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

FORM 10-K

(Mark one)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

for the fiscal year ended December 31, 2021

OR

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number 000-26372

ADAMIS PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**82-0429727**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11682 El Camino Real, Suite 300, San Diego, CA 92130
(Address of Principal Executive Offices) (zip code)

Registrant's telephone number, including area code: **(858) 997-2400**
Securities registered pursuant to Section 12(b) of the Act:

None	**None**
(Title of each class)	(Name of each exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.0001 par value
(Title of class)

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 and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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 definitions of "large accelerated filer," "accelerated filer," "small reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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. ☐

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 stock held by non-affiliates of the Registrant as of June 30, 2021, was $162,839,042.

At March 25, 2022, the Company had 149,733,265 shares outstanding.

Documents Incorporated by Reference: Portions of the registrant's proxy statement for its 2022 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Except as expressly incorporated by reference, the registrant's definitive proxy statement shall not be deemed to be part of this report.

ADAMIS PHARMACEUTICALS CORPORATION

TABLE OF CONTENTS

Information Relating to Forward-Looking Statements

This Annual Report on Form 10-K (this "Report") includes forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Report, including statements regarding our future results of operations and financial position, strategy and plans, are forward-looking statements within the meaning of the federal securities laws and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology. Such statements are not historical facts, but are based on our current expectations, estimates and beliefs about our business and industry. Such forward-looking statements may include, without limitation, statements about the following matters: our strategies, objectives and our future achievements; our expectations for growth; estimates of future revenue; our sources and uses of cash; our liquidity needs; our current or planned clinical trials or research and development activities; anticipated completion dates for clinical trials; product development timelines; anticipated dates for commercial introduction of products; our future products; regulatory matters; our expectations concerning the timing of regulatory approvals; anticipated dates for meetings with regulatory authorities and submissions to obtain required regulatory marketing approvals; expense, profit, cash flow, or balance sheet items or any other guidance regarding future periods; and other statements concerning our future operations and activities. Such forward-looking statements include those that express plans, anticipation, intent, contingencies, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events, and they are subject to risks and uncertainties, known and unknown, that could cause actual results and developments to differ materially from those expressed or implied in such statements. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this Report.

The following factors, among others, could cause our future results and financial performance to differ materially from that expressed in forward-looking statements in this Report:

- our ability to continue as a going concern and ability to raise additional capital if needed;
- the commercial success of our SYMJEPI™ (epinephrine) Injection 0.3mg and 0.15 mg products, our ZIMHI™ (naloxone HCL Injection, USP) 5 mg/0.5 mL product, and amounts that we may receive with respect to sales of such products;
- future actions by the FDA and other regulatory agencies regarding our product candidates and our regulatory filings relating to our product candidates, including without limitation concerning our Tempol product candidate;
- the success of our product research and development programs;
- our future development plans concerning our product candidates, and ongoing and planned preclinical or clinical trials for our product candidates, including the timing of initiation of these trials, the timing of progress of those trials, anticipated completion dates of trials, and the results of any such trials, including without limitation the timing and outcome of our current Phase 2/3 clinical trial relating to our Tempol product candidate;
- the timing of, or delay in the timing of, commercial introduction of any of our products;
- our ability to enter into collaborations and agreements for the development and commercialization of our products and product candidates, and the potential benefits of any future commercialization or collaboration agreements with third parties;
- regulatory and personnel issues;
- our ability to generate significant revenues;
- competition and market developments;
- the failure of any of our product candidates, if approved, to achieve commercial success;
- our ability to protect our intellectual property from infringement by third parties;
- the extent and enforceability of intellectual property rights protections afforded by patents and patent applications that we own or have licensed;
- regulatory and health reform legislation and regulations;
- the introduction of technological innovations or new commercial products by our competitors, and competitive developments in the relevant markets;
- the outcome of any legal proceedings in which we are involved or in which we may in the future become involved;
- federal and state regulatory matters relating to compounding pharmacy outsourcing facilities;
- the effects of public health crises, pandemics and epidemics, such as the COVID-19 pandemic; and
- other risks and uncertainties detailed from time to time in our SEC filings, including without limitation the risk factors referred to in this Report under the heading "Risk Factors."

In addition, many forward-looking statements concerning our anticipated future business activities assume that we have sufficient funding to support such activities and continue our operations and planned activities. As discussed elsewhere in this Report, we will require additional funding in the future to continue operations, and there are no assurances that such funding will be available if needed. Failure to timely obtain required funding would adversely affect and could delay or prevent our ability to realize the results contemplated by such forward looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor 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. Important risks and factors that could cause actual results to differ materially from those in these forward-looking statements are disclosed in this Annual Report on Form 10-K, including, without limitation, under the headings "Item 1A. Risk Factors," "Item 1. Business" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as in our subsequent filings with the Securities and Exchange Commission, press releases and other communications.

Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at which or by which the actions, events or results anticipated by such statements will be achieved. Forward-looking statements are based on information available at the time they are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from what is expressed in or suggested by the forward-looking statements.

Forward-looking statements speak only as of the date they are made. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable laws. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

The Adamis Pharmaceuticals logo and other trademarks or service marks of Adamis Pharmaceuticals Corporation appearing in this Annual Report on Form 10-K are the property of Adamis Pharmaceuticals Corporation. All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective owners. Unless the context otherwise requires, the terms "we," "our," and "the company" refer to Adamis Pharmaceuticals Corporation, a Delaware corporation, and its subsidiaries.

Investors and others should note that we may announce material information to our investors using our website (www.adamispharmaceuticals.com), SEC filings, press releases, public conference calls and webcasts, as well as social media and blogs. We use these channels as a means of disclosing material non-public information and making disclosures pursuant to Regulation FD, and to communicate with our members and the public about our company. It is possible that the information we post on our website or social media and blogs could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on our website, social media channels and blogs listed on our investor relations website.

Summary of Material Risks Associated With Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "Risk Factors." These risks include, but are not limited to, the following:

- There is substantial doubt about our ability to continue as a going concern. We have incurred significant losses since our inception, anticipate that we will continue to incur losses in 2022, and may continue to incur losses in the future. We may never achieve or sustain profitability.
- Statements in this Report concerning our future plans and operations are dependent on our having adequate funding and the absence of unexpected delays or adverse developments. We will require additional funding in the future to help fund the development and commercialization of our products and product candidates, conduct research, development and trials relating to our product candidates, fund our ongoing operations and satisfy our obligations and liabilities. We may not be able to secure required funding, which could force us to delay, reduce or eliminate our commercialization efforts or product development programs and could cause us to reduce or cease operations.
- We may never commercialize additional product candidates that are subject to regulatory approval or earn a profit.
- Several of our potential products and technologies are in early stages of development, or have been discontinued or are suspended.
- Our development plans concerning our products and product candidates are affected by many factors, the outcome of which is difficult to predict.
- We could experience delays in the commencement or completion of clinical testing of our product candidates, which could result in increased costs and delays and adversely affect our business and financial condition. We may be required to suspend, repeat or terminate our clinical trials if trials are not well designed, do not meet regulatory requirements or the results are negative or inconclusive.
- We are subject to the risk of lawsuits or other legal proceedings.
- We are subject to substantial government regulation and are impacted by state and federal statutes and regulations, which could materially adversely affect our business. We may encounter difficulties or delays in applying for or obtaining regulatory approval for our products. If we do not receive required regulatory approvals for our products, we may not be able to develop and commercialize our products or technologies.
- Even if they are approved and commercialized, our potential products may not be able to compete effectively with other products targeting similar markets.
- Our failure to adequately protect or to enforce our intellectual property rights or secure rights to third party patents could materially harm our proprietary position in the marketplace or prevent the commercialization of our products. We may become involved in patent litigation or other intellectual property proceedings, which could result in liability for damages and have a material adverse effect on our business and financial position.
- We borrowed funds pursuant to the Paycheck Protection Program ("PPP"). Even though our loans have been forgiven pursuant to the program, we remain subject to possible review and audit in connection with such loans.
- The COVID-19 pandemic has adversely affected and may continue to adversely affect our business, results of operations and financial condition.
- If there are injuries or deaths associated with use of our products, or if there is a product recall affecting one or more of our products, we may be exposed to significant liabilities. We have announced a voluntary recall of four lots of our SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringe products. As of the date of this Report, neither we nor our commercialization partner have received, or is aware of, any adverse events related to this recall. However, in the event of adverse events or deaths associated with our products, we could become subject to product and professional liability lawsuits or other claims or proceedings. In addition, the recall could adversely affect our business, results of operations, financial condition and liquidity.

- Our US Compounding Inc. subsidiary, or USC, which is registered as a human drug compounding outsourcing facility under Section 503B of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, is subject to many federal, state and local laws, regulations, and administrative practices, including, among others: federal registration as an outsourcing facility, state and local licensure, and registration requirements concerning the operation of outsourcing facilities and the compounding, labeling, marketing, sale and distribution of products from our registered outsourcing facility. Effective as of July 30, 2021, we entered into an asset purchase agreement pursuant to which we sold and transferred certain assets of USC related to its human compounding pharmaceutical business. The remaining operations and business of USC have been or will be wound down and terminated, and remaining assets relating to USC's business have been or will be sold or otherwise disposed of. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer selling compounded pharmaceutical or veterinary products. Nevertheless, USC and we could become involved in proceedings with the U.S. Food & Drug Administration, or FDA, or other federal or state regulatory authorities alleging non-compliance with applicable federal or state regulatory legal requirements, or in other legal proceedings relating to the winding down of USC's business, which could adversely affect our business, financial condition and results of operations.
- Changes in healthcare laws could adversely affect the ability or willingness of customers to purchase our products and, as a result, adversely impact our business and financial results.
- We have received a grand jury subpoena issued in connection with a criminal investigation. As we have previously disclosed, on May 11, 2021, each of the company and our USC subsidiary received a grand jury subpoena from the U.S. Attorney's Office, or USAO, for the Southern District of New York issued in connection with a criminal investigation, requesting a broad range of documents and materials relating to, among other matters, certain veterinary products sold by the company's USC subsidiary, certain practices, agreements and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC. The Audit Committee of the board of directors, or the Board, has engaged outside counsel to conduct an independent internal investigation to review these and other matters. The company has also received a request from the Securities and Exchange Commission, or the SEC, that the company voluntarily provide documents and information relating to certain matters including the subject matter of the subpoena from the USAO. The company has produced and will continue to produce and provide documents in response to the subpoena and requests. The company intends to cooperate with the USAO and SEC. At this time, the company is unable to determine what, if any, additional actions the USAO, SEC or other federal or state authorities may take, what, if any, remedies or remedial measures the USAO, SEC or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the company's business, previously reported financial results, financial results included in this Report, or future financial results. We could receive additional requests from the USAO, SEC or other authorities, which may require further investigation. The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, result in fines, penalties, equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, future financial results. The occurrence of any of these events could have a material adverse effect on the company's business, financial condition and results of operations.
- We identified a material weakness in our internal control over financial reporting and concluded that our internal control over financial reporting was not effective as of March 31, 2021, June 30, 2021 and September 30, 2021. In addition, we identified a material weakness in our internal control over financial reporting, concluded that our internal control over financial reporting was not effective and that our disclosure controls and procedures were not effective at the reasonable assurance level, and restated our unaudited condensed consolidated financial statements for the periods ended March 31, 2020, June 30, 2020, and September 30, 2020. These matters could lead to additional risks and uncertainties, including loss of investor confidence, legal investigations or proceedings, and negative impacts on our business, financial condition and stock price. If we fail to effectively remediate material weaknesses in our internal control over financial reporting, it could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.
- Our business depends on complex information systems, and any failure to successfully maintain these systems or implement new systems to handle our changing needs could materially harm our operations. Cybersecurity or other system failures could disrupt our business, result in liabilities, and adversely affect our business, financial condition and results of operations.
- Provisions of our charter documents could discourage an acquisition of our company that would benefit our stockholders and may have the effect of entrenching, and making it difficult to remove, management.
- Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock, which could negatively impact the market price and liquidity of our common shares and our ability to access the capital markets.

PART I

ITEM 1. BUSINESS

Company Overview

Adamis Pharmaceuticals Corporation ("we," "us," "our," "Adamis" or the "company") is a specialty biopharmaceutical company focused on developing and commercializing products in various therapeutic areas, including allergy, opioid overdose, respiratory and inflammatory disease. Our products and product candidates in the allergy, respiratory, and opioid overdose markets include: SYMJEPI™ (epinephrine) Injection 0.3mg, which was approved by the U.S. Food and Drug Administration, or FDA, in 2017 for use in the emergency treatment of acute allergic reactions, including anaphylaxis, for patients weighing 66 pounds or more; SYMJEPI (epinephrine) Injection 0.15mg, which was approved by the FDA in September 2018, for use in the treatment of anaphylaxis for patients weighing 33-65 pounds; ZIMHI™ (naloxone HCL Injection, USP) 5 mg/0.5 mL, which was approved by the FDA in October 2021 for the treatment of opioid overdose; and Tempol, an investigational drug. In June 2020, we entered into a license agreement with a third party to license rights under certain patents, patent applications and related know-how of the licensor relating to Tempol. The exclusive license includes the worldwide use under the licensed patent rights and related rights for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection, as well as the field of use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. We commenced Phase 2/3 clinical trial start-up activities to examine the safety and efficacy of Tempol in COVID-19 patients early in the infection,and on September 2, 2021, we announced the initiation of patient dosing in the trial. In February 2022 we announced the enrollment and dosing of more than 100 subjects in the Phase 2/3 trial, and on March 14, 2022, we announced that the Data Safety Monitoring Board, or DSMB, overseeing the Phase 2/3 clinical trial met to evaluate the clinical and safety data from the first planned interim analysis and, following its evaluation, recommended that the study continue without modification. Assuming continuation of the trial and continued enrollment of patients, following submission of additional data and information to the DSMB, the DSMB will conduct a second planned review, currently anticipated to be in May 2022, which may provide additional insight into the safety and clinical results at that time. Our goal is to create low cost therapeutic alternatives to existing treatments. Consistent across all specialty pharmaceuticals product lines, we intend to submit New Drug Applications, or NDAs under Section 505(b)(2), of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, or Section 505(j) Abbreviated New Drug Applications, or ANDAs, to the FDA, whenever possible, in order to potentially reduce the time to market and to save on costs, compared to those associated with Section 505(b)(1) NDAs for new drug products.

Our US Compounding Inc. subsidiary, or USC, which we acquired in April 2016 and which is registered as a human drug compounding outsourcing facility under Section 503B of the FDCA and the U.S. Drug Quality and Security Act, or DQSA, provided prescription compounded medications, including compounded sterile preparations and nonsterile compounds, to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. In July 2021, we sold certain assets relating to USC's human compounding pharmaceutical business and approved a restructuring process to wind down the remaining USC business and sell, liquidate or otherwise dispose of the remaining USC assets. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer selling compounded pharmaceutical or veterinary products.

To achieve our goals and support our overall strategy, we will need to raise additional funding in the future and make significant investments in, among other things, product development and working capital.

The current status of our development programs is as follows:

Product Portfolio

Specialty Pharmaceutical Products	Target Indication	Status
SYMJEPI (epinephrine) Injection 0.3mg	Anaphylaxis	FDA Approved, June 2017
SYMJEPI (epinephrine) Injection 0.15mg	Anaphylaxis	FDA Approved, September 2018
ZIMHI (naloxone) Injection	Opioid Overdose	FDA Approved, October 2021
Tempol (APC-400)	Treatment of COVID-19	Phase 2/3 trial underway

Anaphylaxis; SYMJEPI; Epinephrine Injection Pre-Filled Single Dose Syringe

The American Academy of Allergy Asthma and Immunology, or AAAAI, defines anaphylaxis as a serious life-threatening allergic reaction. The most common anaphylactic reactions are to foods, insect stings, medications and latex. According to information published by AAAAI reporting on findings from a 2009-2010 study, up to 8% of U.S. children under the age of 18 had a food allergy, and approximately 38% of those with a food allergy had a history of severe reactions. Anaphylaxis requires immediate medical treatment, including an injection of epinephrine.

We estimate that sales of prescription epinephrine products in 2021 were more than $1.8 billion, based on assumptions and estimates utilizing industry data. We cannot provide any assurances concerning any possible future rates of annual growth or whether annual prescription sales will decline or grow. The market for prescription epinephrine products is competitive, and a number of factors have resulted in, and could continue to result in, downward pressure on the pricing of, and revenues from sales of, our SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg prescription epinephrine products. Our SYMJEPI (epinephrine) Injection 0.15mg and 0.3mg products allow users to administer a pre-measured epinephrine dose quickly with a device that we believe, based on human factors studies, to be intuitive to use.

On June 15, 2017, the FDA approved our SYMJEPI (epinephrine) Injection 0.3mg product for the emergency treatment of allergic reactions (Type I) including anaphylaxis. SYMJEPI (epinephrine) Injection 0.3mg is intended to deliver a dose of epinephrine, which is used for emergency, immediate administration in acute anaphylactic reactions to insect stings or bites, allergic reaction to certain foods, drugs and other allergens, as well as idiopathic or exercise-induced anaphylaxis for patients weighing 66 pounds or more. On September 27, 2018, the FDA approved our lower dose SYMJEPI (epinephrine) Injection 0.15mg product, for the emergency treatment of allergic reactions (Type I) including anaphylaxis in patients weighing 33 to 66 pounds.

In July 2018, we entered into a Distribution and Commercialization Agreement, or the Sandoz Agreement, with Sandoz Inc., or Sandoz, to commercialize both of our SYMJEPI products. In January 2019, we announced that Sandoz had launched SYMJEPI (epinephrine) 0.3 mg Injection in the U.S. market, initially available in the institutional setting. On July 9, 2019, we announced the full launch (institutional and retail) by Sandoz of both dose forms of the SYMJEPI injection products.

On May 11, 2020, we announced that we entered into an agreement, or the Termination Agreement, with Sandoz to terminate the Sandoz Agreement and simultaneously announced that we entered into an exclusive distribution and commercialization agreement, or the USWM Agreement, with USWM, LLC, or USWM or US WorldMeds, for the United States commercial rights for the SYMJEPI products, as well as for our ZIMHI product. Under the terms of the USWM Agreement, we appointed USWM as the exclusive distributor of SYMJEPI in the United States and related territories, or the Territory, effective upon the termination of the Sandoz Agreement, and of the ZIMHI product if approved by the FDA for marketing, and granted USWM an exclusive license under our patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the products in the Territory, in partial consideration of an initial payment of $1,000,000 by USWM and potential additional regulatory and commercial based milestone payments. There can be no assurances that any of these milestones will be met or that any milestone payments will be paid to us. We retain rights to the intellectual property subject to the USWM Agreement and to commercialize both products outside of the Territory. In addition, we may continue to use the licensed intellectual property (excluding certain of the licensed trademarks) to develop and commercialize other products (with certain exceptions), including products that utilize our Symject™ syringe product platform.

The USWM Agreement provides that, after deducting the supply price and subject to certain other deductions and adjustments, including an allocation for USWM sales and distribution expenses from net sales of the products, USWM will pay to us 50% of the net profit from net sales, as each such term is defined in the USWM Agreement, of the product in the Territory to third parties, determined on a quarterly basis. We will be the supplier of the products to USWM, and USWM will order and pay us a supply price for quantities of products ordered. The agreement does not include minimum payments to us by USWM, minimum requirements for sales of product by USWM or, with certain exceptions, minimum purchase commitments by USWM.

On January 22, 2021, we announced that the SYMJEPI products added to the Walgreens Prescription Savings Club program and were available to members of the program. The Walgreens Prescription Savings Club offers customers, who pay an annual membership fee, savings off retail prices on a large variety of medications.

On October 1, 2019, we entered into an exclusive distribution and commercialization agreement with a company in Australia to register and commercialize the SYMJEPI products in the Australia and New Zealand markets, after all required regulatory registration and approvals have been obtained. Following several communications with the applicable Australian regulatory authority and requests by the authority for additional data and modifications to current specifications that were beyond the scope of our FDA-approved dossier, we and our commercial partner in Australia voluntarily withdrew our regulatory application until we determine if the commercial case for SYMJEPI in Australia justifies the additional development efforts and expense. There can be no assurances that we will decide to resubmit the application, nor regarding the outcome of the regulatory review should we decide to resubmit the application.

On March 21, 2022, we announced a voluntary recall of four lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes to the consumer level. The four lots are being recalled due to the potential clogging of the needle preventing the dispensing of epinephrine. USWM will handle the entire recall process for the company, with company oversight. SYMJEPI is manufactured and tested for us by Catalent Belgium S.A. As of the date of this Report, neither USWM nor we have received, or are aware of, any adverse events related to this recall. The recall is being conducted with the knowledge of the FDA. As of the date of this Report, manufacturing of SYMJEPI is currently on hold pending the results of investigation that is underway to determine the root cause.We currently anticipate a resolution and resumption of manufacturing after the investigation is completed and any issues are satisfactorily addressed, although there can be no assurance concerning the outcome of the investigation. Our consolidated financial statements for the year ended December

31, 2021, included elsewhere in this Report, include and reflect a reserve of approximately $2.0 million associated with the recall. The company may be able to be reimbursed by certain third parties for some of the costs of the recall under the terms of its manufacturing agreements, but there are no assurances regarding the amount or the timing of any such recovery,

Opioid Overdose

ZIMHI (naloxone) Injection

Naloxone is an opioid antagonist used to treat narcotic overdoses. Naloxone, which is generally considered the drug of choice for immediate administration for opioid overdose, blocks or reverses the effects of the opioid, including extreme drowsiness, slowed breathing, or loss of consciousness. Common opioids include morphine, heroin, tramadol, oxycodone, hydrocodone and fentanyl.

The number of deaths due to opioids has increased over five-fold compared to 1999. According to statistics published by the Centers for Disease Control and Prevention (CDC), drug overdoses resulted in approximately 96,779 deaths in the United States during the 12-month period ending March 2021, which was a 29% increase over the prior 12-month period. Drug overdoses are now the leading cause of death for Americans under age 50, with more powerful synthetic opioids, like fentanyl and its analogues, responsible for the largest number of those deaths. Studies from 2013 to 2016 have revealed an approximately 87% increase in deaths associated with synthetic opioids, whereas, death rates due to natural and semisynthetic opioids remained relatively stable. With this significant increase in synthetic opioid abuse are published studies that have suggested that the current recommended doses of naloxone may be inadequate in that frequent redosing is required. Repeat dosing of the commonly utilized dose of naloxone suggests the need for a higher dosage product.

On December 31, 2018, we filed an NDA with the FDA relating to our higher dose naloxone injection product, ZIMHI, for the treatment of opioid overdose. On November 22, 2019, we received a Complete Response Letter, or CRL, from the FDA regarding our NDA for ZIMHI. A CRL is issued by the FDA's Center for Drug Evaluation and Research when it has completed its review of a file and questions remain that preclude the approval of the NDA in its current form. The CRL stated that the FDA determined that it could not approve the NDA in its present form and provided recommendations needed for resubmission. In May 2020 we resubmitted the NDA for ZIMHI to the FDA. On November 13, 2020, we received a second CRL from the FDA regarding the resubmitted NDA. In May 2021 we resubmitted the NDA for ZIMHI to the FDA. On October 18, 2021, we announced that the FDA had approved ZIMHI for the treatment of opioid overdose. On March 31, 2022, our commercial partner USWM and we issued a press release announcing the commercial launch of ZIMHI.

Tempol (APC400)

On June 12, 2020, we entered into a license agreement with Matrix Biomed, Inc., or the Licensor, to license rights under certain patents, patent applications and related know-how of Licensor relating to Tempol, an investigational drug. The exclusive license includes the worldwide use under the licensed patent rights and related rights for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection. In addition, the exclusive license includes the field of use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. In consideration for the Licensor providing the rights under the licensed patent rights and related know-how relating to Tempol within the licensed fields, we paid Licensor $250,000 and also issued to the Licensor 1,000,000 shares of our Series B Convertible Preferred Stock, which has previously converted into an equal number of shares of our common stock.

Tempol is a redox cycling nitroxide that promotes the metabolism of many reactive oxygen species and improves nitric oxide bioavailability. It has been studied extensively in animal models of oxidative stress and inflammation. Overall, Tempol acts as both a super-oxide dismutase mimetic and also has demonstrated anti-inflammatory, anticoagulant activity and antiviral activity. Inflammation and oxidative stress occur in various disease states including COVID-19. COVID-19 is a complex disease that manifests in multiple phases including, among others, viral replication and hyperinflammation. Both inflammatory cytokines and reactive oxygen species (ROS) from cells of the immune system called macrophages and neutrophils damage the lung in Acute Respiratory Distress Syndrome (ARDS). Many published articles describing animal models of ARDS show Tempol caused a decrease in lung inflammation and preserved lung pathology associated with acute and chronic lung injury. In animal models, Tempol has been shown to decrease proinflammatory cytokines (cytokine storm), and through its antioxidant activity has been shown to decrease the harmful effects of ROS. In addition, Tempol has been shown to decrease platelet aggregation, a problem observed in many COVID-19 patients. More recently, Tempol has been shown to have antiviral activity against the virus that causes COVID-19 in-vitro and may have synergy with the antiviral Remdesivir.

Preclinical studies of Tempol have shown it to have antiviral, anti-inflammatory, and antioxidant activity. The company believes this unique mechanism of action could provide physicians with a tool to intervene to slow or stop progression of COVID-19 or inflammation at multiple phases of the disease. If proven, this could provide Tempol with an advantage over the two oral antiviral drugs for which the FDA has recently granted Emergency Use Authorization for the treatment of COVID-19, although there can be no assurance that this would be the case.

On January 28, 2021, we announced that in collaboration with the Human Immune Monitoring Center at Stanford University we conducted a study to investigate the effects of Tempol on immune cells from COVID-19 patients, and that preliminary data from that study showed that Tempol decreases cytokines from stimulated cells from COVID-19 patients, Subsequent analysis of the data confirmed that preincubation of immune cells with Tempol resulted in a significant decrease in multiple T cell and APC-derived cytokines from both cells of COVID-19 and uninfected donors. In March 2021, we announced that in studies conducted at Galveston National Laboratory, or GNL, University of Texas Medical Branch, hamsters challenged with the virus that causes COVID-19 (SARS-CoV-2) showed decreased inflammation in the lungs when treated with Tempol compared to controls, and on March 22, 2022, we announced that in studies conducted at the GNL, hamsters challenged with high levels of the Omicron variant of the SAR-CoV-2 virus, resulted in significant decrease of inflammation in the lungs of animals treated with Tempol compared to controls.

In July 2020, we submitted to the FDA a pre-IND package which provided a protocol for a Phase 2/3 study examining Tempol in COVID-19 patients, and the FDA provided comments regarding the prospective use of Tempol in a randomized placebo controlled trial. In January 2021, we submitted an IND to the FDA for the investigational use of Tempol for the treatment of COVID-19. On February 22, 2021, we announced that the FDA notified the company that the agency had completed the safety review of the IND and concluded that the company may proceed with the proposed clinical investigation and trial described in the IND. The goal of the study titled, "A Phase 2/3, Adaptive, Randomized, Double-Blind, Placebo-Controlled Study to Examine the Effects of Tempol (MBM-02) on Preventing COVID-19 Related Hospitalization in Subjects with COVID-19 Infection," is to examine the safety and activity of Tempol in COVID-19 patients early in the infection. In addition to safety, the study will examine markers of inflammation, clinical resolution of symptoms, and the rate of hospitalization for patients taking Tempol versus placebo early in COVID-19 infection. The trial is designed to enroll a total of approximately 248 patients. On June 11, 2021, we announced that clinical trial start-up activities were underway, that the company was carrying out those activities with a large clinical research organization, that commenced activities included site identification and initiation, data base production, vendor management, and the establishment of an independent data safety monitoring board, or DSMB, of infectious disease experts, which will review the safety and efficacy of the trial, and that clinical trial drug product and placebo have also been obtained. On September 2, 2021, we announced the initiation of patient dosing in the trial. Our trial requires individuals with moderate COVID-19 symptoms to be unvaccinated and have co-morbidities such as heart disease, as those patients typically have worse outcomes, requiring hospitalization. We initially experienced enrollment challenges primarily as a result of the decrease in COVID-19 infections and increased immunizations in the United States. We took certain responsive steps including opening new sites across the U.S. and modifying the protocol to include vaccinated subjects.

In February 2022 we announced the enrollment and dosing of more than 100 subjects in the Phase 2/3 trial. On March 14, 2022, we announced that the Data Safety Monitoring Board, or DSMB, overseeing the Phase 2/3 clinical trial met to evaluate the clinical and safety data from the first planned interim analysis and, following its evaluation, recommended that the study continue without modification. The trial is continuing, and following submission of additional data and information to the DSMB, the DSMB will conduct a second planned review, currently anticipated to be in May 2022, which may provide additional insight into the safety and clinical results at that time. In January 2022, we submitted a Fast Track Application to the FDA for Tempol for the treatment and prevention of COVID-19. Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fulfills an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions, and the request can be initiated by the drug company at any time during the development process. The FDA will review the request and decide based on whether the drug fulfills an unmet medical need in a serious condition. Once a drug receives Fast Track designation, early and frequent communication between the FDA and the drug company is encouraged throughout the entire drug development and review process. In March 2022, we received a communication from the FDA denying our request for Fast Track designation for our Tempol product at this time, indicating that the program did not satisfy the requirements for Fast Track designation.

We intend to continue to explore the availability of government and/or non-government funding to help support study the efficacy of Tempol as a therapeutic treatment for COVID-19. We also continue to explore options regarding the funding and design of a clinical study to examine the effects of Tempol for other clinical indications including, but not limited to, the treatment of methamphetamine and cocaine use disorder, and are engaged in additional activities intended to support such development, should we determine to pursue and proceed with such activities.

Under our agreement with the Licensor, we will be responsible for funding preclinical and clinical development relating to products developed for the licensed fields of use, and for matters relating to compliance of any licensed products or development and testing of licensed products with laws and regulations. Licensor will provide, and we will purchase from Licensor, Tempol material for preclinical or clinical work or use in licensed products, and Licensor agreed to provide us with other information and materials relating to testing and development of products within the licensed fields of use. The agreement provides for representatives of the company and Licensor to meet periodically and discuss issues relating to the development, testing and approval of products within the licensed fields of use. Under the license agreement, if any products are commercialized, profits (as defined in the agreement) from sales of licensed products will be shared equally between the parties. Profits are generally determined as net sales of licensed products less costs incurred by us for manufacturing, marketing and distribution of licensed products. The license agreement contains other covenants of the company and Licensor relating to, among other matters, funding of testing and development of licensed products, confidentiality, compliance with laws, and other matters. The agreement also includes provisions regarding prosecution, maintenance, infringement and enforcement of the licensed patents, books and records, indemnification and other matters. The company may not sublicense its rights under the agreement without the consent of Licensor, and neither party may assign its rights under the agreement without the consent of the other party. The term of the agreement continues until the expiration of the last to expire of the patents licensed under the agreement and will terminate or may be terminated earlier upon the occurrence of certain other events including an uncured breach of the agreement or failure to satisfy certain covenants. The company may also terminate the agreement with advance written notice to Licensor.

US Compounding, Inc.

On July 30, 2021, the company and its wholly-owned USC subsidiary entered into an Asset Purchase Agreement, or the USC Agreement, effective as of July 30, 2021, or the Effective Date, with Fagron Compounding Services, LLC d/b/a Fagron Sterile Services, or the Purchaser, providing for the sale and transfer by USC and the purchase by the Purchaser, effective as of the Effective Date, of certain assets of USC related to its human compounding pharmaceutical business, or the Business, including certain customer information and information on products sold to such customers by USC, together, the "Book of Business," including related formulations, know-how, and expertise regarding the compounding of pharmaceutical preparations, clinical support knowledge and other data and certain other information relating to the customers and products, collectively referred to as the "Assets." After the Effective Date, Purchaser may use the Book of Business to secure customers for its products and services and may otherwise use the Book of Business. Pursuant to the USC Agreement, the Purchaser will not assume any liabilities of USC, and the transaction did not include the sale or transfer of any USC equipment, buildings or real property, or any products, information, agreements, relationships or other assets relating to the veterinary business of USC.

The USC Agreement provides that the consideration payable by the Purchaser to the company for the Assets sold and transferred will consist of the following amounts: (i) a payment of $107,500 on the Effective Date; and (ii) monthly payments in an amount equal to (a) two (2.0) times the amount actually collected by Purchaser or its affiliates for sales of products or services made to certain identified customers included in the Book of Business during the 12-month period following the Effective Date, or the "Payment Term." and (b) a lower multiple of the amount actually collected by Purchaser or its affiliates for sales of products or services made to certain other customers included in the Book of Business. In addition, to the extent that such product or service is supplied by USC pursuant to the supply arrangement provided for by the USC Agreement, or the "Supply Agreement," the Purchaser agreed to reimburse USC for the cost of such product or service, as set forth in the Supply Agreement. The USC Agreement provides that during the Payment Term, the Purchaser will maintain the Book of Business and use commercially reasonable efforts to maximize the consideration payable to the company and collect amounts outstanding related to sales of products or services made to customers included in the Book of Business. However, the USC Agreement does not provide for any minimum purchase price consideration to the company or USC. Accordingly, there is no assurance as to the amount of purchase price consideration that the company or USC may ultimately receive as a result of the transactions contemplated by the USC Agreement. Certain of the customers included in the Book of Business may decide to not purchase products or to reduce their purchases of products from Purchaser after the Effective Date, and Purchaser may, in good faith, decide not to change its product mix from those products offered by Purchaser as of the Effective Date and may decide not to carry all of the products offered and sold by USC as part of the Business prior to the Effective Date.

The USC Agreement includes certain restrictive covenants of the company and USC, including noncompetition provisions, pursuant to which, for a period of five years from the Effective Date, or the "Restricted Period," and subject to certain exceptions, the company and USC have agreed, among other matters, not to solicit any Business from any customers included in the Book of Business or engage in certain other activities. Each of the USC Agreement and the Supply Agreement includes standard indemnification provisions, and a number of other covenants and agreements of the parties concerning the transactions contemplated by the USC Agreement and the Supply Agreement, including concerning cooperation and assistance, confidentiality, non-disparagement and the transfer of information and documents, compliance with laws, and personnel matters. The USC Agreement includes indemnification provisions pursuant to which the company and USC agreed to indemnify the Purchaser and certain related parties against losses incurred by such indemnified parties arising or resulting from certain matters including breach of the USC Agreement by USC and third party claims relating to product sales to customers by USC before the Effective Date. In connection with the transaction, the company accrued a $700,000 liability for a transaction fee payable to a financial advisor.

Plan for the Remaining Operations, Business and Assets of USC

In light of a number of factors including the sale of assets to the Purchaser pursuant to the USC Agreement, in August 2021 the Board approved a restructuring process of winding down the remaining operations and business of USC and selling, transferring or disposing of the remaining assets of USC. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer selling compounded pharmaceutical or veterinary products. The restructuring and winding down includes, without limitation, the termination of USC's veterinary business and USC sales to veterinary customers; the termination of employment of all or substantially all employees engaged in the USC business (except as determined to be necessary or appropriate in connection with the company's and USC's performance of their obligations under the USC Agreement and the transactions contemplated thereby, or in connection with resolving matters relating to the winding down of USC's business), and providing such notices and making such payments to such employees as the officers of the company determine are necessary or appropriate, including as maybe required by law or as maybe provided for pursuant to any retention agreement, severance agreement, incentive agreement, or other written agreement with such employees; the sale or other disposition from time to time of the remaining equipment, real property, buildings and tangible and intangible assets relating to USC's business that are unrelated to the USC Agreement; the termination, assignment or other resolution of agreements with third parties relating to the USC business; making regulatory filings and taking appropriate actions with federal and state regulatory authorities in connection with the winding down and winding up of USC's business; and taking such other actions as the officers of the company or USC (as appropriate) determine are necessary or appropriate in connection with the winding down and winding up of the remaining business, operations and assets of USC. The company has sold and disposed of certain customer information and other assets related to USC's veterinary compounded pharmaceuticals business and will continue the process of selling or otherwise disposing of the remaining assets relating to USC's business.

Other Product Candidates or Technologies

C31G. We also have a microbicide product candidate, named C31G. In December 2010, we announced the successful completion of a Phase 3 contraceptive trial of C31G. The study met its primary endpoint and was conducted by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), NIH, in the Contraceptive Clinical Trials Network at 14 sites in the United States. The clinical investigators found that C31G was not inferior in contraceptive efficacy to the comparator drug Conceptrol. Moreover, the gel was well-tolerated and had a high degree of acceptability in women who completed the study. C31G does not contain nonoxynol-9 and, if commercialized, could offer an alternative for women who seek a non-hormonal method of contraception. In addition, in September 2013 we announced that a published study conducted by university researchers at Louisiana State University Health Science Center found that C31G was effective in treating Herpes Simplex Virus, or HSV, in an eye infection (ocular keratitis) animal model using live rabbits. In the same study the researchers also reported that ocular administration of C31G was safe and well tolerated, confirming earlier clinical studies that established C31G safety and tolerability in other applications. HSV-1 is the same virus that causes cold sores and is common in humans. In previous animal studies, C31G was also active against HSV-2, the cause of genital herpes. Before considering any actions to further develop or consider commercialization alternatives for a C31G product candidate, further meetings with the FDA would be required to discuss the regulatory pathways for submitting an NDA for marketing approval, including the additional trials that would be required before an NDA is submitted, and in addition, we would seek to enter into an out-licensing or similar transaction with third party entities or organizations. The C31G product candidate is held by our Biosyn, Inc. subsidiary, which we acquired in 2004. Provisions in the agreement pursuant to which we acquired Biosyn, and/or in certain of the funding or other agreements relating to the C31G product, provide for payments to the former Biosyn shareholders upon marketing approval by the FDA (or, in certain circumstances, certain foreign regulatory authorities) of C31G for one or more indications, and for payments to certain other third parties in the event of sales or other revenues relating to C31G or certain other events. In addition, sale or out-licensing of the C31G product candidate may require the consent of one or more such third parties. Accordingly, there can be no assurances that we will pursue commercialization of or enter into any agreement or transaction involving C31G or that any C31G product will be developed, submitted for regulatory approval, approved or marketed.

Our development plans and decisions regarding our products and product candidates, including whether to continue, resume or terminate product development efforts, are affected by a number of factors, including without limitation the availability of adequate funding, the development, clinical trial and regulatory pathway for the product candidate, the costs and results of preparing for and conducting any additional studies, trials or development efforts that we may determine to undertake, the pace of conduct, progress, and completion of, studies relating to our product candidates, the absence of unexpected regulatory issues or delays, the time period required to enroll a sufficient number of patients in the study, our success in negotiating and entering into development or commercialization agreements relating to our products should we choose to seek commercialization partners for one or more of our products or product candidates, and the commercial and competitive landscape for the product including the introduction of potentially competing new products by our competitors. As a result, our product development plans, as well as the anticipated dates for development and introduction of products in our product pipeline, could be affected by such considerations. In considering development and commercialization alternatives for our products and product candidates and technologies, we may seek to enter into development or commercialization agreements, license agreements, or other strategic agreements with third parties relating to development, commercialization and marketing of one or more of our products or product candidates. We currently have no in-house manufacturing capabilities, and as a result we intend to rely on third-party contract manufacturers to manufacture the materials needed for our clinical trials, products and product candidates.

Additional factors that could affect the development and launch dates for our products and product candidates include general market conditions, the outcome of discussions with the FDA concerning the regulatory approval pathway of the applicable product candidate including the number and kind of clinical trials that the FDA will require before the FDA will consider regulatory approval of the applicable product, any unexpected difficulties in licensing or sublicensing intellectual property rights that may be required for other components of the product, patent infringement lawsuits relating to Paragraph IV certifications as part of any Section 505(b)(2) or ANDA filings, any unexpected difficulties in the ability of our suppliers to timely supply quantities for commercial launch of the product, any unexpected delays or difficulties in assembling and deploying an adequate sales force to market the product, and receipt of adequate funding to support product development and sales and marketing efforts.

Clinical Supplies and Manufacturing

We have no in-house manufacturing or distribution capabilities and have no current plans to establish manufacturing facilities for significant clinical or commercial production. We rely on third-party contract manufacturers to manufacture our products and make the material used to support the development of our product candidates. Our third-party manufacturers are subject to extensive governmental regulation. The FDA mandates that drugs be manufactured, packaged and labeled in conformity with current good manufacturing practices, or cGMP, regulations. In complying with cGMP regulations, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to ensure that their services and products meet applicable specifications and other requirements. We intend to continue to outsource the manufacture and distribution of our products for the foreseeable future, and we believe this manufacturing strategy will enable us to direct our financial resources to development of products without devoting the resources and capital required to build cGMP compliant manufacturing facilities. Our SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg products are manufactured by a third-party manufacturer, Catalent Belgium SA/NV, utilizing materials to complete the manufacturing process obtained from various companies and suppliers. Our ZIMHI (naloxone) Injection 5 mg product is also manufactured by a third-party manufacturer, Siegfried, Irvine, USA, utilizing materials to complete the manufacturing process obtained from various companies and suppliers. The assembly and final packaging of all our products are implemented by a third-party entity, Phillips-Medisize, LLC. There are potential sources of supply other than our existing suppliers, although new suppliers would be required to qualify under applicable regulatory requirements.

Sales and Marketing

Our SYMJEPI (epinephrine) products were initially marketed and sold in the U.S. markets by Sandoz pursuant to our commercialization agreement with Sandoz. Following termination of the Sandoz Agreement in 2020, our SYMJEPI products and our ZIMHI product are marketed and sold in the U.S. markets by USWM pursuant to our USWM Agreement.

Customers and Distribution

Our SYMJEPI (epinephrine) 0.15 mg and 0.3 mg Injection products and our ZIMHI product are distributed in the U.S. markets by our commercialization partner USWM pursuant to the USWM Agreement. The FDA approved ZIMHI for marketing in October 2021, and on March 31, 2022, our commercialization partner USWM and we issued a press release announcing the commercial launch of ZIMHI. Pursuant to our agreement with USWM, we are responsible for supplying the SYMJEPI and ZIMHI products to USWM at a supply price for quantities of products ordered. On January 22, 2021, we announced that the SYMJEPI products added to the Walgreens Prescription Savings Club program and were available to members of the program. The Walgreens Prescription Savings Club offers customers, who pay an annual membership fee, savings off retail prices on a large variety of medications.

Competition

The biotechnology and pharmaceutical industries are extremely competitive. Our potential competitors in the field are many in number and include major pharmaceutical and specialized biotechnology companies. Many of our potential competitors have significantly more financial, technical and other resources than we do, which may give them a competitive advantage. In addition, they may have substantially more experience in effecting strategic combinations, in-licensing technology, developing drugs, obtaining regulatory approvals and manufacturing and marketing products. We cannot give any assurances that we can compete effectively with these other biotechnology and pharmaceutical companies. Our potential competitors in these markets may succeed in developing products that could render our products and those of our collaborators obsolete or non-competitive. In addition, many of our competitors have significantly greater experience than we do in the fields in which we compete.

Our products and product candidates, if developed, approved and launched, will compete with numerous prescription and non-prescription over-the-counter products targeting similar conditions, as well as prescription generic products. In addition, a number of large pharmaceuticals companies produce similar pharmaceutical products for similar indications. Moreover, certain products that previously have been available by prescription only have been or could in the future be approved by the FDA for sale over-the-counter without a prescription at a lower price than competing prescription products, which could adversely affect our ability to successfully develop and market a competing prescription product.

The SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg products compete against other self-administered epinephrine products, including EpiPen, EpiPen Jr., Auvi-Q and Adrenaclick. There has been market and regulatory focus in recent years on the prices to consumers of self-administered epinephrine products, which have exerted downward pressure on the pricing of such products. The company that markets EpiPen, introduced an authorized generic version of the auto-injector product at a lower price than the EpiPen. Additionally, in late 2018 a generic, or A/B rated, competitor to EpiPen was approved and launched. Other competing products have been introduced or prices on existing competing products have been reduced, and if additional competing products are introduced in the future, including additional generic versions of one or more existing spring-loaded auto-injector devices, at lower prices than the current market leading products, the competitive success of our SYMJEPI products could be adversely affected. The competitive success of our products could also be adversely affected by changes in the willingness of insurance companies and other third-party payors to cover or reimburse some or all of the costs to consumers of our products. Our ZIMHI high dose naloxone injection product, for opioid overdose, is expected to compete with other products in the markets for opioid overdose. If we successfully develop and obtain regulatory approval of our Tempol product candidate for the treatment of COVID-19, such product would compete with a variety of COVID-related therapeutic products in the marketplace that are intended to address the approved indications.

Intellectual Property

Our success will depend in part on our ability to:

- obtain and maintain international and domestic patents and other legal protections for the proprietary technology, inventions and improvements we consider important to our business;
- prosecute and defend our patents;
- preserve our trade secrets; and
- operate without infringing on the patents and proprietary rights of other parties.

We intend to continue to seek appropriate patent protection for product candidates in our research and development programs where applicable and their uses by filing patent applications in the United States and other selected countries. We intend for these patent applications to cover, where possible, claims for composition of matter, medical uses, processes for preparation and formulations. As of December 31, 2021, the company had: (i) 27 issued patents in the United States and 10 pending United States patent applications, one of which has been allowed; (ii) 91 issued and 42 pending foreign patent applications, two of which have been allowed, relating to our Symject™ injection device, DPI and C31G products and product candidates, among other things. The issued patents and allowed patents applications are expected to expire between 2022 and 2041, not taking into account any potential patent-term extensions that may be available in the future.

In addition, we have licensed certain rights under certain patents, patent applications and related know-how of the Licensor relating to Tempol pursuant to our license agreement with the Licensor. The exclusive license includes the worldwide use under the licensed patent rights and related rights of Licensor for Tempol for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection, as well as the exclusive license includes the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer.

Although we believe that our rights under patents and patent applications provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes, and may not be able to obtain patents from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. It is possible that any patents or patent rights that we obtain or license may be circumvented, challenged or invalidated by our competitors.

We also rely on trade secrets, proprietary know-how and continuing innovation to develop and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. We seek protection of these trade secrets, proprietary know-how and any continuing innovation, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide meaningful protection for, or adequate remedies to protect, our technology in the event of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

Government Regulation

The marketing of pharmaceutical products in the United States is subject to extensive government regulation. Likewise, if we seek to market and distribute any such products abroad, they would also be subject to extensive foreign government regulation.

In the United States, the FDA regulates pharmaceutical products. FDA regulations govern the testing, manufacturing, marketing, advertising, promotion, labeling, sale and distribution of pharmaceutical products, and generally require a rigorous process for the approval of new drugs. We also may be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are tested or marketed abroad. The approval process outside the United States varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

Regulation in the United States

Seeking and obtaining FDA approval to market a drug requires substantial time, effort and money. Our product candidates that require marketing approval by the FDA will be regulated as drugs. In the United States, drugs are subject to regulation under the FDCA. The statute and related regulations govern, among other things, testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and other promotional practices. The FDA approval process for new drugs generally includes, without limitation:

- preclinical studies;
- submission of an Investigational New Drug application, or IND, for clinical trials;
- adequate and well-controlled human clinical trials to establish safety and efficacy of the product;
- review of a New Drug Application, or NDA; and
- inspection of the facilities used in the manufacturing of the drug to assess compliance with the FDA's current Good Manufacturing Practices, or cGMP, regulations.

Failure to comply with FDA and other governmental regulations at any time during the product development process, approval process, or after approval can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs injunctions and criminal prosecution. Any of these actions could have a material adverse effect on us.

Preclinical Trials

Preclinical studies include laboratory evaluation of the product, as well as animal studies to assess the potential safety and effectiveness of the product. Most of these studies must be performed according to FDA's Good Laboratory Practice, or GLP, requirements, a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results. The results of the preclinical studies and existing clinical and/or human use data (if applicable), together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which we are required to file before we can commence any clinical trials for our product candidates in the United States. Clinical trials may begin 30 days after an IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, an IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. We cannot assure you that submission of any additional IND for any of our preclinical product candidates will result in authorization to commence clinical trials.

Human Clinical Trials under an IND

Clinical trials involve the administration of the product candidate that is the subject of the trial to volunteers or patients under the supervision of a qualified principal investigator. Each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at each institution at which the study will be conducted. The IRB will consider, among other things, ethical factors, safety of human subjects and the possible liability of the institution arising from the conduct of the proposed clinical trial. Also, clinical trials must be performed according to standards, commonly referred to as Good Clinical Practice, or GCP, requirements, which are enumerated in FDA regulations and guidance documents.

Clinical trials typically are conducted in sequential phases: Phases 1, 2 and 3. The phases may overlap. The FDA may require that we suspend clinical trials at any time on various grounds, including if the FDA makes a finding that the subjects participating in the trial are being exposed to an unacceptable health risk. In Phase 1 clinical trials, a drug is usually tested on a limited number of healthy subjects to determine safety, existence of adverse effects, proper dosage, absorption, metabolism, distribution, excretion and other drug effects. In Phase 2 clinical trials, a drug is usually tested on a limited patient population to preliminarily evaluate the efficacy of the drug for specific, targeted indications, determine dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks. In Phase 3 clinical trials, a drug is usually tested on a larger patient population to determine efficacy and to further determine safety, usually at multiple clinical sites. We cannot assure you that any of our current or future clinical trials will result in approval to market additional products.

U.S. Review and Approval Processes

An NDA must include comprehensive and complete descriptions of the preclinical testing, clinical trials and the chemical, manufacturing and control requirements of a drug that enable the FDA to determine the drug's or biologic's safety and efficacy. An NDA must be accompanied by payment of a user fee unless a waiver or exemption applies, and must be submitted, filed and approved by the FDA before any drug product that we may successfully develop and that requires marketing approval by the FDA can be marketed commercially in the United States.

Once the FDA receives an NDA, it has 60 days to review the application to determine if it is substantially complete and the data is readable, before it accepts the NDA for filing. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. Once the submission is accepted for filing, the FDA begins an in-depth review of the submission to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA agrees to specific goals for NDA review time through a two-tiered classification system, Priority Review and Standard Review. A Priority Review designation is given to drugs that are intended to treat serious conditions, and would provide a significant improvement in safety and effectiveness if approved. For a Priority Review

application, the FDA aims to complete the initial review cycle for New Molecular Entities, or NMEs, within six months of the 60 day filing date, and for non-NMEs within six months of the date of receipt. Standard Review applies to all applications that are not eligible for Priority Review. The FDA aims to complete Standard Review NDAs for NMEs within ten months of the 60 day filing date, and for non-NMEs within ten months of the date of receipt. Such dates are often referred to as the PDUFA dates. The FDA does not always meet its PDUFA dates for either Standard Reviews or Priority Reviews of NDAs. The review process and the PDUFA date may be extended by three months if the FDA requests or the sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA date. In addition, the FDA's review processes can extend beyond, and in some cases significantly beyond, anticipated completion dates due to FDA requests for additional information or clarification, issuance of a complete response letter, difficulties scheduling an advisory committee meeting, negotiations regarding any required risk evaluation and mitigation strategies, FDA workload issues or other reasons.

The FDA also has established programs to expedite the development and review of drugs intended to treat serious conditions. For example, the fast track designation is designed to facilitate the development, and expedite the review, of drugs that are intended to treat serious or life-threatening conditions and address an unmet medical need. The FDA generally attempts to facilitate early and frequent meetings with sponsors of fast track drugs. The breakthrough therapy designation is granted to drugs intended to treat a serious or life-threatening condition where preliminary clinical evidence indicates the drug may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies. In addition to early and frequent meetings between the sponsor and FDA, benefits of breakthrough designation include intensive guidance on efficient drug development from FDA, as well as organizational commitment from FDA. Finally, accelerated approval may be granted for a drug that treats a serious or life-threatening condition and provides a meaningful therapeutic advantage over available treatments, and the drug demonstrates an effect on a surrogate endpoint reasonably likely to predict a clinical benefit or a clinical endpoint other than irreversible morbidity or mortality.

The amount of time taken for the approval process is a function of a number of variables, including whether the product has received priority review or has received another expedited program designation, the quality of the submission and studies presented, the potential contribution that the compound will make in improving the treatment of the disease in question, and the workload at the FDA. The FDA may, during its review of an NDA, ask for additional test data or the conducting of additional clinical trials.

Prior to regulatory approval, the FDA may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under FDA review. These outside experts are convened through the FDA's Advisory Committee process. An Advisory Committee will report to the FDA and make recommendations. Views of the Advisory Committee may differ from those of the FDA, and the FDA is not bound by the recommendations of an Advisory Committee.

Before approving an NDA, the FDA generally will inspect the facilities at which the product is manufactured. The FDA will not approve the NDA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The facilities, procedures and operations for any of our contract manufacturers must be determined to be adequate by the FDA before product approval. Foreign manufacturing facilities are also subject to periodic FDA inspections or inspections by foreign regulatory authorities. Vendors that may supply us with finished products or components used to manufacture, package and label products are also subject to similar regulations and periodic inspections. Among other things, the FDA may withhold approval of NDAs or other product applications if deficiencies are found at any of these facilities.

Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical studies were conducted in compliance with GCP requirements. If the FDA determines that the processes and procedures used are not acceptable, it will outline the deficiencies in the submission and often will request additional clinical testing or information before an NDA can be approved. The FDA may also inspect one or more of the preclinical toxicology research sites to assure that the preclinical studies were conducted in compliance with GLP requirements. If the FDA determines that the studies were not performed in compliance with applicable GLP rules and regulations, the FDA may request additional preclinical testing or information before an NDA can be approved.

The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter describes the specific deficiencies in the submission identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or more significant, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. The FDA also may impose restrictions on the use of the product, which may be difficult and expensive to administer. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. Moreover, the FDA may require prior approval of promotional materials. As a condition of approval, the FDA may require an applicant to develop a risk evaluation and mitigation strategy, or REMS. A REMS uses risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professional, and elements to assure safe use.

In addition, the FDA may require post marketing studies, sometimes referred to as Phase 4 testing, which involves clinical trials designed to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, certain changes to the approved drug or biologic, such as adding new indications, manufacturing changes or additional labeling claims, are subject to further FDA review and approval. Depending on the nature of the change proposed, an NDA supplement must be filed and approved before the change may be implemented. For many proposed post-approval changes to an NDA, the FDA review period can be lengthy and is often significantly extended by FDA requests for additional information or clarification.

Post-approval requirements

Following receipt of regulatory approval, any products that we market continue to be subject to extensive regulation including, among other things, record-keeping requirements; reporting of adverse experiences with the product; providing the FDA with updated safety and efficacy information; product storage, sampling and distribution requirements; complying with certain electronic records and signature requirements; and complying with FDA promotion and advertising requirements, which include, among others, restrictions on direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the product's approved labeling, known as "off-label" use, and requirements relating to industry-sponsored scientific and educational activities and promotional activities involving the internet. These regulations impact many aspects of our operations, including the manufacture, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping related to the products. The FDA also frequently requires post-marketing testing and surveillance to monitor the effects of approved products or places conditions on any approvals that could restrict the commercial applications of these products. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, disgorgement of money, civil injunctions, operating restrictions and criminal prosecution.

In addition, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning record keeping and control procedures. Any failure to comply with the regulations may result in significant criminal and civil penalties as well as damage to our credibility in the marketplace.

The FDA closely regulates the post-approval marketing and promotion of drugs, including through standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are not unusual across certain medical specialties and may constitute an appropriate treatment for many patients in varied circumstances. Federal regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Federal regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to delay its approval, and could result in other consequences such as recalls, fines, disgorgement of money, operating restrictions, injunctions, civil or criminal prosecution or penalties, or other possible legal or regulatory actions, such as warning letters, seizure of product, mandated corrective advertising or communications with healthcare professionals, or criminal penalties or other negative consequences, including adverse publicity. Any of these consequences could harm our business.

We will rely, and expect to continue to rely, on third-parties for the production of clinical and commercial quantities of our products. Our collaborators may also utilize third-parties for some or all of a product we are developing with such collaborator. Manufacturers are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Emergency Use Authorization

The Emergency Use Authorization, or EUA, authority allows the FDA to temporarily authorize emergency use of unapproved drugs, biologics and medical devices, or approved drugs, biologics and medical devices for unapproved uses. FDA may authorize emergency use of products when the Secretary of Health and Human Services has made a declaration that the circumstances justifying emergency use exist, which itself may be made on the basis of a determination regarding a domestic emergency, military emergency, or public health emergency made by the Secretary of Homeland Security, Secretary of Defense, or the Secretary of Health and Human Services, respectively, or on the basis of the identification of a material threat under the Public Health Service Act. Such emergencies and threats generally are determined to exist on the basis of a chemical, biological, radiological, or nuclear, or CBRN, agent or agents, or a disease or condition that may be attributable to such agent or agents.

An EUA authorized medical product may be used to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a CBRN agent. The FDA may issue an EUA if it determines that (i) a product may be effective in diagnosing, treating, or preventing a disease or condition, (ii) the known and potential benefits of a product outweigh the known and potential risks of the product, (iii) there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition, and if other regulatory criteria are met. An EUA request must be submitted by the product sponsor and generally includes a summary of the available scientific evidence regarding the product's safety and effectiveness, risks (including an adverse event profile) and benefits, and any available, approved alternatives to the product. Also included are manufacturing information and fact sheets that convey important information about the product. Even if a product is authorized for emergency use, the FDA may revoke an EUA if it determines that circumstances justifying emergency use no longer exist, the criteria for authorization are no longer met, or other circumstances justify revocation of the authorization. There are no assurances that, if we seek an EUA for any of our products, any EUAs will be granted or approved for any of our products.

Section 505(b)(2) New Drug Applications

New drug products may obtain FDA marketing approval pursuant to a Section 505(b)(1) NDA filing or a 505(b)(2) NDA filing. Whereas a 505(b)(1) NDA requires that the applicant must support its application with its own information or information to which it has a right of reference, a Section 505(b)(2) NDA enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. 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 upon the FDA's findings with respect to certain pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or provide other data to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

In seeking approval for a drug through an NDA, applicants are required to submit to the FDA information about each patent that claims the applicant's drug or a method of using the drug, and for which a claim of patent infringement reasonably could be asserted. Upon approval of a drug, information about each of those patents is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

To the extent that a Section 505(b)(2) NDA relies on published literature relating to a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, where the underlying studies were not conducted by or for the applicant and the applicant lacks a right of reference or use to the underlying data, the Section 505(b)(2) applicant must submit in its Section 505(b)(2) application a patent certification or statement with respect to any patents that are subject to the Orange Book listing requirement in connection with the previously approved product on which the applicant's application relies. Specifically, the applicant must certify for each such patent that, in relevant part, (1) the required patent information has not been filed; (2) the patent has expired; (3) the patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. Alternatively, with respect to a method of use patent, the applicant may submit a statement that the patent does not claim a use for which the applicant is seeking approval. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge the listed patents through a Paragraph IV certification or submit a statement that a method of use patent does not claim a use for which the applicant is seeking approval, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents for the previously approved product have expired. Further, the FDA will also not approve a Section 505(b)(2) NDA until any applicable non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three-year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the referenced product, has expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the FDA sends the Section 505(b)(2) NDA applicant notice that the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, unless, before the end of the 30-month period, a court determines that the patent is invalid, unenforceable or not infringed; a court enters a settlement order or consent decree stating that the patent is invalid, unenforceable, or not infringed; the patent owner or exclusive licensee consents to approval of the Section 505(b)(2) NDA; or the court enters an order of dismissal without a finding of infringement. Even if a patent infringement claim is not brought within the 45-day period, a patent infringement claim may be brought under traditional patent law, but it does not invoke the 30-month stay. Moreover, in cases where a Section 505(b)(2) application containing a Paragraph IV certification is submitted during the final year of a previously approved drug's five-year exclusivity period and the patent holder brings suit within 45 days of notice of certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30 month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation.

As a result, we may invest a significant amount of time and expense in the development of a product and our Section 505(b)(2) applications only to be subject to significant delay and patent litigation before our product may be commercialized. Alternatively, if the prior NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45-day period, the FDA may approve the Section 505(b)(2) application at any time, assuming the application is otherwise approvable.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last several years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

We successfully pursued a Section 505(b)(2) regulatory pathway for our SYMJEPI (epinephrine) Injection 0.3 mg product and our lower dose 0.15 mg version; as well as our ZIMHI naloxone injection product; and we may pursue Section 505(b)(2) applications in connection with other product candidates as appropriate, if successfully developed. Accordingly, if we rely in our section 505(b)(2) application on published literature or the FDA's prior findings of safety and effectiveness for a previously approved drug product for which patents are listed in the Orange Book, and if the underlying studies were not conducted by or for us and we lack a right of reference or use to the underlying data, then we will need to submit an appropriate patent certification or statement for each such patent as described above. If we make a Paragraph IV certification and the holder of the previously approved product that we referenced in our application initiates patent litigation within the time periods described above, then we will be subject to the risks of patent litigation, with the accompanying delay described above and potentially material expense of patent litigation, before we could commercially market our product.

In addition, even if we submit a Section 505(b)(2) application that relies on published literature or the FDA's prior findings of safety and effectiveness for a previously approved product where there are no patents for such other product with respect to which we have to provide a patent certification or statement, we are subject to the risk that the FDA could disagree with our reliance on the particular previously approved product that we chose to rely on, conclude that such previously approved product is not an acceptable reference product, and require us instead to reference another previously approved product for which patents are listed in the Orange Book, requiring us to make an appropriate patent certification or statement as described above and subjecting us to the risks of delay and expense described above.

Abbreviated New Drug Applications

In contrast to the kind of clinical trial and other data that is required for an NDA submitted pursuant to Section 505(b)(1) or Section 505(b)(2) of the FDCA, an Abbreviated New Drug Application, or ANDA, contains data that, when submitted to the FDA pursuant to Section 505(j) of the FDCA, provides for the review and ultimate approval of a product commonly referred to as a "generic equivalent" or a "generic" drug product. These kinds of drug applications are called "abbreviated" because ANDA applicants are generally not required to conduct or submit preclinical (animal) and clinical (human) data to establish safety and effectiveness of their product, other than the requirement for bioequivalence testing. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent, that is, that the product performs in the same manner as the listed drug. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug, among other requirements. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

In seeking approval for a new drug through an NDA, applicants are required to submit to the FDA information about each patent that claims the applicant's drug or a method of using the drug. Upon approval of a drug, information about each of those patents is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be referenced by potential competitors in support of approval of an ANDA. The ANDA applicant is required to submit to the FDA an appropriate certification or statement concerning any patents listed for the approved product in the FDA's Orange Book, in a manner generally similar to the certification or statement that is required in connection with Section 505(b)(2) applications as described above. As with Section 505(b)(2) applications, if the applicant does not challenge the listed patents and has not submitted a statement that a method of use patent does not claim a use for which the applicant is seeking approval, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, then the procedures described above in connection with Section 505(b)(2) applications also apply, and the risks of the patent holder initiating a patent infringement lawsuit as described above also apply. The ANDA application also will not be approved until any applicable non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing a new chemical entity, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV certification to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that does not contain a new chemical entity, but is approved, for example, in a new dosage form, route of administration or combination, or for a new use, the approval of which was supported by new clinical trials (other than bioavailability studies) that were conducted or sponsored by the applicant and were essential to approval of the application, during which FDA cannot grant effective approval of an ANDA referencing that listed drug for the conditions of approval supported by the new clinical trials.

Regulation Outside the United States

If we market our products in foreign countries, we also will be subject to foreign regulatory requirements governing human clinical trials, marketing approval, and commercial sales and distribution for pharmaceutical products. The requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for such approvals may differ substantially from that required for FDA approval. There is no assurance that any future FDA approval of any of our clinical trials or drugs will result in similar foreign approvals or vice versa.

Additional Regulation

Third-Party Reimbursement

In the United States, physicians, hospitals and other healthcare providers that purchase pharmaceutical products generally rely on third-party payors, principally private health insurance plans, Medicare, or Medicaid, to reimburse the cost of the product and related procedure, with varying degrees of patient cost sharing. Even if a product is approved for marketing by the FDA, there is no assurance that third-party payors will cover the cost of the product and related medical procedures. If they do not, end-users of the product generally would not be eligible for any reimbursement of the cost, and our ability to successfully market any such product would be materially and adversely impacted. The level of reimbursement also varies significantly by payor and setting of care, and inadequate reimbursement also could materially and adversely impact our ability to successfully market our products.

Reimbursement systems vary significantly by country and, within some countries, by region, and coverage and reimbursement for our products must be obtained on a country-by-country basis. In many foreign markets, the pricing of prescription pharmaceuticals is subject to government pricing control or other mechanisms, including health technology assessments, mandatory rebates, and reference pricing. In these markets, once marketing approval is received, establishing coverage and reimbursement could take significant additional time. The lack of satisfactory reimbursement or inadequate government pricing of any of our products would limit their widespread use and lower potential product revenues.

Fraud and Abuse Laws and Reporting Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws may restrict certain research and marketing practices in the pharmaceutical industry. These laws include federal and state anti-kickback and false claims laws. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service reimbursable under a federal healthcare program, or purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under a federal healthcare program. The Anti-Kickback Statute has been interpreted to apply to various arrangements between pharmaceutical manufacturers and prescribers, purchasers, formulary managers and other entities, including arrangements where any one purpose of the remuneration was a prohibited inducement under the Statute even if the primary purpose was compensation of legitimate services. Violations of the Anti-Kickback Statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Regulations finalized by the Department of Health and Human Services have amended existing safe harbors or added new safe harbors, and certain of these regulations are subject to ongoing review. Additionally, if a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug Improvement and Modernization Act of 2003, as amended, and other federal laws. Compliance with these fraud and abuse and reporting requirements requires significant resources. We could be required to devote significant additional financial resources and management attention if we ever become the focus of an investigation for failure to comply with these requirements.

The federal civil False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, including any claim submitted in violation of fraud and abuse and reporting requirements, or knowingly making, or causing to be made, a false statement to have a false claim paid. Claims that include items or services resulting from a violation of the Anti-Kickback Statute can constitute false or fraudulent claims under the False Claims Act. In addition, certain marketing practices, including off-label promotion, may violate the False Claims Act. Actions under the civil False Claims Act may be brought by the Attorney General or by a private individual acting as an informer or whistleblower in the name of the government, and violations can result in significant monetary penalties. The federal government has used the civil False Claims Act, and the threat of significant liability, in its investigations of healthcare providers, suppliers and drug and device manufacturers throughout the country for a wide variety of drug and device marketing and research practices, and has obtained large settlements. Numerous pharmaceutical and other healthcare companies have been pursued under this law, including for allegedly inflating drug prices used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. There is also a criminal False Claims Act, which prohibits making or presenting any false, fictitious or fraudulent claims to the government and authorizes penalties including imprisonment and fines for individuals and organizations. Many states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment. Federal and state authorities may continue to devote substantial resources toward investigating healthcare providers', suppliers' and drug and device manufacturers' compliance with these and other fraud and abuse and reporting requirements.

HIPAA

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, addresses the privacy, security, and transmission of individually identifiable health information and, among other things, requires the use of standard transactions, imposes privacy and security standards and requires breach notification, by covered entities, which include many healthcare providers, health plans and healthcare clearinghouses. HITECH makes HIPAA's privacy and security standards directly applicable to business associates, such as 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. Material monetary penalties and other remedies can result from violation of these laws and regulations. In addition, many state laws also address the privacy and security of health information, and many of these laws differ from each other in significant ways, thus complicating compliance efforts. In addition, the European Union, or EU, has a separate data security and privacy legal framework, including the European General Data Protection Regulation, or GDPR, which was adopted in 2018, which contains new provisions specifically directed at the processing of health information. To the extent that we conduct clinical trials in the EU or otherwise expand our business operations to include operations in the EU, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.

Healthcare Reform

The Patient Protection and Affordable Care Act, or ACA, enacted in 2010, was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. The law thus included changes that significantly impact the pharmaceutical industry. The Physician Payments Sunshine Act, which is part of the ACA, and its implementing regulations impose federal reporting and disclosure requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to covered recipients, including physicians, teaching hospitals, advanced-practice nurses and physician assistants. In addition, pharmaceutical and device manufacturers also are required to report certain investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties.

The ACA also established: an annual nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increased the rebates that a manufacturer must pay under the Medicaid Drug Rebate Program. In December 2017, portions of the ACA dealing with the individual mandate insurance requirement were effectively repealed by the Tax Cuts and Jobs Act of 2017, and other aspects of the ACA may be altered or repealed by future legislation. A recent court challenge to the validity of the ACA failed in June 2021, when the U.S. Supreme Court decided that the plaintiffs in the lawsuit did not have standing to challenge the constitutionality of the individual mandate provisions of the ACA. As of the date of this Report the ACA remains in effect.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, including several U.S. Congressional inquiries and proposed and enacted federal and state legislation and regulation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and patient assistance programs, reduce the cost of drugs under federal and state healthcare programs, and reform government program reimbursement methodologies for drugs. Any changes at the federal or state level to drug pricing or reimbursement policies could affect our ability to successfully commercialize approved products.

Additionally, several states require pharmaceutical companies to report information to state agencies, including information relating to drug pricing, marketing and promotion expenses, and gifts and payments to individual health care providers in the states. Other states limit or prohibit certain marketing related activities. In addition, certain states require pharmaceutical companies to implement compliance programs or marketing codes. Additional states may consider similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. If in the future some of our business activities were subject to challenge under one or more of such laws, an adverse outcome could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Other Laws

We are also subject to other federal, state and local laws of general applicability, such as laws regulating working conditions, and various federal, state and local environmental protection laws and regulations, including laws such as the Occupational Safety and Health Act, the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal and state laws regarding, among other things, occupational safety, the use and handling of radioisotopes, environmental protection and hazardous substance control. There can be no assurance that we will not be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development activities may involve the controlled use of hazardous materials, including chemicals that cause cancer, volatile solvents, radioactive materials and biological materials that have the potential to transmit disease, and our operations may produce hazardous waste. If we fail to comply with these laws and regulations, we could be subjected to criminal sanctions and substantial financial liability or be required to suspend or modify our operations. We cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources.

In addition, as an owner and operator of real property, we may also be subject to liability for environmental investigations and cleanups, including at properties currently or previously owned or operated by us, even if such contamination was not caused by us, as well as to claims for harm to health or property or for natural resource damages arising out of contamination or exposure to hazardous substances. Liability in many situations may be imposed not only without regard to fault, but may also be joint and several, so that we may be held responsible for more than our share of the contamination or other damages, or even for the entire share. We may also be subject to similar liabilities and claims in connection with locations at which hazardous substances or wastes that we have generated have been stored, treated, otherwise managed or disposed. The costs of complying with, or other impact of, current or future environmental, health and safety requirements could adversely affect our business, financial condition and results of operations.

Outsourcing Facility Regulation

Our compounding business formerly conducted by USC is subject to federal, state and local laws, regulations, and administrative practices, including, among others: requirements relating to federal registration as an outsourcing facility; state and local licensure and registration requirements concerning the operation of outsourcing facilities; HIPAA; ACA and the Health Care and Education Reconciliation Act of 2010; statutes and regulations of the FDA and the U.S. Drug Enforcement Administration, or DEA; and state laws and regulations promulgated by comparable state agencies concerning the preparation, sale, advertisement and promotion of drugs that were sold by USC. As described elsewhere in this Report, we have ceased the sale of compounding pharmaceutical formulations and are winding down the business of USC, but it is possible that issues could arise in the future relating to our previous activities or the activities of USC under such laws, which could have an adverse impact on our business. In addition, see "Legal Proceedings" elsewhere in this Report for additional matters relating to our former compounding pharmaceutical formulation business.

Employees and Human Capital Resources

As of December 31, 2021, we had 15 full-time employees, including one located outside of the United States. None of our employees is subject to a collective bargaining agreement or represented by a labor or trade union, and we believe that our relations with our employees are good.

Our human capital management goals include, as applicable, identifying, attracting, retaining, and incentivizing our employees, directors and consultants. We seek to create a safe, supportive, and rewarding work environment and to align employees' goals with our overall strategic direction. Our equity and cash compensation and incentive plans are primarily intended to attract, retain and motivate personnel through compensation and equity-based and cash-based compensation awards, with a goal of increasing the success of our company.

COVID-19. As a result of the COVID-19 pandemic, we have implemented safety protocols to mitigate the risks of infection to our employees. Our COVID-19 pandemic preparedness and response was and is a focus. Our pandemic response measures incorporate guidance issued by external health authorities and are designed with the goal of keeping workers at our facilities safe and healthy.

Corporate Background; Investor Information

Adamis Pharmaceuticals Corporation was founded in June 2006 as a Delaware corporation. Effective April 1, 2009, the company formerly named Adamis Pharmaceuticals Corporation, or Old Adamis, completed a business combination transaction with Cellegy Pharmaceuticals, Inc., or Cellegy. Before the merger, Cellegy was a public company and Old Adamis was a private company. In connection with the consummation of the merger and pursuant to the terms of the definitive merger agreement relating to the transaction, Cellegy was the surviving corporation in the merger and changed its name from Cellegy Pharmaceuticals, Inc. to Adamis Pharmaceuticals Corporation, and Old Adamis survived as a wholly-owned subsidiary and changed its corporate name to Adamis Corporation. We have three wholly-owned subsidiaries: Adamis Corporation, USC and Biosyn, Inc. On April 11, 2016, we completed the acquisition of USC, pursuant to the terms of an Agreement and Plan of Merger dated March 28, 2016. Pursuant to the terms of the merger agreement, a new-created wholly-owned subsidiary merged with and into USC, with USC surviving as a wholly owned subsidiary of the company.

Our corporate headquarters are located at 11682 El Camino Real, Suite 300, San Diego, CA 92130, and our telephone number is (858) 997-2400. Financial and other information about us is available on our website at www.adamispharmaceuticals.com. We have included our website address as a factual reference and do not intend it to be an active link to our website. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission, or SEC. In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected, without charge, at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.)

ITEM 1A. RISK FACTORS

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings in evaluating our business. Our business, financial condition, results of operations and future prospects could be materially and adversely affected by these risks if any of them actually occurs. In these circumstances, the market price of our common stock would likely decline. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business.

Risks Related to Our Financial Condition

There is substantial doubt about our ability to continue as a going concern.

Our consolidated financial statements are prepared using the generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, as shown in our consolidated financial statements for the year ended December 31, 2021, included in this Report, we have sustained substantial recurring losses from operations. In addition, we have used, rather than provided, cash in our continuing operations. The above conditions raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued. Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be unable to continue in existence. Uncertainty concerning our ability to continue as a going concern, among other factors, may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent, among other factors, on our ability to successfully develop and commercialize products, the market acceptance and success of our products and our ability to obtain additional required funding If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

We will require additional funding to continue as a going concern.

We incurred significant net losses for the years ended December 31, 2021 and December 31, 2020. The development of our business will require additional capital to help fund the development and commercialization of our products and product candidates, conduct research, development and trials relating to our product candidates, fund our ongoing operations and satisfy our obligations and liabilities. There are no assurances that required funding will be available at all or will be available in sufficient amounts or on reasonable terms. In addition to product revenues, we have historically relied upon sales of our equity or debt securities to fund our operations. We currently have no available balance in our credit facility or committed sources of capital, and a number of factors may limit or prevent our current ability to access capital markets to obtain any required funding. Delays in obtaining, or the inability to obtain, required funding from debt or equity financings, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions or sources, could adversely affect our ability to develop and commercially introduce products and cause us to be unable to comply with our obligations under outstanding instruments, and could adversely affect our ability to continue operations. In addition, our previously announced sale of assets pursuant to the USC Agreement relating to the human compounding pharmaceuticals business of our USC subsidiary, together with our previously announced process of winding down, winding up and disposing of the remaining operations, business and assets of USC, will result in the company not receiving revenues in the future from sales of products by USC, other than the consideration receivable by the company pursuant to the terms of the USC Agreement or from other agreements or arrangements relating to the sale or disposition of the remaining USC assets.

Our ability to obtain required financing will be subject to a number of factors, including without limitation market conditions, our capitalization, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, and which could result in additional dilution to our stockholders. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us.

Statements in this Report concerning our future plans and operations are dependent on our ability to secure adequate funding and the absence of unexpected delays or adverse developments. We may not be able to secure required funding.

The statements contained in this Report concerning future events or developments or our future activities, such as concerning current or planned clinical trials, anticipated research and development activities, anticipated dates for commencement of clinical trials, anticipated completion dates of clinical trials, anticipated meetings with the FDA or other regulatory authorities concerning our product candidates, anticipated dates for submissions to obtain required regulatory marketing approvals, anticipated dates for commercial introduction of products, anticipated outcome of any legal proceedings in which we are involved, and other statements concerning our future operations and activities, are forward-looking statements that in each instance assume that we have or are able to obtain sufficient funding to support such activities and continue our operations and planned activities in a timely manner. There can be no assurance that this will be the case. Also, such statements assume that there are no significant unexpected developments or events that delay or prevent such activities from occurring. Failure to timely obtain any required additional funding, or unexpected developments or events, could delay the occurrence of such events or prevent the events described in any such statements from occurring which could adversely affect our business, financial condition and results of operations.

We restated our unaudited condensed consolidated financial statements for the interim periods of 2020, which may lead to additional risks and uncertainties, including loss of investor confidence and negative impacts on our business, financial condition and stock price.

On April 14, 2021, we concluded that, because of a misapplication of valuation principles used to determine the amount of our non-cash warrant liabilities and the associated gain or loss recognized as a result of the change in the fair value of the warrant liabilities, relating to warrants that we issued in August 2019 (the "2019 Warrants") and February 2020 (the "2020 Warrants" and, together with the 2019 Warrants, the "Warrants"), our previous quarterly and year-to-date unaudited condensed consolidated financial statements for the periods ended March 31, 2020, June 30, 2020 and September 30, 2020 (the "Affected Periods"), should no longer be relied upon. As a result, we restated our unaudited condensed consolidated financial statements for the Affected Periods. The issues identified were all non-cash and did not impact our revenues, operating expenses, operating loss, cash and cash equivalents, assets, liquidity or cash position for the Affected Periods or the year ended December 31, 2020. As a result of the foregoing matters, or if we determine in the future that other financial restatements are required, we may become subject to additional risks and uncertainties, including, among others, unanticipated costs for accounting and legal fees, the increased possibility of legal proceedings, shareholder lawsuits, governmental agency investigations, and inquiries by the Nasdaq Stock Market or other regulatory bodies, which could cause investors to lose confidence in our reported financial information and could subject us to civil or criminal penalties, shareholder class actions or derivative actions. We could face monetary judgments, penalties or other sanctions that could have a material adverse effect on our business, financial condition and results of operations and could cause our stock price to decline. If any such actions occur, they will, regardless of the outcome, consume a significant amount of management's time and attention and may result in additional legal, accounting, insurance and other costs. If we do not prevail in any such proceedings, we could be required to pay substantial damages or settlement costs. In addition, any restatement or related matters could impair our reputation. Each of these occurrences could have a material adverse effect on our business, results of operations, financial condition and stock price.

We have incurred losses since our inception, and we anticipate that we will continue to incur losses. We may never achieve or sustain profitability.

We incurred significant net losses for the years ended December 31, 2021 and December 31, 2020, as reflected in the financial statements included elsewhere in this Report. We expect that these losses may continue as we continue our research and development activities, seek regulatory approvals for our product candidates and seek to commercialize any approved products. These losses will cause, among other things, our stockholders' equity and working capital to decrease. Any future earnings and cash flow from operations of our business are dependent on our ability to further develop our products and on revenue and profitability from sales of products.

There can be no assurance that we will be able to generate sufficient product revenue and amounts payable to us under our commercialization agreement relating to our SYMJEPI and ZIMHI products or other commercialization agreements that we may enter into to become profitable at all or on a sustained basis. We expect to have quarter-to-quarter fluctuations in revenue and expenses, some of which could be significant, due in part to variations in expenses and activities relating to research, development, clinical trials, marketing and manufacturing. If our product candidates fail in clinical trials or do not gain regulatory approval, or if our products do not achieve market acceptance, we may never become profitable. As we commercialize and market products, we may incur expenses for product marketing and brand awareness and conduct significant research, development, testing and regulatory compliance activities that, together with general and administrative expenses, could result in substantial operating losses for the foreseeable future. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We have received grand jury subpoenas issued in connection with a criminal investigation.

As we have previously disclosed, on May 11, 2021, each of the company and its USC subsidiary received a grand jury subpoena from the U.S. Attorney's Office for the Southern District of New York (the "USAO") issued in connection with a criminal investigation, requesting a broad range of documents and materials relating to, among other matters, certain veterinary products sold by the company's USC subsidiary, certain practices, agreements and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC. The Audit Committee of the Board engaged outside counsel to conduct an independent internal investigation to review these and other matters. Additional issues or facts could arise or be determined, which may expand the scope, duration, or outcome of the investigation. In addition to the subpoena from the USAO, the company has also received requests from the Securities and Exchange Commission ("SEC") for the voluntary production of documents and information relating to the subject matter of the USAO's subpoenas and certain other matters. The company has produced documents and will continue to produce and provide documents in response to the subpoenas and requests, and interact with the USAO and SEC concerning the foregoing matters. The company intends to cooperate with the USAO and the SEC. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, or other agencies, or determine what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate, what, if any, remedies or remedial measures the USAO, SEC, or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the company's business, previously reported financial results, financial results included in this Report, or future financial results. We could receive additional requests from the USAO, SEC, or other authorities, which may require further investigation. There can be no assurance that any discussions with the SEC or USAO to resolve these matters will be successful. The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings and depending on the resolution of the matters or any proceedings, result in fines, penalties, equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, or future financial results. The occurrence of any of these events could have a material adverse effect on the company's business, financial condition and results of operations.

Our PPP loans may be audited or reviewed by federal or state regulatory authorities.

We applied for and obtained loan funding under the PPP pursuant to the PPP Loan and PPP Note, the balance of which has been forgiven, and under the Second Draw PPP Loan and PPP2 Note in the principal amount of $1,765,495, the balance of which has also been forgiven. However, even though the PPP Loan and the Second Draw PPP Loan have been forgiven, our PPP loans and applications for forgiveness of loan amounts remain subject to future review and audit by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form, including without limitation the required economic necessity certification by the company that was part of the PPP loan application process. Accordingly, the company is subject to audit or review by federal or state regulatory authorities as a result of applying for and obtaining the PPP Loan and Second Draw PPP Loan or obtaining forgiveness of those loans. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return or repay the full amount of the applicable loan and could be subject to fines or penalties, which could reduce our liquidity and adversely affect our business, financial condition and results of operations. If it is determined that the company was ineligible to receive the PPP Loan and/or the Second Draw Loan, the company may be required to repay the PPP Loan and Second Draw Loan in its entirety and/or be subject to additional penalties, which could reduce our liquidity and adversely affect our business, financial condition and results of operations.

Risk Relating to Our Business and Industry

We may never commercialize additional product candidates that are subject to regulatory approval or earn a profit.

Except for our SYMJEPI and ZIMHI products, we have not received regulatory approval for any drugs or products. Since our fiscal 2010 year, except for revenues from sales of compounded pharmacy formulations after our acquisition of USC in 2016 and amounts that we have received and may receive in the future pursuant to our commercialization agreements relating to our SYMJEPI and ZIMHI products, we have not generated commercial revenue from marketing or selling any drugs or other products. We expect to incur substantial net losses for the foreseeable future. We may never be able to commercialize any additional product candidates that are subject to regulatory approval or be able to generate revenue from sales of such products. Because of the risks and uncertainties associated with developing and commercializing our specialty pharmaceuticals and other product candidates, we are unable to predict when we may commercially introduce such products, the extent of any future losses or when we will become profitable, if ever.

Our development plans concerning our products and product candidates are affected by many factors, the outcome of which are difficult to predict.

The development of new pharmaceutical products is a highly risky undertaking. Our potential products may require significant additional research and development before any commercial introduction. Our product development plans concerning our products and product candidates, and the anticipated dates for development and introduction of products in our product pipeline, are affected by many factors, many of which are difficult to predict. Some of the factors that could affect our development plans for our products and product candidates include: general market conditions and developments in the marketplace including the introduction of potentially competing new products by our competitors; the availability of adequate funding to support product development efforts and sales and marketing efforts for approved products; the outcome of discussions with the FDA concerning the regulatory pathway for our products and the number and kind of clinical trials that the FDA will require before the FDA will consider regulatory approval of the applicable product; the time required to conduct required clinical trials and unexpected delays in the anticipated timing of the commencement, conduct or completion of clinical trials; the outcome and results of clinical trials; the FDA's review and acceptance of NDAs that we may file concerning our product candidates; any unexpected difficulties in licensing or sublicensing intellectual property rights that may be required for other components of the product; patent infringement lawsuits relating to Paragraph IV certifications as part of any Section 505(b)(2) or ANDA filings; any unexpected difficulties in the ability of our suppliers to timely supply quantities for commercial launch of the product; and our ability to successfully market and sell our products or enter into commercialization arrangements with third parties to market our products. There can be no assurance that any future research, development or clinical trial efforts will result in viable products or meet efficacy standards. Future clinical or preclinical results may be negative or insufficient to allow us to successfully develop and market our product candidates. Obtaining needed data and results may take longer than planned or may not be obtained at all. Any such delays or setbacks could have a material adverse effect on our ability to achieve our financial goals.

Business or economic disruptions or global health concerns, including the COVID-19 pandemic, could harm our business.

Business or economic disruptions or global health concerns, such as the COVID-19 pandemic, could adversely affect our business. The novel strain of coronavirus and the related COVID-19 pandemic, which the World Health Organization announced in January 2020 was a global health emergency and which has continued, has spread throughout most of the world including the United States. The outbreak resulted in extended shutdowns of businesses in the United States and elsewhere and has had ripple effects on businesses and activities around the world.

The COVID-19 outbreak and continued spread of COVID-19, including the identification of novel strains of COVID-19, has affected and may continue to affect our operations, our customers and third parties on which we rely. Restrictions on outpatient surgeries and other medical procedures due to the COVID-19 pandemic, in part due to reductions or cancellations of elective surgeries and reductions in office visits to physicians' offices, healthcare facilities or clinics by patients, decreased demand from USC's customers for certain of USC's products and adversely affected revenues from sales of USC products in 2020 and 2021, and may continue to adversely affect revenues from sales of products to customers covered by the USC Agreement. In addition, we could experience delays in obtaining products or services from our third party manufacturers or suppliers as a result of the impact of the COVID-19 pandemic on such parties. The pandemic and related matters also could result in interruptions or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines relating to our NDAs or other actions relating to our products or product candidates, or could result in delays relating to patient enrollment or the conduct of clinical trials that we undertake. The outbreak and any preventative or protective actions that we, our customers, our respective manufacturers, suppliers or other third parties with which we have business relationships, or governments may take in respect of the coronavirus and COVID-19 pandemic could disrupt our business and the business of our customers or third parties with which we have business relationships. The extent to which the COVID-19 pandemic will continue to impact our business is difficult to predict and subject to change, and will depend on future developments, which are highly uncertain and cannot be predicted, including without limitation the severity of the disease and duration of the outbreak, travel restrictions and social distancing requirements in the United States and other countries, future mutations and variations of the coronavirus, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and address its impact. In addition, a severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all.

A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making purchases or payments for our products. Any of the foregoing could harm our business. In addition, the COVID-19 pandemic has resulted in significant governmental measures being implemented to control the spread of the virus, including, at various times, quarantines, shelter-in-place or work-from-home orders or policies, travel restrictions, social distancing and business shutdowns. The effects of such measures could negatively impact productivity of our employees and disrupt our business activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and our ability to conduct business in the ordinary course. Although we have taken precautions intended to avoid the spread of the coronavirus among our employees, our operations could be adversely affected by outbreaks of COVID-19 among our employees. If we, our customers, or any of the third parties with whom we engage, including the suppliers, manufacturers, regulators and other third parties with whom we conduct business or have business relationships, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner presently anticipated could be materially and negatively impacted.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain, or may experience delays in obtaining, regulatory approval, or may not be successful in commercializing our planned and future products.

Like many companies our size, we do not have the ability to conduct preclinical or clinical studies for our product candidates without the assistance of third parties who conduct the studies on our behalf. These third parties are often toxicology facilities and clinical research organizations, or CROs, that have significant resources and experience in the conduct of pre-clinical and clinical studies. The toxicology facilities conduct the pre-clinical safety studies as well as associated tasks connected with these studies. The CROs typically perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. We have relied on and intend to rely on third parties to conduct clinical trials of our product candidates and to use third party toxicology facilities and CROs for our pre-clinical and clinical studies. We may also rely on academic institutions or clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our products.

Our reliance on these third parties for development activities will reduce our control over these activities. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, we may be required to replace them, and our clinical trials may be extended, delayed or terminated. Although we believe there are a number of third-party contractors that we could engage to continue these activities, replacing a third-party contractor may result in a delay of the affected trial.

If there are injuries or deaths associated with use of our products, or if there is a product recall affecting one or more of our products, we may be exposed to significant liabilities.

The production, manufacturing, labeling of pharmaceutical products and compounded pharmaceutical preparations is inherently risky. We could be adversely affected if any of our products, or the formulations or other products previously sold by USC, prove to be, or are asserted to be, harmful to patients. There are a number of factors that could result in the injury or death of a patient who receives one of our products or one of the compounded formulations previously sold by USC, including quality issues, manufacturing or labeling flaws, improper packaging or unanticipated or improper uses of the products, any of which could result from human or other error. Any of these situations could lead to a recall of, safety alert, or other proceedings or actions, relating to one or more of such products. On March 21, 2022, we announced a voluntary recall of four lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes, due to the potential clogging of the needle preventing the dispensing of epinephrine. As of the date of this Report, neither USWM nor we have received, or is aware of, any adverse events related to this recall. However, if adverse events or deaths or a product recall, either voluntarily or as required by the FDA or a state board of pharmacy, were associated with our products, or one of the formulations or compounds previously sold by USC, we could become subject to product and professional liability lawsuits or other proceedings, including enforcement actions by state and federal authorities or other healthcare self-regulatory bodies or product liability claims or lawsuits. In addition, such matters could result in indemnification claims by third parties or claims relating to the product recall or associated expenses, including third parties that have purchased our SYMJEPI products or that may purchase our ZIMHI product, or to which we have sold certain assets of USC, including claims pursuant to our agreements with third parties. Any of the foregoing matters could result in a material adverse effect on our business, results of operations, financial condition and liquidity. Our consolidated financial statements for the year ended December 31, 2021, included elsewhere in this Report, include and reflect a reserve of approximately $2.0 million associated with the SYMJEPI recall. The recall may have an adverse effect on the amount or the timing of our revenues, and on our financial results and liquidity, for fiscal quarters in 2022 or thereafter, although as of the date of this Report the amount of any such impact cannot be predicted with certainty. In addition, current or future insurance coverage may prove insufficient to cover any liability claims brought against USC or us.

Delays in the commencement or completion of clinical testing of our product candidates could result in increased costs and delay our ability to generate significant revenues.

The actual timing of commencement and completion of clinical trials can vary substantially from our anticipated timing due to factors such as funding limitations, scheduling conflicts with participating clinicians and clinical institutions, and the rate of patient enrollment. Clinical trials involving our product candidates may not commence or be completed as forecast. Delays in the commencement or completion of clinical testing could significantly impact our product development costs. We do not know whether current or planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining required funding;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- obtaining sufficient quantities of clinical trial materials for product candidates;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting participants for a clinical trial; and
- delays related to the impact of the COVID-19 pandemic.

In addition, once a clinical trial has begun, it may be suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- failure to achieve certain efficacy and/or safety standards; or
- lack of adequate funding to continue the clinical trial.

Clinical trials require sufficient participant enrollment, which is a function of many factors, including the size of the target patient population, the nature of the trial protocol, the proximity of participants to clinical trial sites, the availability of effective treatments for the relevant disease, the eligibility criteria for our clinical trials and competing trials. Delays in enrollment can result in increased costs and longer development times. Our failure to enroll participants in our clinical trials could delay the completion of the clinical trials beyond current expectations. In addition, the FDA could require us to conduct clinical trials with a larger number of participants than we may project for any of our product candidates. As a result of these factors, we may not be able to enroll a sufficient number of participants in a timely or cost-effective manner.

Furthermore, enrolled participants may drop out of clinical trials, which could impair the validity or statistical significance of the clinical trials. A number of factors can influence the discontinuation rate, including, but not limited to: the inclusion of a placebo in a trial; possible lack of effect of the product candidate being tested at one or more of the dose levels being tested; adverse side effects experienced, whether or not related to the product candidate; and the availability of numerous alternative treatment options that may induce participants to withdraw from the trial.

We may be required to suspend, repeat or terminate our clinical trials if the trials are not well designed, do not meet regulatory requirements or the results are negative or inconclusive, which may result in significant negative repercussions on business and financial condition.

Before regulatory approval for a potential product can be obtained, we must undertake clinical testing on humans to demonstrate the tolerability and efficacy of the product. We cannot assure you that we will obtain authorization to permit product candidates that are in the preclinical development phase to enter the human clinical testing phase. In addition, we cannot assure you that any authorized preclinical or clinical testing will be completed successfully within any specified time period by us, or without significant additional resources or expertise to those originally expected to be necessary. We cannot assure you that such testing will show potential products to be safe and efficacious or that any such product will be approved for a specific indication. Further, the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials. In addition, we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks.

We are subject to the risk of clinical trial and product liability lawsuits.

The testing of human health care product candidates entails an inherent risk of allegations of clinical trial liability, while the marketing and sale of approved products entails an inherent risk of allegations of product liability and associated adverse publicity. We currently maintain liability insurance. However, such insurance policies are expensive, may not provide sufficient coverage, and may not be available in the future on acceptable terms, or at all. As we conduct additional clinical trials and introduce products into the United States market, the risk of adverse events increases and our requirements for liability insurance coverage are likely to increase. We are subject to the risk that substantial liability claims from the testing or marketing of pharmaceutical products could be asserted against us in the future. There can be no assurance that we will be able to obtain or maintain insurance on acceptable terms, particularly in overseas locations, for clinical and commercial activities or that any insurance obtained will provide adequate protection against potential liabilities. An inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could inhibit our business.

Moreover, our current and future coverages may not be adequate to protect us from all of the liabilities that we may incur. If losses from liability claims exceed our insurance coverage, we may incur substantial liabilities that exceed our financial resources. In addition, a product or clinical trial liability action against us would be expensive and time-consuming to defend, even if we ultimately prevailed. If we are required to pay a claim, we may not have sufficient financial resources and our business and results of operations may be harmed. A product liability claim brought against us in excess of our insurance coverage, if any, could have a material adverse effect upon our business, financial condition and results of operations.

We do not have commercial-scale manufacturing capability, and we lack commercial manufacturing experience. We will likely rely on third parties to manufacture and supply our product candidates for which we will be seeking FDA approval.

Except for our facilities at USC that were previously utilized to prepare compounded formulations, we do not own or operate manufacturing facilities for clinical or commercial production of pharmaceutical products and product candidates, we do not have any experience in drug formulation or manufacturing, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. Accordingly, we expect to depend on third-party contract manufacturers for the foreseeable future. Any performance failure on the part of our contract manufacturers could delay clinical development, regulatory approval or commercialization of our current or future product candidates, depriving us of potential product revenue and resulting in additional losses. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our existing and potential products. Any business interruptions resulting from geopolitical actions, including war and terrorism, adverse public health developments such as the outbreak of the COVID-19 coronavirus, or natural disasters including earthquakes, typhoons, floods and fires, could adversely affect our supply chain. These risks and uncertainties are compounded in the presence of the COVID-19 pandemic. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our manufacturers or suppliers could delay shipment of any of our products, increase our cost of goods sold and result in lost sales.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production.

These problems can include difficulties with production costs and yields, quality control (including stability of the product candidate and quality assurance testing), shortages of qualified personnel, and compliance with strictly enforced federal, state and foreign regulations. If our third-party contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations or under applicable regulations, our ability to provide product candidates to patients in our clinical trials or commercially would be jeopardized. If we file an application for marketing approval of the product and the FDA grants marketing approval, any delay or interruption in the supply of product could delay the commercial launch of the product or impair our ability to meet demand for the product. Difficulties in supplying products for clinical trials could increase the costs associated with our clinical trial programs and, depending upon the period of delay, require us to commence new trials or qualify new manufacturers at significant additional expense, possibly causing commercial delays or termination of the trials.

Our products can only be manufactured in a facility that has undergone a satisfactory inspection by the FDA and other relevant regulatory authorities. For these reasons, we may not be able to replace manufacturing capacity for our products quickly if we or our contract manufacturer(s) were unable to use manufacturing facilities as a result of a fire, natural disaster (including an earthquake), equipment failure, or other difficulty, or if such facilities were deemed not in compliance with the regulatory requirements and such non-compliance could not be rapidly rectified. An inability or reduced capacity to manufacture our products could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to substantial government regulation, which could materially adversely affect our business. If we do not receive regulatory approvals, we may not be able to develop and commercialize our technologies.

We need FDA approval to market our products in the United States that are subject to regulatory approval, and similar approvals from foreign regulatory authorities to market products outside the United States. The production and marketing of such products and potential products and our ongoing research and development, pre-clinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities in the United States and will face similar regulation and review for overseas approval and sales from governmental authorities outside of the United States. The regulatory review and approval process, which may include evaluation of preclinical studies and clinical trials of our products that are subject to regulatory review, as well as the evaluation of manufacturing processes and contract manufacturers' facilities, is lengthy, expensive and uncertain. We have limited experience in filing and pursuing applications necessary to gain regulatory approvals. Many of the product candidates that we are currently developing must undergo rigorous pre-clinical and clinical testing and an extensive regulatory approval process before they can be marketed. This process makes it longer, more difficult and more costly to bring our potential products to market, and we cannot guarantee that any of our potential products will be approved. Many products for which FDA approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If we or our collaboration partners do not comply with applicable regulatory requirements, such violations could result in non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Regulatory authorities generally have substantial discretion in the approval process and may either refuse to accept an application, or may decide after review of an application that the data submitted is insufficient to allow approval of the proposed product, as we have experienced with previous CRLs that we have received from the FDA. If regulatory authorities do not accept or approve our applications, they may require that we conduct additional clinical, preclinical or manufacturing studies and submit that data before regulatory authorities will reconsider such application. We may need to expend substantial resources to conduct further studies to obtain data that regulatory authorities believe is sufficient. Depending on the extent of these studies, acceptance or approval of applications may be delayed by several years, or may require us to expend more resources than we may have available. It is also possible that additional studies may not suffice to make applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval.

Failure to obtain FDA or other required regulatory approvals, or withdrawal of previous approvals, would adversely affect our business. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted, or may prevent us from broadening the uses of products for different applications.

Following regulatory approval of any of our drug candidates, we will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential products.

With regard to our drug candidates that are approved by the FDA or by another regulatory authority, we are held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market. In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

We intend to pursue Section 505(b)(2) regulatory approval filings with the FDA for our products where applicable. Such filings involve significant costs, and we may also encounter difficulties or delays in obtaining regulatory approval for our products. Similar difficulties or delays may also arise in connection with any Abbreviated New Drug Applications that we may file.

We submitted a Section 505(b)(2) NDA regulatory filing to the FDA in connection with our approved SYMJEPI products and our ZIMHI (naloxone) Injection product, and we may pursue Section 505(b)(2) NDA filings with the FDA in connection with one or more other product candidates. A Section 505(b)(2) NDA is a special type of NDA that enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing previously approved product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Such filings involve significant filing costs, including filing fees.

To the extent that a Section 505(b)(2) NDA relies on published literature relating to a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, where the underlying studies were not conducted by or for the applicant and the applicant lacks a right of reference or use to the underlying data, the Section 505(b)(2) applicant must submit in its Section 505(b)(2) application a patent certification or statement with respect to any patents that are subject to the Orange Book listing requirement in connection with the previously approved product on which the applicant's application relies. Specifically, the applicant must certify for each such patent that, in relevant part, (1) the required patent information has not been filed; (2) the patent has expired; (3) the patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. Alternatively, with respect to a method of use patent, the applicant may submit a statement that the patent does not claim a use for which the applicant is seeking approval. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge the listed patents through a Paragraph IV certification or submit a statement that a method of use patent does not claim a use for which the applicant is seeking approval, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents for the previously approved product have expired. Further, the FDA will also not approve a Section 505(b)(2) NDA until any applicable non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three-year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the referenced product, has expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the FDA sends the Section 505(b)(2) NDA applicant notice that the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, unless, before the end of the 30-month period, a court determines that the patent is invalid, unenforceable or not infringed; a court enters a settlement order or consent decree stating that the patent is invalid, unenforceable, or not infringed; the patent owner or exclusive licensee consents to approval of the Section 505(b)(2) NDA; or the court enters an order of dismissal without a finding of infringement.

If we rely in our Section 505(b)(2) regulatory filings on published literature relating to a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product where the underlying studies were not conducted by or for us and we lack a right of reference or use to the underlying data, and that involves patents referenced in the Orange Book, then we will need to make the patent certifications or the Paragraph IV certification described above. If we make a Paragraph IV certification and the holder of the previously approved product that we referenced in our application initiates patent litigation within the time periods described above, then any FDA approval of our 505(b)(2) application would be delayed until the earlier of 30 months, resolution of the lawsuit, or the other events described above. Accordingly, our anticipated dates relating to review and approval of a product that was subject to such litigation would be delayed. In addition, we would incur the expenses, which could be material, involved with any such patent litigation. As a result, we may invest a significant amount of time and expense in the development of our product only to be subject to significant delay and patent litigation before our product may be commercialized, if at all.

In addition, even if we submit a Section 505(b)(2) application, such as we may submit for other future products, that relies on published literature relating to a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product where there are no patents referenced in the Orange Book for such other product with respect to which we have to provide certifications, we are subject to the risk that the FDA could disagree with our reliance on the particular previously approved product that we chose to rely on, conclude that such previously approved product is not an acceptable reference product, and require us instead to rely as a reference product on another previously approved product that involves patents referenced in the Orange Book, requiring us to make the certifications described above and subjecting us to additional delay, expense and the other risks described above.

Similarly, if we submit one or more ANDA applications to the FDA pursuant to Section 505(j) of the FDCA in connection with one or more of our product candidates, we could encounter generally similar difficulties or delays, including difficulties or delays resulting from the Paragraph IV certification process or from the development of any bioequivalence or other data that might be required in connection with any such ANDAs.

If we fail to obtain acceptable prices or appropriate reimbursement for our products, our ability to successfully commercialize our products will be impaired.

Government and insurance reimbursements for healthcare expenditures play an important role for all healthcare providers, including physicians and pharmaceutical companies such as Adamis, that plan to offer various products in the United States and other countries in the future. Physicians and patients may decide not to order our products unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid, pay a substantial portion of the price of the products. Market acceptance and sales of our specialty pharmaceutical products and potential products will depend in part on the extent to which reimbursement for the costs of such products will be available from government health administration authorities, private health coverage insurers, managed care organizations, and other organizations. In the United States, our ability to have our products eligible for Medicare, Medicaid or private insurance reimbursement will be an important factor in determining the ultimate success of our products. If, for any reason, Medicare, Medicaid or the insurance companies decline to provide reimbursement for our products, our ability to commercialize our products would be adversely affected.

Third-party payors may challenge the price of medical and pharmaceutical products. Reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that our product candidates are:

- not experimental or investigational;
- effective;
- medically necessary;
- appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; or
- included in clinical practice guidelines.

If purchasers or users of our products and related treatments are not able to obtain appropriate reimbursement for the cost of using such products, they may forego or reduce such use. Significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products, and there can be no assurance that adequate third-party coverage will be available for any of our products. Even if our products are approved for reimbursement by Medicare, Medicaid and private insurers, of which there can be no assurance, the amount of reimbursement may be reduced at times or even eliminated, which could have a material adverse effect on our business, financial condition and results of operations.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and certain foreign jurisdictions, there have been and are expected to be a number of legislative and regulatory changes to the healthcare system in ways that could impact our ability to sell our products profitably. The impact of these changes on the biotechnology and pharmaceutical industries and our business is uncertain. The U.S. Congress continues to consider issues relating to the healthcare system, and future legislation or regulations may affect our ability to market and sell products on favorable terms, which would affect our results of operations, as well as our ability to raise capital, obtain additional collaborators or profitably market our products. Such legislation or regulation may reduce our revenues, increase our expenses or limit the markets for our products. In particular, we expect to experience pricing pressures in connection with the sale of our products due to the influence of health maintenance and managed health care organizations and additional legislative proposals.

We are subject to a variety of federal, state and local laws and regulations relating to the general healthcare industry, which are subject to frequent change.

Participants in the healthcare industry, including the company and, before the winding down of its business as described elsewhere in this Report, USC, are subject to a variety of federal, state, and local laws and regulations. Laws and regulations in the healthcare industry are extremely complex and, in many instances, industry participants do not have the benefit of significant regulatory or judicial interpretation. Such laws and regulations are subject to change and often are uncertain in their application. There can be no assurance that we will not be subject to scrutiny or challenge under one or more of these laws or regulations or that any such challenge would not be successful. Any such challenge, whether or not successful, could adversely affect our business, financial condition or results of operations.

In addition, we are subject to the federal anti-kickback statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service reimbursable under a federal healthcare program, or purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under a federal healthcare program. We are also subject to state anti-kickback laws and regulations. Violations of the anti-kickback statutes can result in imprisonment, civil or criminal fines, and fines and disciplinary actions relating to our state licensure. Any violation or alleged violation of such federal or state laws could harm our reputation, customer relationships or otherwise have a material adverse effect on our business, financial condition and results of operations.

We have limited sales, marketing and distribution experience.

We have limited experience in the sales, marketing, and distribution of pharmaceutical products. There can be no assurance that we will be able to establish sales, marketing, and distribution capabilities or make arrangements with collaborators or others to perform such activities or that such efforts will be successful. If we decide to market any products directly ourselves, we would be required to either acquire or internally develop a marketing and sales force with technical expertise and with supporting distribution capabilities. The acquisition or development of a sales, marketing and distribution infrastructure would require substantial resources, which may not be available to us or, even if available, could divert the attention of our management and key personnel and have a negative impact on further product development efforts.

We may seek to enter into arrangements to develop and commercialize our products. These collaborations, even if secured, may not be successful.

We have entered and sought to enter into arrangements with third parties regarding development or commercialization of some of our products or product candidates and may in the future seek to enter into collaborative arrangements to develop and commercialize some of our potential products both in North America and international markets. There can be no assurance that we will be able to negotiate commercialization or collaborative arrangements on favorable terms or at all or that our current or future collaborative arrangements will be successful. The amount and timing of resources such third parties will devote to these activities may not be within our control. There can be no assurance that such parties will perform their obligations as expected. There can be no assurance that our collaborators will devote adequate resources to our products.

Even if they are approved and commercialized, if our potential products are unable to compete effectively with current and future products targeting similar markets as our potential products, our commercial opportunities will be reduced or eliminated.

The markets for our SYMJEPI products and ZIMHI product, and our other product candidates, are intensely competitive and characterized by rapid technological progress. We face competition from numerous sources, including major biotechnology and pharmaceutical companies worldwide. Many of our competitors have substantially greater financial and technical resources, and development, production and marketing capabilities, than we do. Our SYMJEPI product competes with a number of other currently marketed epinephrine products for use in the emergency treatment of acute allergic reactions, including anaphylaxis. Our ZIMHI product competes with a number of other currently marketed products utilizing naloxone, for the treatment of acute opioid overdose. Our Tempol product candidate for use in treatment of COVID-19, if successfully developed, approved and commercialized, will compete with a number of other current and future products and therapies for use in the treatment of COVID-19. Certain companies have established technologies that may be competitive with our product candidates and any future products that we may develop or acquire. Some of these products may use different approaches or means to obtain results, which could be more effective or less expensive than our products for similar indications. In addition, many of these companies have more experience than we do in pre-clinical testing, performance of clinical trials, manufacturing, and obtaining FDA and foreign regulatory approvals. They may also have more brand name exposure and expertise in sales and marketing. We also compete with academic institutions, governmental agencies and private organizations that are conducting research in the same fields.

Competition among these entities to recruit and retain highly qualified scientific, technical and professional personnel and consultants is also intense. As a result, there is a risk that one or more of our competitors will develop a more effective product for the same indications for which we are developing a product or, alternatively, bring a similar product to market before we can do so. Failure to successfully compete will adversely impact the ability to raise additional capital and ultimately achieve profitable operations.

Our product candidates may not gain acceptance among physicians, patients, or the medical community, thereby limiting our potential to generate revenue, which will undermine our future growth prospects.

Even if our pharmaceutical product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, health care professionals and third-party payors, and our profitability and growth will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- pricing and cost effectiveness, which may be subject to regulatory control;
- our ability to obtain sufficient third-party insurance coverage or reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects; and
- availability of alternative treatments.

If any product candidate that we develop does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide some additional patient benefit over the current standard of care, that product will likely not achieve market acceptance and we will not generate sufficient revenues to achieve profitability.

If we suffer negative publicity concerning the safety of our products in development, our sales may be harmed and we may be forced to withdraw such products.

If concerns should arise about the safety of any of our products that are marketed, regardless of whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research, such concerns could adversely affect the market for these products. Similarly, negative publicity could result in an increased number of product liability claims, whether or not these claims are supported by applicable law.

Our failure to adequately protect or to enforce our intellectual property rights or secure rights to third party patents could materially harm our proprietary position in the marketplace or prevent the commercialization of our products.

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technologies and products. The patents and patent applications in our existing patent portfolio are either owned by us or licensed to us. Our ability to protect our product candidates from unauthorized use or infringement by third parties depends substantially on our ability to obtain and maintain, or license, valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions for which important legal principles are unresolved.

There is a substantial backlog of patent applications at the United States Patent and Trademark Office, or USPTO. There can be no assurance that any patent applications relating to our products or methods will be issued as patents, or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide a competitive advantage. We may not be able to obtain patent rights on products, treatment methods or manufacturing processes that we may develop or to which we may obtain license or other rights. Even if we do obtain or license patent rights, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against our competitors or their competitive products or processes. Patents and intellectual property that we own or license may not afford us the rights that we anticipate. It is possible that no patents will be issued from any pending or future patent applications owned by us or licensed to us. Others may challenge, seek to invalidate, infringe or circumvent any patents we own or license. Alternatively, we may in the future be required to initiate litigation against third parties to enforce our intellectual property rights. The defense and prosecution of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to us. Any adverse outcome could subject us to significant liabilities, require us to license disputed rights from others, or require us to cease selling our future products.

In addition, many other organizations are engaged in research and product development efforts that may overlap with our products. Such organizations may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods under development or consideration by us. These rights may prevent us from commercializing technology, or may require us to obtain a license from the organizations to use the technology. We may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and we cannot be sure that the patents underlying any such licenses will be valid or enforceable. As with other companies in the pharmaceutical industry, we are subject to the risk that persons located in other countries will engage in development, marketing or sales activities of products that would infringe our patent rights if such activities were conducted in the United States.

Our patents also may not afford protection against competitors with similar technology. We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our products or by covering the same or similar technologies that may affect our ability to market or license our product candidates. Many companies have encountered difficulties in protecting and defending their intellectual property rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in either the United States or foreign jurisdictions, our business prospects could be substantially harmed. In addition, we may not have adequate cash funding to devote the resources that might be necessary to prepare or pursue patent applications, either at all or in all jurisdictions in which we might desire to obtain patents, or to maintain already-issued patents.

We may become involved in patent litigation or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications, trademarks, and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights, or that one of our trademarks or trade names infringes the third party's trademark rights; in such case, we will need to defend against such proceedings. For example, the field of generic pharmaceuticals is characterized by frequent litigation that occurs in connection with the regulatory filings under Section 505(b)(2) of the FDCA and attempts to invalidate the patent of the reference drug.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our potential competitors will be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult, and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

If we determine that our intangible assets have become impaired in the future, our total assets and earnings could be adversely affected.

Goodwill represents the purchase price of acquisitions in excess of the amounts assigned to acquired tangible or intangible assets and assumed liabilities. Goodwill and indefinite lived intangible assets are not amortized but rather are evaluated for impairment annually or more frequently, if indicators of impairment exist. Finite lived intangible assets are evaluated for impairment annually or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If the impairment evaluations for goodwill and intangible assets indicate the carrying amount exceeds the estimated fair value, an impairment loss is recognized in an amount equal to that excess. During and for the years ended December 31, 2020 and 2021, we recorded significant impairment charges for impairment of goodwill and other intangible assets. If in the future we determine that our intangible assets have become impaired, our total assets, financial results, and earnings could be adversely affected.

We are subject to certain data privacy and security requirements, which are very complex and difficult to comply with at times. Any failure to ensure adherence to these requirements could subject us to fines and penalties, and damage our reputation.

We are required to comply, as applicable, with numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, which govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who may prescribe products we may sell in the future and from whom we may obtain patient health information are subject to privacy and security requirements under HIPAA and comparable state laws. These laws could create liability for us or increase our cost of doing business, and any failure to comply could result in harm to our reputation, and potentially fines and penalties.

There are significant limitations on our ability in the future to utilize any net operating loss carryforwards for federal and state income tax purposes.

At December 31, 2021, we had federal and state net operating loss carryforwards, or NOLs, and credit carryforwards which, subject to certain limitations, we may use to reduce future taxable income or offset income taxes due. Insufficient future taxable income will adversely affect our ability to utilize these NOLs and credit carryforwards. Pursuant to Internal Revenue Code Section 382, the annual use of the NOLs and research and development tax credits could be limited by any greater than 50% ownership change during any three-year testing period. As noted in Note 20 of the audited consolidated financial statements appearing in this Report, our existing NOLs are subject to limitations arising from previous ownership changes, and if we undergo additional ownership changes, our ability to use our NOLs could be further limited by Section 382 of the Code. As a result of these limitations, we may be materially limited in our ability to utilize our NOLs and credit carryforward.

Risks Related to Our Former Compounding Pharmacy Business

We have sold a substantial portion of the assets of USC and are winding down the remaining business of USC and selling or otherwise disposing of the remaining assets of USC. There is no assurance regarding the proceeds that we may receive from the sale or disposition of any assets of USC. We may incur significant costs in connection with such winding down activities.

As previously disclosed in our reports with the SEC and as disclosed elsewhere in this Report, pursuant to the USC Agreement we have sold and transferred certain assets relating to the human compounding pharmaceutical business of USC and have agreed to a variety of restrictive covenants preventing us from engaging in certain business and competitive activities relating to the human compounding pharmaceutical business. The remaining operations and business of USC have been or will be wound down and terminated, and remaining assets relating to USC's business have been sold or will be sold or otherwise transferred or disposed of. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer engaged in the human or veterinary compounding pharmaceutical business. The USC Agreement provides for payment of consideration over time based on future sales of products by the Purchaser. The ongoing impact of the COVID-19 pandemic, or other factors, could adversely affect the amount that we receive in the future pursuant to the USC Agreement or other agreements or activities relating to the sale or disposition of USC's assets. There is no assurance regarding the amount of proceeds that we may receive from the Purchase Agreement or any other sale or disposition of any other assets of USC.

We have indemnification obligations under the USC Agreement, and we may have indemnification obligations under other agreements relating to the sale or disposition of other USC assets, pursuant to which we may be required to indemnify, hold harmless, and pay losses, liabilities, expenses and amounts arising out of certain claims relating to the assets that are the subject of such agreements, including without limitation relating to, among other matters, our breach of the USC Agreement or other applicable agreement, third party claims relating to previous sales of products by USC to customers, or other matters. These indemnification provisions could require us to pay significant amounts to satisfy our indemnification obligations under such agreements, which would reduce the net amounts that we ultimately receive from the sale of the assets subject to such agreements.

In addition, other matters may arise in the future relating to the USC business, USC assets, or USC employees, or arising out of the restructuring, winding down and winding up activities, that could require us to pay amounts in the future. The process of winding down and winding up the remaining business of USC could require us to incur significant expenses or pay significant amounts in connection with or relating to the termination of employment of USC's employees, the disposition of remaining USC assets, the termination of agreements relating to the USC business, or the resolution of outstanding obligations, liabilities, or current or future claims or proceedings. In addition, we could be required to pay significant fines, penalties or other amounts as a result of proceedings by federal or state regulatory authorities relating to the business and operations of USC.

The compounding pharmaceuticals business formerly conducted by USC is significantly impacted by state and federal statutes and regulations.

The compounding pharmaceuticals business formerly conducted by USC is subject to federal, state and local laws, regulations, and administrative practices, including, among others: federal registration as an outsourcing facility, state and local licensure and registration requirements concerning the operation of outsourcing facilities, and federal and state laws relating to the preparation, purchase, sale, advertisement, promotion, distribution, management, compounding, dispensing, reimbursement, marketing, and labeling of drugs that USC sells and related services as well as state pharmacy, manufacturer, wholesaler and distribution licensure and registration or permit standards; HIPAA and other laws relating to the use, disclosure and transmission of health or other personal information; the Patient Protection and Affordable Care Act, or ACA, and the Health Care and Education Reconciliation Act of 2010; statutes and regulations of the FDA and the U.S. Drug Enforcement Administration, or DEA, and states including relating to controlled substances; and state pharmacy, manufacturer, wholesaler and distribution licensure and registration or permit standards and other state laws and regulations.

The federal, state and local laws and regulations applicable to the pharmaceutical and compounding industries are subject to frequent change, whether through change in law or through interpretation. There can be no assurance that we or USC have been or are compliant in material respects with applicable federal and state regulatory requirements. Failure to comply with FDA requirements and other federal or state governmental laws and regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, exposure to product liability claims, total or partial suspension of production or distribution, enforcement actions, injunctions and civil or criminal prosecution, any of which could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to Our Common Stock

Provisions of our charter documents could discourage an acquisition of our company that would benefit our stockholders and may have the effect of entrenching, and making it difficult to remove, management.

Provisions of our restated certificate of incorporation and bylaws may make it more difficult for a third party to acquire control of us, even if a change of control would benefit our stockholders. For example, shares of our preferred stock may be issued in the future without further stockholder approval, and upon such terms and conditions, and having such rights, privileges and preferences, as our board of directors may determine, including, for example, rights to convert into our common stock. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any of our preferred stock that may be issued in the future. The issuance of our preferred stock could have the effect of making it more difficult for a third party to acquire control of us. This could limit the price that certain investors might be willing to pay in the future for shares of our common stock and discourage those investors from acquiring a majority of our common stock. Similarly, our bylaws require that any stockholder proposals or nominations for election to our board of directors must meet specific advance notice requirements and procedures, which make it more difficult for our stockholders to make proposals or director nominations. The existence of these charter provisions could have the effect of entrenching management and making it more difficult to change our management. Furthermore, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law. These provisions may prohibit or restrict large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us, unless one or more exemptions from such provisions apply. These provisions under Delaware law could discourage potential takeover attempts and could reduce the price that investors might be willing to pay for shares of our common stock in the future.

The price of our common stock may be volatile.

The market price of our common stock may fluctuate substantially. For example, from January 2019 to December 31, 2021, the market price of our common stock has fluctuated between $0.27 and $3.29. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- relatively low trading volume, which can result in significant volatility in the market price of our common stock based on a relatively smaller number of trades and dollar amount of transactions;
- the timing and results of our current and any future preclinical or clinical trials of our product candidates;
- the entry into or termination of key agreements, including, among others, key collaboration and license agreements;
- the results and timing of regulatory reviews relating to the approval of our product candidates;
- the timing of, or delay in the timing of, commercial introduction of any of our products;
- the initiation of, material developments in, or conclusion of, litigation to enforce or defend any of our intellectual property rights;
- failure of any of our product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the results of clinical trials conducted by others on products that would compete with our product candidates;
- issues in manufacturing our product candidates or any approved products;
- the loss of key employees;
- the introduction of technological innovations or new commercial products by our competitors;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- future sales of our common stock;
- publicity or announcements regarding regulatory developments relating to our products;
- period-to-period fluctuations in our financial results, including our cash and cash equivalents balance, operating expenses, cash burn rate or revenue levels;
- common stock sales in the public market by one or more of our larger stockholders, officers or directors;
- our filing for protection under federal bankruptcy laws;
- a negative outcome in any litigation or potential legal proceeding;
- effects of public health crises, pandemics and epidemics, such as the COVID-19 outbreak; or
- other potentially negative financial announcements, such as a review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC.

The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

Trading of our common stock is limited.

Trading of our common stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce our trading, making it difficult for our stockholders to sell their shares.

The foregoing factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock. In addition, without a large public float, our common stock is less liquid than the stock of companies with broader public ownership, and as a result, the trading price of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his or her investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the price at which our common stock will trade at any given time.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock, which could negatively impact the market price and liquidity of our common shares and our ability to access the capital markets.

Our common stock is listed on the Nasdaq Capital Market. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would have a negative effect on the price of our common stock, impair the ability to sell or purchase our common stock when persons wish to do so, and any delisting materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from the Nasdaq Capital Market could also have other negative results, including the potential loss of institutional investor interest and fewer business development opportunities. In the event of a delisting, we would attempt to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

On December 31, 2021, we received a notice from the Nasdaq Listing Qualifications Department of The NASDAQ Capital Market ("Nasdaq") informing us that because the closing bid price of our common stock had been below $1.00 per share for 30 consecutive business days, we no longer complied with the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) (the "Rule") requires listed securities to maintain a minimum bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The notice had no immediate effect on the listing or the trading of our common stock on The Nasdaq Capital Market. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), the notice letter stated that we had an initial compliance period of 180 calendar days, or until June 29, 2022, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. If at any time before June 29, 2022, the bid price of our common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the minimum bid price requirement, and the matter would be resolved. The notice letter also disclosed that if we do not regain compliance within the initial compliance period, we may be eligible for an additional 180-day compliance period. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of a plan to cure the deficiency during the second compliance period, including by effecting a reverse stock split if necessary. If the company meets these requirements, Nasdaq would inform us that we have been granted an additional 180 calendar days to regain compliance. However, if it appears to the staff of Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, the staff would notify us that we will not be granted additional 180 days for compliance and will be subject to delisting at that time. In the event of such notification, we may appeal the staff's determination to delist its securities, but there can be no assurance that any such appeal would be successful. We intend to monitor the closing bid price for our common stock and will consider available strategies in an effort to satisfy the minimum bid price requirement. However, there are no assurances that we will be able to regain compliance with the minimum bid price requirements or will otherwise be in compliance with other Nasdaq listing rules. In addition, at various times from October 2019 through September 2020, we received similar notices from Nasdaq regarding the minimum bid price requirement of Listing Rule 5550(a)(2), and on each such occasion, following such notice we have regained compliance with the Rule.

On May 25, 2021, we received a notification letter from Nasdaq notifying us that, because the company has not yet filed its Quarterly Report on Form 10-Q for the period ended March 31, 2021, the company was no longer in compliance with NASDAQ Marketplace Rule 5250(c)(1), which requires timely filing of periodic reports with the SEC. The Notice also indicated that the company had 60 calendar days to submit a plan to regain compliance and, if Nasdaq accepts the plan, Nasdaq can grant an exception of up to 180 calendar days from the Filing's due date to regain compliance. We submitted a plan to regain compliance on July 26, 2021. On August 20, 2021, we received a notification letter from Nasdaq notifying us that because we had not filed our Quarterly Report on Form 10-Q for the period ended June 30, 2021, as well as its Quarterly Report on Form 10-Q for the period ended March 31, 2021, we did not comply with NASDAQ Marketplace Rule 5250(c)(1). Nasdaq subsequently requested that we submit an updated plan to regain compliance, which we submitted, and Nasdaq granted an exception of up to November 22, 2021, to regain compliance and file all Quarterly Reports on Form 10-Qs required to be filed before that date. We filed the Form 10-Qs before the specified date and regained compliance with the applicable Nasdaq listing requirements.

Our common stock could become subject to additional trading restrictions as a "penny stock," which could adversely affect the liquidity and price of such stock. If our common stock became subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.

Prior to the listing of our common stock on the NASDAQ Capital Market, our common stock was traded on the OTCQB. The OTCQB, the OTC Bulletin Board and Pink Sheets are viewed by most investors as a less desirable, and less liquid, marketplace. As a result, if our common stock was delisted from the NASDAQ Capital Market and was traded on the OTCQB, the OTC Bulletin Board or the Pink Sheets, an investor could find it more difficult to purchase, dispose of or obtain accurate quotations as to the value of our common stock.

Unless our common stock is listed on a national securities exchange, such as the NASDAQ Capital Market, our common stock may also be subject to the regulations regarding trading in "penny stocks," which are those securities trading for less than $5.00 per share, and that are not otherwise exempted from the definition of a penny stock under other exemptions provided for in the applicable regulations. The following is a list of the general restrictions on the sale of penny stocks:

- Before the sale of penny stock by a broker-dealer to a new purchaser, the broker-dealer must determine whether the purchaser is suitable to invest in penny stocks. To make that determination, a broker-dealer must obtain, from a prospective investor, information regarding the purchaser's financial condition and investment experience and objectives. Subsequently, the broker-dealer must deliver to the purchaser a written statement setting forth the basis of the suitability finding and obtain the purchaser's signature on such statement.
- A broker-dealer must obtain from the purchaser an agreement to purchase the securities. This agreement must be obtained for every purchase until the purchaser becomes an "established customer."
- The Securities Exchange Act of 1934, or the Exchange Act, requires that before effecting any transaction in any penny stock, a broker-dealer must provide the purchaser with a "risk disclosure document" that contains, among other things, a description of the penny stock market and how it functions, and the risks associated with such investment. These disclosure rules are applicable to both purchases and sales by investors.
- A dealer that sells penny stock must send to the purchaser, within 10 days after the end of each calendar month, a written account statement including prescribed information relating to the security.

These requirements can severely limit the liquidity of securities in the secondary market because fewer brokers or dealers are likely to be willing to undertake these compliance activities. If our common stock is not listed on a national securities exchange, the rules and restrictions regarding penny stock transactions may limit an investor's ability to sell to a third party and our ability to raise additional capital. We make no guarantee that market-makers will make a market in our common stock, or that any market for our common stock will continue.

Our stockholders may experience significant dilution as a result of any additional financing using our securities, or as the result of the exercise or conversion of our outstanding securities.

In the future, to the extent that we raise additional funds by issuing equity securities or securities convertible into or exercisable for equity securities, our stockholders may experience significant dilution. In addition, conversion or exercise of other outstanding options, warrants or convertible securities could result in there being a significant number of additional shares outstanding and dilution to our stockholders. If additional funds are raised through the issuance of preferred stock, holders of preferred stock could have rights that are senior to the rights of holders of our common stock, and the agreements relating to any such issuance could contain covenants that would restrict our operations.

We have not paid cash dividends on our common stock in the past and do not expect to pay cash dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock.

No cash dividends have been paid on our common stock, and we do not expect to pay cash dividends on our common stock in the foreseeable future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on a stockholder investment will only occur if our stock price appreciates.

The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.

Our restated certificate of incorporation gives our board of directors the right to create new series of preferred stock. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the voting power and equity interest of the holders of common stock. Preferred stock, which could be issued with the right to more than one vote per share, could be utilized as a method of discouraging, delaying or preventing a change of control. The possible impact on takeover attempts could adversely affect the price of our common stock.

Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

If in the future we sell additional equity securities to help satisfy funding requirements, those securities may be subject to registration rights or may include warrants with anti-dilutive protective provisions. Future sales in the public market of our common stock, or shares issued upon exercise of our outstanding stock options, warrants or convertible securities, or the perception by the market that these issuances or sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon the sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

As of December 31, 2021, we had 149,594,262 shares of common stock issued and outstanding, substantially all of which we believe may be sold publicly, subject in some cases to volume and other limitations, provisions or limitations in registration rights agreements, or prospectus-delivery or other requirements relating to the effectiveness and use of registration statements registering the resale of such shares.

As of December 31, 2021, we had reserved for issuance 4,985,415 shares of our common stock issuable upon the exercise of outstanding stock options under our equity incentive plans at a weighted-average exercise price of $4.21 per share, we had outstanding restricted stock units covering 1,039,003 shares of common stock, and we had outstanding warrants to purchase 14,202,824 shares of common stock at a weighted-average exercise price of $1.17 per share. Subject to applicable vesting requirements, upon exercise of these options or warrants or issuance of shares following vesting of the restricted stock units, the underlying shares may be resold into the public market, subject in some cases to volume and other limitations or prospectus delivery requirements pursuant to registration statements registering the resale of such shares. In the case of outstanding options or warrants that have exercise prices that are below the market price of our common stock from time to time, or upon issuance of shares following vesting of restricted stock units, our stockholders would experience dilution upon the exercise of these options.

Exercise of our outstanding warrants may result in dilution to our stockholders.

As of December 31, 2021, we had outstanding warrants, other than the warrants described in the next sentence, to purchase 58,824 shares of common stock, at a weighted average exercise price of $8.50 per share. As of December 31, 2021, 13,794,000 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants, at an exercise price of $1.15 per share, that we issued in connection with our underwritten public offering of common stock and warrants in August 2019; 350,000 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants, at an exercise price of $0.70 per share, that we issued in connection with our private placement of warrants in February 2020.

Our Bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for a wide variety of disputes between us and our stockholders, and that the federal district courts of the United States of the America are the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Exclusive forum provisions in our Bylaws could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Bylaws, as amended, provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders, including (i) any derivative action or proceeding brought on behalf of the company; (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the company to the company or the company's stockholders; (iii) any action asserting a claim against the company or any director or officer or other employee of the company arising pursuant to any provision of the Delaware General Corporation Law, the certificate of incorporation or the Bylaws of the company, or as to which the Delaware General Corporation Law confers jurisdiction on the Courts of Chancery of the State of Delaware; or (iv) any action asserting a claim against the company or any director or officer or other employee of the company governed by the internal affairs doctrine, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants (including without limitation as a result of the consent of such indispensable party to the personal jurisdiction of such court). The Bylaws provide that the foregoing provisions do not apply to actions or suits brought to enforce any liability or duty created by the Securities Act of 1933, as amended (the "Securities Act"), the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or any other claim for which the federal courts have exclusive jurisdiction. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our Bylaws do not relieve us of our duties to comply with federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. In addition, our Bylaws, as amended, provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and to have consented to these provisions.

Under the Securities Act, federal and state courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act. There is uncertainty as to whether a court (other than state courts in the State of Delaware, where the Supreme Court of the State of Delaware decided in March 2020 that exclusive forum provisions for causes of action arising under the Securities Act are facially valid under Delaware law) would enforce forum selection provisions and whether investors can waive compliance with the federal securities laws and the rules and regulations thereunder. We believe the forum selection provisions in Bylaws, as amended, may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits against us and/or our directors, officers and employees as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers or employees. In addition, stockholders who do bring a claim in the Court of Chancery in the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a future court could find the choice of forum provisions contained in our Bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, identify or discover material weaknesses in our internal control over financial reporting or fail to effectively remediate any identified material weaknesses, our business and financial condition could be materially and adversely affected and our stock price could decline.

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any material changes and weaknesses identified through such evaluation. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and our business and financial condition could be adversely affected. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could decline significantly.

As disclosed in our Quarterly Reports on Form 10-Q for the first three quarters of 2021, we identified material weaknesses in our internal control over financial reporting and concluded that our internal control over financial reporting was not effective as of March 31, 2021, June 30, 2021 and September 30, 2021. We believe that the identified weakness was remediated as of December 31, 2021. Nevertheless, any failure to effectively remediate an identified material weakness or otherwise maintain adequate internal controls over financial reporting could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, and legal proceedings by stockholders or regulatory authorities, which could result in a material adverse effect on our business. We could face monetary judgments, penalties or other sanctions that could have a material adverse effect on our business, financial condition and results of operations and could cause our stock price to decline. Failure to timely file required reports with the SEC, as occurred with respect to our Quarterly Reports on Form 10-Q for the first three quarters of 2021, results in loss of eligibility to utilize short form registration statements on Form S-3 and prospectuses outstanding under previous registration statements not being current or available, which may impair our ability to obtain required capital in a timely manner or issue shares for other purposes, and may subject us to legal claims from stockholders or warrant holders. Inadequate internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We take responsive actions to address identified material weaknesses in our internal control over financial reporting. However, we can give no assurance that such measures will remediate any material weakness that are identified or that any additional material weaknesses or restatements of financial results will not arise in the future. In the future, our management may determine that our disclosure controls and procedures are ineffective or that there are one or more material weaknesses in our internal controls over financial reporting, resulting in a reasonable possibility that a material misstatement to the annual or interim financial statements would not have been prevented or detected. Accordingly, a material weakness increases the risk that the financial information we report contains material errors. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Efforts to correct any material weaknesses or deficiencies that may be identified could require significant financial resources to address. Moreover, if remedial measures are insufficient to address the deficiencies that are determined to exist, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements could contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, and we could become subject to class action litigation or investigations or proceedings from regulatory authorities. Any of these matters could adversely affect our business, reputation, revenues, results of operations, financial condition and stock price.

General Risk Factors

We depend on our officers. If we are unable to retain our key employees or to attract additional qualified personnel, our product operations and development efforts may be seriously jeopardized.

Our success will be dependent upon the efforts of our management team and staff, including Dennis J. Carlo, Ph.D., our chief executive officer. The employment of Dr. Carlo may be terminated at any time by either us or Dr. Carlo. We currently do not have key person life insurance policies covering any of our executive officers or key employees. If key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly recruited. There is competition for qualified personnel in all functional areas, which makes it difficult to attract and retain the qualified personnel necessary for the operation of our business. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. If we are unable to attract new employees and retain existing key employees, the development and commercialization of our product candidates could be delayed or negatively impacted. In addition, any staffing interruptions resulting from geopolitical actions, including war and terrorism, adverse public health developments such as the COVID-19 pandemic, or natural disasters including earthquakes, typhoons, floods and fires, could have an adverse effect on our business.

We may experience difficulties in managing growth.

We are a small company. Any significant growth in the future could impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. Our future financial performance and our ability to compete effectively may depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our clinical studies effectively;
- integrate additional management, administrative, manufacturing and regulatory personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

Our business and operations would suffer in the event of cybersecurity or other system failures. Our business depends on complex information systems, and any failure to successfully maintain these systems or implement new systems to handle our changing needs could materially harm our operations.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information of employees. Similarly, our third-party providers possess certain of our sensitive data. The secure maintenance of this information is material to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline and may impair our ability to raise capital in the future.

There have been and may continue to be periods when our common stock could be considered "thinly-traded," meaning that the number of persons interested in purchasing our common stock at or near bid prices at any given time may be relatively small or non-existent. Finance transactions resulting in a large amount of newly issued shares that become readily tradable, conversion of outstanding convertible notes or exercise of outstanding warrants and sale of the shares issuable upon conversion of such notes or exercise of such warrants, issuance of shares following vesting of outstanding restricted stock units, or other events that cause stockholders to sell shares, could place downward pressure on the trading price of our stock. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock. If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our common stock in the public market, the market price of our common stock could decline. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We may never obtain substantial research coverage by industry or financial analysts. If no or few analysts commence or continue coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

The company's principal headquarters, consisting of approximately 7,525 square feet of leased premises, is located at 11682 El Camino Real, Suite 300, San Diego, CA 92130. As amended, the current lease term expires on November 30, 2023. Commencing on December 1, 2018 with one month free rent, base rent was initially $28,219 per month for the succeeding 11 months and will increase annually to $31,760 for the 12 months ending November 30, 2023.

The company's wholly owned subsidiary, USC, occupies a company-owned property consisting of approximately 16,065 square feet, two-story, office building/laboratory in a lot of approximately 1.65 acres located at 1270 Don's Lane, Conway, Arkansas 72032. This property was included in the assets held for sale classification as a result of the sale of assets pursuant to the USC Agreement and the winding down of USC's remaining business. The company is actively marketing the sale of this asset. See Note 4 to the financial statements included elsewhere herein.

The company also entered into a lease agreement for additional space relating to the company's compounding business, to lease a building consisting of approximately 44,880 square feet located in Conway, Arkansas, with a current term expiring December 31, 2023. Monthly rent for the period commencing January 1, 2019 is $10,000 per month for the succeeding 12 months, increasing annually to $10,824 for the 12 months ending December 31, 2023. As a result of the sale of assets pursuant to the USC Agreement and the winding down of USC's remaining business, the company will not need the leased property. The company is exploring alternatives with respect to termination of the lease or sub-lease of the property.

ITEM 3. LEGAL PROCEEDINGS

We may from time to time become party to actions, claims, suits, investigations or proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, breach of contract claims, labor and employment claims and other matters. We may also become party to litigation in federal and state courts relating to opioid drugs. Any litigation could divert management time and attention from Adamis, could involve significant amounts of legal fees and other fees and expenses, or could result in an adverse outcome having a material adverse effect on our financial condition, cash flows or results of operations. Actions, claims, suits, investigations and proceedings are inherently uncertain and their results cannot be predicted with certainty. Except as described below, we are not currently involved in any legal proceedings that we believe are, individually or in the aggregate, material to our business, results of operations or financial condition. However, regardless of the outcome, litigation can have an adverse impact on us because of associated cost and diversion of management time.

Investigation

On May 11, 2021, the company and USC each received a grand jury subpoena from the U.S. Attorney's Office for the Southern District of New York ("USAO"). The USAO issued the subpoenas in connection with a criminal investigation and requested a broad range of documents and materials relating to, among other matters, certain veterinary products sold by USC, certain practices, agreements, and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC. On May 11, 2021, the Audit Committee of the Board engaged outside counsel to conduct an independent internal investigation to review the matters brought forth in the subpoenas and certain other matters. The investigation involved, among other matters, interviews with employees and collection and review of a large number of documents. The company has taken a number of actions in response to the internal investigation, including personnel actions relating to certain USC veterinary sales employees. In addition, following the commencement of the investigation, as disclosed elsewhere in this Report the company has sold assets relating to its compounding pharmacy business, ceased selling human and veterinary compounded pharmaceutical products, is engaged in a process of winding down USC's business, and the employment of substantially all USC employees has ended or will end in connection with the winding down of that business. As a result, the company is no longer be engaged in the sale of human or veterinary compounded pharmaceutical products. The company is also considering a number of additional actions in response to the internal investigation. As of the date of this Report, we believe that the investigation initially commenced by the Audit Committee is substantially complete. However, additional issues or facts could arise or be determined, which may expand the scope, duration, or outcome of the Audit Committee's investigation. In addition to the subpoenas from the USAO, the company has also received requests from the U.S. Securities and Exchange Commission ("SEC") for the voluntary production of documents and information relating to the subject matter of the USAO's subpoenas and certain other matters. The company has produced documents and will continue to produce and provide documents in response to the subpoenas and requests. The company intends to cooperate with the USAO and the SEC. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, or other agencies, or determine what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate, what, if any, remedies or remedial measures the USAO, SEC, or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the company's business, previously reported financial results, financial results included in this Report, or future financial results. We could receive additional requests from the USAO, SEC, or other authorities, which may require further investigation. There can be no assurance that any discussions with the SEC or USAO to resolve these matters will be successful. The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require

the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, result in fines, penalties or equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, or future financial results. The occurrence of any of these events, or any determination that our activities were not in compliance with existing laws or regulations, could have a material adverse effect on the company's business, financial condition, and results of operations.

Regulatory

In October 2021, following the sale in July 2021 of certain assets of the company's USC subsidiary relating to USC's human compounding pharmaceutical business and the company's approval of a restructuring process of winding down the remaining operations and business of USC and selling or disposing of the remaining assets of USC, the company entered into a Consent Order with the Arkansas State Board of Pharmacy to resolve an ongoing administrative proceeding before the pharmacy board, pursuant to which USC agreed to surrender its Arkansas retail pharmacy permit and wholesaler/outsourcer permit effective October 31, 2021, to pay a civil penalty of $75,000 relating to violations of various Arkansas pharmacy laws and the pharmacy board's regulations, and to pay $75,000 in investigative costs of the pharmacy board.

Nasdaq Compliance

In response to the company's May 2021 Form 12b-25 disclosure that it would be unable to file in a timely manner its Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 due to the need for additional time to address matters relating to the USAO's subpoenas, Nasdaq sent the company a letter determining that the company was no longer in compliance with Nasdaq Listing Rule 5250(c)(1). We submitted a plan to regain compliance. In August, we received a notification letter from Nasdaq notifying us that because we had not filed our Quarterly Report on Form 10-Q for the period ended June 30, 2021, as well as the Form 10-Q for the period ended March 31, 2021 (together, the "Form 10-Qs"), we did not comply with NASDAQ Listing Rule 5250(c)(1). Nasdaq subsequently requested that we submit an updated plan to regain compliance, which we submitted, and Nasdaq granted an exception of up to November 22, 2021, to regain compliance. We filed the Form 10-Qs as well as the Quarterly Report on Form 10-Q for the period ended September 30, 2021, and returned to full compliance with the relevant listing rule.

On December 31, 2021, we received a notice from the Nasdaq Listing Qualifications Department of The NASDAQ Capital Market ("Nasdaq") informing us that because the closing bid price of our common stock had been below $1.00 per share for 30 consecutive business days, we no longer complied with the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) (the "Rule") requires listed securities to maintain a minimum bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The notice had no immediate effect on the listing or the trading of our common stock on The Nasdaq Capital Market. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), the notice letter stated that we had an initial compliance period of 180 calendar days, or until June 29, 2022, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. If at any time before June 29, 2022, the bid price of our common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the minimum bid price requirement, and the matter would be resolved. The notice letter also disclosed that if we do not regain compliance within the initial compliance period, we may be eligible for an additional 180-day compliance period. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of a plan to cure the deficiency during the second compliance period, including by effecting a reverse stock split if necessary. If the company meets these requirements, Nasdaq would inform us that we have been granted an additional 180 calendar days to regain compliance. However, if it appears to the staff of Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, the staff would notify us that we will not be granted additional 180 days for compliance and will be subject to delisting at that time. In the event of such notification, we may appeal the staff's determination to delist its securities, but there can be no assurance that any such appeal would be successful. We intend to monitor the closing bid price for our common stock and will consider available strategies in an effort to satisfy the minimum bid price requirement. However, there are no assurances that we will be able to regain compliance with the minimum bid price requirements or will otherwise be in compliance with other Nasdaq listing rules. In addition, at various times from October 2019 through September 2020, we received similar notices from Nasdaq regarding the minimum bid price requirement of Listing Rule 5550(a)(2), and on each such occasion, following such notice we have regained compliance with the Rule.

Jerald Hammann

On June 8, 2021, Jerald Hammann filed a complaint against the Company and each of its directors in the Court of Chancery of the State of Delaware, captioned *Jerald Hammann v. Adamis Pharmaceuticals Corporation et al.*, C.A. No. 2021-0506-PAF (the "Complaint"), seeking injunctive and declaratory relief. The Complaint alleges, among other things, that the defendants (i) violated Rule 14a-5(f) and 14a-9(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in connection with the Company's 2021 annual meeting of stockholders—which was subsequently held on July 16, 2021 (the "2021 annual meeting")—and disseminated false and misleading information in the Company's proxy materials relating to the 2021 annual meeting, (ii) violated certain provisions of the Company's bylaws relating to the 2021 annual meeting, (iii) violated section 220 of the Delaware General Corporation Law ("DGCL") in connection with a request for inspection of books and records submitted by the plaintiff, and (iv) breached their fiduciary duties of disclosure and loyalty, including relating to establishing and disclosing the date of the Company's 2021 annual meeting and to the Company's determination that a solicitation notice delivered to the Company by plaintiff was not timely and was otherwise deficient. The Complaint alleges, among other things, that plaintiff intended to initiate a proxy contest against the Company, that defendants' conduct made it difficult or impossible for plaintiff to initiate a proxy context, and that the Company's definitive proxy statement included false and misleading disclosures and omissions of material information. The Complaint sought injunctive relief (i) to prevent the Board, the Company, and their employees and agents from soliciting any stockholders pursuant to the Company's proxy statement and (ii) to prevent the defendants from interfering in the effectiveness of stockholder voting for the 2021 annual meeting. The Complaint also seeks declaratory relief (i) finding that plaintiff's solicitation notice was timely and properly submitted; (ii) directing the defendants to comply with Rules 14a-5(f) and 14a-9(a) of the Exchange Act; (iii) directing the Company to produce the materials set forth in the plaintiff's books and records request; (iv) finding that the director defendants breached their fiduciary obligations to stockholders; and (v) finding that the director defendants engaged in self-dealing. The Complaint seeks an award of fees, costs, and expenses in this action, including attorneys' and experts' fees.

On June 10, 2021, the plaintiff filed a motion for a temporary restraining order and for expedited proceedings, seeking an order enjoining the Company from printing or disseminating its proxy statement relating to the 2021 annual meeting or from convening the 2021 annual meeting on July 16, 2021. Following a hearing, on June 17, 2021, the Court determined that: (i) it did not have jurisdiction to consider the plaintiff's claims relating to alleged violations of the Exchange Act; (ii) plaintiff's claims regarding the books and records request and alleged violations of section 220 of the DGCL should be pursued in a separate proceeding, and the Court denied the plaintiff's motion to expedite the books and records claims; (iii) certain of the plaintiff's claims alleging breach of the fiduciary duty of disclosure against the individual defendants, including claims based on alleged misrepresentations and omissions in the Company's proxy statement, were not colorable; and (iv) plaintiff's claim alleging that the individual defendants violated their fiduciary duty by taking action purportedly intended to prevent the plaintiff from pursuing a proxy contest survived a low threshold of colorability, but the Court denied the plaintiff's motion for a temporary restraining order. The Court granted in part the motion to expedite the proceedings.

The case is proceeding and the parties are currently engaged in discovery. In March 2022, plaintiff filed a motion for a temporary restraining order and for expedited proceedings, seeking an order enjoining the Company and its directors from (a) changing the number of members of the Company's board of directors, (b) adding members to the Company's board of directors, and/or (c) replacing any resigning members of the Company's board of directors. The Company filed responses to the plaintiff's motion. The court held a hearing on March 28, 2022, and denied the plaintiff's motion in full. The Company believes the claims in plaintiff's Complaint are without merit, and intends to vigorously dispute them.

Nephron

On September 21, 2018, Nephron Pharmaceuticals Corporation, Nephron S.C., Inc., and Nephron Sterile Compounding Center LLC (collectively, "Nephron") filed a lawsuit in the United States District Court for the Middle District of Florida, Orlando Division, alleging claims against our wholly owned subsidiary USC —and a USC employee who previously was an employee of Nephron. The original complaint asserted thirteen causes of action against the employee and USC alleging generally misappropriation of Nephron's trade secrets. The plaintiffs subsequently amended their complaint to include Adamis as a defendant. After several motions to dismiss, only four claims remained from the third amended complaint: (1) misappropriation under the Federal Defend Trade Secrets Act ("DFSA"), (2) breach of contract (against the employee only), (3) misappropriation under the Florida Uniform Trade Secrets Act ("FUTSA"), and (4) tortious interference with an advantageous business relationship. The gravamen of these claims was that the employee improperly misappropriated trade secret information from the employee's former employer, Nephron, prior to starting employment at USC and that USC improperly recruited the employee for employment at USC. The third amended complaint alleged that Adamis and USC aided in this misappropriation by "using and/or disclosing and/or retaining the same in an effort to unfairly compete against Nephron." The third amended complaint sought actual, compensatory, consequential, special, and punitive damages, attorneys' fees and costs, prejudgment interest, preliminary and permanent injunctive relief, and other relief. On September 3, 2019, Adamis and USC answered denying the claims and asserting various defenses and affirmative defenses.

Fact discovery closed on March 2, 2020. Expert discovery, including regarding the alleged damages that Nephron sought against Adamis and USC, occurred during the second and third quarters of 2020. On May 6, 2020, Adamis and USC moved for summary judgment to dismiss the three claims that remained pending against them. In October 2020, the magistrate judge presiding over the motion delivered a Report and Recommendation recommending that the court enter an order granting the motion in part and denying the motion in part. The magistrate recommended that the court deny the motion for summary judgment by Adamis and USC with respect to the plaintiffs' claims under the DFSA and FUTSA, concluding that there were triable issues of material fact that precluded the entry of summary judgment, and that the court grant the motion for summary judgment in favor of Adamis and USC with respect to the claim for tortious interference. Adamis and USC filed objections to the Report and Recommendation with the court; however, the court adopted the recommendation of the magistrate and granted in part and denied in part the motion of Adamis and USC for summary judgment. Pursuant to court procedures, a mediation between the parties was held in October 2020, and the case was not resolved. In March 2021, the court granted a motion by Nephron to hold Adamis and USC in civil contempt for violation of a previous consent preliminary injunction related to the hiring by USC of an employee, and ordered that Adamis and USC compensate Nephron for certain fees and expenses in the litigation relating to the matter as well as pay a fine, in an amount to be determined. A hearing on the amount of such sanctions was held on April 6, 2021, but decisions regarding sanctions were deferred until after trial. After the hearing, the court ruled on various pre-trial motions relating to the conduct of the trial. The case was set for trial on April 19, 2021.

While we continue to believe that the claims and damages sought by the plaintiff were without merit, in light of several factors including the recent hearing and outcome of decisions concerning pre-trial motions, the legal expenses of ongoing litigation and trial, the uncertainties of litigation and jury trials, and the possibility of punitive damages and other adverse awards or sanctions, on April 9, 2021, Adamis, USC and Nephron agreed to terms of settlement of the Florida litigation as well as a related case filed by Nephron against USC, Adamis and a second USC employee in the United States District Court for the District of New Jersey alleging misappropriation of trade secrets from Nephron. The terms of the settlement will be reflected in a definitive settlement agreement and related documents to be prepared and entered into by the parties thereto. Pursuant to the proposed terms of the settlement, Adamis will pay Nephron an amount equal to $7,900,000 following execution of the settlement agreement, Adamis and USC will destroy or delete all Nephron information and materials in their possession, Adamis and USC will agree to a permanent injunction reflecting certain terms of the settlement and pursuant to which they will agree, among other things, not to use any proprietary or confidential information of Nephron, and Nephron will agree to dismissal of the litigation and dismissal of or withdrawal from the related legal proceeding in New Jersey. See Note 14 of the Notes to the consolidated financial statements included elsewhere herein for additional information.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Common Stock

Our common stock is traded on the Nasdaq Capital Market under the trading symbol "ADMP." As of December 31, 2021, we had approximately 79 common stock holders of record. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of our common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. The actual number of common stockholders is greater than the number of record holders, and includes shareholders 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. Information required by Item 5 of Form 10-K regarding our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Dividend Policy

We have never declared or paid any cash dividends on our common stock, and we do not intend to do so in the foreseeable future. Accordingly, our stockholders will not receive a return on their investment unless the value of our shares increases, which may or may not occur. Any future determination to pay cash dividends will be at the discretion of our board of directors and will depend upon our financial condition, operating results, capital requirements, any applicable contractual restrictions and such other factors as our deems relevant.

Recent Sales of Unregistered Securities

Except as set forth below, information concerning our sales of unregistered securities during the year ended December 31, 2021, has previously been reported in reports on Form 10-Q and reports on Form 8-K that we filed during that fiscal year.

As we previously reported on a Form 8-K filed with the SEC on October 4, 2021, in connection with the appointment of Meera J. Desai, Ph.D., as a director of the company, on October 1, 2021, Dr. Desai was granted a cash stock appreciation right (the "SAR"). The SAR provides for a reference price equal to the fair market value of the common stock of the company of the date of grant of the SAR, and a reference number of shares equal to 50,000 shares. The SAR vests with respect to 1/6 of the reference number of shares on the six-month anniversary of the grant date and vests monthly thereafter in equal installments over a period of three years from the grant date, subject to the recipient providing continuous service to the company. The SAR has a term of seven years. The vested portion of the SAR may be settled only in cash and may be exercised for a period of 12 months after the date of termination of the recipient's service to the company. Upon settlement, the company will pay to the recipient an amount of cash equal to the difference between the fair market value of the common stock on the date of termination of service or, if lower, on the date of exercise, and the initial reference price, multiplied by the number of shares as to which the SAR is being exercised. In the event of a change of control of the company before the SAR is fully vested, vesting and exercisability is accelerated. The SAR was granted to an accredited investor, in reliance on the exemption from registration requirements under Section 4(a)(2) of the Securities Act. Dr. Desai represented that the SAR was being acquired for investment purposes, for her own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the Securities Act.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements and accompanying notes of the company appearing elsewhere in this Report. This discussion of our financial condition and results of operations contains certain statements that are not strictly historical and are "forward-looking" statements and involve a high degree of risk and uncertainty. Actual results may differ materially from those projected in the forward-looking statements due to other risks and uncertainties that exist in our operations, development efforts and business environment, including those set forth in this Item 7, and in the sections entitled "1A. Risk Factors" and "1. Business" in this Report and uncertainties described elsewhere in this Report. All forward-looking statements included in this Report are based on information available to the company as of the date hereof.

General

Company Overview

Adamis Pharmaceuticals Corporation ("we," "us," "our," "Adamis" or the "company") is a specialty biopharmaceutical company focused on developing and commercializing products in various therapeutic areas, including allergy, opioid overdose, respiratory and inflammatory disease. Our products and product candidates in the allergy, respiratory, and opioid overdose markets include: SYMJEPI™ (epinephrine) Injection 0.3mg, which was approved by the U.S. Food and Drug Administration, or FDA, in 2017 for use in the emergency treatment of acute allergic reactions, including anaphylaxis, for patients weighing 66 pounds or more; SYMJEPI (epinephrine) Injection 0.15mg, which was approved by the FDA in September 2018, for use in the treatment of anaphylaxis for patients weighing 33-65 pounds; ZIMHI™ (naloxone HCL Injection, USP) 5 mg/0.5 mL, which was approved by the FDA in October 2021 for the treatment of opioid overdose; and Tempol, an investigational drug. In June 2020, we entered into a license agreement with a third party to license rights under patents, patent applications and related know-how of the licensor relating to Tempol. The exclusive license includes the worldwide use under the licensed patent rights and related rights for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection, as well as the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. We commenced Phase 2/3 clinical trial start-up activities to examine the safety and efficacy of Tempol in COVID-19 patients early in the infection and on September 2, 2021, we announced the initiation of patient dosing in the trial, and in February 2022 we announced that due to the acceleration of patient enrollment in the trial, the Data Safety Monitoring Board, or DSMB, held an *ad hoc* meeting to evaluate initial interim clinical and safety data for the trial and determined that the trial may continue as there were no safety or clinical concerns identified, and that the data from the first 50 subjects will be reviewed again, anticipated to be in March 2022, when the DSMB will examine additional clinical and safety data as part of the first planned DSMB interim analysis. Assuming continuation of the trial and continued enrollment of patients, following submission of additional data and information to the DSMB, the DSMB will conduct a second planned review, which may provide additional insight into the safety and clinical results at that time. Our goal is to create low cost therapeutic alternatives to existing treatments. Consistent across all specialty pharmaceuticals product lines, we intend to submit NDAs under Section 505(b)(2), of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, or Section 505(j) Abbreviated New Drug Applications, or ANDAs, to the FDA, whenever possible, in order to potentially reduce the time to market and to save on costs, compared to those associated with Section 505(b)(1) NDAs for new drug products.

Our US Compounding Inc. subsidiary, or USC, which we acquired in April 2016 and which is registered as a human drug compounding outsourcing facility under Section 503B of the FDCA and the U.S. Drug Quality and Security Act, or DQSA, provided prescription compounded medications, including compounded sterile preparations and nonsterile compounds, to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. In July 2021, we sold certain assets relating to USC's human compounding pharmaceutical business and approved a restructuring process to wind down the remaining USC business and sell, liquidate or otherwise dispose of the remaining USC assets. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer selling compounded pharmaceutical or veterinary products.

To achieve our goals and support our overall strategy, we may need to raise additional funding in the future and make significant investments in, among other things, product development and working capital.

SYMJEPI (epinephrine) Injection Product

On June 15, 2017, the FDA approved our SYMJEPI (epinephrine) Injection 0.3mg product for the emergency treatment of allergic reactions (Type I) including anaphylaxis. SYMJEPI (epinephrine) Injection 0.3mg is intended to deliver a dose of epinephrine, which is used for emergency, immediate administration in acute anaphylactic reactions to insect stings or bites, allergic reaction to certain foods, drugs and other allergens, as well as idiopathic or exercise-induced anaphylaxis for patients weighing 66 pounds or more. On September 27, 2018, the FDA approved our lower dose SYMJEPI (epinephrine) Injection 0.15mg product, for the emergency treatment of allergic reactions (Type I) including anaphylaxis in patients weighing 33 to 66 pounds.

In July 2018, we entered into a Distribution and Commercialization Agreement, or the Sandoz Agreement, with Sandoz Inc., or Sandoz, to commercialize both of our SYMJEPI products. In January 2019, we announced that Sandoz had launched

SYMJEPI (epinephrine) 0.3 mg Injection in the U.S. market, initially available in the institutional setting. On July 9, 2019, we announced the full launch (institutional and retail) by Sandoz of both dose forms of the SYMJEPI injection products.

On May 11, 2020, we announced that we entered into an agreement, or the Termination Agreement, with Sandoz to terminate the Sandoz Agreement and simultaneously announced that we entered into an exclusive distribution and commercialization agreement, or the USWM Agreement, with USWM, LLC, or USWM or US WorldMeds, for the United States commercial rights for the SYMJEPI products, as well as for our ZIMHI product. Under the terms of the USWM Agreement, we appointed USWM as the exclusive distributor of SYMJEPI in the United States and related territories, or the Territory, effective upon the termination of the Sandoz Agreement, and of the ZIMHI product if approved by the FDA for marketing, and granted USWM an exclusive license under our patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the products in the Territory, in partial consideration of an initial payment of $1,000,000 by USWM and potential additional regulatory and commercial based milestone payments. There can be no assurances that any of these milestones will be met or that any milestone payments will be paid to us. We retain rights to the intellectual property subject to the USWM Agreement and to commercialize both products outside of the Territory. In addition, we may continue to use the licensed intellectual property (excluding certain of the licensed trademarks) to develop and commercialize other products (with certain exceptions), including products that utilize our Symject™ syringe product platform.

The USWM Agreement provides that, after deducting the supply price and subject to certain other deductions and adjustments, including an allocation for USWM sales and distribution expenses from net sales of the products, USWM will pay to us 50% of the net profit from net sales, as each such term is defined in the USWM Agreement, of the product in the Territory to third parties, determined on a quarterly basis. We will be the supplier of the products to USWM, and USWM will order and pay us a supply price for quantities of products ordered. The agreement does not include minimum payments to us by USWM, minimum requirements for sales of product by USWM or, with certain exceptions, minimum purchase commitments by USWM.

On March 21, 2022, we announced a voluntary recall of four lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes to the consumer level. The four lots are being recalled due to the potential clogging of the needle preventing the dispensing of epinephrine. USWM will handle the entire recall process for the company, with company oversight. SYMJEPI is manufactured and tested for us by Catalent Belgium S.A. As of the date of this Report, neither USWM nor we have received, or are aware of, any adverse events related to this recall. The recall is being conducted with the knowledge of the FDA.

ZIMHI (naloxone) Injection

Naloxone is an opioid antagonist used to treat narcotic overdoses. Naloxone, which is generally considered the drug of choice for immediate administration for opioid overdose, blocks or reverses the effects of the opioid, including extreme drowsiness, slowed breathing, or loss of consciousness. Common opioids include morphine, heroin, tramadol, oxycodone, hydrocodone and fentanyl.

On December 31, 2018, we filed an NDA with the FDA relating to our higher dose naloxone injection product, ZIMHI, for the treatment of opioid overdose. On November 22, 2019, we received a Complete Response Letter, or CRL, from the FDA regarding our NDA for ZIMHI. A CRL is issued by the FDA's Center for Drug Evaluation and Research when it has completed its review of a file and questions remain that preclude the approval of the NDA in its current form. The CRL stated that the FDA determined that it could not approve the NDA in its present form and provided recommendations needed for resubmission. In May 2020 we resubmitted to the FDA the NDA for ZIMHI. On November 13, 2020, we received a second CRL from the FDA regarding the resubmitted NDA. In May 2021 we resubmitted the NDA for ZIMHI to the FDA. On October 18, 2021, we announced that the FDA had approved ZIMHI for the treatment of opioid overdose. On March 31, 2022, our commercial partner USWM and we issued a press release announcing the commercial launch of ZIMHI.

Tempol (APC400)

On June 12, 2020, we entered into a license agreement with Matrix Biomed, Inc., or the Licensor, to license rights under patents, patent applications and related know-how of Licensor relating to Tempol, an investigational drug. The exclusive license includes the worldwide use under the licensed patent rights and related rights of Tempol for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection. In addition, the exclusive license includes the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. In consideration for the Licensor providing the rights under its patent rights and related know-how relating to Tempol within the licensed fields, we paid Licensor $250,000 and also issued to the Licensor 1,000,000 shares of our Series B Convertible Preferred Stock, which has previously converted into an equal number of shares of our common stock.

Tempol is a redox cycling nitroxide that promotes the metabolism of many reactive oxygen species and improves nitric oxide bioavailability. It has been studied extensively in animal models of oxidative stress and inflammation. Overall, Tempol acts as both a super-oxide dismutase mimetic and also has demonstrated anti-inflammatory, anticoagulant activity and antiviral activity. Inflammation and oxidative stress occur in various disease states including COVID-19. Both inflammatory cytokines and reactive oxygen species (ROS) from cells of the immune system called macrophages and neutrophils damage the lung in Acute Respiratory Distress Syndrome (ARDS). Many published articles describing animal models of ARDS show Tempol caused a decrease in lung inflammation and preserved lung pathology associated with acute and chronic lung injury. In animal models, Tempol has been shown to decrease proinflammatory cytokines (cytokine storm), and through its antioxidant activity has been shown to decrease the harmful effects of ROS. In addition, Tempol has been shown to decrease platelet aggregation, a problem observed in many COVID-19 patients. More recently, Tempol has been shown to have antiviral activity against the virus that causes COVID-19 in-vitro and may have synergy with the antiviral Remdesivir.

Preclinical studies of Tempol have shown it to have antiviral, anti-inflammatory, and antioxidant activity. The company believes this unique mechanism of action, combined with a relatively benign safety profile shown in prior preclinical studies, could provide physicians with a tool to intervene to slow or stop progression of COVID-19 or inflammation at multiple phases of the disease. If proven, this could provide Tempol with an advantage over oral antiviral drugs the FDA has recently cleared for the treatment of COVID-19.

On January 28, 2021, we announced that in collaboration with the Human Immune Monitoring Center at Stanford University we conducted a study to investigate the effects of Tempol on immune cells from COVID-19 patients, and that preliminary data from that study showed that Tempol decreases cytokines from stimulated cells from COVID-19 patients. In March 2021, we announced that in studies conducted at Galveston National Laboratory, or GNL, University of Texas Medical Branch, hamsters challenged with the virus that causes COVID-19 (SARS-CoV-2) showed decreased inflammation in the lungs when treated with Tempol compared to controls, and on March 22, 2022, we announced that in studies conducted at the GNL, hamsters challenged with high levels of the Omicron variant of the SAR-CoV-2 virus, resulted in significant decrease of inflammation in the lungs of animals treated with Tempol compared to controls.

In July 2020, we submitted to the FDA a pre-IND package which provided a protocol for a Phase 2/3 study examining Tempol in COVID-19 patients, and the FDA provided comments regarding the prospective use of Tempol in a randomized placebo controlled trial. In January 2021, we submitted an IND to the FDA for the investigational use of Tempol for the treatment of COVID-19. On February 22, 2021, we announced that the FDA notified the company that the agency had completed the safety review of the IND and concluded that the company may proceed with the proposed clinical investigation and trial described in the IND. The goal of the study titled, "A Phase 2/3, Adaptive, Randomized, Double-Blind, Placebo-Controlled Study to Examine the Effects of Tempol (MBM-02) on Preventing COVID-19 Related Hospitalization in Subjects with COVID-19 Infection," is to examine the safety and activity of Tempol in COVID-19 patients early in the infection. In addition to safety, the study will examine markers of inflammation and the rate of hospitalization for patients taking Tempol versus placebo early in COVID-19 infection. On June 11, 2021, we announced that clinical trial start-up activities were underway, that the company was carrying out those activities with a large clinical research organization, that commenced activities included site identification and initiation, data base production, vendor management, and the establishment of an independent data safety monitoring board, or DSMB, of infectious disease experts, who will review the safety and efficacy of the trial, and that clinical trial drug product and placebo have also been obtained. On September 2, 2021, we announced the initiation of patient dosing in the trial. Our trial requires individuals with moderate COVID-19 symptoms to be unvaccinated and have co-morbidities such as heart disease, as those patients typically have worse outcomes, requiring hospitalization. We initially experienced enrollment challenges primarily as a result of the decrease in COVID-19 infections and increased immunizations in the United States. We took certain responsive steps including opening new sites across the U.S. and modifying the protocol to include vaccinated subjects.

In February 2022 we announced the enrollment and dosing of more than 100 subjects in the Phase 2/3 trial. On March 14, 2022, we announced that the Data Safety Monitoring Board, or DSMB, is overseeing the Phase 2/3 clinical trial met to evaluate the clinical and safety data from the first planned interim analysis and, following its evaluation, recommended that the study continue without modification. Assuming continuation of the trial and continued enrollment of patients, following submission of additional data and information to the DSMB, the DSMB will conduct a second planned review, currently anticipated to be in May 2022, which may provide additional insight into the safety and clinical results at that time. In January 2022, we submitted a Fast Track Application to the FDA for Tempol for the treatment and prevention of COVID-19. Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fulfill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions and the request can be initiated by the drug company at any time during the development process. The FDA will review the request and decide based on whether the drug fills an unmet medical need in a serious condition. Once a drug receives Fast Track designation, early and frequent communication between the FDA and the drug company is encouraged throughout the entire drug development and review process. In March 2022, we received a communication from the FDA denying our request for Fast Track designation for our Tempol product at this time, indicating that the program did not satisfy the requirements for Fast Track designation.

US Compounding, Inc.

On July 30, 2021, the company and its wholly-owned USC subsidiary entered into an Asset Purchase Agreement, or the USC Agreement, effective as of July 30, 2021, or the Effective Date, with Fagron Compounding Services, LLC d/b/a Fagron Sterile Services (the "Purchaser"), providing for the sale and transfer by USC and the purchase by the Purchaser, effective as of the Effective Date, of certain assets of USC related to its human compounding pharmaceutical business, or the Business, including certain customer information and information on products sold to such customers by USC, together, the "Book of Business," including related formulations, know-how, and expertise regarding the compounding of pharmaceutical preparations, clinical support knowledge and other data and certain other information relating to the customers and products, collectively referred to as the "Assets." After the Effective Date, Purchaser may use the Book of Business to secure customers for its products and services and may otherwise use the Book of Business. Pursuant to the USC Agreement, the Purchaser will not assume any liabilities of USC, and the transaction did not include the sale or transfer of any USC equipment, buildings or real property, or any products, information, agreements, relationships or other assets relating to the veterinary business of USC.

The USC Agreement provides that the consideration payable by the Purchaser to the company for the Assets sold and transferred will consist of the following amounts: (i) a payment of $107,500 on the Effective Date; and (ii) monthly payments in an amount equal to (a) two (2.0) times the amount actually collected by Purchaser or its affiliates for sales of products or services made to certain identified customers included in the Book of Business during the 12-month period following the Effective Date, or the "Payment Term." and (b) a lower multiple of the amount actually collected by Purchaser or its affiliates for sales of products or services made to certain other customers included in the Book of Business. In addition, to the extent that such product or service is supplied by USC pursuant to the supply arrangement provided for by the USC Agreement, or the "Supply Agreement," the Purchaser agreed to reimburse USC for the cost of such product or service, as set forth in the Supply Agreement. The USC Agreement provides that during the Payment Term, the Purchaser will maintain the Book of Business and use commercially reasonable efforts to maximize the consideration payable to the company and collect amounts outstanding related to sales of products or services made to customers included in the Book of Business. However, the USC Agreement does not provide for any minimum purchase price consideration to the company or USC. Accordingly, there is no assurance as to the amount of purchase price consideration that the company or USC may ultimately receive as a result of the transactions contemplated by the USC Agreement. Certain of the customers included in the Book of Business may decide to not purchase products or to reduce their purchases of products from Purchaser after the Effective Date, and Purchaser may, in good faith, decide not to change its product mix from those products offered by Purchaser as of the Effective Date and may decide not to carry all of the products offered and sold by USC as part of the Business prior to the Effective Date.

The USC Agreement includes certain restrictive covenants of the company and USC, including noncompetition provisions, pursuant to which, for a period of five years from the Effective Date, or the "Restricted Period," and subject to certain exceptions, the company and USC have agreed, among other matters, not to solicit any Business from any customers included in the Book of Business or engage in certain other activities. Each of the USC Agreement and the Supply Agreement includes standard indemnification provisions, and a number of other covenants and agreements of the parties concerning the transactions contemplated by the USC Agreement and the Supply Agreement, including concerning cooperation and assistance, confidentiality, non-disparagement and the transfer of information and documents, compliance with laws, and personnel matters. The USC Agreement includes indemnification provisions pursuant to which the company and USC agreed to indemnify the Purchaser and certain related parties against losses incurred by such indemnified parties arising or resulting from certain matters including breach of the USC Agreement by USC and third party claims relating to product sales to customers by USC before the Effective Date. In connection with the transaction, the company accrued a $700,000 liability for a transaction fee payable to a financial advisor as of December 31, 2021.

Plan for the Remaining Operations, Business and Assets of USC

In light of a number of factors including the sale of assets to the Purchaser pursuant to the USC Agreement, in August 2021 the Board approved a restructuring process of winding down the remaining operations and business of USC and selling, transferring or disposing of the remaining assets of USC. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer selling compounded pharmaceutical or veterinary products. The restructuring and winding down includes, without limitation, the termination of USC's veterinary business and USC sales to veterinary customers; the termination of employment of all or substantially all employees engaged in the USC business (except as determined to be necessary or appropriate in connection with the company's and USC's performance of their obligations under the USC Agreement and the transactions contemplated thereby, or in connection with resolving matters relating to the winding down of USC's business), and providing such notices and making such payments to such employees as the officers of the company determine are necessary or appropriate, including as maybe required by law or as maybe provided for pursuant to any retention agreement, severance agreement, incentive agreement, or other written agreement with such employees; the sale or other disposition from time to time of the remaining equipment, real property, buildings and tangible and intangible assets relating to USC's business that are unrelated to the USC Agreement; the termination, assignment or other resolution of agreements with third parties relating to the USC business; making regulatory filings and taking appropriate actions with federal and state regulatory authorities in connection with the winding down and winding up of USC's business; and taking such other actions as the officers of the company or USC (as appropriate) determine are necessary or appropriate in connection with the restructuring and the winding down and winding up of the remaining business, operations and assets of USC. The company has sold and disposed of certain customer information and other assets related to USC's veterinary compounded pharmaceuticals business, and will continue the process of selling or otherwise disposing of the remaining assets relating to USC's business.

In connection with the winding down of the USC business, we incurred significant expenses and made a number of payments. The substantial majority of cash payments related to personnel-related restructuring charges, including without limitation costs associated with providing termination payments to USC employees, employee salaries and incentive payments during a transition period after the effective date of the sale of the Assets pursuant to the USC Agreement, severance or other termination benefits or payments in connection with workforce reduction and termination of employment, and payments pursuant to retention agreements or incentive agreements with certain employees, were made during the third and fourth quarters of 2021 and were approximately $1.6 million. In addition, as part of the winding down of USC's business, we have incurred other costs. We also expect to incur commissions and other costs associated with the sale or other disposition of certain USC tangible assets such as building, property and certain equipment.

As a result of the transactions contemplated by the USC Agreement and the restructuring activities described above, the company's financial results for the 2021 year include approximately $8.6 million for the impairment charges of inventory, fixed assets, intangibles, goodwill and right of use assets. The impairment charges that the company incurred and expects to incur in connection with the matters described above are subject to a number of assumptions, and the actual amount of impairment charges may differ materially from those estimated by the company. In addition, the company may determine in the future that additional impairments of assets are appropriate in connection with the matters described above.

Going Concern and Management Plan

The financial statements included elsewhere herein for the year ended December 31, 2021, were prepared under the assumption that we would continue our operations as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. However, as of December 31, 2021, we had cash and cash equivalents of approximately $23.2 million, an accumulated deficit of approximately $278.1 million, and liabilities of approximately $12.4 million. We have incurred substantial recurring losses from continuing operations, have used, rather than provided, cash in our continuing operations, and are dependent on additional financing to fund operations. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued. The financial statements included elsewhere herein do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Our management intends to attempt to secure additional required funding through equity or debt financing if available, sales or out-licensing of product candidates or intellectual property assets, revenues relating to supply and sale of SYMJEPI and ZIMHI products and share of net profits received relating to sales in the U.S. of our SYMJEPI and ZIMHI products, seeking partnerships or commercialization agreements with other pharmaceutical companies or third parties to co-develop and fund research and development or commercialization efforts of our products, from a business combination, or similar transactions. However, there can be no assurance that we will be able to obtain any sources of funding. Such additional funding may not be available, may not be available on reasonable terms, and, in the case of equity financing transactions, could result in significant additional dilution to our stockholders. If we do not obtain required additional equity or debt funding, our cash resources will be depleted and we could be required to materially reduce or suspend operations, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that could result in our stockholders losing some or all of their investment in us.

Funding that we may receive during fiscal 2022 is expected to be used to satisfy existing and future obligations and liabilities and working capital needs, to support commercialization of our products and conduct the clinical and regulatory work to develop our product candidates, to begin building working capital reserves and to help fund a number of projects, which may include, without limitation, some or all of the following:

- commercialization of our ZIMHI (naloxone) product;
- continue development of our allergy and respiratory product candidates;
- pursue the development of other product candidates that we may develop or acquire;
- fund clinical trials of Tempol and other product candidates;
- expand research and development activities;
- access manufacturing, commercialization and sales capabilities;
- implement additional internal systems and infrastructure;
- maintain, defend and expand the scope of our intellectual property portfolio;
- acquire products, technologies, intellectual property or companies and support continued development and funding thereof; and
- hire additional management, sales, research, development and clinical personnel.

Results of Operations

Our consolidated results of operations are presented for the year ending December 31, 2021 and for the year ending December 31, 2020. The financial results (revenues and expenses) relating to the USC business are reflected in Note 4, Discontinued Operations and Assets Held for Sale, of the notes to the consolidated financial statements appearing elsewhere in this Report. The discussion below, and the revenues and expenses discussed below, are based on and relate to the continuing operations of the company, which we sometimes refer to as our drug development and commercialization business, unless otherwise noted.

Years Ended December 31, 2021 and 2020

Revenues. Revenues were approximately $2,209,000 and $2,777,000 for the year ended December 31, 2021 and 2020, respectively. Revenue relating to the sales of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg increased approximately $1,432,000 primarily due to increased unit sales of SYMJEPI as a result of the sales and marketing initiatives of our distribution partner, USWM, when compared with the comparable 2020 period, but were offset by and reflect approximately $2.0 million in product recall reserves recorded for the year ended December 31, 2021, relating to the voluntary recall, initiated in March 2022, of certain lots of SYMJEPI from the marketplace. The company may be able to be reimbursed by certain third parties for some of the costs of the recall under the terms of its manufacturing agreements, but there are no assurances regarding the amount or timing of any such recovery. The recall may have an adverse effect on the amount or timing of our revenues, and on our financial results and liquidity, for fiscal quarters in 2022 or thereafter, although as of the date of this Report the amount of any such impact cannot be predicted with certainty.

Cost of Goods Sold. Our cost of goods sold includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, shipping and handling costs, the write-off of obsolete inventory and other related expenses. Cost of goods sold was approximately $6,872,000 and $6,327,000 for the year ended December 31, 2021 and 2020, respectively. The gross loss percentage for the year ended December 31, 2021 was approximately 211% compared to approximately 128% for the year ended December 31, 2020. Cost of goods sold for the year ended December 31, 2021 compared to the comparable period of 2020 increased by approximately $545,000 primarily due to an increase of approximately $1,210,000 in direct material costs, including a loss of approximately $245,000 related to the derecognition of certain inventory , partially offset by an approximately $665,000 decrease in maintenance fees and other related expense.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses consist primarily of depreciation and amortization, professional fees which include legal, accounting and audit fees, consulting, and employee compensation. *SG&A expenses* for the year ended December 31, 2021 and 2020 were approximately $16,144,000 and $20,090,000, respectively. The decrease was primarily attributable to expenses relating to a legal settlement of approximately $7,900,000 recorded in 2020 compared to $0 recorded for the year ending in December 31, 2021. There was also a decrease of approximately $971,000 in depreciation and amortization expense for the 2021 year compared to 2020 as a result of the write-off of the company's Taper dry powder inhaler intellectual property intangible asset in the fourth quarter of 2020, which eliminated amortization expense relating to that asset in future periods, and a decrease of approximately $1,382,000 of compensation related expenses largely attributable to decreased stock compensation expenses as a result of the completion of vesting of certain option grants through February 2021 and also stock-based compensation expense forfeiture credits related to employee terminations. These decreases were partially offset by an increase in 2021 compared to 2020 in professional fees of approximately $5,499,000 primarily attributable to increases in legal expenses, an increase of approximately $700,000 for a fee payable to a financial advisor related to the sale of certain USC assets, and an increase of approximately $108,000 in other administrative costs.

Research and Development Expenses. Our research and development, or R&D, costs are expensed as incurred. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as an asset and are expensed when the research and development activities are performed. R&D expenses were approximately $11,262,000 and $8,040,000 for the year ended December 31, 2021 and 2020, respectively. Approximately $4,333,000 of the increase in R&D expenses for the year ended December 31, 2021, compared to the comparable 2020 period was primarily related to increased development spending on Tempol and ZIMHI, offset by decreased development spending of approximately $65,000 in development spending for other projects. In addition, wages, benefits, and other compensation expenses for research and development employees decreased approximately $1,046,000 during the year ended December 31, 2021, compared to the comparable 2020 period, largely attributed to decreased stock compensation expenses as a result of the completion of vesting certain option grants through February 2021 and unvested RSU fair value modifications.

Impairment Expense Intangibles. Impairment expense of intangibles for the years ended December 31, 2021 and 2020 was approximately $0 and $2,913,000, respectively. The impairment expense in 2020 was primarily due to the impairment of the Taper dry powder inhaler intellectual property asset, as a result of the company's determination not to pursue further development efforts regarding the product candidate related to this intangible.

Impairment Expense, Contract Costs. Impairment expenses of contract costs for the year ended December 31, 2021 and 2020 were approximately $0 and $1,750,000, respectively. As a result of entering into the Termination Agreement with Sandoz, our financial results for the year ended December 31, 2020, included an impairment of the Adamis capitalized cost to obtain a contract of $1,750,000.

Other Income (Expense). Other Income (Expenses) consists primarily of interest income, interest expense, changes to the fair value of warrant liabilities, and other transactions. Other income (expense) for the year ended December 31, 2021 and 2020 was approximately ($2,530,000) and $498,000 respectively. The decrease in other income (expense) during the year ended 2021, compared to the same period in 2020, was primarily due to the increase of other expense of approximately $8,005,000 associated with the change in fair value of warrants, a decrease in interest income of approximately $31,000, and an increase of interest expense of approximately $2,000, offset by an approximately $5,010,000 gain on forgiveness of first and second draws of the Paycheck Protection Program Loan.

Loss from Discontinued Operations. The company recorded a net loss from discontinued operations, after taxes, of approximately $11,228,000 and $13,545,000 related to the US Compounding business for the year ended December 31, 2021 and 2020, respectively. The decrease in loss from discontinued operations of approximately $2.3 million for 2021 compared to 2020 was primarily due to (i) the decrease in gross margin of approximately $4.6 million resulting from a decrease in net revenues of approximately $7.5 million primarily due to decreased unit sales of USC products in 2021 compared to 2020, (ii) a decrease in operating expenses of approximately $2.8 million, partially offset by an approximately $0.7 million increase in impairment expenses, (iii) an increase in other income of approximately $4.7 million primarily due to the gain on sale of assets to Fagron pursuant to the USC Agreement, and (iv) an increase in income tax benefit of approximately $0.1 million. The changes in net revenues, gross margin, operating expenses and other income (expense) were primarily related to the sale of certain assets of USC and the decision to wind down and cease USC's operations. For additional information on discontinued operations, see Note 4, Discontinued Operations and Assets Held for Sale, to our consolidated financial statements included elsewhere in this Report.

Liquidity and Capital Resources

We have incurred net losses of approximately $45.8 million and $49.4 million for the years ended December 31, 2021 and 2020, respectively. Since our inception, June 6, 2006, and through December 31, 2021, we have an accumulated deficit of approximately $278.1 million. Since inception and through December 31, 2021, we have financed our operations principally through debt financing and through public and private issuances of common stock and preferred stock. Since inception, we have raised a total of approximately $269.7 million in debt and equity financing transactions, consisting of approximately $28.5 million in debt financing and approximately $241.2 million in equity financing transactions.

In February 2020, we completed a registered direct offering of 11,600,000 shares of common stock, and a concurrent private placement of warrants to purchase 8,700,000 shares of common stock, to a small number of accredited institutional investors, resulting in estimated net proceeds of approximately $6.2 million. In September 2020, we completed an underwritten public offering of 18,548,386 shares of common stock, resulting in estimated net proceeds of approximately $10.7 million. In February 2021, we completed an underwritten public offering of 46,621,621 shares of common stock, resulting in estimated net proceeds of approximately $48.4 million. In January and February 2021, we received gross proceeds of approximately $5.8 million from the exercise for cash of previously issued investor warrants.

Net cash used in operating activities for the years ended December 31, 2021 and 2020, was approximately $37.8 million and $20.9 million, respectively. Net cash used in operating activities increased primarily due to the increase in operating losses and the payment of contingent loss liability in 2021 as compared to 2020. Following the winding up of the business of USC and sale or other disposal of its assets, the company believes, based on USC's historical financial results, that there could be a cash benefit to the company as a result of not having to provide continued cash funding to help support USC's business operations.

Net cash provided by (used in) investing activities was approximately $0.3 million and ($0.9) million for the years ended December 31, 2021 and 2020, respectively. The net cash used in investing activities decreased primarily due to the decrease in process research and development ("IPR&D") purchases and cash received on sale of assets, partially offset by the purchase of additional equipment during the year ended December 31, 2021 compared to the year ended December 31, 2020.

Net cash provided by financing activities was approximately $53.9 million and $19.9 million for the years ended December 31, 2021 and 2020, respectively. Net cash flows provided by financing activities increased for the year ended December 31, 2021 primarily due to the issuance of common stock, exercise of warrants and Second Draw PPP Loan under the PPP. For the year ended of 2020, net cash used in financing activities consisted primarily of issuance of common stock and the initial draw of PPP Loan.

At December 31, 2021, we did not have any off balance sheet arrangements.

Loan Agreements

USC Building Loan. In connection with our acquisition of USC in 2016, we assumed approximately $5,722,000 principal amount of debt obligations under two loan agreements and related loan documents relating to the building, real property and equipment that certain third parties agreed to transfer to the company or USC in connection with the merger transaction, as well as the two loan agreements to which USC is a party, a working capital loan and an equipment loan, and related loan documents evidencing loans previously made to USC, and we agreed to become an additional co-borrower under the loan agreement and related documents, such documents as amended referred to as the "Loan Documents." The lender in all of the Loan Documents was First Federal Bank and/or its successor Bear State Bank (together with Arvest Bank, as successor in interest to Bear State Bank, referred to as "Lender" or the "Bank"). All amounts owed under the working capital loan and the equipment loan have previously been paid and there are no outstanding balances under those Loan Documents, and the working capital loan has not been renewed or extended. Periodic interest and principal payments under the building loan agreement were approximately $19,000 per month, with a final payment of all outstanding amounts due and payable in August 2021. Our aggregate indebtedness under the building loan agreement was approximately $2,018,000, which we paid in full in July 2021. There is no outstanding balance under the building loan or any of the other Loan Documents.

PPP Loans. As discussed in Note 12 to the financial statements included elsewhere herein, we applied for and obtained loan funding under the PPP pursuant to the PPP Loan and PPP Note in the principal amount of approximately $3.2 million, the balance of which has been forgiven, and under the Second Draw PPP Loan and PPP2 Note in the principal amount of $1,765,495, the balance of which has also been forgiven. However, even though the PPP Loan and the Second Draw PPP Loan have been forgiven, our PPP loans and applications for forgiveness of loan amounts remain subject to future review and audit by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form, including without limitation the required economic necessity certification by the Company that was part of the PPP loan application process. Accordingly, the Company is subject to audit or review by federal or state regulatory authorities as a result of applying for and obtaining the PPP Loan and Second Draw PPP Loan or obtaining forgiveness of those loans. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return or repay the full amount of the applicable loan and could be subject to fines or penalties, which could reduce our liquidity and adversely affect our business, financial condition and results of operations. If it is determined that the Company was ineligible to receive the PPP Loan and/or the Second Draw PPP Loan, the Company may be required to repay the PPP Loan and Second Draw PPP Loan in its entirety and/or be subject to additional penalties, which could reduce our liquidity and adversely affect our business, financial condition and results of operations.

For additional information concerning our debt and equity financing transactions, and our loan agreements, see Notes 10, 12, 17, 18 and 19 accompanying our consolidated financial statements included elsewhere herein.

As noted above under the heading "Going Concern and Management Plan," through December 31, 2021, we have incurred substantial losses. We will be required to devote significant cash resources in order to continue development and commercialization of our product candidates and to support our other operations and activities. The availability of any required additional funding cannot be assured. In addition, an adverse outcome in legal or regulatory proceedings in which we are or in the future could be involved could adversely affect our liquidity and financial position. See Note 14 of the notes to our consolidated financial statements included elsewhere herein. If in the future we are not able to obtain additional required equity or debt funding, our cash resources could be depleted and we could be required to materially reduce or suspend operations. No assurance can be given as to the timing or ultimate success of obtaining future funding, if required. Even if we are successful in obtaining required additional funding to permit us to continue operations at the levels that we desire, substantial time may pass before we obtain regulatory marketing approval for any additional specialty pharmaceutical products and begin to realize revenues from sales of such additional products. No assurance can be given as to the timing or ultimate success of obtaining any required future funding. As a result of the COVID-19 pandemic and actions taken to slow its spread, national or global developments, or other factors, there can be no assurance that deterioration in credit and financial markets will not occur, which would make it more difficult, or more costly or dilutive, to obtain any necessary debt or equity financing.

As disclosed elsewhere in this Report, including in Part I, Item 3, "Legal Proceedings," on May 11, 2021, each of the company and its USC subsidiary received a grand jury subpoena from the U.S. Attorney's Office for the Southern District of New York issued in connection with a criminal investigation, requesting a broad range of documents and materials relating to, among other matters, certain veterinary products sold by the company's USC subsidiary, certain practices, agreements and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC. The Audit Committee of the Board engaged outside counsel to conduct an independent internal investigation to review these and other matters. In addition to the subpoenas from the USAO, the company has also received requests from the SEC for the voluntary production of documents and information relating to the subject matter of the USAO's subpoenas and certain other matters. The company has produced documents and will continue to produce and provide documents in response to the subpoenas and requests. The company intends to cooperate with the USAO and the SEC. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, or other agencies, or determine what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate, what, if any, remedies or remedial measures the USAO, SEC or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the company's business, previously reported financial results, financial results included in this Report, or future financial results. The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, result in fines, penalties, equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, or future financial results. The occurrence of any of these events could have a material adverse effect on the company's business, financial condition and results of operations.

Material Cash Requirements

Based on our current and anticipated level of operations, we believe that our cash, cash equivalents and short-term investments, together with anticipated revenues from operations and amounts that we expect to receive as a result of our sales of assets relating to our former USC business, will be sufficient to meet our anticipated obligations for at least 12 months from December 31, 2021, although there can be no assurance that this will be the case. Thereafter, we believe that additional capital will be required to help fund the development and commercialization of our products and product candidates, conduct research, development and trials relating to our product candidates, fund our ongoing operations and satisfy our obligations and liabilities. Additional financing that may be required may not be available on a timely basis, on favorable terms, or at all, and such funding, if raised, may not be sufficient to meet our obligations or enable us to continue to implement our long-term business strategy.

As December 31, 2021, we had an operating lease for office space for our offices in San Diego, California, with a remaining term expiring in November 2023. Monthly rent through the remaining term of the lease is approximately $32,000 per month. We also have a lease agreement for space located in Conway, Arkansas, relating to the compounding pharmaceutical products business formerly conducted by our USC subsidiary, with a current term expiring December 31, 2023. As a result of the sale of assets pursuant to the USC Agreement and the winding down of USC's remaining business, the company will not need the leased property. Monthly rent for the remaining term of this lease is approximately $10,600 per month. The company is exploring alternatives with respect to termination of the lease or sub-lease of the property. See Note 10 of the notes to the consolidated financial statements included elsewhere herein for additional information about our lease obligations.

We have entered into arrangements with clinical sites and clinical research organizations, or CROs, for the conduct of our clinical trials. We make payments to these clinical sites and CROs based in part on the number of eligible patients enrolled, the length of their participation in the clinical trials and activities undertaken by the clinical sites and CROs. At this time, due to the variability associated with clinical site agreements, CRO agreements and manufacturing agreements, we are unable to estimate with certainty the future costs we will incur, including in connection with our ongoing Phase 2/3 clinical trial relating to Tempol, but such expenses could be material. In addition, we have entered into agreements and arrangements with third parties for the manufacture and supply of clinical and commercial materials and drug products, including for our SYMJEPI and ZIMHI products and our current clinical trial for our Tempol product candidate. In some of our agreements with manufacturers, we have a production threshold commitment where we would be required to pay for maintenance fees if we do not meet certain periodic purchase order minimums. Maintenance fees for the year ended December 31, 2021 were $0. Under certain of these agreements, we may be subject to penalties in the event that we prematurely terminate these agreements. We intend to use our current financial resources to fund our obligations under these commitments.

As disclosed elsewhere in this Report, on March 21, 2022, we announced a voluntary recall of four lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes to the consumer level, due to the potential clogging of the needle preventing the dispensing of epinephrine. USWM will handle the entire recall process for the company, with company oversight. SYMJEPI is manufactured and tested for us by Catalent Belgium S.A. The costs of the recall and the allocation of costs of the recall, including the costs to us resulting from the recall, are unknown as of the date of this Report; however, the recall could cause the company to suffer reputational harm, depending on the resolution of matters relating to the recall could result in the company incurring financial costs and expenses which could be material, could adversely affect the supply of SYMJEPI products until manufacturing is resumed, and depending on the resolution of matters relating to the recall could have a material adverse effect on our business, financial condition, and results of operations.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our audited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies and estimates are most critical to aid you in understanding and evaluating our reported financial results. For further discussion of our accounting policies, see Note 3 in the accompanying notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Acquisitions and Intangibles. The accounting for business combinations requires management to make judgments and estimates of the fair value of assets acquired, including the identification and valuation of intangible assets, as well as liabilities assumed. Such judgments and estimates directly impact the amount of goodwill recognized in connection with each acquisition, as goodwill represents the excess of the purchase price of an acquired business over the fair value of its net tangible and identifiable intangible assets.

Discontinued Operations. In accordance with ASC 205-20 *Presentation of Financial Statements: Discontinued Operations*, a disposal of a component of an entity or a group of components of an entity is required to be reported as discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results when the component/s of an entity meets the criteria in paragraph 205-20-45-10. In the period in which the component meets held-for-sale or discontinued operations criteria the major current assets, other assets, current liabilities, and noncurrent liabilities are reported as components of total assets and liabilities separate from those balances of the continuing operations. At the same time, the results of all discontinued operations, less applicable income taxes, is reported as components of net loss separate from the net loss of continuing operations. The company's financial statements as of and for the period ended December 31, 2021 reflect a gain on sale of assets to Fagron pursuant to the USC Agreement of approximately $4.6 million and a receivable from Fagron in the amount of approximately $5.1 million, reflecting in part the estimated fair value of the variable consideration payable to us by Fagron pursuant to the USC Agreement. As described in Note 4 - Discontinued Operations, in the notes to the consolidated financial statements appearing elsewhere in this Report, determining the amount of such variable consideration involves estimates using the expected value method to estimate Fagron's sales to former USC customers over the 12-month period after the date of the USC Agreement, as well as historical data and the company's judgments concerning the expected amount of such variable consideration. As such, the total amount of variable consideration that we may receive in the future as a result of the USC Agreement is subject to change as more information becomes available, and we could receive more, or less, variable consideration proceeds than is reflected in such estimate, which could affect our business, financial condition, and liquidity.

The company disposed of a component of its business in August 2021 and met the definition of a discontinued operation as of December 31, 2021. Accordingly, the operating results of the business disposed are reported as loss from discontinued operations in the accompanying consolidated statements of operations for the years ended December 31, 2021 and 2020. For additional information, see Note 4 - Discontinued Operations, in the notes to the consolidated financial statements appearing elsewhere in this Report.

Goodwill. Goodwill, which has an indefinite useful life, represents the excess of purchase consideration over fair value of net assets acquired. Goodwill is reviewed for impairment at least annually as of December 31 each year, or more frequently if events occur indicating the potential for impairment. During its goodwill impairment review, the company may assess qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and market considerations, and the overall financial performance and outlook of the company. If, after assessing the totality of these qualitative factors, the company determines that it is not more likely than not that the fair value of its reporting unit is less than its carrying amount, then no additional assessment is deemed necessary. Otherwise, the company proceeds to perform the two-step test for goodwill impairment. The first step involves comparing the estimated fair value of the reporting unit with its carrying value, including goodwill. If the carrying amount of the reporting unit exceeds its fair value, the company performs the second step of the goodwill impairment test to determine the amount of loss, which involves comparing the implied fair value of the goodwill to the carrying value of the goodwill. These determinations require management to make significant estimates and assumptions.

The company evaluates its long-lived assets with definite lives, such as property and equipment, acquired technology, customer relationships, patent and license rights, for impairment by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate.

As of March 31, 2020, in light of recent events associated with the global spread of COVID-19 and other factors, we performed a goodwill impairment interim review and recorded a charge of approximately $3,143,000 for impairment of goodwill during the first quarter of 2020. As of December 31, 2020, with the continued decline in revenue during 2020 primarily attributable to the COVID-19 pandemic and other factors affecting our USC compounded pharmaceutical reporting unit, we performed a goodwill impairment review and recorded an additional charge of approximately $3,629,000 for impairment of goodwill in 2020. For the 2021 year, as a result of the transactions contemplated by the USC Agreement and the winding down of activities relating to USC described elsewhere in this Report, our financial results for the year ended December 31, 2021, included an impairment of approximately $868,000 to goodwill. The goodwill impairments were reported under discontinued operations. See Note 4 of the Notes to the consolidated financial statements included elsewhere herein for additional information.

Other Long-Lived Assets. The company evaluates its long-lived assets with definite lives, such as property and equipment, acquired technology, customer relationships, patent and license rights, for impairment by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate.

As of the year ending December 31, 2021, USC's intangible assets were fully impaired as a result of the decision to wind down and cease USC's operations. Prior to that impairment, approximately $1,856,000 of USC's customer relationships intangible asset was allocated to the asset sale to Fagron pursuant to the USC Agreement. That amount is recorded within the gain from sale of assets of discontinued operations. The remaining intangibles had a carrying balance of approximately $3,835,000, which were fully impaired during the year ended December 31, 2021. USC's intangible assets had a carrying value of approximately $0 and $6,280,000 at December 31, 2021 and December 31, 2020, respectively.

As of December 31, 2020, in light of the time and costs involved in further product development efforts and competitive conditions in the relevant markets related to the Taper DPI intellectual property, and our determination not to devote any further substantial financial resources to development of this product candidate or pursue further development efforts regarding this product candidate, we recorded a full impairment charge of approximately $2,913,000 for the year ended December 31, 2020.

The Construction In Progress - Equipment ("CIP") assets were primarily for the expansion of USC's operations, to be placed into service contingent upon the completion of equipment validation and when the economy has recovered from the COVID - 19 pandemic. In light of the delay in putting the CIP assets into service and the lingering effect of the COVID -19 pandemic as of December 31, 2020, the Company had recorded an impairment charge of approximately $1,116,000 for the year ended December 31, 2020. The carrying value of the CIP assets was determined by estimating the fair value of the assets. During the year ended December 31, 2021, we recorded approximately $2,150,000 in losses relating to the fair value of CIP included in the net loss from discontinued operations.

Stock-Based Compensation. We account for stock-based compensation transactions in which we receive employee services in exchange for options to purchase common stock. Stock-based compensation cost for restricted stock units or RSUs is measured based on the closing fair market value of our common stock on the date of grant. Stock-based compensation cost for stock options is estimated at the grant date based on each option's fair-value as calculated by the Black-Scholes option-pricing model. We recognize stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period.

Warrant Liabilities. Warrants are accounted for in accordance with the applicable authoritative accounting guidance as either liabilities or as equity instruments depending on the specific terms of the agreements. Liability-classified instruments are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of warrant liabilities in the consolidated statements of operations and comprehensive loss. The fair value measurement of the warrants issued by the company are based on significant inputs that are unobservable and thus represents a Level 3 measurement. The company's estimated fair value of the Warrant liability is calculated using the Black Scholes Option Pricing Model. Key assumptions include the expected volatility of the company's stock, the company's stock price at valuation date, expected dividend yield and average risk-free interest rate. The Level 3 estimates are based, in part, on subjective assumptions. The company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs.

*Product Recall***.** The company establishes reserves for product recalls on a product-specific basis when circumstances giving rise to the recall become known. The company, when establishing reserves for a product recall, considers cost estimates for any fees and incentives to customers for their effort to return the product, freight and destruction charges for returned products, warehouse and inspection fees, repackaging materials, point-of-sale materials and other costs including costs incurred by contract manufacturers. Additionally, the company estimates product returns from consumers and customers across distribution channels, utilizing third-party data and other assumptions. These factors are updated and reevaluated each period and the related reserves are adjusted when these factors indicate that the recall reserves are either insufficient to cover or exceed the estimated product recall expenses.

Significant changes in the assumptions used to develop estimates for product recall reserves could affect key financial information, including accounts receivable, inventory, accrued liabilities, net sales, gross profit, operating expenses and net income. In addition, estimating product recall reserves requires a high degree of judgment in areas such as estimating consumer returns, shelf and in-stock inventory at retailers across distribution channels, fees and incentives to be earned by customers for their effort to return the products, future freight rates and consumers' claims. During the year ended December 31, 2021, the company recorded $2.0 million in reserves for product recall. The recall of certain lots of SYMJEPI from the marketplace was initiated in March 2022.

Recent Accounting Pronouncements

Recent accounting pronouncements are disclosed in Note 3 to the accompanying consolidated financial statements included in Item 15 of this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and financial information required by Item 8 are set forth below commencing on page F-1.

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

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, filed under the Securities Exchange Act of 1934, 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 chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance and not absolute assurance of achieving their objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by the SEC Rule 13a-15(b), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2021, for the reasons described below.

Internal Control over Financial Reporting

Management's report on our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) in the Exchange Act), is included in this Annual Report on Form 10-K, under the heading "Management's Report on Internal Control Over Financial Reporting". We have not experienced any material impact to our internal controls over financial reporting during the 2021 year due to the COVID-19 pandemic. We are continually monitoring and assessing the impact of the COVID-19 pandemic on our internal controls to reduce or minimize the impact on their design and operating effectiveness.

This report shall not be deemed to be filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, unless we specifically state that the report is to be considered "filed" under the Exchange Act or incorporate it by reference into a filing under the Securities Act of 1933, as amended, or under the Exchange Act.

Management's Report on Internal Control over Financial Reporting

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) promulgated under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by a company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America 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, particularly those related to subjective measurements and complex transactions, 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.

All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission 2013 Framework in Internal Control - Integrated Framework and Internal Control over Financial Reporting-Guidance for Smaller Public Companies. As a result of this assessment, management identified a material weakness in internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Based on the remediation of the material weakness described below, management has concluded that as of December 31, 2021, our internal control over financial reporting was effective.

We previously identified a weakness relating to our controls over adherence to certain company policies and procedures relating to hiring, monitoring and supervision of USC's sales personnel and the activities of such personnel, which were not strictly implemented and observed. We also identified a weakness in controls regarding inadequate oversight by senior management to ensure compliance with and adherence to company policies and procedures by USC sales personnel and to ensure performance of adequate monitoring and supervision of personnel. This control deficiency was assessed as a material weakness as of September 30, 2021. We determined that the weakness was remediated as of December 31, 2021 as a result of the sale of assets relating to the USC business and the winding down and termination of sales activities relating to that business.

This Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules that permit us to provide only management's report in this Annual Report.

Changes in Internal Controls Over Financial Reporting

Other than the remediation of the material weakness described above, there were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended December 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 of Part III is incorporated by reference to the registrant's proxy statement, to be filed within 120 days of the registrant's fiscal year end, or will be included in an amendment to this Annual Report on Form 10-K.

ITEM 11: EXECUTIVE COMPENSATION

The information required by Item 11 of Part III is incorporated by reference to the registrant's proxy statement, to be filed within 120 days of the registrant's fiscal year end, or will be included in an amendment to this Annual Report on Form 10-K.

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

The information required by Item 12 of Part III is incorporated by reference to the registrant's proxy statement, to be filed within 120 days of the registrant's fiscal year end, or will be included in an amendment to this Annual Report on Form 10-K.

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

The information required by Item 13 of Part III is incorporated by reference to the registrant's proxy statement, to be filed within 120 days of the registrant's fiscal year end, or will be included in an amendment to this Annual Report on Form 10-K.

ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 of Part III is incorporated by reference to the registrant's proxy statement, to be filed within 120 days of the registrant's fiscal year end, or will be included in an amendment to this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibits

The following exhibits are attached hereto or incorporated herein by reference.

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference	
			Form/ File No.	Date
2.1	Agreement and Plan of Share Exchange dated as of October 7, 2004, by and between the Company and Biosyn, Inc.		8-K	10/26/04
2.2	Agreement and Plan of Merger by and among the Company, US Compounding, Inc., Ursula Merger Sub Corp. and Eddie Glover dated as of March 28, 2016		8-K	03/29/16
3.1	Restated Certificate of Incorporation of the Registrant		S-8	03/17/14
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock dated August 19, 2014		8-K	08/20//14
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A-1 Convertible Preferred Stock		8-K	01/26/16
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A-2 Convertible Preferred Stock		8-K	07/12/16
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock		8-K	06/12/20
3.6	Certificate of Amendment to Restated Certificate of Incorporation		8-K	09/08/20
4.1	Amended and Restated Bylaws of the Company		8-K	06/22/20
4.2	Specimen stock certificate for common stock		8-K	04/03/09
4.3	Form of Common Stock Purchase Warrant		8-K	08/01/19
4.4	Description of the Registrant's Capital Stock		10-K	04/15/21
4.5	Form of Common Stock Purchase Warrant		8-K	02/21/20
10.1	2009 Equity Incentive Plan*		S-8	07/18/18
10.2	Form of Stock Option Agreement for option awards*		8-K	09/16/11
10.3	Form of Option Agreement for Non-Employee Directors*		8-K	01/13/11
10.4	Form of Stock Appreciation Rights Agreement for Non-employee Directors		10-Q	11/12/19
10.5	Form of Restricted Stock Unit Agreement*		10-K	03/30/17
10.6	Form of Indemnity Agreement with directors and executive officers*		8-K	01/13/11
10.7	Funding Agreement dated October 12, 1992, by and between Ben Franklin Technology Center of Southeastern Pennsylvania and Biosyn, Inc.		S-4/A 333-155322	01/12/09
10.8	Executive Employment Agreement between the Company and Dennis J. Carlo dated December 31, 2015*		10-K	03/23/16
10.9	Executive Employment Agreement between the Company and David J. Marguglio dated December 31, 2015*		10-K	03/23/16
10.10	Executive Employment Agreement between the Company and Robert O. Hopkins dated December 31, 2015*		10-K	03/23/16
10.11	Exclusive License and Asset Purchase Agreement dated as of August 1, 2013, by and among the Registrant, 3M Corp. and 3M Innovative Properties Company		8-K	08/06/13

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference Form/ File No.	Date
10.12	Lease Agreement dated April 1, 2014, between the Registrant and Pacific North Court Holdings, L.P.		10-KT	03/26/15
10.13	First Amendment to Lease between the Registrant and Pacific North Court Holdings, L.P.		10-K	04/15/21
10.14	Registration Rights Agreement dated August 18, 2014, by and between the Company and Sio Partners LP, Sio Partners QP LP and Sio Partners Offshores, Ltd.		8-K	08/20/14
10.15	Purchase Agreement dated January 26, 2016		8-K	01/26/16
10.16	Amended and Restated Registration Rights Agreement dated January 26, 2016		8-K	01/26/16
10.17	Purchase Agreement dated July 11, 2016		8-K	07/12/16
10.18	Registration Rights Agreement dated July 11, 2016		8-K	07/12/16
10.19	Placement Agency Agreement between Maxim Group LL and the Company dated July 29, 2016		8-K	07/29/16
10.20	Form of Securities Purchase Agreement dated July 29, 2016		8-K	07/29/16
10.21	Compensation Committee Authorization Regarding Discretionary Payments		8-K	02/27/18
10.22	Offer Letter between the Company and David C. Benedicto	X		
10.23	Executive Employment Agreement between the Company and Ronald B. Moss, M.D., dated as of February 28, 2017.*		10-K	03/30/17
10.24	Underwriting Agreement dated August 2, 2018		8-K	08/02/18
10.25	Distribution and Commercialization Agreement between the Company and Sandoz, Inc. **		10-Q	11/9/2018

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference Form/ File No.	Date
10.26	Placement Agency Agreement between Maxim Group LLC and the Company dated February 20, 2020		8-K	02/21/20
10.27	Form of Securities Purchase Agreement dated February 21, 2020		8-K	02/21/20
10.28	Underwriting Agreement dated January 29, 2021		8-K	01/29/21
10.29	Underwriting Agreement dated September 18, 2020		8-K	09/18/20
10.30	August 2020 Amendment to Loan Amendment and Assumption Agreement		8-K	09/15/20
10.31	Amended Promissory Note		8-K	09/15/20
10.32	2020 Equity Incentive Plan *		8-K	08/24/20
10.33	Adamis Pharmaceuticals Corporation Bonus Plan *		8-K	06/22/20
10.34	Promissory Note		8-K	04/15/20
10.35	Termination and Transfer Agreement between Sandoz Inc. and the Company ***+		10-Q	08/17/20
10.36	Transition Service Agreement ***+		10-Q	08/17/20
10.37	License Agreement between the Company and Matrix Biomed, Inc. ***+		10-Q	08/17/20
10.38	Distribution and Commercialization Agreement between the Company and USWM, LLC***		10-Q	08/17/20
10.39	Lease Agreement between the Company and Oil States Energy Services, LLC, as amended +		10-K	04/15/21
10.40	Promissory Note dated March 15, 2021		10-K	04/15/21
10.41	Underwriting Agreement		8-K	01/29/21
10.42	Asset Purchase Agreement effective as of July 30, 2021, by and among the Registrant, US Compounding, Inc.. and Fagron Compounding Services, LLC. +***		8-K	08/05/21
10.43	Supply Agreement Addendum by and among the Registrant, US Compounding Inc. and Fagron Compounding, LLC***		8-K	08/05/21
10.44	Settlement Agreement between the Company, US Compounding Inc., Nephron Pharmaceuticals Corporation, Nephron S.C., Inc., Nephron Sterile Compounding Center, LLC and certain other parties. +***		10-Q	11/22/21
10.45	First Amendment to Exclusive License Agreement dated November 9, 2021 between the Company and Matrix Biomed, Inc.***	X		
21.1	Subsidiaries of the Registrant		10-K	04/15/21
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm	X		
24.1	Power of Attorney (See signature page)	X		
31.1	Certification by CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X		
31.2	Certification by CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X		
32.1	Certification by CEO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X		
32.2	Certification by CFO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X		
101.INS	The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document			
101.SCH	XBRL Taxonomy Extension Schema Document			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101)			

\+ Non-material schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplemental copies of any of the omitted schedules and exhibits upon request by SEC.

* Represents a compensatory plan or arrangement.

** We have received confidential treatment for certain portions of this exhibit.

*** Certain marked information (indicated by "[***]") has been omitted from this exhibit as the registrant has determined it is both not material and is the type that the registrant customarily and actually treats as private or confidential.

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, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California.

ADAMIS PHARMACEUTICALS CORPORATION

By: /s/ DENNIS J. CARLO
Dennis J. Carlo
Chief Executive Officer

Dated: March 31, 2022

Power of Attorney

Each person whose signature appears below constitutes and appoints each of Dennis J. Carlo and David C. Benedicto, true and lawful attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons in the capacities and on the dates indicated:

Name	Title	Date
Principal Executive Officer:		
/s/ DENNIS J. CARLO Dennis J. Carlo	Chief Executive Officer and Director	March 31, 2022
Principal Financial Officer and Principal Accounting Officer:		
/s/ DAVID C. BENEDICTO David C. Benedicto	Chief Financial Officer	March 31, 2022
Directors:		
/s/ DAVID J. MARGUGLIO David J. Marguglio	Director	March 31, 2022
/s/ RICHARD C. WILLIAMS Richard C. Williams	Chairman	March 31, 2022
/s/ MEERA J. DESAI Meera J. Desai	Director	March 31, 2022

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

TABLE OF CONTENTS

DECEMBER 31, 2021 AND 2020

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Adamis Pharmaceuticals Corporation
San Diego, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Adamis Pharmaceuticals Corporation (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and 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 at December 31, 2021 and 2020, 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.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 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 Matter

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: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter 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.

Discontinued Operations and Assets Held for Sale

As described in Note 4 to the consolidated financial statements, in 2021 the Company completed the sale of certain assets to Fagron Compounding Services, LLC ("Fagron") and wound down the remaining operations of their subsidiary, U.S. Compounding, Inc. ("USC"). The sale of certain customer information and information on products sold to customers by USC to Fagron resulted in fixed consideration of $107,000 and variable consideration of $6,385,000 and resulted in a gain upon sale of $4,637,000. Upon the sale of certain assets and the wind down of USC's operations, the remaining assets were assessed to determine whether the USC assets were abandoned or held for sale resulting in a loss from held for sale classification of $2,601,442.

We have identified the asset sales to Fagron and the subsequent measurement of the remaining assets at USC as a critical audit matter. The accounting guidance surrounding the Company's asset sale and wind down of USC was complex, involving multiple agreements, and required significant judgment by management, including the determination of: (i) the initial carrying value of USC's customer relationship intangible, (ii) the fair value of the variable consideration, (iii) the gain on sale of assets, and (iv) the loss from held for sale classification. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters, including the extent of specialized skills and knowledge needed.

The primary procedures we performed to address this critical audit matter include:

- Analyzing the relevant agreements and other related documents including asset purchase agreements, board minutes, press releases and public filings to evaluate management's determination of whether the various USC assets were sold, held for sale, or abandoned.
- Analyzing management's allocation of the initial carrying value of USC's customer relationships intangible.
- Assessing the reasonableness of certain significant assumptions used in valuing the variable consideration by: (i) testing of subsequent royalty collections and (ii) performing a retrospective review including developing an independent expectation with a range of alternative assumptions and compared to the Company's initial estimate to the actual royalties collected subsequently.
- Recalculating the gain on sale of assets and the loss from held for sale classification.
- Utilizing professionals with specialized knowledge and expertise to assist in reviewing and evaluating management's conclusions for the transactions related to the discontinued operations and assets held for sale.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2020.

San Diego, California

March 31, 2022

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents	$ 23,220,770	$ 6,748,945
Restricted Cash	30,023	—
Accounts Receivable	815,565	242,221
Receivable from Fagron	5,084,452	—
Inventories	418,607	1,227,061
Prepaid Expenses and Other Current Assets	1,313,546	1,289,667
Current Assets of Discontinued Operations, Note 4	4,320,659	3,016,227
Total Current Assets	35,203,622	12,524,121
LONG TERM ASSETS		
Fixed Assets, net	2,334,768	2,497,878
Right-of-Use Assets	650,460	969,999
Other Non-Current Assets	109,137	52,174
Long-Term Assets of Discontinued Operations, Note 4	—	14,823,290
Total Assets	$ 38,297,987	$ 30,867,462
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable	$ 3,754,010	$ 1,780,104
Deferred Revenue, current portion	100,000	100,000
Accrued Other Expenses	2,800,241	1,659,089
Accrued Bonuses	535,624	1,047,719
Contingent Loss Liability	—	7,900,000
Product Recall Liability	2,000,000	—
Lease Liabilities, current portion	349,871	325,766
Paycheck Protection Plan (PPP) Loans, current portion	—	2,300,253
Current Liabilities of Discontinued Operations, Note 4	1,683,246	4,812,795
Total Current Liabilities	11,222,992	19,925,726
LONG TERM LIABILITIES		
Deferred Revenue, net of current portion	750,000	850,000
Lease Liabilities, net of current portion	342,562	692,433
PPP Loan, net of current portion	—	891,447
Warrant Liabilities, at fair value	99,655	4,485,000
Long Term Liabilities of Discontinued Operations, Note 4	—	525,316
Total Liabilities	12,415,209	27,369,922
COMMITMENTS AND CONTINGENCIES, see Note 16		
STOCKHOLDERS' EQUITY		
Preferred Stock - Par Value $0.0001; 10,000,000 Shares Authorized; no shares Issued and Outstanding at December 31, 2021 and December 31, 2020.	—	—
Common Stock - Par Value $0.0001; 200,000,000 Shares Authorized; 150,117,219 and 94,365,015 Issued, 149,594,262 and 93,842,058 Outstanding at December 31, 2021 and December 31, 2020, respectively.	15,012	9,437
Additional Paid-in Capital	303,958,829	233,404,968
Accumulated Deficit	(278,085,813)	(229,911,615)
Treasury Stock, at cost - 522,957 Shares at December 31, 2021 and December 31, 2020.	(5,250)	(5,250)
Total Stockholders' Equity	25,882,778	3,497,540
Total Liabilities and Stockholders' Equity	$ 38,297,987	$ 30,867,462

The accompanying notes are an integral part of these Consolidated Financial Statements

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2021	Year Ended December 31, 2020
REVENUE, net of reserves for product recall of $2.0 million	$ 2,208,680	$ 2,776,587
COST OF GOODS SOLD	6,872,131	6,326,971
Gross Loss	(4,663,451)	(3,550,384)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	16,143,585	20,089,660
RESEARCH AND DEVELOPMENT	11,262,373	8,039,776
IMPAIRMENT EXPENSE - Contract Asset	—	1,750,000
IMPAIRMENT EXPENSE - Intangibles	—	2,912,610
Loss from Operations	(32,069,409)	(36,342,430)
OTHER INCOME (EXPENSE)		
Interest Expense	(6,649)	(4,921)
Other Income	7,216	38,319
Gain on Forgiveness of PPP Loans	5,009,590	—
Change in Fair Value of Warrant Liabilities	(7,540,305)	465,000
Total Other Income (Expense), net	(2,530,148)	498,398
Net Loss from Continuing Operations before Income Taxes	(34,599,557)	(35,844,032)
Income Tax Expense	(796)	(2,400)
Net Loss from Continuing Operations	$ (34,600,353)	$ (35,846,432)
DISCONTINUED OPERATIONS		
Net Loss from Discontinued Operations before Income Taxes	(11,294,433)	(13,544,883)
Income Taxes - Discontinued Operations	66,588	226
Net Loss from Discontinued Operations	(11,227,845)	(13,544,657)
Net Loss Applicable to Common Stock	$ (45,828,198)	$ (49,391,089)
Basic & Diluted Loss Per Share:		
Continuing Operations	$ (0.24)	$ (0.46)
Discontinued Operations	(0.08)	(0.18)
Basic & Diluted Loss Per Share	$ (0.32)	$ (0.64)
Basic & Diluted Weighted Average Shares Outstanding	144,157,229	77,569,745

The accompanying notes are an integral part of these Consolidated Financial Statements

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Convertible Preferred Stock		Common Stock			Treasury Stock			
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Shares	Amount	Accumulated Deficit	Total Stockholders' Equity
Balance December 31, 2019	—	$ —	62,352,465	$ 6,235	$ 213,520,785	522,957	$ (5,250)	$ (180,520,526)	$ 33,001,244
Common Stock Issued, net of issuance cost of $1,436,787	—	—	30,148,386	3,016	16,788,197	—	—	—	16,791,213
Series B Convertible Preferred Stock Issued	1,000,000	100	—	—	589,900	—	—	—	590,000
Preferred Stock Conversion to Common Stock	(1,000,000)	(100)	1,000,000	100	—	—	—	—	—
Issuance of Restricted Stock Units (RSU)	—	—	864,164	86	(86)	—	—	—	—
Share Based Compensation	—	—	—	—	4,420,172	—	—	—	4,420,172
Issuance of 2020 Warrants	—	—	—	—	(1,914,000)	—	—	—	(1,914,000)
Net Loss	—	—	—	—	—	—	—	(49,391,089)	(49,391,089)
Balance December 31, 2020	—	—	94,365,015	$ 9,437	$ 233,404,968	522,957	$ (5,250)	$ (229,911,615)	$ 3,497,540
Adjustment, Conversion of 2019 Warrant Liability upon Adoption of ASU 2020-06	—	—	—	—	4,830,000	—	—	(2,346,000)	2,484,000
Balance, December 31, 2020, as adjusted	—	—	94,365,015	9,437	238,234,968	522,957	(5,250)	(232,257,615)	5,981,540
Common Stock Issued, net of issuance cost of $3,330,752	—	—	46,621,621	4,661	48,414,585	—	—	—	48,419,246
Exercise of Warrants	—	—	8,356,000	836	5,851,064	—	—	—	5,851,900
Close-out of Warrant Liabilities Due to Warrant Exercise	—	—	—	—	9,441,650	—	—	—	9,441,650
Issuance of Restricted Stock Units (RSUs)	—	—	774,583	78	(78)	—	—	—	—
Share Based Compensation	—	—	—	—	2,016,640	—	—	—	2,016,640
Net Loss	—	—	—	—	—	—	—	(45,828,198)	(45,828,198)
Balance December 31, 2021	—	$ —	150,117,219	$ 15,012	$ 303,958,829	522,957	$ (5,250)	$ (278,085,813)	$ 25,882,778

The accompanying notes are an integral part of these Consolidated Financial Statements

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2021	Year Ended December 31, 2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (45,828,198)	$ (49,391,089)
Less: Loss from Discontinued Operations	11,227,845	13,544,657
Adjustments to Reconcile Net Loss to Net		
Cash Provided by (Used in) Operating Activities:		
Stock Based Compensation	1,982,905	4,100,310
Gain on Forgiveness of PPP Loans	(5,009,590)	—
Purchased IPR&D	—	840,000
Provision for Excess and Obsolete Inventory	1,044,607	874,531
Change in Fair Value of Warrant Liability	7,540,305	(465,000)
(Cash Payments in Excess of Lease Expense) Lease Expense in Excess of Cash	(6,227)	4,261
Depreciation and Amortization Expense	1,435,744	2,329,093
Impairment of Contract Asset	—	1,750,000
Impairment of Intangibles	—	2,912,610
Change in Operating Assets and Liabilities:		
Accounts Receivable	(573,344)	324,840
Receivable from Fagron	(6,492,321)	—
Inventories	(236,153)	(1,773,505)
Prepaid Expenses and Other Current & Non-current Assets	(80,842)	(517,654)
Accounts Payable	1,908,597	(388,375)
Contingent Loss Liability	(7,900,000)	7,900,000
Product Recall Liability	2,000,000	—
Deferred Revenue	(100,000)	50,000
Accrued Other Expenses and Bonuses	675,329	1,378,200
Net Cash Used in Operating Activities of Continuing Operations	(38,411,343)	(16,527,121)
Net Cash Provided by (Used in) Operating Activities in Discontinued Operations	626,046	(4,374,239)
Net Cash Used in Operating Activities	(37,785,297)	(20,901,360)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of Equipment	(1,223,449)	(450,468)
Purchase of IPR&D License	—	(250,000)
Proceeds from Sale of Assets to Fagron	1,407,869	—
Net Cash Provided by (Used in) Investing Activities of Continuing Operations	184,420	(700,468)
Net Cash Provided by (Used in) Investing Activities of Discontinued Operations	98,317	(245,746)
Net Cash Provided by (Used in) Investing Activities	282,737	(946,214)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from Issuance of Common Stock	51,749,998	18,228,000
Costs of Issuance of Common Stock	(3,330,752)	(1,436,787)
Proceeds from Exercise of Warrants	5,851,900	—
Proceeds of PPP Loans	1,765,495	3,191,700
Net Cash Provided by Financing Activities of Continuing Operations	56,036,641	19,982,913
Net Cash Used in Financing Activities of Discontinued Operations	(2,100,796)	(90,620)
Net Cash Provided by Financing Activities	53,935,845	19,892,293
Increase (Decrease) in Cash and Cash Equivalents and Restricted Cash	16,433,285	(1,955,281)
Cash and Cash Equivalents and Restricted Cash:		
Beginning, December 31, 2020	6,748,945	8,418,382
Change in Cash and Cash Equivalents of Discontinued Operations	68,563	285,844
Ending, December 31, 2021	$ 23,250,793	$ 6,748,945

The accompanying notes are an integral part of these Consolidated Financial Statements

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2021	Year Ended December 31, 2020
RECONCILIATION OF CASH & CASH EQUIVALENTS AND RESTRICTED CASH		
Cash & Cash Equivalents	$ 23,220,770	$ 6,748,945
Restricted Cash	30,023	—
Total Cash & Cash Equivalents and Restricted Cash	$ 23,250,793	$ 6,748,945
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash Paid for Income Taxes	$ 4,125	$ 9,401
Cash Paid for Interest	$ —	$ 135,827
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES		
Decrease in Accrued Capital Expenditures	$ 49,185	$ (34,230)
Series B Preferred Stock Issuance for License Agreement	$ —	590,000
Forgiveness of PPP Loans	$ 5,009,590	—

The accompanying notes are an integral part of these Consolidated Financial Statements

Notes to the Consolidated Financial Statements

NOTE 1: NATURE OF BUSINESS

Adamis Pharmaceuticals Corporation (the "Company," "Adamis Pharmaceuticals" or "Adamis") has three wholly-owned subsidiaries: Adamis Corporation; U.S. Compounding, Inc. ("USC"); and Biosyn, Inc.

USC, which is registered as a drug compounding outsourcing facility under Section 503B of the U.S. Food, Drug & Cosmetic Act and the U.S. Drug Quality and Security Act, provides prescription compounded medications, including compounded sterile preparations and non-sterile compounds, to patients, physician clinics, hospitals, surgery centers and other clients in many states throughout the United States. USC also provides certain veterinary pharmaceutical products for animals. In July 2021, we sold certain assets relating to USC's human compounding pharmaceutical business and approved a restructuring process to wind down the remaining USC business and sell, liquidate or otherwise dispose of the remaining USC assets. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer selling compounded pharmaceutical or veterinary products.

NOTE 2: GOING CONCERN

The Company's consolidated financial statements are prepared using the generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, the Company has incurred substantial recurring losses from continuing operations, has used, rather than provided, cash in the Company's continuing operations, and is dependent on additional financing to fund operations. We incurred a net loss of approximately $45.8 million and $49.4 million for the years ended December 31, 2021 and 2020. As of December 31, 2021, the Company had cash and cash equivalents of approximately $23.2 million and an accumulated deficit of approximately $278.1 million. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence. The Company may in the future need additional funding to help fund the development and commercialization of products and product candidates, conduct research, development and trials relating to product candidates, fund the Company's ongoing operations and satisfy the Company's obligations and liabilities. Management intends to attempt to secure additional funding, if required, through equity or debt financings, sales or out-licensing of product candidates or other intellectual property assets, revenues relating to supply and sale of SYMJEPI and ZIMHI products and share of profits received relating to sales in the U.S. of the Company's SYMJEPI products, seeking partnerships or commercialization agreements with other pharmaceutical companies or third parties to co-develop and fund research and development or commercialization efforts relating to the Company's products, from a business combination, or similar transactions. However, there can be no assurance that the Company will be able to obtain any sources of funding.

NOTE 3: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include Adamis Pharmaceuticals and its wholly-owned operating subsidiaries. All significant intra-entity balances and transactions have been eliminated in consolidation.

Accounting Estimates

In preparing financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include warrant liabilities, valuing equity securities in share-based payments, estimating the useful lives of depreciable and amortizable assets, goodwill impairment, estimates related to the calculation of the variable consideration from the Company's transaction with Fagron in the connection with the sale of certain assets of US Compounding and estimates associated with the assessment of impairment for long-lived assets.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash equivalents are comprised of money market funds and certificates of deposit.

Accounts Receivable

Accounts receivable are reported at the amount management expects to collect on outstanding balances. Management provides for probable uncollectible amounts through a charge to earnings and credit to allowance for doubtful accounts. Uncollectible amounts are based on the Company's history of past write-offs and collections and current credit conditions. Allowance for doubtful accounts as of December 31, 2021 and 2020 was approximately $0.

Inventories

Inventories are stated at the lower of standard cost, which approximates actual cost determined on the weighted average basis, or net realizable value. Inventories are recorded using the first-in, first-out method. The Company routinely evaluates quantities and values of inventories in light of current market conditions and market trends, and records a write-down for quantities in excess of demand and product obsolescence. The evaluation may take into consideration historic usage, expected demand, anticipated sales price, new product development schedules, the effect new products might have on the sale of existing products, product obsolescence, customer concentrations, product merchantability and other factors. Market conditions are subject to change and actual consumption of inventory could differ from forecasted demand. The Company also regularly reviews the cost of inventories against their estimated market value and records a lower of cost or market write-down for inventories that have a cost in excess of estimated market value, resulting in a new cost basis for the related inventories which is not reversed.

Fixed Assets

Property, plant and equipment are stated at cost, net of accumulated depreciation and amortization. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives ranging from 3 - 5 years.

Acquired IPR&D

We assess whether IPR&D assets acquired from others in an asset acquisition have alternative future use (in research and development projects or otherwise) at the acquisition date. If such assets have alternative future use, they are capitalized and recognized as an intangible asset. If such assets do not have alternative use, nor is there an alternative indication that the Company plans to pursue, the upfront consideration transferred, including any contingent consideration that is probable and reasonably estimable, is charged to expense at the acquisition date.

Other Long-Lived Assets

The Company evaluates its long-lived assets with definite lives, such as fixed assets, acquired technology, customer relationships, patent and license rights, for impairment by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If the assets are not recoverable, the impairment charge is measured as the amount by which the carrying value of the asset group exceeds the fair value.

The carrying value of intangible assets and other long-lived assets is reviewed on a regular basis for the existence of facts or circumstances, both internally and externally, that may suggest impairment. Some factors which the Company considers to be triggering events for impairment review include a significant decrease in the market value of an asset, a significant change in the extent or manner in which an asset is used, a significant adverse change in the business climate that could affect the value of an asset, an accumulation of costs for an asset in excess of the amount originally expected, a current period operating loss or cash flow decline combined with a history of operating loss or cash flow uses or a projection that demonstrates continuing losses and a current expectation that, it is more likely than not, a long-lived asset will be disposed of at a loss before the end of its estimated useful life.

As of December 31, 2020, in light of the time and costs involved in further product development efforts and competitive conditions in the relevant markets related to the Taper DPI intellectual property, and our determination not to devote any further substantial financial resources to development of this product candidate or pursue further development efforts regarding this product candidate, we recorded an impairment charge of approximately $2,913,000 for the year ended December 31, 2020. The intangible asset had a gross carrying value of approximately $9,709,000 and an accumulated amortization of approximately $6,796,000. If in the future we determine that our intangible assets have become impaired, our total assets, financial results, and earnings could be adversely affected. See Note 15.

Warrant Liabilities

Warrants are accounted for in accordance with the applicable authoritative accounting guidance as either liabilities or as equity instruments depending on the specific terms of the agreements. Liability-classified instruments are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of warrant liabilities in the consolidated statements of operations and comprehensive loss.

Revenue Recognition

The Company recognizes revenues pursuant to ASC Topic 606, "*Revenue from Contracts with Customers*" (ASC 606). See Note 5.

Product Recall

The Company establishes reserves for product recalls on a product-specific basis when circumstances giving rise to the recall become known. The Company, when establishing reserves for a product recall, considers cost estimates for any fees and incentives to customers for their effort to return the product, freight and destruction charges for returned products, warehouse and inspection fees, repackaging materials, point-of-sale materials and other costs including costs incurred by contract manufacturers. Additionally, the Company estimates product returns from consumers and customers across distribution channels, utilizing third-party data and other assumptions. These factors are updated and reevaluated each period and the related reserves are adjusted when these factors indicate that the recall reserves are either insufficient to cover or exceed the estimated product recall expenses. Significant changes in the assumptions used to develop estimates for product recall reserves could affect key financial information, including accounts receivable, inventory, accrued liabilities, net sales, gross profit, operating expenses and net income. In addition, estimating product recall reserves requires a high degree of judgment in areas such as estimating consumer returns, shelf and in-stock inventory at retailers across distribution channels, fees and incentives to be earned by customers for their effort to return the products, future freight rates and consumers' claims. During the year ended December 31, 2021, the company recorded products recall reserves. The recall of certain lots of SYMJEPI from the marketplace was initiated in March 2022.

Cost of Goods Sold

The Company's cost of goods sold includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, shipping and handling costs, the write-off of obsolete inventory and other related expenses.

Stock-Based Compensation

The Company accounts for stock-based compensation transactions in which the Company receives employee services in exchange for restricted stock units ("RSUs") or options to purchase common stock and the Company recognizes stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period. Stock-based compensation cost for RSUs is measured based on the closing fair market value of the Company's common stock on the date of grant. Stock-based compensation cost for stock options is estimated at the grant date based on each option's fair-value as calculated by the Black-Scholes option-pricing model.

Research and Development

Research and development costs are expensed as incurred. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as an asset and are expensed when the research and development activities are performed. For the years ended December 31, 2021 and 2020, the Company incurred approximately $11.3 million and $8.0 million, respectively, on research and development activities.

Legal Expense

Legal fees are expensed as incurred and are included in selling, general and administrative expenses on the consolidated statements of operations.

Income Taxes

The Company accounts for income taxes under the deferred income tax method. Under this method, deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax basis of assets and liabilities given the provisions of enacted tax laws.

Deferred income tax provisions and benefits are based on changes to the assets and liabilities from year to year. In providing for deferred taxes, the Company considers tax regulations of the jurisdictions in which they operate, estimates of future taxable income, and available tax planning strategies. If tax regulations, operating results or the ability to implement tax planning strategies vary, adjustments to the carrying value of deferred tax assets and liabilities may be required. Valuation allowances are recorded related to deferred tax assets based on the “more-likely-than-not” criteria.

The Company accounts for uncertain tax positions in accordance with accounting guidance which requires the Company to recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would, more likely than not, sustain the position following an audit. For tax positions meeting the more likely than not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

The Company is subject to income taxes in the United States and various states. Tax years since the Company’s inception remain open to examination by the major taxing jurisdictions to which the Company is subject. The Company recognizes interest and penalties accrued related to unrecognized tax benefits in its income tax expense, if any. No interest or penalties have been accrued for any presented periods.

The Company sold USC related customer relationship intangibles in the calendar year 2021 and recategorized the remaining USC assets and liabilities as held for sale, and the related operation as discontinued operation, and the related tax benefit of approximately $67,000 was allocated to discontinued operations.

Basic and Diluted Net Loss Per Share

The Company computes basic loss per share by dividing the loss attributable to holders of common stock for the period by the weighted average number of shares of common stock outstanding during the period. The diluted loss per share calculation is based on the treasury stock method and gives effect to dilutive options, warrants, convertible notes, convertible preferred stock and other potential dilutive common stock. The effect of common stock equivalents was anti-dilutive and was excluded for all periods presented from the calculation of weighted average shares outstanding. Potential dilutive securities for the years ended December 31, 2021 and 2020 consist of outstanding warrants (14,202,824 shares and 24,634,670 shares, respectively), outstanding options (4,985,415 shares and 6,508,296 shares, respectively), and outstanding restricted stock units (1,039,003 shares and 2,136,893 shares, respectively).

	For the Years Ended December 31,	
	2021	2020
Loss per Share - Basic & Diluted		
Numerator for basic & diluted loss per share:		
Continuing Operations	$ (34,600,353)	$ (35,846,432)
Discontinued Operations, net of tax	$ (11,227,845)	$ (13,544,657)
Denominator for basic & diluted loss per share	144,157,229	77,569,745
Loss per common share - basic & diluted:		
Continuing Operations	$ (0.24)	$ (0.46)
Discontinued Operations, net of tax	(0.08)	(0.18)
Total loss per common share - basic & diluted	$ (0.32)	$ (0.64)

Discontinued Operations

In accordance with ASC 205-20 *Presentation of Financial Statements: Discontinued Operations*, a disposal of a component of an entity or a group of components of an entity is required to be reported as discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results when the component/s of an entity meets the criteria in paragraph 205-20-45-10. In the period in which the component meets held-for-sale or discontinued operations criteria the major current assets, noncurrent assets, current liabilities, and noncurrent liabilities shall be reported as components of total assets and liabilities separate from those balances of the continuing operations. At the same time, the results of all discontinued operations, less applicable income taxes, shall be reported as components of net loss separate from the net loss of continuing operations.

The Company disposed of a component of its business in August 2021 and met the definition of a discontinued operation as of December 31, 2021. Accordingly, the major current assets, noncurrent assets, current liabilities, and noncurrent liabilities shall be reported as components of total assets and liabilities separate from those balances of the continuing operations as of December 31. 2021 and 2020, and the operating results of the business disposed are reported as loss from discontinued operations in the accompanying consolidated statement of operations for the years ended December 31, 2021 and 2020. For additional information, see Note 4 - Discontinued Operations.

Recently Adopted Accounting Pronouncement

Accounting Standards Update ("ASU") 2020-06—Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, simplifies accounting for convertible instruments by removing major separation models required under current Generally Accepted Accounting Principles (GAAP). Consequently, more convertible debt instruments will be reported as a single liability instrument and more convertible preferred stock as a single equity instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The ASU also simplifies the diluted earnings per share (EPS) calculation in certain areas. The Company adopted this amendment on January 1, 2021 under the modified retrospective approach, recognizing the cumulative effect of the change as an adjustment to the opening balance of retained earnings at the date of adoption.

The Company has issued and outstanding warrants that contain certain clauses that may require cash settlement in certain circumstances. As of December 31, 2020, the Company had Warrant Liabilities of $ 4,485,000, of which $ 2,484,000 pertained to the warrants issued in August 2019 (the "2019 Warrants"). Prior to the adoption of ASU 2020-06, the 2019 warrants were required to be accounted for as liabilities as the contract did not permit settlement in unregistered shares and did not explicitly state that the warrants would be settled in shares if an active registration statement was not available. ASU 2020-06 removed this condition and upon adoption the 2019 warrants are accounted for within equity.

Recent Accounting Pronouncements

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* which provides guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this ASU No. 2021-04 are effective for all entities for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, including interim periods within those fiscal years. The amendment currently has no impact to the Company as the effect will largely depend on the terms of written call options or financings issued or modified in the future.

NOTE 4: DISCONTINUED OPERATIONS AND ASSETS HELD FOR SALE

In August 2021, we announced our agreement with Fagron Compounding Services, LLC ("Fagron") to sell to Fagron certain assets of our subsidiary, US Compounding, Inc. ("USC"), related to its human compounding pharmaceutical business including certain customer information and information on products sold to such customers by USC, including related formulations, know-how, and expertise regarding the compounding of pharmaceutical preparations, clinical support knowledge and other data and certain other information relating to the customers and products. The agreement includes fixed consideration of approximately $107,000 and variable consideration estimated at approximately $6,385,000, and the Company has recorded a gain of approximately $4,637,000 within discontinued operations related to this asset sale to Fagron, which was the total estimated consideration net of approximately $1,856,000 of allocated costs related to USC's customer relationships intangible that was sold to Fagron. The variable consideration is tied to Fagron's sales to former USC customers over the twelve-month-period commencing on the agreement date. The Company used the expected value method to estimate Fagron's sales over the twelve-month period following the agreement date. Additionally, the Company relied on historical data and its judgement to make estimates, and as such, the total variable consideration is subject to change as more information becomes available, which would result in adjustments to the gain originally recorded within discontinued operations. In connection with the transaction, the Company accrued a $700,000 liability for a transaction fee payable to a financial advisor as of December 31, 2021 which was recorded in selling, general and administrative expenses of continuing operations.

In July 2021, the Company approved a restructuring process to wind down and cease the remaining operations at USC, with the remaining USC assets to be sold, liquidated or otherwise disposed of. As of December 31, 2021, the Company had shut down the operations of USC, terminated all of USC's employees and is engaged in the process of selling or attempting to sell or otherwise dispose of USC's remaining assets. The Company's current goal is to attempt to substantially complete the disposal of USC's assets by the end of December 2022.

In August 2021, the Company and its wholly-owned USC subsidiary entered into an Asset Purchase Agreement effective as of August 31, 2021 with a third party buyer, providing for the sale and transfer by USC of certain assets related to USC's veterinary compounded pharmaceuticals business. The sale covers the transfer of all the veterinary business customers' information belonging to USC or in USC's control and possession and USC's know how, information and expertise regarding the veterinary business. Pursuant to the agreement, the buyer agreed to pay the Company, for any sales of products in USC's veterinary products list or equivalent products made to the customers included in the agreement during the five-year period after the date of the agreement, an amount equal to twenty percent (20%) of the amount actually collected by the buyer on such sales during the period ending three months after the end of such five year period. The Company did not record a receivable related to the variable consideration as it was deemed immaterial.

Discontinued operations comprise those activities that were disposed of during the period, abandoned or which were classified as held for sale at the end of the period and represent a separate major line of business or geographical area that was previously distinguished as Compounded Pharmaceuticals segment for operational and financial reporting purposes in prior reported financial statements.

Assets Held for Sale

The Company considers assets to be held for sale when management approves and commits to a plan to actively market the assets for sale at a reasonable price in relation to its fair value, the assets are available for immediate sale in their present condition, an active program to locate a buyer and other actions required to complete the sale have been initiated, the sale of the assets is expected to be completed within one year and it is unlikely that significant changes will be made to the plan. Upon designation as held for sale, the Company ceases to record depreciation and amortization expenses and measures the assets at the lower of their carrying value or estimated fair value less costs to sell. Assets held for sale are included as other current assets in the Company's consolidated balance sheets and the gain or loss from sale of assets held for sale is included in the Company's general and administrative expenses.

The major assets and liabilities associated with discontinued operations included in our consolidated balance sheets are as follows:

Carrying amounts of major classes of assets included as part of discontinued operations	December 31, 2021	December 31 2020
Cash and Cash Equivalents	$ 37,849	$ 106,410
Accounts Receivable, net	693	850,636
Inventories	12,000	1,888,865
Fixed Assets, Held for Sale	6,799,090	7,088,715
Intangible Assets, net	—	6,280,010
Goodwill	—	868,412
Right-of-Use Assets	—	573,998
Other Assets	72,469	182,471
Less: Loss recognized on classification as held for sale	(2,601,442)	—
Total assets of the disposal group classified as discontinued operations in the statement of financial position	**$ 4,320,659**	**$ 17,839,517**
Carrying amounts of major classes of liabilities included as part of discontinued operations		
Accounts Payable	$ 681,646	$ 1,711,613
Accrued Other Expenses	133,313	865,323
Lease Liabilities	412,357	581,362
Contingent Loss Liability	410,000	—
Deferred Revenue	—	70
Bank Loans - Building	—	2,067,213
Deferred Tax Liability, net	45,930	112,530
Total liabilities of the disposal group classified as discontinued operations in the statement of financial position	**$ 1,683,246**	**$ 5,338,111**

The revenues and expenses associated with discontinued operations included in our consolidated statements of operations were as follows:

	Year Ended December 31,	
	2021	**2020**
Major line items constituting pretax loss of discontinued operations		
REVENUE, net	$ 6,216,545	$ 13,750,810
COST OF GOODS SOLD	(5,620,313)	(8,566,851)
	596,232	5,183,959
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(7,802,066)	(10,491,080)
RESEARCH AND DEVELOPMENT	(89,710)	(240,974)
Impairment Expense – Intangible	(3,835,158)	—
Impairment Expense – Goodwill	(868,412)	(6,772,210)
Impairment Expense – Inventory	(871,180)	—
Impairment Expense – Right of Use Asset	(448,141)	—
Impairment Expense – Fixed Assets	(9,346)	(1,115,560)
Loss from Held for Sale Classification	(2,601,442)	—
	(15,929,223)	(13,435,865)
OTHER INCOME (EXPENSE)		
Interest Expense	(70,903)	(154,707)
Interest Income	45	45,689
Gain on Sale of Assets to Fagron	4,636,702	—
Other Income	68,946	—
Net Loss from discontinued operations before income taxes	(11,294,433)	(13,544,883)
Income Tax Benefit	66,588	226
Net Loss from discontinued operations	**$ (11,227,845)**	**$ (13,544,657)**

Discontinued Operations - Revenue

Compounded Pharmaceuticals Facility Revenue Recognition. With respect to sales of prescription compounded medications by the Company's USC subsidiary, revenue arrangements consist of a single performance obligation which is satisfied at the point in time when goods are delivered to the customer. The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer which is the price reflected in the individual customer's order. Additionally, the transaction price for medication sales is adjusted for estimated product returns that the Company expects to occur under its return policy. The estimate is based upon historical return rates, which has been immaterial. The standard payment terms are 2%/10 and Net 30. The Company does not have a history of offering a broad range of price concessions or payment term changes, however, when the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value method. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. Variable consideration is not a significant component of the transaction price for sales of medications by USC.

Discontinued Operations - Lease

USC has two operating leases, one for an office space and one for office equipment. As of December 31, 2021, the leases have remaining terms between more than one year and less than four years. The operating leases do not include an option to extend beyond the life of the current term. There are no short-term leases, and the lease agreements do not require material variable lease payments, residual value guarantees or restrictive covenants. The company leases a building which requires monthly base rent of $10,824 through December 31, 2023.

As part of the restructuring process to wind down and cease the operations at USC, the Company is working to cancel or transfer the leases of the discontinued operations. During the year ended December 31, 2021, the Right-of-Use assets related to the leases of approximately $448,000 were fully impaired because there is no benefit expected from the subject leases. As of December 31, 2021, the liabilities of the discontinued operations include approximately $412,000 in lease liabilities.

Discontinued Operations - Impairments

Impairment of Intangibles – For the year ending December 31, 2021, USC's intangible assets were fully impaired as a result of the decision to wind down and cease USC's operations. Prior to that impairment, approximately $1,856,000 of USC's customer relationships intangible asset was allocated to the asset sale to Fagron. That amount is recorded within the gain from sale of assets of discontinued operations. The remaining intangibles had a carrying balance of approximately $3,835,000, which were fully impaired during the year ended December 31, 2021. USC's intangible assets had a carrying value of approximately $0 and $6,280,000 at December 31, 2021 and December 31, 2020, respectively.

Impairment of Goodwill—In the third quarter of 2021, USC's Goodwill was completely impaired, since there are no more expected future cash flows relating to USC's Goodwill as a result of the decision to wind down and cease operations. USC recognized an impairment expense of approximately $868,000 related to USC's Goodwill for the year ended December 31, 2021. The carrying value of Goodwill at December 31, 2021 and December 31, 2020 was $0 and $868,412, respectively.

Loss from Held for Sale Classification— For the year ended December 31, 2021, USC's fixed assets were impaired as a result of meeting the criteria to be classified as held for sale. USC determined that the fair value, less costs to sell, of the disposal group was lower than the book values of certain assets, thus USC recorded fixed asset impairments related to the held for sale classification of $2,601,442 for the year ended December 31, 2021. The Company made certain estimates and relied on its appraisals, vendor quotes, and its judgement in order to estimate the fair value of USC's fixed assets and believes USC's fixed assets are fairly valued as of December 31, 2021. Due to the nature of estimates, the actual amounts realized upon sale may be more than or less than estimated fair value of the fixed assets. Any difference will be recognized as a gain or loss in discontinued operations of future financial statements. The fair value measurements of the fixed assets are based on significant inputs that are unobservable and thus represents a Level 3 measurement.

Impairment of Right of Use (ROU) Assets—For the year ended December 31, 2021, USC's ROU assets related to leases were impaired as a result of the decision to wind down and cease operations. USC determined that the future expected cash flows to be generated by those ROU assets were $0, thus USC recorded a full impairment totaling approximately $448,000 during the year ended December 31, 2021. The balance of USC's ROU assets at December 31, 2021 and December 31, 2020 was $0 and $573,998, respectively.

Impairment of Inventory—For the year ended December 31, 2021, USC's Inventory was impaired as a result of the decision to wind down and cease operations. USC determined that certain inventories needed to be destroyed or that the net realizable value (NRV) for certain inventories was lower than cost, resulting in an impairment expense recognition of approximately $871,000 related to its inventory for the year ended December 31, 2021. Approximately $598,000 of the impairment was related to chemicals and non-sellable finished goods that were destroyed, and approximately $273,000 of the impairment was related to devices which were impaired based on a NRV analysis that showed the device costs exceeded recent sales prices. The balance of USC's inventory at December 31, 2021 and 2020 was $12,000 and $1,888,865, respectively.

Inventories at December 31, 2021 and 2020 consisted of the following:

	December 31, 2021	December 31, 2020
Finished Goods	$ —	$ 1,166,198
Devices	12,000	722,667
Inventories	$ 12,000	$ 1,888,865

Reserve for obsolescence as of December 31, 2021 and 2020 was approximately $0 and $191,000, respectively.

Restructuring Costs

Due to the facts and circumstances detailed above, the Company has identified three major types of restructuring activities related to the disposal of USC in addition to the approximately $8.6 million of asset impairments detailed above. These three types of activities are employee terminations, contract termination costs, and chemical destruction costs. For those restructuring activities, the Company recorded approximately $920,000 for employee termination costs, approximately $410,000 for contract termination costs, and approximately $422,000 for chemical destruction costs for the year ended December 31, 2021 within selling, general and administrative expenses of discontinued operations. The estimated amount of approximately $410,000 of contract termination cost was related to the termination of a contract between USC and a vendor. The amount for contract termination cost was recorded as a loss contingency as the Company believes a loss is probable and can be reasonably estimated. The Company records accruals for loss contingencies associated with legal matters when the Company determines it is probable that a loss has been or will be incurred and the amount of the loss can be reasonably estimated. Where a material loss contingency is reasonably possible and the reasonably possible loss or range of possible loss can be reasonably estimated, U.S. GAAP requires us to disclose an estimate of the reasonably possible loss or range of loss or make a statement that such an estimate cannot be made. The following summarizes the restructuring activities and their related accruals as of December 31, 2021:

	Employee Termination Costs	Contract Termination Cost	Chemical Destruction Costs	Total
Balance at December 31, 2020	$ -	$ -	$ -	$ -
Restructuring charges	919,947	410,000	421,508	1,751,455
Payments	(919,947)	-	(418,485)	(1,338,432)
Balance at December 31, 2021	$ -	$ 410,000	$ 3,023	$ 413,023

The liabilities of approximately $410,000 related to the contract termination costs was recorded in contingent loss liability of discontinued operations. The liability of approximately $3,000 related to chemical destruction costs was recorded in accounts payable of discontinued operations.

Discontinued Operations - Debt

Building Loan

On November 10, 2016, a Loan Amendment and Assumption Agreement was entered with into the lender. Pursuant to the agreement, as subsequently amended, the Company agreed to pay the lender monthly payments of principal and interest which were approximately $19,000 per month, with a final payment due and payable in August 2021.

In July 2021, the Company, in connection with the sale of certain USC assets to Fagron, paid to the lender the outstanding principal balance, accrued unpaid interest and other obligations under the Company's loan agreement, promissory note and related loan documents relating to the outstanding building loan relating to the building and property on which USC's offices are located. The land and building were included in the assets of discontinued operations.

As of December 31, 2021 and December 31, 2020, the outstanding principal balance owed on the applicable note was approximately $0 and $2,067,000, respectively. The loan currently bore an interest of 6.00% per year and interest expense for the years ended December 31, 2021 and 2020 was approximately $49,000 and $136,000, respectively. The amount of interest allocated to the discontinued operations was based on the legal obligations of USC.

NOTE 5: REVENUES

Revenue from Contracts with Customers

Revenue is recognized pursuant to ASC Topic 606, "*Revenue from Contracts with Customers*" (ASC 606). Accordingly, revenue is recognized at an amount that reflects the consideration to which the Company expects to be entitled in exchange for transferring goods or services to a customer. This principle is applied using the following 5-step process:

1. Identify the contract with the customer.
2. Identify the performance obligations in the contract.
3. Determine the transaction price.
4. Allocate the transaction price to the performance obligations in the contract.
5. Recognize revenue when (or as) each performance obligation is satisfied.

Adamis is a specialty biopharmaceutical company focused on developing and commercializing products in various therapeutic areas, including allergy, opioid overdose, respiratory and inflammatory disease. The Company's subsidiary US Compounding, Inc. or USC, provided compounded sterile prescription medications and certain nonsterile preparations and compounds, for human and veterinary use by patients, physician clinics, hospitals, surgery centers, vet clinics and other clients throughout most of the United States. USC's product offerings broadly include, among others, corticosteroids, hormone replacement therapies, hospital outsourcing products, and injectables. In July 2021, we sold certain assets relating to USC's human compounding pharmaceutical business and approved a restructuring process to wind down the remaining USC business and sell, liquidate or otherwise dispose of the remaining USC assets. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer selling compounded pharmaceutical or veterinary products.

Adamis and USC have contracts with customers when (i) the Company enters into an enforceable contract with a customer that defines each party's rights regarding the goods or services to be transferred and identifies the related payment terms, (ii) the contract has commercial substance, and (iii) the Company determines that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

Termination of the Distribution and Commercialization Agreement for SYMJEPI with Sandoz Inc.

On May 11, 2020, the Company entered into an agreement (the "Termination Agreement") with Sandoz Inc. ("Sandoz") to terminate the Distribution and Commercialization Agreement dated as of July 1, 2018 (the "Sandoz Agreement") and entered into between the Company and Sandoz, following an initial transition period which has ended as a result of the execution of a transition services agreement, and reacquire rights to the SYMJEPI products. The Termination Agreement provided for the mutually agreed return to Adamis of the marketing, promotion, and distribution rights, and certain marketing and promotional materials, relating to the SYMJEPI products, and the termination of the Sandoz Agreement, supported by a transition services agreement that the Company entered into with Sandoz and USWM, LLC ("USWM" or "US WorldMeds"), concerning certain transition services, activities and arrangements relating to the SYMJEPI products. As part of the Termination Agreement, Sandoz continued to support the products in the U.S. under the Sandoz Agreement through the end of the transition period to help reduce or minimize any potential impact to patients and customers. The Termination Agreement also provided for a future resolution of any amounts that may be payable or owed with respect to the net sales and profit sharing provisions of the Sandoz Agreement, and for survival of certain provisions of the Sandoz Agreement. As a result of entering into the Termination Agreement with Sandoz, the Company's financial results for the quarter ending June 30, 2020, included an impairment of the capitalized cost to obtain a contract of $1,750,000.

Entering Into an Exclusive Distribution and Commercialization Agreement for SYMJEPI and ZIMHI with US WorldMeds

On May 11, 2020, the Company also entered into an exclusive distribution and commercialization agreement (the "USWM Agreement") with USWM for the United States commercial rights for the SYMJEPI products, as well as for the Company's ZIMHI™ (naloxone HCI Injection, USP) 5mg/0.5mL product candidate intended for the emergency treatment of opioid overdose.

Under the terms of the USWM Agreement, the Company appointed USWM as the exclusive (including as to the Company) distributor of SYMJEPI in the United States and related territories ("Territory") effective upon the termination of the Sandoz Agreement, and of the ZIMHI product if approved by the U.S. Food and Drug Administration ("FDA") for marketing, and granted USWM an exclusive license under the Company's patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the products in the Territory, subject to the provisions of the USWM Agreement, in partial consideration of an initial payment by USWM and potential regulatory and commercial based milestone payments totaling up to $26 million, if the milestones are achieved. There can be no assurances that any of these milestones will be met or that any milestone payments will be paid to the Company. The Company retains rights to the intellectual property subject to the USWM Agreement and to commercialize both products outside of the Territory. In addition, the Company may continue to use the licensed intellectual property (excluding certain of the licensed trademarks) to develop and commercialize other products (with certain exceptions), including products that utilize the Company's Symject™ syringe product platform.

Drug Development and Commercialization Revenue Recognition

Sandoz

Effective July 1, 2018, Adamis signed an exclusive distribution and commercialization agreement with Sandoz. This agreement granted Sandoz the exclusive rights to market, sell and distribute the Company's SYMJEPI epinephrine pre-filled syringe injectable products ("Products") throughout the United States only. The Company generated revenue from this agreement by manufacturing and supplying Sandoz with Products. The Company's performance obligation was to manufacture and supply the Products to Sandoz based on the Purchase Orders received.

The initial term for the agreement with Sandoz began on the effective date of the agreement and continued for a period of 10 years from the first launch of Product in the United States, unless terminated earlier in accordance with its terms. We have determined that the individual Purchase Orders, whose terms and conditions taken with the distribution and commercialization agreement, created the Topic 606 contracts. Under the agreement, the term automatically renewed for one year terms after the initial 10-year term and subsequent renewal terms, unless terminated by either party. The revenue arrangements (including Purchase Orders) generally consist of a single performance obligation, which was satisfied at the point in time when the Product is delivered to the carrier, as control, title and risk of loss is passed on to Sandoz upon delivery of the products to the carrier.

The Company had the following payment considerations with Sandoz: (1) one-time milestone payment, which grants Sandoz the option for the distribution and commercialization of the Product in the United States market only. This one-time milestone payment was a non-refundable up-front fee and was considered a material right. Revenue from this up-front fee was recognized as the option to distribute is exercised, which is substantially the expected customer life, estimated as 10 years. The period of recognition was subject to adjustment if the expected customer life changes; and (2) considerations which were recognized upon satisfaction of the performance obligation, comprised of the following:

(i) Firm Orders based on Purchased Orders received, specifying quantities ordered by Sandoz. Sandoz was obligated to pay Adamis for Products ordered based on a supply pricing arrangement plus additional cost of shipping and distribution. This fixed consideration did not require estimation, as the terms of the fixed payment relate to the Company's efforts to satisfy distinct goods in the contract; and

(ii) Profit sharing arrangement, which required Sandoz to pay Adamis 50% of the net profit generated from the sale of Products by Sandoz over a given quarter. The variable consideration from profit sharing is estimated based on current sales levels and historical experience using the expected value method, subject to constraint.

The arrangement with Sandoz also included sales-based royalties in the form of commercial milestone payments that were payable upon successful achievement of certain milestone events specified under the agreement. There were five commercial milestone events, based on certain revenue thresholds from Products sold over the term. The variable consideration from milestone payments was estimated using the most likely amount method, subject to constraint.

In accordance to ASC 606, an estimate of the expected net profit share or commercial milestone payments that the Company has present rights to, shall be recognized when there is a basis to reasonably estimate the amount of these considerations and only to the extent that it is probable that a significant reversal of any incremental revenue will not occur, taking into consideration historic activity, performance against established targets and other factors affecting the estimates. Revenues do not include any state or local taxes collected from customers on behalf of governmental authorities. The Company made the accounting policy election to continue to exclude these amounts from revenues.

USWM

Effective May 11, 2020 (the "Effective Date"), Adamis and USWM entered into the USWM Agreement. The initial term for the USWM Agreement began on the Effective Date and continues for a period of 10 years from the launch by USWM of the first product in the United States pursuant to the agreement, unless terminated earlier in accordance with its terms. We have determined that the individual purchase orders, whose terms and conditions taken with the distribution and commercialization agreement, creates a contract according to ASC 606. The term will automatically renew for five year terms after the initial 10-year term, unless terminated by either party.

The Company has determined that there are two performance obligations in the contract: (i) the manufacture and supply of SYMJEPI™ and ZIMHI™ products to USWM; and (ii) the exclusive distribution and commercialization in the United States.

Revenues from the manufacture and supply of SYMJEPI™ and ZIMHI™ are recognized at a point in time upon delivery to USWM. The right of exclusive distribution and commercialization is considered a symbolic license and will be recognized over time over the life of the contract. The Company believes that due to ongoing efforts to comply with regulations that a performance obligation continues to exist over the life of the contract. Under the USWM Agreement, the Company is entitled to receive various amounts and milestone payments, including: (1) certain non-refundable up-front fees for executing the agreement and regulatory milestone payments, both of which will be recognized over the expected customer life, estimated to be equal to the initial 10-year term of the agreement; (2) net-profit sharing payments based on certain percentages of net profit generated from the sale of products over a given quarter; (3) commercial milestone payments. Items (2) and (3) are royalties generated from the exclusive right to distribute and commercialize SYMJEPI and ZIMHI in the United States; these are considered sales-based royalties of intellectual property and recognized as they occur. Receivable from USWM has a payment term of Net 30.

Revenues do not include any state or local taxes collected from customers on behalf of governmental authorities. The Company made the accounting policy election to continue to exclude these amounts from revenues.

Revenue

The Company outsources the manufacturing of the SYMJEPI product to third party manufacturers who bear the responsibility of maintaining a suitable environment as governed by specific regulatory and quality requirements. The Company's revenues relating to its FDA approved product SYMJEPI are dependent on an exclusive distribution agreement with USWM, which replaced the previous Sandoz Agreement in May 2020.

Deferred Revenue

Deferred Revenue are contract liabilities that the Company records when cash payments are received or due in advance of the Company's satisfaction of performance obligations. The Company's performance obligation is met when control of the promised goods is transferred to the Company's customers. For the years ended December 31, 2021 and 2020, $100,000 and $900,000 of the revenues recognized were reported as deferred revenue as of December 31, 2020 and 2019, respectively. The balance of deferred revenue December 30, 2021 and December 31, 2020 was $850,000 and $950,000, respectively, relating to the non-refundable upfront payment received from USWM pursuant to the USWM Agreement. As of January 1, 2020, the balance of deferred revenue was $900,000, relating to the non-refundable upfront payment received from Sandoz. On May 11, 2020, the Company entered into a termination agreement with Sandoz which resulted in the acceleration of recognition of the upfront payment from Sandoz to revenue over the transition service agreement period.

Cost to Obtain a Contract

The Company capitalizes incremental costs of obtaining a contract with a customer if the Company expects to recover those costs and that it would not have been incurred if the contract had not been obtained. The deferred costs, reported in the prepaid expenses and other current assets and other non-current assets on the Company's Consolidated Balance Sheets, will be amortized over the economic benefit period of the contract.

In 2018, the Company capitalized the $2.0 million fee paid to a financial advisor as an incremental cost of obtaining a contract to commercialize and distribute the Company's first FDA approved product SYMJEPI with Sandoz. On May 11, 2020, the Company entered into a termination agreement with Sandoz. As a result of entering into the termination agreement, the Company determined that its financial results for the year ended December 31, 2020 included the recognition of a full $1,750,000 impairment of the unamortized cost to obtain a contract.

Practical Expedients

As part of the adoption of the ASC Topic 606, the Company elected to use the following practical expedients: (i) incremental costs of obtaining a contract in the form of sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded within Selling, General and Administrative expenses; (ii) taxes collected from customers and remitted to government authorities and that are related to the sales of the Company's products, are excluded from revenues; and (iii) shipping and handling activities are accounted for as fulfillment costs and recorded in cost of sales.

NOTE 6: CONCENTRATIONS

Financial instruments that potentially subject the Company to credit risk consist principally of cash, trade receivables, and accounts payable.

Cash and Cash Equivalents

The Company at times may have cash in excess of the Federal Deposit Insurance Corporation ("FDIC") limit. The Company maintains its cash with larger financial institutions. The Company has not experienced losses on these accounts and management believes that the Company is not exposed to significant risks on such accounts.

Sales and Trade Receivables

Trade receivables are primarily short-term receivables from sales of compounded products to clinics/hospitals and directly to patients, and of the FDA approved SYMJEPI products through a distribution channel.

The Company had one customer that have a balance greater than 10% of the accounts receivables at December 31, 2021 and 2020.

	December 31, 2021	December 31, 2020
Customer A	100%	100%

The Company had two customers that accounted for more than 10% of total sales for the years ended December 31, 2021 and 2020.

	December 31, 2021	December 31, 2020
Customer A	100%	52.8%
Customer B	—	47.2%

For the years ended December 31, 2021 and 2020 Customer A had approximately $4.2 million and $1.5 million of total sales for the year, respectively. Customer B had approximately $0 and $1.3 million of total sales for the years ended December 31, 2021 and 2020, respectively. Customer A and B are reputable distribution firms and have generally paid their obligations to the Company in a timely manner. Moreover, due diligence and review of credit worthiness were made prior to entering into the distribution contract with the customers. The Company mitigates its credit risks by performing ongoing credit evaluations of its customers' financial conditions.

Purchases and Accounts Payable

The Company had six vendors that had a balance of greater than 10% of trade accounts payables at December 31, 2021 and 2020.

	December 31, 2021	December 31, 2020
Vendor A	19%	Less than 10%
Vendor B	13%	Less than 10%
Vendor C	12 %	Less than 10%
Vendor D	11%	Less than 10%
Vendor E	Less than 10%	29%
Vendor F	Less than 10%	17%

The Company had two vendors that accounted for more than 10% of total purchases for the years ended December 31, 2021 and 2020.

	December 31, 2021	December 31, 2020
Vendor E	13%	10%
Vendor F	10%	11%

Vendor E had approximately $3.5 million and $2.7 million of total purchases for the years ended December 31, 2021 and 2020, respectively. Vendor F accounted for approximately $2.6 million and $2.8 million of total purchases for the years ended December 31, 2021 and 2020, respectively. The Company has minimal or no exposure to the elimination of Vendor E or Vendor F, there are a number of companies which could provide the same services, and management believes, on comparable terms.

NOTE 7: INVENTORIES

Inventories at December 31, 2021 and December 31, 2020 consisted of the following:

	December 31, 2021	December 31, 2020
Finished Goods	$ —	$ 892,897
Work-in-Process	386,610	334,164
Raw Materials	31,997	—
Total Inventories	$ 418,607	$ 1,227,061

Reserve for obsolescence as of December 31, 2021 and December 31, 2020 was approximately $0 and $255,000, respectively.

NOTE 8: PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2021 and December 31, 2020:

	December 31, 2021	December 31, 2020
Prepaid Insurance	$ 347,511	$ 153,240
Prepaid - Research and Development	115,119	562,832
Other Prepaid	635,620	560,510
Other Current Assets	215,296	13,085
	$ 1,313,546	$ 1,289,667

NOTE 9: FIXED ASSETS

Fixed assets at December 31, 2021 and December 31, 2020 are summarized in the table below:

Description	Useful Life (Years)	December 31, 2021	December 31, 2020
Machinery and Equipment	3 - 5	4,522,583	4,072,261
Less: Accumulated Depreciation		(3,181,567)	(1,745,823)
Construction In Progress - Equipment		993,752	171,440
Fixed Assets, net		$ 2,334,768	$ 2,497,878

For the years ended December 31, 2021 and 2020, depreciation expense was approximately $1,436,000 and $1,308,000, respectively.

NOTE 10: LEASES

The Company has one operating lease for an office space. As of December 31, 2021, the lease has a remaining term of approximately 23 months. The operating lease does not include an option to extend beyond the life of the current term. There are no short-term leases, and the lease agreements do not require material variable lease payments, residual value guarantees or restrictive covenants.

The Company previously entered into a lease agreement to occupy leased premises with a term commencing December 1, 2014 (as amended, the "Lease") and expiring on November 30, 2018. On December 29, 2017, the Company entered into a First Amendment to Lease (the "Amendment") with the Lessor of the space, amending the Lease. Pursuant to the Amendment, the Company and Lessor agreed to extend the term of the Lease through November 30, 2023. The Amendment provides that the Company will pay its current base rent through November 30, 2018. Commencing on December 1, 2018 base rent was initially approximately $28,000 per month for the first 12 months and will increase annually to approximately $32,000 for the 12 months ending November 30, 2023. The Amendment also provides for one option to expand pursuant to which the Company has a right of first refusal for additional office space within the property. Total annual rent expense for the years ended December 31, 2021 and 2020 was approximately $356,000, respectively.

The Company elected the practical expedient to not separate lease and non-lease components. The tables below present the operating lease asset and liabilities recognized on the consolidated balance sheets as of December 31, 2021 and December 31, 2020:

Right-of Use Assets	December 31, 2021	December 31, 2020
Operating Lease	$ 650,460	$ 969,999

Lease Liabilities, Current	December 31, 2021	December 31, 2020
Operating Lease	$ 349,871	$ 325,766
Lease Liabilities, Non-Current		
Operating Lease	342,562	692,433
Total Lease Liabilities	$ 692,433	$ 1,018,199

The amortizable lives of operating leased asset is limited by the expected lease term.

The Company's lease generally do not provide an implicit rate, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment. The Company used incremental borrowing rates as of January 1, 2019 for leases that commenced prior to that date and the prevailing incremental borrowing rate thereafter.

The Company's weighted average remaining lease term and weighted average discount rate for operating and financing leases as of December 31, 2021 and 2020 are:

December 31, 2021	**Operating**
Weighted Average Remaining Lease Term	1.92 Years
Weighted Average Discount Rate	3.95%

December 31, 2020	**Operating**
Weighted Average Remaining Lease Term	2.92 Years
Weighted Average Discount Rate	3.95%

The table below reconciles the undiscounted future minimum lease payments (displayed by year and in the aggregate) under non-cancelable leases with terms of more than one year to the total lease liabilities recognized on the audited consolidated balance sheets as of December 31, 2021:

December 31, 2021	**Operating**
2022	$ 370,950
2023	349,365
Undiscounted Future Minimum Lease Payments	720,315
Less: Difference between undiscounted lease payments and discounted lease liabilities	27,882
Total Lease Liabilities	$ 692,433
Short-Term Lease Liabilities	$ 349,871
Long-Term Lease Liabilities	$ 342,562

Operating lease expense was approximately $354,000 and $354,000 for the years ended December 31, 2021 and 2020. Operating lease costs are included within selling, general and administrative expenses on the consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities were approximately $360,000 and $350,000 for the years ended December 31, 2021 and 2020, respectively.

NOTE 11: ACCRUED OTHER EXPENSES

Accrued other expenses at December 31, 2021 and December 31, 2020:

	December 31, 2021	December 31, 2020
Accrued Expenses - R&D	$ 741,521	$ 6,069
Accrued Expenses - COGS	658,282	858,178
Accrued Expenses - Inventory	584,731	222,011
Accrued Expenses - Other	500,309	99,080
Accrued PTO	315,398	383,514
Deferred Social Security	—	71,660
	$ 2,800,241	$ 1,640,512

NOTE 12: DEBT

First Draw Paycheck Protection Program Loan

On April 13, 2020, the Company received $3,191,700 in loan funding from the Paycheck Protection Program (the "PPP"), established pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and administered by the U.S. Small Business Administration ("SBA"). The unsecured loan (the "PPP Loan") is evidenced by a promissory note of the Company (the "Note"), in the principal amount of $3,191,700, to Arvest Bank (the "Bank"), the lender. The application for these funds required the Company to, in good faith, certify that the current economic uncertainty made the loan request necessary to support the ongoing operations of the Company. Subsequent guidance from the SBA and the Department of the Treasury indicated that in assessing the economic need for the loan, a borrower must take into account its current activity and ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. The receipt of these funds pursuant to the PPP Loan, and the forgiveness of the PPP Loan attendant to these funds, is dependent on the Company having initially qualified for the loan and, in the case of forgiveness, qualifying for the forgiveness of such loan based on our future adherence to the forgiveness criteria.

Under the terms of the Note and the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the Note is two years, unless sooner provided in connection with an event of default under the Note. To the extent the loan amount is not forgiven under the PPP, the Company is obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the Note (or later if a timely loan forgiveness application has been submitted), until the maturity date.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, the Company may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by the Company during a specified period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 60% of the loan amount is used for eligible payroll costs; the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week or 24-week period will qualify for forgiveness.

In December 2020, the Company submitted an application for the forgiveness of our PPP Loan. In August 2021, the Company received notification through the Bank that as of August 5, 2021, the PPP Loan, including principal and interest thereon, has been fully forgiven by the SBA and that the remaining PPP Loan balance is zero. The Company recognized the amount forgiven as other income.

Second Draw PPP Loan

On March 15, 2021, the Company entered into a Note (the "PPP2 Note") in favor of the Bank, in the principal amount of $1,765,495 relating to funding under a Second Draw loan (the "Second Draw Loan") pursuant to the terms of the PPP, the CARES Act, and the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act enacted in December 2020. Under the terms of the PPP2 Note and Second Draw Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP2 Note is five years, unless sooner provided in connection with an event of default under the PPP2 Note. The Company may prepay the Second Draw Loan at any time prior to maturity with no prepayment penalties. Under the PPP, the proceeds of the Second Draw Loan may be used to pay payroll and make certain covered interest payments, lease payments and utility payments. The Company may apply for forgiveness of some or all of the Second Draw Loan pursuant to the PPP. In order to obtain full or partial forgiveness of the Second Draw Loan, the borrower must timely request forgiveness, must provide satisfactory documentation in accordance with applicable SBA guidelines, and must satisfy the criteria for forgiveness under the PPP and applicable SBA requirements. If the Company timely applies for forgiveness, payments will be deferred in accordance with the CARES Act, as modified by the Paycheck Protection Program Flexibility Act of 2020, and we will not be obligated to make any payments of principal or interest before the date on which the SBA remits the loan forgiveness amount to the Bank or notifies the Bank that no loan forgiveness is allowed; and the Bank will then notify us of remittance by SBA of the loan forgiveness amount or notify us that the SBA determined that no loan forgiveness is allowed and the date that our first payment is due. Interest will accrue during the deferral period. The PPP2 Note contains customary events of default relating to, among other things, payment defaults, breaches of representations, warranties or covenants, defaults on other loans with the Bank, failure to disclose material facts or making materially false or misleading representations to the Bank or SBA, certain defaults on other loan agreements or agreements with creditors, bankruptcy or insolvency events, certain change of control events, material adverse changes or events, certain events that the Bank believes may materially affect the Company's ability to pay the PPP2 Note, and certain other events.

Upon the occurrence of an event of default, the Bank has customary remedies and may, among other things, require immediate payment of all amounts owed under the Note, collect all amounts owing from the Company, and file suit and obtain judgment against the Company.

In September 2021, the Company submitted an application for the forgiveness of our Second Draw PPP Loan. In October 2021, the Company received notification through the Bank that as of September 28, 2021, the Second Draw PPP Loan, including principal and interest thereon, has been fully forgiven by the SBA and that the remaining PPP Loan balance is zero. The Company recognized the amount forgiven as other income.

Even though the PPP Loan and the Second Draw PPP Loan have been forgiven, our PPP loans and applications for forgiveness of loan amounts remain subject to review and audit by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form, including without limitation the required economic necessity certification by the Company that was part of the PPP loan application process. Accordingly, the Company is subject to audit or review by federal or state regulatory authorities as a result of applying for and obtaining the PPP Loan and Second Draw PPP Loan or obtaining forgiveness of those loans. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return or repay the full amount of the applicable loan and could be subject to fines or penalties, which could reduce our liquidity and adversely affect our business, financial condition and results of operations. If it is determined that the Company was ineligible to receive the PPP Loan and/or the Second Draw Loan, the Company may be required to repay the PPP Loan and Second Draw Loan in its entirety and/or be subject to additional penalties.

NOTE 13: FAIR VALUE MEASUREMENTS

The carrying value of the Company's cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to the short-term nature of these items. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the debt approximates fair value.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1: Unadjusted quoted prices in active markets for identical assets or liabilities;

Level 2: Inputs other than quoted prices included within Level 1 that are observable, unadjusted quoted prices 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 related assets or liabilities; and

Level 3: Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy:

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Liabilities				
2020 Warrant liability	$ 99,655	—	—	$ 99,655
Total common stock warrant liabilities	$ 99,655	$ —	$ —	$ 99,655

The fair value measurement of the warrants issued by the Company in February 2020 (the "2020 Warrants") are based on significant inputs that are unobservable and thus represents a Level 3 measurement. The Company's estimated fair value of the Warrant liability is calculated using the Black Scholes Option Pricing Model. Key assumptions at December 31, 2021 include the expected volatility of the Company's stock of approximately 70%, the Company's stock price at valuation date of $0.605, expected dividend yield of 0.0% and average risk-free interest rate of approximately 1.038%. The Level 3 estimates are based, in part, on subjective assumptions. During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs.

	Fair Value Measurements at December 31, 2020			
	Total	Level 1	Level 2	Level 3
Liabilities				
2019 Warrant liability	$ 2,484,000	$ —	$ —	$ 2,484,000
2020 Warrant liability	2,001,000	—	—	2,001,000
Total common stock warrant liabilities	$ 4,485,000	$ —	$ —	$ 4,485,000

The fair value measurement of the warrants issued by the Company in August 2019 (the "2019 Warrants") and the 2020 Warrants are based on significant inputs that are unobservable and thus represents a Level 3 measurement. The Company's estimated fair value of the Warrant liability is calculated using the Black Scholes Option Pricing Model. Key assumptions include the expected volatility of the Company's stock of approximately 80% and 70% for 2019 and 2020 Warrants, respectively; the Company's stock price at valuation date of $0.49; expected dividend yield of 0.0% and; average risk-free interest rate of approximately 0.26% and 0.36% for 2019 and 2020 Warrants, respectively. The Level 3 estimates are based, in part, on subjective assumptions. During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments, which are treated as liabilities, as follows:

	2019 Warrant		2020 Warrant	
	Number of Warrants	Liability (in thousands)	Number of Warrants	Liability (in thousands)
Balance at December 31, 2019	13,800,000	3,036,000	—	—
2020 Warrant Issuance	—	—	8,700,000	1,914,000
Change in Fair Value, December 31, 2020		(552,000)	—	87,000
Balance at December 31, 2020	13,800,000	$ 2,484,000	8,700,000	$ 2,001,000
Adoption of ASC 2020-06	(13,800,000)	(2,484,000)	—	—
Change in Fair Value of Warrants at Date of Exercise	—	—	—	7,521,150
Exercise of Warrants	—	—	(8,350,000)	(9,441,650)
Change in Fair Value, Year ended December 31, 2021	—	—	—	19,155
Balance at December 31, 2021	—	$ —	350,000	$ 99,655

NOTE 14: LEGAL MATTERS

The Company may from time to time become party to actions, claims, suits, investigations or proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, breach of contract claims, labor and employment claims and other matters. We may also become party to litigation in federal and state courts relating to opioid drugs. Any litigation could divert management time and attention from Adamis, could involve significant amounts of legal fees and other fees and expenses, or could result in an adverse outcome having a material adverse effect on our financial condition, cash flows or results of operations. Actions, claims, suits, investigations and proceedings are inherently uncertain and their results cannot be predicted with certainty. Except as described below, we are not currently involved in any legal proceedings that we believe are, individually or in the aggregate, material to our business, results of operations or financial condition. However, regardless of the outcome, litigation can have an adverse impact on us because of associated cost and diversion of management time.

Investigation

On May 11, 2021, the company and USC each received a grand jury subpoena from the U.S. Attorney's Office for the Southern District of New York ("USAO"). The USAO issued the subpoenas in connection with a criminal investigation and requested a broad range of documents and materials relating to, among other matters, certain veterinary products sold by USC, certain practices, agreements, and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC. On May 11, 2021, the Audit Committee of the Board engaged outside counsel to conduct an independent internal investigation to review the matters brought forth in the subpoenas and certain other matters. The investigation involved, among other matters, interviews with employees and collection and review of a large number of documents. The company has taken a number of actions in response to the internal investigation, including personnel actions relating to certain USC veterinary sales employees. In addition, following the commencement of the investigation, the company has sold assets relating to its compounding pharmacy business, ceased selling human and veterinary compounded pharmaceutical products, is engaged in a process of winding down USC's business, and the employment of substantially all USC employees has ended or will end in connection with the winding down of that business. As a result, the company will no longer be engaged in the sale of human or veterinary compounded pharmaceutical products. The company is also considering a number of additional actions in response to the internal investigation. As of the date of this Report, we believe that the investigation initially commenced by the Audit Committee is substantially complete. However, additional issues or facts could arise or be determined, which may expand the scope, duration, or outcome of the Audit Committee's investigation. In addition to the subpoenas from the USAO, the company has also received requests from the U.S. Securities and Exchange Commission ("SEC") for the voluntary production of documents and information relating to the subject matter of the USAO's subpoenas and certain other matters. The company has produced documents and will continue to produce and provide documents in response to the subpoenas and requests. The company intends to cooperate with the USAO and the SEC. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, or other agencies, or determine what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate, what, if any, remedies or remedial measures the USAO, SEC, or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the company's business, previously reported financial results, financial results included in this Report, or future financial results. We could receive additional requests from the USAO, SEC, or other authorities, which may require further investigation. There can be no assurance that any discussions with the SEC or USAO to resolve these matters will be successful. The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, result in fines, penalties or equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, or future financial results. The occurrence of any of these events, or any determination that our activities were not in compliance with existing laws or regulations, could have a material adverse effect on the company's business, financial condition, and results of operations.

Regulatory

In October 2021, following the sale in July 2021 of certain assets of the Company's USC subsidiary relating to USC's human compounding pharmaceutical business and the Company's approval of a restructuring process of winding down the remaining operations and business of USC and selling or disposing of the remaining assets of USC, the Company entered into a Consent Order with the Arkansas State Board of Pharmacy to resolve an ongoing administrative proceeding before the pharmacy board, pursuant to which USC agreed to surrender its Arkansas retail pharmacy permit and wholesaler/outsourcer permit effective October 31, 2021, to pay a civil penalty of $75,000 relating to violations of various Arkansas pharmacy laws and the pharmacy board's regulations, and to pay $75,000 in investigative costs of the pharmacy board. The total amount of $150,000 levied by the pharmacy board was paid during the year ended December 31, 2021.

Jerald Hammann

On June 8, 2021, Jerald Hammann filed a complaint against the Company and each of its directors in the Court of Chancery of the State of Delaware, captioned *Jerald Hammann v. Adamis Pharmaceuticals Corporation et al.*, C.A. No. 2021-0506-PAF (the "Complaint"), seeking injunctive and declaratory relief. The Complaint alleges, among other things, that the defendants (i) violated Rule 14a-5(f) and 14a-9(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in connection with the Company's 2021 annual meeting of stockholders—which was subsequently held on July 16, 2021 (the "2021 annual meeting")—and disseminated false and misleading information in the Company's proxy materials relating to the 2021 annual meeting, (ii) violated certain provisions of the Company's bylaws relating to the 2021 annual meeting, (iii) violated section 220 of the Delaware General Corporation Law ("DGCL") in connection with a request for inspection of books and records submitted by the plaintiff, and (iv) breached their fiduciary duties of disclosure and loyalty, including relating to establishing and disclosing the date of the Company's 2021 annual meeting and to the Company's determination that a solicitation notice delivered to the Company by plaintiff was not timely and was otherwise deficient. The Complaint alleges, among other things, that plaintiff intended to initiate a proxy contest against the Company, that defendants' conduct made it difficult or impossible for plaintiff to initiate a proxy context, and that the Company's definitive proxy statement included false and misleading disclosures and omissions of material information. The Complaint sought injunctive relief (i) to prevent the Board, the Company, and their employees and agents from soliciting any stockholders pursuant to the Company's proxy statement and (ii) to prevent the defendants from interfering in the effectiveness of stockholder voting for the 2021 annual meeting. The Complaint also seeks declaratory relief (i) finding that plaintiff's solicitation notice was timely and properly submitted; (ii) directing the defendants to comply with Rules 14a-5(f) and 14a-9(a) of the Exchange Act; (iii) directing the Company to produce the materials set forth in the plaintiff's books and records request; (iv) finding that the director defendants breached their fiduciary obligations to stockholders; and (v) finding that the director defendants engaged in self-dealing. The Complaint seeks an award of fees, costs, and expenses in this action, including attorneys' and experts' fees.

On June 10, 2021, the plaintiff filed a motion for a temporary restraining order and for expedited proceedings, seeking an order enjoining the Company from printing or disseminating its proxy statement relating to the 2021 annual meeting or from convening the 2021 annual meeting on July 16, 2021. Following a hearing, on June 17, 2021, the Court determined that: (i) it did not have jurisdiction to consider the plaintiff's claims relating to alleged violations of the Exchange Act; (ii) plaintiff's claims regarding the books and records request and alleged violations of section 220 of the DGCL should be pursued in a separate proceeding, and the Court denied the plaintiff's motion to expedite the books and records claims; (iii) certain of the plaintiff's claims alleging breach of the fiduciary duty of disclosure against the individual defendants, including claims based on alleged misrepresentations and omissions in the Company's proxy statement, were not colorable; and (iv) plaintiff's claim alleging that the individual defendants violated their fiduciary duty by taking action purportedly intended to prevent the plaintiff from pursuing a proxy contest survived a low threshold of colorability, but the Court denied the plaintiff's motion for a temporary restraining order. The Court granted in part the motion to expedite the proceedings.

The case is proceeding and the parties are currently engaged in discovery. In March 2022, plaintiff filed a motion for a temporary restraining order and for expedited proceedings, seeking an order enjoining the Company and its directors from (a) changing the number of members of the Company's board of directors, (b) adding members to the Company's board of directors, and/or (c) replacing any resigning members of the Company's board of directors. The Company has responses to the plaintiff's motion. The court held a hearing on March 28, 2022, and denied the plaintiff's motion in full. The Company believes the claims in plaintiff's Complaint are without merit, and intends to vigorously dispute them.

The Company records accruals for loss contingencies associated with legal matters when the Company determines it is probable that a loss has been or will be incurred and the amount of the loss can be reasonably estimated. Where a material loss contingency is reasonably possible and the reasonably possible loss or range of possible loss can be reasonably estimated, U.S. GAAP requires us to disclose an estimate of the reasonably possible loss or range of loss or make a statement that such an estimate cannot be made. The company has not accrued any amount in respect of the matters described under the headings "Investigation" or "Jerald Hammann," since even if it is probable that such matters may result in a material loss contingency, we cannot estimate the probable loss or the range of probable losses that we may incur. We are unable to make such an estimate because (i) with respect to the matters described under the heading "Investigation," we are unable to predict whether any proceedings will be initiated by the USAO, SEC or other authorities arising from such matters, what, if any, relief, remedies or remedial measures the USAO, SEC, or other authorities may seek if proceedings are commenced, and the duration, scope, or outcome of any such proceedings, if they are commenced, (ii) litigation and other proceedings are inherently uncertain and unpredictable, and (iii) with respect to the matters described under the heading "Jerald Hammann," the complaint seeks declaratory and injunctive relief. Because legal proceedings and investigations are uncertain and unpredictable and unfavorable results could occur, assessing contingencies is highly subjective and requires significant judgments about future events, including determining both the probability and reasonably estimated amount of a possible loss or range of loss. The amount of any ultimate loss may differ from any accruals or estimates that the Company may make.

NOTE 15: LICENSING AGREEMENTS

3M License and Asset Acquisition Agreement

The Company recognized certain intellectual property and assets relating to 3M's Taper Dry Powder Inhaler (DPI) technology that was under development for the treatment of asthma and chronic obstructive pulmonary disease upon acquisition in 2013.

In light of the time and costs involved in further product development efforts and competitive conditions in the relevant markets related to the Taper DPI intellectual property, we are not devoting, and do not intend to devote, any substantial financial resources to development of this product candidate, and we have determined not to pursue further development efforts regarding this product candidate. As a result, the Company recorded an impairment charge of approximately $2,913,000, which was the carrying value of the Taper DPI intellectual property, for the year ended December 31, 2020.

Tempol

On June 12, 2020, we entered into a license agreement with Matrix Biomed, Inc., or the Licensor, to license rights under patents, patent applications and related know-how of Licensor relating to Tempol, an investigational drug. The exclusive license includes the worldwide use under the licensed patent rights and related rights of Tempol for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection. In addition, the exclusive license includes the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. In consideration for the Licensor providing the rights under its patent rights and related know-how relating to Tempol within the licensed fields, we paid Licensor $250,000 and also issued to the Licensor 1,000,000 shares of our Series B Convertible Preferred Stock, which was converted into an equal number of shares of our common stock during the year ended December 31, 2020.

NOTE 16: COMMITMENTS AND CONTINGENCIES

The Company has a production threshold commitment to a manufacturer of our SYMJEPI Products where the Company would be required to pay for maintenance fees if it does not meet certain periodic purchase order minimums. Any such maintenance fees would be prorated as a percentage of the required minimum production threshold. Maintenance fees for the years ended December 31, 2021 and 2020 were approximately $0 and $746,000, respectively.

For information concerning contingencies relating to legal proceedings, see Note 14 of the notes to the consolidated financial statements.

Ben Franklin Note

Biosyn (a wholly owned subsidiary of the Company issued a note payable to Ben Franklin Technology Center of Southeastern Pennsylvania ("Ben Franklin Note") in October 1992, in connection with funding the development of Savvy (C31G), a compound then under development to prevent the transmission of HIV/AIDS.

The repayment terms of the non-interest bearing obligation include the remittance of an annual fixed percentage of 3.0% applied to future revenues of Biosyn, if any, until the principal balance of $777,902 (face amount) is satisfied. Under the terms of the obligation, revenues are defined to exclude the value of unrestricted research and development funding received by Biosyn from nonprofit sources. Absent a material breach of contract or other event of default, there is no obligation to repay the amounts in the absence of future Biosyn revenues. Cellegy accreted the discount of $572,902 against earnings using the effective interest rate method (approximately 46%) over the discount period of five years, which was estimated in connection with the Ben Franklin Note's valuation at the time of the acquisition.

The Ben Franklin Note's repayment terms outlined above affects its comparability with main stream market issues and also affects its transferability. The value of the Ben Franklin Note would also be impacted by the ability to estimate Biosyn's expected future revenues which in turn hinge largely upon future efforts to commercialize the product candidate, the results of which efforts are not known by the Company. Given the above factors and therefore the lack of market comparability, the Ben Franklin Note would be valued based on Level 3 inputs (see Note 13). As such, management has determined that the Ben Franklin Note will have no future cash flows, as the Company does not believe the product will create a revenue stream in the future. As a result, the Note has no fair market value.

NOTE 17: CAPITAL STRUCTURE

On February 25, 2020, the Company completed a registered direct offering of 11,600,000 shares of common stock, pursuant to its existing shelf registration statement and a prospectus supplement and accompanying prospectus, and a concurrent private placement of warrants to purchase 8,700,000 shares of common stock, to a small number of investors. The combined purchase price for one share and 0.75 warrant was $0.58, and the aggregate gross proceeds was $6,700,000, excluding any future proceeds from the potential exercise of the warrants and before deducting placement agent fees and other offering expenses of approximately $495,000 payable by the Company. The warrants have an exercise price of $0.70 per share. The warrants are exercisable commencing on the later of (i) six months from the date of issuance or (ii) the date that the Company's stockholders approve a reverse stock split or an increase in the number of authorized shares of common stock of the Company in an amount sufficient to permit the exercise in full of all of the Warrants. As of September 3, 2020, the Company's stockholders approved an increase in the number of authorized shares and as a result, the warrants become exercisable and will expire on September 3, 2025. The placement agent in connection with the offering received a fee equal to 6.0% of the gross proceeds of the securities sold in the offering and reimbursement of certain out-of-pocket expenses.

On September 22, 2020, the Company completed the closing of an underwritten public offering of 18,548,386 shares of common stock at a public offering price of $0.62 per share, which included 2,419,354 shares pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds were approximately $10.7 million, after deducting approximately $840,000 in underwriting discounts and commissions and estimated offering expenses payable by the Company.

On December 31, 2021, the Company received a notice from the Listing Qualifications Department of Nasdaq notifying the Company that for 30 consecutive business days, the closing bid price of the Company's common stock was below $1.00 per share, which is the minimum required closing bid price for continued listing on the Nasdaq Capital Market pursuant to Marketplace Rule 5550(a)(2). This notice has no immediate effect on the Company's Nasdaq listing or the trading of its common stock. In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from the date of notification, or until June 29, 2022, to regain compliance. If at any time before June 29, 2022, the bid price of the Company's common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that the Company has achieved compliance with the minimum bid price requirement, and the matter would be resolved. The notice letter also disclosed that if the Company does not regain compliance within the initial compliance period, it may be eligible for an additional 180-day compliance period. To qualify for additional time, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of a plan to cure the deficiency during the second compliance period. If the Company meets these requirements, Nasdaq will inform the Company that it has been granted an additional 180 calendar days to regain compliance. However, if it appears to the staff of Nasdaq that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, the staff would notify the Company that it will not be granted additional 180 days for compliance and will be subject to delisting at that time. In the event of such notification, the Company may appeal the staff's determination to delist its securities, but there can be no assurance that any such appeal would be successful. The Company intends to monitor the closing bid price for its common stock and will consider available strategies in an effort to satisfy the minimum bid price requirement. However, there are no assurances that the Company will be able to regain compliance with the minimum bid price requirements or will otherwise be in compliance with other Nasdaq listing rules.

In January and February 2021, the Company issued common stock upon exercise of investor warrants. The warrant holders exercised for cash at exercise prices ranging from $0.70 to $1.15 per share. The Company received total proceeds of approximately $5,852,000 and the warrant holders received 8,356,000 shares of common stock.

On February 2, 2021, the Company completed the closing of an underwritten public offering of 46,621,621 shares of common stock at a public offering price of $1.11 per share, which included 6,081,081 shares pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds were approximately $48.4 million, after deducting approximately $3.3 million in underwriting discounts and commissions and estimated offering expenses payable by the Company.

NOTE 18: CONVERTIBLE PREFERRED STOCK

June 2020 Series B Preferred Stock

In June 2020, the Company entered into a license agreement with Matrix Biomed, Inc. ("Matrix") to license rights under patents, patent applications and related know-how of Matrix relating to Tempol, an investigational drug. In consideration for Matrix providing the rights under its patent rights and related know-how relating to Tempol within the licensed fields, Adamis paid Matrix $250,000 and also issued to Matrix 1,000,000 shares of Adamis Series B Convertible Preferred Stock ("Series B Preferred"). The Series B Preferred was convertible into common stock at an initial conversion rate of 1-for-1. Each share of Series B Preferred will automatically convert into common stock after the occurrence of a Capital Event. "Capital Event" is defined as the filing and effectiveness of an amendment to the Company's certificate of incorporation (or similar charter documents) to either (i) increase the number of shares of common stock the Company is authorized to issue or (ii) effect a reverse split of the common stock, in either event sufficient to permit the conversion in full of the Series B Preferred in accordance with its terms. The conversion rate of the Series B Preferred was subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but was not subject to adjustment based on price anti-dilution provisions or other events. Except with respect to certain stock dividends or distributions payable in shares of common stock or certain other events affecting the common stock, holders of Series B Preferred were not entitled to receive any dividends paid on shares of the Common Stock, and no other dividends were payable on shares of Series B Preferred.

In September 2020, the Capital Event occurred and all of the 1,000,000 shares of Series B Preferred were converted into 1,000,000 shares of common stock. As of December 31, 2020, there are no outstanding shares of Series B Preferred.

NOTE 19: STOCK-BASED COMPENSATION, WARRANTS AND SHARES RESERVED

The Company accounts for stock-based compensation transactions in which the Company receives employee services in exchange for restricted stock units ("RSUs") or options to purchase common stock and the Company recognizes stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period. Stock-based compensation cost for RSUs is measured based on the closing fair market value of the Company's common stock on the date of grant. Stock-based compensation cost for stock options is estimated at the grant date based on each option's fair-value as calculated by the Black-Scholes option-pricing model. The Company accounts for forfeitures as they occur and will reduce compensation cost at the time of forfeiture. Cash-settled Stock Appreciation Rights provide for the cash payment of the excess of the fair market value of the Company's common stock price on the date of exercise over the grant price. The fair value of the SARs is calculated during each reporting period and estimated using the Black-Scholes option pricing model. The SARs will vest over a period of three years and are accounted for as liability awards since they will be settled in cash. Cash-settled SARs have no effect on dilutive shares or shares outstanding as any appreciation of the Company's common stock over the grant price is paid in cash and not in common stock.

At the Company's 2020 annual meeting of stockholders, the stockholders approved the Company's 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards, and other forms of equity compensation (collectively "stock awards"). In addition, the 2020 Plan provides for the grant of cash awards. The initial aggregate number of shares of common stock that may be issued initially pursuant to stock awards under the 2020 Plan is 2,000,000 shares. The number of shares of common stock reserved for issuance automatically increases on January 1 of each calendar year during the term of the 2020 Plan, commencing January 1, 2021, by 5.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares of common stock determined by the Company's board of directors before the start of a calendar year for which an increase applies. One of the provisions of the 2020 Plan is that no award may be granted, issued or made under the 2020 Plan until such time as the fair market value of the common stock, which is generally the closing sales price of the common stock on the principal stock market on which the common stock is traded, has been equal to or greater than $3.00 per share (subject to proportionate adjustment for stock splits, reverse stock splits, and similar events) for at least ten consecutive trading days, after which time awards may be made under the 2020 Plan without regard to any subsequent increase or decrease in the fair market value of the common stock. No awards were made pursuant to the 2020 Plan as of December 31, 2021. As of December 31, 2021, the aggregate balance of shares reserved under the 2020 plan was 6,692,103.

On January 1, 2022, pursuant to the 2020 Equity Incentive Plan the number of shares reserved for the issuance of stock awards increased by 7,479,713 shares.

The Company had a 2009 Equity Incentive Plan (the "2009 Plan"). The 2009 Plan terminated effective February 2019 and no new awards may be made under the 2009 Plan.

On October 1, 2021, the Company granted cash SARs with respect to a total of 50,000 reference units of common stock to certain non-employee director of the Company, with initial reference price of $1.01 per stock appreciation rights ("SARs"). The SARs will vest with respect to the one-sixth of the reference units on the date that is six months after the vesting commencement date and one thirty-sixth of the reference units thereafter on each subsequent monthly anniversary of the vesting commencement date, and is exercisable in full after the third anniversary of the vesting commencement date (and earlier upon a change in control of the Company). The SARs may be settled only in cash.

Stock Options

The following summarizes the stock option activity for the year ended December 31, 2021 below:

	2009 Equity Incentive Plan		Weighted Average Exercise Price	Weighted Average Remaining Contract Life *
Total Outstanding Vested and Expected to Vest as of December 31, 2020	6,508,296	$	4.29	5.60 years
Options Canceled/Expired	(1,522,881)		4.58	—
Total Outstanding Vested and Expected to Vest as of December 31, 2021	4,985,415	$	4.21	4.05 years
Vested as of December 31, 2021	4,980,482	$	4.21	4.05 years

* Maximum contractual term for options is 10 years,

Continuing operations expense related to stock options for the year ended December 31, 2021 and 2020, was approximately $113,000 and $910,000, respectively. Discontinued operations expense related to stock options for the year ended December 31, 2021 and 2020 was approximately $34,000 and $320,000, respectively. As of December 31, 2021, the compensation expense related to stock options issued under the Company's 2009 Equity Incentive Plan have been fully recognized.

The aggregate intrinsic value (the difference between the Company's closing stock price on the last trading day of the year and the exercise price, multiplied by the number of in-the-money options) of 4,985,415 and 6,508,296 stock options outstanding at December 31, 2021 and December 31, 2020 was $0, respectively. The aggregate intrinsic value of 4,980,482 and 6,397,703 stock options exercisable at December 31, 2021 and December 31, 2020 was $0, respectively.

Restricted Stock Units

The following summarizes the RSU activity for the year ended December 31, 2021 below:

	Number of Shares/Unit	Weighted Average Grant Date Fair Value
Non-vested RSUs as of December 31, 2020	2,136,893	$ 3.64
RSUs vested during the period	(774,583)	$ 3.05
RSUs forfeited during the period	(323,307)	$ 3.34
Non-vested RSUs as of December 31, 2021	1,039,003	$ 4.16

The following summarizes the non-vested RSU's as of December 31, 2021:

December 31, 2021	RSUs	Price Per Share at Grant Date
Non-Employee Board of Directors	150,000(1)	$ 8.46
Company Executive	750,000(1)	$ 3.50
Company Executives and Employees	139,003(2)	$ 3.09
Total RSUs	1,039,003	

(1) The RSUs will have cliff vesting after seven years of continuous service or upon change of control from date of grant or upon death or disability.

(2) The RSUs vest ratably quarterly over a period of three years if the recipient has provided continuous service or upon change of control or upon death or disability.

Expense related to RSUs for the year ended December 31, 2021 and 2020 was approximately $1,870,000 and $3,190,000, respectively. For the year ended December 31, 2021 and 2020, there was no RSU related expense within discontinued operations. As of December 31, 2021, the unamortized compensation expense related to RSUs options was approximately $1,146,000 and will be recorded as compensation expense in 1.58 years. The recorded expense related to RSUs for the year ended December 31, 2021 was reduced by approximately $493,000, due to the termination of employees during the year ended December 31, 2021. The Company accounts for forfeiture as they occur and reduces the compensation cost at the time of forfeiture.

Warrants

The following table summarizes warrants outstanding at December 31, 2021 and December 31, 2020:

December 31, 2021	Warrant Shares		Exercise Price Per Share	Date Issued	Expiration Date
Old Adamis Warrants	58,824****	$	8.50	November 15, 2007	November 15, 2022
2019 Warrants	13,794,000**	$	1.15	August 5, 2019	August 5, 2024
2020 Warrants	350,000***	$	0.70	February 25, 2020*	September 3, 2025
Total Warrants	14,202,824				

* On September 3, 2020, the Company's stockholders approved an increase in the number of authorized shares of common stock sufficient to permit exercise in full of all the 2020 warrants, and as a result, the warrants are exercisable effective September 3, 2020.
** The company adopted ASU 2020-06. See Note 3.
*** As of December 31, 2021, the fair value of the warrant liability related to the 2020 Warrants was $99,655. See Note 13.
**** The expiration date was extended by another year.

December 31, 2020	Warrant Shares		Exercise Price Per Share	Date Issued	Expiration Date
Old Adamis Warrants	58,824	$	8.50	November 15, 2007	November 15, 2021
Preferred Stock Series A-1 Warrants	1,183,432	$	4.10	January 26, 2016	January 26, 2021
Preferred Stock Series A-2 Warrants	192,414	$	2.90	July 11, 2016	July 11, 2021
2016 Warrants	700,000	$	2.98	August 3, 2016	August 3, 2021
2019 Warrants	13,800,000**	$	1.15	August 5, 2019	August 5, 2024
2020 Warrants	8,700,000***	$	0.70	February 25, 2020*	September 3, 2025
Total Warrants	24,634,670				

* On September 3, 2020, the Company's stockholders approved an increase in the number of authorized shares of common stock sufficient to permit exercise in full of all the 2020 warrants, and as a result, the warrants are exercisable effective September 3, 2020.
** As of December 31, 2020, the fair value of the warrant liability related to the 2019 Warrants was $2,484,000. See Note 13.
*** As of December 31, 2020, the fair value of the warrant liability related to the 2020 Warrants was $2,001,000. See Note 13.

Shares Reserved

At December 31, 2021, the Company has reserved shares of common stock for issuance upon exercise of outstanding options and warrants, and vesting of RSUs, as follows:

Warrants	14,202,824
RSU	1,039,003
2009 Equity Incentive Plan	4,985,415
Total Shares Reserved	20,227,242

NOTE 20: INCOME TAXES

Net operating losses and tax credit carryforwards as of December 31, 2021 are as follows:

	Amount	Expiration Years
Net operating losses, federal (Post December 31, 2017)	$ 117,511,243	N/A
Net operating losses, federal (Pre January 1, 2018)	86,660,717	2027 - 2038
Net operating losses, state	74,081,135	2030 - 2042
Tax credits, federal	3,016,106	2037 - 2042
Tax credits, state	1,965,946	N/A

Pursuant to Internal Revenue Code Section 382, the annual use of the net operating loss carry forwards and research and development tax credits could be limited by any greater than 50% ownership change during any three year testing period. As a result of any such ownership change, portions of the Company's net operating loss carry forwards and research and development tax credits are subject to annual limitations. The Company completed a Section 382 analysis in 2017, and the net operating loss deferred tax assets reflect the results of the analysis. The recoverability of these carry forwards could be subject to limitations upon future changes in ownership as defined by Section 382 of the Internal Revenue Code. The Company has not completed an ownership change analysis pursuant to IRC Section 382 since 2017. However, the Company has established a valuation allowance as the realization of such deferred tax assets has not met the more likely than not threshold requirement. If ownership changes within the meaning of IRC Section 382 have occurred, the amount of remaining tax attribute carryforwards available to offset future taxable income and income taxes in future years may be significantly restricted or eliminated. Further, the Company's deferred tax assets, along with the corresponding valuation allowance, associated with such tax attributes could be significantly reduced upon an ownership change within the meaning of IRC Section 382 and such changes could be material. Due to the existence of the valuation allowance, changes in the Company's deferred tax assets from any such limitation will not impact the Company's effective tax rate.

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carry forwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carry forward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance.

At December 31, 2021 and 2020, the Company reassessed its need for valuation allowance and decreased the valuation allowance because it impaired an indefinite lived trademark during the year which previously represented a taxable temporary difference for which no deferred tax asset could be realized. This was determined to be a future source of taxable income. This reassessment resulted in a tax benefit of $65,000 and tax expense of $2,000, respectively. Of this, $67,000 and $0 were allocated to the discontinued operation for the years ended December 31, 2021 and December 31, 2020, respectively.

The expense for income taxes from operations consists of the following for the years ended December 31, 2021 and 2020:

	December 31, 2021	December 31, 2020
Current	$ 2,000	$ 2,000
Deferred	(67,000)	—
Tax Expense (Benefit)	(65,000)	2,000
Tax Benefit Allocated to Discontinued Operations	67,000	—
Tax Expense Allocated to Continuing Operations	$ 2,000	$ 2,000

At December 31, 2021 and December 31, 2020 the significant components of the deferred tax assets from operations are summarized below:

	December 31, 2021	December 31, 2020[1]
Deferred Tax Assets		
Net Operating Losses Carryforwards	$ 47,419,000	$ 38,796,000
Tax Credits	4,982,000	4,618,000
Stock Compensation	1,008,000	962,000
Accrued Expenses	189,000	2,259,000
Warranty Expenses	449,000	—
Intangibles	1,017,000	—
Fixed Assets	127,000	—
Lease Liabilities	248,000	382,000
Other	838,000	139,000
Total Deferred Tax Assets	56,277,000	47,156,000
Valuation Allowance	(54,261,000)	(44,744,000)
Deferred Tax Assets, Net of Valuation Allowance, Total	$ 2,016,000	$ 2,412,000
Deferred Tax Liabilities		
Intangibles - Indefinite Lived	$ (187,000)	$ (464,000)
Right-of-use Assets	(146,000)	(369,000)
State Taxes	(1,729,000)	(1,615,000)
Fixed Assets	—	(76,000)
Total Deferred Tax Liabilities	(2,062,000)	(2,524,000)
Net Deferred Tax Liability	$ (46,000)	$ (112,000)

(1) Certain adjustments have been made to the numbers reported in the Form 10-K for the year ended December 31, 2020, to reflect the revision of immaterial presentation errors in the prior period primarily due to the incorrect recognition of a deferred tax asset and offsetting valuation allowance for the Company's stock compensation.

Deferred income taxes are provided for the temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities.

The Company has determined at December 31, 2021 and December 31, 2020 that a full valuation allowance would be required against of all the Company's operating loss carry forwards and deferred tax assets that the Company does not expect to be utilized from the reversal of its deferred tax liabilities.

The following table reconciles the Company's losses from operations before income taxes for the year ended December 31, 2021 and December 31, 2020.

	December 31, 2021		December 31, 2020	
Federal Statutory Rate	$ (9,637,000)	21.00%	$ (10,337,000)	21.00%
State Income Tax, net of Federal Tax	(9,000)	0.02%	3,000	(0.01%)
Indefinite Lived - DTL	(52,000)	0.11 %	—	—
Other Permanent Differences	1,032,000	(2.25%)	1,762,000	(3.58%)
Research and Development Credits	(377,000)	0.82%	(422,000)	0.85%
Other	(539,000)	1.17%	—	—
Change in Valuation Allowance	9,517,000	(20.74%)	8,996,000	(18.27%)
Expected Tax Expense	$ (65,000)	0.13%	$ 2,000	(0.01%)

Interest and penalties related to uncertain tax positions are recognized as a component of income tax expense. For the tax year ended December 31, 2021 and 2020, the Company recognized no interest or penalties, and identified no material amount of unrecognized tax benefits.

NOTE 21: SUBSEQUENT EVENTS

As disclosed elsewhere in this Report, on March 21, 2022, we announced a voluntary recall of four lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes to the consumer level, due to the potential clogging of the needle preventing the dispensing of epinephrine. USWM will handle the entire recall process for the company, with company oversight. SYMJEPI is manufactured and tested for us by Catalent Belgium S.A. The costs of the recall and the allocation of costs of the recall, including the costs to us resulting from the recall, was estimated at approximately $2.0 million; moreover, the recall could cause the company to suffer reputational harm, depending on the resolution of matters relating to the recall could result in the company incurring financial costs and expenses which could be material, could adversely affect the supply of SYMJEPI products until manufacturing is resumed, and depending on the resolution of matters relating to the recall could have a material adverse effect on our business, financial condition, and results of operations.

Our consolidated financial statements for the year ended December 31, 2021, included elsewhere in this Report, include and reflect a reserve of approximately $2.0 million associated with the recall. The reserve was recorded as a reduction of net sales because we expect to offer the customers a cash refund or credit. The company may be able to be reimbursed by certain third parties for some of the costs of the recall under the terms of its manufacturing agreements, but there are no assurances regarding the amount or timing of any such recovery.

Exhibit 10.22

CERTAIN MARKED INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS AS PRIVATE OR CONFIDENTIAL. SUCH OMITTED INFORMATION IS INDICATED BY BRACKETS ("[…*…]" IN THIS EXHIBIT.**

November 21, 2014

Dennis J. Carlo, Ph.D.
President & CEO

Personal and Confidential

[***]

David Dwight C. Benedicto
[***]

Dear Mr. Benedicto:

We are pleased to offer you the full-time position with Adamis Pharmaceuticals Corporation ("Company") of Accounting Manager based in San Diego, CA. We anticipate that, following your acceptance of this offer, your full-time employment will commence no later than [***], or a date to be mutually agreed by the Company and you.

You will report to the Chief Financial Officer will be paid at the rate of $9,166.67 per month during your employment, which reflects an annualized amount of $110,000. Your position is classified as exempt, which means, in part, that your work for the Company is not subject to the laws related to tracking of daily hours of work, minimum wage, overtime or meal and rest periods (and therefore, you will not be eligible for overtime). You will be paid in accordance with the Company's normal payroll practices; currently, the Company provides for payment of salaries and wages on a semi-monthly basis. Compensation is subject to adjustment (upwards or downwards) as the discretion of the Company or the compensation committee of the Board. All compensation and other payments described hereunder are subject to and will be reduced by normal payroll withholdings and the Company's standard payroll practices.

As a full-time employee, you will be eligible for participation in the Company's annual bonus program that currently provides for a bonus of up to [***] of your base salary. As a full time employee, you will also be entitled to receive other benefits as are currently provided to employees generally by Company policies from time to time, subject to applicable eligibility requirements. These benefits currently include Company paid [***] insurance. [***] insurance are available at the option and expense of the employee. All plans are available to you on the 1st day of the month following your start date.

You will be entitled to [***] vacation days ([***] hours) each year which will be prorated for a partial year. Employees can accrue to a maximum one and a half times their annual eligibility. You will also receive [***] holidays. Vacation, paid sick leave, and holidays are detailed in the Company's employee manual. You agree to comply with Company policies, including those set forth in the Company's employee manual.

As a full-time employee, your compensation will generally be reviewed annually in a manner similar to other employees generally, and you will be eligible for additional performance based compensation in a manner similar to other employees generally, in the sole discretion of the Company and the Board.

In addition, we will recommend that the Board or tire compensation committee of the Board approve the grant to you, under the Company's 2009 Equity Incentive Plan, of an incentive stock option to purchase [***] shares of common stock, with terms and conditions (including vesting) to be described in the option grant and related option agreement. The exercise price will be equal to the fair market value of the common stock on the date of grant, determined as provided in the plan.

You should be aware that your employment with the Company is for no specific period and constitutes at will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and without notice. The at-will status of your employment cannot be changed except in writing executed by a duly authorized officer of the Company. Additionally, your duties, title, compensation, benefits, and reporting structure may be changed or modified at any time at the discretion of the Company, with or without notice.

Please be advised that our offer of employment is conditioned upon you signing the Company's standard employee proprietary information and invention assignment agreement or similar agreement, in such form and substance as the Company may require, and such other agreements and instruments that the Company customarily requires new employees to execute. For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated. The Company also reserves the right to conduct background investigations and/or reference checks on all of its potential employees, and therefore your employment may be contingent upon a clearance of such a background investigation and/or reference check, if any.

You agree to devote your full time, attention and skills solely to working for the Company and performing the duties assigned or delegated to you. You agree that, during the term of your employment with the Company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company.

You agree that you will not, during your employment with the Company, improperly use or disclose any proprietary information or trade secrets of any former employer or other person or entity or violate any confidentiality, proprietary information or similar agreement between you mid any former employer, and that you will not bring onto the premises of the Company any unpublished document or proprietary information belonging to any such employer, person, or entity unless consented to in writing by such employer, person, or entity. You represent to the Company that you are not subject to any obligation, contractual or otherwise, that prevents or restricts you from becoming employed by the Company. You also represent that you understand that the Company is in the early stages of development and that there are high risks associated with employment at such a company.

As a Company employee, you will be expected to abide by company rules and regulations. You will be specifically required to sign an acknowledgment that you have read and understand the company rules of conduct, which are included in our handbook.

In the event of any dispute or claim relating to or arising out of our employment relationship, you and the Company agree to initially attempt to resolve the issue informally or with the assistance of a neutral, outside mediator. If a dispute cannot be resolved by these means, the sole and exclusive means of final dispute resolution is through binding arbitration, as described in the Company's arbitration policy and/or the proprietary information agreement. Note that this paragraph is only a short summary of the Adamis employment dispute resolution process.

In the event of termination of your employment with the Company, or at any other time at the Company's request, you agree to deliver promptly to the Company all property of the Company that is in your possession or control, including but not limited to computers, data, software, cell phones, drawings, manuals, correspondence, notes, notebooks, sketches, formulae, records, emails, service parts, memoranda, access cards or keys to the Company's facilities, equipment or vehicles, and all other materials relating to the Company's business or which contain proprietary information. You further agree not to make or retain copies of any of the foregoing and will so represent to the Company upon termination of employment.

To indicate your acceptance of the Company's offer, please sign and date this letter in the space provided below and return it to me in an email as well as in the self-addressed stamped envelope. A duplicate original is enclosed for your records.

This letter, along with the agreement relating to proprietary rights between you and the Company, set forth the terms of your employment with the Company and supersede any prior representations or agreements, whether written or oral. This letter may not be modified or amended except by a written agreement, signed by an officer of the Company and by you.

Please acknowledge your acceptance in the foregoing offer by signing in the space below. This offer will be considered null and void if a signed copy is not returned within [***] business days of the date of this letter.

We look forward to you joining the team at Adamis Pharmaceuticals and contributing to our success.

Sincerely,

/s/ Dennis J. Carlo
Dennis J. Carlo, Ph.D.
President & CEO

ACCEPTED AND AGREE TO this 21st day of November, 2014.

/s/ David Dwight C. Benedicto
David Dwight C. Benedicto

Enclosures: Duplicate Letter
Confidentiality Agreement

Exhibit 10.45

Confidential

CERTAIN MARKED INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS AS PRIVATE OR CONFIDENTIAL. SUCH OMITTED INFORMATION IS INDICATED BY BRACKETS ("[…*…]" IN THIS EXHIBIT.**

FIRST AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT

This Amendment No. 1 ("Amendment No. 1") is dated this 9th day of November by and between Matrix Biomed, Inc., a Delaware corporation ("Licensor"), on the one hand, and Adamis Pharmaceuticals, a Delaware corporation (the "Licensee"), on the other hand, to amend the terms of that certain License Agreement entered into by and between the parties dated June 12, 2020 (the "LICENSE AGREEMENT"). Licensor and Licensee shall be referred to herein as a "Party" and collectively as the "Parties". In the event the terms of the LICENSE AGREEMENT and this Amendment No. 1 conflict, the terms of this amendment No. 1 control. Any defined terms herein that are not defined herein have the meaning set forth in the LICENSE AGREEMENT.

RECITALS

WHEREAS, in the LICENSE AGREEMENT Licensor granted Licensee a license to the Licensed Patents and Related Know How (as defined below) solely for the purpose of developing, producing and selling Licensed Products within the Licensed Field of Use.

WHEREAS, the Parties now wish to amend the scope of the patent grant set forth in said License Agreement at Section 1.8 therein; and

WHEREAS, the parties now wish to amend the License Agreement on the terms set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants and License Agreements set forth below, the parties agree as follows:

AMENDMENT

1. **Terms**. Capitalized terms in this Amendment shall have the same meaning as those in the License Agreement, unless specifically defined in this Amendment. All section and paragraph references refer to sections or paragraphs as applicable, in the License Agreement. References to the term "License Agreement" in the License Agreement shall be deemed to include the Amendment.

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

3. For the convenience of the parties hereto, this First Amendment may be executed in two counterparts, each of which shall me deemed to be an original, but both of which together shall constitute one and the same instrument, without necessity of production of the others. Signatures may be exchanged by electronic transmission and each of the parties to this First Amendment agrees that it will be bound by its own facsimile signature and that it accepts the facsimile signature of the other party.

4. **Amendment to Section 3 of the LICENSE AGREEMENT to hereby include the following paragraph:**

3.1.1 Licensor also grants a license to license in US Patent Number [***] issued [***] based upon U.S. Patent Application Serial Number [***] entitled [***] exclusively for the treatment of SARS-COV-2 (COVID-19) in the Licensed Territory.

5. **Amendment to Section 7.2.2 of the LICENSE AGREEMENT to:**

7.2.2 Licensor has sole control over whether to bring suit upon learning of infringement and shall control any litigation, claim, action or proceeding it initiates, including the selection of counsel. Licensee may retain additional counsel of its own selection and at its own expense to observe the litigation and to advise or assist Licensor. Licensor and its counsel will cooperate with and seek the input of Licensee's counsel in such matters.

6. **Delete Section 7.2.3.**

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of the day and year first above the written.

"**LICENSOR**"

Matrix Biomed, Inc,
a Delaware Corporation

By: /s/ Allyn Burroughs
Allyn Burroughs, Chairman

"**LICENSEE**"

Adamis Pharmaceuticals, Inc.
a Delaware Corporation

By: /s/ Dennis J. Carlo
Dennis J. Carlo, CEO and President

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Adamis Pharmaceuticals Corporation
11682 El Camino Real, Suite #300
San Diego, CA 92130

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-159229, 333-169106, 333-175383, 333-194635, 333-201742, 333-211773, 333-218945, 333-226230, and 333-229379), and Form S-3 (Nos. 333-196976, 333-199454, 333-200447, 333-209401, 333-212880, 333-217400, 333-217408, 333-226100 and 333-249331) of Adamis Pharmaceuticals Corporation and Subsidiaries (the "Company") of our report dated March 31, 2022, relating to the consolidated financial statements, which appear in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

San Diego, CA 92130

March 31, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dennis J. Carlo, certify that:

1. I have reviewed this annual report on Form 10-K of Adamis Pharmaceuticals Corporation;

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

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

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

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

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

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

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

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

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

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

Date: March 31, 2022

By: /s/ Dennis J. Carlo
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David C. Benedicto, certify that:

1. I have reviewed this annual report on Form 10-K of Adamis Pharmaceuticals Corporation;

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

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

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

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

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

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

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

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

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

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

Date: March 31, 2022

By: /s/ David C. Benedicto
Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Dennis J. Carlo, the Chief Executive Officer of Adamis Pharmaceuticals Corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

/s/ DENNIS J. CARLO
Dennis J. Carlo
Chief Executive Officer

Dated: March 31, 2022

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, David C. Benedicto, as Chief Financial Officer of Adamis Pharmaceuticals, Corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

/s/ DAVID C. BENEDICTO
David C. Benedicto
Chief Financial Officer

Dated: March 31, 2022

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.