



2020 ANNUAL REPORT

Making everyday life significantly better for people affected by neurological diseases.





Neil F. McFarlane
CEO, Adamas

Dear Shareholders,

It has been a notable year since my last letter to you, remarkable for its unexpected challenges but also for exceptional performance and results. I am proud of the way our team at Adamas successfully navigated 2020 by swiftly adapting to the ever-changing environment, while continuing to remain laser-focused on our mission to serve patients.

I am pleased with the significant progress Adamas achieved in 2020 and continues to realize in 2021. We have delivered strong performance, expanded our neurology portfolio, and strengthened the company's foundation. We increased our revenue by 36%, with strong sales growth that reflects the disciplined and consistent execution of our commercial strategy to advance our strategic priorities, implemented in late 2019.

Adamas has accomplished a great deal in the past year, with several key milestones driving our success. We filed a supplemental new drug application for GOCOVRI in 2020, receiving FDA-approval earlier this year. This approval adds a second indication for GOCOVRI as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing OFF episodes. This is a significant and exciting accomplishment, doubling the size of the patient population for which GOCOVRI is indicated. GOCOVRI is now the first and only medication approved to treat OFF and dyskinesia motor complications in Parkinson's disease—both of which significantly impact patients' daily lives.

In early 2021, we acquired the global rights to OSMOLEX ER and integrated it into our product portfolio, ensuring patients received uninterrupted care. This endeavor demonstrated our ability to integrate and commercialize new products. During this integration, we remain strongly committed to optimizing our first commercial product, GOCOVRI.

We demonstrated the robustness of our intellectual property by settling patent litigation, giving us the confidence to invest in GOCOVRI's future growth. To expand our operational strength and industry expertise, we bolstered our senior leadership team and Board of Directors with additional members, putting the right people in place to lead us into future growth.

We entered 2021 with optimism, and looking ahead we remain focused on our mission, executing and investing to deliver value to patients and shareholders. We are building upon our performance and leveraging our operational capabilities for growth. Our team is working diligently to advance the business in line with our corporate strategy, accelerating our ability to bring our products to a greater number of patients, while navigating an environment which remains fluid and uncertain.

I would like to express my deep appreciation to all the patients and healthcare professionals who work with us, as well as our partners, dedicated Board of Directors, and employees. Their resilience, agility, and commitment to making a positive impact on patients' lives are central to our success. Their efforts have enabled us to drive into 2021 with a multi-product portfolio, improved execution, a long-term strategic plan, and high confidence in our ability to deliver sustainable long-term growth.

I am grateful for our shareholders' confidence in Adamas and our future. Your support has helped us get where we are today, and we will rely on you to help us achieve our goal of becoming a fully integrated pharmaceutical company with a leading portfolio and pipeline of therapies that transform the lives of people living with neurological diseases.

Sincerely,

Neil F. McFarlane
Chief Executive Officer



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

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

For the Fiscal Year Ended December 31, 2020

or

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

Commission file number: 001-36399

ADAMAS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

42-1560076

(I.R.S. Employer Identification No.)

1900 Powell Street, Suite 1000, Emeryville, CA 94608

(Address of principal executive offices) (Zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class Common Stock, par value \$0.001 per share	Trading Symbol(s) ADMS	Name of each exchange on which registered The Nasdaq Global Market
---	----------------------------------	--

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☒

Emerging growth company ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. and just one check box. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was \$60,114,071 computed by reference to the last sales price of \$2.56 as reported by the Nasdaq Global Market, as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2020. Shares of common stock held by each officer and director, and each entity affiliated with a director, have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of February 16, 2021, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 30,568,421.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to the definitive proxy statement for the registrant's 2021 Annual Meeting of Stockholders, to be filed within 120 days of the registrant's fiscal year ended December 31, 2020.

ADAMAS PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2020
TABLE OF CONTENTS

	<u>Page</u>
Part I	
Item 1. Business	4
Item 1A. Risk Factors	22
Item 1B. Unresolved Staff Comments	44
Item 2. Properties	44
Item 3. Legal Proceedings	44
Item 4. Mine Safety Disclosures	44
Part II	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	45
Item 6. Selected Financial Data	45
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	46
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	56
Item 8. Financial Statements and Supplementary Data	57
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	92
Item 9A. Controls and Procedures	92
Item 9B. Other Information	93
Part III	
Item 10. Directors, Executive Officers and Corporate Governance	94
Item 11. Executive Compensation	94
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	94
Item 13. Certain Relationships and Related Transactions, and Director Independence	94
Item 14. Principal Accountant Fees and Services	94
Part IV	
Item 15. Exhibit and Financial Statement Schedules	95
Item 16. Form 10-K Summary	98
Signatures	99

“Adamas Pharmaceuticals,” our logo and other trade names, trademarks and service marks of Adamas appearing in this report are the property of Adamas. Other trade names, trademarks and service marks appearing in this report are the property of their respective holders.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the sections titled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases you can identify these statements by forward-looking words, such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “potential,” “seek,” “expect,” “goal” or the negative or plural of these words or similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectations as to the extent to which we will be able to continue to commercialize GOCOVRI[®] (amantadine) extended release capsules, OSMOLEX ER[®] (amantadine) extended release tablets, and any of our other product candidates that are approved;
- the anticipated scope, rate of progress and cost of our preclinical studies and clinical trials and other research and development activities that we may pursue;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectations as to the sufficiency of our capital resources;
- our expectations as to our ability to obtain and maintain intellectual property protection for our products and any of our product candidates;
- our expectation as to the legal proceedings and related stays and terms of settlements;
- the anticipated receipt and timing of any royalties from our collaborators;
- our expectations as to the revenues from our collaborations;
- our expectations as to our ability to retain and recruit key personnel;
- our anticipated financial performance; and
- our anticipated developments and projections relating to our competitors or our industry.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this report and the documents that we reference in this report and have filed with the Securities and Exchange Commission as exhibits to this report with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

RISK FACTOR SUMMARY

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading “Item 1A. Risk Factors” below.

- The outbreak of the novel Coronavirus (“COVID-19”) has negatively impacted our business, including the commercialization strategy and sales of GOCOVRI® (amantadine) extended release capsules.
- Our success depends heavily on the success of GOCOVRI for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, and as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing OFF episodes. To the extent GOCOVRI is not commercially successful, our business, financial condition and results of operations will be materially harmed.
- If we are unable to recruit and retain qualified personnel and third-party distributors, our business will be substantially harmed.
- 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.
- We face substantial competition in the commercialization of GOCOVRI.
- 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.
- If manufacturers obtain approval for generic versions of GOCOVRI, or of products with which we compete, our business may suffer.
- If we are found to have improperly promoted GOCOVRI, or if physicians misuse it, we may be subject to restrictions on the sale or marketing of GOCOVRI and significant fines, penalties, sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.
- GOCOVRI is complex to manufacture, and manufacturing disruptions may occur that could cause us to experience disruptions in the supply of GOCOVRI.
- Risks related to the commercialization of GOCOVRI will be substantially the same for OSMOLEX ER® (amantadine) extended release tablets.
- We may in the future seek to acquire additional product candidates, which may subject us to additional risks and expense.
- We rely on third-party organizations to manufacture, supply, and distribute GOCOVRI. If one of these organizations fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new third-party vendors and/or face delays in the commercialization and supply of GOCOVRI.
- We rely on a single-source third-party contract manufacturing organization for the manufacture and supply of drug product for GOCOVRI.
- 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.
- Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payer cost-containment initiatives and current societal pressures regarding pharmaceutical product pricing, may negatively impact our ability to generate revenues from or could limit or prevent our products’ commercial success.

- We are subject to ongoing regulatory obligations and regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.
- If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations, and financial condition could be adversely affected.
- 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.
- 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.
- The regulatory approval process is expensive, time consuming, and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates.
- Our ability to successfully commercialize GOCOVRI and any product candidates may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our products and product candidates.
- We may not be able to protect our intellectual property rights throughout the world.
- 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.
- Under our license agreement with Allergan, if Allergan fails to successfully commercialize NAMZARIC for any reason or if the license agreement with Allergan is terminated, the royalties we are eligible to receive under our license agreement with Allergan may not occur or may be minimal, and would have a negative impact on our revenue potential and harm our business.
- We are the subject of litigation claiming violation of Federal and state false claims acts in connection with the commercialization of NAMENDA XR and NAMZARIC by Allergan, which may have a material and negative impact on our business.
- 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.
- 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 outstanding debt backed by three of our principal assets, GOCOVRI, OSMOLEX ER, 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.

PART I

ITEM 1. BUSINESS

Overview

At Adamas Pharmaceuticals, Inc., our mission is to make everyday life significantly better for people affected by neurological diseases. We are a fully integrated company focused on growing a portfolio of therapies to address a range of neurological diseases. With commercial and partnered medicines, we are focused on supporting our patient community and growing a portfolio of differentiated neurological therapies. We combine our proven expertise in discovery, development and commercialization with our passion for improving lives to deliver innovative medicines to reduce the burden of neurological diseases on patients, caregivers, and society. Currently, we are primarily focused on the commercialization of GOCOVRI in the United States. Additionally, we are integrating OSMOLEX ER, which we acquired on January 4, 2021, and are commercializing the product in the United States.

GOCOVRI® (amantadine) extended release capsules is the first and only FDA-approved medicine indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, and as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing OFF episodes. GOCOVRI was approved for marketing by the U.S. Food and Drug Administration, or FDA, on August 24, 2017 for its initial indication to treat dyskinesia. On February 1, 2021, we announced we had received marketing authorization from the FDA for a supplemental New Drug Application (sNDA) for GOCOVRI, gaining a second indication for the product as an adjunctive treatment for OFF episodes. The recent update to the label indication makes GOCOVRI the only medicine clinically proven and approved to reduce both OFF and dyskinesia in Parkinson's patients taking a levodopa-based medication, resulting in a clinically meaningful increase in good ON time. On June 17, 2020, we announced that we had discontinued further development of (ADS-5102) a potential additional indication for GOCOVRI for the treatment of walking impairment in patients with multiple sclerosis ("MSW").

OSMOLEX ER® (amantadine) extended release tablets, was approved by the FDA on February 16, 2018, for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions in adult patients. On January 4, 2021, we acquired the global rights to OSMOLEX ER from Osmotica Pharmaceuticals US LLC, a subsidiary of Osmotica Pharmaceuticals plc.

NAMZARIC® (memantine hydrochloride extended release and donepezil hydrochloride) capsules for the treatment of moderate to severe dementia of an Alzheimer's type, is marketed in the United States by Allergan plc under an exclusive license agreement between us and Forest Laboratories Holdings Limited ("Forest"), an indirect, wholly-owned subsidiary of Allergan plc (collectively, "Allergan"). We began recognizing royalty revenue on net sales of NAMZARIC in May 2020.

Going forward, we intend to expand our product pipeline by acquiring, through license or otherwise, additional candidates for research and development and potential commercialization.

Our Strategy

Our business strategy is to discover, develop, and commercialize clinically differentiated medicines for patients suffering from chronic neurological diseases. We have built a portfolio of approved products that we have commercialized through our own specialty sales force, or through partnerships. We are focused on:

Maximizing the potential of our GOCOVRI brand for patients: By executing our three commercial strategic priorities: first, to raise the urgency to diagnose and treat by educating physicians and patients on the functional disruption caused by OFF and dyskinesia, and the challenges with managing one without worsening the other; second, to differentiate to drive adoption by communicating the unique clinical profile, label, and health economic value, thereby ensuring appropriate patients are started on therapy; and third, to improve access and fulfillment, ensuring the new expanded indication is covered by payers, and by enhancing the overall customer experience through optimizing fulfillment and distribution.

Expanding our pipeline of neurological medicines: We have expanded our neurology portfolio with OSMOLEX ER which is approved for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions in adult

patients. Going forward we intend to align OSMOLEX ER positioning with its FDA-approved label, ensuring clear differentiation of GOCOVRI and OSMOLEX ER to provide distinct patient populations with the best therapeutic solution for their symptoms while ensuring uninterrupted care to current OSMOLEX ER patients. We will continue to evaluate additional opportunities for pipeline and portfolio development.

Building a sustainable, fully integrated company: We aim to fully leverage our internal capabilities and industry experience in drug development and commercialization of neurological medicines. We intend to grow our capabilities and brand in line with our vision while operating with disciplined management of operating expenses. We are building a nimble and responsive organization that has rapidly and effectively embraced new ways of working in the ongoing COVID-19 pandemic.

Our Portfolio

Approved Products

GOCOVRI for the Treatment of OFF and Dyskinesia in Patients with Parkinson's Disease

Parkinson's disease (PD) is a chronic, progressive neurodegenerative disorder affecting close to one million people in the United States. It is caused by the gradual loss of brain cells that produce the neurotransmitter dopamine. PD is characterized by prominent motor symptoms including tremors, rigidity, bradykinesia and postural instability. As the disease progresses, people with PD taking levodopa-based therapy are likely to experience reemergence or sudden return of stiffness, rigidity and tremors, referred to as OFF episodes between medication doses, that may be unpredictable. The primary treatment for PD is with levodopa; however, over time levodopa may lead to involuntary, uncontrolled movements known as dyskinesia. Approximately 90 percent of people on levodopa therapy will eventually experience OFF and dyskinesia. We estimate approximately 200,000 people with PD currently experience dyskinesia (with or without OFF episodes), and a further 200,000 to 300,000 people with PD experience OFF episodes. This results in a total addressable market of 400,000 to 500,000 people with Parkinson's who may potentially benefit from GOCOVRI's full newly-expanded label. The abrupt and unpredictable transitions between episodes of OFF time, normal movement, and dyskinesia leads to considerable impact on patients' lives.

GOCOVRI® (amantadine) extended release capsules, is the first and only FDA-approved medication indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, and as adjunctive treatment for patients with Parkinson's disease taking levodopa/carbidopa experiencing OFF episodes. GOCOVRI, taken once daily at bedtime, provides an initial lag and a slow rise in amantadine concentration during the night, resulting in a high concentration from the morning and throughout the waking day, when OFF and dyskinesia occur. GOCOVRI has a time dependent amantadine release, utilizing a delayed release coating followed by an extended release coating (i.e., a DR/ER formulation) providing a high concentration in the morning that gradually falls throughout the day into the evening. Additionally, in the pivotal clinical trials, the adjunctive use of GOCOVRI did not require changes to dopaminergic therapies.

GOCOVRI was approved for marketing by the FDA on August 24, 2017, with seven years of orphan exclusivity and additional patent protections out to 2034. GOCOVRI was commercially launched in January 2018 for its initial indication to treat dyskinesia. On February 1, 2021, we announced that we had received marketing authorization from the FDA for a second indication for GOCOVRI, gaining a second indication for the product as an adjunctive treatment to levodopa/carbidopa in patients with PD experiencing OFF episodes. The GOCOVRI prescribing information states that GOCOVRI is not interchangeable with other amantadine immediate or extended release products.

On January 2, 2020, we announced we had granted Sandoz Inc. a license for its generic version of GOCOVRI as of March 4, 2030, which is over 12 years post GOCOVRI launch, or earlier in certain circumstances typical for such agreements. The agreement contains provisions that may accelerate the license date, including if unit sales of GOCOVRI for the 12-month period ending July 31, 2025 or any subsequent 12-month period decline by a specified percentage below GOCOVRI unit sales for the year ended December 31, 2019. On February 1, 2021, we announced we had granted Zydus a license for its generic version of GOCOVRI as of March 4, 2030. The agreement has similar terms as the Sandoz agreement, including the potential license acceleration provision. With these licenses granted to Sandoz and Zydus, the first filer ANDA challenges for GOCOVRI's two available strengths have now been settled.

In a robust clinical program consisting of three randomized, placebo-controlled studies and a two-year open label safety study, GOCOVRI demonstrated a durable reduction in dyskinesia and OFF time in people with Parkinson's disease. Specifically, the pooled data analysis (placebo adjusted) from the two positive Phase 3 pivotal trials of GOCOVRI demonstrates:

- A 27% decrease in dyskinesia compared to placebo at week 12 based on a 41% reduction in dyskinesia as measured on the Unified Dyskinesia Rating Scale total score, compared to 14% for placebo at week 12;
- A 36% reduction in OFF time (placebo adjusted), or approximately one hour per day; and
- A 29% increase or approximately 2.4 hours in 'good ON' time daily (ON time without troublesome dyskinesia).

The most common adverse reactions, which were reported by $\geq 10\%$ of patients receiving GOCOVRI, were hallucinations, dizziness, dry mouth, peripheral edema, fall, constipation, orthostatic hypotension, and urinary tract infection. Warnings and precautions with GOCOVRI include falling asleep during activities of daily living, suicidality and depression, hallucinations/psychotic behavior, dizziness and orthostatic hypertension, and impulse control/compulsive behaviors.

In addition, the open label safety study of GOCOVRI, EASE LID 2, demonstrated a sustained improvement in dyskinesia and OFF among patients using GOCOVRI in a real-world setting. Results showed the treatment effect of GOCOVRI on motor complications (OFF and dyskinesia) was maintained for at least two years, providing long-term durability and safety data for GOCOVRI. This effect was seen in all patients in the study, including those who were switched from amantadine immediate release treatment to GOCOVRI and patients who had received deep brain stimulation treatment. Data from the open label study, which is the longest-running amantadine study to date, were accepted for publication in the Journal of Parkinson's Disease and published online in January 2020 and in print in April 2020.

OSMOLEX ER for the Treatment of Parkinson's Disease and Drug-Induced Extrapyrimal Reactions in Adults

On January 4, 2021, we acquired the global rights to OSMOLEX ER[®] (amantadine) extended release tablets from Osmotica Pharmaceuticals US LLC, a subsidiary of Osmotica Pharmaceuticals plc, as part of a litigation settlement agreement. In February 2018, the FDA approved OSMOLEX ER for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions in adult patients based on demonstration of bioequivalence to Symmetrel (amantadine immediate release). OSMOLEX ER time dependent amantadine release profile is an immediate release followed by an extended release (i.e., IR/ER), providing high doses directly upon ingestion followed by a more continuous extended release. The OSMOLEX ER prescribing information states that OSMOLEX ER is not interchangeable with other amantadine immediate or extended release products.

An OSMOLEX ER capsule contains an outer layer that immediately releases the medication upon the patient taking the pill and an inner core that slowly releases the medication over long periods of time. This allows OSMOLEX ER to be taken just once a day, easing complicated medication routines.

Amantadine immediate release has been used as monotherapy in early Parkinson's disease progression or in those patients with mild symptoms, as an option to lessen motor symptoms. Extrapyrimal reactions, also known as extrapyramidal symptoms (EPS) are defined as a group of motor complications associated with antipsychotic medication treatment. EPS adverse effects most typically include acute dystonia, akathisia, parkinsonism, tardive dyskinesia and tremor. EPS symptoms are mediated by changes in dopaminergic pathways, chiefly dopamine receptor blockade, due to antipsychotic medications. Approximately eleven million people in the U.S. are treated with anti-psychotic medications with approximately 21 percent of patients experiencing extrapyramidal symptoms.

Partnered Products

NAMZARIC and NAMENDA XR (commercialized by Allergan plc)

NAMZARIC[®] (memantine hydrochloride extended release and donepezil hydrochloride) capsules and NAMENDA XR[®] (memantine hydrochloride) extended release capsules are two commercially available medicines for the treatment of moderate to severe dementia of an Alzheimer's type, currently marketed by Forest, an indirect, wholly-

owned subsidiary of Allergan plc, in the United States under an exclusive license agreement between us and Forest. We began recognizing royalties on net sales of NAMZARIC in May of 2020. We do not expect to receive royalties on net sales of NAMENDA XR, due to the entry of generic versions of NAMENDA XR.

Investigational Programs

ADS-5102 for the Treatment of Walking Impairment in Patients with Multiple Sclerosis

Multiple sclerosis (MS) is a chronic autoimmune-mediated disorder that affects approximately 1 million people in the United States. Among the MS patients in the US, nearly 270,000 have walking impairment, which is present throughout the day.

We have evaluated ADS-5102 (amantadine) extended release capsules, an investigational agent, taken once-daily at bedtime, in multiple sclerosis patients with walking impairment in a Phase 3 (INROADS) study. Data from the study, announced in December 2019, showed that subjects taking 274 mg ADS-5102 had a statistically significant improvement in walking demonstrated by response rate of 21.1% compared to 11.3% taking placebo ($p=0.01$) and 17.6% ($p=0.08$) for subjects taking 137 mg ADS-5102. However, additional patient, physician, and payer research based on the revised target product profile informed by this level of clinical benefit projected a limited commercial opportunity and we discontinued additional development of this program in June 2020. The open-label extension study of ADS-5102 in this population will be closed out by the second quarter of 2021.

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

Epilepsy affects an estimated three million Americans, of which approximately 60% have partial onset seizures. Of those people with partial onset seizures, about 30% to 40% of patients have poor seizure control with current anti-epilepsy drugs. There are limited data on the temporal distribution of seizures over the 24-hour day; however, published studies suggest that seizures occur in a diurnal pattern, characterized by a peak between 11 a.m. and 5 p.m. and lowest between 11 p.m. and 5 a.m.

ADS-4101 is an investigational high-dose, modified release lacosamide capsule, taken once-daily at bedtime. Lacosamide is an anti-epilepsy active ingredient previously approved by the FDA and currently marketed by UCB SA/NV as VIMPAT[®] (lacosamide). Based upon the patents and regulatory exclusivities listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book, it is estimated that VIMPAT will lose patent exclusivity in March 2022. ADS-4101 was designed to reduce the initial rate-of-rise in lacosamide concentrations, potentially improving the adverse event profile and dose limitations due to dizziness following administration of VIMPAT. By matching the timing pattern of seizures to the concentration of the anti-epileptic drug, with a higher drug concentration during the day and lower drug concentration during the night, ADS-4101 may enable improved seizure control for adults with epilepsy in the United States.

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

We had an initial meeting with the FDA in 2018 regarding our planned Phase 3 pivotal programs for ADS-4101. In 2019, we placed this development program on hold in order to focus our resources on our priorities of GOCOVRI commercialization, and our MSW development program. We continue to fully evaluate the potential value of ADS-4101 and options for its further development both internally and through partnering opportunities.

License agreement with Allergan

In November 2012, we granted Allergan an exclusive license, with right to sublicense, to certain of our 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. We 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.

We are entitled to receive royalties on net sales in the United States by Allergan, its affiliates, or any of its sublicensees of controlled-release versions of memantine products covered by the terms of the license agreement. Beginning in May 2020, we began recognizing tiered royalties from Allergan in the low double digits to mid-teens, as a percent of net sales of NAMZARIC in the United States. Based on recent trends of NAMZARIC sales, we expect the tiered royalty to be in the low double digits through the term of the agreement. At this point, we will not receive royalties on sales of NAMENDA XR because of the entry of multiple generic versions of NAMENDA XR in 2018. 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 us covering such product. 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. Based on Allergan's and our current settlement agreements with the NAMZARIC ANDA filers to date, the earliest date on which any of these agreements grant a license to market a NAMZARIC ANDA filer's generic version of NAMZARIC is January 1, 2025 (or earlier in certain circumstances). Alternatively, the NAMZARIC ANDA filers with the earliest license date have the option to launch an authorized generic version of NAMZARIC beginning on January 1, 2026 instead of launching their own generic version of NAMZARIC on January 1, 2025. For further information, see *Litigation and Other Legal Proceedings* in "Note 9 - Commitments and Contingencies" in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report.

Royalty-Backed Loan

In May 2017, we entered into a Royalty-Backed Loan with HealthCare Royalty Partners ("HCR") whereby we initially borrowed \$35 million, followed by an additional \$65 million received in the fourth quarter 2017 and additionally amended certain key terms with an effectiveness date of January 4, 2021. Principal and interest is payable quarterly from the proceeds of a 12.5% royalty on net sales of GOCOVRI, OSMOLEX ER, and up to \$15 million on annual royalties of NAMZARIC. The royalty rate is subject to increase to 22.5% if total principal and interest payments have not reached minimum specified levels on December 2022. The royalty rate will drop to 6.25% after the principal amount of the loan has been repaid in full, until we have made total payments of \$200 million. If we are required to prepay due to a change of control provision, the obligation is fully satisfied by making a prepayment sufficient to bring the cumulative payments to \$175 million, if such prepayment is made on or prior to December 31, 2022, or \$195 million if made thereafter. The loan agreement matures on March 31, 2027, if not repaid earlier. We must maintain cash, cash equivalents and marketable securities of at least \$25 million at all times through the term. As of December 31, 2020, the total remaining payment obligation of the Royalty-Backed Loan was \$179.2 million. Under the terms of the loan, HCR has recourse to Adamas Pharma, LLC, not Adamas Pharmaceuticals, Inc.

Intellectual property

Our discoveries and products are protected by a robust intellectual product portfolio and available regulatory exclusivities. In developing therapies, we search for clinically meaningful treatment effects, including from existing medicines.

As with any pharmaceutical or biotechnology company, our success significantly depends upon our ability to obtain and maintain exclusivity for our products, product candidates, and any in- and out-licensed programs, including GOCOVRI, OSMOLEX ER, NAMZARIC, ADS-5102, and ADS-4101. These protections may include regulatory exclusivity, patent protection, unpatented trade secrets, know-how, and/or continuing technological innovation to develop and maintain our competitive position.

We actively protect our proprietary information, in part, by using confidentiality agreements with our commercial partners, collaborators, employees, and consultants and invention assignment agreements with our employees and selected consultants. Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed, or misappropriated, or such intellectual property and proprietary

rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, please see “Risk factors—Risks related to intellectual property” and *Litigation and Other Legal Proceedings* in “Note 9 - Commitments and Contingencies.”

As of February 9, 2021, we owned 38 issued U.S. patents and multiple U.S. patent applications, as well as additional patents and patent applications in other jurisdictions. The patent portfolios for GOCOVRI, OSMOLEX ER, ADS-4101 and NAMZARIC as of February 1, 2021, are summarized below:

GOCOVRI

GOCOVRI is currently covered for its FDA-approved indication by a total of 15 issued U.S. patents and additional patent applications containing method and composition claims relating to the pharmacokinetic profile and dosing of amantadine as well as the GOCOVRI formulation. These issued patents expire through 2034 and applications, if issued, expire as late as 2038. These patents and patent applications are wholly owned by us and are not subject to any license agreements. We also own additional foreign patents and patent applications covering GOCOVRI. On December 30, 2019, as part of a litigation settlement, we granted Sandoz a license to make, use, sell, offer to sell and import a generic version of GOCOVRI (amantadine) extended release capsules (including for any new indications approved under the GOCOVRI NDA), effective as of March 4, 2030, or earlier in certain circumstances typical for such agreements. The agreement contains provisions that may accelerate the license date, including if unit sales of GOCOVRI for the 12-month period ending July 31, 2025 or any subsequent 12-month period decline by a specified percentage below GOCOVRI unit sales for the year ended December 31, 2019. On January 30, 2021, as part of a litigation settlement, we granted Zydus a license to make, use, sell, offer to sell and import a generic version of GOCOVRI (amantadine) extended release capsules (including for any new indications approved under the GOCOVRI NDA), effective as of March 4, 2030, or earlier in certain circumstances typical for such agreements. The agreement contains provisions that may accelerate the license date, including if unit sales of GOCOVRI for the 12-month period ending July 31, 2025 or any subsequent 12-month period decline by a specified percentage below GOCOVRI unit sales for the year ended December 31, 2019. For more information, please see *Litigation and Other Legal Proceedings* in “Note 9 - Commitments and Contingencies.”

OSMOLEX ER

OSMOLEX ER is currently covered for its FDA-approved indications by a total of 18 issued U.S. patents and additional applications containing method and composition claims relating to the pharmacokinetic profile and dosing of amantadine as well as OSMOLEX ER formulation. These issued patents expire through 2038. These patents and patent applications are wholly owned by us and are not subject to any license agreements. We also own additional foreign patents covering OSMOLEX ER.

ADS-4101

ADS-4101 is currently covered by U.S. and ex-U.S. patent applications containing method and composition claims relating to their pharmacokinetic profile and dosing of antiepileptic agents. On January 25, 2021, a Notice of Allowance was received in U.S. Patent Application No. 15/396,161, and on February 18, 2021, a Notice of Allowance was received in U.S. Patent Application No. 15/863,746. Both of these applications are expected to issue as patents within the first half of 2021. Patents issuing from these applications, if issued, will expire at least as late as 2036. These patent applications are wholly owned by us and are not subject to any license agreements.

NAMZARIC

NAMZARIC is covered by a total of seven of our issued U.S. patents containing method and compositions claims relating to the pharmacokinetic profile and dosing of memantine. These patents expire as late as 2029 and are exclusively licensed to Allergan. We also own additional foreign patents and patent applications covering NAMZARIC.

Commercial activities, including sales and marketing

We commenced the full commercial launch of GOCOVRI in January 2018. To drive awareness and adoption of GOCOVRI by movement disorder centers, specialists and other neurologists for their Parkinson’s disease patients with OFF and dyskinesia, we deploy a field sales team of approximately 60 experienced neurology account specialists. This team is equipped with compelling educational materials demonstrating the benefit and safety profile of GOCOVRI for appropriate patients. Also, to facilitate patient access to, and physician experience with, GOCOVRI, we have both in-

office and direct to patient free trial programs. We support a number of financial support programs for eligible patients including: a co-pay assistance program for commercially insured patients, which requires no more than a \$20 copay per prescription; a patient assistance program ‘GOCOVRI ONBOARD’ for under-insured or non-insured patients; and the provision of information for government insured patients about available programs to assist with their out-of-pocket costs.

A significant portion of our operating expenses in 2020 were related to commercializing GOCOVRI. We expect this to continue in 2021. For 2020 and 2019, sales of GOCOVRI accounted for 96% and 100% of our revenues, respectively.

We sell GOCOVRI to a specialty pharmacy and certain limited specialty distributors, which we collectively refer to as our customers. For the years ended December 31, 2020 and 2019, our largest customer, Alliance Rx Walgreens Prime, or AllianceRx, was responsible for approximately 95% and 98% of our product revenue, respectively. We have a product purchase agreement with Walgreen Co., acting on behalf of itself and its specialty pharmacy affiliates, including AllianceRx, through which AllianceRx purchases its supply of GOCOVRI. The agreement provides that AllianceRx has the nonexclusive right to purchase GOCOVRI from us or our authorized distributors solely to dispense to patients in the United States and Puerto Rico, and that AllianceRx will purchase GOCOVRI only from us or our authorized distributors. There are no minimum purchase requirements under the product purchase agreement. We do not believe the loss of this customer would significantly impact the ability to distribute our product as we believe alternative distributors are available.

We obtained the global rights to sell OSMOLEX ER on January 4, 2021, and began selling product through select specialty pharmacies and distributors. To drive awareness and adoption of OSMOLEX ER for the treatment of Parkinson’s disease and drug-induced extrapyramidal reactions in adults, we utilize a tele-sales team to educate both neurologists and psychiatrists on the benefit and safety profile of OSMOLEX ER for appropriate patients. Also, to facilitate patient access to, and physician experience of OSMOLEX ER, we have a patient assistance program ‘ACCESS OSMOLEX’ and physician in-office free trial program.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our development experience and scientific knowledge provide us with competitive advantages, we may face competition from large pharmaceutical and biotechnology companies, smaller pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, academic institutions, government agencies and research institutions, and others.

Many of our competitors may have significantly greater financial, technical, and human resources than we have. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel technologies that are more effective, safer, or less costly than any that will be commercialized by us. Our success will be based in part on our ability to identify, develop, and manage a portfolio of drugs that are safer, more efficacious, and/or more cost-effective than alternative therapies.

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, and, as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing OFF episodes, we face competition from various branded and generic drugs approved for the treatment of Parkinson’s disease that physicians either have historically used or may use in an attempt to manage dyskinesia. Competition may arise from all versions of levodopa (SINEMET (Merck & Co., Inc.), PARCOPA (Schwartz Pharma), RYTARY (Amneal Pharmaceuticals, Inc.), DUOPA (AbbVie), INBRIJA (Acorda)); dopamine agonists (APOKYN subcutaneous apomorphine, EQUIP XL (GlaxoSmithKline plc), MIRAPEX and MIRAPEX ER (Boehringer Ingelheim Pharmaceuticals Inc.), NEUPRO Patch (UCB SA/NV), KYNMOBI (Sunovion)); MAOB inhibitors (selegiline (Somerset Pharmaceuticals, Inc.), AZILECT (Teva Pharmaceuticals Industries, Ltd.), XADAGO (Newron Pharmaceuticals S.p.A.)); adenosine receptor antagonist (NOURIANZ (Kyowa Kirin, Inc.)); COMT inhibitors

(ONGENTYS (Neurocrine Biosciences), COMTAN (Novartis), TASMAR (Valeant)); and other versions of amantadine (Symmetrel (Endo Pharmaceuticals, Inc.) - amantadine immediate release).

We will also face competition from investigational drugs in late stage development for the treatment of Parkinson's disease, if approved, including product candidates from 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, Neurolix, Amaranthus BioScience, Addex Pharma, and Neurim Pharmaceuticals Ltd.

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

OSMOLEX ER

Anticholinergics are the mainstay of therapy for typical Extrapyramidal symptoms (EPS) and tetrabenazine is the mainstay for Tardive Dyskinesia. Anticholinergics are reportedly used prophylactically and as a treatment for EPS. The first-generation VMAT2 inhibitor tetrabenazine was commonly used off-label for the treatment of Tardive Dyskinesia prior to the approval of longer-acting analogues AUSTEDO (deutetetrabenazine) and INGREZZA (valbenazine) for Tardive Dyskinesia. Immediate release tetrabenazine is associated with poor compliance due to inconvenient three times a day (TID) dosing and a high rate of adverse events, including sedation and somnolence. These adverse events are correlated with drug exposure and in many cases limit the titration to an effective dose of tetrabenazine, resulting in suboptimal clinical outcomes. These issues helped pave the way for longer-acting formulations, such as AUSTEDO and INGREZZA, with reduced adverse peak-dose effects and more convenient administration. The pipeline for competitive agents is limited for treatments for EPS due to antipsychotics. One example is the post-marketing study being conducted by Acadia for NUPLAZID in patients with neuropsychiatric symptoms related to neurodegenerative diseases.

NAMZARIC

In the market for Alzheimer's disease treatments, NAMZARIC competes or will compete with branded and generic products such as galantamine, rivastigmine, memantine, and donepezil. In addition, Allergan currently markets NAMENDA, the immediate-release version of memantine, which physicians and patients may favor instead of NAMZARIC. Generic versions of memantine, including generic versions of NAMENDA XR, extended release memantine, are currently available to patients. Several generic manufacturers have or are currently seeking regulatory approval or have received regulatory approval to market generic versions of NAMZARIC, although generic versions of NAMZARIC are not currently available to patients. We and our partner Allergan continue enforcement of our patent rights with respect to this product. We are also aware that other biopharmaceutical companies are developing treatments for Alzheimer's disease that may compete with NAMZARIC. See *Litigation and Other Legal Proceedings* in "Note 9 - Commitments and Contingencies" in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report for more information.

Manufacturing

We currently have no manufacturing facilities. We rely on third-party manufacturers to produce bulk drug substance and finished drug products required for commercialization of GOCOVRI and OSMOLEX ER, and to supply our clinical trials of ADS-5102. We have entered into a supply agreement with Osmotica Pharmaceutical US LLC ("Osmotica"), a subsidiary of Osmotica Pharmaceuticals plc, in which Osmotica will be the sole manufacturer of OSMOLEX ER. We plan to continue to rely upon contract manufacturers to manufacture commercial quantities of GOCOVRI, OSMOLEX ER, and ADS-5102, and for any other product candidates we may pursue, if and when we receive approval for marketing by the applicable regulatory authorities. With respect to GOCOVRI and ADS-5102, we are seeking to qualify additional manufacturers of finished drug products and have recently qualified an additional manufacturer of bulk drug substance.

GOCOVRI, ADS-5102 and ADS-4101 are based upon controlled release coated pellet technology and can be difficult to manufacture. These products consist of an inert core, a drug layer, an optional seal coating, and controlled

release coatings. Our products are made in a fluidized bed coating machine in sequential steps. Once the extended or modified release coating is applied, the coated pellets are tested to ensure that the desired dissolution rate is achieved. These coatings are relatively thin, and susceptible to changes in raw materials, temperature, humidity, and other manufacturing process parameters.

OSMOLEX ER is a tablet that uses an osmotic pump mechanism to provide an extended release of the product. This product consists of a core tablet surrounded by multiple coatings including a coating with a laser-drilled hole in order to facilitate release of the drug over time. This product is made in standard equipment used to prepare and compress tablets and then apply film coatings in addition to the laser drilling equipment used in processing. Once bulk tablets are produced, they are tested to ensure compliance with dissolution and other specification requirements. This product is also susceptible to changes in raw materials, temperature, humidity, and other manufacturing process parameters.

Allergan is responsible for all manufacturing related to NAMZARIC.

Our third-party manufacturers, their facilities, and all lots of drug substance and drug products used commercially or in our clinical trials are required to be in compliance with current Good Manufacturing Practices, or cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements and FDA satisfaction before any product is approved and we can manufacture commercial products. Our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. These actions could have a material impact on the availability of our products.

Government regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state, and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, tracking, approval, import, export, advertising, and promotion of our products.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests, including some that must be conducted in accordance with Good Laboratory Practices;
- submission of an IND, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug candidate for its intended use;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with cGMP and Good Clinical Practices; and
- FDA approval of an NDA to permit commercial marketing for particular indications for use.

The testing and approval process requires substantial time, effort, and financial resources. Prior to commencing the first clinical trial with a product candidate, we must submit an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive

clinical trial conducted during product development. Further, an independent institutional review board for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial commences at that center. Regulatory authorities or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—Studies are initially conducted to test the product candidate for safety, dosage tolerance, absorption, metabolism, distribution, and excretion in healthy volunteers or patients.
- Phase 2—Studies are conducted with groups of patients with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule, and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—These clinical trials are undertaken in larger patient populations to further evaluate dosage, to provide statistically significant evidence of clinical efficacy, and to further test for safety in an expanded patient population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These trials may be done globally to support global registrations.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate, as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA submission, review and approval by the FDA

The Federal Food, Drug, and Cosmetic Act (“FDCA”) provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b)(1) of the FDCA is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of preclinical and clinical studies conducted by or on behalf of the applicant to characterize and evaluate the product candidate.

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to obtain FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA’s findings of safety and effectiveness for an approved product that acts as the reference listed drug (“RLD”), and submit its own product-specific data—which may include data from preclinical or clinical studies conducted by or on behalf of the applicant—to address differences between the product candidate and the RLD.

The submission of an NDA under either Section 505(b)(1) or Section 505(b)(2) generally requires payment of a substantial user fee to the FDA. The FDA reviews applications to determine, among other things, whether a product is

safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. The FDA may determine that a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to ensure that the benefits of a new product outweigh its risks, and such REMS can be imposed either at the time of approval or subsequent to a product's marketing. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug or biological product in relevant pediatric populations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Once the NDA submission has been accepted for filing, which occurs, if at all, within 60 days after submission of the NDA, the FDA's goal for review of an NDA is based upon goals set under annual user fee guidance, although the review process can be and often is significantly extended by FDA requests for additional information, studies, or clarification. Upon completion of its review, the FDA will respond to the applicant by approving the application or issuing a Complete Response letter. A Complete Response letter outlines deficiencies in the NDA and may request additional information, including additional preclinical or clinical data. Even if an applicant submits this additional information, the FDA may determine that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. The timing of approval, if any, of any NDA we submit will depend on when the FDA determines that the NDA satisfies all requirements for approval. Also, even if the FDA approves an NDA, such approval may entail limitations on the uses or conditions for which such product may be marketed, or the FDA may require Phase 4 post-marketing studies to monitor the safety or efficacy of the product, and may further limit the marketing of the product based on the results of these post-marketing studies. The FDA may withdraw approval of an NDA if the sponsor does not comply with extensive post-marketing regulatory requirements (as described below) or if problems occur after the product reaches the marketplace.

The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, established two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products: the 505(b)(2) NDA pathway, described above, and the abbreviated new drug application ("ANDA") pathway. To facilitate these abbreviated approval pathways, NDA applicants are required to list the FDA information concerning certain patents with claims that cover the applicant's product. Upon approval of an NDA and upon the issuance of any new patent claims that meet the requirements for submission to the FDA, the NDA holder is required to update the information and submit any new information concerning applicable patents, which will then be published in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA (1) that no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) that such patent has expired; (3) the date on which such patent expires; or (4) that such patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. If the ANDA or 505(b)(2) applicant provides a Paragraph IV certification to the FDA, the competitor must also send notice of the Paragraph IV certification to the holder of the NDA for the RLD and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. If the NDA holder or patent owner files a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification, the FDA may not approve the 505(b)(2) application or ANDA until the earlier of 30 months from the date the NDA or patent holder receives notice of the certification, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. If a listed patent claims a method of using the approved drug, the ANDA or 505(b)(2) NDA applicant may, instead of submitting a certification to the patent, submit a "Section viii" statement certifying that the labeling for the proposed product does not contain, or carves out, any language regarding the patented method-of-use.

The Hatch-Waxman Act also provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a new chemical entity, or NCE—generally meaning that the active moiety has never before been approved in any drug—there is a period of five years from the product’s approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor makes a Paragraph IV certification challenging a listed patent. Because of relevant statutory and regulatory provisions, as well as the time it takes for the FDA to review and approve an application, five-year NCE exclusivity usually effectively means an ANDA or 505(b)(2) application is not approved for a period well beyond five years after approval of the RLD.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains clinical data that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of the ANDA or 505(b)(2) application; rather, the FDA may not grant final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. For example, if an NDA is submitted for a product that seeks approval for a new indication, and clinical data were required to demonstrate the safety or effectiveness of the product for that use, the FDA could not approve an ANDA or 505(b)(2) application for another product with that active moiety for that use.

Orphan Drug designation and exclusivity

The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States. If a sponsor demonstrates that a drug or biologic is intended to treat a rare disease or condition and meets other qualifying criteria, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. In general, a drug that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity, and during that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity.

Post-approval requirements

Any drug products we manufacture, market, or distribute pursuant to FDA approvals are subject to continuing regulation by the FDA. For example, drug manufacturers and their subcontractors must register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by regulatory authorities, including by the FDA for compliance with cGMP, which imposes significant manufacturing-related requirements.

The FDA closely regulates the marketing and promotion of drugs. A company’s promotional claims about the safety and efficacy of its drug products must be consistent with FDA-approved labeling, truthful, and non-misleading. Failure to comply with these requirements can result in adverse publicity, warning or untitled letters, corrective advertising, and potential civil and criminal penalties. Physicians may legally prescribe approved drugs for uses that are not described in the product’s labeling and that differ from those tested by us and approved by the FDA. Such “off-label” use is common in some areas of medicine and reflects physicians’ professional judgment that such use is an appropriate treatment option for patients under certain circumstances. The FDA does not regulate physicians’ practice of medicine, but the FDA does restrict manufacturers’ communications about their drug products, including communications about unapproved uses of approved products. However, a manufacturer that is found to have promoted off-label use of its product may be subject to significant liability, including administrative, civil and criminal sanctions.

In addition to these post-marketing requirements, companies that manufacture or distribute drug products or that hold approved NDAs must comply with numerous other post-marketing regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records.

The extensive laws and regulations that apply to the research, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising, and promotion of drug products and product candidates in the United States are subject to change, and it is difficult to foresee whether, how, and when such changes may affect our business.

Other healthcare regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the Centers for Medicare and Medicaid Services, and state and local governments. Our business activities must comply with numerous healthcare laws, including but not limited to, the federal Anti-Kickback Statute, the False Claims Act, the Veterans Health Care Act, and similar state laws.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from 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 in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. We seek to comply with these exceptions and safe harbors whenever possible, but the exceptions and safe harbors are drawn narrowly, and our business practices may be subject to scrutiny if they do not qualify for an exception or safe harbor or if there is no exception or safe harbor available. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Many pharmaceutical and other healthcare companies have been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, among other things. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

We and our business activities are subject to the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Additionally, the federal Open Payments program requires certain manufacturers of drugs, devices, biological, 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. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives.

The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and federal False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Additionally, there are state laws that require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states, restrict when pharmaceutical companies may provide meals to prescribers or engage

in other marketing related activities, impose price reporting obligations with respect to certain drug products, and/or require pharmaceutical companies to implement compliance programs or marketing codes of conduct. In addition, certain state and local laws require the registration of pharmaceutical sales representatives. Outside the U.S., we may be subject to similar laws and regulations in those countries where we market and sell products.

In addition, we may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that negatively affects our business. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”). HIPAA and its implementing regulations impose certain requirements on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information, relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to business associates, which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we will have to comply with the Veterans Health Care Act of 1992 (“VHCA”). The VHCA requires manufacturers to offer their covered drugs (biologics and single source and innovator multiple source drugs) for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs (“VA”), on a Federal Supply Schedule contract, at a price no higher than the statutory Federal Ceiling Price (“FCP”). The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we will have to calculate and report to the VA on a quarterly and annual basis. In addition, the Federal Supply Schedule contract requires compliance with applicable federal procurement laws.

Depending on the circumstances, failure to comply with these laws can result in penalties, including significant criminal, civil, and/or administrative criminal penalties, damages, fines, disgorgement, exclusion of products from reimbursement under government programs, “qui tam” actions brought by individual whistleblowers in the name of the government, 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, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits, and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our business.

Health reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, in March 2010, the Patient Protection and Affordable Care Act (“PPACA”) was passed, which has substantially changed how health care is financed by both governmental and private insurers, and has significantly impacted the U.S. pharmaceutical industry. The PPACA, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program (“MDRP”) are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the MDRP, extended the MDRP to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government’s comparative effectiveness research, and provided for a Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

There remain legal and political challenges to certain aspects of the PPACA. Since January 2017, former President Trump signed several 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 comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 included a provision which repealed, effective January 1, 2019, the tax-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, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. In December 2018, the Centers for Medicare and Medicaid Services (“CMS”) published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when or how the Supreme Court will rule. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA.

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 went into effect in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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, and 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 ended the use of the statutory formula for clinician payment and established a quality payment program. 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.

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, the Trump Administration’s budget proposal for fiscal

year 2021 included a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump Administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services (“HHS”) has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019. Further, on July 24, 2020 and September 13, 2020, the Trump Administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration’s proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 20, 2020, CMS issued an interim final rule implementing former President Trump’s Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. The likelihood of implementation of any of the other Trump administration reform initiatives is uncertain, particularly in light of the recent U.S. presidential election. 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 any of our product candidates that we successfully commercialize. 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 us owing additional rebates, which could have a negative impact on revenues from sales of any of our product candidates that we successfully commercialize. Further, it is possible that additional government action is taken in response to the COVID-19 pandemic.

Pharmaceutical pricing and reimbursement

Our ability to commercialize our product candidates successfully, and to attract commercialization partners for our products, will depend in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the U.S., governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. We intend to participate in and then will have certain price reporting and other obligations to the Medicaid Drug Rebate program and other governmental pricing programs. These obligations are discussed in greater detail under the heading “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” in Part 1, Item 1A. Risk Factors, of this Annual Report on Form 10-K. Political, economic, and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell any of our product candidates that we successfully commercialize profitably. We expect to experience pricing pressure in the U.S. in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations, additional legislative proposals to curb healthcare costs, and negative publicity regarding pricing and price increases generally, which could limit the prices that we charge for any of our product candidates that we successfully commercialize, limit our commercial opportunity, and/or negatively impact revenues from sales of our products. We anticipate that the U.S.

Congress, state legislatures, and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs, particularly given the current atmosphere of mounting criticism of prescription costs in the U.S. These cost containment measures include controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; pharmaceutical cost transparency bills that aim to require drug companies to justify their prices; controls on healthcare providers; challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and public funding for cost effectiveness research, which may be used by government and private third-party payers to make coverage and payment decisions. For example, much attention has been paid to legislation proposing federal rebates on Medicare Part D and Medicare Advantage utilization for drugs issued to certain groups of lower income beneficiaries and the desire to change the provisions that treat these dual-eligible patients differently from traditional Medicare patients. Any such changes could have a negative impact on revenues from sales of any of our product candidates that we successfully commercialize.

Coverage, reimbursement, and formulary placement decisions are being negotiated on a plan by plan basis for GOCOVRI for the treatment of dyskinesia in Parkinson's disease and, as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing OFF episodes. Coverage, reimbursements, and placement decisions for products are based on many factors including the coverage, reimbursement, and placement of already marketed branded drugs for the same or similar indications, the safety and efficacy of the product, availability of generics for similar indications, and the clinical need for the product. Within the Medicare program, as self-administered drugs, GOCOVRI would be reimbursed under the expanded prescription drug benefit, known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These Part D plans negotiate discounts with drug manufacturers, which are passed on to each of the plan's enrollees. Historically, Part D beneficiaries have been exposed to significant out-of-pocket costs after they surpass an annual coverage limit and until they reach a catastrophic coverage threshold. However, changes made by recent legislation will reduce this patient coverage gap, known as the "donut hole", by transitioning patient responsibility in that coverage range from 100% in 2010 to only 25% currently. To help achieve this reduction, since 2011, pharmaceutical manufacturers are required to pay quarterly discounts of 50% off the negotiated price of branded drugs issued to Medicare Part D patients in the donut hole, and such quarterly discounts have increased to 70% on January 1, 2019. In 2020, drug manufacturers have been responsible for a larger share of total drug costs due to an increase to the catastrophic coverage threshold. Such increase will also result in a higher out-of-pocket costs paid by Part D beneficiaries.

If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as applicable, as well as with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, or the OBRA, and the Veterans Health Care Act of 1992, or the VHCA, each as amended. Among other things, the OBRA requires drug manufacturers to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate rebates on pharmaceutical prices, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

Third-party payers decide which drugs they will pay for and establish reimbursement and co-pay levels. Third-party payers are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. Even with studies, any of our product candidates that we successfully commercialize may be considered less safe, less effective, or less cost-effective than other products, and third-party payers may not provide coverage and reimbursement for any of our product candidates that we commercialize, in whole or in part. The process for determining whether a payer will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the product once coverage is approved. Third-party payers may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. For example, third-party payers have started to require discounts and/or exclusivity arrangements with some drug manufacturers in exchange for including a specific product on their formularies. Any such requirements could have a negative impact on revenues from sales of our products.

Payers also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price, and actual acquisition cost. Payers may also impose price protection or inflation protection in their contracts with manufacturers to limit the manufacturer's ability to increase prices. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. Both Medicare and Medicaid are administered by CMS. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It is difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover our products.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Human Capital

As of December 31, 2020, we employed 138 full-time equivalent employees, have not experienced work stoppages and believe our employee relations are good.

Corporate and other Information

We were incorporated in Delaware in November 2000 under the name NeuroMolecular, Inc. In December 2004, we changed our name to NeuroMolecular Pharmaceuticals, Inc., and in July 2007 we changed our name to Adamas Pharmaceuticals, Inc. Our principal executive offices are located at 1900 Powell Street, Suite 1000, Emeryville, California 94608, and our telephone number is (510) 450-3500. Our website address is www.adamaspharma.com. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

We make available, free of charge on our corporate website, copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. Our common stock is traded on the Nasdaq Stock Market under the symbol "ADMS".

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 Annual Report on Form 10-K, including our consolidated financial statements and related notes.

Risks related to the COVID-19 pandemic

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

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

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

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

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

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

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

- GOCOVRI’s efficacy and safety profile;
- our success in the marketing, sales, and distribution of GOCOVRI, especially in light of the COVID-19 pandemic;
- the duration of the COVID-19 pandemic, the stay-at-home restrictions and access of our staff to clinics to be able to interact with healthcare providers;

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

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

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

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

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

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

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

Even if we obtain coverage for GOCOVRI, the level of coverage might not be adequate or may require co-payments or co-insurance payments that patients find unacceptably high. Coverage and reimbursement determinations by third-party payers can impact the demand for GOCOVRI and therefore our revenues. Patients may choose not to use GOCOVRI if coverage is not provided or the payer's determined out of pocket cost for the patient is unaffordable for the patient. If coverage and reimbursement are not available or are available only to limited levels making the drug

unaffordable to patients, our business could be harmed.

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

We face substantial competition in the commercialization of GOCOVRI.

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

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

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

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

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

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

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

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

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers, their patients or payers. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. If we cannot successfully defend ourselves against claims that GOCOVRI caused injuries, we will incur substantial liabilities.

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

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

Under the U.S. Food, Drug and Cosmetic Act, or FDCA, the FDA can approve an Abbreviated New Drug Application, or ANDA, for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form, route of administration and that it is bioequivalent to the branded product. We have recently settled an ANDA litigation with a generic filer. See *Litigation and Other Legal Proceedings* in "Note 9 - Commitments and Contingencies" in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report for more information. However, other filers could submit an ANDA to the FDA requesting permission to manufacture and market another generic version of GOCOVRI, which could result in our expending significant time and incurring significant expenses in challenging the submissions. Further, if one or more of these filers is successful, the introduction of a generic version of GOCOVRI could harm our business and results of operations and cause our stock price to decline.

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

The FDA and other regulatory agencies, including regulatory authorities outside the United States, strictly regulate the marketing and promotional claims that are made about drug products, such as GOCOVRI. In particular, promotion of a product must be consistent with its labeling approved by the FDA or by regulatory agencies in other countries. For example, in the case of GOCOVRI, for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, and as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing OFF episodes, we cannot prevent physicians from prescribing GOCOVRI for indications or uses that are inconsistent with the approved label based on the physician's professional medical judgment. 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.

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

GOCOVRI is a high-dose, extended release amantadine, specifically designed to be taken once-daily at bedtime to provide an initial lag, then a slow rise in amantadine concentration during the night, and high levels of amantadine in the morning that gradually fall throughout the day into the evening. The manufacture of extended release versions of drugs is more complex than the manufacture of the immediate release versions of drugs. Notwithstanding the fact that we have validated our process, manufacturing disruptions may occur, including disruptions related to the impact or

uncertainties of the duration of the COVID-19 pandemic. Such problems may prevent the production of lots that meet the specifications required for sale of the product and may be difficult and expensive to resolve. Although we have an adequate supply of GOCOVRI to address patient needs into mid-2022 and have not observed disruptions in our supply chain to date as a result of COVID-19, there is no guarantee that we will not experience interruption of, or delays in receiving, supply due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems in the future. If any such issues were to arise with respect to GOCOVRI, our business, financial results, or stock price could be adversely affected.

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

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

Risks related to the commercialization of GOCOVRI will be substantially the same for OSMOLEX ER[®] (amantadine) extended release tablets.

We rely on a single supplier of OSMOLEX ER, and if that supplier is unable to supply OSMOLEX ER, or is unable to supply OSMOLEX ER in sufficient quantities, we may not be able to meet demand for OSMOLEX ER which could impair our investment in OSMOLEX ER.

We obtained the global rights to sell OSMOLEX ER on January 4, 2021, and began selling product through select specialty pharmacies and distributors. We have entered into a supply agreement with Osmotica Pharmaceutical US LLC ("Osmotica"), a subsidiary of Osmotica Pharmaceuticals plc, in which Osmotica will be the sole manufacturer of OSMOLEX ER. If Osmotica is unable to supply sufficient quantities of OSMOLEX ER to meet market demand, we may be unable to realize on our investment in OSMOLEX ER, which could have an adverse effect on our financial results and condition.

We have just begun to market OSMOLEX ER, and are subject to the same commercialization and regulatory risks regarding OSMOLEX ER as we have with respect to the commercialization and regulatory compliance for GOCOVRI.

We have just begun to market OSMOLEX ER, and we are subject to the same commercialization and post-approval regulatory risks with respect to OSMOLEX ER as we have with respect to the commercialization and regulatory compliance for GOCOVRI. Further, although our commercial team has experience with the marketing and sale of GOCOVRI, it has only begun to market and sell OSMOLEX ER, and we may encounter unexpected difficulties in marketing and selling OSMOLEX ER.

Risks related to clinical development of potential future product candidates

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

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

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

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

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

Because we have limited financial and managerial resources, we may choose to focus on research programs and products for specific indications. As a result, we may forego or delay pursuit of opportunities with our product candidate or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our investment in current and future research and development programs and product candidates for specific indications may not yield any commercially viable products for us or future partners. For example, we discontinued the development of ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis in June 2020 following a comprehensive evaluation of the INROADS Phase 3 data, including evaluating the ongoing, open label extension study, and engaging with the FDA, the revised product profile and potential path to submission.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

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

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

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

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

Risks related to our reliance on third parties

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

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

We also rely on a single specialty pharmacy to distribute and provide access to GOCOVRI for the vast majority of our patients. Accordingly, this specialty pharmacy is our largest customer representing approximately 95% of our product revenue. If this specialty pharmacy fails to perform, it could materially harm our business.

All third-party manufacturers of our products and ingredients thereof must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time or change their interpretation and enforcement of existing standards for manufacture, packaging, or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers'

failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical studies, regulatory submissions, approvals, commercialization or supply of our products, entail higher costs, impair our reputation, and potentially disrupt patient access or our approved products.

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

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

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of these trials.

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

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

Risks related to government regulation

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

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact

legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, the Patient Protection and Affordable Care Act (“PPACA”) was passed, which has substantially changed how healthcare is financed by both governmental and private insurers, and has significantly impacted the U.S. pharmaceutical industry. Details of healthcare regulations, including changes under the PPACA, are discussed in the business heading “Other healthcare regulations” in Part I, Item 1, of this Annual Report on Form 10-K.

The constitutionality of the PPACA is currently under review by the U.S. Supreme Court, and it is unclear when a decision will be reached. We expect that the PPACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products.

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

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

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

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

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

- warning letters or untitled letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension, variation, or withdrawal of regulatory approval;
- suspension of ongoing clinical studies;
- voluntary or mandatory product recalls;

- requirements for dissemination of corrective information or modifications to promotional materials;
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications filed by us;
- refusal to permit import or export of our products;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products.

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

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

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

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

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures, and most European Union member states now have an HTA system. The HTA process in the European Union member states is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the national healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

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

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

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

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program, as administered by the Centers for Medicare and Medicaid Services (CMS), and other governmental pricing programs in the United States, and we may participate in additional government pricing programs in the future.

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. 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.

Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by the reporting manufacturer, governmental or regulatory agencies and the courts. We will be liable for errors associated with any submission of pricing data and for any overcharging of government payers. 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 will not be found by CMS to be incomplete or incorrect. There also 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 order to be eligible to have any of our product candidates that we successfully commercialize paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs, or VA, Department of Defense, Public Health Service, and Coast Guard, referred to collectively as the Big Four agencies, and certain federal grantees, we are required to participate in the VA Federal Supply Schedule, or FSS, pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make any of our product candidates that we successfully commercialize that meet the statutory definition of "covered drug" (biologics and single and innovator multiple source drugs) available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price, or FCP, which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the "non-federal average manufacturer price," or Non-FAMP, which we will be required to calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements.

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

Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, 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.

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

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

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

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

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

The research, development, manufacturing, quality control, labeling, approval, safety, effectiveness, storage, record keeping, reporting, selling, import, export, advertising, promotion, marketing, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, and by regulatory authorities in other countries, with different regulations from country to country. We are not permitted to market our products in the United States or other countries until we receive regulatory approvals.

To receive approval to commercialize any of our product candidates in the United States, we must demonstrate with substantial evidence from adequate and well-controlled clinical studies, and to the satisfaction of the FDA, that such

product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA. Administering any of our product candidates to humans may produce undesirable side effects, which could interrupt, delay, or cause suspension of clinical studies of our product candidates and result in the denial of approval of our product candidates for any or all targeted indications.

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

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

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

Risks related to intellectual property

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

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

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of

our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the United States Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights is highly uncertain.

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

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

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of our owned or licensed patents being narrowed, invalidated, or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

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

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

Filing, prosecuting, and defending patents on all of our products and product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products and product candidates in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in

foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Obtaining and maintaining our patent protection depends upon compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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

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

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property for GOCOVRI, our partnered products, any product candidates, and any in- and out-licensed programs. To counter infringement or unauthorized use, we or our licensees may be required to file infringement claims, which can be expensive and time-consuming. For example, two companies filed Abbreviated New Drug Applications and we filed suit against each of them to enforce our patents and have subsequently settled these lawsuits.

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

Third parties may initiate legal proceedings alleging that we or our partners are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our partners to develop, manufacture, market, and sell our products and product candidates and to use our proprietary discoveries and technologies without infringing, misappropriating, or otherwise violating the proprietary rights or intellectual property of third parties. We or our partners may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, re-examination, *inter partes* review, post-grant review, opposition, or similar proceedings before the USPTO and its foreign counterparts. The costs of these proceedings could be substantial, and the proceedings may result in a loss of such intellectual property rights. Some of our competitors may be able to sustain the costs of complex patent disputes and litigation more effectively than we can, because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any disputes or litigation could adversely affect our ability to raise the funds necessary to continue our operations. Third parties may assert infringement claims against us or our partners based on existing patents or patents that may be granted in the future. Under our license agreement with Allergan we are obliged to indemnify Allergan under certain circumstances and our royalty entitlements may also be reduced. Our indemnification obligation to Allergan, while subject to customary limitations, has no monetary cap, and our right to

receive royalties from Allergan may be eliminated in any calendar quarter in which certain third-party generic competition exists. If we or our partners are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our products and product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

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

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

Risks related to NAMZARIC®

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

In November 2012, we entered into a license agreement with Allergan pursuant to which we granted Allergan a right to develop and commercialize NAMZARIC in the United States. Under that agreement, we began to receive royalties from Allergan on the net sales of NAMZARIC, starting in May 2020. If for any reason Allergan fails to successfully commercialize NAMZARIC, including due to the impact of the COVID-19 pandemic, on which we are eligible to receive royalties in the low double digits to mid-teens, we may not receive such future royalties or receive minimal amounts, and our business may be harmed. Even if we do receive royalties, based on recent trends of NAMZARIC net sales, we expect the tiered royalty to be in the low double digits through the term of the agreement.

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

On April 1, 2019, we were served with a complaint against us and several Allergan entities alleging violations of Federal and state false claims acts ("FCA") in connection with the commercialization of NAMENDA XR and NAMZARIC by Allergan, as further described in Litigation and Other Legal Proceedings in "Note 9 - Commitments and Contingencies" in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report. The complaint alleges that patents held by Allergan and us covering NAMENDA XR and NAMZARIC were procured through fraud on the United States Patent and Trademark Office and that these patents were asserted against potential generic

manufacturers of NAMENDA XR and NAMZARIC to prevent the generic manufacturers from entering the market, thereby wrongfully excluding generic competition resulting in artificially high price being charged to government payors. The complaint includes a claim for damages of “potentially more than \$2.5 billion dollars,” treble damages and statutory penalties. We are in the early stages of this litigation. Defending this litigation may be costly, divert time and attention of our management from the conduct of our business, and if we are unable to prevail in this litigation it may result in substantial damages, each of which could have a material and negative impact on our business.

Risks related to our financial condition and need for additional capital

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

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

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

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

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

We began to commercialize GOCOVRI for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, in January 2018, and it will require substantial funds to continue to commercialize GOCOVRI. In addition, funds are required for the continued operation of our business. We have entered into a Sales Agreement with Cowen and Company, LLC under which we may offer and sell our common stock having aggregate sales proceeds of up to \$50 million from time to time through Cowen and Company, LLC as our sales agent. As of December 31, 2020, we had issued 217,403 shares of common stock and raised net proceeds of \$1.0 million under this facility. Subsequent to December 31, 2020, and through February 16, 2021, we issued an additional 1,335,896 shares of common stock under the sales agreement and raised net proceeds of approximately \$7.2 million. As of December 31, 2020, we had approximately \$83.4 million in cash, cash equivalents, and investments. We believe that our available cash, cash equivalents, and investments will be sufficient to fund our anticipated level of operations for at least the next 12 months, but there can be no assurance that this will be the case, especially in light of the uncertainties related to, and the duration of, the COVID-19 pandemic.

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

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

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

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

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

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

In May 2017, we, through a newly formed wholly-owned subsidiary, entered into a Royalty-Backed Loan with HCR, 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. Certain key terms of the Royalty-Backed Loan were amended, with an effectiveness date of January 4, 2021.

Effective with the January 4, 2021 amendment, interest and principal on the loan are payable from the proceeds of royalty on U.S. net sales of GOCOVRI, OSMOLEX ER, and up to \$15 million of our annual royalties from Allergan on U.S. net sales of NAMZARIC. The HCR notes mature in March 2027, if not earlier repaid.

The loan is secured with rights to GOCOVRI (ADS-5102), OSMOLEX ER, 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 and OSMOLEX ER. The loan documents contain customary events of default permitting HCR 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, OSMOLEX ER, and royalty payments with respect to NAMZARIC, either of which would seriously harm our business.

General Risk Factors

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

Our share price is volatile and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We have become the target of this type of litigation and in May 2019 a putative class action lawsuit alleging violations of the federal securities laws was filed against us and certain of our current and former directors and officers alleging violations of the securities laws by us and certain of our current and former directors and officers in connection with our January 2018 secondary public offering of common stock. In addition, in December 2019, another putative class action lawsuit was filed against us and certain former officers alleging violations of the Securities Act of 1934. For more information, please see *Litigation and Other Legal Proceedings* in "Note 9 - Commitments and Contingencies" in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report. Lawsuits such as this one can be expensive to defend and could divert our management's attention from the conduct of our business, which could have an adverse effect on our business.

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

Our stock price has fluctuated in the past and may be volatile in the future. The stock market in general and the market for securities of pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investments in our stock.

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

- uncertainties related to, and the duration of, the COVID-19 pandemic;

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

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

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

As of December 31, 2020, we had federal and, subject to the recent California franchise tax law change affecting California state net operating losses mentioned below, state net operating loss carryforwards of \$375.1 million and \$345.2 million, respectively. Portions of the federal net operating loss carryforwards will begin to expire, if not utilized, beginning in 2024, and the state net operating loss carryforward begins expiring in 2028. Portions of these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the current federal income tax law, federal net operating losses incurred in taxable years beginning after December 31, 2017,

and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020, is limited. It is still uncertain if and to what extent various states will conform to the changes in federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. It is possible that we have experienced an ownership change. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, including a recent California franchise tax law change limiting the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023.

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

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

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

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

- impacts of the COVID-19 pandemic;
- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- different payer reimbursement regimes, governmental payers or patient self-pay systems and price controls;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- difficulties in assuring compliance with foreign corrupt practices laws;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- compliance with privacy laws;

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

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

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

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

Provisions in our corporate charter and our bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include that:

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

preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease approximately 37,626 square feet of office space in Emeryville, California, under an operating lease that expires April 30, 2025. We believe that our existing facility will be sufficient for our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

For information regarding legal proceedings, refer to *Litigation and Other Legal Proceedings* in “Note 9 - Commitments and Contingencies” in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report, which information is incorporated by reference here.

ITEM 4. MINE SAFETY DISCLOSURES

The disclosure required by this item is not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the Nasdaq Global Market under the symbol "ADMS".

Holders

As of February 16, 2021, there were 17 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid, and do not anticipate declaring, or paying in the foreseeable future, any cash dividends on our capital stock. Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our operating results, financial conditions, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

ITEM 6. SELECTED FINANCIAL DATA

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

ITEM 7. 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 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, and the expected impact that the COVID-19 pandemic will continue to have on our business. Our actual results could differ materially from those discussed in these forward-looking statements. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report titled “Risk factors.”

This discussion and analysis generally covers our financial condition and results of operations for the year ended December 31, 2020, as compared to the year ended December 31, 2019. For a discussion of the year ended December 31, 2019, as compared to the year ended December 31, 2018, refer to Item 7 of Part II, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the United States Securities and Exchange Commission on February 25, 2020.

Overview

At Adamas Pharmaceuticals, Inc., our mission is to make everyday life significantly better for people affected by neurological diseases. We are a fully integrated company focused on growing a portfolio of therapies to address a range of neurological diseases. With commercial and partnered medicines, we are focused on supporting our patient community and growing a portfolio of differentiated neurological therapies. We combine our proven expertise in discovery, development and commercialization with our passion for improving lives to deliver innovative medicines to reduce the burden of neurological diseases on patients, caregivers, and society. Currently, we are primarily focused on the commercialization of GOCOVRI in the United States. Additionally, we are integrating OSMOLEX ER, which we acquired on January 4, 2021, and are commercializing the product in the United States.

GOCOVRI® (amantadine) extended release capsules is the first and only FDA-approved medicine indicated for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, and as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing OFF episodes. GOCOVRI was approved for marketing by the U.S. Food and Drug Administration, or FDA, on August 24, 2017 for its initial indication to treat dyskinesia. On February 1, 2021, we announced we had received marketing authorization from the FDA for a supplemental New Drug Application (sNDA) for GOCOVRI, gaining a second indication for the product as an adjunctive treatment for OFF episodes. The recent update to the label indication makes GOCOVRI the only medicine clinically proven and approved to reduce both OFF and dyskinesia in Parkinson’s patients taking a levodopa-based medication, resulting in a clinically meaningful increase in good ON time. On June 17, 2020, we announced that we had discontinued further development of (ADS-5102) a potential additional indication for GOCOVRI for the treatment of walking impairment in patients with multiple sclerosis (“MSW”).

OSMOLEX ER® (amantadine) extended release tablets, was approved by the FDA on February 16, 2018, for the treatment of Parkinson’s disease and drug-induced extrapyramidal reactions in adult patients. On January 4, 2021, we acquired the global rights to OSMOLEX ER from Osmotica Pharmaceuticals US LLC, a subsidiary of Osmotica Pharmaceuticals plc.

NAMZARIC® (memantine hydrochloride extended release and donepezil hydrochloride) capsules for the treatment of moderate to severe dementia of an Alzheimer’s type, is marketed in the United States by Allergan plc under an exclusive license agreement between us and Forest Laboratories Holdings Limited (“Forest”), an indirect, wholly-owned subsidiary of Allergan plc (collectively, “Allergan”). We began recognizing royalty revenue on net sales of

NAMZARIC in May 2020.

Going forward, we intend to expand our product pipeline by acquiring, through license or otherwise, additional candidates for research and development and potential commercialization.

On December 1, 2020, we entered into a purchase agreement (the “Asset Purchase Agreement”) with Osmotica pursuant to which we acquired the global rights to OSMOLEX ER and existing inventory for \$7.5 million and the assumption of certain liabilities. The Asset Purchase Agreement closed on January 4, 2021.

On December 1, 2020, we entered into an agreement with HealthCare Royalty Partners III, L.P. (“HCR”) to amend certain key terms of our royalty-backed loan agreement (“Royalty-Backed Loan”) with HCR, to be effective upon the closing of the Asset Purchase Agreement with Osmotica which subsequently closed on January 4, 2021. For further discussion of the amended terms of the Royalty-Backed Loan, see “Note 16 - Subsequent Events” in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report.

On January 2, 2020, we announced we had granted Sandoz Inc. a license for its generic version of GOCOVRI as of March 4, 2030, which is over 12 years post GOCOVRI launch, or earlier in certain circumstances typical for such agreements. The agreement contains provisions that may accelerate the license date, including if unit sales of GOCOVRI for the 12-month period ending July 31, 2025 or any subsequent 12-month period decline by a specified percentage below GOCOVRI unit sales for the year ended December 31, 2019. On February 1, 2021, we announced we had granted Zydus a license for its generic version of GOCOVRI as of March 4, 2030. The agreement has similar terms as the Sandoz agreement, including the potential license acceleration provision. With these licenses granted to Sandoz and Zydus, the first filer ANDA challenges for GOCOVRI’s two available strengths have now been settled.

Impact of the COVID-19 pandemic on our company

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

How we are operating in the current COVID-19 shutdown

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

Impact on our ability to sell GOCOVRI

We continue to see stable GOCOVRI prescription refill rates due to our continued strong patient persistence, adequate supply of GOCOVRI, and patient access to GOCOVRI through distribution from our specialty pharmacy directly to a patient’s home. However, we have seen that new prescription rates have been impacted due to several factors, including: a fluid environment in which office practices are changing frequently including many healthcare providers have temporarily closed their offices or are restricting patient visits; patients are postponing visits to healthcare provider facilities; and our sales force has moved to a mix of virtual and live interactions with healthcare providers, adapting to the local environment. While we believe this initial decline and continued impact on new prescriptions to be temporary, the duration and severity is dependent on future developments, which are highly uncertain and cannot be predicted with confidence.

Impact on our supply chain

Our GOCOVRI supply chain remains robust and thus far we have observed no disruptions to our inventory on hand or our planned manufacturing schedule. In October 2020, the FDA approved our sNDA for AMSA S.p.A. as a secondary supplier of active pharmaceutical ingredient for GOCOVRI. We have an adequate supply of GOCOVRI to address patients’ needs into mid-2022. Based on current information, we believe that our partners in our supply chain have been and will continue to operate during the current COVID-19 outbreak.

Impact on our financial condition and capital resources

The extent of the impact of COVID-19 on our business, financial results, liquidity and cash flows will depend largely on future developments, including new information that may emerge concerning the severity and duration of actions taken to contain or prevent further spread. With already imposed shelter-at-home orders in place, we have observed widespread closure of clinics, and cancellation or rescheduling of patient appointments have been combined with restriction of access to sales representatives in some institutions and a marked increase in telemedicine consultations that may result in further sales reductions. In light of restrictions on travel and in-person meetings, we have also experienced cost reductions related to the transition to virtual formats and other travel related costs, in addition to other certain cost management activities. As of December 31, 2020, we had cash, cash equivalents, and investments of \$83.4 million.

Financial operations overview

Revenue

The following table summarizes the sources of our revenue for the years ended December 31, 2020 and 2019 (in thousands):

	Years Ended December 31,	
	2020	2019
Product sales	\$ 71,166	\$ 54,637
Royalty revenue	3,295	—
Total revenues	<u>\$ 74,461</u>	<u>\$ 54,637</u>

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 in January 2018.

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

Prior to the generation of product sales from GOCOVRI, our revenue had been generated primarily from payments under our license agreement with Allergan for non-refundable upfront license payments, milestone payments and reimbursements for research and development expenses for full-time equivalent employees assigned to the license agreement. There are no further milestone payments to be earned under our license agreement with Allergan, and we expect reimbursements for full-time equivalents assigned to the license agreement to be inconsequential in future periods. Beginning in May 2020, we began to recognize tiered royalties from Allergan in the low double digits to mid-teens, as a percent of net sales of NAMZARIC in the United States. Based on recent trends of NAMZARIC net sales, we expect the tiered royalty to be in the low double digits through the term of the agreement, but is eliminated in any quarter where there is significant competition from generics. Based on Allergan's and our current settlement agreements with the NAMZARIC ANDA filers to date, the earliest date on which any of these agreements grant a license to market a NAMZARIC ANDA filer's generic version of NAMZARIC is January 1, 2025 (or earlier in certain circumstances). Alternatively, the NAMZARIC ANDA filers with the earliest license date have the option to launch an authorized generic version of NAMZARIC beginning on January 1, 2026 instead of launching their own generic version of NAMZARIC on January 1, 2025. For further discussion of NAMZARIC ANDA filers, see *Litigation and Other Legal Proceedings* in "Note 9 - Commitments and Contingencies" in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report.

Cost of product sales

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

Research and development expenses

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

Research and development expenses consist of:

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

The following table summarizes our research and development expenses incurred during the years ended December 31, 2020 and 2019 (in thousands):

	Years Ended December 31,	
	2020	2019
GOCOVRI(1)	\$ 8,024	\$ 23,448
ADS-4101(2)	—	2,516
Other research and development expenses	1,722	4,070
Total research and development expenses	<u>\$ 9,746</u>	<u>\$ 30,034</u>

- (1) Includes program costs we incurred for GOCOVRI (formerly referred to as ADS-5102) for the treatment of dyskinesia in patients with Parkinson's disease, and ADS-5102 (GOCOVRI) for additional potential CNS indications, including for the treatment of walking impairment in patients with multiple sclerosis.
- (2) We placed the ADS-4101 development program on hold during the quarter ended June 30, 2019.

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

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

The process of conducting the necessary clinical research to obtain FDA approval is costly and time consuming.

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

Selling, general and administrative expenses, net

Selling, general and administrative expenses, net, consist primarily of personnel and related benefit costs, including stock-based compensation, facilities, professional services, insurance, public company related expenses, charitable contribution expenses, costs associated with supporting the commercialization of GOCOVRI, as well as litigation settlement charges. We anticipate our selling, general and administrative expenses will remain significant and may increase as we continue to support the commercialization of GOCOVRI.

Interest and other income, net

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

Interest expense

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

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. We base our estimates on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. 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.

While our significant accounting policies are described in more detail in Note 2 of our financial statements included in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers* ("ASC606"), which we adopted on January 1, 2018, using the full retrospective transition method. We recognize revenue upon transfer of control of promised products or services to customers in an amount that reflects the consideration we expect to receive in exchange for those products or services. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

Product sales

Our product sales in 2020 and 2019 consist solely of U.S. sales of GOCOVRI. We sell our products principally to a specialty pharmacy and certain specialty distributors (each a “Customer” or collectively our “Customers”). The Customer subsequently dispenses product directly to a patient. In addition, except for limited circumstances, the Customer has no right of product return to us. We recognize revenue from product sales when the Customer obtains control of our product, which occurs at a point in time, typically upon delivery to the Customer. We record revenue from product sales after considering the impact of various forms of variable consideration, which include Medicare Part D coverage gap, rebates, chargebacks, co-payment assistance, distribution fees, and product returns. Each of these items of variable consideration we record at the time of revenue recognition and requires significant estimates, judgment and information obtained from external sources. If management’s estimates differ from actual results, we will record adjustments that would affect product sales in the period of adjustment. For a full description of our various forms of variable consideration, see *Revenue Recognition* in “Note 2 - Basis of Presentation and Summary of Significant Accounting Policies” in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report. Medicare Part D coverage gap, rebates and chargebacks require the most complex and significant judgment and are described further below.

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. We estimate the Medicare Part D coverage gap using the expected-value method based on an amount expected to be incurred for the current quarter’s activity based on expected utilization, plus an accrual balance for known prior quarters and is adjusted quarterly based on actual experience. We estimate for expected utilization of the Medicare Part D coverage gap based on data received from the specialty pharmacy and historical utilization.

Rebates: Rebates include discounts under the Medicaid Drug Rebate Program, TRICARE Retail Pharmacy Refunds Program (TRICARE), and Managed Care contracts. 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. We estimate rebates based on statutory discount rates and expected utilization. We estimate for expected utilization of rebates based on data received from the specialty pharmacy and specialty distributor. We use the expected-value method for estimating rebates and we adjust the estimates quarterly to reflect actual experience.

Chargebacks: Chargebacks are discounts that occur when Healthcare Providers purchase directly from our Customer. Healthcare Providers, which currently consist of Public Health Service institutions, non-profit clinics, government entities, group purchasing organizations, and health maintenance organizations, generally purchase the product at a discounted price. Our Customer, in turn, charges back to us the difference between the price initially paid by our Customer and the discounted price paid by the Healthcare Providers to our Customer. We base the allowance for chargebacks on an estimate of sales through to Healthcare Providers from our Customer.

The following table summarizes activity with respect to our sales allowances and accruals for the years ended December 31, 2020 and 2019 (in thousands):

	Government and other rebates, and chargebacks	Co-payment assistance, data fees, cash discounts and returns	Total
Balances at December 31, 2018	\$ 924	\$ 242	\$ 1,166
Provision related to current period sales	5,546	2,579	8,125
Credit or payments made during the period	(4,832)	(2,444)	(7,276)
Balances at December 31, 2019	1,638	377	2,015
Provision related to current period sales	9,073	3,294	12,367
Credit or payments made during the period	(8,223)	(3,242)	(11,465)
Adjustment related to prior period sales	(829)	(115)	(944)
Balances at December 31, 2020	<u>\$ 1,659</u>	<u>\$ 314</u>	<u>\$ 1,973</u>

Stock-Based Compensation

We account for stock-based compensation of restricted stock units granted to employees based on the closing price of our common stock on the date of grant. We account for stock-based compensation of stock options and for employee stock purchase plan shares by estimating the fair value using the Black-Scholes option-pricing model. We recognize and amortize the fair value of stock-based awards, net of estimated forfeitures, over the applicable vesting period.

The Black-Scholes option pricing model requires the use of certain subjective assumptions. The most significant subjective assumptions are management's estimates of the expected volatility and the expected term of the award. Judgment is also required in estimating the amount of share-based awards that we expect to be forfeited.

Long-Term Debt

Long-term debt consists of our Royalty-Backed Loan with HCR, accounted for as a debt financing arrangement. We accrue interest expense using the effective interest rate method over the estimated period we expect the debt to be repaid. We must make certain assumptions and estimates, including future royalties and net product sales, in determining the expected repayment term, amortization period of the debt discount, and accretion of interest expense, as well as the classification between current and long-term portions. We will base payment amounts to HCR on actual royalties and net product sales. We periodically assess our assumptions and estimates and adjust the liabilities accordingly.

Embedded Derivatives Related to Debt Instruments

We evaluate and value embedded derivatives that are required to be bifurcated from their host contract separately from the debt instrument. Under our loan agreement with HCR, upon the occurrence of a default or a change in control, we may be required to make mandatory prepayments of the borrowings. The prepayment premium is considered an embedded derivative, as the holder of the loans may exercise the option to require prepayment by us. Further, in the event of a regulatory change that results in a material adverse effect on HCR's rate of return, we shall pay directly to HCR an amount that compensates HCR for such reduction. We remeasure the embedded derivatives each reporting period and report changes in the estimated fair value as gains or losses in interest and other income, net, in our consolidated statements of operations.

The model used in valuing the embedded derivative as a result of a change in control requires the use of significant estimates and assumptions including but not limited to: 1) expected cash flows we expect to receive on U.S. net sales of GOCOVRI and on royalties from Allergan on U.S. net sales of NAMZARIC; 2) our 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. We 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.

Results of operations

Fluctuations in Operating Results

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

Comparison of the years ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019 (in thousands, except percentages):

	Years Ended December 31,		Increase/	% Increase/
	2020	2019	(Decrease)	(Decrease)
Product sales	\$ 71,166	\$ 54,637	\$ 16,529	30 %
Royalty revenue	3,295	—	3,295	NM
Cost of product sales	2,038	2,469	(431)	(17)%
Research and development expenses	9,746	30,034	(20,288)	(68)%
Selling, general and administrative expenses, net	106,841	114,369	(7,528)	(7)%
Interest and other income, net	748	2,093	(1,345)	(64)%
Interest expense	13,987	15,044	(1,057)	(7)%

NM - Not meaningful.

The following table summarizes the approximate number of total GOCOVRI paid prescriptions for the years ended December 31, 2020 and 2019:

	Years Ended December 31,		Increase	% Increase
	2020	2019		
Total GOCOVRI Paid Prescriptions	31,070	25,780	5,290	21 %

Strong patient persistence of 45%-50% at 12 months continued in the fourth quarter of 2020. In addition to total paid prescriptions, we monitor new paid prescriptions as a key performance indicator for our business and starting with the first quarter of 2020 are reporting this metric. The following table summarizes the approximate number of total GOCOVRI paid prescriptions and approximate number of new GOCOVRI paid prescriptions for each of the quarterly periods presented:

	Three months ended			
	December 31	September 30	June 30	March 31
Total GOCOVRI paid prescriptions:				
2020(1)	8,165	7,785	7,915	7,205
2019	7,160	6,640	6,160	5,820
New GOCOVRI paid prescriptions:				
2020	510	430	370	500

(1) Total GOCOVRI paid prescriptions in 2020 for the three months ended September 30, June 30, and March 31 have been adjusted from previously reported amounts of 7,930, 8,150, and 7,210, respectively, to reflect reconciled 340b dispenses through the specialty distribution channel.

Product sales

Product sales increased by \$16.5 million, or 30%, to \$71.2 million for the year ended December 31, 2020, from \$54.6 million for the year ended December 31, 2019, due to growth in sales of GOCOVRI since its launch, in addition to a 3% price increase that went into effect in January 2020. The approximate number of total paid prescriptions increased by 5,290, or 21%, to 31,070 for the year ended December 31, 2020, from 25,780 for the year ended December 31, 2019.

Royalty revenue

Royalty revenue was \$3.3 million for the year ended December 31, 2020. We began recognizing royalty revenue on net sales of NAMZARIC in May 2020 and accordingly had no royalty revenue for the year ended December 31, 2019.

Cost of product sales

Cost of product sales decreased by \$0.4 million to \$2.0 million, or 3% of product sales, for the year ended

December 31, 2020, from \$2.5 million, or 5% of product sales, for the year ended December 31, 2019. Included in cost of product sales for the year ended December 31, 2019 is a one-time charge related to amending our agreement with our CMO. Prior to receiving FDA approval in August 2017, we recorded all inventory costs incurred in the manufacture of GOCOVRI to be sold upon commercialization as research and development expense. As of December 31, 2020, substantially all the inventory that was previously expensed to research and development had been sold to customers. We do not expect our cost of product sales of GOCOVRI as a percentage of product sales to exceed 6% for the foreseeable future, excluding potential unknown one-time charges.

Research and development expenses

Research and development expenses decreased by \$20.3 million, or 68%, to \$9.7 million for the year ended December 31, 2020, from \$30.0 million for the year ended December 31, 2019. The decrease in research and development expenses was mainly attributable to: decreased costs related to clinical activity for our Phase 3 study in support of ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis mainly due to completion of the Phase 3 INROADS trial at the end of 2019; decreased costs related to the decision during the second quarter of 2019 to defer additional investment in the development of our product candidate ADS-4101 for the treatment of partial onset seizures in patients with epilepsy; and decreased costs related to early stage programs. Included in research and development expenses was stock-based compensation expense, which was \$0.4 million compared to \$1.7 million for the years ended December 31, 2020 and 2019, respectively.

Selling, general and administrative expenses, net

Selling, general and administrative expenses, net, decreased by \$7.5 million, or 7%, to \$106.8 million for the year ended December 31, 2020, from \$114.4 million for the year ended December 31, 2019, primarily due to: decreased costs of approximately \$6.6 million in personnel related costs, including stock-based compensation and other certain one-time charges in conjunction with a consulting agreement entered into during the prior year with our former Chief Executive Officer; and decreased costs of approximately \$7.8 million related to legal fees, cost management activities, and other general corporate expense. The decrease for the year ended December 31, 2020 was offset in part by a one-time charge of approximately \$5.0 million related to a probable loss associated with the OSMOLEX ER settlement of patent litigation, in addition to approximately \$1.9 million for GOCOVRI related promotional costs, market research, and other external professional services, as compared to the same period in the prior year. Included in selling, general and administrative expenses was stock-based compensation expense, which was \$6.0 million compared to \$11.1 million for the years ended December 31, 2020 and 2019, respectively.

Interest and other income, net

Interest and other income, net, decreased by \$1.3 million, or 64%, to \$0.7 million for the year ended December 31, 2020, from \$2.1 million for the year ended December 31, 2019. The decrease in interest and other income, net, was primarily driven by lower interest income earned on lower cash and investment balances, offset in part by a change in fair value of the embedded derivative liability related to our Royalty-Backed Loan with HCR, which was \$0.2 million compared to \$0.8 million for the years ended December 31, 2020 and 2019, respectively.

Interest expense

Interest expense decreased by \$1.1 million, or 7%, to \$14.0 million for the year ended December 31, 2020, compared to \$15.0 million in the year ended December 31, 2019. The decrease in interest expense was mainly related to a lower estimated effective interest rate on our Royalty-Backed Loan with HCR, offset in part by a higher principal balance.

Liquidity and Capital Resources

Our principal sources of liquidity are our cash, cash equivalents, and investments, which totaled \$83.4 million and \$132.6 million at December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of \$505.3 million.

Prior to 2018, we raised an aggregate of approximately \$202.3 million in sales of equity securities and entered into a Royalty-Backed Loan with HCR, whereby we borrowed a total of \$100.0 million. As of December 31, 2020, the total remaining payment obligation of the Royalty-Backed Loan was \$179.2 million. During the last three fiscal years,

we have funded our operations primarily through sales of GOCOVRI, through sales of our common stock, and to a lesser extent through royalties received on net sales of NAMZARIC. We made GOCOVRI available for physician and patient use in the fourth quarter of 2017, with a full commercial launch in January 2018. Prior to the generation of revenue from GOCOVRI, we had not generated any commercial revenue from the sale of our products. In January 2018, we completed a follow-on public offering of our common stock from which proceeds raised were approximately \$134.3 million, net of underwriting discounts, commissions, and offering-related transaction costs from the sale of 3,450,000 shares of common stock. In November 2019, we entered into a sales agreement with Cowen and Company, LLC, pursuant to which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to \$50.0 million. As of December 31, 2020, we had issued 217,403 shares of common stock and raised net proceeds of \$1.0 million under the sales agreement. Subsequent to December 31, 2020, and through February 16, 2021, we issued an additional 1,335,896 shares of common stock under the sales agreement and raised net proceeds of approximately \$7.2 million. Beginning in May 2020, we began to recognize tiered royalties from Allergan in the low double digits to mid-teens, as a percent of net sales of NAMZARIC in the United States. As of December 31, 2020, we had non-cancelable purchase commitments of \$2.4 million due within one year.

We believe our existing cash, cash equivalents, and investments at December 31, 2020 will be sufficient to fund our projected operating requirements, including continued commercialization of GOCOVRI for the treatment of OFF and dyskinesia in patients with Parkinson's disease and operations related to completing activities for ADS-5102 in MSW, for at least 12 months from the issuance of this annual report on Form 10-K. However, it is possible that we will not achieve the progress that we expect, because revenues from GOCOVRI may be less than anticipated, especially in light of the current COVID-19 pandemic, and the actual costs and timing of drug development, particularly clinical studies, and regulatory approvals are difficult to predict, subject to substantial risks and delays, and often vary depending on the particular indication and development strategy. The duration and severity of the COVID-19 pandemic is unknown and makes projecting the outcome of future developments highly uncertain and cannot be predicted with confidence. Moreover, the costs associated with commercializing drugs are high and market acceptance is uncertain.

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

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

	Years Ended December 31,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	\$ (50,708)	\$ (80,779)
Investing activities	54,940	88,863
Financing activities	1,654	1,085
Net increase (decrease) in cash and cash equivalents	<u>\$ 5,886</u>	<u>\$ 9,169</u>

Net Cash Used In Operating Activities

Net cash used in operating activities was \$50.7 million for the year ended December 31, 2020 and consisted primarily of our net loss of \$57.4 million less non-cash adjustments of \$21.9 million, mainly for accretion of interest expense of \$14.0 million and stock-based compensation of \$6.4 million, in addition to payments related to our Royalty-Backed Loan with HCR of \$11.7 million, and changes to our assets and liabilities of \$3.5 million due to timing of payments in the ordinary course of business.

Net cash used in operating activities was \$80.8 million for the year ended December 31, 2019 and consisted primarily of our net loss of \$105.2 million less non-cash adjustments of \$29.6 million, mainly for stock-based compensation of \$12.9 million and interest expense of \$15.0 million, in addition to payments related to our Royalty-Backed Loan with HCR of \$6.5 million.

Net Cash Provided By Investing Activities

Net cash provided by investing activities was \$54.9 million for the year ended December 31, 2020, as a result of maturities and sales of available-for-sale securities, net of purchases.

Net cash provided by investing activities was \$88.9 million for the year ended December 31, 2019, primarily as a result of maturities of available-for-sale securities, net of purchases.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was \$1.7 million for the year ended December 31, 2020, as a result of cash proceeds of \$1.0 million related to the sale of common stock under a controlled equity offering coupled with \$0.6 million related to the exercise of stock options and purchases of common stock under the Employee Stock Purchase Plan (ESPP).

Net cash provided by financing activities was \$1.1 million for the year ended December 31, 2019, as a result of cash proceeds related to the exercise of stock options and purchases of common stock under the ESPP.

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

As a smaller reporting company, we are not required to provide the disclosure required by Item 303(a)(5) of Regulation S-K.

Recent Accounting Pronouncements

For a discussion of new accounting pronouncements, see “Note 2 - Basis of Presentation and Summary of Significant Accounting Policies” in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**ADAMAS PHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

Report of Independent Registered Public Accounting Firm	58
Consolidated Financial Statements:	
Consolidated Balance Sheets	60
Consolidated Statements of Operations	61
Consolidated Statements of Comprehensive Loss	62
Consolidated Statements of Stockholders' Equity (Deficit)	63
Consolidated Statements of Cash Flows	64
Notes to Consolidated Financial Statements	65

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Adamas Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Adamas Pharmaceuticals, Inc. and its subsidiaries (the “Company”) as of December 31, 2020 and 2019, and the related consolidated statements of operations, of comprehensive loss, of stockholders’ equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Sales Deductions for the Medicare Part D Coverage Gap

As described in Notes 2 and 5 to the consolidated financial statements, revenue from product sales is recorded after considering the impact of the variable consideration, including mandated payments to fund a portion of the Medicare Part D coverage gap, which can decrease the transaction price, at the time of revenue recognition. As of December 31, 2020, the liability for accrued sales deductions was \$1.6 million, of which a portion related to accrued sales deductions for the Medicare Part D coverage gap. Management estimates the liability related to accrued sales deductions for the Medicare Part D coverage gap using the expected-value method based on an amount expected to be incurred for the current quarter’s activity based on expected utilization. The liability is adjusted quarterly based on actual experience.

Management's estimate for expected utilization of the Medicare Part D coverage gap is based on data received from the specialty pharmacy and historical utilization.

The principal considerations for our determination that performing procedures relating to accrued sales deductions for the Medicare Part D coverage gap is a critical audit matter are the high degree of auditor judgment, subjectivity, and effort in performing procedures relating to accrued sales deductions due to the significant judgment by management when developing the estimate.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others (i) obtaining an understanding of management's process and methodology used to develop the estimate of the accrued sales deductions for the Medicare Part D coverage gap, (ii) performing retrospective comparison of actual third party invoices received subsequent to the prior and current year-end to evaluate the reasonableness of the prior and current period estimate, (iii) developing an independent estimate by utilizing third party data, (iv) comparing the independent estimate to management's estimate, and (v) testing claims paid by the Company.

/s/ PricewaterhouseCoopers LLP

San Jose, California
February 23, 2021

We have served as the Company's auditor since 2007.

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

	December 31,	
	2020	2019
Assets		
Current assets		
Cash and cash equivalents	\$ 71,660	\$ 65,774
Available-for-sale securities	11,705	66,833
Accounts receivable, net	8,042	5,770
Inventory	7,294	5,267
Prepaid expenses and other current assets	13,035	6,676
Total current assets	111,736	150,320
Property and equipment, net	1,598	2,449
Operating lease right-of-use assets	6,657	8,048
Prepaid expenses and other non-current assets	38	1,341
Total assets	<u>\$ 120,029</u>	<u>\$ 162,158</u>
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable	\$ 2,144	\$ 6,932
Accrued liabilities	27,164	16,117
Current portion of long-term debt	3,657	2,041
Other current liabilities	1,902	1,858
Total current liabilities	34,867	26,948
Long-term debt	126,307	125,674
Long-term portion of operating lease liabilities	6,453	8,272
Other non-current liabilities	2,378	2,157
Total liabilities	<u>170,005</u>	<u>163,051</u>
Commitments and Contingencies (Note 9)		
Stockholders' deficit		
Preferred stock, \$0.001 par value — 5,000,000 shares authorized, and zero shares issued and outstanding at December 31, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value — 100,000,000 shares authorized, 28,866,956 and 27,964,778 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	34	33
Additional paid-in capital	455,277	446,942
Accumulated other comprehensive income	—	16
Accumulated deficit	(505,287)	(447,884)
Total stockholders' deficit	<u>(49,976)</u>	<u>(893)</u>
Total liabilities and stockholders' deficit	<u>\$ 120,029</u>	<u>\$ 162,158</u>

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

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

	Years Ended December 31,	
	2020	2019
Revenues:		
Product sales	\$ 71,166	\$ 54,637
Royalty revenue	3,295	—
Total revenues	<u>74,461</u>	<u>54,637</u>
Costs and operating expenses:		
Cost of product sales	2,038	2,469
Research and development	9,746	30,034
Selling, general and administrative, net	106,841	114,369
Total costs and operating expenses	<u>118,625</u>	<u>146,872</u>
Loss from operations	(44,164)	(92,235)
Interest and other income, net	748	2,093
Interest expense	(13,987)	(15,044)
Net loss	<u>\$ (57,403)</u>	<u>\$ (105,186)</u>
Net loss per share, basic and diluted	<u>\$ (2.03)</u>	<u>\$ (3.80)</u>
Weighted average shares used in computing net loss per share, basic and diluted	<u>28,305</u>	<u>27,677</u>

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

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

	Years Ended December 31,	
	2020	2019
Net loss	\$ (57,403)	\$ (105,186)
Other comprehensive income (loss)		
Reclassification of realized gain on available-for-sale securities recognized in interest and other income, net	(34)	—
Unrealized gain on available-for-sale securities	18	280
Total other comprehensive income (loss)	(16)	280
Comprehensive loss	<u>\$ (57,419)</u>	<u>\$ (104,906)</u>

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balances at December 31, 2018	27,434,358	\$ 32	\$ 432,815	\$ (264)	\$ (342,698)	\$ 89,885
Exercise of stock options	184,626	—	293	—	—	293
Restricted stock units vested	151,288	—	—	—	—	—
Stock issued under employee stock purchase plan	194,506	1	774	—	—	775
Other comprehensive income	—	—	—	280	—	280
Stock-based compensation	—	—	13,060	—	—	13,060
Net loss	—	—	—	—	(105,186)	(105,186)
Balances at December 31, 2019	27,964,778	\$ 33	\$ 446,942	\$ 16	\$ (447,884)	\$ (893)
Exercise of stock options	237,425	—	176	—	—	176
Restricted stock units vested	258,819	—	—	—	—	—
Stock issued under employee stock purchase plan	188,531	—	437	—	—	437
Issuance of common stock in conjunction with equity offering, net of commissions and issuance costs	217,403	1	1,040	—	—	1,041
Other comprehensive loss	—	—	—	(16)	—	(16)
Stock-based compensation	—	—	6,682	—	—	6,682
Net loss	—	—	—	—	(57,403)	(57,403)
Balances at December 31, 2020	28,866,956	\$ 34	\$ 455,277	\$ —	\$ (505,287)	\$ (49,976)

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

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

	Years Ended December 31,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (57,403)	\$ (105,186)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	851	1,214
Stock-based compensation	6,431	12,852
Accretion of interest expense	13,987	15,044
Change in fair value of embedded derivative liability	221	805
Net accretion of discounts and amortization of premiums of available-for-sale securities	(135)	(1,219)
Realized gain on available-for-sale securities	(55)	—
Provision for write-down of inventory	595	884
Changes in assets and liabilities		
Accrued interest of available-for-sale securities	362	50
Accounts receivable, net	(2,272)	(259)
Inventory	(2,205)	(970)
Prepaid expenses and other assets	(5,056)	1,560
Operating lease right-of-use assets	1,437	1,008
Accounts payable	(4,979)	398
Current portion of long-term debt	(11,738)	(6,450)
Long-term portion of operating lease liabilities	(1,696)	(1,188)
Accrued liabilities and other liabilities	10,947	678
Net cash used in operating activities	<u>(50,708)</u>	<u>(80,779)</u>
Cash flows from investing activities		
Purchases of property and equipment	—	(18)
Purchases of available-for-sale securities	(68,936)	(93,869)
Maturities of available-for-sale securities	106,810	182,750
Sales of available-for-sale securities	17,066	—
Net cash provided by investing activities	<u>54,940</u>	<u>88,863</u>
Cash flows from financing activities		
Proceeds from public offerings, net of offering costs	1,041	—
Proceeds from Paycheck Protection Program Loan	2,650	—
Repayment of Paycheck Protection Program Loan	(2,650)	—
Proceeds from issuance of common stock upon exercise of stock options	176	310
Proceeds from employee stock purchase plan	437	775
Net cash provided by financing activities	<u>1,654</u>	<u>1,085</u>
Net increase in cash and cash equivalents	5,886	9,169
Cash and cash equivalents at beginning of period	65,774	56,605
Cash and cash equivalents at end of period	<u>\$ 71,660</u>	<u>\$ 65,774</u>
Supplemental disclosure		
Cash paid for interest	\$ 11,738	\$ 6,450
Supplemental disclosure of noncash activities		
Right-of-use assets obtained in exchange for operating lease liabilities	\$ 46	\$ 9,056
Stock-based compensation capitalized in inventory	\$ 251	\$ 208

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

ADAMAS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

Adamas Pharmaceuticals, Inc. (the “Company”) is a commercial-stage pharmaceutical company focused on growing a portfolio of therapies to address a range of neurological diseases. In August 2017, the U.S. Food and Drug Administration (FDA) approved GOCOVRI[®] (amantadine) extended release capsules, the first and only FDA-approved medication indicated for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. In February 2021, the FDA approved a second indication for GOCOVRI for use as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing OFF episodes. On January 4, 2021, the Company acquired the global rights to OSMOLEX ER[®] (amantadine) extended release tablets from Osmotica Pharmaceuticals US LLC, a subsidiary of Osmotica Pharmaceuticals plc. 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[®] (memantine hydrochloride extended release and donepezil hydrochloride) capsules for the treatment of moderate to severe dementia related to Alzheimer’s disease. In May 2020, the Company became entitled to receive royalties at rates in the low double digits to mid-teens from Allergan for sales of NAMZARIC in the United States.

The Company 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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

Use of Estimates

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

Risks and Uncertainties

The outbreak of the novel Coronavirus (“COVID-19”), which is understood to have begun in December 2019, continues to grow both within the U.S. and globally. The World Health Organization has declared the outbreak of COVID-19 to be a pandemic, and the U.S. federal government has declared it a national emergency. The Company is subject to risks and uncertainties as a result of the outbreak of COVID-19. Despite disruptions to the Company’s business operations, the COVID-19 pandemic did not significantly impact GOCOVRI prescription refill rates for the year ended December 31, 2020, and thus far management has observed no disruptions to its inventory on hand or planned manufacturing schedule. However, new prescription rates have been impacted due to several factors, including: a fluid environment in which office practices are changing frequently including many healthcare providers have temporarily closed their offices or are restricting patient visits; patients are postponing visits to healthcare provider facilities; and the sales force has moved to a mix of virtual and live interactions with healthcare providers, adapting to the local environment. While management believes this initial decline and continued impact on new prescriptions to be temporary, the duration and severity is dependent on future developments, including new information that may emerge concerning the actions taken to contain or prevent further spread, all of which are highly uncertain and cannot be predicted with confidence.

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

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

Liquidity

During the last three fiscal years, the Company has funded its operations primarily through sales of GOCOVRI, through sales of its common stock, and to a lesser extent through royalties received on net sales of NAMZARIC. The Company made GOCOVRI available for physician and patient use in the fourth quarter of 2017, with a full commercial launch in January 2018. Prior to the generation of revenue from GOCOVRI, the Company had not generated any commercial revenue from the sale of its products. In January 2018, the Company completed a follow-on public offering of its common stock from which proceeds raised were approximately \$134.3 million, net of underwriting discounts, commissions, and offering-related transaction costs. In November 2019, the Company entered into a sales agreement with Cowen and Company, LLC, pursuant to which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to \$50.0 million. As of December 31, 2020, the Company had issued 217,403 shares of common stock and raised net proceeds of \$1.0 million under the sales agreement.

As of December 31, 2020, the Company had \$83.4 million of cash, cash equivalents, and investments, which management believes will be sufficient to fund its projected operating requirements for at least 12 months from the issuance of these consolidated financial statements. However, it is possible that the Company will not achieve the progress it expects, because revenues from GOCOVRI may be less than anticipated, especially in light of the current COVID-19 pandemic.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first-in first-out method. Inventory consists of raw materials, work-in-process, and GOCOVRI finished goods. Raw materials and work-in-process that may be utilized for both commercial and clinical programs are identical and, as a result, the inventory has an "alternative future use" as defined in authoritative guidance and are included in inventory. Amounts in inventory associated with clinical development programs are charged to research and development expense when the product enters the research and development process and can no longer be used for commercial purposes and, therefore, does not have "alternative future use". Costs include active pharmaceutical ingredient (API), third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, and indirect overhead costs. If the Company identifies excess, obsolete or unsalable product, the Company will write down its inventory to net realizable value in the period it is identified.

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

Cash and Cash Equivalents

Cash and cash equivalents consist of highly liquid investments with original maturities, when purchased, of less than three months.

Investments

The Company classifies its investments as "available-for-sale." In general, these investments are free of trading restrictions. The Company carries these investments at fair value, based on quoted market prices or other readily available market information. Quoted market prices for U.S. government and corporate bonds include both principal and accrued interest components. Unrealized gains and losses are included in accumulated other comprehensive income, which is reflected as a separate component of stockholders' equity in its consolidated balance sheets. Gains and losses are recognized when realized as gains or losses in interest and other income, net, in the consolidated statements of operations. When the Company determines that an other-than-temporary decline in fair value has occurred, the amount of the decline that is related to a credit loss is recognized in income. Gains and losses are determined using the specific identification method. The Company considers all marketable debt securities with a maturity of less than one year to be short-term investments, with all others considered to be long-term investments.

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

All of the Company's available-for-sale securities are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. Factors considered in determining whether a loss is temporary include the length of time and extent to which the investments' fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, extent of the loss related to credit of the issuer, the expected cash flows from the security, its intent to sell or hold the security, and whether or not the Company will be required to sell the security before the recovery of its amortized cost.

Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

Segments

In accordance with ASC 280-10-50, Segment Reporting, operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company operates in one reportable segment: the development and commercialization of therapeutics targeting chronic disorders of the central nervous system. All revenues for the years ended December 31, 2020 and 2019 were generated in the United States.

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.

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

The Company considers the 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 discounts under the Medicaid Drug Rebate Program, TRICARE Retail Pharmacy Refunds Program (TRICARE), and Managed Care contracts. 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 and specialty distributor. The Company uses the expected-value method for estimating rebates and estimates are adjusted quarterly to reflect actual experience.

Chargebacks: Chargebacks are discounts that occur when Healthcare Providers purchase directly from a Customer. Healthcare Providers, which currently consist of Public Health Service institutions, non-profit clinics, government entities, group purchasing organizations, and health maintenance organizations, generally purchase the product at a discounted price. The Customer, in turn, charges back to the Company the difference between the price initially paid by the Customer and the discounted price paid by the Healthcare Providers to the Customer. The allowance for chargebacks is based on an estimate of sales through to Healthcare Providers from the Customer.

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 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 based on expected utilization, plus an accrual balance for known prior quarters and is adjusted quarterly based on actual experience. The expected utilization of the Medicare Part D coverage gap is estimated based on data received from the specialty pharmacy and historical utilization.

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 periods presented. 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,

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

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.

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. Sales-based royalties are recorded based on estimated quarterly net sales of NAMZARIC. Differences between actual results and estimated amounts are adjusted in the period in which they become known, which typically follows the quarterly period in which the estimate is made. To date, actual royalties received have not differed materially from estimates. Receivables related to NAMZARIC royalties are recorded in prepaid expenses and other current assets on the consolidated balance sheets.

Cost of Product Sales

Cost of product sales consists primarily of direct and indirect costs related to the manufacturing of GOCOVRI products sold, including third-party manufacturing costs, packaging services, freight, and allocation of overhead costs. Cost of product sales may also include period costs related to certain inventory manufacturing services, inventory adjustment charges, as well as manufacturing variances. In connection with the FDA approval of GOCOVRI on August 24, 2017, the Company began capitalizing inventory manufactured at the FDA approved location starting in August

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

2017. Prior to receiving regulatory approval for GOCOVRI from the FDA, the Company expensed all costs incurred in the manufacture of GOCOVRI as research and development.

Concentration of Risk

Credit Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents and short and long-term investments. Cash, cash equivalents, and investments are deposited with financial institutions or invested in security issuers that management believes are credit worthy. Deposits may, at times, exceed the amount of insurance provided on such deposits. Risks associated with cash, cash equivalents, and investments are mitigated by the Company's investment policy which defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity.

Major Customers

The Company has entered into distribution agreements with a specialty pharmacy and certain limited specialty distributors. For the years ended December 31, 2020 and 2019, the Company's largest customer represented approximately 95% and 98% of the Company's product revenue, respectively, and approximately 94% and 96% of the Company's accounts receivable balance at December 31, 2020 and 2019, respectively.

Major Suppliers

The Company does not currently have any of its own manufacturing facilities, and therefore it depends on an outsourced manufacturing strategy for the production of GOCOVRI for commercial use and for the production of its product candidates for clinical trials. The Company has contracts in place with one third-party manufacturer that is approved for the commercial production of GOCOVRI and two third-party suppliers that are approved for GOCOVRI's active pharmaceutical ingredient. Although there are potential sources of supply other than the Company's existing manufacturers and suppliers, any new supplier would be required to qualify under applicable regulatory requirements.

Accounts Receivable, net

The Company's accounts receivable balance consists of amounts due from sales of GOCOVRI. Receivables from sales of GOCOVRI are recorded net of allowances which generally include chargebacks, doubtful accounts, and discounts. The Company's estimate of the allowance for doubtful accounts is based on an evaluation of the aging of its receivables. Accounts receivable balances are written off against the allowance when it is probable that the receivable will not be collected. Given the nature and historical collectability of the Company's accounts receivable, the Company determined that an allowance for doubtful accounts was not required at December 31, 2020.

Property and Equipment

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheets and any resulting gain or loss is reflected in operations in the period realized.

Estimated useful lives by major asset category are as follows:

	<u>Useful Lives</u>
Computer equipment and software	3 years
Equipment	5 years
Furniture and fixtures	10 years

Leases

The Company determines if an arrangement is, or contains, a lease at inception. An arrangement is, or contains, a lease if it conveys the right to control the use of identified property, plant or equipment (i.e., an identified asset) for a

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

period of time in exchange for consideration. The Company's arrangements determined to be or contain a lease include explicitly or implicitly identified assets where the Company has the right to substantially all of the economic benefits of the assets and has the ability to direct how and for what purpose the assets are used during the lease term. Operating leases are included in operating lease right-of-use ("ROU") assets, other current liabilities, and operating lease liabilities on its consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term and any amounts probable of being owed under a residual value guarantee (if applicable). In determining the incremental borrowing rate used to calculate the present value of lease payments, the Company uses the interest rate specified in the lease. If the rate is not readily determinable, which is generally the case for the Company, the Company uses its incremental borrowing rate based on the information available at the commencement date. The operating lease ROU assets also include any lease payments made (including any prepaid rents and initial direct costs) and excludes lease incentives. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise any such options. Lease expense for lease payments is recognized on a straight-line basis over the expected lease term. The Company has lease agreements with lease components and non-lease components. For its facility and office equipment lease, the Company accounts for the lease and non-lease components separately. For its vehicle leases, the Company elected the practical expedient to not separate lease components, such as base rent payments, and non-lease components, such as interest, and also applies a portfolio approach to effectively account for the operating lease ROU assets and liabilities, given the volume of individual leases involved in the overall arrangement.

Accounting for Long-Lived Assets

The Company reviews its long-lived assets, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by the comparison of the carrying amount to the future net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There have been no such impairments of long-lived assets as of December 31, 2020.

Clinical Trial Accruals

The Company's clinical trial accruals are based on estimates of patient enrollment and related activities at clinical investigator sites, as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations ("CROs") that conduct and manage clinical trials on the Company's behalf. The Company estimates clinical trial expenses based on the estimated services performed pursuant to these contracts, as provided by the CRO. These estimates are reviewed for reasonableness by the Company's internal clinical personnel. The Company monitors patient enrollment levels and related activities using available information; however, if the Company underestimates activity levels associated with various studies at a given point in time, the Company could be required to record significant additional R&D expenses in future periods when the actual activity level becomes known. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Research and Development

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

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

Long-Term Debt

Long-term debt consists of the Company's royalty-backed loan agreement ("Royalty-Backed Loan") with HealthCare Royalty Partners ("HCR"). The Company accounted for the loan agreement as a debt financing arrangement. Interest expense is accrued using the effective interest rate method over the estimated period the debt will be repaid. Debt issuance costs have been recorded as a debt discount in the Company's consolidated balance sheets and are being amortized and recorded as interest expense throughout the life of the loan using the effective interest rate method. The Company must make certain assumptions and estimates, including future royalties and net product sales, in determining the expected repayment term, amortization period of the debt discount, accretion of interest expense, as well as the classification between current and long-term portions. The Company periodically assesses these assumptions and estimates, and adjusts the liabilities accordingly. Under the terms of the loan, HCR has recourse to Adamas Pharma, LLC, not the Company. See Note 10 - Long-Term Debt, for further details of the Company's long-term debt.

Embedded Derivatives Related to Debt Instruments

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

Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, short-term investments, accounts receivable, long-term investments and other current assets, other assets, accounts payable, accrued liabilities approximate fair value due to the short-term nature or determinable value of these items. See also Note 3 - Fair Value Measurements for further details of the Company's fair value instruments.

Income Taxes

The Company accounts for income taxes under the asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company follows the provisions of ASC 740, Income Taxes, under which it assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Basic and Diluted Net Loss Per Share

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net loss per share is based upon the weighted average number of common shares outstanding and dilutive common stock equivalents outstanding during the period. Common stock equivalents are equity awards 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

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

their effect is anti-dilutive, or if the exercise price of such options is greater than the average market price of the stock for the period.

Stock-Based Compensation

The Company accounts for stock-based compensation of stock options and employee stock purchase plan shares by estimating the fair value of stock-based awards using the Black-Scholes option-pricing model. The Company accounts for stock-based compensation of restricted stock units granted to employees based on the closing price of the Company's common stock on the date of grant. The fair value of stock-based awards, net of estimated forfeitures, is recognized and amortized over the applicable vesting period.

Contingencies

In the normal course of business, the Company is involved from time to time in various legal proceedings and other matters which are complex in nature and have outcomes that are difficult to predict. The company records accruals for loss contingencies when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company considers all relevant factors when making assessments regarding these contingencies. Litigation expenses are expensed as incurred.

Recent Accounting Pronouncements

Accounting Pronouncements Adopted in 2020

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

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

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments*; in November 2018 the FASB issued a subsequent amendment ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*; in April 2019 the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*; in May 2019 the FASB issued ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief*; and in November 2019 the FASB issued ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*. The new guidance changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. In November 2019 the FASB issued ASU No. 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)—Effective Dates*, which defers the effective date of ASU 2016-13 for all entities except SEC reporting companies that are not smaller reporting companies. As a smaller reporting company, this guidance is effective for fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company is currently evaluating the timing and effect the new guidance will have on its consolidated financial statements.

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

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

3. FAIR VALUE MEASUREMENTS

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

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

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

		December 31, 2020			
		Total	Level 1	Level 2	Level 3
Assets:					
Money market	\$	48,152	\$ 48,152	\$ —	\$ —
Corporate debt		6,706	—	6,706	—
U.S. Treasury securities		4,999	—	4,999	—
Total assets measured at fair value	\$	59,857	\$ 48,152	\$ 11,705	\$ —
Liabilities:					
Embedded derivative liability	\$	2,378	\$ —	\$ —	\$ 2,378
Total liabilities measured at fair value	\$	2,378	\$ —	\$ —	\$ 2,378
		December 31, 2019			
		Total	Level 1	Level 2	Level 3
Assets:					
Money market	\$	27,720	\$ 27,720	\$ —	\$ —
Corporate debt		22,576	—	22,576	—
U.S. Treasury securities		37,811	—	37,811	—
Commercial paper		10,928	—	10,928	—
Total assets measured at fair value	\$	99,035	\$ 27,720	\$ 71,315	\$ —
Liabilities:					
Embedded derivative liability	\$	2,157	\$ —	\$ —	\$ 2,157
Total liabilities measured at fair value	\$	2,157	\$ —	\$ —	\$ 2,157

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

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

Corporate debt, U.S. Treasury securities, and commercial paper are measured at fair value using Level 2 inputs. The Company reviews trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy. In certain cases where there is limited activity or less transparency around inputs to valuation, the related assets or liabilities are classified as Level 3. The Company classified an embedded derivative related to its Royalty-Backed Loan with HCR 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 consolidated statements 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 10 "Long-Term Debt" for further description.

At December 31, 2020, the embedded derivative related to the Royalty-Backed Loan was the only recurring fair value measurement with Level 3 unobservable inputs. A risk-adjusted discount rate of 16.7% and a probability of a change in control of 3.0% were applied to calculate the value of the embedded derivative. Significant increases (or decreases) in the discount rate, and significant increases (or decreases) in the probability of a change in control would result in a significantly higher (or lower) fair value measurement.

The following table sets forth changes in Level 3 liabilities measured at fair value on a recurring basis for the years ended December 31, 2020 and 2019 (in thousands):

Balance as of December 31, 2018	\$ 1,352
Change in fair value included in interest and other income, net	805
Balance as of December 31, 2019	2,157
Change in fair value included in interest and other income, net	221
Balance as of December 31, 2020	<u>\$ 2,378</u>

There were no transfers into or out of Level 3 during the years ended December 31, 2020 and 2019.

4. INVESTMENTS

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

The Company limits the amount of investment exposure as to institution, maturity, and investment type. To mitigate credit risk, the Company invests in investment grade corporate debt, U.S. Treasury securities, and commercial paper. Such securities are reported at fair value, with unrealized gains and losses excluded from earnings and shown separately as a component of accumulated other comprehensive income (loss) within stockholders' equity. Realized gains and losses are reclassified from other comprehensive income (loss) to other income on the 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.

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

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

December 31, 2020				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Investments:				
Corporate debt	\$ 6,706	\$ —	\$ —	\$ 6,706
U.S. Treasury securities	4,999	—	—	4,999
Total	<u>\$ 11,705</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11,705</u>
Reported as:				
Short-term investments	\$ 11,705	\$ —	\$ —	\$ 11,705
Total	<u>\$ 11,705</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11,705</u>

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

Short-term investments include accrued interest of \$0.1 million and \$0.4 million as of December 31, 2020 and 2019, respectively. For the year ended December 31, 2020, there were gross realized gains on investments of \$55,000 and no gross realized losses. There were no gross realized gains or losses on investments for the year ended December 31, 2019. Realized gains are reflected in interest and other income, net, in the consolidated statements of operations, using the specific-identification method. Investments are classified as short-term or long-term depending on the underlying investment's maturity date. The Company had no investments with a maturity date greater than 12 months as of December 31, 2020 and 2019. All investments with unrealized losses at December 31, 2020, have been in a loss position for less than twelve months or the loss is not material and were temporary in nature. The Company does not intend to sell the investments that are in an unrealized loss position before recovery of their amortized cost basis.

5. BALANCE SHEET COMPONENTS

Prepaid expenses and other current assets (in thousands)

	December 31,	
	2020	2019
Insurance litigation recovery	\$ 7,500	\$ —
Prepaid expenses	3,126	2,624
Royalty receivables	1,252	—
Prepaid clinical trial	928	2,710
Income tax receivable	—	1,259
Other current assets	229	83
Prepaid expenses and other current assets	<u>\$ 13,035</u>	<u>\$ 6,676</u>

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

Property and equipment, net (in thousands)

	December 31,	
	2020	2019
Computer equipment and software	\$ 3,297	\$ 3,297
Equipment	384	384
Furniture and fixtures	336	336
Leasehold improvements	1,891	1,891
	5,908	5,908
Less: Accumulated depreciation and amortization	(4,310)	(3,459)
Property and equipment, net	<u>\$ 1,598</u>	<u>\$ 2,449</u>

Depreciation expense was \$0.9 million and \$1.2 million for the years ended December 31, 2020 and 2019, respectively.

Accrued liabilities (in thousands)

	December 31,	
	2020	2019
Litigation settlement liability (see Note 9)	\$ 7,500	\$ —
Accrued employee related costs	9,403	7,682
Patent litigation settlement liability (see Note 9)	5,000	—
Clinical trial accruals	616	1,680
Accrued consulting and other professional fees	2,657	4,867
Accrued sales deductions	1,571	1,822
Other	417	66
Accrued liabilities	<u>\$ 27,164</u>	<u>\$ 16,117</u>

6. INVENTORY

If the Company identifies excess, obsolete, or unsalable product, the Company will write down its inventory to net realizable value in the period it is identified. During the years ended December 31, 2020 and 2019, the Company recorded a provision for the write-down of inventory to cost of sales of \$0.6 million and \$0.9 million, respectively. Inventory consists of the following (in thousands):

	December 31,	
	2020	2019
Raw materials	\$ 795	\$ 1,057
Work-in-process	4,403	1,925
Finished goods	2,096	2,285
Total inventory	<u>\$ 7,294</u>	<u>\$ 5,267</u>

7. 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

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

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 twelve months ended December 31, 2020 and 2019, there were no reimbursable external costs for prosecution or litigation of intellectual property rights were not material.

In addition, the Company may earn tiered royalty payments based on net sales of NAMZARIC and NAMENDA XR. Beginning in May 2020, the Company became entitled to receive royalties at rates in the low double digits to mid-teens from Allergan for sales of NAMZARIC in the United States. The Company recognized \$3.3 million in NAMZARIC royalty revenue for the twelve months ended December 31, 2020, and recognized no royalty revenue for the twelve months ended December 31, 2019. Allergan's obligation to pay royalties with respect to fixed-dose memantine-donepezil products, including NAMZARIC, continues until the later of (i) 15 years after the commercial launch of the first fixed-dose memantine-donepezil product by Allergan in the United States or (ii) the expiration of the Orange Book listed patents for which Allergan obtained rights from the Company covering such product, but is eliminated in any quarter where there is significant competition from generics. Based on Allergan's and the Company's current settlement agreements with the NAMZARIC ANDA filers to date, the earliest date on which any of these agreements grant a license to market a NAMZARIC ANDA filer's generic version of NAMZARIC is January 1, 2025 (or earlier in certain circumstances). Alternatively, the NAMZARIC ANDA filers with the earliest license date have the option to launch an authorized generic version of NAMZARIC beginning on January 1, 2026 instead of launching their own generic version of NAMZARIC on January 1, 2025. For further discussion of NAMZARIC ANDA filers, see *Litigation and Other Legal Proceedings* in "Note 9 - Commitments and Contingencies." Beginning in June 2018, the Company was entitled to receive royalties at rates in the low to mid-single digits for sales of NAMENDA XR in the United States. The Company does not expect to receive royalties on net sales of NAMENDA XR, due to the entry of generic versions of NAMENDA XR. Royalties under the license agreement will be recognized when the related sales occur, in accordance with the sales-based royalty exception.

8. LEASES

Lease Commitments

The Company performed an evaluation of its contracts in accordance with Topic 842 and determined that, except for its facility, vehicle, and office equipment leases, described below, none of its other contracts contain a lease. The Company evaluated all its leases and determined they were operating leases.

In January 2018, the Company amended its Emeryville, California, office facility lease agreement to extend the term to April 30, 2025, and relocate and expand its office space to 37,626 rentable square feet within the same building. The lease contains an option to extend the term for one additional five-year period. The extension option has not been considered in the determination of the right-of-use asset or the lease liability as the Company did not consider it reasonably certain that it would exercise such option. The lease provides for a tenant improvement allowance of approximately \$1.1 million, which the Company fully utilized during the third quarter of 2018.

In 2018, the Company entered into a three-year lease for office equipment that commenced in June 2018 and will be required to make cash payments totaling \$0.2 million during the term of the lease.

In March 2019, the Company entered into a three-year vehicle lease agreement, pursuant to which it currently leases 67 vehicles. Delivery of the vehicles commenced during the second quarter of 2019. The term for each leased vehicle commences upon the delivery of the vehicle and is for a period of 12 months, with renewal terms at the Company's discretion that can extend the lease term up to 50 months.

As of December 31, 2020, the Company did not have additional operating leases that have not yet commenced.

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

Supplemental balance sheet information related to operating leases were as follows (in thousands):

	December 31,	
	2020	2019
Assets		
Operating lease right-of-use assets	\$ 6,657	\$ 8,048
Total right-of-use assets	<u>\$ 6,657</u>	<u>\$ 8,048</u>
Liabilities		
Current portion included in other current liabilities	\$ 1,855	\$ 1,669
Long-term portion of operating lease liabilities	6,453	8,272
Total operating lease liabilities	<u>\$ 8,308</u>	<u>\$ 9,941</u>

The Company's total lease cost was approximately \$2.8 million and \$2.4 million for the years ended December 31, 2020 and 2019, respectively. The components of lease costs, which were included in selling, general and administrative, net in its consolidated statements of operations, were as follows (in thousands):

	Years Ended December 31,	
	2020	2019
Operating lease cost	\$ 2,373	\$ 2,037
Variable lease cost	464	320
Total lease cost	<u>\$ 2,837</u>	<u>\$ 2,357</u>

As of December 31, 2020, the maturities of operating lease liabilities were as follows (in thousands):

	Operating leases
2021	\$ 2,622
2022	2,446
2023	2,191
2024	2,247
2025	764
Thereafter	—
Total lease payments	10,270
Less: Imputed interest	(1,962)
Operating lease liabilities	<u>\$ 8,308</u>

As of December 31, 2020, the weighted average remaining lease term is 4.1 years and the weighted average operating discount rate used to determine the operating lease liability was 10.5%.

9. COMMITMENTS AND CONTINGENCIES

Purchase Commitments

The Company has entered into agreements for the supply of active pharmaceutical ingredients with Moehs Ibérica, S.L. and AMSA S.p.A., and the manufacture of commercial supply of GOCOVRI with Catalent Pharma Solutions, LLC. 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.

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

As of December 31, 2020, the Company had non-cancelable purchase commitments of \$2.4 million due within one year.

Contingencies

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

Indemnification

In accordance with the Company's amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. The Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for claims. In addition, in the normal course of business, the Company enters into contracts and agreements that may contain a variety of representations and warranties and provide for general indemnifications.

Litigation and Other Legal Proceedings

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

In 2018 and as of the issuance date of these consolidated financial statements, multiple generic companies have launched generic versions of NAMENDA XR.

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

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

On February 16, 2018, Osmotica Pharmaceutical US LLC and Vertical Pharmaceuticals LLC ("Osmotica") filed an action against the Company in U.S. District Court for the state of Delaware, requesting a declaratory judgment that Osmotica's newly-approved product OSMOLEX ER[®] (amantadine) extended release tablets do not infringe certain of the Company's patents. On September 20, 2018, the Company filed its first amended answer including infringement counterclaims against Osmotica asserting Osmotica has infringed nine Company patents under 35 U.S.C. §§ 271(a), (b), and/or (c) and 35 U.S.C. § 271(e)(2)(A) and seeking various forms of relief, including damages, treble damages, injunctive relief, and an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Osmotica's NDA for OSMOLEX ER be a date that is not earlier than the latest expiration date of the Company patents involved in the lawsuit. On December 1, 2020, the Company entered into a purchase agreement (the "Asset Purchase Agreement") with Osmotica pursuant to which: both parties gave each other mutual releases and agreed to dismiss their respective claims relating to the patent litigation; the Company will acquire the global rights to OSMOLEX ER and existing inventory for \$7.5 million and the assumption of certain liabilities; and Osmotica will not engage in the U.S. in the

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

development, manufacture, or sale of any product that is a generic version of any dosage strength of OSMOLEX ER for a period of five years from the closing of the Asset Purchase Agreement. The Company also entered into a supply agreement pursuant to which Osmotica will be the sole manufacturer of OSMOLEX ER. The Asset Purchase Agreement subsequently closed on January 4, 2021. Management determined, in accordance with ASC 450, that as of December 31, 2020, a probable loss had occurred as a result of the litigation settlement. As a result, the Company recorded a patent litigation settlement liability of \$5.0 million, based on management's best estimate, which is included in other current liabilities on the consolidated balance sheets and reported as selling, general and administrative, net, in the consolidated statements of operations for the twelve months ended December 31, 2020.

On July 1, 2020, the Company received a letter dated June 29, 2020, notifying the Company that Zydus Worldwide DMCC ("Zydus Worldwide") submitted to the FDA an ANDA for Amantadine Extended-Release Capsules, 68.5 mg and 137 mg that contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Company's U.S. Patent Nos. 8,389,578; 8,741,343; 8,796,337; 8,889,740; 8,895,614; 8,895,615; 8,895,616; 8,895,617; 8,895,618; 9,867,791; 9,867,792; 9,867,793; 9,877,933; and 10,154,971, that these patents are invalid or will not be infringed by the manufacture, use or sale of Zydus Worldwide's Amantadine Extended-Release Capsules, 68.5 mg and 137 mg. On August 13, 2020, the Company filed a lawsuit against Zydus Worldwide and Zydus Pharmaceuticals (USA), Inc. (collectively "Zydus") alleging infringement of those patents and U.S. Patent No. 10,646,456 by Zydus in the United States District Court for the District of New Jersey. U.S. Patent No. 10,646,456 was not listed in the Orange Book at the time Zydus Worldwide filed its ANDA, but on or about September 3, 2020, the Company received a letter dated September 2, 2020, notifying the Company that Zydus Worldwide submitted a certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Company's U.S. Patent No. 10,646,456 with respect to its ANDA for Amantadine Extended-Release Capsules, 68.5 mg and 137 mg. On January 30, 2021, Adamas Pharma, LLC entered into a definitive agreement (the "Settlement Agreement") with Zydus pursuant to which the parties agreed to end the lawsuit and dismiss it without prejudice, and the Court dismissed the lawsuit on February 3, 2021. Pursuant to the Settlement Agreement, Adamas Pharma, LLC grants Zydus a license to make, use, sell, offer to sell and import a generic version of GOCOVRI (amantadine) extended release capsules (including for any new indications approved under the GOCOVRI NDA), effective as of March 4, 2030, or earlier in certain circumstances typical for such agreements. The Settlement Agreement contains provisions that may accelerate the license date, including if unit sales of GOCOVRI for the 12-month period ending July 31, 2025 or any subsequent 12-month period decline by a specified percentage below GOCOVRI unit sales for the year ended December 31, 2019. The Company and Adamas Pharma LLC intend to continue to enforce the patents associated with GOCOVRI.

On April 1, 2019, the Company was served with a complaint filed in the United States District Court for the Northern District of California (Case No. 3:18-cv-03018-JCS) against the Company and several Allergan entities alleging violations of Federal and state false claims acts ("FCA") in connection with the commercialization of NAMENDA XR and NAMZARIC by Allergan. The lawsuit is a qui tam complaint brought by a named individual, Zachary Silbersher, asserting rights of the Federal government and various state governments. The lawsuit was originally filed in May 2018 under seal, and the Company became aware of the lawsuit when it was served. The complaint alleges that patents held by Allergan and the Company covering NAMENDA XR and NAMZARIC were procured through fraud on the United States Patent and Trademark Office and that these patents were asserted against potential generic manufacturers of NAMENDA XR and NAMZARIC to prevent the generic manufacturers from entering the market, thereby wrongfully excluding generic competition resulting in an artificially high price being charged to government payors. The Company's patents in question were licensed exclusively to Forest. The complaint includes a claim for damages of "potentially more than \$2.5 billion dollars," treble damages "under the federal FCA and most of the State FCAs," and "statutory penalties that can be assessed for each false claim." This action is ongoing. The federal and state governments have declined to intervene in this action. To the Company's knowledge, the individual plaintiff is pursuing the lawsuit in his individual capacity. This case is currently stayed pending the Company and Allergan's Petition for Permission to Appeal Under 28 U.S.C. § 1292(b) in the United States Court of Appeals for the Ninth Circuit (Case No. 21-80005), which was filed on February 8, 2021, and seeks permission for an interlocutory appeal of the District Court's December 11, 2020 order denying the Company's and Allergan's motion to dismiss the complaint. The Company believes it has strong factual and legal defenses and intends to defend itself vigorously.

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

On May 13, 2019, a putative class action lawsuit alleging violations of the federal securities laws was filed by Plymouth County Contributory Retirement System against the Company and certain of the Company's current and former directors and officers in California Superior Court for the County of Alameda (Case No. RG19018715). The lawsuit alleges violations of the Securities Act of 1933 by the Company and certain of the Company's current and former directors and officers for allegedly making false statements and omissions in the registration statement and prospectus filed by the Company in connection with its January 24, 2018, secondary public offering of common stock. On October 29, 2020, Adamas signed a Memorandum of Understanding to settle this lawsuit for a payment of \$7.5 million to eligible settlement class members in resolution of claims asserted against the Company, its officers, directors, and the other defendants. The settlement will be paid by the Company's Director & Officer liability insurance. As a result of signing the Memorandum of Understanding and the potential liability becoming probable and estimable, the Company has recorded a litigation settlement liability of \$7.5 million, which is included in accrued liabilities on the consolidated balance sheets. Additionally, the Company has recorded an insurance litigation recovery of \$7.5 million within prepaid expenses and other current assets on the consolidated balance sheets, which represents the estimated insurance proceeds agreed with the Company's insurance carrier in excess of the Company's retention. The Company and the other defendants continue to deny each of the plaintiff's claims and all liability. The Company has agreed to the settlement to resolve the disputes, avoid the costs and risks of further litigation, and avoid further distractions to management. This settlement remains subject to final documentation and approval by the court. A final non-appealable closure of this court action is expected in mid-2021.

On December 10, 2019, another putative class action lawsuit alleging violations of the federal securities laws was filed by Ali Zaidi against the Company and certain of the Company's current and former directors and officers in federal court in the Northern District of California (Case No. 4:19-cv-08051). This lawsuit alleges violations of the Securities Exchange Act of 1934 by the Company and certain of the Company's current and former officers. On March 16, 2020, a shareholder derivative lawsuit was filed by Patrick Van Camp in federal court in the Northern District of California (Case No. 4:20-cv-01815) naming the Company and certain of the Company's current and former directors and officers as defendants. This lawsuit alleges breaches of fiduciary duty and violations of the Securities Exchange Act of 1934 by certain of the Company's current and former directors and officers. The Company is named as a nominal defendant only. On April 6, 2020, another, virtually identical, shareholder derivative lawsuit was filed by James Druzvik in federal court in the Northern District of California (Case No. 4:20-cv-02320) naming the Company and certain of the Company's current and former directors and officers as defendants. This lawsuit contains the same allegations, claims, and defendants as the first derivative action. The Company is named as a nominal defendant only. Other similar cases may be filed in the future. In all of these actions, Plaintiffs seek unspecified monetary damages and other relief. These actions are ongoing. The Company believes it has strong factual and legal defenses to all actions and intends to defend itself vigorously.

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

10. 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 HCR, whereby the Company initially borrowed \$35 million, followed by an additional \$65 million received in the fourth quarter 2017 upon FDA's recognition in the Orange Book of seven-year orphan drug exclusivity, which GOCOVRI earned upon approval on August 24, 2017. Principal and interest will be payable quarterly from the proceeds of a 12.5% royalty on U.S. net sales of GOCOVRI and up to \$15 million of the Company's annual royalties from Allergan on U.S. net sales of NAMZARIC starting in May 2020, pursuant to the Company's license agreement with Allergan. The royalty rate on net sales of GOCOVRI will drop to 6.25% after the principal amount of the loan has been repaid in full, until the Company has made total payments of 200% of the funded amounts. The Company may elect to voluntarily prepay the loan at any time, or may be required to prepay subject to specified prepayment trigger events as described below, in which case the amount due will be 200% of the funded amounts, less total payments made to date. Royalty rates are subject to increase to 17.5% and 22.5% if total principal and interest payments have not reached minimum specified levels at measurement dates on December 2021 and December 2022, respectively. Under the

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

terms of the loan, HCR has recourse to Adamas Pharma, LLC, not the Company. The loan agreement matures in December 2026 but as the repayment of the loan amount is contingent upon the sales volumes of GOCOVRI and royalties from Allergan, the repayment term may be shortened depending on the actual sales of GOCOVRI and actual royalties received from Allergan.

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

In connection with the Royalty-Backed Loan, in 2017 the Company paid HCR 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 \$14.0 million and \$15.0 million for the twelve months ended December 31, 2020 and 2019, respectively. Interest expense over the life of the Royalty-Backed Loan includes an annual interest rate of 11% on the outstanding principal, a royalty rate of 6.25% on net sales of GOCOVRI after the principal amount is paid, and amortization of the debt discount. The effective interest rate as of December 31, 2020 on the amounts borrowed under the Royalty-Backed Loan, including the amortization of the debt discount, was 12.8%.

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 HCR, as the holder of the loans, may exercise the option to require prepayment by the Company, the prepayment premium is considered to be an embedded derivative which is required to be bifurcated from its host contract and accounted for as a separate financial instrument. The valuation of the embedded derivative is described further in Note 3 - Fair Value Measurements.

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

	December 31,	
	2020	2019
Total repayment obligation	\$ 200,000	\$ 200,000
Less: Interest to be accreted in future periods	(49,230)	(63,217)
Less: Payments made	(20,806)	(9,068)
Carrying value of loans payable	\$ 129,964	\$ 127,715
Less: Current portion of long-term debt	(3,657)	(2,041)
Non-current portion of long-term debt	<u>\$ 126,307</u>	<u>\$ 125,674</u>

The estimated fair value of the long-term debt, as measured using Level 3 inputs, approximates \$109.4 million as of December 31, 2020. The estimated fair value was calculated in the same methodology as the valuation of the embedded derivative as described further in Note 3 - Fair Value Measurements.

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

On December 1, 2020, Adamas Pharma, LLC entered into an agreement with HCR to amend certain key terms of the Royalty-Backed Loan to be effective upon the closing of the Company's Asset Purchase Agreement with Osmotica. The Asset Purchase Agreement subsequently closed on January 4, 2021, and is described further in Note 9 -

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

Commitments and Contingencies. For further discussion of the key terms amended under the Royalty-Backed Loan, see Note 17 - Subsequent Events.

Paycheck Protection Program

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

11. CONVERTIBLE PREFERRED STOCK

The Company’s amended and restated certificate of incorporation filed on April 15, 2014, authorizes 5,000,000 shares of preferred stock, of which there were no shares outstanding as of December 31, 2020 and 2019.

12. STOCKHOLDERS’ EQUITY

Common Stock

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

Sales Agreement

In November 2019, the Company entered into a sales agreement (“Sales Agreement”) with Cowen and Company, LLC (“Cowen”), as sales agent, pursuant to which the Company may, from time to time, issue and sell at its option, shares of the Company’s common stock for an aggregate offering price of up to \$50.0 million under an at-the-market offering (“ATM Offering”). Sales of the common stock, if any, will be made pursuant to a shelf registration statement that was declared effective by the Securities and Exchange Commission (“SEC”) on December 2, 2019. Cowen is acting as sole sales agent for any sales made under the Sales Agreement and the Company will pay Cowen a commission of up to 3% of the gross proceeds. The Company’s common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. The Company is not obligated to make any sales of shares of common stock under the Sales Agreement. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. No shares were sold under the Sales Agreement during the fiscal year ended December 31, 2019. During the fiscal year ended December 31, 2020, 217,403 shares were sold at an average price of \$4.94, for net proceeds of \$1.0 million.

Shares Reserved for Future Issuance

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

	December 31,	
	2020	2019
Common stock awards issued and outstanding	7,172,029	6,874,633
Authorized for future issuance under 2014 Equity Incentive Plan	3,518,414	2,376,613
Authorized for future issuance under 2016 Inducement Plan	469,419	236,269
Employee stock purchase plan	1,018,060	926,943
Total	<u>12,177,922</u>	<u>10,414,458</u>

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

13. STOCK-BASED COMPENSATION

Stock Compensation Plans

In October 2002, the Company established its 2002 Employee, Director, and Consultant Stock Plan and in December 2007, the Company established its 2007 Stock Plan. No further grants were then made under the 2002 Plan.

In February 2014, the Company's board of directors adopted, and in March 2014 the Company's stockholders approved, the 2014 Equity Incentive Plan (the "2014 Plan"), which became effective on the completion of the IPO. No further grants were then made under the 2007 Plan. Under the 2014 Plan, 1,993,394 shares of the Company's common stock were made available for issuance which included all shares that, as of the effective time, were reserved for issuance pursuant to the 2007 Plan, and is subject to further increase for shares that were subject to outstanding options under the 2007 Plan and the 2002 Plan as of the effective time that thereafter expire, terminate, or otherwise are forfeited or reacquired. The number of shares of the Company's common stock reserved for issuance pursuant to the 2014 Plan will automatically increase on the first day of each fiscal year for a period of up to ten years, commencing on the first day of the fiscal year following 2014, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding fiscal year, or a lesser number of shares as determined by the Company's board of directors. On January 1, 2020, the common stock available for issuance under the 2014 Plan increased by 1,118,591 shares. As of December 31, 2020, the number of shares available for issuance under the 2014 Plan was 3,518,414.

Options granted under the 2014 Stock Plan may have terms of up to ten years. All options issued to date have had a ten year life. The exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the board of directors. The exercise price of an ISO and NSO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, respectively, as determined by the board of directors. The exercise price of a NSO shall not be less than the par value per share of common stock. Options and restricted stock units granted generally vest over four years. Certain grants have other vesting periods approved by the Company's Board of Directors or an authorized committee.

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. An amendment to the Inducement Plan was approved to increase the number of shares available for issuance by an additional 450,000 shares in each of January 2017, November 2017, March 2019, and February 2020, and an additional 600,000 shares in October 2020, for a total of 2,400,000 shares, resulting in a total of 2,850,000 shares of common stock issuable under the Inducement Plan. As of December 31, 2020, the number of shares available for issuance under the Inducement Plan was 469,419. Options granted under the Inducement Plan may have terms of up to ten years. All options issued to date have had a ten year life. Consistent with the 2014 Plan, options and restricted stock units granted generally vest over four years. The Inducement Plan was adopted by the board of directors without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

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

Stock Option Activity

Stock option activity under all of the Company's stock compensation plans is summarized as follows:

Stock Options	Outstanding Options		Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (thousands)
	Number of Shares	Weighted Average Exercise Price		
Balances, December 31, 2019	5,516,684	\$ 12.06		
Options granted	1,562,148	3.71		
Options exercised	(237,425)	0.74		
Options forfeited	(558,612)	12.48		
Options expired	(693,580)	17.98		
Balances, December 31, 2020	5,589,215	\$ 9.43	5.56	\$ 2,806
Vested and expected to vest, December 31, 2020	5,369,025	\$ 9.57	5.43	\$ 2,700
Exercisable, December 31, 2020	3,387,312	\$ 11.69	3.53	\$ 1,740

The aggregate intrinsic value of options outstanding, vested and expected to vest, and exercisable were calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of December 31, 2020 of \$4.33. The intrinsic value of options exercised, calculated as the difference between the exercise price and the fair value of the Company's common stock on the date of exercise, was approximately \$0.9 million and \$0.9 million for the years ended December 31, 2020 and 2019, respectively.

During the years ended December 31, 2020 and 2019, the Company granted stock options to employees to purchase 1,562,148 and 1,721,508 shares of common stock, respectively, with a weighted-average grant date fair value of \$2.19 and \$4.01, respectively. As of December 31, 2020, there was total unrecognized compensation cost related to unvested options of approximately \$6.6 million. This cost is expected to be recognized over a weighted average remaining vesting period of 2.7 years. The total fair value of employee stock options vested for the years ended December 31, 2020 and 2019 was \$4.6 million and \$9.6 million, respectively.

Restricted Stock Unit Activity

Restricted stock unit activity under all of the Company's stock compensation plans is summarized as follows:

Restricted Stock Units	Outstanding Units	
	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2019	1,357,949	\$ 7.79
Granted	928,998	3.29
Vested	(258,819)	9.46
Forfeited	(445,314)	7.50
Unvested, December 31, 2020	1,582,814	\$ 4.95

The aggregate intrinsic value of RSUs outstanding on December 31, 2020 was \$6.9 million based on the fair value of the Company's common stock on that date. The aggregate intrinsic value of RSUs vested for the years ended December 31, 2020 and 2019 was \$0.9 million and \$1.0 million, respectively. As of December 31, 2020, there was total unrecognized compensation cost related to unvested RSUs of approximately \$4.7 million. This cost is expected to be recognized over a weighted average remaining vesting period of 2.2 years.

Employee Stock Purchase Plan

In February 2014, the Company's board of directors adopted and, in March 2014, the Company's stockholders approved, the 2014 Employee Stock Purchase Plan (the "ESPP"), which became effective on the completion of the Company's IPO. The ESPP authorized the issuance of 262,762 shares. Under the ESPP, employees, subject to certain restrictions, may purchase shares of common stock at 85% of the fair market value at either the beginning of the offering

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

period or the date of purchase, whichever is less. Purchases are limited to the lesser of 15% of each employee's eligible annual compensation or \$25,000. Through the end of 2020, the Company has issued a total of 612,357 shares under the ESPP. The number of shares available for future issuance under the plan were 1,018,060 at December 31, 2020. Beginning January 1, 2015 and continuing through and including January 1, 2024, the amount of common stock reserved for issuance under the ESPP will increase annually on that date by the lesser of (i) one percent (1%) of the total number of shares of common stock outstanding on such December 31, (ii) 520,000 shares of common stock, or (iii) a number of shares as determined by the board of directors prior to the beginning of each year, which shall be the lesser of (i) or (ii) above. On January 1, 2020, the common stock available for issuance under the ESPP increased by 279,648 shares.

Stock-Based Compensation Expense

The following table reflects stock-based compensation expense recognized for the years ended December 31, 2020 and 2019 (in thousands):

	Years Ended December 31,	
	2020	2019
Research and development	\$ 385	\$ 1,732
Selling, general and administrative	6,046	11,120
Total stock-based compensation expense	<u>\$ 6,431</u>	<u>\$ 12,852</u>

Stock-based compensation of \$0.3 million and \$0.2 million was capitalized into inventory for the twelve months ended December 31, 2020 and 2019. Stock-based compensation capitalized into inventory is recognized as cost of sales when the related product is sold.

The Company's method of valuation for share-based awards is based on the Black-Scholes model. The Company's determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to the Company's expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. A description of the assumptions follows:

- The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers, as well as taking into consideration the Company's own historical volatility since its IPO in 2014. Beginning in 2021, the Company will calculate expected volatility based solely on the historical volatility of its own common stock as it will have a sufficient amount of historical information.
- The risk-free interest rate is based on the U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.
- The expected term of the options granted represents the average period the stock options are expected to remain outstanding. The Company has elected to use the "simplified method" for estimating the expected term, which is calculated as the mid-point between the vesting period and the contractual term of the options.
- The expected dividend yield assumption was based on the fact that the Company has never paid cash dividends and currently has no intention to pay cash dividends.

Stock-based compensation expense in the consolidated statements of operations is based on awards ultimately expected to vest and is reduced for estimated forfeitures, based on historical experience.

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

The Company estimated the fair value of employee stock options and ESPP shares on the date of grant using the Black-Scholes model with the following weighted-average assumptions:

	Years Ended December 31,	
	2020	2019
Stock Options		
Expected price volatility	65% - 66%	65% - 69%
Risk-free interest rate	0.37% - 1.75%	1.52% - 2.58%
Expected term (in years)	5.50 - 6.25	5.50 - 6.25
Dividend yield	—	—
Employee Stock Purchase Plan		
Expected price volatility	67% - 80%	53% - 56%
Risk-free interest rate	0.10% - 0.18%	1.60% - 2.35%
Expected term (in years)	0.50	0.50
Dividend yield	—	—

Stock-based compensation expense related to employee stock options for the years ended December 31, 2020 and 2019 was \$3.2 million and \$9.4 million, respectively. Stock-based compensation expense related to the ESPP plan for the years ended December 31, 2020 and 2019 was \$0.2 million and \$0.4 million, respectively. Stock-based compensation expense related to restricted stock units was \$2.9 million and \$3.1 million for the years ended December 31, 2020 and 2019, respectively.

Included in stock-based compensation expense for the year ended 2019 was expense of approximately \$2.2 million recognized as a result of the modification of certain stock options and restricted stock units associated with the termination of employment in September 2019 of the Company's Chief Executive Officer and notification of retirement in August 2019 of the Company's Chief Financial Officer.

Non-Employee Stock-Based Compensation

During both the years ended 2020 and 2019, the Company granted no options to purchase common stock and no restricted stock units to consultants and recorded no stock compensation expense.

14. INCOME TAXES

Loss before benefit for income tax is summarized as follows (in thousands):

	Years Ended December 31,	
	2020	2019
United States	\$ (57,378)	\$ (105,186)
International	(25)	—
Total	<u>\$ (57,403)</u>	<u>\$ (105,186)</u>

The provision for income taxes differs from the amount computed by applying the federal income tax rate of 21% to pretax loss from operations as a result of the following:

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

	December 31,	
	2020	2019
Statutory federal income tax rate	\$ (12,054)	\$ (22,079)
State income taxes, net of federal tax benefits	(4,390)	(8,473)
Tax credits	(435)	(1,398)
Stock compensation	2,646	2,648
Nondeductible compensation	164	278
Other	426	198
Change in valuation allowance	13,643	28,826
Income tax provision	<u>\$ —</u>	<u>\$ —</u>

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets		
Net operating loss carryforwards	\$ 105,264	\$ 99,449
Research and development tax credits	20,609	20,174
Accruals and reserves	9,780	7,004
Stock compensation	8,017	9,291
Depreciation and amortization	1,062	1,108
Lease liabilities	2,380	2,889
Other	6,014	—
Gross deferred tax assets	153,126	139,915
Less: Valuation allowance	(151,219)	(137,576)
Net deferred tax assets	<u>1,907</u>	<u>2,339</u>
Deferred tax liabilities		
Right of use assets	(1,907)	(2,339)
Net deferred tax liabilities	<u>(1,907)</u>	<u>(2,339)</u>
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

The deferred income tax assets have been fully offset by a valuation allowance, as realization is dependent on future earnings, if any, the timing and amount of which are uncertain. The net change in the valuation allowance was \$13.6 million and \$28.8 million for the years ended December 31, 2020 and 2019, respectively.

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realization of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood, and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. The Tax Act repealed corporate alternative minimum tax ("AMT") for tax years beginning after December 31, 2017, and provided that any existing AMT credit carryovers were refundable beginning in 2018 through 2022. The Company has received the refund in full relating to its AMT credit carryover as of December 31, 2020. The Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the accompanying balance sheets.

As of December 31, 2020, the Company had federal net operating loss carryforwards of approximately \$375.1 million available to reduce future taxable income and state net operating loss carryforwards of approximately \$345.2 million. The federal net operating loss carryforward begins expiring in 2024, and state net operating loss carryforward begins expiring in 2028.

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

The Company has federal research and development tax credit carryforwards of approximately \$6.9 million. If not utilized, the carryforwards will begin expiring in 2023. The Company has state research and development credit carryforwards of approximately \$4.6 million which do not expire. The Company also has orphan drug credit carryforwards of \$14.4 million which begin to expire in 2035.

Under federal and similar state tax statutes, changes in the Company's ownership may limit its ability to use its available net operating loss and tax credit carryforwards. The annual limitation, as a result of a change of control, may result in the expiration of net operating losses and credits before utilization.

The Company's ability to use its remaining net operating loss and tax credit carryforwards may be further limited if the Company experiences a Section 382 ownership change in connection with future changes in its stock ownership. The Company has completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards through April 2018 and found that there is no forfeiture of the Company's attributes.

Uncertain Tax Positions

The total amounts of unrecognized tax benefits for the years ended December 31, 2020 and 2019 were \$5.2 million and \$5.1 million, respectively. If recognized, none of the unrecognized tax benefits would affect the effective tax rate.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	December 31,	
	2020	2019
Balance at the beginning of the year	\$ 5,065	\$ 4,697
Additions based on current period tax positions	119	368
Balance at the end of the year	<u>\$ 5,184</u>	<u>\$ 5,065</u>

The Company's policy is to account for interest and penalties as income tax expense. The Company accrued no interest related to unrecognized tax benefits during the years ended December 31, 2020 and 2019.

The Company files income tax returns in the U.S. federal jurisdiction, Pennsylvania, California, other state jurisdictions, and India. The Company is subject to U.S. federal income tax examination for the calendar years ending 2003 through 2020 due to net operating losses that have been carried forward for tax purposes. Additionally, the Company is subject to state income tax examinations for the 2003 through 2020 calendar years due to net operating losses that are being carried forward for tax purposes. The Company is subject to audit by the Indian tax authorities from 2014 onward. The Company is not currently under audit in any major tax jurisdiction.

15. NET LOSS PER SHARE

For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position. The following table presents the calculation of the basic and diluted net loss per share (in thousands, except per share data):

	Years Ended December 31,	
	2020	2019
Net loss attributable to common stockholders, basic and diluted	<u>\$ (57,403)</u>	<u>\$ (105,186)</u>
Weighted average common shares used in calculating net loss per common share, basic and diluted	<u>28,305</u>	<u>27,677</u>
Net loss per share attributable to common stockholders, basic and diluted . . .	<u>\$ (2.03)</u>	<u>\$ (3.80)</u>

The following total outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented, because including them would have been anti-dilutive (in thousands):

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

	December 31,	
	2020	2019
Options to purchase common stock	5,589	5,517
Restricted stock units	1,583	1,358
Total	<u>7,172</u>	<u>6,875</u>

16. SUBSEQUENT EVENTS

On January 4, 2021, the Company closed its Asset Purchase Agreement with Osmotica for the acquisition of OSMOLEX ER, as described further in Note 9 - Commitments and Contingencies. At closing, the Company paid \$7.3 million, including a \$7.5 million base purchase price less \$0.2 million for the assumption of certain liabilities.

On January 4, 2021, upon the closing of the Asset Purchase Agreement with Osmotica, the Company's December 1, 2020 agreement to amend certain key terms of its Royalty-Backed Loan with HCR also became effective. Pursuant to the amendment, upon its effectiveness of January 4, 2021, the Royalty-Backed Loan was amended, *inter alia*, to: (i) provide for repayment from a royalty on OSMOLEX ER on the same terms as, and in addition to, the royalty for GOCOVRI; (ii) eliminate the potential royalty rate step-up to 17.5%; (iii) revise the prepayment provisions after a change of control provision to provide that the full obligation to HCR is fully satisfied by making a prepayment sufficient to bring the cumulative payments to HCR to \$175 million, if such prepayment is made on or prior to December 31, 2022, or \$195 million if made thereafter; (iv) extend the maturity date to March 31, 2027; and (v) add a covenant requiring the Company to maintain minimum cash, cash equivalents and marketable securities of at least \$25 million.

Subsequent to December 31, 2020, and through February 16, 2021, the Company issued an aggregate of 1,335,896 shares of common stock under its 2019 Sales Agreement, at an average price of \$5.57, for net proceeds of approximately \$7.2 million.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 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 December 31, 2020. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in conformity with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on this assessment, management has concluded that, as of December 31, 2020, our internal control over financial reporting is effective based on those criteria.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this annual report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our 2021 Annual Meeting of Stockholders, or the Proxy Statement, which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2020.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item concerning our directors is incorporated by reference to the information set forth in the section titled “Election of Directors” and “Corporate Governance” in our Proxy Statement. Information required by this item concerning our executive officers is incorporated by reference to the information set forth in the section titled “Executive Officers and Key Employees” in our Proxy Statement. Information regarding Section 16 reporting compliance, if any, is incorporated by reference to the information set forth in the section titled “Delinquent Section 16(a) Reports” in our Proxy Statement.

Our written Code of Conduct and Ethics applies to all of our directors and employees, including our executive officers, including without limitation our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Conduct and Ethics is available on our website at <http://www.adamaspharma.com> in the Investors section under “Corporate Governance”. Changes to or waivers of the Code of Conduct and Ethics will be disclosed on the same website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver of, any provision of the Code of Conduct and Ethics in the future by disclosing such information on our website.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled “Non-Employee Director Compensation,” “Executive Compensation” and “Compensation Committee Interlocks and Insider Participation” in our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item regarding certain relationships and related transactions and director independence is incorporated by reference to the information set forth in the sections titled “Certain Relationships and Related Persons Transactions” and “Corporate Governance”, respectively, in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section titled “Principal Accountant Fees and Services” in our Proxy Statement.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

Consolidated Financial Statements are listed in the “Index to Consolidated Financial Statements” under Part II, Item 8 of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.

(a)(3) Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation By Reference				Filed / Furnished Herewith
		Form	SEC File No.	Exhibit	Filing Date	
2.1	Asset Purchase Agreement by and between Adamas Pharmaceuticals, Inc. and Osmotica Pharmaceutical US LLC.					X
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	
4.4	Description of Capital Stock.	10-K	001-36399	4.4	2/25/2020	
10.1*	Adamas Pharmaceuticals, Inc. 2007 Stock Plan, as amended, and Form of Stock Option Grant Notice, Option Agreement and Form of Notice of Exercise.	S-1	333-194342	10.2	3/5/2014	
10.2*	Adamas Pharmaceuticals, Inc. 2014 Employee Stock Purchase Plan.	S-1	333-194342	10.4	3/26/2014	
10.3*	Adamas Pharmaceuticals, Inc. 2014 Equity Incentive Plan.	S-1	333-194342	10.3	4/7/2014	
10.4*	Adamas Pharmaceuticals, Inc. Form of Stock Option Grant Notice and Option Agreement.	10-Q	001-36399	10.24	8/11/2015	
10.5*	Adamas Pharmaceuticals, Inc. Form of Restricted Stock Unit Grant Notice and Award Agreement.	10-K	001-36399	10.24	2/23/2016	
10.6*	Adamas Pharmaceuticals, Inc. Amended and Restated 2016 Inducement Plan.					X
10.7*	Form of Restricted Stock Unit Grant Notice and Award Agreement under the Adamas Pharmaceuticals, Inc. 2016 Inducement Plan.	S-8	333-210255	99.6	3/17/2016	

Exhibit Number	Exhibit Description	Incorporation By Reference				Filed / Furnished Herewith
		Form	SEC File No.	Exhibit	Filing Date	
10.8*	Form of Stock Option Grant Notice and Option Agreement under the Adamas Pharmaceuticals, Inc. 2016 Inducement Plan.	S-8	333-210255	99.7	3/17/2016	
10.9	Office Lease Agreement by and between the registrant and CA-Emeryville Properties Limited Partnership, dated as of October 25, 2006.	S-1	333-194342	10.7	3/5/2014	
10.10	First Amendment to Lease by and between the registrant and NOP Watergate LLC (as successor in interest to CA-Emeryville Properties Limited Partnership), dated as of April 29, 2009.	S-1	333-194342	10.8	3/5/2014	
10.11	Second Amendment to Office lease Agreement by and between the registrant and Emeryville Office, L.L.C. (as successor to NOP Watergate, LLC), dated as of January 18, 2011.	S-1	333-194342	10.9	3/5/2014	
10.12	Third Amendment to Lease by and between the registrant and Emeryville Office, L.L.C., dated as of June 17, 2011.	S-1	333-194342	10.10	3/5/2014	
10.13	Fourth Amendment to Lease by and between the registrant and Emeryville Office, L.L.C., dated as of January 31, 2013.	S-1	333-194342	10.11	3/5/2014	
10.14	Fifth Amendment to Lease by and between the registrant and Emeryville Office, L.L.C., dated as of May 23, 2014.	10-Q	001-36399	10.3	8/7/2014	
10.15	Sixth Amendment to Lease by and between the registrant and KBSIII Towers At Emeryville, LLC, dated as of October 27, 2015.	10-K	001-36399	10.23	2/23/2016	
10.16	Seventh Amendment to Lease by and between the registrant and KBSIII Towers At Emeryville, LLC, dated as of January 16, 2018.	10-K	001-36399	10.38	2/22/2018	
10.17	Eighth Amendment to Lease by and between the registrant and KBSIII Towers At Emeryville, LLC, dated as of August 8, 2018.	10-Q	001-36399	10.1	11/1/2018	
10.18**	License Agreement by and between the registrant and Forest Laboratories Holdings Limited, dated as of November 13, 2012.	S-1/A	333-194342	10.6	4/7/2014	
10.19*	Adamas Pharmaceuticals, Inc. Amended and Restated Executive Severance Plan.					X
10.20*	Offer Letter by and between Adamas Pharmaceuticals, Inc. and Gregory Went, dated as of March 8, 2006.	S-1	333-194342	10.12	3/5/2014	
10.21*	Transition, separation, and consulting agreement by and between Adamas Pharmaceuticals, Inc. and Gregory T. Went, Ph.D., dated September 11, 2019.	10-Q	001-36399	10.2	11/7/2019	
10.22*	Compensation arrangements with Executive Officers.					X
10.23*	Offer Letter by and between Adamas Pharmaceuticals, Inc. and Vijay Shreedhar, Ph.D., dated May 14, 2019.	10-Q	001-36399	10.2	8/8/2019	

Exhibit Number	Exhibit Description	Incorporation By Reference				Filed / Furnished Herewith
		Form	SEC File No.	Exhibit	Filing Date	
10.24*	Employment Offer by and between Adamas Pharmaceuticals, Inc. and Neil F. McFarlane, dated September 12, 2019.	10-Q	001-36399	10.3	11/7/2019	
10.25*	Form of Indemnity Agreement between the registrant and its directors and officers.	S-1	333-194342	10.17	3/5/2014	
10.26*	Compensation arrangements with respect to Non-Employee Directors.	10-Q	001-36399	10.3	5/7/2020	
10.27**	Loan Agreement dated May 11, 2017 between Adamas Pharma, LLC and Healthcare Royalty Partners III, L.P.	10-Q	001-36399	10.4	8/8/2017	
10.28	Secured Promissory Note dated May 11, 2017 between Adamas Pharma, LLC and Healthcare Royalty Partners III, L.P.	10-Q	001-36399	10.5	8/8/2017	
10.29	Secured Promissory Note dated November 27, 2017 between Adamas Pharma, LLC and Healthcare Royalty Partners III, L.P.	10-K	001-36399	10.37	2/22/2018	
10.30***	Amendment No. 2 to the Loan Agreement dated January 2, 2020 between Adamas Pharma, LLC and Healthcare Royalty Partners III, L.P.	10-K	001-36399	10.37	2/25/2020	
10.31***	Amendment No. 3 to the Loan Agreement dated December 1, 2020 between Adamas Pharma, LLC and Healthcare Royalty Partners III, L.P.					X
10.32**	Amended and Restated Commercial Supply Agreement by and between Adamas Pharmaceuticals, Inc. and Catalent Pharma Solutions, LLC.	10-Q	001-36399	10.1	11/2/2017	
10.33**	First Amendment to Amended and Restated Commercial Supply Agreement by and between Adamas Pharmaceuticals, Inc. and Catalent Pharma Solutions, LLC.	10-Q	001-36399	10.3	8/8/2019	
10.34**	Amended and Restated API Supply Agreement by and between Adamas Pharma, LLC and Moehs Ibérica, S.L.	10-Q	001-36399	10.2	11/2/2017	
10.35***	Binding Term Sheet by and between Adamas Pharma, LLC and Sandoz, Inc.	10-K	001-36399	10.41	2/25/2020	
21.1	List of the subsidiaries of the Registrant.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (included on the signature page hereto).					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

Exhibit Number	Exhibit Description	Incorporation By Reference				Filed / Furnished Herewith
		Form	SEC File No.	Exhibit	Filing Date	
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(1).					X
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					X

- (1) This certification accompanies the Form 10-K 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-K), irrespective of any general incorporation language contained in such filing.

* Management compensatory contract or arrangement.

** Confidential treatment has been granted for certain portions of this exhibit.

*** Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would cause competitive harm to Adamas Pharmaceuticals, Inc.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: February 23, 2021

/s/ Neil F. McFarlane

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

Date: February 23, 2021

/s/ Christopher B. Prentiss

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Neil F. McFarlane and Christopher B. Prentiss, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Neil F. McFarlane</u> Neil F. McFarlane	Chief Executive Officer (Principal Executive Officer)	February 23, 2021
<u>/s/ Christopher B. Prentiss</u> Christopher B. Prentiss	Chief Financial Officer (Principal Financial and Accounting Officer)	February 23, 2021
<u>/s/ David L. Mahoney</u> David L. Mahoney	Chairman of the Board and Director	February 23, 2021
<u>/s/ Michael F. Bigham</u> Michael F. Bigham	Director	February 23, 2021
<u>/s/ Martha J. Demski</u> Martha J. Demski	Director	February 23, 2021
<u>/s/ Mardi C. Dier</u> Mardi C. Dier	Director	February 23, 2021
<u>/s/ William W. Ericson</u> William W. Ericson	Director	February 23, 2021
<u>/s/ John A. MacPhee</u> John A. MacPhee	Director	February 23, 2021
<u>/s/ Spyridon Papapetropoulos</u> Spyridon Papapetropoulos, M.D., Ph.D.	Director	February 23, 2021
<u>/s/ Anna S. Richo</u> Anna S. Richo	Director	February 23, 2021

[This page intentionally left blank]

[This page intentionally left blank]



Board of directors

David L. Mahoney

*Chairman of the Board
Former Co-Chief Executive Officer
McKesson HBOC, Inc. and Chief
Executive Officer McKesson LLC*

Neil F. McFarlane

*Chief Executive Officer
Adamas Pharmaceuticals, Inc.*

Michael F. Bigham

*Executive Chairman and
Former Chief Executive Officer
Paratek Pharmaceuticals, Inc.*

Martha J. Demski

*Chair of the Board
Chimerix, Inc.*

Mardi C. Dier

*Chief Financial Officer and
Executive Vice President
Ultragenyx Pharmaceutical Inc.*

William W. Ericson

*Managing Partner
Mohr Davidow Ventures and
Wildcat Venture Partners*

John A. MacPhee, M.P.H.

*Executive Director and
Chief Executive Officer
The JED Foundation*

Spyridon Papapetropoulos, M.D., Ph.D.

*Chief Medical Officer
Vigil Neuroscience*

Anna S. Richo, J.D.

*General Counsel,
Chief Compliance Officer,
and Corporate Secretary
Cargill, Incorporated*

Leadership team

Neil F. McFarlane

Chief Executive Officer

Christopher B. Prentiss

Chief Financial Officer

Adrian Quartel, M.D.

Chief Medical Officer

Vijay Shreedhar

Chief Commercial Officer

Jill Jene

*Vice President,
Corporate Development*

Sarah Mathieson

*Vice President, Corporate
Communications*

Eric Schlezinger

Vice President, Human Resources

Obtaining financial statements

A copy of our Annual Report on
Form 10-K is posted to our website.
www.adamaspharma.com

You may also obtain a copy
by written or email request to:

Adamas Pharmaceuticals, Inc.
1900 Powell Street, Suite 1000
Emeryville, CA 94608
Attn: Investor Relations

Email: IR@adamaspharma.com

Annual meeting

June 2, 2021 at 8:00 a.m. PT

View the meeting, submit questions,
and vote online at
www.virtualshareholdermeeting.com/ADMS2021

Trading information

The common stock of Adamas
Pharmaceuticals, Inc. is traded on the
Nasdaq Stock Market (symbol: ADMS).

If you wish to become a stockholder,
please contact a stockbroker.

Transfer agent

Information regarding stock
certificates, change of address,
ownership transfer or other stock
matters can be obtained from:

American Stock Transfer &
Trust Company, LLC
Address: 6201 15th Avenue
Brooklyn, NY 11219

Phone: 800.937.5449 (toll-free)
E-mail: info@amstock.com
Web: www.amstock.com

Independent public accounting firm

PricewaterhouseCoopers LLP

Legal counsel

Cooley LLP

On the cover:

People with Parkinson's
and their care partners





ADAMAS PHARMACEUTICALS, INC.

1900 Powell St., Ste. 1000 Emeryville, CA 94608
adamaspharma.com

