Adamas Pharmaceuticals Inc
Form 10-Q
August 02, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

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

For the quarterly period ended June 30, 2018

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 | 42-1560076 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |
| 1900 Powell Street, Suite 750 Emeryville, CA (Address of Principal Executive Offices) | 94608 (Zip Code) |

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

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.

| | |
|---|---|
| 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 July 27, 2018 was 27,190,453.

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

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | $40,604 | $ 91,316 |
| Available-for-sale securities | 162,380 | 82,126 |
| Accounts receivable, net | 3,412 | 367 |
| Inventory | 3,768 | 1,704 |
| Prepaid expenses and other current assets | 4,815 | 3,662 |
| Total current assets | 214,979 | 179,175 |
| Property and equipment, net | 2,809 | 3,132 |
| Available-for-sale securities, non-current | 53,293 | 2,991 |
| Prepaid expenses and other non-current assets | 5,165 | 878 |
| Total assets | $276,246 | $ 186,176 |
| Liabilities and stockholders' equity | | |
| Current liabilities | | |
| Accounts payable | $7,823 | $ 3,878 |
| Accrued liabilities | 13,124 | 12,385 |
| Other current liabilities | 735 | 344 |
| Total current liabilities | 21,682 | 16,607 |
| Long-term debt | 111,283 | 102,647 |
| Other non-current liabilities | 721 | 796 |
| Total liabilities | 133,686 | 120,050 |
| 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 June 30, 2018 and December 31, 2017 | — | — |
| Common stock, $0.001 par value — 100,000,000 shares authorized, 27,184,443 and 23,320,551 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively | 32 | 28 |
| Additional paid-in capital | 423,616 | 277,964 |
| Accumulated other comprehensive loss | (425) | (167) |
| Accumulated deficit | (280,663) | (211,699) |
| Total stockholders' equity | 142,560 | 66,126 |
| Total liabilities and stockholders' equity | $276,246 | $ 186,176 |

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenues: | | | | |
| Product sales | $7,565 | $— | $10,118 | $— |
| License and grant revenue | — | 2 | — | 2 |
| Total revenues | 7,565 | 2 | 10,118 | 2 |
| Costs and operating expenses: | | | | |
| Cost of product sales | 73 | — | 98 | — |
| Research and development | 9,806 | 7,176 | 16,994 | 14,264 |
| Selling, general and administrative, net | 27,699 | 13,115 | 54,062 | 22,259 |
| Total costs and operating expenses | 37,578 | 20,291 | 71,154 | 36,523 |
| Loss from operations | (30,013) | (20,289) | (61,036) | (36,521) |
| Interest and other income, net | 1,132 | 222 | 2,010 | 426 |
| Interest expense | (5,112) | (729) | (9,938) | (729) |
| Loss before income taxes | (33,993) | (20,796) | (68,964) | (36,824) |
| Benefit for income taxes | — | (51) | — | (51) |
| Net loss | $(33,993) | $(20,745) | $(68,964) | $(36,773) |
| Net loss per share, basic and diluted | $(1.26) | $(0.93) | $(2.61) | $(1.65) |
| Weighted average shares used in computing net loss per share, basic and diluted | 27,040 | 22,392 | 26,454 | 22,300 |

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net loss | $(33,993) | $(20,745) | $(68,964) | $(36,773) |
| Unrealized gain (loss) on available-for-sale securities | (62) | (17) | (258) | 10 |
| Comprehensive loss | $(34,055) | $(20,762) | $(69,222) | $(36,763) |

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

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2018 | 2017 |
| Cash flows from operating activities | | |
| Net loss | $(68,964) | $(36,773) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation | 734 | 572 |
| Stock-based compensation | 7,890 | 6,649 |
| Accretion of interest expense | 9,938 | 729 |
| Change in fair value of embedded derivative liability | 44 | — |
| Net accretion of discounts and amortization of premiums of available-for-sale securities | (344) | (71) |
| Changes in assets and liabilities | | |
| Accrued interest of available-for-sale securities | (234) | (50) |
| Inventory | (1,726) | — |
| Prepaid expenses and other assets | (4,979) | 730 |
| Accounts receivable, net | (3,045) | 760 |
| Accounts payable | 3,861 | 509 |
| Accrued liabilities and other liabilities | (558) | 325 |
| Net cash used in operating activities | (57,383) | (26,620) |
| Cash flows from investing activities | | |
| Purchases of property and equipment | (497) | (621) |
| Purchases of available-for-sale securities | (183,796) | (40,071) |
| Maturities of available-for-sale securities | 53,560 | 41,100 |
| Net cash provided by (used in) investing activities | (130,733) | 408 |
| Cash flows from financing activities | | |
| Proceeds from public offerings, net of offering costs | 134,268 | — |
| Proceeds from issuance of long-term debt | — | 34,600 |
| Payment of debt issuance costs | — | (136) |
| Proceeds from issuance of common stock upon exercise of stock options | 2,293 | 1,201 |
| Proceeds from employee stock purchase plan | 843 | 430 |
| Net cash provided by financing activities | 137,404 | 36,095 |
| Net increase (decrease) in cash and cash equivalents | (50,712) | 9,883 |
| Cash and cash equivalents at beginning of period | 91,316 | 23,735 |
| Cash and cash equivalents at end of period | $40,604 | $33,618 |
| Supplemental disclosure of noncash investing and financing activities | | |
| Purchases of inventory in accounts payable and accrued expenses | $236 | $— |
| Debt issuance costs in accounts payable and accrued expense | $— | $460 |
| Purchases of property and equipment in accounts payable and accrued expense | $10 | $51 |
| Stock-based compensation capitalized in inventory | $122 | $— |
| Stock option exercise settled after period end | $240 | $— |

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

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

1. DESCRIPTION OF BUSINESS

Adamas Pharmaceuticals, Inc. (the "Company") focuses on time-dependent biology to redefine the treatment experience for patients suffering from chronic neurological diseases. In August 2017, the U.S. Food and Drug Administration (FDA) approved GOCOVRI™ (amantadine) extended release capsules (previously ADS-5102), the first and only FDA-approved medicine for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The Company is also advancing its pipeline of differentiated investigational programs, which includes: ADS-5102 in development for the treatment of multiple sclerosis walking impairment; and ADS-4101, a high-dose, modified-release lacosamide in development for the treatment of partial onset seizures in patients with epilepsy. The Company's goal is to create and commercialize a new generation of medicines intended to lessen the burden of disease on patients, caregivers and society.

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

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) considered necessary for the fair presentation of the periods presented. The condensed consolidated balance sheet at December 31, 2017 was derived from the audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP.

These interim financial results are not necessarily indicative of results to be expected for the full fiscal year ending December 31, 2018, or any other future period. Readers should read these interim unaudited condensed consolidated financial statements in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2017, included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC. The Company's critical accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2017. Effective January 1, 2018, the Company adopted Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, using the full retrospective transition method. Other than the adoption of the new accounting guidance, the Company's critical accounting policies have not changed materially from December 31, 2017.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in the consolidated financial statements and the accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition and variable consideration, 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.

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Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, using the full retrospective transition method. The Company recognizes revenue upon transfer of control of promised products or services to customers in an amount that reflects the consideration the Company expects to receive in exchange for those products or services. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less.

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct.

Product sales

The Company's product sales consist of U.S. sales of GOCOVRI. GOCOVRI was approved by the FDA on August 24, 2017, and the Company commenced shipments of GOCOVRI to a specialty pharmacy during October 2017. The Company sells its products principally to a specialty pharmacy and certain specialty distributors (each a "Customer" or collectively its "Customers"). These agreements with its Customers provide for transfer of title to the product at the time the product has been delivered to and accepted by the Customer. The Customer subsequently dispenses product directly to a patient. In addition, except for limited circumstances, the Customer has no right of product return to the Company.

The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the Customer. The Company has determined that the delivery of its product to Customers constitutes a single performance obligation as there are no other promises to deliver goods or services. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. The Company has assessed the existence of a significant financing component in the agreements with its Customers. The trade payment terms with its Customers do not exceed one year and therefore the Company has elected to apply the practical expedient and no amount of consideration has been allocated as a financing component.

The Company considers effects of items which can decrease the transaction price such as variable consideration and consideration payable to a Customer or payer. Amounts related to such items are estimated at contract inception and updated at the end of each reporting period as additional information becomes available. The amount of variable consideration may be constrained and is included in the transaction price only to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. Revenue from product sales is recorded after considering the impact of the following variable consideration amounts at the time of revenue recognition:

Distribution Fees: Distribution fees include fees paid to the Company's Customers for data and prompt payment discounts. Distribution fees are recorded based on contractual terms.

Rebates: Rebates include mandated discounts under the Medicaid Drug Rebate Program, Medicare Part D Prescription Drug Benefit Program, and TRICARE Retail Pharmacy Refunds Program (TRICARE). Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements with benefit providers. Rebates are estimated based on statutory discount rates and expected utilization. The expected utilization of rebates is estimated based on data received from the specialty pharmacy. The Company uses the expected-value method for estimating rebates and estimates are adjusted quarterly to reflect actual experience.

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Product Returns: Consistent with industry practice, the Company offers limited product return rights and generally allows for the return of product that is damaged or defective, and within a few months prior to and up to a few months after the product expiration date. The Company does not allow product returns for product that has been dispensed to a patient. The Company considers several factors in the estimation of potential product returns, including expiration dates of the product shipped, the limited product return rights, third-party data in monitoring channel inventory levels, shelf life of the product, prescription trends, and other relevant factors. Product returns have been insignificant to date and are expected to be immaterial in the future.

Medicare Part D Coverage Gap: Medicare Part D coverage gap is a federal program to subsidize the costs of prescription drugs for Medicare beneficiaries in the United States, which mandates manufacturers to fund a portion of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Funding of the coverage gap is generally invoiced and paid in arrears. The impact of the Medicare Part D coverage gap is estimated using the expected-value method based on an amount expected to be incurred for the current quarter’s activity, plus an accrual balance for known prior quarters and is adjusted quarterly based on actual experience.

Co-payment Assistance: The Company provides co-payment assistance to patients who have commercial insurance and meet certain eligibility requirements. Co-payment assistance is estimated using the expected-value method based on historical program participation and estimates of program redemption using data provided by third-party administrators.

Each of the above items are variable consideration, are recorded at the time of revenue recognition, and require significant estimates, judgment and information obtained from external sources. The Company determined a significant reversal of revenue would not occur in a future period for the estimates of variable consideration detailed above and, therefore, the transaction price was not reduced during the three and six months ended June 30, 2018. If management's estimates differ from actual results, the Company will record adjustments that would affect product sales in the period of adjustment.

License agreement revenue

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 milestone payments based on the achievement of defined objectives, and royalties on sales of commercialized products. Such agreements may contain various promises to customers which are generally capable of being distinct and accounted for as separate performance obligations. The Company’s duties and responsibilities under the collaboration and license agreements typically 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. These promises may be regarded as separate performance obligations, or bundled as a single performance obligation, depending upon the nature of the arrangement.

For agreements with multiple performance obligations, the Company allocates estimated revenue to each performance obligation at contract inception based on the estimated relative standalone selling price (SSP) of each performance obligation in the arrangement. Revenue allocated to each performance obligation is then recognized when the entity satisfies the performance obligation by transferring control of the promised good or service to the customer.

Licenses for Intellectual Property (IP): If the Company determines that the license for IP is distinct from the other performance obligations identified in the arrangement, revenue from non-refundable, up-front fees allocated to the license is recognized when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, judgment is applied to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

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Milestone Payments: For contracts with customers that contain payments that are contingent upon achievement of a substantive milestone, at the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative SSP basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

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

Royalties: For arrangements that include sales-based royalties, and the licensed IP is deemed to be the predominant item to which the royalties relate, the Company recognizes the related royalty revenue at the later of (i) when the related sales occur, or (ii) the satisfaction or partial satisfaction of the performance obligation to which the royalty relates.

Recent Accounting Pronouncements

Accounting Pronouncements Adopted in 2018

In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers with amendments in 2015, 2016, and 2017. 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. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. This standard replaces most existing revenue recognition guidance. The Company adopted the new standard effective January 1, 2018, using the full retrospective transition method. The Company has evaluated the effect the new guidance will have on its consolidated financial statements and determined the adoption of this guidance to have no material impact on amounts previously reported in its consolidated financial statements.

ASU 2014-09 also codified the guidance on other assets and deferred costs relating to contracts with customers with the addition of ASC 340-40. This guidance relates to the accounting for costs of an entity to obtain and fulfill a contract to provide goods or services to the customer. Under the new guidance, an entity shall recognize as an asset the incremental costs of obtaining a contract with a customer if the entity expects to recover those costs. In the Company’s review of the various costs to obtain contracts with customers, it has determined that currently no significant costs are incurred that meet the capitalization criteria. The Company’s costs to fulfill contracts are outside the scope of ASC 340-40 and are typically expensed as incurred.

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. The Company adopted the new standard effective January 1, 2018, on a prospective basis. The adoption of this guidance did not have an impact on the Company’s consolidated financial statements or disclosures.

New Accounting Pronouncements Not Yet Adopted

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

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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 June 2018, the FASB issued ASU 2018-07, Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Previously, accounting for share-based payments to employees was covered by ASC Topic 718 while accounting for such payments to non-employees was covered by ASC Subtopic 505-50. Under this new guidance, both sets of awards, for employees and non-employees, will essentially follow the same model, with small variations related to determining the term assumption when valuing a non-employee award as well as a different expense attribution model for non-employee awards as opposed to employee awards. This guidance is effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the effect the new guidance will have 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.

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

| | June 30, 2018 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| Assets: | | | | |
| Money market | $14,269 | $14,269 | $— | $ — |
| Corporate debt | 28,146 | — | 28,146 | — |
| U.S. Treasury notes | 187,527 | — | 187,527 | — |
| Total assets measured at fair value | $229,942 | $14,269 | $215,673 | $ — |
| Liabilities: | | | | |
| Embedded derivative liability | $514 | $— | $— | $ 514 |
| Total liabilities measured at fair value | $514 | $— | $— | $ 514 |

| | December 31, 2017 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| Assets: | | | | |
| Money market | $68,501 | $68,501 | $— | $ — |
| Corporate debt | 23,471 | — | 23,471 | — |
| U.S. Treasury notes | 61,646 | — | 61,646 | — |
| Total assets measured at fair value | $153,618 | $68,501 | $85,117 | $ — |
| Liabilities: | | | | |
| Embedded derivative liability | $470 | $— | $— | $ 470 |
| Total liabilities measured at fair value | $470 | $— | $— | $ 470 |

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

Corporate debt, U.S. Treasury notes, and commercial paper are measured at fair value using Level 2 inputs. The Company reviews trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy. In certain cases where there is limited activity or less transparency around inputs to valuation, the related assets or liabilities are classified as Level 3. The Company classified an embedded derivative related to the 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; 2) the Company's risk adjusted discount rates; and 3) the probability of a change in control occurring during the term of the note based on the percentage of similar companies that were acquired over the previous five year period. Changes in the estimated fair value of the bifurcated embedded derivative are reported as gains or losses in interest and other income, net, in the condensed consolidated statement of operations. In the periods presented, the Company evaluated the embedded derivative value as a result of an event of default and the value as a result of increased costs due to a regulatory change and considered both to have no material value based on current assessment of probability, but could become material in future periods if a specified event of default or regulatory change became more probable than is currently estimated. See Note 8 "Long-Term Debt" for further description.

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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, 2017 | $470 |
| Change in fair value included in interest and other income, net | 44 |
| Balance as of June 30, 2018 | $514 |

There were no transfers between any of the levels of the fair value hierarchy during the three and six months ended June 30, 2018.

4. INVESTMENTS

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

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

The following table is a summary of amortized cost, unrealized gain and loss, and the fair value of available-for-sale securities as of June 30, 2018 and December 31, 2017 (in thousands):

| | June 30, 2018 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Investments: | | | | |
| Corporate debt | $28,221 | $ — | $ (75) | $28,146 |
| U.S. Treasury notes | 187,877 | — | (350) | 187,527 |
| Commercial paper | — | — | — | — |
| Total | $216,098 | $ — | $ (425) | $215,673 |
| Reported as: | | | | |
| Short-term investments | $162,662 | $ — | $ (282) | $162,380 |
| Long-term investments | 53,436 | — | (143) | 53,293 |
| Total | $216,098 | $ — | $ (425) | $215,673 |

| | December 31, 2017 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Investments: | | | | |
| Corporate debt | $23,507 | $ — | $ (36) | $23,471 |
| U.S. Treasury notes | 61,777 | — | (131) | 61,646 |
| Total | $85,284 | $ — | $ (167) | $85,117 |
| Reported as: | | | | |
| Short-term investments | $82,280 | $ — | $ (154) | $82,126 |
| Long-term investments | 3,004 | — | (13) | 2,991 |
| Total | $85,284 | $ — | $ (167) | $85,117 |

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Short-term and long-term investments include accrued interest of $0.7 million and $0.2 million, respectively, as of June 30, 2018. Short-term and long-term investments includes accrued interest of $0.6 million and $14,000, respectively, as of December 31, 2017. The Company has not incurred any realized gains or losses on investments for the three and six months ended June 30, 2018 and 2017. 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 18 months as of June 30, 2018. All investments with unrealized losses at June 30, 2018 have been in a loss position for less than twelve months or the loss is not material and were temporary in nature. The Company does not intend to sell the investments that are in an unrealized loss position before recovery of their amortized cost basis.

5. INVENTORY

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

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| Raw materials | $ 1,288 | $ 859 |
| Work-in-process | 1,642 | 817 |
| Finished goods | 838 | 28 |
| Total inventory | $ 3,768 | $ 1,704 |

6. LICENSE AGREEMENTS

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

Pursuant to the agreement, Allergan made an upfront payment of $65.0 million. The Company earned and received additional cash payments totaling $95.0 million upon achievement by Allergan of certain development and regulatory milestones. Under the agreement, external costs incurred related to the prosecution and litigation of intellectual property rights are reimbursable. Reimbursable external costs are recorded as a reduction to selling, general and administrative, net. For the six months ended June 30, 2018 and 2017, there were no reimbursable external costs. In addition, the Company may earn tiered royalty payments based on future net sales of Namzaric and Namenda XR. Beginning in May 2020, the Company will be entitled to receive royalties in the low to mid-teens from Allergan for sales of Namzaric 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 in the United States. Allergan's obligation to pay royalties with respect to fixed-dose memantine-donepezil products, including Namzaric, continues until the later of (i) 15 years after the commercial launch of the first fixed-dose memantine-donepezil product by Allergan in the United States or (ii) the expiration of the Orange Book listed patents for which Allergan obtained rights from the Company covering such product. Allergan's obligation to pay royalties with respect to Namenda XR 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. The Company does not expect to receive royalties on net sales of Namenda XR, due to the entry of generic versions of Namenda XR. The Company evaluated the Allergan agreement under Topic 606. Based on that evaluation, the Company has determined that at the date of adoption it has satisfied all performance obligations associated with the upfront and milestone payments for each comparative period presented. Royalties under the license agreement will be recognized when the related sales occur, in accordance with the sales-based royalty exception.

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## 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. On January 16, 2018, the Company amended its lease agreement to extend its lease until April 30, 2025, and relocate the Company within its current building from the seventh to the tenth and eleventh floors, containing approximately 37,626 rentable square feet. The lease provides for a tenant improvement allowance of approximately $1.1 million. As of June 30, 2018, none of the allowance was utilized. The initial monthly lease payments are $160,000, increasing to $197,000 in the final year of the agreement, with a lease abatement for the first three months after the lease commencement. The Company expects to relocate in the third quarter of 2018.

### Purchase Commitments

The Company has entered into agreements for the supply of API and the manufacture of commercial supply of GOCOVRI, with Moehs Ibérica, S.L. and Catalent Pharma Solutions, LLC, respectively. Under the terms of the agreements, the Company will supply the vendors with non-cancelable firm commitment purchase orders. The Company has also entered into other agreements with certain vendors for the provision of services, including services related to data access and packaging, under which the Company is contractually obligated to make certain payments to the vendors.

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

### Contingencies

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

### Indemnification

In accordance with the Company’s amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. 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 and Namenda XR for the treatment of moderate to severe dementia related to Alzheimer’s disease. The Company has a right to participate in, but not control, such enforcement actions by Forest.

As of August 2, 2018, 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, on which the Company is entitled to receive royalties from Forest beginning in June 2018 in any quarter for which there is not significant competition from generics. In the notices, these companies allege that the patents associated with Namenda XR, 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. The Company, Forest, Merz Pharma GmbH &

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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.

As of August 2, 2018, the Company and Forest have entered into a series of settlement agreements with all Namenda XR ANDA filers that the Company and Forest chose to file suit against, including with the ANDA filer against whom the Company and Forest filed a lawsuit on June 2, 2017, 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). Entry dates for generic Namenda XR are governed by the settlement agreements in that action.

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 ("Federal Circuit"). On December 11, 2017, the Federal Circuit issued a non-precedential opinion affirming the final judgment of the district court. On January 10, 2018, the Company and Forest filed a petition for rehearing/rehearing en banc with the Federal Circuit. On February 12, 2018, the appellate court denied that petition and on February 20, 2018, the mandate of the court was issued. Based upon the terms of certain settlement agreements with generic filers related to Namenda XR, certain generic filers can now commercialize generic versions of Namenda XR, if approved by the FDA. As of June 30, 2018, multiple generic companies have launched generic versions of Namenda XR.

Additionally, as of August 2, 2018, 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 August 2, 2018, the Company and Forest have settled with all such Namzaric ANDA filers, including all first filers on all the available dosage forms of Namzaric, including with the ANDA filer against whom the Company and Forest filed a lawsuit on June 2, 2017 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 Namzaric that included one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv). 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, or earlier in certain circumstances. The Company and Forest intend to continue to enforce the patents associated with Namzaric.

On April 20, 2017, an opposition was filed against the Company's 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. On March 7, 2018, the European Patent Office issued a Preliminary Opinion of the Opposition Division and a Summons to appear at oral proceedings on October 8, 2018.

On February 16, 2018, Osmotica Pharmaceuticals LLC and Vertical Pharmaceuticals LLC ("Osmotica") filed an action against the Company in U.S. District Court for the state of Delaware, requesting a declaratory judgment that Osmotica's newly-approved product Osmolex ER™ (amantadine) extended release tablets does not infringe certain of the Company's patents. This action is ongoing and is in an early stage.

On March 13, 2018, the FDA's New Paragraph IV Certifications list was updated to reflect that an ANDA seeking authorization from the FDA to manufacture, use, or sell a generic version of GOCOVRI™ (amantadine) extended release capsules, containing one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV

certification"), was submitted to the FDA on January 16, 2018, and has been accepted for filing. Subsequent to this date, the Company received a letter from attorneys representing Sandoz, Inc. ("Sandoz") dated March 29, 2018, notifying it that Sandoz filed an ANDA for Amantadine Extended-Release Capsules, 137 mg that contains

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paragraph IV certifications seeking to obtain approval to engage in the commercial manufacture, use or sale of Amantadine Extended-Release Capsules, 137 mg before the expiration of U.S. Patent Nos. 8,389,578; 8,741,343; 8,796,337; 8,889,740; 8,895,614; 8,895,615; 8,895,616; 8,895,617; 8,895,618; 9,867,791; 9,867,792; 9,867,793; and 9,877,933. On May 10, 2018, the Company filed a lawsuit against Sandoz alleging infringement of the patents against Sandoz in the United States District Court for the District of New Jersey. This action is ongoing and is in an early stage.

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, followed by an additional $65.0 million received in the fourth quarter 2017 upon FDA's recognition in the Orange Book of seven-year orphan drug exclusivity, which GOCOVRI earned upon approval on August 24, 2017. Principal and interest will be payable quarterly from the proceeds of a 12.5% royalty on U.S. net sales of GOCOVRI and up to $15.0 million of the Company's annual royalties from Allergan on U.S. net sales of Namzaric starting in May 2020, pursuant to the Company's license agreement with Allergan. The royalty rate on net sales of GOCOVRI will drop to 6.25% after the principal amount of the loan has been repaid in full, until the Company has made total payments of 200% of the funded amounts. The Company may elect to voluntarily prepay the loan at any time, or may be required to prepay subject to specified prepayment trigger events as described below, in which case the amount due will be 200% of the funded amounts, less total payments made to date. Royalty rates are subject to increase to 17.5% and 22.5% if total principal and interest payments have not reached minimum specified levels at measurement dates on December 2021 and December 2022, respectively. Under the terms of the loan, HCRP has recourse to Adamas Pharma, LLC, not the Company. The loan agreement matures in December 2026 but as the repayment of the loan amount is contingent upon the sales volumes of GOCOVRI and royalties from Allergan, the repayment term may be shortened depending on the actual sales of GOCOVRI and actual royalties received from Allergan.

The loans bear interest at an annual rate of 11% on the outstanding principal amount and includes an interest-only period until the interest payment date following the ninth full calendar quarter after the $65.0 million additional loan. 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.

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 $5.1 million and $9.9 million for the three and six months ended June 30, 2018, respectively; and $0.7 million for both the three and six ended June 30, 2017. Interest expense over the life of the Royalty-Backed Loan includes an annual interest rate of 11% on the outstanding principal, a royalty rate of 6.25% on net sales of GOCOVRI after the principal amount is paid, and amortization of the debt discount. The effective interest rate as of June 30, 2018 on the amounts borrowed under the Royalty-Backed Loan, including the amortization of the debt discount, was 19.9%.

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

The Company may be required to make mandatory prepayments of the borrowings under the Royalty-Backed Loan upon the occurrence of specified prepayment trigger events, including: (1) the occurrence of any event of default or (2) the occurrence of a change in control. Upon the prepayment of all or any of the outstanding principal balance, the Company shall pay, in addition to such prepayment, a prepayment premium. As HCRP, as the holder of the loans, may exercise the option to require prepayment by the Company, the prepayment premium is considered to be an

embedded

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derivative which is required to be bifurcated from its host contract and accounted for as a separate financial instrument. The valuation of the embedded derivative is described further in Note 3.

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

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| Total repayment obligation | $200,000 | $ 200,000 |
| Less: Interest to be accreted in future periods | (87,415) | (97,353) |
| Less: Payments made | (368) | — |
| Carrying value of loans payable | $112,217 | $ 102,647 |
| Less: Current portion of long-term debt | (934) | — |
| Non-current portion of long-term debt | $111,283 | $ 102,647 |

The estimated fair value of the long-term debt, as measured using Level 3 inputs, approximates $115.7 million as of June 30, 2018. The estimated fair value was calculated in the same methodology as the valuation of the embedded derivative as described further in Note 3.

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

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 2018, the Company completed a follow-on public offering of 3,450,000 shares of common stock, which includes the exercise in full by the underwriters of their option to purchase 450,000 shares of common stock, at an offering price of $41.50 per share. Proceeds from the follow-on public offering were approximately $134.3 million, net of underwriting discounts and offering-related transaction costs.

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 June 30, 2018, no shares have been sold under the Sales Agreement.

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Shares Reserved for Future Issuance

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

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| Common stock awards issued and outstanding | 6,135,087 | 5,564,635 |
| Authorized for future issuance under 2014 Equity Incentive Plan | 1,794,105 | 1,723,733 |
| Authorized for future issuance under 2016 Inducement Plan | 551,439 | 188,715 |
| Employee stock purchase plan | 892,444 | 693,856 |
| Total | 9,373,075 | 8,170,939 |

10. STOCK-BASED COMPENSATION

Stock Compensation Plans

In January 2018, 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, 2017, or 932,822 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 each of January 2017 and November 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, resulting in a total of 1,350,000 shares of common stock issuable under the Inducement Plan.

Employee Stock Purchase Plan

In January 2018, 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, 2017, or 233,206 shares.

Stock-Based Compensation Expense

The following table reflects stock-based compensation expense recognized for the three and six months ended June 30, 2018 and 2017 (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Research and development | $717 | $895 | $1,489 | $1,716 |
| Selling, general and administrative | 3,432 | 2,870 | 6,401 | 4,933 |
| Total stock-based compensation expense | $4,149 | $3,765 | $7,890 | $6,649 |

Stock-based compensation of $73,000 and $122,000 was capitalized into inventory for the three and six months ended June 30, 2018, respectively; stock-based compensation of zero was capitalized into inventory for both the three and six ended June 30, 2017. Stock-based compensation capitalized into inventory is recognized as cost of sales when the related product is sold.

11. 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

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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 six months ended June 30, 2018, approximately 6,205,000 and 5,971,000, 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 six months ended June 30, 2017, approximately 6,107,000 and 5,899,000, 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.

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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 Pharmaceuticals, Inc., we seek to redefine the treatment experience for patients suffering from chronic neurological diseases. Our vision is to create and commercialize a new generation of medicines intended to lessen the burden of disease on patients, caregivers and society. With a new commercial medicine and robust pipeline of investigational programs focused on meaningfully differentiated treatment options for patients, we believe we are well on our way. Our therapeutic targets include a broad range of neurologic diseases, including Parkinson's disease, multiple sclerosis, epilepsy and Alzheimer's disease.

Our treatment innovations stem from a deep scientific understanding of time-dependent biology–the deliberate mapping of disease patterns and drug activity–along with a goal to meaningfully increase the efficacy of known molecules without compromising tolerability. This approach is designed to ensure that our medicines fit within, rather than define, people's daily lives. 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 expanding portfolio includes:

Approved Product:

- 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. GOCOVRI was approved for marketing by the U.S. Food and Drug Administration, or FDA, on August 24, 2017, with seven years of orphan exclusivity and additional patent protections, and we fully launched GOCOVRI with a deployed sales force in January 2018.

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

- ADS-5102 in development for the treatment of walking impairment in patients with multiple sclerosis. We have initiated our Phase 3 pivotal study in this supplemental indication with the enrollment of the first patient in March 2018.
- ADS-5102 in research and potential development for additional indications, including the treatment of wearing OFF and delaying motor complications in Parkinson's disease, tardive dyskinesia, Huntington's chorea, Tourette syndrome, and non-motor disorders, including depression, and anti-psychotic induced weight gain. We expect to complete the assessment of additional indications for ADS-5102 by first quarter 2019.

Product Candidates:

- ADS-4101 (lacosamide) modified release capsules in development for the treatment of partial onset seizures in patients with epilepsy. We are continuing to advance our manufacturing capabilities to support the clinical development program for ADS-4101.
- Additional product candidates in research based on potential new discoveries in Parkinson's disease, multiple sclerosis, epilepsy, as well as new research programs in psychiatry.

Partnered Products:

- Namzaric® (memantine hydrochloride extended release and donepezil hydrochloride) capsules for the treatment of moderate to severe dementia of an Alzheimer's type, marketed in the United States by Allergan

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plc under an exclusive license agreement between us and Forest Laboratories Holdings Limited ("Forest"), an indirect wholly-owned subsidiary of Allergan plc.

- Namenda XR® (memantine hydrochloride) extended release capsules for the treatment of moderate to severe dementia of an Alzheimer's type, marketed in the United States by Allergan plc under the Forest license agreement. We do not expect to receive royalties on net sales of Namenda XR, due to the entry of generic versions of Namenda XR.

Products in our wholly-owned, non-partnered portfolio, potential additional indications for these products, and our product candidates, are protected by an array of intellectual property, including robust and diversified patent claims, and regulatory exclusivities. For example, GOCOVRI is protected by seven-year orphan drug exclusivity, three-year new use exclusivity, and issued patents out to 2030 and pending patent applications out to 2035.

Financial operations overview

Summary

As of June 30, 2018, we had cash, cash equivalents, and available-for-sale securities of $256.3 million. We are commercializing GOCOVRI through our deployed sales force targeting neurologists and movement disorder specialists in the United States, and may possibly commercialize GOCOVRI through partnership agreements with pharmaceutical companies outside the United States. We expect selling, general and administrative expenses to increase as we continue to support the commercialization of GOCOVRI. In addition, we expect to continue to incur significant research and development expenses as we continue to advance our product candidates through preclinical and clinical development. Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to predict future revenue, the timing or amount of expenses incurred, or when, or if, we will be able to achieve or maintain profitability. We believe that period to period comparisons of our revenue, expenses and operating results are not a good indication of our future performance. As of June 30, 2018, we had an accumulated deficit of $280.7 million.

Prior to 2017, we raised an aggregate of approximately $202.3 million in sales of equity securities. 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 the $50.0 million. As of June 30, 2018, no shares had 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 a total of $100.0 million. In January 2018, we raised $134.3 million in net proceeds from the sale of 3,450,000 shares of common stock in a follow-on public offering.

Revenue

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

Prior to the generation of product sales from GOCOVRI, our revenue had been generated primarily from payments under our license agreement with Allergan for non-refundable upfront license payments, milestone payments, reimbursements for research and development expenses and full-time equivalents assigned under our license agreement with Allergan. There are no further milestone payments to be earned under our license agreement with Allergan, and we expect reimbursements for full-time equivalents assigned to the license agreement to be inconsequential in future periods. Beginning in May 2020, we are entitled to receive tiered royalties from Allergan in the low to mid-teens, as a percent of net sales of Namzaric in the United States.

Cost of product sales

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

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Research and development expenses

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

Research and development expenses consist of:

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

The following table summarizes our research and development expenses incurred during the three and six months ended June 30, 2018 and 2017 (in thousands):

| | Three Months Ended June 30, | | Increase (Decrease) | Six Months Ended June 30, | | Increase (Decrease) |
|---|---|---|---|---|---|---|
| | 2018 | 2017 | | 2018 | 2017 | |
| GOCOVRI(1) | $7,107 | $4,864 | $ 2,243 | $12,689 | $10,546 | $ 2,143 |
| ADS-4101 | 1,426 | 1,924 | (498) | 2,363 | 2,976 | (613) |
| Other research and development expenses | 1,273 | 388 | 885 | 1,942 | 742 | 1,200 |
| Total research and development expenses | $9,806 | $7,176 | $ 2,630 | $16,994 | $14,264 | $ 2,730 |

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

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 patients with multiple sclerosis, or MS Walking, and other Parkinson's disease indications earlier in the Parkinson's disease treatment journey; ADS-4101 for the treatment of partial onset seizures in patients with 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

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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 supporting 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 remain significant and continue to increase as we continue to support the commercialization of GOCOVRI.

Interest and other income, net

Interest and other income, net, consists of changes in fair value of the embedded derivative liability related to our Royalty-Backed Loan with HCRP, in addition to interest received on our investments.

Interest expense

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

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. 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 – Basis of Presentation and 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 six months ended June 30, 2018, 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, 2017.

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Results of operations

Comparison of the three and six months ended June 30, 2018 and 2017

The following table summarizes our results of operations for the three and six months ended June 30, 2018 and 2017 (in thousands, except percentages):

| | Three Months Ended June 30, | | Increase (Decrease) | % Increase (Decrease) | Six Months Ended June 30, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|---|---|---|---|
| | 2018 | 2017 | | | 2018 | 2017 | | |
| Product sales | $7,565 | $ — | $ 7,565 | NM | $10,118 | $ — | $ 10,118 | NM |
| License and grant revenue | — | 2 | (2) | (100)% | — | 2 | (2) | (100)% |
| Cost of product sales | 73 | — | 73 | NM | 98 | — | 98 | NM |
| Research and development expenses | 9,806 | 7,176 | 2,630 | 37 % | 16,994 | 14,264 | 2,730 | 19 % |
| Selling, general and administrative expenses, net | 27,699 | 13,115 | 14,584 | 111 % | 54,062 | 22,259 | 31,803 | 143 % |
| Interest and other income, net | 1,132 | 222 | 910 | 410 % | 2,010 | 426 | 1,584 | 372 % |
| Interest expense | 5,112 | 729 | 4,383 | NM | 9,938 | 729 | 9,209 | NM |

NM – Not meaningful.

Product sales

Product sales of $7.6 million and $10.1 million for the three and six months ended June 30, 2018, respectively, consist of sales of GOCOVRI, which was approved by the FDA on August 24, 2017. We commenced shipments of GOCOVRI during October 2017 and fully launched with a deployed sales force in January 2018.

Cost of product sales

Cost of product sales of $73,000 and $98,000 for the three and six months ended June 30, 2018, is related to certain fill finish costs incurred after FDA approval related to the cost of GOCOVRI products sold, in addition to certain distribution and overhead costs. Prior to receiving regulatory approval for GOCOVRI from the FDA in August 2017, we recorded all inventory costs incurred in the manufacture of GOCOVRI to be sold upon commercialization as research and development expense. We expect to use inventory expensed to research and development within the next two years, and accordingly we expect our cost of product sales of GOCOVRI to increase as a percentage of net sales in future periods once this inventory has been sold and we produce and then sell inventory that reflects the full cost of manufacturing the product.

Research and development expenses

Research and development expenses increased by $2.6 million, or 37%, to $9.8 million for the three months ended June 30, 2018 from $7.2 million for the three months ended June 30, 2017. The increase in research and development expenses was mainly attributable to our Phase 3 registration trials in support of ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis. The increase was offset in part by decreased costs related to manufacturing of GOCOVRI for the treatment of dyskinesia in patients with Parkinson’s disease, due to our policy of expensing such costs prior to regulatory approval and capitalizing such costs thereafter, in addition to a decrease in personnel related costs. Included in research and development expenses was stock-based compensation expense, which was $0.7 million for the three months ended June 30, 2018 compared to $0.9 million for the three months ended June 30, 2017.

Research and development expenses increased by $2.7 million, or 19% to $17.0 million for the six months ended June 30, 2018 from $14.3 million for the six months ended June 30, 2017. The increase in research and development expenses was mainly attributable to our Phase 3 registration trials in support of ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis. The increase was offset in part by decreased costs related to manufacturing of GOCOVRI for the treatment of dyskinesia in patients with Parkinson’s disease, due to our policy of expensing such costs prior to regulatory approval and capitalizing such costs thereafter, in addition to a decrease in

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personnel related costs. Included in research and development expenses was stock-based compensation expense, which was $1.5 million for the six months ended June 30, 2018 compared to $1.7 million for the six months ended June 30, 2017.

Selling, general and administrative expenses, net

Selling, general and administrative expenses, net, increased by $14.6 million, or 111%, to $27.7 million for the three months ended June 30, 2018 from $13.1 million for the three months ended June 30, 2017. The increase in selling, general and administrative expenses, net, was primarily due to increased costs associated with the commercialization of GOCOVRI, which we made available for physician and patient use in the fourth quarter of 2017 and commenced the full commercial launch in January 2018. The overall increase consists of a $4.7 million increase for personnel related costs, including $0.6 million for stock-based compensation expense, due to additional headcount, and a $9.9 million increase for expenses including GOCOVRI promotional costs, market research, and other professional services.

Selling, general and administrative expenses, net, increased by $31.8 million, or 143% to $54.1 million for the six months ended June 30, 2018 from $22.3 million for the six months ended June 30, 2017. The increase in selling, general and administrative expenses, net, was primarily due to increased costs associated with the commercialization of GOCOVRI, which we made available for physician and patient use in the fourth quarter of 2017 and commenced the full commercial launch in January 2018. The overall increase consists of a $10.7 million increase for personnel related costs, including $1.5 million for stock-based compensation expense, due to additional headcount, and a $21.1 million increase for expenses including GOCOVRI promotional costs, market research, and other professional services.

Interest and other income, net

Interest and other income, net, for the three and six months ended June 30, 2018 was $1.1 million and $2.0 million, respectively, compared to $0.2 million and $0.4 million for the three and six months ended June 30, 2017, respectively. The increase in interest and other income, net, for both the three and six months ended June 30, 2018, was primarily due to interest income earned on investments. Also included in interest and other income, net, is a change in fair value of the embedded derivative liability related to our Royalty-Backed Loan with HCRP.

Interest expense

Interest expense for the three and six months ended June 30, 2018 was $5.1 million and $9.9 million, respectively, compared to $0.7 million in both the three and six months ended June 30, 2017. The increase in interest expense for both the three and six months ended June 30, 2018, was due to the interest expense incurred on the $100 million Royalty-Backed Loan entered into in May 2017 and borrowed in two tranches: $35 million in May 2017 and $65 million in December 2017.

Liquidity, capital resources and plan of operation

Since January 1, 2017, we have funded our operations primarily through sales of our common stock, our Royalty-Backed Loan with HCRP, and to a lesser extent through our license agreement with Allergan. 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 $50.0 million. As of June 30, 2018, no shares had been sold under the sales agreement. Also in May 2017, we entered into a Royalty-Backed Loan with HCRP, whereby we initially borrowed $35.0 million, followed by an additional $65.0 million received in the fourth quarter 2017 upon FDA’s recognition in the Orange Book of the seven-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. In January 2018, we completed a follow-on public offering of 3,450,000 shares of our common stock, which includes the exercise in full by the underwriters of their option to purchase 450,000 shares of common stock, at an offering price of $41.50 per share. Proceeds from the follow-on public offering were approximately $134.3 million, net of underwriting discounts, commissions, and offering-related transaction costs.

We made GOCOVRI available for physician and patient use in the fourth quarter of 2017, with a full commercial launch via the deployment of our sales team in January 2018. Prior to the generation of revenue from GOCOVRI, we had not generated any commercial revenue from the sale of our products. We expect to incur substantial

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and increasing losses for the foreseeable future. Our principal sources of liquidity were our cash, cash equivalents, and investments, which totaled $256.3 million and $176.4 million at June 30, 2018 and December 31, 2017, respectively. 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 12 months from the issuance of this quarterly report on Form 10-Q. However, it is possible that we will not achieve the progress that we expect, because revenues from GOCOVRI may be less than anticipated 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 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, the development of ADS-4101 for indications in epilepsy, for which we expect to initiate Phase 3 clinical trials in 2019, and development of additional product candidates. 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):

| | Six Months Ended June 30, | |
|---|---|---|
| | 2018 | 2017 |
| Net cash (used in) provided by: | | |
| Operating activities | $(57,383) | $(26,620) |
| Investing activities | (130,733) | 408 |
| Financing activities | 137,404 | 36,095 |
| Net increase (decrease) in cash and cash equivalents | $(50,712) | $9,883 |

Net Cash Used In Operating Activities

Net cash used in operating activities was $57.4 million for the six months ended June 30, 2018. Net loss of $69.0 million for the six months ended June 30, 2018, included net non-cash adjustments of $18.3 million, which consisted primarily of stock-based compensation of $7.9 million and interest expense of $9.9 million. The use of cash for the six months ended June 30, 2018 was primarily related to commercialization activities for GOCOVRI. Additionally, we used cash to fund research and development programs, including the development of ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis.

Net cash used in operating activities was $26.6 million for the six months ended June 30, 2017. Net loss of $36.8 million for the six months ended June 30, 2017, included net non-cash adjustments of $7.9 million, primarily related to $6.6 million of stock-based compensation. The primary use of cash for the six months ended June 30, 2017, was to fund activities in support of the NDA and pre-commercial activities in preparation for the commercialization of GOCOVRI, formerly referred to as ADS-5102, for the treatment of dyskinesia in patients with Parkinson's disease. Additionally, cash was used to fund development of ADS-4101 for indications in epilepsy.

Net Cash Provided By (Used In) Investing Activities

Net cash used in investing activities was $130.7 million for the six months ended June 30, 2018 as a result of net purchases of available-for-sale securities of $130.2 million and purchases of property and equipment of $0.5 million.

Net cash provided by investing activities was $0.4 million for the six months ended June 30, 2017. In the six months ended June 30, 2017, we received $1.0 million as a result of net maturities of available-for-sale securities, offset in part by $0.6 million in purchases of property and equipment.

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Net Cash Provided By Financing Activities

Net cash provided by financing activities was $137.4 million for the six months ended June 30, 2018. In the six months ended June 30, 2018, we received net cash proceeds of $134.3 million related to the sale of common stock under a follow-on public offering; in addition, we received cash proceeds of $3.1 million related to the exercise of stock options and purchases of common stock under the Employee Stock Purchase Plan.

Net cash provided by financing activities was $36.1 million for the six months ended June 30, 2017. In the six months ended June 30, 2017, we received net proceeds of $34.5 million from long-term debt and received cash proceeds of $1.6 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 non-cancelable contractual obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2017 that was filed with the SEC on February 22, 2018. Other than the following, there have been no material changes outside the ordinary course of our business to our future non-cancelable contractual obligations during the six months ended June 30, 2018. On January 16, 2018, we amended our lease agreement to extend our lease until April 30, 2025, and relocate within the current building from the seventh to the tenth and eleventh floors, containing approximately 37,626 rentable square feet. The initial monthly lease payments are $160,000, increasing to $197,000 in the final year of the agreement, with a lease abatement for the first three months of the lease term. Monthly lease payments prior to this amendment were approximately $53,000, with the lease expiring April 30, 2020. We expect to relocate the company in the third quarter of 2018.

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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 June 30, 2018, we had cash, cash equivalents, and investments of $256.3 million, compared to $176.4 million at December 31, 2017, 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 1% 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 June 30, 2018. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2018, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended June 30, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

Risks related to the commercialization of GOCOVRI™ (amantadine) extended release capsules (formerly ADS-5102)

Our success depends heavily on successful commercialization of GOCOVRI, which received approval in August 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 in 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. 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 physicians, patients and the healthcare community;
- the acceptance of pricing and placement of GOCOVRI on payers' formularies and the associated tiers;
- 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:

- its efficacy, duration of response, and potential advantages compared to alternative treatments;

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- the prevalence and severity of any side effects;
- the acceptability of the price of GOCOVRI relative to other treatments;
- the willingness of physicians to change their current treatment practices;
- its 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 our 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.

If we are unable to effectively market, promote, sell, and distribute GOCOVRI and to retain experienced commercial personnel, our business will be substantially harmed.

We currently have limited experience in marketing, selling and distributing pharmaceutical products. With respect to GOCOVRI in particular, it is a newly marketed drug and 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. Therefore, none of the members of our recently hired commercial team, including our sales force, has ever promoted GOCOVRI prior to its launch, and we have only recently established our distribution and reimbursement capabilities, all of which will be necessary to successfully commercialize GOCOVRI. As a result, we will be required to expend significant time and resources to market, sell, and distribute GOCOVRI to neurologists and movement disorder specialists in a credible, persuasive, and compliant manner consistent with applicable laws. There is no guarantee that the strategies, tactics and marketing messages, or the distribution and reimbursement capabilities, that we have developed will be successful. Specifically, for distribution of GOCOVRI, we are heavily dependent on third-party logistics, pharmacy and distribution partners. If they are unable to perform effectively or if they do not provide efficient distribution of the medicine to patients, our business will suffer. Also, if we are unable to effectively market and sell GOCOVRI for any reason, including ineffective training of our sales force or equipping them with ineffective 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 could be put in jeopardy.

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

Our ability to commercialize GOCOVRI successfully in the United States will depend in part on the extent to which coverage and reimbursement for GOCOVRI 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 reimbursement discussions are currently ongoing with payers. Coverage and adequate reimbursement from both governmental healthcare programs, such as Medicare and Medicaid, and commercial payers are critical to GOCOVRI's commercial success. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or cheaper therapeutic alternatives are already available or subsequently become available. For example, even though other versions of amantadine are not approved for dyskinesia, some payers have asked physicians if patients have had prior experience with such versions or required that physicians actually prescribe such versions prior to providing reimbursement for GOCOVRI.

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

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As with any newly approved medicine for a particular indication, there may be significant delays in obtaining final coverage and reimbursement decisions for GOCOVRI. Third-party payers are increasingly challenging the price and reviewing the cost-effectiveness of medical drug products, in addition to questioning their safety and efficacy. Coverage and reimbursement decisions for GOCOVRI by third-party payers are generally subject to change and may not be permanent.

Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs, such as the federal 340B Drug Pricing Program, or by private third-party payers and could also be adversely affected 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 and adequate reimbursement rates from both government-funded and private third-party payers for GOCOVRI could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

We face substantial competition in the commercialization of GOCOVRI.

The commercialization of new pharmaceutical products is highly competitive, and we face substantial competition with respect to GOCOVRI. For example, although GOCOVRI is the first and only FDA-approved medicine for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, we face competition from various drugs approved for the treatment of Parkinson’s disease, 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 (Schwartz Pharma, Mylan and others), Rytary (Impax), Duopa (AbbVie), Xadago (Newron Pharmaceuticals S.p.A.), Osmolex ER (Osmotica Pharmaceuticals, LLC) and immediate release amantadine. Other products in late stage development for Parkinson’s disease includes product candidates from Acorda, Mitsubishi Tanabe, Bial-Portela CSA, Genervon Biopharmaceuticals, and Pharma Two B. 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 Novartis, Avanir Pharmaceuticals, Neurolixis, Amarantus BioScience, Addex Pharma, and Neurim Pharmaceuticals Ltd. In addition, GOCOVRI faces competition from the medical strategies historically used by physicians to manage dyskinesia, such as levodopa dose fractionation.

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

Also, GOCOVRI may face competition from other extended release versions of amantadine approved by the FDA or that may be in development, even if not approved for the treatment of dyskinesia in patients with Parkinson’s disease or approved without new clinical efficacy and safety data. For example, on February 16, 2018, the FDA approved Osmolex ER (amantadine) extended release tablets, manufactured by Osmotica Pharmaceuticals, LLC, for the treatment of Parkinson’s disease and drug-induced extrapyramidal reactions in adult patients.

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

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 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 seven years of orphan drug exclusivity. The FDA has

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recognized GOCOVRI's orphan drug exclusivity by letter to us on its Orphan Drug Designation and Approvals database listing and the Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.

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 or more effective or makes a major contribution to patient care, or if we are unable to assure that sufficient quantities of medicine are available to meet patient needs. If we are unable to maintain orphan drug exclusivity for GOCOVRI for the treatment of dyskinesia, our business would be substantially harmed.

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 Orange Book or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon notice of a paragraph IV challenge, a patent 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. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. 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.

The ANDA process can 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. If this were to occur with respect to GOCOVRI or products with which it competes, our business would be materially harmed. Furthermore, even if ultimately successful, ANDA litigation can take several years and is generally time-consuming and costly. Such litigation has been commenced by us to enforce certain patents related to GOCOVRI. See Litigation and Other Legal Proceedings in "Note 7 – Commitments and Contingencies" in the accompanying "Notes to Condensed Consolidated Financial Statements (unaudited)" for more information.

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

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

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

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

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- sales of GOCOVRI may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

Further, GOCOVRI may also be affected by the safety and tolerability of its parent drug or drugs with similar mechanisms of action. Although amantadine, which is a component of GOCOVRI, has been used in patients for many years, 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, their patients or payers. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. If we cannot successfully defend ourselves against claims that GOCOVRI caused injuries, we will incur substantial liabilities. 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.

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 2017 approval of GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, we currently are permitted to market or promote it 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. 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 to obtain regulatory approval for such uses. Additionally, our current 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.

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

The FDA and other regulatory agencies, including regulatory authorities outside the United States, strictly regulate the marketing and promotional claims that are made about drug products, such as GOCOVRI. In particular, promotion 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 the Centers for Medicare and Medicaid Services, or CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries/recipients of these programs. 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 $18,107 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

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other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

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

GOCOVRI is 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.

Risks related to our product candidates in clinical development

Our success depends on the timely clinical 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 will face risks in the development of ADS-5102 (GOCOVRI) for additional indications, ADS-4101 and other product candidates.

There are risks associated with pursuing clinical trials in other indications for ADS-5102 (GOCOVRI), ADS-4101 and other product candidates, as we may experience numerous unforeseen events during, or as a result of clinical studies that could harm our ability to commercialize such products and candidates or to receive regulatory approval, including that:

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- 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, or CROs, and contract manufacturing organizations, or CMOs, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies for various reasons, including a finding that our 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;
- the supply or quality of ADS-5102, ADS-4101, or other materials necessary to conduct clinical studies may be insufficient or inadequate; and
- our new product discovery or research program may not be successful or warrant clinical development.

With respect to the development of additional indications for GOCOVRI, 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 that could lead to changes in the GOCOVRI prescribing information. 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.

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.

Failure to gain approval of or successfully commercialize our product candidates in the United States could substantially harm our business.

Our product candidates will face the same or similar challenges in obtaining FDA approval and in commercialization as GOCOVRI, as outlined above, including but not limited to market acceptance by physicians and patients and coverage and reimbursement by third party payers.

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Failure to obtain regulatory approvals in foreign jurisdictions would 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, or EU, 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 EMA, 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 United States, both MA 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 current good manufacturing practices, or 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 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 cGMP 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

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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 or 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 or product candidates 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;

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- 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 Namzaric, which would negatively impact any royalties we may 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.

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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 regulatory approvals. In August 2017, GOCOVRI was FDA-approved for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The FDA will need to approve supplemental NDAs for GOCOVRI before we can market the drug for other indications, such as 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, or IRB, Data Safety Monitoring Board, or DSMB, Data Monitoring Committee, or DMC, or the FDA that the clinical trial exposes subjects or patients to an unacceptable health risk;
- disapproval of our or our third-party manufacturer's processes or facilities; or
- changes to FDA's approval policies or regulations.

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

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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, or 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

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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 Patient Protection and Affordable Care Act ("PPACA") was passed, which has substantially changed how healthcare is financed by both governmental and private insurers, and has significantly impacted the U.S. pharmaceutical industry. Details of changes under the PPACA are discussed in the business heading "Other healthcare regulations" in Part I, Item 1, of our 2017 Annual Report on Form 10-K.

Some of the provisions of the PPACA have yet to be fully implemented, and there have been legal and political challenges to certain aspects of the PPACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-

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based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 23, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans. Moreover, in July 2018, CMS announced that it has suspended further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program pending the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which will be fully implemented in 2019. At this time it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

In addition, 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.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, have been designed to encourage importation from other countries and bulk purchasing.

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

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

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

Our ability to commercialize our products successfully, and to attract commercialization partners for our products, will depend in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the United States, governmental payers such as the Medicare and Medicaid programs,

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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 2017 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 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 2017 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,

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

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

Healthcare providers, physicians, distributors, and third-party payers play a primary role in the distribution, recommendation, and prescription of any pharmaceutical product for which we obtain marketing approval. Our arrangements with third-party payers and customers expose us to broadly applicable federal and state fraud and abuse and other laws and regulations that may constrain the business or financial arrangements through which we market, sell and distribute GOCOVRI and other products for which we may obtain marketing approval. The laws and regulations that may affect our ability to operate include:

- the federal healthcare program Anti-Kickback Statute, 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 and criminal false claims laws, and civil monetary penalties laws, including 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, or 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, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which impose obligations on HIPAA covered entities and their business associates, including mandatory contractual terms and required implementation of administrative, physical and technical safeguards to maintain the privacy and security of individually identifiable health information;
- the federal Physician Payments 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,

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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, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these or other laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, and fraud laws may prove costly.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. Moreover, the requirements governing drug pricing and reimbursement vary widely from country to country. 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, or 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.

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

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

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

In the EU, the General Data Protection Regulation (GDPR) took effect on May 25, 2018, introducing sweeping new data protection requirements that carry potential fines of up to the greater of 20 million Euros or 4% of annual global revenue. The GDPR introduces strict requirements for processing personal data, including potentially burdensome documentation requirements, more stringent requirements for obtaining valid consent, obligations to honor expanded rights of individuals to control the use and retention of their personal data, and requirements to notify regulators and affected individuals of certain personal data breaches. The GDPR also imposes heightened restrictions on processing of sensitive personal data, such as health and genetic data. In addition, the GDPR prohibits the transfer of personal data to countries outside of the European Economic Area (EEA), such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, they are subject to pending legal challenges that, if successful, could invalidate these mechanisms, restrict our ability to process personal data of Europeans outside of Europe and adversely impact our business. The GDPR will increase our responsibility and potential liability in relation to personal data that we process, expose us to substantial potential fines violations, increase our compliance costs and could restrict our operations in Europe. 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.

Risks related to intellectual property

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

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to GOCOVRI and our product candidates. We have

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sought to protect GOCOVRI and our product candidates 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.

Current 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 and/or uncertain, 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, 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 continued 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

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from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

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

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

Filing, prosecuting, and defending patents on all of our 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 if unsuccessful could materially harm our business.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property for GOCOVRI, our partnered products, and our product candidates. 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 and Namenda XR. In addition, on February 16, 2018, Osmotica Pharmaceuticals LLC and Vertical Pharmaceuticals LLC ("Osmotica") filed an action against us in U.S. District Court for the state of Delaware, requesting a declaratory judgment that Osmotica's newly-approved product Osmolex ER™ (amantadine) extended release tablets does not infringe certain of our patents. This action is ongoing and is in an early stage.

We anticipate that the prosecution of the lawsuits related to our partnered products and any lawsuits related to GOCOVRI 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 product in question. An adverse result in any litigations or proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Such a result could limit our ability to prevent others from using or

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commercializing similar or identical products, limit our ability to prevent others from launching generic versions of our products and could limit the duration of patent protection for our products, all of which could have a material adverse effect on our business. Also, a successful challenge to our patents could reduce or eliminate our right to receive royalties from 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.

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Risks related to Namzaric®

Under our license agreement with Allergan, if Allergan fails to successfully commercialize Namzaric for any reason or if the license agreement with Allergan is terminated, the 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 and Namzaric in the United States. Under that agreement, we expect to receive future royalties from Allergan on the net sales of Namzaric, starting in 2020. If for any reason Allergan fails to successfully commercialize Namzaric, on which we are eligible to receive double digits percentage royalties, we may not receive such future royalties or receive minimal amounts, and our business will be harmed. We are also eligible to receive royalties on net sales of Namenda XR beginning in June 2018, but we do not expect to receive such royalties, due to the entry of generic versions Namenda XR.

Under the license agreement, we are reliant on Allergan to commercialize Namzaric 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 have been involved in ANDA litigation to enforce our intellectual property rights against generic manufacturers, who are seeking to bring generic versions of Namenda XR and Namzaric to the market. See Litigation and Other Legal Proceedings 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 Namzaric, 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 and Namzaric. This could harm our business.

Based on adverse trial and appellate court rulings to date with respect to Namenda XR, we do not expect to receive royalties on net sales of Namenda XR due to the entry of generic versions Namenda XR. Additionally, based upon settlement agreements with all the ANDA filers for Namzaric, the earliest date on which any of these agreements grants a license to market generic version of Namzaric is January 1, 2025 or earlier in certain limited circumstances.

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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 have just begun to commercialize GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, in January 2018, and it will require substantial funds to 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. In May 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 June 30, 2018, we have not made any sales under this facility. As of June 30, 2018, we had approximately $256.3 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, our Royalty-Backed Loan with HealthCare Royalty Partners III, L.P., or HCRP, and, to a lesser extent, government grants, venture debt, and benefits from tax credits made available under a federal stimulus program supporting drug development. We 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 on favorable terms or at all, we may need to delay or reduce the scope of our research and clinical development programs or commercialization efforts. We do not have any committed external source of funds or other support for our development efforts. We expect to finance future cash needs through a combination of public or private equity offerings, debt financings, royalty financings, collaborations, strategic alliances, licensing arrangements, asset sales, and other marketing and distribution arrangements. 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

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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 HCRP, pursuant to which we initially borrowed $35 million and then borrowed an additional $65 million upon FDA approval and FDA's recognition in the Orange Book of the seven-year orphan drug exclusivity that GOCOVRI earned upon approval in August 2017, for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

Interest and principal on the loan will be payable from the proceeds of royalty on U.S. net sales of GOCOVRI and up to $15 million of our annual royalties from Allergan on U.S. net sales of Namzaric starting in May 2020. The HCRP notes mature in December 2026, if not earlier repaid.

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

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 Namzaric, or the establishment of potential future collaboration and license agreements, if any, and the achievement of any upfront or milestone payments provided thereunder. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including:

- 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;

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- 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 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, scientific, and commercial 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. 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 June 30, 2018, we had 153 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred

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in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. Investors should consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

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

As of December 31, 2017, we had federal and state net operating loss carryforwards of $163.3 million and $131.3 million, respectively. The federal net operating loss carryforwards will begin to expire, if not utilized, beginning in 2025, and the state net operating loss carryforwards began to expire in 2016. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. It is possible that we have experienced an ownership change limitation. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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 $700 million as of the prior June 30$^{th}$, 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.

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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;
- compliance with privacy laws;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes or typhoons, floods, and fires.

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

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, specialty pharmacy, distributors, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we are not aware of any 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

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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 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 commercial-stage operations, we have selected and implemented a number of company-wide information systems, and may select and implement additional systems in the future, including adding new functionality to our enterprise resource planning, or 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. Any deficiencies in the design and implementation of these systems could result in potentially much higher costs than we had anticipated 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 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;

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- 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.

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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 acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may issue, without stockholder approval, shares of undesignated preferred stock, and the ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting

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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.

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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.

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ITEM 6. EXHIBITS

EXHIBIT INDEX

| Exhibit Number | Exhibit Description | Incorporation By Reference | | | | Filed / Furnished Herewith |
|---|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date | |
| 3.1 | Amended and Restated Certificate of Incorporation of Adamas Pharmaceuticals, Inc. | 8-K | 001-36399 | 3.1 | 4/15/2014 | |
| 3.2 | Amended and Restated Bylaws of Adamas Pharmaceuticals, Inc. | S-1 | 333-194342 | 3.4 | 3/5/2014 | |
| 4.1 | Reference is made to Exhibits 3.1 through 3.2. | | | | | |
| 4.2 | Form of Common Stock Certificate of Adamas Pharmaceuticals, Inc. | S-1 | 333-194342 | 4.1 | 3/26/2014 | |
| 4.3 | 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 | |
| 10.1 | 2018 compensation actions with respect to Non-Employee Directors. | | | | | X |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended. | | | | | X |
| 31.2 | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended. | | | | | X |
| 32.1 | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(1) | | | | | X |
| 101.INS | 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 | | | | | |

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|---|---|
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

(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.

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SIGNATURES

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

Adamas Pharmaceuticals, Inc.
(Registrant)

Date: August 2, 2018 /s/ Gregory T. Went, Ph.D.
Gregory T. Went, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 2, 2018 /s/ Alfred G. Merriweather
Alfred G. Merriweather
Chief Financial Officer
(Principal Financial Officer)