventions and developments; there are no patents owned by others related to the Client IP utilized with the Product that would be infringed or misused by Client's performance of the Agreement; and, to its knowledge, no trade secrets or other proprietary rights of others related to the Client IP utilized with the Product that would be infringed or misused by Client's performance of this Agreement; and

F. To its knowledge, the services to be performed by Catalent under this Agreement will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other intellectual property or other right held by any person or entity.

12.3 Mutual Representation. Furthermore, Catalent and Client both represent, warrant and undertake that no transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.

12.4 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS AGREEMENT ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY WITH RESPECT TO THE SUBJECT MATTER HEREOF, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY

IMPLIED WARRANTIES OF MERCHANTABILITY, NON INFRINGEMENT; OR FITNESS FOR A PARTICULAR PURPOSE.

### ARTICLE 13 INDEMNIFICATION

13.1 Indemnification by Catalent. Catalent shall indemnify and hold harmless Client, its Affiliates, and their respective directors, officers and employees (“ **Client Indemnitees** ”) from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys’ fees and reasonable investigative costs) in connection with any suit, demand or action by any third party (“ **Losses** ”) arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement, (B) any actual or alleged infringement or violation of any third party patent, trade secret, copyright, trademark or other proprietary rights by intellectual property or other information arising from the performance of services or Processing of the Product by Catalent hereunder, or (C) any negligence or willful misconduct by Catalent; in each case except to the extent that any of the foregoing arises out of or results from any Client Indemnitee’s negligence, willful misconduct or breach of this Agreement.

13.2 Indemnification by Client. Client shall indemnify and hold harmless Catalent, its Affiliates, and their respective directors, officers and employees (“ **Catalent Indemnitees** ”) from and against any and all Losses arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement, (B) any manufacture, packaging, sale, promotion, distribution or use of or exposure to Product or Client-supplied Materials, including product liability or strict liability, (C) Client’s exercise of control over the Processing, to the extent that Client’s instructions or directions violate Applicable Laws, (D) the conduct of any clinical trials utilizing Product or API, (E) any actual or alleged infringement or violation of any third party patent, trade secret, copyright, trademark or other proprietary rights by intellectual property or other information provided by Client, including Client-supplied Materials, or (F) any negligence or willful misconduct by Client; in each case except to the extent that any of the foregoing arises out of or results from any Catalent Indemnitee’s negligence, willful misconduct or breach of this Agreement. In addition, Client shall indemnify and hold harmless the Catalent Indemnitees from and against any and all Losses arising out of or resulting from any federal regulatory filings by or on behalf of Client or any of its Affiliates, including Losses incurred by Catalent arising from filings under 21 U.S.C. 355 and/or Section 505 of the Food and Drug Act (or non-U.S. equivalents) and related claims or proceedings (including Losses associated with Catalent’s obligation to respond to third party subpoenas).

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified party (A) promptly notifying the indemnifying party of any claim or liability of which the indemnified party becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder

except to the extent the indemnifying party is prejudiced by such failure, (B) allowing the indemnifying party, if the indemnifying party so requests, to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense), (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party.

**ARTICLE 14  
LIMITATIONS OF LIABILITY**

14.1 EXCEPT FOR LOSSES RESULTING FROM CATALENT'S GROSS NEGLIGENCE WILLFUL MISCONDUCT OR FRAUD, IN NO EVENT SHALL CATALENT'S LIABILITY FOR LOSSES TO API OR CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT INCORPORATED INTO PRODUCT, EXCEED [\*].

14.2 EXCEPT FOR LIABILITY ARISING FROM CATALENT'S GROSS NEGLIGENCE WILLFUL MISCONDUCT OR FRAUD INCLUDING CATALENT'S INTENTIONAL FAILURE TO PERFORM, CATALENT'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED [\*]. FOR THE AVOIDANCE OF DOUBT, THE FOREGOING LIMITATION SHALL NOT APPLY TO LOSSES OWING TO CLIENT UNDER SECTION 13.1.

14.3 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (PROVIDED, HOWEVER, FOR PURPOSES OF CLARITY THAT INDEMNIFIABLE LOSSES UNDER ARTICLE 13 SHALL NOT BE CHARACTERIZED AS CONSEQUENTIAL TO CLIENT OR CATALENT SOLELY BY THE BASIS THAT SUCH LOSSES ARISE FROM DAMAGES SUFFERED BY A THIRD PARTY) OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

**ARTICLE 15  
INSURANCE**

Each party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than [\*]; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than [\*] (in the case of Client, prior to the commercialization of the Product); (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than [\*] per accident; and (D) All Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, a Catalent facility as required under this Agreement. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth

is greater than [\*] or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than [\*]. Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A-VII. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least [\*]thereafter. Each party shall obtain a waiver of subrogation clause from its property insurance carriers in favor of the other party. Each party shall be named as an additional insured within the other party's products liability insurance policies; provided, that such additional insured status will apply solely to the extent of the insured party's indemnity obligations under this Agreement. Such waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other party's written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance.

## ARTICLE 16 TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the fifth (5<sup>th</sup>) Contract Year, unless either party earlier terminates this Agreement within thirty (30) days of the end of the third (3) Contract year or fourth (4) Contract Year with 24 months' notice to the other party or this Agreement is earlier terminated in accordance with Section 16.2 (as may be extended in accordance with this Section, the "**Term**"). The Term shall automatically be extended for successive 2-year periods unless and until one party gives the other party at least 24 months' prior written notice of its desire to terminate as of the end of the then-current Term.

16.2 Termination. This Agreement may be terminated immediately without further action:

A. by either party if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within 90 days, or takes any equivalent or similar action in consequence of debt in any jurisdiction; or

B. by either party if the other party materially breaches any of the provisions of this Agreement and such breach is not cured within 60 days after the giving of written notice requiring the breach to be remedied; *provided*, that (i) in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such payment breach is not cured within 30 days of receipt of notice of non payment from Catalent unless disputed by Client in good faith, or (ii) in the case of two or more Supply Failures of Catalent which are not cured within 30 days of receipt of breach notice in accordance with the terms of this Agreement within an 18 month period, Client may terminate this Agreement if the most recent Supply Failure is not cured or (iii) if Client determines that Catalent has failed to meet the warranties in Sections 12.1 (G), Client may terminate this Agreement within 60 days after giving written notice;

C. by Client with 30 days' notice to Catalent in the event of (i) a failure to obtain the Regulatory Approval of the FDA for sale of the Product in the U.S. within 24 months of the Effective Date, or (ii) Client's withdrawal of the Product completely from the U.S. market due to serious adverse health and safety reasons; or

D. by Client in the first Contract Year with 18 months' notice to Catalent for any reason and without cause.

16.3 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either party prior to such expiration or termination. In the event of a termination of this Agreement:

A. Catalent shall promptly return to Client, at Client's expense (except in the case of termination by Client pursuant to Section 16.2(A) or (B) in which case shall be Catalent's expense) and direction, any remaining inventory of Product or Client-supplied Materials; *provided*, that all outstanding undisputed invoices have been paid in full;

B. Client shall pay Catalent all undisputed invoiced amounts outstanding hereunder, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), all Product in the process of being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii)); and

C. In the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), Client shall pay Catalent for all costs and expenses incurred, and all noncancellable commitments made, in connection with Catalent's performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations. In addition, in the event that this Agreement is terminated by Client pursuant to Section 16.2(A) or (B), Catalent shall (i) use commercially reasonable efforts in providing cooperation and assistance to Client in any technology transfer that may be necessary to establish sufficient supply of Product at another manufacturer, (ii) reimburse Client for any credits or advance payments including payment of any Product Maintenance Fee which shall be prorated for the remaining year, and (iii) not be entitled to any unpaid Shortfall Payments hereunder.

16.4 Survival. The rights and obligations of the parties shall continue under Articles 9 (Records; Regulatory Matters), 11 (Intellectual Property), 12 (Representation and Warranties), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 7.3 (Payment Terms), 7.5 (Taxes), 7.6 (Client and Third Party Expenses), 9.5 (Recall), 12.4 (Limitations on Warranties), 16.3 (Effect of Termination) and 16.4 (Survival), in each

case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

**ARTICLE 17**  
**NOTICE**

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered, if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided* , that notices of a change of address shall be effective only upon receipt thereof):

To Client: Adamas Pharmaceuticals, Inc.  
1900 Powell St., Suite 750  
Emeryville, CA 94608  
Attn: Chief Executive Officer  
Facsimile: 510-428-0519

With a copy to: Address and Facsimile same as above  
Attn: General Counsel (Legal Department)

To Catalent: Catalent Pharma Solutions, LLC  
14 Schoolhouse Road  
Somerset, NJ 08873  
Attn: General Manager  
Facsimile: (732) 537-6491

With a copy to: Address and Facsimile same as above  
Attn: General Counsel (Legal Department)

**ARTICLE 18**  
**MISCELLANEOUS**

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement, constitutes the entire understanding between the parties, and supersedes any contracts, agreements or understandings (oral or written) of the parties, with respect to the subject matter hereof, including the Original Agreement. For the avoidance of doubt, this Agreement does not supersede (i) any existing generally applicable confidentiality agreement between the parties as it relates to time periods prior to the date hereof or (ii) business dealings not covered by this Agreement including the Master Services Agreement entered into as of June 13, 2013 between the parties. No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular shall include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (E) the word “or” shall be deemed to include the word “and” (e.g., “and/or”) and (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an Attachment or other appendix, without reference to a document are to the

specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and neither party will incur any debts or make any commitments for the other party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint ventures, co-partners, employer/employee or principal and agent. Neither party shall have any responsibility for the hiring, termination or compensation of the other party's employees or contractors or for any employee benefits of any such employee or contractor.

18.7 Successors and Assigns; Subcontracting. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party's consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning party or the assigning party's business unit responsible for performance under this Agreement; provided, however, that the assigning party shall remain responsible for the Affiliate's performance, acts and omissions under the terms of the Agreements hereof. Catalent may not subcontract its obligation under this Agreement, in whole or in part, without the prior written consent of Client, except that Catalent may, without the Client's consent (but subject to prior written notice), subcontract under this Agreement to an Affiliate; provided, however, that Catalent shall remain responsible for the Affiliate's performance, acts and omissions under the terms of the Agreements hereof.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person or entity other than the parties named herein and their respective successors and permitted assigns.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of New York, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Alternative Dispute Resolution. Any dispute that arises between the parties in connection with this Agreement shall first be presented for consideration and resolution by the JSC and in the event such dispute is not resolved satisfactorily therein to senior executives of the parties, who are designated as the CEO in the case of Client and President, Advanced Delivery Technologies, in the case of Catalent. If such executives cannot reach a resolution of the dispute within a reasonable time, then such dispute shall be resolved by binding alternative dispute resolution in accordance with the then existing commercial arbitration rules of CPR Institute for Dispute Resolution, 366 Madison Avenue, New York, NY 10017. Arbitration shall be conducted in the jurisdiction of the defendant party, in the English language.

18.11 Prevailing Party. In any dispute resolution proceeding between the parties in connection with this Agreement, the prevailing party will be entitled to recover its reasonable attorney's fees and costs in such proceeding from the other party.

18.12 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Right to Dispose and Settle. If Catalent requests in writing from Client direction with respect to the disposal, but not sale, of any inventories of Product, Client-supplied Materials, equipment, samples or other items belonging to Client and is unable to obtain a response from Client within a reasonable time period after making reasonable efforts to do so, Catalent shall be entitled in its sole discretion to (A) dispose of all such items and (B) set-off any and all amounts due to Catalent or any of its Affiliates from Client against any credits Client may hold with Catalent or any of its Affiliates.

18.14 Force Majeure. Neither party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such party's performance hereunder if such default or delay is caused by events beyond such party's reasonable control, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, vendors, public utilities or common carriers; *provided*, that the party seeking relief under this Section shall immediately notify the other party of such cause(s) beyond such party's reasonable control. The party that may invoke this Section shall use commercially reasonable efforts to reinstate its ongoing obligations to the other party as soon as practicable. If the cause(s) shall continue unabated for 180 days, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

*{Signature page follows}*

**IN WITNESS WHEREOF**, the parties have caused their respective duly authorized representatives to execute this Amended and Restated Agreement effective as of the Restatement Effective Date.

**CATALENT PHARMA SOLUTIONS, LLC**

**ADAMAS PHARMACEUTICALS, INC.**

By: /s/ Jonathan Arnold

Name: Jonathan Arnold

Title: Vice President & General Manager  
Drug Delivery Solutions

By: /s/ Rajesh Mahey

Name: Rajesh Mahey

Title: Vice President  
Manufacturing Operations

**LIST OF SCHEDULES, ATTACHMENTS AND EXHIBITS**

Schedule 1.51: Territory

Schedule 4.2: Initial Forecast

Attachment A: Validation, Processing and Related Services

Attachment B: Specifications

- I. Client-supplied Materials (and associated specifications)
- II. Raw Materials (and associated specifications) and Qualified Vendor List
- III. Product Specifications (including Batch size)

Attachment C: Unit Pricing, Fees and Minimum Requirement

Attachment D: Rolling Forecast Example

Exhibit I: Form of Work Order

Exhibit II: Form of Purchase Order

**SCHEDULE 1.51**

**TERRITORY**

[\*]

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

---

**ATTACHMENT A****VALIDATION, PROCESSING & RELATED SERVICES**

The parties acknowledge and agree that the Validation Services are being performed in accordance with that certain Project Work Order No. QTE-9002055 Version 6, dated 17 May 2016 entitled [\*] (“the “**PWO**””) and pursuant to the terms and conditions of the Master Services Agreement between the parties dated June 13, 2013 (the “**MSA**”).

Further, the parties agree that upon successful completion of the manufacture of the validation batches pursuant to Section 4.3 of the PWO, such validation batches shall thereafter be deemed “development batches” under Section 7.7 of this Agreement, subject to the terms and conditions of this Agreement and, for the avoidance of doubt, no longer subject to the terms and conditions of the MSA. Further, upon acceptance of the validation report with respect to such validation batches by each of Client and Catalent, the validation batches shall no longer be deemed “development batches” but shall be deemed Product under this Agreement and available for commercial sale by Client and thereupon shall contribute to the satisfaction of Client’s Minimum Requirement obligation hereunder. For clarity, Client shall not be obligated to pay Unit Pricing or any other amount (other than amounts set forth in the PWO) for such validation batches.

**ATTACHMENT B**  
**SPECIFICATIONS**

**I. Client-Supplied Materials (and associated specifications)**

**II. Raw Materials (and associated specifications and approved vendor lists)**

**III. Product Specifications**

[\*] (8 pages omitted)

**ATTACHMENT C**

**UNIT/BATCH PRICING, FEES, AND MINIMUM REQUIREMENT**

[\*] (6 pages omitted)

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

---

**ATTACHMENT D**

**Rolling Forecast Example**

[\*]

**EXAMPLES - MINIMUM REQUIREMENTS, SHORTFALLS AND CATALENT COMMITMENTS**

Examples for illustrative purposes only

[\*]

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

---

**EXHIBIT I**

**FORM OF WORK ORDER**

The form of the work order shall be provided by Catalent and approved by Client, which approval shall not be unreasonably withheld.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

---

**EXHIBIT II**

**FORM OF PURCHASE ORDER**

The form of the purchase order shall be provided by Client and approved by Catalent, which approval shall not be unreasonably withheld.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**CONFIDENTIAL**

**AMENDED AND RESTATED API SUPPLY AGREEMENT**

This Amended and Restated API Supply Agreement (this “Agreement”) is effective as of July 07, 2009 (the “Effective Date”) and amended and restated as of Oct 2, 2017 (“Restatement Date”) by and between Adamas Pharma, LLC, with an address of 1900 Powell St., Suite 750, Emeryville, CA 94608 USA (“Company”), and Moehs Ibérica, S.L., a Spanish corporation, having its principal place of business at Poligono Industrial Rubi Sud - C/ Cesar, Martinell i Brunet 12A, 08191 Rubi, Barcelona, Spain (“Manufacturer”). Company and Manufacturer may be referred to individually as a “Party” or collectively as “Parties.”

**RECITALS**

WHEREAS, Company is engaged in the research and development and manufacturing of pharmaceutical products;

WHEREAS, Manufacturer is engaged in the manufacture and supply of active pharmaceutical ingredients for clinical trials and commercial use;

WHEREAS, Company desires, in accordance with the terms of this Agreement, to purchase, on its own or through its designee, from the Manufacturer the API (as defined below) for the purpose of manufacturing finished dosage formulation for clinical trials and/or commercial use;

WHEREAS, Manufacturer is willing to provide to Company the API, on the terms and conditions set forth herein;

WHEREAS, Moehs Ibérica, S.L. and Adamas Pharmaceuticals, Inc. (“Adamas”) entered into that certain API Supply Agreement effective as of July 7, 2009 (the “Original Agreement”);

WHEREAS, Company is a wholly owned subsidiary of Adamas and Company agreed to be bound by all of the terms and conditions of the Original Agreement;

WHEREAS, Manufacturer is the successor to Moehs Ibérica, S.L. as a result of change on legal form from public limited company Moehs Iberica, S.A. to private limited company Moehs Iberica, S.L. and Manufacturer agreed to be bound by all the terms and conditions of the Original Agreement; and.

WHEREAS, the Parties now desire to amend and replace the Original Agreement in its entirety with this Agreement.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties agree as follows.

**Section 1. DEFINITIONS**

---

As used herein, the following terms, when used with initial capital letters, shall have the following meanings:

- 1.1 “Active Pharmaceutical Ingredient” or “API” shall mean the substance listed in Exhibit 1.1, manufactured in accordance with all API Requirements, and suitable for use in human clinical trials and for commercial use.
- 1.2 “Affiliate” shall mean any person or entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with a Party, but for only so long as such control exists. “Control” shall mean direct or indirect beneficial ownership of at least fifty percent (50%) of such Party, or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction.
- 1.3 “API Requirements” shall mean the Specifications, instructions of Company, master batch record, current, agreed standard operating procedures, Applicable Law, and any relevant warranties provided by Manufacturer hereunder, including all warranties set forth in Section 8.2.
- 1.4 “Applicable Laws” means: (i) all relevant U.S. and foreign federal, state and local laws, statutes, rules, regulations, and ordinances and industry standards and guidelines as in effect on the Effective Date or adopted thereafter and which are applicable to a Party's activities hereunder, including, the U.S. Federal Food, Drug and Cosmetic Act (“FDCA”); (ii) GMPs; and (iii) all applicable regulations and guidelines of any Regulatory Authority; in each case, together, with any and all amendments thereto.
- 1.5 “FDA” means the United States Food and Drug Administration or any successor thereto.
- 1.6 “GMPs” shall mean current good manufacturing practices, as provided for (and as amended from time to time) in the Current Good Manufacturing Practice regulations promulgated by the FDA under the United States Food, Drug and Cosmetic Act, 21 C.F.R. Part 210 *et seq.*, and in the European Community directive 2003/94/EC (Principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use), as well as applicable documents developed by the International Conference on Harmonization (ICH), and similar requirements of other Regulatory Authorities, and subject to any arrangements, additions or clarifications, and the respective roles and responsibilities, agreed from time to time between the Parties.
- 1.7 “Regulatory Authority” means the FDA or a regulatory body with similar regulatory authority in a jurisdiction outside the United States, including without limitation the European Medicines Agency.
- 1.8 “Specifications” means the procedures, process parameters, analytical tests, control procedures, acceptance criteria, validation protocols, storage and release requirements and other similar requirements and specifications for the manufacture of API, as the same are set forth and attached hereto as Exhibit 1.7 (as may be updated and supplemented from time to time in accordance with Section 3.4 below).

**Section 2. MANUFACTURE AND SALE**

2.1 Supply of API. Manufacturer shall manufacture, and provide to Company and its designees, API on a non-exclusive basis, as set forth in this Agreement. All API to be supplied under this Agreement shall be manufactured by Manufacturer at the facility [\*] (the “Manufacturing Facility”), in conformance with the API Requirements, the Quality Agreement and the terms of this Agreement.

2.2 Forecasts. By the first quarter following the first NDA submission for a product comprising the API, and for each calendar quarter thereafter during the Term, not less than[\*] days prior to the beginning of each such calendar quarter, the Company shall provide Manufacturer with a good-faith written forecast of the quantities of API estimated to be required by Company and its designees from Manufacturer during the [\*] following the date on which such forecast is provided and the following [\*] (the “Rolling Forecast”). The forecasted quantities for the [\*] of each Rolling Forecast shall be binding and the forecasted quantities for all subsequent [\*] covered by each Rolling Forecast shall be non-binding; provided that Manufacturer shall notify Company promptly following receipt of the applicable Rolling Forecast in the event Manufacturer anticipates that it will be unable to meet Company’s forecasted quantities of API during any month of such Rolling Forecast. For each Rolling Forecast submitted prior to the first date upon which a Regulatory Authority approves Company’s product incorporating the API and Manufacturer as a manufacturer of API for such product (“Commencement Date”), Company shall indicate the anticipated date for the Commencement Date. In the event of a delay in the anticipated Commencement Date, the parties agree that the binding portion of the Rolling Forecast shall be adjusted such that Company shall not be required to purchase API prior to the Commencement Date.

2.3 Orders. Together with each Rolling Forecast, Company shall provide to Manufacturer a purchase order covering the API requirements set forth in the [\*] of such Rolling Forecast. For the avoidance of doubt, Company may order additional quantities of API for delivery hereunder in accordance with the lead times therefor and subject to Manufacturer’s total capacity constraints. Manufacturer shall accept all purchase orders that Company issues in accordance with this Article 2, including portions of purchase orders up to [\*] more than the quantity forecasted in the most recent Rolling Forecast. Each purchase order shall specify the delivery date(s), delivery location(s) and amount of API to be delivered in accordance with reasonable delivery schedules and lead times as may be agreed upon from time to time by the Parties, provided that the maximum lead time shall not exceed [\*] unless otherwise mutually agreed. No terms or conditions contained in any purchase order, order acknowledgement or similar standardized form given or received pursuant to this Agreement shall be construed to amend or modify the terms of this Agreement and, in the event of any conflict, the terms and conditions of this Agreement shall control, unless the Parties otherwise expressly agree in writing.

2.4 Packaging and Delivery. All API to be delivered hereunder shall be packaged in containers in accordance with the applicable Specifications or as otherwise mutually agreed by the Parties in writing. Each container will be individually labeled with a description of its contents, including the lot number, quantity of API, date of manufacture and any other information as may be required in order to trace the history of such lot. All API shall be delivered [\*]. [\*], title of the goods shall transfer to Adamas. [\*] will arrange to deliver API ordered by Company to the appropriate

delivery location to the address set forth in a purchase order within [\*] of the delivery dates specified in each purchase order unless the material is detained by the FDA or Customs. [\*] associated with [\*] as indicated on the purchase order. Adamas will [\*]; such [\*] within [\*]. [\*] shall ship the API along with all relevant documentation relating to the API in accordance with this Agreement or as otherwise reasonably directed by Company in writing using Company's designated carrier. [\*] shall ship all API to Company or its designees, as directed by the Company, in accordance with all Applicable Laws. Company shall only be obligated to pay for quantities of API actually delivered in compliance with the applicable purchase order and the terms of the Agreement.

2.5 Waste. Manufacturer shall generate, handle, store, ship and dispose of all wastes associated with its manufacture of API in accordance with Applicable Laws.

2.6 Shortage of Supply. If Manufacturer is unable, or anticipates that it will not be able, to deliver API in the quantities and within the time periods specified in any purchase order accepted in accordance with this Agreement (a " Shortage of Supply "), Manufacturer shall notify Company, in writing within [\*] of receiving a purchase order, of the same with its best estimate of the duration of the delay. Manufacturer shall, at its own cost, use its best efforts to remedy any Shortage of Supply and resume supplying API meeting the requirements of this Agreement to Company and its designees as soon as possible and, upon Company's request, Manufacturer shall fully cooperate with Company to secure adequate supplies of API from alternative sources. In the event of a Shortage of Supply, in addition to any other remedies the Company may have at law or in equity, (a) the Company shall be relieved from its obligations to purchase any quantities of API identified in any purchase order and may cancel such quantities effective upon notice to Manufacturer and (b) Manufacturer shall use its best efforts to prioritize supply of API to Company and shall allocate its available capacity to provide Company with API at least in proportion of API forecasted by Company and API forecasted by Third Parties.

2.7 Supply of Samples. Upon Company's request, and at no cost to Company, Manufacturer will provide Company or its designees with samples of API, reasonable quantities of any non-compendial or not commercially available reference standards and impurities necessary to perform the tests included in the Specification, with certificates of analysis for testing purposes.

2.8 Long-Term Capacity Planning. Not less than once per year, Manufacturer and Company shall discuss Company's forecasted needs for API and Manufacturer's capability to meet those needs. Additionally, in the event Manufacturer notifies Company that it will be unable to meet Company's forecasted quantities for API as set forth in any Rolling Forecast, or upon Company's reasonable request, the Parties shall discuss in good faith those activities available to the Parties that will enable Manufacturer to meet Company's long-term requirements for API. The Parties understand and agree that such activities may include, among other items, the qualification of manufacturing sites operated by Affiliates of Manufacturer.

### **Section 3. REJECTED GOODS; CHANGES AND DEVIATIONS.**

3.1 Quality and Release. All API supplied by Manufacturer shall meet the current Specifications therefor and shall be manufactured in accordance with all applicable GMPs for the API at the Manufacturing Facility. Prior to each shipment of API, Manufacturer shall perform

quality control procedures and inspections to verify that the API to be shipped conform fully with the API Requirements. Each shipment of API shall be accompanied by a certificate of analysis describing all current requirements of the Specifications and results of tests performed certifying that the quantities of API supplied have been manufactured, controlled and released according to the Specifications and all applicable GMPs at the Manufacturing Facility.

3.2 Quality Agreement. No later than ninety (90) days after the Effective Date, the Parties shall enter into technical agreement specifying the Parties' respective responsibilities for storage, release, quality control and quality assurance with respect to the API (the "Quality Agreement"). The Quality Agreement is not intended and shall not be construed to limit any of the rights and obligations of the Parties set forth in this Agreement. Subject to the foregoing, to the extent possible, the Quality Agreement will be interpreted with the terms set forth in the body of this Agreement. If there is any conflict or inconsistency between the terms of the Quality Agreement and the terms set forth in this Agreement, however, the terms set forth in this Agreement shall control in all non-quality related matters. The Quality Agreement will take precedence in all quality related matters.

3.3 Acceptance Procedure.

(a) Rejection. Acceptance by Company or its designee of API delivered by Manufacturer hereunder shall be subject to inspection and applicable testing by Company or its designee. If as a result of such inspection Company or its designee discovers that any API delivered by Manufacturer under this Agreement fails to conform with the API Requirements, Company or such designee may reject such API by providing Manufacturer written notice thereof within [\*] after Company's or its designee's receipt of such API. Manufacturer shall either, at Company's option, replace all properly rejected API within [\*] after its receipt of notice of such rejection at no additional cost to Company or its designee (including transportation costs) or refund any amounts Company paid for such properly rejected API. Manufacturer shall make arrangements with Company or its designee, as applicable, for the return or disposal of any API rejected hereunder, and such return, shipping and disposal charges shall be paid by Manufacturer. The warranties given by Manufacturer in Section 8.2 below shall survive any failure to reject by Company under this Section 3.3.

(b) Disputes. Manufacturer shall respond in writing to any rejection notice provided by Company or its designee pursuant to Section 3.3(a) within [\*] from Manufacturer's receipt of such rejection notice. If Manufacturer does not agree with Company's or its designee's determination that such API fails to conform to the API Requirements, then the Manufacturer and Company, or Company's designee, shall use reasonable efforts to resolve such disagreement as promptly as possible. Without limiting the foregoing, Manufacturer and Company, or Company's designee, shall discuss in good faith mutually acceptable testing procedures pursuant to which both the Manufacturer and Company, or Company's designee, will re-test a sample of the disputed API to determine whether such API complies with the API Requirements. Notwithstanding the foregoing, in the event Manufacturer and Company, or Company's designee, are unable to resolve such disagreement within [\*] of the date of the applicable rejection notice, either Party (or, in the case of Company, its designee) may submit a sample of such API to an independent laboratory to review records, test data and perform comparative tests and/or analyses promptly on samples of

such API. Such independent laboratory shall be mutually agreed upon by the Parties, provided that if the Parties are unable to agree, then Company shall designate the independent testing laboratory. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the non-prevailing Party.

3.4 Changes to Specifications. Manufacturer shall not make any major changes to the Specifications, processes, Manufacturing Facility or any other item in any manner that would impact the manufacturing activities related to API, without Company's prior written approval (which approval shall not be unreasonably withheld), except that Manufacturer shall promptly make and implement such changes as are required by Applicable Law ("Required Changes"). Prior to implementation, all Required Changes shall be subject to Company's written approval, including the timelines, estimated effect on pricing and other issues regarding such implementation. For clarity, for the purposes of this Section 3.4 a "major" change shall include, without limitation, any change that would require the approval by an applicable Regulatory Authority in connection with Company's finished product containing the API or may affect a regulatory filing made by or under the authority of Company with respect to a finished product containing the API. Without limiting the foregoing, Manufacturer shall provide advance notice to Company of any changes to the Specifications, processes, Manufacturing Facility or any other item in any manner that would impact the manufacturing activities related to API sufficiently in advance of the proposed implementation thereof to allow Company to properly evaluate the impact of such change on any of Company's products containing the API and to implement appropriate changes to Company's (or its designee's) regulatory filings pertaining to such products.

3.5 Deviations. Without limiting Section 3.4 above, in the event any material deviations occur during the course of the manufacture of any batch of API for Company under this Agreement, Manufacturer shall immediately provide Company with a detailed written description of such deviation. In addition, Manufacturer shall undertake all reasonable and appropriate actions to investigate the cause of such deviation and, to the extent applicable to the manufacture of any batch of API for Company under this Agreement, to correct the same as set forth in the Quality Agreement.

#### **Section 4. RECORDS; INSPECTIONS**

4.1 Record Keeping. Manufacturer shall generate and maintain complete and accurate records and samples as necessary to evidence compliance with this Agreement and all Applicable Laws and other requirements of applicable governmental authorities relating to the manufacture of API, including validation data, stability testing data, certificates of analysis, batch and lot records, quality control and laboratory testing, and any other data required by Applicable Laws. All such records and samples shall be maintained for such periods as may be required by Applicable Law. Upon request by Company or its designee, and through the corresponding audit, Manufacturer shall provide Company or such designee reasonable access to, and copies and portions of, such records and samples, including all batch and lot records, and any supporting data relating thereto.

4.2 Inspection. During the Term, and in the absence of critical quality incidents or other non-compliance with the terms of this Agreement no more than [\*], or as otherwise required by Applicable Law, Company or its designee shall have the right, upon reasonable advance notice and

during regular business hours, to inspect and audit: (a) the Manufacturing Facility or other facility at which any of the manufacturing or processing activities relating to the API are performed; (b) any of Manufacturer's manufacturing and quality control records and all other documentation relating to the manufacturing and processing activities with respect to the API; and (c) accounts and records for the purpose of determining the amounts payable or owed under this Agreement. Such right to inspect and audit shall extend to Manufacturer's Affiliates and any subcontractors of Manufacturer and shall include reasonable access to any of Manufacturer's/their personnel. Such inspections and audits shall be for the purpose of ascertaining compliance with Applicable Laws, the Specifications and environmental, health and safety regulations and other aspects of this Agreement, and evaluating the implementation of all manufacturing and process changes pursuant to this Agreement. Any information obtained by Company through such inspections and audits shall be treated as Confidential Information of Manufacturer in accordance with Article 10 below.

## **Section 5. REGULATORY MATTERS**

5.1 Permits. Manufacturer shall be responsible for obtaining and maintaining at its expense any facility or other licenses or permits, and any regulatory approvals necessary for the manufacture and supply of API in accordance with the terms and conditions of this Agreement.

5.2 Regulatory Actions. Manufacturer shall permit the FDA and other Regulatory Authorities to conduct inspections of the Manufacturing Facility and/or any other facility at which any of the manufacturing or processing activities relating to the API are performed as such Regulatory Authorities may request, including pre-approval inspections, and shall cooperate with such Regulatory Authorities with respect to the inspections and any related matters, in each case that is related to the API or its manufacture. Manufacturer shall inform Company upon Customer request, to the extent practicable, of any such inspections, and keep Company informed about the results and conclusions of each regulatory inspection. However, Customer shall be immediately notified in the event of adverse regulatory findings that may impact the supply of the API. Upon Customer request, Manufacturer will provide Company with copies of any written inspection reports, or any other request, directive or other communication issued by any Regulatory Authority and all correspondence between Manufacturer and any Regulatory Authority with respect thereto (including, but not limited to, FDA Form 483s, Notices of Observation, warning letters, citation or other similar notifications), in each case relating to the API, its manufacture or general manufacturing concerns (e.g., facility compliance or the like); provided that copies of such inspection reports and/or correspondence provided to Company may be redacted by Manufacturer to remove any confidential information of Manufacturer or a Third Party that is not related to the API or its manufacture.

5.3 Regulatory Cooperation. Manufacturer agrees to promptly provide to Company or directly to the Regulatory Authority in a Drug Master File to which Company and its designee is granted a right to reference (depending if the information is confidential according to Manufacturer's standard policy applied consistently across its entire business), as requested, at no additional charge to Company, with all information and data in Manufacturer's possession or control necessary or useful for Company and/or its designees to apply for, obtain and maintain regulatory approvals for any finished product incorporating API in any country, including information relating to the Manufacturing Facility, or the process, methodology, raw materials and intermediates used in the

manufacture, processing or packaging of API and all information required to be submitted in the CMC (chemistry, manufacturing and controls, or equivalent) section of an IND or an NDA (each, as described in 21 CFR §§ 312 and 314) (or any similar regulatory filings in any jurisdiction outside the United States), or required or requested to be provided to the FDA or any other Regulatory Authority. In addition, Manufacturer agrees to cooperate with Company or its designees with respect to obligations to submit or report information relevant to API pursuant to FDA regulations and other Applicable Laws. In case of Registrations in a Territory, Company and Manufacturer will mutually agree on the procedure and payment of the fees incurred by the DMF holder. Company should send information to Manufacturer regarding regulatory submissions in new countries with enough time in advance to ensure evaluation at Manufacturer.

5.4 Company Access to Manufacturing Data and Documentation. Manufacturer shall provide, or cooperate with Company to provide, each Regulatory Authority with written notice of authorization granting, and Manufacturer hereby grants, Company the right to reference any data and documentation to support any IND, NDA or other filing with the FDA or any other Regulatory Authority (including any Drug Master File for API). Manufacturer shall be responsible for maintaining all Drug Master Files for API in accordance with Applicable Laws and ensuring that all data and information incorporated therein is accurate and current as necessary to support obtaining and maintaining the applicable regulatory filing(s) and regulatory approval(s) by Company and/or its designees.

5.5 Recall. Immediately after Manufacturer has become aware of it, Manufacturer will inform Company of any issue that may result in a recall of supplied API or finished drug product made incorporating such API. Manufacturer and Company shall consult and decide on roles and responsibilities regarding co-ordination of the investigation and decisions. Notwithstanding the forgoing, (a) Company shall have the sole right with respect to the final decision making and the coordination of any recalls or field alert activities related to Company's finished drug product incorporating API and (b) if a recall of Company's finished product incorporating API arises out of or results from: (i) the gross negligence or willful misconduct of Manufacturer; or (ii) a material breach by Manufacturer of this Agreement (including a breach of any of the representations or warranties in Article 8), Manufacturer shall bear the cost and expense of such recall to the extent caused by the Manufacturer. Manufacturer shall provide assistance to Company, as reasonably requested, in conducting such recall, including providing all pertinent records that may assist Company in effecting such recall.

## **Section 6. COMPENSATION**

6.1 Generally. The price for API supplied by Manufacturer in accordance with this Agreement is contained in Exhibit 6.1. All costs, fees and expenses, including administrative overhead, are included in the API pricing set forth in Exhibit 6.1.

6.2 Invoicing and Payment. All invoices issued under, and all amounts stated in, this Agreement shall be in U.S. Dollars. All payments under this Agreement shall be made in United States Dollars. US Agent shall invoice Company for the price of API upon the shipment of such

API to Company or its designees. Payment of all properly submitted invoices shall be made by Company or its designee within [\*] after the invoice date; provided that Company or its designee has not rejected the API during such [\*] period. Except as otherwise expressly set forth in this Agreement, Company shall not be obligated to pay any amounts other than the price for API supplied by Manufacturer to Company or its designee in accordance with this Agreement.

6.3 Taxes. All income taxes, VAT, levies, surcharges or other similar charges and any penalties levied thereon which relate to any amounts paid to Manufacturer hereunder shall be the responsibility of, and paid by, the Manufacturer.

## Section 7. INTELLECTUAL PROPERTY

7.1 Ownership of Inventions. As between the Parties all right, title and interest to inventions and other intellectual property (together with all intellectual property rights therein) conceived or created or first reduced to practice in connection with the exercise of rights or performance of obligations under this Agreement (“Inventions”) (i) [\*], shall be owned by Company, (ii) [\*], shall be owned by Manufacturer and (iii) [\*] shall be jointly owned by Company and Manufacturer. Except as expressly provided otherwise in this Agreement, neither Party shall have any obligation to obtain any approval of the other Party for, nor pay the other Party any share of the proceeds from or otherwise account to the other Party for, the practice, enforcement, licensing, assignment or other exploitation of such jointly owned inventions or intellectual property or intellectual property rights therein, and each Party hereby waives any right it may have under the laws of any country to require such approval, sharing or accounting. Filing, prosecution, maintenance and enforcement of any patent with respect to such jointly-owned Inventions and intellectual property shall be by mutual agreement of the Parties. Notwithstanding anything to the contrary in this Agreement, neither Party is obligated to assign any title or interest in its inventions and other intellectual property (together with all intellectual property rights therein) conceived or created or first reduced to practice before the Effective Date.

7.2 No Other Rights. Except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party.

## Section 8. REPRESENTATIONS AND WARRANTIES

8.1 General. Each Party represents and warrants that: (a) it has full power to enter into this Agreement and to grant to the other Party the rights granted to such other Party under this Agreement and (b) it has obtained all necessary corporate approvals to enter into and execute the Agreement.

8.2 API Warranties. Manufacturer represents and warrants that:

(a) Applicable Laws. The Manufacturing Facility and all API supplied hereunder shall comply with all Applicable Laws and all API Requirements, and Manufacturer shall perform and document all manufacturing and supply activities contemplated herein in compliance with all Applicable Laws. Without limiting the foregoing, at the time of delivery to Company, none

of the API shall be adulterated or misbranded within the meaning of the FDCA, as amended and in effect at the time of shipment.

(b) Shelf Life. All API supplied by Manufacturer under this Agreement shall have a shelf life of at least [\*] after the time of delivery to Company or its designee, i.e. all such API shall comply with the Specifications from at the time of delivery to Company and shall continue to comply with the Specifications throughout such [\*] period.

(c) No Encumbrance. Title to all API provided to Company under this Agreement shall pass as provided in this Agreement, free and clear of any security interest, lien, or other encumbrance.

(d) Intellectual Property. The manufacture and supply of API hereunder shall not infringe or misappropriate any intellectual property right of any third party.

8.3 Personnel. Manufacturer represents and warrants to Company that neither Manufacturer nor any of its employees, agents or contractors have been “debarred” by the FDA or excluded from any federal healthcare program or procurement and non-procurement programs, or subject to a similar sanction from another Regulatory Authority or other governmental authority, nor have debarment or exclusion proceedings against Manufacturer or any of its employees been commenced. Manufacturer will promptly notify Company in writing if any such proceedings have commenced or if Manufacturer or any of its employees, agents or contractors are debarred or excluded by the FDA or any other Regulatory Authority or other governmental authority.

8.4 Disclaimer. EXCEPT AS PROVIDED IN THIS ARTICLE 8, NEITHER PARTY MAKES ANY WARRANTIES OR WARRANTIES (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER HEREOF AND EACH PARTY EXPRESSLY DISCLAIMS ANY SUCH ADDITIONAL WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

## **Section 9. TERM AND TERMINATION**

9.1 Term. This Agreement shall commence on the Effective Date and, unless terminated earlier pursuant Section 9.2 or 9.3 or Article 12 below, shall continue in full force and effect until the fourteenth (14<sup>th</sup>) anniversary of the Effective Date (the “Initial Term”). Following the Initial Term, this Agreement may be extended for additional twenty-four (24) month periods (each, a “Renewal Term” and all such Renewal Terms together with the Initial Term, the “Term”) by written agreement by manufacturer and company one (1) year prior to the expiration of the then-current Term.

9.2 Termination for Breach. Either Party may terminate this Agreement upon written notice to the other Party in the event that the other Party shall have materially breached this Agreement, and such breach is not cured within thirty (30) days after receiving written notice specifying such breach and referencing this Section 9.2.

9.3 Permissive Termination By Company. Company may terminate this Agreement upon one hundred eighty (180) days' prior written notice to Manufacturer. Manufacturer may terminate this Agreement upon three (3) years' prior written notice to Company.

9.4 Effect of Expiration or Termination.

(a) Rights and Obligations. Termination or expiration of this Agreement shall not relieve a Party from any liability that, at the time of such termination or expiration, has already accrued to the other Party. Upon expiration or termination of this Agreement and at the written request of a Party, the other Party shall promptly return to the requesting Party all of the requesting Party's Confidential Information (whether in written, electronic or other tangible form, including all embodiments and copies thereof) which are in the other Party's possession or control; except that, following any termination or the expiration of this Agreement, notwithstanding the foregoing or any request by Manufacturer under this Section 9.4(a), Company may retain and shall continue to have the right to use and disclose (and to authorize the use and disclosure of) any records, correspondence, validation documentation, reports, analyses and other data and documentation of Manufacturer for the purposes of satisfying any regulatory requirements with respect to any product containing API provided by Manufacturer under this Agreement; provided further that one copy of the requesting Party's Confidential Information may be retained by the other Party solely for purposes of ensuring compliance with the terms of this Agreement.

(b) Transition Services. In the event of any termination, Manufacturer shall assist Company without additional charges to transition all relevant services to Company or its designee.

(c) API in Progress. Within thirty (30) days after the effective date of the expiration or termination of this Agreement or at such earlier time as Company requests, Manufacturer shall notify Company of any quantity of API remaining in Manufacturer's inventory, including any API in the process of manufacture, as of the date on which Manufacturer received or gave notice of termination, and Company shall have the option, upon notice to Manufacturer, to purchase any such quantities of API at the price that would have been payable for such API pursuant to Section 6.1 immediately prior to the expiration or termination of this Agreement.

(d) Survival. The provisions of Sections 3.3 and 9.4 and Articles 4, 5, 7, 8, 10, 11, 13 and 14 of this Agreement shall survive the termination of this Agreement for any reason.

## Section 10. CONFIDENTIALITY

10.1 Confidential Information. "Confidential Information" means all data, specifications, training and any other know-how related to the design, development, manufacture (including equipment and processes), marketing, distribution or performance of the API, as well as all other information and data provided by either Party to the other Party pursuant to this Agreement; provided that, unless the confidentiality of any information, data or material is expressly provided in this Agreement, if any such information, data or material are in tangible form, they are marked "Confidential" or "Proprietary," or if disclosed orally, they are identified as confidential or proprietary when disclosed and are confirmed in writing as confidential or proprietary within thirty (30) days following such disclosure. Confidential Information of Company shall include any

information provided to Manufacturer by any designee of the Company. Notwithstanding the foregoing, each Party's non-use and non-disclosure obligations under this Article 10 shall not apply to any information that the receiving Party can prove: (a) is or becomes generally available to the public other than as a result of a breach of this Agreement by the receiving Party; (b) is known to the receiving Party prior to receipt from the disclosing Party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing Party; (c) becomes known to the receiving Party (independently of disclosure by the disclosing Party) directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing Party; or (d) is independently developed by the receiving Party.

10.2 Non-Disclosure and Non-Use. It is contemplated that a Party may from time to time disclose its Confidential Information to the other Party. Each Party shall not disclose to third parties any Confidential Information of the disclosing Party and shall not use any Confidential Information of the disclosing Party, except for the limited purposes of performing the receiving Party's obligations or exercising the receiving Party's rights as set forth in this Agreement, including, in the case of Company, manufacturing or having manufactured finished products incorporating such API. The receiving Party shall take all reasonable steps to prevent any unauthorized use or disclosure of the Confidential Information of the disclosing Party. The receiving Party may disclose Confidential Information to employees and third parties who have a need to have access to such Confidential Information in connection with such Party's performance of its obligations, and/or exercise of its rights, under this Agreement; provided that such employees and third parties are bound by confidentiality and non-disclosure obligations at least as protective of the disclosing Party and its Confidential Information as this Article 10. The provisions of this Section 10.2 shall survive termination or expiration of this Agreement and shall continue for [\*] after the date of such expiration or termination.

10.3 Disclosures Required By Law. The terms of this Article 10 shall not be construed to limit either Party's right to disclose the other Party's Confidential Information if: (a) required in response to a valid order of a court of competent jurisdiction or other governmental authority of competent jurisdiction; provided that the receiving Party shall first have given notice to the disclosing Party and provided the disclosing Party a reasonable opportunity to seek the confidential treatment of such Confidential Information (through protective order, injunctive relief or otherwise) and shall reasonably cooperate with the disclosing Party in seeking such treatment; provided further that the Confidential Information disclosed in response to such court or governmental order shall be limited to that Confidential Information which is legally required to be disclosed; or (b) otherwise required by Applicable Law to be disclosed.

10.4 Confidential Terms. Each Party agrees not to disclose to any third party any of the terms of this Agreement without the prior written consent of the other Party, except that each Party may do so (a) to its legal and financial advisors, potential or actual investors, acquisition partners and others on a need-to-know basis, under reasonable obligations of confidentiality or (b) as required by law, including, without limitation, SEC reporting requirements, or by the rules or regulations of any stock exchange that a Party is subject to.

## **Section 11. INDEMNIFICATION AND INSURANCE**

11.1 Company. Company shall indemnify, defend, and hold harmless Manufacturer and US Agent, its directors, officers, employees, agents, successors and assigns from and against any liabilities, expenses, or costs (including reasonable attorneys' fees and court costs) arising out of any claim, complaint, suit, proceeding, or cause of action brought against any of them by a third party resulting from: (a) the negligent or intentionally wrongful acts or omissions of Company; or (b) breach by Company of covenants, obligations, representations or warranties made or undertaken by Company under this Agreement, in each case subject to the requirements set forth in Section 11.3 below. Notwithstanding the foregoing, Company shall have no obligations under this Section 11.1 for any liabilities, expenses, or costs arising out of or relating to claims covered under Sections 11.2 and 11.3 below.

11.2 Manufacturer. Manufacturer shall indemnify, defend, and hold harmless Company and US Agent, its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses, and costs (including reasonable attorneys' fees and court costs) arising out of any claim, complaint, suit, proceeding, or cause of action brought against any of them by a third party resulting from: (a) the negligent or intentionally wrongful acts or omissions of Manufacturer; or (b) breach by Manufacturer of any covenants, obligations, representations or warranties made or undertaken by Manufacturer under this Agreement, in each case subject to the requirements set forth in Section 11.4. Notwithstanding the foregoing, Manufacturer shall have no obligations under this Section 11.2 for any liabilities, expenses, or costs arising out of or relating to claims covered under Sections 11.1 above and 11.3 below.

11.3 US Agent. US Agent shall indemnify, defend, and hold harmless Company and Manufacturer, its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses, and costs (including reasonable attorneys' fees and court costs) arising out of any claim, complaint, suit, proceeding, or cause of action brought against any of them by a third party resulting from: (a) the negligent or intentionally wrongful acts or omissions of US Agent; or (b) breach by US Agent of any covenants, obligations, representations or warranties made or undertaken by US Agent under this Agreement, in each case subject to the requirements set forth in Section 11.4. Notwithstanding the foregoing, US Agent shall have no obligations under this Section 11.3 for any liabilities, expenses, or costs arising out of or relating to claims covered under Sections 11.1 and 11.2 above.

11.4 Indemnification Procedure. A Party that intends to claim indemnification (“Indemnitee”) under this Article 11 shall promptly notify the indemnifying Party (“Indemnitor”) in writing of any third party claim, suit, or proceeding included within the indemnification described in this Article 11 (each a “Claim”) with respect to which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and settlement of the Claim. The Indemnitee shall have the right to participate, at its own expense, with counsel of its own choosing in the defense or settlement of the Claim. The indemnification obligations under this Article 11 shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the consent of the Indemnitor. The Indemnitee and its employees, at the Indemnitor's request and expense, shall provide full information and reasonable assistance to Indemnitor and its legal representatives with respect to Claims.

11.5 Insurance. During the Term of this Agreement, each Party shall maintain, with financially sound and reputable insurers, insurance reasonably sufficient to cover each Party's activities and obligations under this Agreement. Without limiting the foregoing, Manufacturer shall maintain: (a) general liability insurance with combined single limits of not less than [\*]; and (b) product liability insurance with combined single limits of not less than [\*]. At the reasonable request of a Party, the other Party shall provide to such Party copies of certificates of insurance evidencing coverage in accordance with this Section 11.4.

## Section 12. FORCE MAJEURE

If either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reason of strike, lockouts, labor troubles, restrictive governmental or judicial orders or decrees, riots, insurrection, war, terrorist acts, acts of God, inclement weather or other reason or cause reasonably beyond such Party's control (each a "Force Majeure Event"), then performance of such act shall be excused for the period of such Force Majeure Event. The Party affected by the Force Majeure Event shall provide notice to the other of the commencement and termination of the Force Majeure Event. Should a Force Majeure Event continue for more than two (2) months, then the Party unaffected by the Force Majeure Event may terminate this Agreement upon prior written notice to the affected Party. If the Force Majeure Event equally affects the ability of each Party to perform under this Agreement, then such termination shall only be by mutual written agreement.

## Section 13. NOTICES

All notices or other communications that are required or permitted by this Agreement shall be in writing and shall be delivered personally, sent by fax (and promptly confirmed by express courier), sent by nationally recognized express courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows (or to such other address or facsimile number for a Party as may be specified by like notice):

If to Company: Adamas Pharma, LLC  
1900 Powell St., Suite 750  
Emeryville, CA 94608  
Attn: Vice President, Manufacturing Operations

Fax No.: (510) 428-0519

With a copy to: Address and Facsimile same as above  
Attn: General Counsel (Legal Department)

If to Manufacturer: Moehs Iberica S.L.  
Poligono Industrial Rubi Sud,  
c/Cesar Martinell i Brunet 12A,

08191 Rubi, Barcelona (Spain)  
Attn: Mr Javier del Rio  
Telephone No.:(+34) 935860520  
Fax No.: (+34) 93 588 8513

All notices delivered pursuant to this Section shall be considered delivered upon receipt by the intended recipient or within ten (10) days of dispatch, whichever is earlier.

#### **Section 14. MISCELLANEOUS**

14.1 Further Actions. The Parties shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and to do and cause to be done such further acts that may be necessary to carry out the provisions and purposes of this Agreement, notwithstanding any expiration or termination of this Agreement.

14.2 Amendments; Assignment. This Agreement may not be altered, amended or modified except by a written document signed by both Parties. Manufacturer will not assign this Agreement without the prior written consent of Company and any purported assignment in contravention of this Section shall be null and void. Company may assign or otherwise transfer its rights and obligations under this Agreement without Manufacturer's consent to (a) an Affiliate, or (b) an entity that acquires all or substantially all of the Company's business or assets relating to the subject matter of this Agreement, whether by merger, acquisition or otherwise; *provided, however*, that in the case of an assignment to an Affiliate, Company shall remain fully and unconditionally responsible for the complete performance of the assigned rights and obligations under this Agreement. Manufacturer shall, at the request of the Company, enter into such supplemental agreements with the applicable Affiliates as may be necessary or advisable to permit such Affiliates to avail itself of any rights or perform any obligations of the Company hereunder. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns.

#### 14.3 Subcontracting.

(a) General Requirements. Manufacturer shall not subcontract or delegate any of its right or obligations under this Agreement to any third party without the express prior written consent of Company (such consent not to be unreasonably withheld), provided however that Manufacturer may subcontract its obligations under this Agreement with respect to its obligations to a subcontractor to which it subcontracts. Restatement Date provided Manufacturer has provided notice thereof to Company prior to such subcontracting. Manufacturer shall cause any permitted subcontractor to agree in writing to the same restrictions, exceptions, obligations, reports, termination provisions and other provisions contained in this Agreement applicable to such subcontractor's activities. Manufacturer shall remain primarily obligated for all acts or omissions of any of its subcontractors as if Manufacturer had performed the subcontracted obligations itself and shall guarantee the performance of the same.

(b) U.S. Agent. Without limiting Section 14.3(a) above, Company acknowledges that Manufacturer has appointed [\*] ("U.S. Agent") as Manufacturer's agent in the

United States as required by Applicable Laws in the United States and U.S. Agent is an approved subcontractor of Manufacturer; provided that, in conjunction with the execution of this Agreement, Manufacturer, U.S. Agent and Company execute the Acknowledgement and Agreement by U.S. Agent attached to this Agreement as Exhibit 14.3. Manufacturer shall promptly notify Company in the event of any termination or expiration of U.S. Agent's appointment as an agent of Manufacturer.

14.4 Successors; Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and each of their respective successors and permitted assigns.

14.5 Severability. If any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties will negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof will remain in full force and effect in such jurisdiction and will be construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

14.6 Entire Agreement. This Agreement (including all exhibits attached hereto and all Rolling Forecasts and purchase orders provided to Manufacturer hereunder) and the Quality Agreement (when such agreement has been executed) constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior and contemporaneous communications, representations, or agreements, either verbal or written between the Parties, including the Original Agreement, with respect to such subject matter. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein.

14.7 Independent Contractor. This Agreement shall not be deemed to create any partnership, joint venture, agency or other fiduciary relationship between the Parties. Each Party shall act hereunder as an independent contractor and such Party, its agents and employees shall have no right or authority under this Agreement to assume or create any obligation on behalf of, or in the name of, the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party, and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

14.8 Waiver. Except as otherwise expressly provided in this Agreement, as applicable, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of either Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

14.9 Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of California, U.S.A, without application of its principles of conflict of laws.

14.10 Dispute Resolution. In the event of a dispute relating to this Agreement, such matter shall be referred for resolution to the Chief Executive Officer of each Party or his or her designee for attempted resolution by good faith negotiation. Such good faith negotiation may include the appointment by either Party of an unaffiliated consultant, who shall be a scientific expert chosen based on such person's experience and expertise in the particular type of issue which is unresolved to advise such officers on the matter. If such officers are unable to resolve the matter within thirty (30) days, then each Party shall be free to seek any remedies available to it including any remedies at law or in equity. Nothing hereunder shall be construed as prohibiting a Party from seeking immediate temporary or permanent relief in any competent court or administrative body in the event that such Party might reasonably be expected to suffer irreparable harm absent such relief.

14.11 Interpretation. Headings included in this Agreement are for convenience only, do not form a part of this Agreement and will not affect the meaning or interpretation of this Agreement. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. In the event of any conflict between the terms of this Agreement and any exhibits attached hereto, the provisions of the main body of this Agreement shall prevail unless such exhibit expressly states an intent to supersede the provisions of the main body of this Agreement on a specific matter.

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

IN WITNESS WHEREOF, each of the Parties hereto has caused this Master API Supply Agreement to be executed by its duly authorized representative as of the date written above.

**ADAMAS PHARMA, LLC**

By: /s/ Rajesh Mahey  
Rajesh Mahey  
Vice President, Manufacturing  
Operations  
Adamas Pharmaceuticals, Inc.

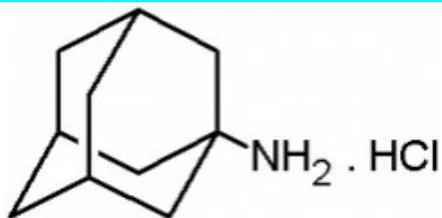
By: /s/ Jennifer Rhodes  
Jennifer Rhodes  
Secretary  
Adamas Pharma, LLC

**MOEHS IBERICA, S.L.**

By: /s/ Javier del Rio  
Javier del Rio  
  
Commercial Director

**Exhibit 1.1****API**

Amantadine HCL according to US DMF 6924

**Synonyms:**

(Tricyclo[3,3,1,<sup>3,7</sup>]decyl-1-ammonium) hydrochloride  
(1-Aminoadamantane) hydrochloride  
1-Adamantanamine hydrochloride  
1-Adamantylamine hydrochloride  
1-Aminoadamantane hydrochloride  
1-Adamantanamine hydrochloride

**Summary formula:**

$C_{10}H_{17}N \cdot HCl$

**CAS No.:**

665-66-7

**Exhibit 1.7**

**Specifications**

[\*]

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

---

## **Exhibit 6.1**

### **Pricing**

Not later than the last business day of each [\*], Manufacturer shall confirm with Company the total quantity (kg) of API ordered (and not cancelled by Company or its designees) pursuant to this Agreement [\*] (the “Aggregate Amount”) and the corresponding “Aggregate Rate” from column C.

Pricing for each order shall be determined from the table below.

Purchase orders received prior to receiving an updated Aggregate Rate shall be adjusted accordingly in the event the Aggregate Rate change results in a purchase price difference.

<b>API</b>	<b>Sum of Orders Placed [*]</b>	<b>Price / kg for Current Order</b>
Amantadine HCl	[*]	[*]

- A. In the event that as a result of an increase or decrease in the cost of any key raw materials included in the API, the direct manufacturing costs incurred by Manufacturer to produce the API for Company increases or decreases by [\*] or more and such increase or decrease in such manufacturing costs persists for at least [\*], Manufacturer will issue a written notice to Company outlining such cost increase or decrease. Upon Company’s receipt of such request, the Parties shall promptly meet, negotiate in good faith and determine whether an adjustment to the prices of the API per kilogram set forth in the table above are appropriate to take into account such increase or decrease in the direct manufacturing costs as a result of an increase or decrease in the cost of such key raw materials.
- B. In addition, during the term of this Agreement, but not more than [\*], the Parties agree to adjust the then current prices listed in the table set forth in this Exhibit 6.1 to address fluctuations in the U.S. dollar to Euro currency exchange rate according to the following procedures. For purposes of this Exhibit 6.1, “Base Rate” shall be initially defined as USD 1.1734 = € 1.00 (the currency exchange rate as of Oct 2, 2017) and going forward the Base Rate will always be defined as the value of the U.S. dollar compared to one (1) Euro (€ 1.00) as described below.
1. If the average of the currency exchange rate between the U.S. Dollar and the Euro, as published in the Wall Street Journal (Eastern Edition) for the first five business days on or after January 1 or July 1 differs from the then current Base Rate in either direction by more than [\*] (such new exchange rate, the “Triggering Rate”), then effective on the first business day following such publication, the Base Rate will thereafter be revised to equal the average of the Base Rate and the Triggering Rate, until the occurrence of a subsequent Triggering Rate according to this Section B(1) of this Exhibit 6.1.<sup>1</sup>

---

<sup>1</sup> For example, [\*]

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

2. Upon revising the Base Rate above, the then current prices for the table above will be adjusted by multiplying each price set forth therein by the ratio of the newly revised Base Rate to the previously effective Base Rate.<sup>2</sup>
3. In the event either Party believes the prices set forth in the table above should be adjusted according to the terms set forth herein, the Manufacturer or Company, as applicable, will provide written documentation evidencing the Triggering Rate to the other Party together with written notice setting forth (a) the revised Base Rate and the calculation supporting such revision, (b) the new pricing for Products in comparison to the current prices set forth in the table above, and (c) the effective date for such change (which for clarity shall be no earlier than the date the foregoing information is provided to the other Party), provided that changes to the prices for Product in accordance with the terms set forth in this Exhibit 6.1 shall be modified no more than [\*]. Any purchase order placed and accepted prior to the effective date for such change in pricing shall not be subject to the pricing adjustment described in Sections B(1) and B(2) of this Exhibit 6.1.
4. The processes described in Sections B(1) through B(3) above shall be repeated in which a Triggering Rate occurs at the beginning of January or July as described in Section B(1) above.

---

<sup>2</sup> For example, [\*]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

---

## EXHIBIT 14.3

### ACKNOWLEDGEMENT AND AGREEMENT BY U.S. AGENT

This Acknowledgement and Agreement by U.S. Agent (“U.S. Agent Agreement”) is made as of Oct 2, 2017 by and between [\*] (“U.S. Agent”), a Corporation with offices at [\*], Adamas Pharma, LLC, with offices at 1900 Powell St., Emeryville, CA 94618 (“Company”) and Moehs Ibérica, S.L. (“Manufacturer”), a Spanish corporation, with offices at Poligono Industrial Rubi Sud - C/ Cesar, Martinell i Brunet 12A, 08191 Rubi, Barcelona, Spain. All capitalized terms used in this U.S. Agent Agreement and not defined herein shall have the meanings given to such terms in that certain API Supply Agreement between Company and Manufacturer dated as of Oct 2, 2017 (“Supply Agreement”).

1. Manufacturer and U.S. Agent represent and warrant that U.S. Agent has been duly appointed by Manufacturer pursuant to a written agreement between Manufacturer and U.S. Agent and is authorized by Manufacturer under that agreement to perform any and all services and activities that are required under Applicable Laws for the agent of a non-United States manufacturer of pharmaceutical products. Manufacturer and U.S. Agent shall promptly notify Company if the agreement between Manufacturer and U.S. Agent terminates or expires and/or of any change to the scope of authority granted by Manufacturer to U.S. Agent that may have a material impact on Company, including Company’s arrangements with Manufacturer or any regulatory filings relating to Company’s product incorporating the API.

2. U.S. Agent represents and warrants that: (a) it is duly organized and validly existing and in good standing under the Laws of its jurisdiction of organization; (b) is qualified and licensed to do business and in good standing in every jurisdiction in which such qualification or licensing is required; and (c) has the corporate power and authority to execute, deliver and perform: (i) its obligations under this U.S. Agent Agreement; and (ii) any activities that may be required under Applicable Laws in the United States as Manufacturer’s U.S. agent and/or any obligations of Manufacturer under the Supply Agreement that may be delegated by Manufacturer to U.S. Agent from time to time.

3. U.S. Agent shall obtain and maintain in good order, at its sole cost and expense, all governmental registrations, permits, licenses and approvals as are required by Applicable Law to perform any activities that may be required by Applicable Laws in the United States as Manufacturer’s U.S. agent and/or any obligations of Manufacturer under the Supply Agreement that may be delegated by Manufacturer to U.S. Agent from time to time. In performing all such activities and/or obligations, U.S. Agent shall comply with all Applicable Laws, the instructions of Manufacturer and any applicable terms of the Supply Agreement.

4. Without limiting Section 3 above, U.S. Agent shall promptly: (a) advise Manufacturer of any requests and/or communications received from the FDA, in its capacity as Manufacturer’s U.S. agent, by notifying Manufacturer in accordance with Section 10 below; (b) assist the FDA, as requested by the FDA, to schedule inspections of the Manufacturing Facility or any other facilities at which Manufacturer manufactures products; and (c) respond to any

---

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



Attn: General Counsel (Legal Department)

If to Manufacturer: Moehs Iberica S.L.  
Poligono Industrial Rubi Sud,  
c/Cesar Martinell I Brunet 12A,  
08191 Rubi, Barcelona (Spain)  
Attn: Mr Javier del Rio  
Telephone No.:(+34) 935860520  
Fax No.: (+34) 93 588 8513

If to U.S. Agent: [\*]

All notices delivered pursuant to this Section shall be considered delivered upon receipt by the intended recipient or within ten (10) days of dispatch, whichever is earlier.

**11.** This U.S. Agent Agreement (and any amendments hereto) may be executed in counterparts, all of which will constitute one instrument. Signatures to this U.S. Agent Agreement delivered by facsimile or similar electronic transmission will be deemed to be binding as originals.

{REMAINDER OF PAGE INTENTIONALLY LEFT BLANK}

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

---

IN WITNESS WHEREOF, the parties execute this U.S. Agent Agreement as of the date first written above. Each person who signs this U.S. Agent Agreement below represents that such person is fully authorized to sign this U.S. Agent Agreement on behalf of the applicable party.

**MOEHS IBÉRICA, S.L.**

By:

\_\_\_\_\_  
Name:

\_\_\_\_\_  
Title:

\_\_\_\_\_

**ADAMAS PHARMA, LLC**

By:

\_\_\_\_\_  
Name:

Rajesh Mahey

Title:

VP, Manufacturing Operations

Adamas Pharmaceuticals, Inc.

\_\_\_\_\_

By:

\_\_\_\_\_  
Name:

Jennifer Rhodes

Title:

Secretary

Adamas Pharma, LLC

[ \* ]

By:

\_\_\_\_\_  
Name:

[ \* ]

Title:

Senior Vice President

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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

I, Gregory T. Went, Ph.D., 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: November 2, 2017

/s/ Gregory T. Went, Ph.D.

---

Gregory T. Went, Ph.D.

Chief Executive Officer

(Principal Executive Officer)

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

I, Alfred G. Merriweather, 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: November 2, 2017

/s/ Alfred G. Merriweather

---

Alfred G. Merriweather  
Chief Financial Officer  
(Principal Financial Officer)

**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), Gregory T. Went, Ph.D., Chief Executive Officer of Adamas Pharmaceuticals, Inc. (the “Company”), and Alfred G. Merriweather, 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 September 30, 2017 , 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 Annual 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 2nd day of November, 2017 .

/s/ Gregory T. Went, Ph.D.

\_\_\_\_\_  
Gregory T. Went, Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

/s/ Alfred G. Merriweather

\_\_\_\_\_  
Alfred G. Merriweather  
Chief Financial Officer  
(Principal Financial 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.