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, 2020

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, 2020, was $ 39,434,675.

At April 13, 2021, the Company had 148,886,141 shares outstanding.

Documents Incorporated by Reference: Portions of the registrant's proxy statement for its 2021 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

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EXPLANATORY NOTE

Overview and Background of Restatement

On April 14, 2021, the Audit Committee of the Board of Directors (the "Audit Committee") of Adamis Pharmaceuticals Corporation (the "Company"), concluded that because of the misapplication of valuation principles used to determine the fair value of the Company's warrant liabilities and related changes in fair value of these warrant liabilities relating to warrants issued by the Company in August 2019 (the "2019 Warrants") and February 2020 (the "2020 Warrants" and, together with the 2019 Warrants, the "Warrants"), the Company's 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 and that the financial statements for such periods should be restated. The issues identified were non-cash, and do not impact the Company's revenues, operating expenses, operating loss, cash and cash equivalents, assets, liquidity or cash position for the Affected Periods.

In connection with the Company's preparation of its financial statements for the year ended December 31, 2020, the Company re-assessed certain matters relating to its determination of the amount of warrant liabilities, and the associated gain or loss recognized as a result of the change in the fair value of the warrant liabilities, related to the outstanding Warrants as of December 31, 2020, and for the Affected Periods. The Company concluded that certain of the valuation principles, estimates, and methods used to determine the valuation

of the Warrants for the Affected Periods were not in accordance with ASC 820 – "Fair Value Measurement and Disclosures," primarily because of the applicability of the Black-Scholes option-pricing model, rather than the Binomial Option Pricing Model used by the Company, to determine the fair value of the Warrants and because the Company's calculation incorporated the estimated exercise behavior of its warrant holders by applying an early exercise multiple, rather than using the full contractual exercise term of the Warrants as an input for determining the fair value of the Warrants.

As a result of the above, the Company has restated its unaudited condensed consolidated financial statements for the Affected Periods. The adjustments to the financial statement items for the Affected Periods are included in this Annual Report on Form 10-K, in Note 4 to the consolidated financial statements included elsewhere in this Report. The Company's previously filed quarterly reports on Form 10-Q for the Affected Periods, have not been amended. Accordingly, investors should no longer rely upon the Company's previously released financial statements for the Affected Periods, and any earnings releases or other communications relating to these periods.

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 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 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 ZIMHI™ product;
- 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;
- 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;
- 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 may 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.

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 2021, 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 may require additional financing in the future and 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 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 are 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 clinical trial, product liability or other lawsuits or litigation.
- We are subject to substantial government regulation, 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.
- If we determine that our intangible assets or other assets have become impaired, our total assets and financial results could be adversely affected.
- We have incurred significant indebtedness. We have borrowed funds pursuant to the Paycheck Protection Program, and some or all of the amount borrowed might not be forgiven.
- The COVID-19 pandemic has adversely affected and may continue to adversely affect our business, results of operations and financial condition.

- Our business is significantly impacted by state and federal statutes and regulations.
- 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. We are subject to significant costs and uncertainties related to such laws and regulations. USC could become involved in proceedings with the FDA or other federal or state regulatory authorities alleging non-compliance with applicable federal or state regulatory legal requirements, which could adversely affect our business, financial condition and results of operations.
- If a compounded drug formulation provided through our compounding services leads to patient injury or death or results in a product recall, we may be exposed to significant liabilities and reputational harm.
- USC relies on third parties to provide active pharmaceutical ingredients and components. If these third parties do not deliver as expected, if USC's agreements with them terminate or if the FDA prohibits use of these active pharmaceutical ingredients, USC's and our business, financial condition, and results of operations could be adversely affected.
- USC's formulations and technologies could potentially conflict with the rights of others.
- We must compound in conformity with applicable cGMP requirements; failure to maintain compliance with applicable cGMP requirements may prevent or delay the compounding or marketing of our compounded preparations.
- Our customers are subject to a variety of federal, state and local laws and regulations relating to the healthcare industry, which are subject to frequent change. 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 identified a material weakness in our internal control over financial reporting as of December 31, 2020. We have 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 as of December 31, 2020. If we fail to effectively remediate this material weakness, it could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.
- We have restated our unaudited condensed consolidated financial statements for the periods ended March 31, 2020, June 30, 2020, and September 30, 2020, which may 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.
- We have entered into a non-binding letter of intent with a potential buyer for sale of substantially all of the assets of our USC subsidiary. The letter of intent is non-binding other than with respect to certain customary confidentiality and exclusivity provisions. There can be no assurances that the parties will negotiate and enter into definitive transaction agreements or concerning the final terms that might be included in any definitive agreements, whether a transaction will be completed, concerning the timing of closing of any such transaction or concerning the amount of consideration that we might receive at the closing or over time from any such transaction.
- 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; a naloxone injection product candidate, ZIMHI, based on the approved Symject™ injection device and intended for the treatment of opioid overdose for which the company resubmitted its New Drug Application, or NDA, in May 2020, received a Complete Response Letter, or CRL, from the FDA in November 2020, submitted responses to the deficiencies identified in the CRL and met with the FDA concerning the responses, and intends to resubmit its NDA; Tempol, an investigational drug; and a Beclomethasone metered dose inhaler product candidate (APC-1000) intended for the treatment of asthma for which the company submitted an Investigational New Drug application, or IND, in January 2018 but has suspended the start-up phase of Phase 3 studies. In June 2020, we entered into a license agreement with a third party to license rights under patents, patent applications and related know-how 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. In January 2021, the company submitted an IND to the FDA for the investigational use of Tempol for the treatment of coronavirus (COVID-19) and in February 2021, we were notified by the FDA 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. 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, provides 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. USC's product offerings broadly include, among others, corticosteroids, hormone replacement therapies, hospital outsourcing products, and injectables. USC's compounded formulations in many circumstances are offered as alternatives to drugs approved by the FDA. USC also provides certain veterinary pharmaceutical products for animals.

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.

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 (APC-6000)	Opioid Overdose	CRL received November 2020 (1)
Tempol		
(APC-410)	Radiation induced dermatitis	Phase 2/3 ready (2)
(APC-400)	Treatment of COVID-19	Phase 2/3 ready; IND submitted January 2021 (3)
Beclomethasone Metered Dose Inhaler (APC-1000)	Asthma	Phase 3 ready (4)

(1) The company resubmitted its NDA to the FDA in May 2020 and received a CRL from the FDA in November 2020. The company submitted responses to the deficiencies identified in the CRL, has held a Type A meeting with the FDA to discuss the CRL and the company's responses, and intends to resubmit the NDA to the FDA.
(2) Phase 2 trial completed by the licensor. Represents the next anticipated development or regulatory stage for the product candidate that we may pursue, assuming the availability of adequate funding.
(3) In January 2021, the company submitted an IND to the FDA for the investigational use of Tempol for the treatment of coronavirus (COVID-19), for a Phase 2/3 study examining Tempol in COVID-19 patients. In February 2021, the company was notified by the FDA 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.
(4) The start-up phase of a Phase 3 trial was initiated after consultation with the FDA, but enrollment and the study was suspended in light of among other factors, the availability of adequate funding to resume and complete the study and changes in market conditions and competitive developments in the relevant markets. There are no assurances that we will pursue this opportunity, for financial or other reasons, and we do not intend to devote substantial resources to pursue this opportunity.

Anaphylaxis; 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 2020 were more than $2.0 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. If the person using an auto-injector is not familiar with the function of the device and if not administered properly, there is a risk that it could misfire or be misused.

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. Under the terms of the agreement, we appointed Sandoz as the exclusive distributor of SYMJEPI in the United States and related territories, in all fields including both the retail market and other markets, and granted Sandoz an exclusive license under our patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the product in the licensed territory, subject to the provisions of the agreement, in partial consideration of an upfront fee by Sandoz and potential performance-based milestone payments. The agreement provided that Sandoz will pay to us 50% of the net profit from net sales, as each such term is defined in the agreement, of the product in the Territory to third parties, determined on a quarterly basis. We were the supplier of the product to Sandoz, and Sandoz ordered and paid us a supply price for quantities of products ordered. We were responsible for all manufacturing and, prior to Sandoz paying us the supply price, the component and supply costs related to manufacturing and supplying the product to Sandoz. 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 following an initial transition period that ended as a result of the execution of a transition services agreement. The Termination Agreement provided for the mutually agreed return to us 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 we entered into with Sandoz and USWM, LLC concerning certain transition services, activities and arrangements relating to the SYMJEPI products. As part of the Termination Agreement, Sandoz agreed to support the products in the U.S. under the Sandoz Agreement through the end of the transition period to help reduce or minimize potential impacts to patients and customers. The Termination Agreement also provided for a future resolution of 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.

On May 11, 2020, we 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 the company’s ZIMHI product candidate. 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 regulatory and commercial based milestone payments totaling up to $26 million, if all of 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 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. Commencing in July 2020, USWM began promoting the SYMJEPI products through its field sales force.

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. We anticipate that it could take many months in order to obtain the required registration and approvals.

Opioid Overdose

ZIMHI (naloxone) Injection, APC-6000

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), in the 12 months ending May 2020 drug overdoses resulted in approximately 81,000 deaths in the United States – greater than approximately 220 deaths per day. Drug overdoses are now the leading cause of death for Americans under 50, and the proliferation of more powerful synthetic opioids, such as fentanyl and its analogues, could result in future increases in the number of deaths resulting from opioid overdoses. Recent 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.

In December 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 CRL from the FDA regarding our NDA for ZIMHI. The CRL stated that the FDA determined that it could not approve the NDA in its present form and provided recommendations needed for resubmission. 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 questions raised by the FDA related generally to Chemistry, Manufacturing and Controls, or CMC. No other clinical safety or efficacy issues were raised. In December 2019, we provided responses to the FDA to the comments included in the CRL. In February 2020, we had a Type A meeting with the FDA to discuss our response to the CRL and the process and timeline for resubmission of the NDA to the FDA. At the meeting, we obtained concurrence from the agency on the CMC information required for resubmission of the NDA, including additional information involving extractables and leachables testing from the syringe and glassware. On May 15, 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. The deficiencies and questions raised in the CRL related generally to new CMC issues. We submitted responses to the deficiencies identified in the CRL and held a Type A meeting with the FDA to discuss the CRL and the company's responses, and obtained input from the agency concerning the resubmission of the NDA. With the input from the meeting, the company intends to resubmit the NDA for ZIMHI to the FDA. The company expects to resubmit the NDA within approximately 45 days from the date of this Report absent unexpected delays, although there can be no assurance regarding the date that our NDA will be resubmitted. At the Type A meeting, the FDA did not provide any specific timeline for review of a resubmitted NDA. If the matters raised in the CRL cannot be resolved with the FDA division that sent the CRL, we may appeal the matter within the agency through a Formal Dispute Resolution process. There can be no assurances regarding the timing or outcome of our resubmission of the NDA to the FDA or the FDA's review of any resubmitted NDA relating to the ZIMHI product, the timing or outcome of any Formal Dispute Resolution process that we may decide to initiate, whether the FDA will regard our responses to the CRL and a resubmitted NDA as satisfactory, whether the FDA will require additional actions, information or trials after review of a resubmitted NDA or issue another CRL, or the timing, costs or outcome of any additional actions that may be required following any resubmission of the NDA, or that the product will be able to compete successfully in the market if approved and launched. The development of an intramuscular injection of naloxone for the treatment of opioid overdose will require commercial scale manufacturing subject to review and approval by the FDA.

On May 11, 2020, we entered into the USWM Agreement with USWM for the United States commercial rights for the ZIMHI product candidate, as well as for the SYMJEPI products.

Tempol (APC400 and APC 410)

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 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, anti-inflammatory and anticoagulant 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.

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. The submission of the IND to the FDA followed a Pre-IND meeting with the FDA in which the agency gave specific recommendations on CMC and conduct of the clinical trial to be included in the IND. On February 22, 2021, we announced that the company was notified by the FDA 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. We currently anticipate that the trial will begin in the second quarter of 2021. 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, 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. 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 the treatment of radiation induced dermatitis and are engaged in additional formulation and development and GMP manufacturing processes intended to support an IND to begin such a study.

Asthma and Bronchospasm

According to the National Institute of Health, or NIH, asthma is a chronic lung disease that inflames and narrows the airways. Asthma causes recurring periods of wheezing, chest tightness, shortness of breath, and coughing. Asthma affects people of all ages, but it most often starts during childhood. According to information published by Centers for Disease Control & Prevention, or CDC, reporting on findings from 2018 the number of people in the U.S. with asthma is approximately 24.8 million and growing. We estimate that global sales of asthma and bronchospasm prescription products were in excess of approximately $6.9 billion in 2020, based on industry data.

Asthma; APC-1000 Metered Dose Inhaler

Our APC-1000 product candidate is a steroid hydrofluoroalkane, or HFA, metered dose inhaler product, intended for the treatment of asthma. Our product candidate, if developed and approved for marketing, would be intended to target a small niche within the larger market for respiratory products. In January 2018, we submitted an IND application to the FDA to begin late-stage clinical studies to evaluate the efficacy of APC-1000 as a treatment for asthma. We received approval from the agency to proceed with the Phase 3 studies, and in December 2018, we initiated the start-up phase of the trial. However, we terminated the start-up phase and start of patient enrollment for the studies, and have suspended the study, in light of, among other factors, the availability of adequate funding to continue and complete the studies and changes in market conditions and competitive developments in the relevant markets. There are no assurances that we will pursue this opportunity, for financial or other reasons, and as of the date of this Report, we do not intend to resume the studies or devote any substantial resources to pursue development of this product candidate.

Other Product Candidates or Technologies

Dry Powder Inhaler (DPI) Device Platform. In December 2013, we acquired assets relating to the 3M Company's patented Taper dry powder inhaler (DPI) technology under development by 3M for the treatment of asthma and bronchospasm. The Taper DPI technology was designed to efficiently deliver dry powder by utilizing a 3M proprietary microstructured carrier tape. We utilized the Taper DPI assets in the development of a DPI device that, if successfully developed, could be utilized to deliver a variety of different drug compounds and be used as a platform delivery device to develop products that will compete in the respiratory markets. Our agreement with 3M contemplated that the microstructured carrier tape would be supplied by 3M under a separate commercial supply agreement to be negotiated with 3M. One advantage of the technology is that it can deliver drug particles without the need for lactose or formulation excipients. The majority of current dry powder products use lactose carrier excipients to enhance flowability; however, they have the disadvantage of increased bulk and require a mechanism for detaching the drug from the surface of the lactose. Lactose carrier formulations require a complicated blending process and delivery that is highly sensitive to excipient powder properties.

Our product candidate considered for development utilizing the DPI technology platform, APC-4000, was intended to deliver Fluticasone Propionate (fluticasone) as a dry powder formulation for the treatment of asthma. Fluticasone belongs to the family of medicines known as corticosteroids or steroids and is the same active ingredient as GlaxoSmithKline's Flovent® Diskus® indicated for the treatment of asthma. We conducted proof of concept studies with the DPI for APC-4000 in 2018 and 2019 which demonstrated that the device functioned as designed. We believe that next steps in development could include the creation of a commercial-ready manufacturing line and, from devices manufactured on the new line, following submission and acceptance of an IND the conduct of one or more Phase 3 trials, although additional trials such as pharmacokinetic, or PK, and/or other studies might be required before or in connection with any Phase 3 trials. However, in light of the time and costs involved in further product development efforts and competitive conditions in the relevant markets, 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.

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 the eye, it usually causes an infection of the cornea, and that infection can cause cornea-derived

blindness. 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 concerning the amounts that we might receive from any such transaction, 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.

Prescription Compounded Medications

Overview. Our USC subsidiary, which is registered as a drug compounding outsourcing facility under Section 503B of the FDCA and the DQSA, provides prescription compounded medications, including compounded sterile preparations or CSPs, and non-sterile compounds to physician clinics, hospitals, surgery centers 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. USC also provides compounded pharmaceutical products for animals.

USC sources raw materials and commercial products only from suppliers registered with the FDA. Utilizing these raw material components, USC prepares and provides a broad range of customized stock keeping units to meet the individual requirements of customers.

USC's business is focused on marketing a portfolio of compounded preparations, including sterile injectable and non-sterile integrative therapies. Most of these formulations are offered in different formats than other available alternatives, such as in suspension or preservative free. Many hospitals and surgery centers look to outsourcing facilities to obtain medications in ready-to-use, or RTU, format, with the specific packaging, volume, and strength often unique to individual facilities. Many facilities and practitioners also look to outsourcing facilities when medications are on temporary backorder from the manufacturer or are discontinued. Veterinary products sold by USC include, without limitation, a formulation of an equine ulcer product that addresses what we believe is a significant market. Many horses that are competing and under stress have been shown to have gastric ulcers. We have completed a study comparing a combination formulation of omeprazole and fenbendazole to placebo, and the study results indicated that the combination formulation was effective in reducing gastric ulcer sores and reducing squamous ulcer disease in horses. We intend to continue development of this product candidate.

Compounding pharmacies and outsourcing facilities combine different ingredients, some of which may be FDA-approved drugs or components of FDA-approved drugs, to create specialized preparations prescribed by a physician. Examples of compounded formulations include medications with alternative dosage strengths or unique dosage forms, such as topical creams or gels, suspensions, or solutions with more tolerable drug delivery vehicles. A physician may also work together with a pharmacist to repurpose or reformulate FDA-approved drugs via the compounding process to meet a patient's specific medical needs. These compounds are distributed to hospitals, surgery centers, and practitioners. Examples of compounded medications prepared by outsourcing facilities include sterile syringes used by hospital and surgery center operating rooms, sterile injectables administered by the practitioner in the office, and unit-dosed sterile and non-sterile medications. USC's outsourcing facility receives its active pharmaceutical ingredients from three main suppliers, which accounted for the majority of USC's drug and chemical purchases in 2020 and 2019.

The pharmacy sterile compounding industry arose in part because hospitals and other healthcare providers administering drugs require concentrations, dosage forms and delivery systems that are not readily commercially available from drug manufacturers in an RTU form. Historically, safety and quality standards for compounded medications were not well defined or implemented, leading to demand for

safer compounding practices, and the level of state regulation varied significantly. The 2012 nationwide fungal meningitis outbreak caused by a compounding pharmacy led to increased regulatory oversight of the industry which, among other things, led to the passage of the DQSA and its creation of Section 503B outsourcing facilities as a new, more highly FDA-regulated category of interstate outsourced CSP providers. Registration as a Section 503B outsourcing facility is currently voluntary. USC was incorporated in Arkansas in 2004 and registered with the FDA as a Section 503B outsourcing facility in December 2013.

In recent years, there have been increases in the cost of certain injectable drugs and related products as a result of (i) enhanced oversight by the FDA and other regulatory bodies of manufacturers of injectable products, and the added costs associated therewith, (ii) decreased competition when drug manufacturers voluntarily cease producing certain drugs or face temporary regulatory suspension or permanent regulatory shut down of their operations, and (iii) consolidation among drug manufacturers. These factors have led some manufacturers to raise prices of some products and have also contributed to market shortages of injectable products, containers and diluents. These shortages and the potential inability to secure an adequate supply of necessary drug formulations can have a significant impact on the day-to-day business and operations of USC and its customers.

Since we acquired USC in April 2016, we have taken several measures intended to support the growth of the business including hiring additional personnel, expanding sales channels, and strengthening our production processes. USC has, and after our acquisition of USC we have, invested capital in efforts to comply with new and anticipated FDA regulations applicable to its business and outsourcing facilities, to expand product offerings, enhance production capabilities, improve warehouse space, develop new packaging, labeling and processing solutions, refine quality and safety measures, and develop technology for the intake and management of customer orders. Historically, research and development costs have consisted primarily of costs associated with the research and development of new CSPs, such as salaries and other personnel-related expenses for employees involved with research and development activities, pre-launch sterility and stability testing and other related expenses. Regulatory guidance provided by the FDA, and additional regulatory guidance is expected to increase the validation and development costs for current and new products.

The COVID-19 outbreak adversely affected revenues in 2020 from sales of USC products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products, and will likely continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted. Moreover, COVID-19 has restricted USC from utilizing traditional sales and marketing efforts, such as regular sales visits to customers, in generating revenues.

Letter of Intent

On January 26, 2021, we announced that we have entered into a non-binding letter of intent with a potential buyer for sale of substantially all of the assets of our USC subsidiary. Under the terms described in the letter of intent, the buyer would agree to acquire substantially all of the assets of US Compounding in exchange for a total gross consideration that could range from approximately $10-$20 million, before transaction fees and expenses and other potential post-closing adjustments.

If a transaction is negotiated, reflected in definitive agreements entered into by the parties, and completed, the proposed purchase price consideration includes a combination of a cash payment at the closing of the transaction, a promissory note representing portion of the purchase price payable at a future date, and potential future performance-based milestone payments over a period of years. The amount and structure of consideration could change as a result of subsequent negotiations, due diligence or other factors.

Any definitive agreement would be subject to approval by the respective parties, including approval by our board of directors, and would likely include a number of customary provisions, including without limitation representations and warranties of USC and us, restrictive covenants and indemnification provisions.

If definitive agreements are negotiated and entered into, the closing of a transaction would be contingent on the satisfaction of closing conditions which might include, among other things: (i) the receipt of required governmental, regulatory, and third-party consents and approvals, (ii) buyer obtaining required licenses, permits, registrations, or other approvals from the necessary state boards of pharmacy and other state and federal governmental authorities, and (iii) other customary closing conditions.

The letter of intent is non-binding other than with respect to certain customary confidentiality and exclusivity provisions. There can be no assurances that the parties will negotiate and enter into definitive transaction agreements or concerning the final terms that might be included in any definitive agreements, whether a transaction will be completed, concerning the timing of closing of any such transaction or concerning the amount of consideration that we might receive at the closing or over time from any such transaction.

Clinical Supplies and Manufacturing

Except for our facilities at USC that are utilized to prepare compounded formulations, 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, and assembly and final packaging of the product is 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, and following the termination of that agreement in 2020 are marketed and sold in the U.S. markets by USWM pursuant to our commercialization agreement with USWM. We sell compounded pharmacy formulations through USC's sales and marketing employees and arrangements with third parties for sales and marketing support. Sales and marketing activities of USC consist primarily of efforts to educate doctors, ambulatory surgery centers, healthcare systems, hospitals, veterinarians, and other users throughout the U.S. about USC's products and services. USC's sales and marketing team is focused on customer retention as well as generating sales from new and existing customers.

Customers and Distribution

On January 16, 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 terminated the distribution and commercialization agreement with Sandoz, supported by a transition services agreement that we entered into with Sandoz and USWM, LLC concerning certain transition services, activities and arrangements relating to the SYMJEPI products. Also, on May 11, 2020, we announced that we entered into an exclusive distribution and commercialization agreement with USWM for the United States commercial rights for the SYMJEPI products, as well as for the company's ZIMHI product candidate. Pursuant to our agreement with USWM, we are responsible for supplying the SYMJEPI 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. A significant portion of revenues from USC sales of human compounded pharmacy formulations consist of sales to physician clinics and hospitals.

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 high dose naloxone injection product candidate ZIMHI (APC-6000) for opioid overdose, if approved and introduced, is expected to compete with other products in the markets for opioid overdose. If we successfully develop and obtain regulatory approval of one or more Tempol products, such products would compete with other products in the markets for the approved indications.

Compounded Pharmacy Formulations. The compounded pharmaceutical and pharmacy industries are highly competitive. We compete against other FDA-registered outsourcing facilities, branded drug companies, generic drug companies, regional compounders that provide patient-specific compounding that decide to expand to 503B outsourcing, non-patient-specific compounding, large hospitals and integrated delivery networks, other compounding pharmacies, and new entrants to the industry. Many competitors that market and sell compounded preparations have longer operating histories and may have greater financial, marketing and other resources than we do. We are smaller than some of such competitors, and we may lack the financial and other resources needed to develop, produce, distribute, market and commercialize any of USC's formulations or compete for market share in these sectors. These potential competitors could leverage existing resources and experience operating in industries that are subject to significant regulatory oversight in order to overcome certain barriers to entry. Consequently, competitors may be able to develop products and services competitive with, or superior to, USC's products and services. Furthermore, we may not be able to differentiate USC's compounded preparations and services from those of our competitors, successfully develop or introduce new services—on a timely basis or at all—that are less costly than those of our competitors or offer customers payment and other commercial terms as favorable as those offered by our competitors. We expect competition to intensify as technology advances, such as those in the field of robotics and automation, and consolidation continues. Also, new developments by pharmaceutical manufacturers, such as increasing the number of abbreviated new drug applications, to cover less frequently used drug formulations, could render some or many of USC's products or services obsolete. In addition, the drug products available through branded and generic drug companies with which USC's formulations compete have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. USC's compounded formulations are not required to be, and have not been, approved for marketing and sale by the FDA. As a result, some physicians may be unwilling to prescribe, and some patients may be unwilling to use, USC's formulations. Increased competition could reduce revenue and gross profit and otherwise materially adversely affect our business, results of operations and financial condition. In addition, guidance documents published by the FDA in 2018 require certain attestation of clinical need on behalf of the ordering physician or his or her delegate, and some entities may be unwilling or logistically unable to accommodate this new requirement.

Pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Products developed by our competitors, including FDA-approved drugs and compounded formulations created by other pharmacies and outsourcing facilities, could render USC's products and technologies obsolete or unable to compete effectively. Other competitive factors include the safety and efficacy of a product, the size of the market for a product, the timing of market entry relative to competitive products, the availability of alternative compounded formulations or approved drugs, the price of a product relative to alternative products, the availability of third-party reimbursement, the success of sales and marketing efforts, brand recognition and the availability of scientific and technical information about a product.

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, 2020, the company had: (i) 23 issued patents in the United States and 13 pending applications, two of which have been allowed; (ii) 96 issued and 43 pending foreign patent applications, four 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 expire between 2020 and 2041, not taking into account any potential patent-term extensions that may be available in the future.

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 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

Pharmaceutical 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

The FDA testing and approval process 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.

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 good laboratory practices, a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results. The results of the preclinical studies, 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.

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 good clinical practices, 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 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 number of subjects 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 number of subjects 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.

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 significant 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.

The facilities, procedures and operations for any of our contract manufacturers must be determined to be adequate by the FDA before product approval. Manufacturing facilities are subject to inspections by the FDA for compliance with cGMP, licensing specifications and other FDA regulations before and after an NDA has been approved. Foreign manufacturing facilities are also subject to periodic FDA inspections or inspections by foreign regulatory authorities. Among other things, the FDA may withhold approval of NDAs or other product applications if deficiencies are found at the facility. 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.

In addition, the FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals, including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet.

Failure to comply with FDA and other governmental regulations 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.

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 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 condition where preliminary clinical evidence indicates the drug may demonstrate substantial improvement on a clinically significant endpoint(s) 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 condition and provides a meaningful advantage over available therapies, and the drug demonstrates an effect on a surrogate endpoint or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality.

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. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to the application's approval. 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. 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.

If the FDA does ultimately approve the product, it may require post-marketing testing to monitor the safety and effectiveness of the product. In addition, the FDA may in some circumstances impose restrictions on the use of the product, which may be difficult and expensive to administer. The FDA also may require prior approval of promotional materials.

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. 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.

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.

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 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 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 for payments, transfers of value or ownership or investment interests not reported in an annual submission.

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. In December 2018, a U.S. federal district court judge in Texas found the ACA's individual mandate to be unconstitutional and therefore the entire law to be invalid. In December 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the ruling regarding the individual mandate, but remanded the case to the district court for additional analysis of the question of severability and whether portions of the law remain invalid. The case is currently under consideration by the U.S. Supreme Court, and a decision is expected by the summer of 2021.

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.

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. 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 measurements 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 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; we are pursuing a Section 505(b)(2) application in connection with 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. For locally acting inhaled products, we believe that demonstration of bioequivalence in most cases will require human clinical studies that demonstrate that the generic 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. 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 and marketing approval 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 procedure for which the product is being used 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, including markets in which we hope to sell our products, 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. As in the United States, 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. Recent 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 litigation. 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 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.

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 conducted by USC is subject to federal, state and local laws, regulations, and administrative practices,

including, among others: laws 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 USC sells. Some of the various federal and state laws and regulations which may govern or impact USC's operations are described below.

USC's compounding operations are regulated by both individual states and the federal government. Every state has laws and regulations addressing compounding operations, including regulations relating specifically to compounding outsourcing facility operations. Many states license outsourcing facilities as pharmacies and apply pharmacy regulations to them. These regulations generally include licensing requirements for pharmacists, pharmacy technicians and pharmacies, as well as regulations related to compounding processes, safety protocols, purity, sterility, storage, controlled substances, recordkeeping and regular inspections, among other things. State rules and regulations are updated periodically, generally under the jurisdiction of individual state boards of pharmacy. Failure to comply with the state pharmacy regulations of a particular state could result in a pharmacy being prohibited from operating in that state, financial penalties and/or becoming subject to additional oversight from that state's board of pharmacy.

In addition, many states are considering imposing, or have already begun to impose, requirements on compounding pharmacies and on outsourcing facilities. Revisions to United States Pharmacopeia Chapters <800> "Hazardous Drugs – Handling in Healthcare Setting," <795> "Pharmaceutical Compounding – Non-Sterile Preparations," and <797> "Pharmaceutical Compounding – Sterile Preparations" were published in July 2019. As of the date of this Report, the effective dates of the revised chapters USP <795> and USP <797> have been postponed indefinitely. New and revised chapter USP <800> is incorporated by reference in some state regulations, and compliance with these revisions may require significant changes to procedures, policies, and facility design. If our compounding operations become subject to additional licensure requirements or, are unable to maintain their required licenses or if states place burdensome restrictions or limitations on outsourcing facilities regulated by the states as pharmacies, USC's ability to operate in some states could be limited. As of the date of this Report, there are no operating restrictions on USC's licensure in any of the states where it is licensed that we believe would have a material adverse effect on us.

Most of the states into which USC delivers its formulations have laws and regulations that require out-of-state outsourcing facilities, at times regulated as pharmacies, to register with, or be licensed by, the boards of pharmacy or similar regulatory bodies in those states. These states generally permit the outsourcing facility regulated as a pharmacy to follow the laws of the state within which the pharmacy is located. However, various state pharmacy boards have enacted laws and/or adopted rules or regulations directed at restricting or prohibiting the operation of out-of-state outsourcing facilities regulated as pharmacies by, among other things, requiring compliance with all laws of the states into which the out-of-state outsourcing facility regulated as a pharmacy dispenses or distributes medications, whether or not those laws conflict with the laws of the state in which the outsourcing facility is located, or requiring the pharmacist-in-charge to be licensed in that state.

Section 503B of the FDCA was enacted as part of the DQSA to establish an outsourcing facility as a new entity that is permitted to compound large quantities of drug formulations without a prescription and distribute them without limitation on the volume that may be shipped out of state. Section 503B includes conditions relating to registration and reporting, use of bulk drug substances in compounding, compounding copies of FDA-approved drugs, wholesaling, and labeling, among others. Entities voluntarily registering as outsourcing facilities are subject to cGMP requirements and regular FDA inspection, among other requirements. USC currently operates as a 503B outsourcing facility, and we cannot predict when FDA will issue, finalize, or enforce new rules and guidance documents that affect our business practices. Several rules and guidance documents from FDA are currently in proposed or draft form, and we cannot predict or control when final rules and final guidance might be issued or if any changes from the proposed or draft versions will be introduced.

Since 2012, the FDA has convened a number of inter-governmental working meetings with government officials from each state, the District of Columbia and Puerto Rico, to discuss topics such as oversight of compounding, including the implementation of the DQSA, and opportunities to better protect public health by strengthening oversight of compounders through improved collaboration between the FDA and the states. As a result of such meetings, the FDA and the states committed, among other things, to enhance inter-agency communication surrounding the implementation of the DQSA, which may lead to additional guidance or regulation in the future. If federal, state or local regulatory authorities place new restrictions or limitations on USC's or our operations, USC's or our business, financial conditions or results of operations could be materially adversely affected.

USC's 503B outsourcing facility operations must continually adhere to applicable cGMP requirements, which are issued and enforced by the FDA through regulations and guidance and interpreted and enforced through its inspection programs. In July 2014, the FDA issued draft guidance for cGMPs for human drug compounding outsourcing facilities, such as USC's. This draft guidance was revised in December 2018, and in January 2020 the FDA published a second revised draft guidance on cGMP requirements. USC has assessed this revised draft guidance and is implementing pertinent improvements or changes to its processes, procedures, policies, or facility to achieve the expected level of compliance. Because this cGMP draft guidance has not been finalized and may be significantly changed prior to being made final, we may need to expend substantial additional resources to comply with the final applicable cGMPs, along with any additional modifications over time.

In January 2018, the FDA published a statement outlining its compounding priorities for 2018, or the 2018 Compounding Plan, which provided an overview of the key priorities the FDA planned to focus on in 2018 in connection with compounding regulations. Included in the 2018 Compounding Plan were references to forthcoming regulations on compounding from bulk drug substances, determination of clinical need, and a revised memorandum of understanding between the FDA and State Boards of Pharmacy setting forth limits on interstate compounding under Section 503A of the FDCA. In keeping with this 2018 Compounding Plan, in March 2018 the FDA issued a draft guidance proposing a framework for determining the clinical need sufficient to permit an outsourcing facility to compound from bulk drug substances ("Bulks Guidance"). The Bulks Guidance received numerous comments, and final guidance was published in March 2019 relating to the method by which the FDA will evaluate bulk drug substances for inclusion/exclusion on the final bulk substances lists ("Bulks List"). In September 2019, Endo International plc ("Endo"), a pharmaceutical company, withdrew a lawsuit based on the FDA's formal action to exclude vasopressin (and one other substance) from the Bulks List, the basis of Endo's complaint. Since then, FDA has published two subsequent notices to the Federal Register that propose to exclude an additional 28, while moving to include

four, substances. As of this date of this Report, FDA has yet to take final action on these two proposals and no timeline is currently available by which the lists are expected to be finalized.

Among the 28 bulk substances FDA has proposed to exclude from the Bulks List is ephedrine sulfate. Ephedrine sulfate represents a portion of USC's hospital outsourcing business, which could result in a loss of revenue resulting from affected USC products. USC is working proactively with industry stakeholders and regulatory authorities regarding the FDA's guidance and actions. Until FDA makes a final determination on its Bulks List proposals, the interim bulk substances lists are effective, and USC does not compound with bulk drug substances not on the interim list as approved for use. We believe that the impact on USC and other 503B outsourcing facilities of the regulatory expectations regarding bulk substances will depend in part on how the guidance is implemented, interpreted, and applied over time.

The DQSA prohibits compounding facilities from compounding products that are considered "essentially a copy" of approved drug products offered by traditional pharmaceutical manufacturers. In January 2018, the FDA published Final Guidance on what it considers to be "essentially a copy" of approved drug products for outsourcing facilities. This guidance documents added the requirement that purchasers and prescribers document on each order and prescription the specific clinical need for the compounded medication. Some purchasers and prescribers may be unwilling to complete this additional documentation, resulting in decreased demand for the compounded drug products. In 2021, the FDA plans to issue a revised draft guidance on compounded drug products that are essentially copies of approved drug products under Section 503B of the FDCA, the prohibition on wholesaling under Section 503B, and safety considerations for Section 503B container labels and carton labeling design to minimize medication errors. This new or revised guidance could have an adverse impact on USC's business.

In November 2019, the FDA issued a draft Guidance for Industry #256: Compounding Animal Drugs from Bulk Drug Substances, or the Draft GFI #256. This guidance describes the FDA's policy regarding the compounding of animal drugs from bulk substances and limits the circumstances in which a compounder may use bulk substances to compound animal medication. Industry comments to the Draft GFI #256 were due by October 15, 2020. No official action has been taken to date. As with other FDA regulations and guidance, when finalized, this guidance could limit the number and type of products USC is permitted to compound for animal use.

USC is currently compounding animal medication in its registered Section 503B outsourcing facility. Section 503B of the FDCA does not apply to animal medication and FDA does not expressly allow 503B registered outsourcing facilities to compound animal medication. However, FDA's August 2015 guidance on whether an entity should register as an outsourcing facility contemplates that outsourcing facilities will be compounding animal medication in addition to human medication, and FDA has not taken action to date against a Section 503B registered outsourcing facility that is compounding both human and animal medications. Nevertheless, as FDA has not expressly stated its position on the compounding of animal medication in a 503B outsourcing facility, there is a risk that FDA could, in the future, consider animal medication compounded in a 503B outsourcing facility to not be exempt from new drug approval requirements, and enforce new drug approval requirements on animal medication compounding in Section 503B outsourcing facilities.

Compliance Matters. Compounding pharmacies have historically been subject to FDA inspections on an irregular basis, whereas outsourcing facilities are subject to FDA inspections on a risk-based schedule in accordance with DQSA Section 503B(b)(4). Observations by the FDA of potentially violative conditions during inspections are required to be reported to facility management at the close of the inspection on Form FDA 483 (Form 483). It is common for such forms to be provided in connection with inspections of compounding outsourcing facilities, and observations may be further followed by Warning Letters and other enforcement actions as the FDA deems warranted. In March 2014, August 2015, July 2016, and February 2019, USC received Form 483s following FDA inspections of its outsourcing facility, noting inspectional observations of a number of observed potential deficiencies relating to USC's facility and practices.

Following the August 2015 Form 483 observations, and prior to our acquisition of USC, USC temporarily suspended production of sterile products and voluntarily recalled certain lots of sterile product. USC determined there was no evidence that any compounded sterile products were defective but decided to voluntarily recall all sterile product that remained within expiry and temporarily halt sterile production. USC responded to the August 2015 Form 483 observations and took a number of corrective actions, including enhancing quality control and production systems**.** Approximately around the time of its acquisition by Adamis, USC resumed production and sale of its sterile products. In July 2016, USC received a Form 483 following FDA inspection of its outsourcing facility, noting inspectional observations of a number of observed deficiencies relating to USC's facility and practices. USC responded in writing to the inspectional observations in July 2016 and provided supplemental responses to FDA in April 2017. In October 2017, USC received a Warning Letter referencing the August 2015 and July 2016 Form 483 inspectional observations. USC provided a written response to the FDA that further described the completed corrective actions that were taken in response to the inspectional observations. In November 2018, FDA responded to the 2017 Warning Letter response submitted by USC and indicated it would look for evidence of corrective action and further clarification of policies and procedures on a future inspection. USC was inspected by FDA in the early part of 2019, with a Form 483 issued to site management in February 2019. USC duly responded to the inspectional observations in writing to the FDA in March 2019, and provided an initial update in April 2019 and a comprehensive update of completed corrective actions and milestones in August 2019. In August 2020, USC received a Regulatory Meeting Letter from FDA as a follow up to USC's correspondence and corrective actions related to the February 2019 Form 483. In October 2020, USC responded to the requests made in the Regulatory Meeting Letter and provided a supplemental response in January 2021. USC is scheduled to complete this Regulatory Meeting with FDA in April 2021 to determine the efficacy of USC's corrective actions. If FDA is not satisfied with the efficacy of USC's corrective actions, then after the Regulatory Meeting, FDA could take enforcement action, which could include a request that USC cease operations or recall product. Any enforcement action may adversely affect USC's and our business, results of operations, and financial condition.

Following the suspension and voluntary recall in 2015, state pharmacy regulatory agencies in certain states initiated inquiries or took other actions regarding sales of USC products in such states. All of those state matters relating to the suspension and voluntary recall have been resolved; however, future proceedings by the FDA or state regulatory agencies alleging violation of applicable federal or state laws or regulations could require significant time and financial resources, and an adverse outcome in one or more of these proceedings could adversely affect USC's and our business, results of operations and financial condition.

We cannot predict when or if we will receive additional Form 483 observations or other communications from the FDA or state regulatory authorities regarding USC's compounding outsourcing facility or compounded drugs. We could be subject to additional regulatory action by the FDA and civil or criminal enforcement action by the Department of Justice under the FDCA, Federal False Claims Act, or other applicable statutes, as well as related private actions, as a result of previous, current or future FDA observations. USC's

suppliers and customers may negatively consider the Form 483 observations issued to us when deciding to award contracts or continue or renew agreements. Other state and federal regulators and agencies may also consider the Form 483 observations when conducting their own inspections, enforcement actions or approvals, including license renewals. Any such actions could significantly disrupt USC's business and harm its and our reputation, resulting in a material adverse effect on our business, results of operations and financial condition.

Confidentiality, Privacy and HIPAA

To the extent that USC's outsourcing facility operations, may involve the receipt, use and disclosure of confidential individually identifiable medical, pharmacy and other health-related information, it may be subject to HIPAA. The federal privacy regulations under HIPAA are designed to protect the medical information of a healthcare patient or health plan enrollee that could be used to identify the individual. Among other things, HIPAA limits certain uses and disclosures of protected health information and requires implementation of security safeguards regarding the storage, utilization and transmission of and access to electronic protected health information. The requirements imposed by HIPAA are extensive. In addition, most states have enacted privacy and security laws that protect identifiable patient information. The European General Data Protection Regulation, or GDPR, contains provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures that are intended to bring non-EU companies under the data security and privacy legal framework specified in the regulation. If we expand our business operations to include operations in the European Union, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.

Additionally, effective January 1, 2020, the California Consumer Privacy Act, or CCPA, created individual privacy rights for California consumers (as that word is broadly defined in the law) and placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. The CCPA and its implementing regulations have already been amended since their enactment. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. The CCPA could impact our business activities and create additional risks relating to cyber security and the evolving regulatory environment related to personal data and protected health information.

Reimbursement

Currently, most of USC's formulations are sold in cash transactions. Compounded formulations sold by USC may not qualify for reimbursement by third-party payors, including Medicare and Medicaid. Further, healthcare reform efforts generally may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could adversely affect USC's business. As a result, reimbursement from third-party payors may never be available for any of USC's products or, if available, may not be sufficient to allow USC to sell the products on a competitive basis and at desirable price points.

Drug Enforcement Administration

USC maintains registrations with the DEA that enable USC to receive, manufacture, store and distribute controlled substances. Under federal law, controlled substances include any drug or other substance, or immediate precursor, that appears on one of five schedules promulgated and administered by the DEA under the Controlled Substances Act, or CSA. DEA drug scheduling is based on the drug's acceptable medical use and the potential for abuse and dependence. Laws enforced by the DEA, as well as similar laws enforced by state agencies, require each location that handles controlled substances to separately register.

The CSA governs, among other things, the ordering, distribution, recordkeeping, handling, security and disposal of controlled substances. USC's compounding outsourcing facilities that handle controlled substances are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with federal and state controlled substances laws and regulations. Any failure to comply with these laws and regulations could lead to a variety of sanctions, including the revocation, or a denial or renewal, of any DEA or state registration, injunctions or civil or criminal penalties.

Procurement quota requirements imposed by the DEA on USC's purchases of materials containing certain controlled substances necessitate regular applications to the DEA for permission to purchase materials essential to the production of many of USC's CSPs. Any inability to obtain authorization from the DEA to procure controlled substances for use in USC's business, or a reduction in USC's quota, could adversely affect our business, financial condition and results of operations. The DEA also establishes aggregate production quotas for certain controlled substances. In 2016, the DEA issued a statement indicating it would significantly decrease the amount of opioid controlled substances to be manufactured in 2017 in an effort to curb the national opioid abuse crisis. DEA announced further reductions for 2018, 2019 and 2020, though the DEA adjusted the 2020 quotas for opioid production in response to the COVID-19 public health emergency. Future decreases could limit USC's ability to procure controlled substances and adversely impact our revenues and results of operations; however, USC works with both the DEA and customers to address these issues.

Environmental and Other Matters

USC is or may become subject to environmental laws and regulations governing, among other things, any use and disposal by USC of hazardous or potentially hazardous substances in connection with research and preparation of compounded formulations. USC is subject to work safety and labor laws that govern certain of its operations and employee relations. In each of these areas, as above, the FDA and other federal, state, and local government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, licenses or permits, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on our business, financial condition and results of operations.

Employees and Human Capital Resources

As of December 31, 2020, we had 116 full-time employees, including one located outside of the United States, and 27 part-time employees. 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. During 2020, our COVID-19 pandemic preparedness and response was 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, which may hinder our ability to obtain further financing.

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, 2020, 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. Additional funding may be required to develop and commercialize 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. The above conditions raise substantial doubt about our ability to continue as a going concern. 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, and there are no assurances that such funding will be available at all or will be available in sufficient amounts or on reasonable terms. Without additional funds, if required, from debt or equity financings, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions or sources, we will exhaust our resources and will be unable to continue operations. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

We may require additional financing to continue as a going concern.

We incurred a net loss of approximately $49.4 million and $27.5 million for the year ended December 31, 2020 and the year ended

December 31, 2019, respectively. At December 31, 2020, we had cash and cash equivalents of approximately $6.9 million, accounts receivable of approximately $1.1 million, and liabilities of approximately $27.4 million. In February 2021, we completed an equity financing transaction resulting in estimated net proceeds of approximately $48.3 million. However, the development of our business may in the future 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. We have historically relied upon sales of our equity or debt securities to help fund our operations. We currently have no available balance in our credit facility or committed sources of capital. Delays in obtaining, or the inability to obtain, required funding 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.

Our ability to obtain financing if required 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 have 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, 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, the restatement and 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 net losses of approximately $49.4 million for the year ended year ended December 31, 2020, and a net loss of approximately $27.5 million for the year ended December 31, 2019. From inception through December 31, 2020, we have an accumulated deficit of approximately $229.9 million. We expect that these losses may increase 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 with USWM 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 will need to 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.

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, 2020, 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 21 to the consolidated financial statements appearing elsewhere 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.

We have incurred significant indebtedness, which will require substantial cash to service and which subjects us to certain financial requirements and business restrictions; we have obtained a Paycheck Protection Loan, which might not be forgiven in whole or in part.

As we have previously disclosed in our SEC filings, in connection with our acquisition of USC and the transactions contemplated by the merger agreement relating to the USC acquisition, 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, 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 Documents. The lender in all of the Loan Documents was First Federal Bank and/or its successor Bear State Bank, and/or Arvest Bank, as successor in interest to Bear State Bank, referred to as Lender or the Bank. We have previously entered into amendments of these loan agreements with the Bank, or the Amended Loan Documents. Under the loans outstanding as of the date of this Report, we are required to make current periodic interest and principal payments under the Amended Loan Documents, in an amount of approximately $19,000 per month; the amount of required interest payments is subject to change depending on future changes in interest rates.

The Amended Loan Documents with the Bank include a variety of representations, warranties and covenants that we are required to comply with. If we do not comply with the provisions of such agreements and documents and the Bank declares an event of default, the Bank would be entitled to accelerate the maturity date of the loans, the principal and accrued interest would become due and payable, and the Bank could elect to exercise its remedies as a secured creditor under the loan documents and applicable law. At December 31, 2020, our aggregate indebtedness under the Amended Loan Documents was approximately $2,067,000.

Our ability to make scheduled payments on our indebtedness depends on our future performance and ability to raise additional capital if required, which is subject to economic, financial, competitive and other factors, some of which are beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, attempting to restructure our debt or obtaining additional capital through sales of equity or incurrence of additional debt on terms that may be onerous or highly dilutive to our stockholders. Our ability to engage in any of these activities would depend on the capital markets and our financial condition at such time, and we may not be able to do so when needed, on desirable terms or at all, which could result in a default on our debt obligations. Additionally, the Amended Loan Documents contain various restrictive covenants, including, among others, our obligation to deliver to the Bank certain financial and other information, our obligation to comply with certain notice and insurance requirements, and our inability, without the Bank's prior consent, to dispose of certain of our assets, incur certain additional indebtedness, enter into certain merger, acquisition or change of control transactions, pay certain dividends or distributions on or make certain repurchases of our capital stock or incur any lien or other encumbrance on our assets, subject to certain permitted exceptions. Any failure by us to comply with any of these covenants, subject to certain cure periods, or to make all payments under the debt instruments when due, would cause us to be in default under the applicable debt instrument. In the event of any such default, the Bank may be able to foreclose on the assets that secure the debt or declare all borrowed funds, together with accrued and unpaid interest, immediately due and payable, thereby potentially causing all of our available cash to be used to pay our indebtedness or forcing us into bankruptcy or liquidation if we do not then have sufficient cash available. Any such event or occurrence could severely and negatively impact our business, financial conditions or results of operations.

In addition, in April 2020, we 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 "PPP Note"), in the principal amount of $3,191,700, to Arvest Bank, the Lender. Under the terms of the PPP Note and the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP Note is two years, unless sooner provided in connection with an event of default under the PPP 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 PPP 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 a borrower to apply for forgiveness of up to the full amount borrowed. 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 certain specified percentages 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. There is no assurance that we will be granted forgiveness of some or all of the amount of the PPP Loan. After the CARES Act was passed and we applied for and obtained the PPP Loan, the SBA issued new guidance that, among other things, questioned whether a public company with substantial market value and access to capital markets would qualify to participate in the PPP and be able to make the required certification that current economic uncertainty makes the loan request necessary to support the ongoing operations of the applicant. Subsequently, the Secretary of the Treasury and SBA has issued guidance that the government will review all PPP loans of more than $2 million for which the borrower applies for forgiveness, and that all PPP loans in excess of $2 million, and other PPP loans as appropriate, will be subject to review by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form. In December 2020, we submitted our application for the forgiveness of the full amount of the PPP Loan. As of the date of this Report, we have not received a determination from SBA regarding our PPP Loan forgiveness application. Should we be audited or reviewed by federal or state regulatory authorities as a result of filing an application for forgiveness of the PPP Loan or otherwise, such audit or review could result in the diversion of management's time and attention and legal and reputational costs. 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 PPP 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.

On March 15, 2021, we entered into a Note, or the PPP2 Note, in favor of Arvest Bank as lender, or the Bank, in the principal amount of $1,765,495 relating to funding under a Second Draw loan, or 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. We 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 eligible payroll and make certain covered interest payments, lease payments and utility payments. We 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, we 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 we timely apply for forgiveness, p ayments 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 in 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. No assurance is provided that the company will obtain forgiveness of the PPP Loan in whole or in part. If the Second Draw Loan is not forgiven in accordance with the terms of the PPP, we will be obligated to make monthly payments of principal and interest to repay the Second Draw Loan in full prior to the maturity date. If we do not submit a loan forgiveness application to the Bank within 10 months after the end of our applicable covered period, as defined under the PPP and applicable regulations and guidance issued by the SBA or the U.S. Department of Treasury, then we must begin paying principal and interest after that 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, bankruptcy or insolvency events, certain change of control events, material adverse changes or events, and certain other events. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from us, or filing suit and obtaining judgment against us.

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 product, 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 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.

On May 15, 2020, we resubmitted to the FDA our NDA relating to our ZIMHI product, responding to matters raised in the FDA's previous CRL regarding our original NDA for ZIMHI and matters discussed in our Type A meeting with the FDA concerning the CRL. On November 13, 2020, we received a CRL from the FDA regarding our resubmitted NDA for our ZIMHI high-dose naloxone injection product for the treatment of opioid overdose. 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 cannot approve our NDA in its present form and provided recommendations needed for resubmission. The questions raised by the FDA related generally to new Chemistry, Manufacturing and Controls (CMC) issues. We submitted responses to the deficiencies identified in the CRL and held a Type A meeting with the FDA to discuss the CRL and the company's responses and obtained input from the agency concerning the resubmission of the NDA. With the input from the meeting, the company intends to resubmit the NDA for ZIMHI to the FDA. The company expects to resubmit the NDA within approximately 45 days from the date of this Report absent unexpected delays, although there can be no assurance regarding the date that our NDA will be resubmitted. At the Type A meeting, the FDA did not provide any specific timeline for review of a resubmitted NDA. If the matters raised in the CRL cannot be resolved with the FDA division that sent the CRL, we may appeal the matter within the agency through a Formal Dispute Resolution process. There can be no assurances regarding the timing or outcome of our resubmission of the NDA to the FDA or the FDA's review of any resubmitted NDA relating to the ZIMHI product, the timing or outcome of any Formal Dispute Resolution process that we may decide to initiate, whether the FDA will regard our responses to the CRL and a resubmitted NDA as satisfactory, whether the FDA will require additional actions, information or trials after review of a resubmitted NDA or issue another CRL, the timing, costs or outcome of any additional actions that may be required following any resubmission of the NDA, or that the product will be able to compete successfully in the market if approved and launched.

Our limited operating history may make it difficult to evaluate our business and our future viability.

We have only a limited operating history on which to base an evaluation of our business and prospects. We are subject to the risks associated with early stage companies with a limited operating history, including without limitation: the possible need for additional financing; the uncertainty of research and development efforts resulting in successful commercial products, as well as the marketing and customer acceptance of such products; unexpected issues with the FDA or other federal or state regulatory authorities; regulatory setbacks and delays; unexpected delays in commercialization of products; competition from larger organizations; reliance on the proprietary technology of others; dependence on key personnel; uncertain patent protection; fluctuations in expenses; and dependence on corporate partners and collaborators. Any failure to successfully address these risks and uncertainties could seriously harm our business and prospects. We may not succeed given the technological, marketing, strategic and competitive challenges we will face. The likelihood of our success must be considered in light of the expenses, difficulties, complications, problems and delays frequently encountered in connection with the growth of a new business, the continuing development of new drug technologies, and the competitive and regulatory environment in which we operate or may choose to operate in the future.

Many of our potential products and technologies are in early stages of development, or have been discontinued or are suspended.

The development of new pharmaceutical products is a highly risky undertaking. In addition, development of some of our potential product candidates has been discontinued or suspended. Our potential products may require significant additional research and development before any commercial introduction. 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.

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

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 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.

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 continued through 2020 and is continuing, has spread throughout most of the world including the United States. As of the date of this Report, this outbreak has 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, have decreased demand from USC's customers for certain of USC's products and have adversely affected revenues from sales of USC products, and may continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted. Moreover, COVID-19 has restricted us from utilizing traditional sales and marketing efforts, such as regular sales visits to customers, in generating revenues. 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. Global health concerns, such as coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. In addition, the COVID-19 outbreak has resulted in an economic downturn and has significantly affected the financial markets of many countries. 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 quarantines, shelter-in-place or work-from-home orders or policies, travel restrictions, social distancing and business shutdowns. The effects of such measures may 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, it is possible that one or more members of our workforce could be diagnosed with COVID-19, which could adversely impact our operations. As of the date of this Report, we cannot presently predict the long-term impact to the scope and severity of potential business or disruptions, but 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 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.

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 are 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, we submitted Section 505(b)(2) NDA regulatory filings to the FDA in connection with our ZIMHI (naloxone) Injection product candidate, 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 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 any clinical trials 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, other than our compounding formulations sold by USC, which are less affected by the willingness of third-party payors to pay a substantial portion of the price of such 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, including the ACA. Given the enactment of these laws and other federal and state legislation and regulations relating to the healthcare system, their impact 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 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 candidate, our allergy and respiratory product candidates, 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 will compete with a number of other currently marketed epinephrine products for use in the emergency treatment of acute allergic reactions, including anaphylaxis. Our ZIMHI product, if approved and commercialized, will compete with a number of other currently marketed products utilizing naloxone, for the treatment of acute opioid overdose. 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 patents, 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. 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. 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 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 year ended December 31, 2020, total goodwill impairment charge recorded was approximately $6,772,000. In addition, 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. 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.

Risks Related to Our Compounding Pharmacy Business

USC's compounded preparations and the pharmacy compounding industry are subject to regulatory and customer scrutiny, which may impair our growth and sales.

As a 503B drug compounding outsourcing facility, USC's human compounded formulations are not subject to the FDA drug approval process. This means that FDA does not verify the safety or effectiveness of the medications compounded and distributed by USC, but rather FDA establishes standards for manufacturing processes controls to ensure drug quality. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed. Drugs available through branded and generic drug companies have been approved for marketing and sale by the FDA and are subject to many more requirements than drugs compounded in outsourcing facilities. In addition, some compounding pharmacies have been the subject of widespread negative media coverage in previous years, and the actions of these pharmacies have resulted in increased scrutiny of compounding pharmacy activities from the FDA and state governmental agencies. As a result, some physicians may be hesitant to prescribe, and some patients may be hesitant to purchase and use, compounded drugs. Other reasons physicians may be unwilling to prescribe or patients may be unwilling to use USC's compounded formulations could include the following, among others: applicable law limits our ability to discuss the efficacy or safety of USC's formulations with potential users to the extent applicable data is available; our compounded preparations are primarily sold on a cash-pay basis and reimbursement may or may not be available from third-party payors, including the private payors and government programs such as Medicare and Medicaid programs; or ordering physicians or their delegates may be unwilling or logistically unable to provide attestation of clinical need as required by FDA pursuant to guidance documents published in 2018. Failure by physicians, patients, other potential customers, or third-party payors, to accept compounded drugs could substantially limit USC's market and cause its and our business and operations to suffer.

The COVID-19 outbreak has adversely affected sales of USC's compounded pharmacy products and may continue to adversely affect USC's business.

The COVID-19 outbreak adversely affected revenues from sales of products by USC during 2020 and may continue to adversely affect such sales. Restrictions on outpatient surgery and other medical procedures due to the COVID-19 pandemic have resulted in a decline in sales of USC's products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products. Moreover, limitations and measures related to the COVID-19 pandemic have restricted USC from utilizing traditional sales and marketing efforts, such as regular sales visits to customers, in generating revenues. These factors may continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted.

We have entered into a non-binding letter of intent with a potential buyer for the sale of substantially all of the assets of our USC subsidiary. There is no assurance that any such transaction will be completed on the terms contained in the letter of intent or otherwise.

As discussed further in this Report in Item 1 under the heading "Business – Company Overview – Prescription Compounded Medications – Letter of Intent," we have entered into a non-binding letter of intent with a potential buyer for sale of substantially all of the assets of our USC subsidiary. If a transaction is negotiated, reflected in definitive agreements entered into by the parties, and completed, the proposed purchase price consideration includes a combination of a cash payment at the closing of the transaction, a promissory note representing portion of the purchase price payable at a future date, and potential future performance-based milestone payments over a period of years. The amount and structure of consideration could change as a result of subsequent negotiations, due diligence or other factors. Any definitive agreement would be subject to approval by the respective parties, including approval by our board of directors, and would likely include a number of customary provisions, including without limitation representations and warranties of USC and us, restrictive covenants and indemnification provisions. The letter of intent is non-binding other than with respect to certain customary confidentiality and exclusivity provisions. There can be no assurance that the parties will ultimately negotiate and enter into definitive transaction agreements on the terms contemplated by the letter of intent or otherwise. In particular, the timing of closing of any such transaction and the aggregate consideration that we may receive may materially differ from that currently contemplated by the letter of intent.

We expect increased competition in the future regarding USC's compounded pharmacy products. If we fail to respond to such competition successfully, USC's and our business, results of operations and financial condition could be materially and adversely affected.

The pharmaceutical and pharmacy industries are highly competitive. We compete against other registered outsourcing facilities, branded drug companies, generic drug companies, regional compounders that provide patient-specific compounding that decide to expand to 503B outsourcing, non-patient-specific compounding, large hospitals and integrated delivery networks, other compounding pharmacies, and new entrants to the industry. Increased competition could reduce revenue and gross profit and otherwise materially adversely affect our business, results of operations and financial condition.

Many competitors that market and sell compounded preparations have longer operating histories and may have greater financial, marketing, and other resources than we do. We are significantly smaller than some of such competitors, and we may lack the financial and other resources needed to develop, produce, distribute, market, and commercialize any of USC's formulations or compete for market share in these sectors. These potential competitors could leverage existing resources and experience operating in industries that are subject to significant regulatory oversight in order to overcome certain barriers to entry. Consequently, competitors may be able to develop products and services competitive with, or superior to, USC's products and services. Furthermore, we may not be able to differentiate USC's compounded preparations and services from those of our competitors, successfully develop or introduce new services—on a timely basis or at all—that are less costly than those of our competitors or offer customers payment and other commercial terms as favorable as those offered by our competitors. In addition, the drug products available through branded and generic drug companies with which USC's formulations compete have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. We expect competition to intensify as technology advances, such as those in the field of robotics and automation, and consolidation continues. Also, new developments by pharmaceutical manufacturers, such as increasing the number of abbreviated new drug applications, to cover less frequently used drug formulations, could render some or most of USC's products or services obsolete.

If a compounded drug formulation provided through our compounding services leads to patient injury or death or results in a product recall, we may be exposed to significant liabilities and reputational harm.

The production, labeling and packaging of compounded sterile preparations, or CSPs, is inherently risky. The success of USC's compounded formulations and pharmacy operations depends to a significant extent upon medical and patient perceptions of USC and us and the safety and quality of USC's products. We could be adversely affected if USC, any other compounding pharmacies or USC's formulations and technologies, are subject to negative publicity. We could also be adversely affected if any of USC's formulations or other products, any similar products sold by other companies, or any products sold by other compounding pharmacies, 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 USC's compounded formulations, 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, or safety alert relating to, one or more of USC's products. Similarly, to the extent any of the components of approved drugs or other ingredients used by USC to produce compounded formulations have quality or other problems that adversely affect the finished compounded preparations, USC's and our sales could be adversely affected. In addition, in the ordinary course of business, we may voluntarily retrieve products in response to a customer complaint. Because of our dependence upon medical and patient perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of USC's products, any similar products sold by other companies or any other compounded formulations, could have a material adverse impact on our business, results of operations and financial condition.

We could become subject to product recalls and termination or suspension of our state pharmacy licenses if laboratory testing does not identify all contaminated products or if our products otherwise cause or appear to have caused injury or harm to patients. In addition, such laboratory testing may produce false positives, which could harm our business and impact our pharmacy operations even if the impacted formulations are ultimately found to be sterile and no patients are harmed by them. 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 one of USC's formulations or compounds, USC's and our reputation could suffer, we could become subject to product and professional liability lawsuits, and USC's or our state pharmacy or other required licenses could be terminated or restricted.

Any retrieval or recall, whether voluntary or requested by the FDA or state regulatory authorities, could result in significant costs and lead to product withdrawals and harm USC's or our ability to successfully launch new products and services. These problems could also result in enforcement actions by state and federal authorities or other healthcare self-regulatory bodies, or product liability claims or lawsuits, including those brought by individuals or groups seeking to represent a class or establish multi-district litigation proceedings. Any such action, litigation, recall or reputational harm, even recalls or negative publicity resulting from patient harm or death caused by compounded medications prepared by a competitor or a hospital pharmacy, could result in a material adverse effect on USC's and our business, results of operations, financial condition and liquidity. Current or future insurance coverage may prove insufficient to cover any liability claims brought against USC or us. Because of the increasing cost of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

USC's ability to generate revenues will be diminished if it fails to obtain acceptable prices.

Currently, USC is paid directly by most of its customers and does not submit large amounts of claims for reimbursement through Medicare, Medicaid or other third-party payors, although its customers may choose to seek available reimbursement opportunities to the extent that they exist. Many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are increasingly attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. The continued efforts of health maintenance organizations, managed care organizations, government programs (such as Medicare, Medicaid and other federal and state-funded programs) and other third-party payors to limit reimbursements to USC's customers may adversely impact our financial results. Further, HIPAA, the Patient Protection and Affordable Care Act, the Health Care and Education Reconciliation Act of 2010, and other healthcare legislation, may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivably adversely affect USC's business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may cease to be available for USC's products. We expect cost pressures from third party payors to continue, and USC's customers have limited bargaining power to counter payor demands for reduced reimbursement rates. If USC's customers increasingly insource pharmaceutical preparations or use alternative third-party providers due to these pressures, USC's and our business, results of operations and financial condition may be materially adversely impacted.

Consolidation in the health care industry could lead to demands for price concessions, which could have an adverse effect on our business, financial condition and results of operations.

Because health care costs have risen significantly, numerous initiatives and reforms by legislatures, regulators, and third-party payors to curb these cost increases have resulted in a trend in the health care industry to consolidate product suppliers and purchasers. Many healthcare industry participants are consolidating to create integrated healthcare delivery systems with significant market power. As provider networks consolidate, thereby decreasing the number of market participants, competition to provide products and services such as those offered by USC will become more intense, and the importance of establishing relationships with key industry participants will become greater. In addition, industry participants may try to use their increased market power to negotiate price reductions for USC's products and services. If we are forced to reduce prices as a result of either an imbalance of market power or decreased demand for USC's products, our business, financial conditions and results of operations would be adversely affected.

If we are unable to maintain our GPO relationships, our revenue could decline.

USC currently derives a significant portion of its revenue from end-user customers that are members of group purchasing organizations, or GPOs. USC is also a member of one or more GPOs. GPOs negotiate pricing arrangements that are then made available to a GPO's affiliated hospitals and other members. GPOs provide end-users access to a broad range of pharmaceutical products and services from multiple suppliers at competitive prices and, in certain cases, exercise influence over the purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs in an effort to lower costs. Maintaining USC's contractual relationships with GPOs will, we believe, help allow USC to continue to provide outsourced compounded formulations, offer a broad product line, and remain price competitive, and failure to maintain such relationships could adversely affect USC's ability to obtain supplies at competitive prices. The GPOs with which USC currently has contractual relationships, or other GPOs, may have relationships with USC's customers, and as such the GPOs may influence the customers' buying patterns regarding USC's products or those of our competitors. If we are unable to maintain USC's relationships with GPOs, USC's and our business, financial condition and results of operations could be adversely affected.

USC relies on third parties to provide active pharmaceutical ingredients and components. If these third parties do not deliver as expected, if USC's agreements with them terminate or if the FDA prohibits use of these active pharmaceutical ingredients, USC's and our business, financial condition, and results of operations could be adversely affected.

USC has contractual relationships with pharmaceutical manufacturers and other suppliers of active pharmaceutical ingredients and containers. Any changes to these relationships, including, but not limited to, a loss of a supplier relationship, product shortages or changes in pricing, could have an adverse effect on USC's and our business, financial condition and results of operations.

USC's business depends to a significant extent on the reliable delivery of drugs from its key suppliers. We strive to identify and maintain relationships with more than one source for active pharmaceutical ingredients and containers used in USC's CSPs. If a drug for which we have not qualified an alternative source becomes unavailable, we may not be able to identify and qualify a replacement supplier

or may suffer a delay in doing so, which could adversely affect USC's and our revenues. Further, we may not receive the same pricing from an alternative supplier. A price increase resulting from using alternative suppliers or due to a shortage of a particular drug, a manufacturer gaining an exclusive right to market and sell a given drug, or any other reason could make USC's compounded preparations containing that drug more expensive, and therefore potentially less attractive, to USC's customers. In addition, active pharmaceutical ingredients and containers that we purchase may not always be available in sufficient quantities to meet USC's needs and the needs of USC's customers. Some pharmaceutical ingredients are only available through a single supplier and may be subject to limits on distribution. Additionally, some of the containers that USC uses in its compounded preparations are particular to a supplier, and USC's customers may use a drug delivery system of a particular supplier. Therefore, if there is a shortage or interruption in the supply of a certain supplier's containers, USC may not be able to sell compounded preparations in alternative containers to certain of its customers. USC regularly searches for and qualifies backup vendors for ingredients and components to improve supply chain security and business continuity. In addition, there is a risk that one or more suppliers could be acquired by another company that owns registered 503B outsourced compounding facilities, in which case we could be required to purchase ingredients or containers from a competitor, which could harm our business.

USC experiences supply interruptions and shortages from time to time. USC retains inventory of drug components and containers in order to help provide our customers continuity of service, but its inventory may not be sufficient. If a supply disruption results in the inability to obtain compounding components, USC's and our business, financial condition and results of operations could be adversely affected.

USC's reliance on suppliers also exposes USC and us to risks that are not within our control, including the following:

- USC relies on suppliers to provide it with drugs, diluents and containers of an acceptable quality in a timely fashion. Any quality issues, recalls, or supply delay or interruption could harm USC's ability to sell products and may subject USC or us to product liability claims.
- USC's suppliers' facilities must satisfy production and quality standards set by the FDA and other regulatory authorities that periodically inspect facilities to determine compliance. If our suppliers fail to satisfy these requirements, their facilities could be shut down permanently or for an extended period of time.
- USC's suppliers may not be able to produce the volume that USC requires or may experience disruptions or delays due to market conditions, natural disasters, labor-related disruptions, failure in supply or other logistical channels or other reasons.
- A supplier could decide to terminate its contract or supply arrangement with USC due to a disagreement with USC or us.

Each of these risks could delay the production of USC's products or result in higher costs or deprive USC and us of potential revenues. Further, delays or interruptions in supply could limit or curtail USC's ability to meet customer demand for its CSPs. Any such delay or interruption could harm USC's reputation as a provider of outsourced CSPs, cause USC's customers to find alternative sources for CSPs or reduce their use of outsourced CSPs, any of which could have a material adverse effect on USC's and our business, financial condition, and results of operations.

A disruption in USC's operations, including as a result of cybersecurity or other system failures, or the delivery of compounded preparations to customers could damage relations with customers.

USC's success depends upon its ability to provide timely, reliable and consistent services and products to its customers. Natural disasters or other catastrophic events, including tornadoes, hurricanes, blizzards and other weather conditions, terrorist attacks, power and data interruptions, fires as well as logistical or delivery disruptions could disrupt USC's or its suppliers' and vendors' operations and impede USC's ability to provide services and deliver products to customers, which could adversely impact USC's and our results of operations. For example, USC's CSPs have expiration dates, and USC's compounded preparations must remain under specified storage conditions, including some items that must remain refrigerated or frozen or those that are sensitive to excessive heat. Any disruption or delay in delivery may cause spoilage and the need to retrieve and replace products. In the event that USC experiences a temporary or longer term interruption in its ability to deliver services or products, USC's and our revenues could be reduced, USC's reputation could be damaged and USC's and our business could be materially and adversely affected. In addition, any continuing disruption in either USC's or our computer systems or telephone system could adversely affect USC's or our ability to receive and process customer orders and ship products on a timely basis, and could adversely affect USC's or our relations with customers, potentially resulting in reduction in orders or loss of customers.

If we are unable to maintain an effective sales and marketing infrastructure, USC's success in selling products will be inhibited.

If USC's sales increase in the future, it may need to expend significant resources to further grow its sales and marketing employees and internal infrastructure and properly train sales personnel, including without limitation with respect to regulatory compliance matters. We may not be able to secure sales personnel or relationships that are adequate in number or expertise to successfully market and sell USC's products and services. A failure to maintain compliant and adequate sales and marketing capabilities could have a material adverse effect on USC's and our business, financial conditions, and results of operations.

USC's formulations and technologies could potentially conflict with the rights of others.

The preparation or sale of USC's formulations and use of USC's technologies may infringe on the patent or other intellectual property rights of others. If USC's products infringe or conflict with the patent or other intellectual property rights of others, third parties could bring legal actions against us claiming damages and seeking to enjoin our manufacturing and marketing of the affected products. Patent litigation is costly and time consuming and may divert management's attention and our resources. We may not have sufficient resources to bring any such actions to a successful conclusion. If we are not successful in defending against these legal actions should they arise, we may be subject to monetary liability or be forced to alter our products, cease some or all of our operations relating to the affected products, or seek to obtain a license in order to continue manufacturing and marketing the affected products, which may not available on acceptable terms or at all. The lawsuit filed against FDA by Endo in 2017 and the suits filed by Allergan against a number of compounding facilities indicate the traditional pharmaceutical manufacturing industry is aggressively defending its patent and intellectual property rights as they perceive them. This trend could progress to include some of USC's compounded drug product formulations, resulting in legal expenses and potential product discontinuation.

Risks Related to Registered Outsourcing Facility Regulation

Our business is significantly impacted by state and federal statutes and regulations, including regulatory risks associated with

operation of USC's 503B registered outsourcing facility.

Our compounding business 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 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. Changes in these laws and regulations may require changes to USC's or our business and operations that may be difficult to implement and require significant expenditures. There can be no assurance that we or USC are fully compliant with applicable federal and state regulatory requirements, and any failure to comply may result in additional costs to bring such facilities into compliance. Moreover, the FDA continues to issue draft and final guidance under the DQSA, including those relating to cGMPs, which may require further changes to USC's business, facilities or processes, some of which may be significant.

Many states have imposed, are considering imposing, or have already begun to impose, regulatory requirements on compounding activities for outsourcing compounders and reminding outsourcing compounders of regulatory requirements already in effect. If federal, state or local regulatory authorities place new restrictions or limitations on USC's or our operations, USC's or our business, financial conditions or results of operations could be materially adversely affected.

State pharmacy laws require facilities dispensing or distributing into that state to be licensed accordingly, and many states require separate licenses for the various activities that USC performs. Various state pharmacy boards have enacted laws and/or adopted rules or regulations directed at restricting the operation of out-of-state pharmacies by, among other things, requiring compliance with all laws of the states into which the out-of-state pharmacy dispenses medications, whether or not those laws conflict with the laws of the state in which the pharmacy is located, or requiring the pharmacist-in-charge to be licensed in that state.

Pharmacy and controlled substance laws often address the qualification of an applicant's personnel, the adequacy of its prescription fulfillment and inventory control practices and the adequacy of its facilities, and subject pharmacies to oversight by state boards of pharmacy and other regulators that could impose burdensome requirements or restrictions on operations if a pharmacy is found not to comply with these laws. If our or USC's activities fail to comply with such requirements, we could be forced to permanently or temporarily cease or limit the applicable compounding operations, which could severely limit USC's ability to market and sell formulations in such states and could materially harm USC's and our business, financial condition and results of operations. Any such noncompliance could also result in complaints or adverse actions by other state boards of pharmacy, FDA inspection of the facility to determine compliance with the FDCA, loss of FDCA exemptions provided under Section 503A or 503B, warning letters, injunctions, prosecution, fines and loss of required government licenses, certifications and approvals, any of which could involve significant costs and adversely affect our business, financial condition, and results of operations.

In January 2018, the FDA published a statement outlining its compounding priorities for 2018, or the 2018 Compounding Plan, which provided an overview of the key priorities the FDA planned to focus on in 2018 in connection with compounding regulations. Included in the 2018 Compounding Plan were references to forthcoming regulations on compounding from bulk drug substances, determination of clinical need, and a revised memorandum of understanding between the FDA and State Boards of Pharmacy setting forth limits on interstate compounding under Section 503A of the FDCA. In keeping with this 2018 Compounding Plan, in March 2018 the FDA issued a draft guidance proposing a framework for determining the clinical need sufficient to permit an outsourcing facility to compound from bulk drug substances ("Bulks Guidance"). The Bulks Guidance received numerous comments, and final guidance was published in March 2019 relating to the method by which the FDA will evaluate bulk drug substances for inclusion/exclusion on the final bulk substances lists ("Bulks List"). In September 2019, Endo International plc, a pharmaceutical company, withdrew a lawsuit based on the FDA's formal action to exclude vasopressin (and one other substance) from the Bulks List, the basis of Endo's complaint. Since then, FDA has published two subsequent notices to the Federal Register that propose to exclude an additional 28, while moving to include four, substances. As of this date of this Report, FDA has yet to take final action on these two proposals and no timeline is currently available by which the lists are expected to be finalized.

Among the 28 bulk substances FDA has proposed to exclude from the Bulks List is ephedrine sulfate. Ephedrine sulfate represents a portion of USC's hospital outsourcing business, which could result in a loss of revenue resulting from affected USC products. Until FDA makes a final determination on its Bulks List proposals, the interim bulk substances lists are effective, and USC does not compound with bulk drug substances not on the interim list as approved for use. We believe that the impact on USC and other 503B outsourcing facilities of the regulatory expectations regarding bulk substances will depend in part on how the guidance is implemented, interpreted, and applied over time.

The DQSA prohibits compounding facilities from compounding products that are considered "essentially a copy" of approved drug products offered by traditional pharmaceutical manufacturers. In January 2018, the FDA published Final Guidance on what it considers to be "essentially a copy" of approved drug products for outsourcing facilities. This guidance documents added the requirement that purchasers and prescribers document on each order and prescription the specific clinical need for the compounded medication. Some purchasers and prescribers may be unwilling to complete this additional documentation, resulting in decreased demand for the compounded drug products. In 2021, the FDA plans to issue a revised draft guidance on compounded drug products that are essentially copies of approved drug products under Section 503B of the FDCA, the prohibition on wholesaling under Section 503B, and safety

considerations for Section 503B container labels and carton labeling design to minimize medication errors. This new or revised guidance could have an adverse impact on USC's business.

In November 2019, the FDA issued a draft Guidance for Industry #256: Compounding Animal Drugs from Bulk Drug Substances, or the Draft GFI #256. This guidance describes the FDA's policy regarding the compounding of animal drugs from bulk substances and limits the circumstances in which a compounder may use bulk substances to compound animal medication. Industry comments to the Draft GFI #256 were due by October 15, 2020. As of the date of this Report, we are not aware of official action taken to date. As with other FDA regulations and guidance, when finalized, this guidance could limit the number and type of products USC is permitted to compound for animal use. USC is currently compounding animal medication in its registered Section 503B outsourcing facility. Section 503B of the FDCA does not apply to animal medication and FDA does not expressly allow 503B registered outsourcing facilities to compound animal medication. However, FDA's August 2015 guidance on whether an entity should register as an outsourcing facility contemplates that outsourcing facilities will be compounding animal medication in addition to human medication, and FDA has not taken action to date against a Section 503B registered outsourcing facility that is compounding both human and animal medications. Nevertheless, as FDA has not expressly stated its position on the compounding of animal medication in a 503B outsourcing facility, there is a risk that FDA could, in the future, consider animal medication compounded in a 503B outsourcing facility to not be exempt from new drug approval requirements, and enforce new drug approval requirements on animal medication compounding in Section 503B outsourcing facilities.

These laws and other restrictions on the activities of compounding pharmacies, or USC's or our failure to comply with any of these laws and regulations, could limit the market available for compounded formulations and limit USC's or our pharmacy operations, which could materially harm USC's and our business, financial conditions and results of operations. Further, our business could be adversely affected by changes in these or any newly enacted laws and regulations, as well as federal and state agency interpretations of such statutes and regulations. We could incur significant costs in order to comply with such regulations. Compliance with these federal, state and local laws and regulations, including compliance with any newly enacted regulations, requires the substantial expenditure of time, money and effort. 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 USC's and our business, financial condition or results of operations. Further, the publicity of any violations or perceived violations of these laws and regulations could result in significant reputational harm to USC's or our business. In the future, we may not be able to satisfy applicable federal and state licensing and other requirements for USC's compounding pharmacy business in a timely manner or at all, changes to federal and state pharmacy regulations may restrict compounding operations or make them more costly, we may be unable to achieve a sufficient physician and patient customer base to sustain our pharmacy operations, or market acceptance of compounding pharmacies generally may be curtailed or delayed.

USC could receive additional Form 483 observations from the FDA, warning letters or other communications from the FDA or state regulatory authorities, and federal or state proceedings alleging non-compliance with FDA requirements and other applicable federal or state regulatory legal requirements could adversely affect our business, financial condition and results of operations.

Future proceedings by the FDA or state regulatory agencies alleging violation of applicable federal or state laws or regulations could require significant time and financial resources, and an adverse outcome in one or more of these proceedings could adversely affect USC's and our business, results of operations and financial condition.

Human drug compounding outsourcing facilities have historically been subject to FDA inspections on an irregular basis and are now subject to FDA inspections on a risk-based schedule in accordance with DQSA Section 503B(b)(4). Observations by the FDA of potentially violative conditions during inspections are required to be reported to facility management at the close of the inspection on Form FDA 483 (Form 483). It is common for such forms to be provided in connection with inspections of compounding outsourcing facilities, and observations may be further followed by Warning Letters and other enforcement actions as the FDA deems warranted. In March 2014, August 2015, July 2016, and February 2019, USC received Form 483s following FDA inspections of its outsourcing facility, noting inspectional observations of a number of observed potential deficiencies relating to USC's facility and practices. We cannot predict when or if we will receive additional Form 483 observations or other communications from the FDA or state regulatory authorities regarding USC's compounding outsourcing facility or compounded drugs. If FDA is not satisfied with the efficacy of USC's corrective actions, the FDA could take enforcement action, which could include a request that USC cease operations or recall product. Any enforcement action may adversely affect USC's and our business, results of operations, and financial condition. We could be subject to additional regulatory action by the FDA and civil or criminal enforcement action by the Department of Justice under the FDCA, Federal False Claims Act, or other applicable statutes, as well as related private actions, as a result of previous, current or future FDA observations. USC's suppliers and customers may negatively consider the Form 483 observations issued to us when deciding to award contracts or continue or renew agreements. Other state and federal regulators and agencies may also consider the Form 483 observations when conducting their own inspections, enforcement actions or approvals, including license renewals. Any such actions could significantly disrupt USC's business and harm its and our reputation, resulting in a material adverse effect on our business, results of operations and financial condition.

We must compound in conformity with applicable cGMP requirements; failure to maintain compliance with applicable cGMP requirements may prevent or delay the compounding or marketing of our compounded preparations.

USC's 503B outsourcing facility operations must continually adhere to (i) applicable cGMP requirements, which are issued and enforced by the FDA through regulations and guidance and interpreted and enforced through its inspection programs, and (ii) sterile product requirements under applicable state law, such as General Chapter <797> ("USP <797>"), published by the U.S. Pharmacopeia or USP Convention, a scientific standard-setting organization, which have been codified in many states and which have historically been enforced by applicable state boards of pharmacy through inspection programs but are also enforceable by the FDA. In complying with applicable cGMPs and USP <797>, we must expend time, money and effort in production, record-keeping, and quality control to ensure that USC's products and services meet applicable specifications and requirements. Revisions to United States Pharmacopeia Chapters <800> "Hazardous Drugs – Handling in Healthcare Setting," <795> "Pharmaceutical Compounding – Non-Sterile Preparations," and <797> "Pharmaceutical Compounding – Sterile Preparations" were published in July 2019. As of the date of this Report, the effective dates of the revised chapters USP <795> and USP <797> have been postponed indefinitely. New and revised chapter USP <800> is incorporated by reference in some state regulations, and compliance with these revisions may require significant changes to procedures, policies, and facility design. If our compounding operations become subject to additional licensure requirements or, are unable to maintain their required licenses or if states place burdensome restrictions or limitations on outsourcing facilities regulated by the states as pharmacies, USC's ability to operate in some states could be limited. In July 2014, the FDA issued draft guidance for cGMPs for human drug compounding

outsourcing facilities, such as USC's. This draft guidance was revised in December 2018. USC has assessed this revised draft guidance and is implementing pertinent improvements or changes to its processes, procedures, policies, or facility to achieve the expected level of compliance. Because this cGMP draft guidance has not been finalized and may be significantly changed prior to being made final, we may need to expend substantial additional resources to comply with the final applicable cGMPs, along with any additional modifications over time.

The FDA and other governmental entities enforce compliance with regulations and guidance through periodic risk-based inspections. We received FDA Form 483 observations following inspections in 2014, 2015, 2016, and 2019. If any of these entities were to deem inspectional observations at USC's facilities or our responses to such observations to be unsatisfactory, operations at such facility could be interrupted or halted, and we may incur unanticipated compliance expenditures and be subject to enforcement actions such as recall or seizure of USC products, injunctions, civil penalties and criminal prosecution. In addition, any regulatory deficiencies or suspension resulting in compounding interruptions or halts may disrupt USC's or our ability to meet our production and contractual obligations to USC's customers and lead to significant delays in the availability of USC's compounded preparations, which could have a material adverse effect on USC's and our business, results of operations and financial condition. Similarly, any adverse publicity associated with any such events could have a material impact on USC's and our reputation and results of operations.

Certain of USC's customers are contractually permitted to inspect USC's facilities to ensure compliance with industry standards. The failure to achieve a compliance level satisfactory to such customers may result in immediate contract termination, penalties or volume reductions or loss of customers immediately or upon the expiration of existing contracts.

Certain of USC's compounded preparations contain controlled substances, and extensive regulation of such controlled substances could have a negative effect on our business, financial conditions or results of operations.

Certain of USC's compounded preparations contain controlled substances or "certain list I chemicals," which are subject to extensive regulation by the DEA regarding procurement, manufacture, storage, shipment, sale, and use. These regulations are also imposed on USC and its suppliers, vendors and customers and add additional complications and costs to the storage, use, sale and distribution of such products. Government quotas on controlled substances limit the supply of components for certain of USC's compounded preparations and restrict the ability to distribute those preparations. Our inability to obtain authorization from the DEA to procure the controlled or listed substances used in USC's compounded preparations could have an adverse impact on USC's and our business, financial condition, and results of operations.

The FDA reviews the safety of controlled substances on an ongoing basis, and it is possible that these regulatory agencies could impose additional restrictions on marketing or distribution of such products, or could withdraw regulatory approval for materials that USC uses as components in its products. Failure to comply with relevant regulations governing controlled substances could result in civil penalties, refusal to renew necessary registrations, initiation of proceedings to revoke such registrations, reductions of the amounts of controlled substances that USC may obtain and, in certain circumstances, criminal prosecution. If the FDA or the DEA withdraw the approval of, or placed additional significant restrictions on, USC's products or the components used in them, sales of USC products and the ability to promote USC products and services could be materially and adversely affected. Also, the DEA or applicable state regulatory bodies may in the future seek to regulate additional ingredients in USC's compounded preparations as controlled substances or listed chemicals.

USC and its customers 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 USC and its suppliers and customers, 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. Though certain of these healthcare laws and regulations are not directly applicable to USC or us, they may be applicable to USC's customers, third-party vendors, and other supply chain partners. For example, the ACA was enacted in 2010, and many of the structural changes enacted by the ACA were implemented in 2014. However, some of the applicable regulations and sub-regulatory guidance under the ACA have not yet been issued or finalized. These reforms affect the coverage and plan designs that are or will be provided by many of USC's customers' third-party payors. As a result, such reforms could affect the ability of customers to purchase USC products or services and, as a result, adversely impact our revenues. We cannot predict what effect, if any, the ACA, related regulations and sub-regulatory guidance may have on USC's or our business.

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 USC's or our reputation, customer relationships or otherwise have a material adverse effect on our business, financial condition and results of operations.

Such laws and regulations are subject to change and often are uncertain in their application. As controversies continue to arise in the healthcare industry, federal, state and local regulation and enforcement priorities may increase. There can be no assurance that USC, or one of its customers, third party vendors or other supply chain partners, 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 USC's or 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 2018 to December 31, 2020, the market price of our common stock has fluctuated between $0.27 and $5.10. 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;
- our ability to successfully expand sales of our compounded pharmacy formulations;
- 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 October 11, 2019, we received a notice from the Nasdaq Listing Qualifications Department of The NASDAQ Capital Market ("Nasdaq") 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), we were provided an initial compliance period of 180 calendar days, or until April 8, 2020, 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. The Company received additional communications from Nasdaq in April 2020 that ultimately extended the deadline to regain compliance to December 21, 2020.

On August 5, 2020, we received a letter from the Listing Qualifications Department of Nasdaq notifying us that as a result of the closing bid price of the Company's common stock having been at $1.00 per share or greater for at least ten consecutive business days, the Company had regained compliance with Nasdaq's minimum bid price requirement under Nasdaq's Marketplace Rule 5550(a)(2) for continued listing on The NASDAQ Capital Market, and the matter was now closed.

On September 29, 2020, we received a notice from 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 and a result the Company no longer complied with the Rule. In accordance with Nasdaq Marketplace Rule and 5810(c)(3)(A), we were provided with a period of 180 calendar days from the date of notification, or until March 29, 2021, to regain compliance. On February 9, 2021, we received a letter from Nasdaq notifying us that as a result of the closing bid price of the Company's common stock having been at $1.00 per share or greater for at least ten consecutive business days, we had regained compliance with the minimum bid price requirement for continued listing on The NASDAQ Capital Market, and the matter was closed.

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, 2020, we had 93,842,058 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, 2020, we had reserved for issuance 6,508,296 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 $4.29 per share, we had outstanding restricted stock units covering 2,136,893 shares of common stock, and we had outstanding warrants to purchase 24,634,670 shares of common stock at a weighted-average exercise price of $1.22 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, 2020, 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, 2020, 13,800,000 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; 8,700,000 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 and 2,075,846 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants that we issued in the following transactions: warrants to purchase 1,183,432 shares at an exercise price of $4.10 per share in our January 2016 Series A-1 Convertible Preferred Stock transaction; warrants to purchase 192,414 shares at an exercise price of $2.90 per share in our July 2016 Series A-2 Convertible Preferred transaction; and warrants to purchase 700,000 shares at an exercise price of $2.98 per share in our August 2016 registered direct offering of common stock and warrants.

Our principal stockholders have significant influence over us, they may have significant influence over actions requiring stockholder approval, and your interests as a stockholder may conflict with the interests of those persons.

Based on the number of outstanding shares of our common stock held by our stockholders as of December 31, 2020, our directors, executive officers and their respective affiliates owned approximately 1.0% of our outstanding shares of common stock and we believe that our largest stockholder beneficially owned approximately 4.9% of the outstanding shares of our common stock. As a result, those stockholders have the ability to exert a significant degree of influence with respect to the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. The interests of these persons may not always coincide with our interests or the interests of our other stockholders. This concentration of ownership could harm the market price of our common stock by (i) delaying, deferring or preventing a change in corporate control, (ii) impeding a merger, consolidation, takeover or other business combination involving us, or (iii) discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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.

We have identified a material weakness in our internal control over financial reporting. If we fail to effectively remediate this material weakness, it could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner. If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, if we fail to effectively remediate the identified material weakness, or if we discover other material weaknesses or deficiencies in our internal controls over financial reporting, 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 elsewhere in this Report, management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020, and as a result of this assessment identified a material weakness in internal control over financial reporting as of that date. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of December 31, 2020, and our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2020. The material weakness resulted in a misstatement of our warrant liabilities and the related gain or loss recognized as a result of the change in the fair value of the warrant liabilities, and related misstatements in, our unaudited condensed consolidated financial statements, for the periods ended March 31, June 30, and September 30, 2020. See Note 4 of the Notes to the consolidated financial statements included elsewhere herein for additional information.

Any failure to effectively remediate the 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 could cause us to be ineligible to utilize short form registration statements on Form S-3 or Form S-4, which may impair our ability to obtain capital in a timely fashion to execute our business strategies, issue shares to effect an acquisition, or 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 intend to take certain remedial actions intended to address the identified material weakness in our internal control over financial reporting. However, we can give no assurance that such measures will remediate the material weakness 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. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. 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. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress of our development of our products and technologies. Our future financial performance and our ability to compete effectively will 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. The company has entered into a lease agreement to lease the space. 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. The company has 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. We believe that the facilities that we currently lease are adequate for our needs for the foreseeable future, and that if needed, additional or alternative space can be leased on commercially reasonable terms.

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.

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 15 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, 2020, we had approximately 80 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

Information concerning our sales of unregistered securities during the year ended December 31, 2020, has previously been reported in reports on Form 10-Q and reports on Form 8-K that we filed during that fiscal year.

ITEM 6. SELECTED FINANCIAL DATA

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

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

We are a specialty biopharmaceutical company focused on developing and commercializing products in various therapeutic areas, including respiratory disease, allergy and opioid overdose. 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; SYMJEPI (epinephrine) Injection 0.15mg which was approved by the FDA in September 2018, for use in the treatment of anaphylaxis for patients weighing 33-66 pounds; a naloxone injection product candidate, ZIMHI, based on the approved Symject™ injection device and intended for the treatment of opioid overdose for which the company resubmitted its NDA to the FDA in May 2020, received a Complete Response Letter, or CRL, from the FDA in November 2020, submitted responses to the deficiencies identified in the CRL and met with the FDA concerning the responses, and intends to resubmit its NDA; Tempol, an investigational drug; and a Beclomethasone metered dose inhaler product candidate (APC-1000) intended for the treatment of asthma for which the company submitted an Investigational New Drug application, or IND, in January 2018 but has suspended the start-up phase of Phase 3 studies. In June 2020, we entered into a license agreement with a third party to license rights under patents, patent applications and related know-how 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. In January 2021, we submitted an IND to the FDA for the investigational use of Tempol for the treatment of coronavirus (COVID-19) and in February 2021, we were notified by the FDA 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. 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 U.S. Compounding, Inc., subsidiary, or USC, which we acquired in April 2016 and which is registered as a drug compounding outsourcing facility under Section 503B of the FDCA and the U.S. Drug Quality and Security Act, or DQSA, provides 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. USC's product offerings broadly include, among others, corticosteroids, hormone replacement therapies, hospital outsourcing products, injectables, urological preparations, topical compounds for pain and men's and women's health products. USC's compounded formulations in many circumstances are offered as alternatives to drugs approved by the FDA. USC also provides certain veterinary pharmaceutical products for animals. On January 26, 2021, we announced that we have entered into a non-binding letter of intent with a potential buyer for sale of substantially all of the assets of our USC subsidiary, as described further in this Report under the heading "Business – Prescription Compounded Medications – Letter of Intent."

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 the company's 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, to patients weighing 66 pounds or greater. On September 27, 2018, the FDA approved our lower dose version (0.15mg) of SYMJEPI (epinephrine) Injection, which is intended for patients weighing 33 to 66 pounds.

In July 2018, we entered into a Distribution and Commercialization Agreement with Sandoz Inc. to commercialize our SYMJEPI product. Under the terms of the agreement, we appointed Sandoz as the exclusive distributor of SYMJEPI in the United States and related territories, in all fields including both the retail market and other markets, and granted Sandoz an exclusive license under our patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the product in the licensed territory, subject to the provisions of the agreement, in partial consideration of an upfront fee by Sandoz and potential performance-based milestone payments. The agreement provided that Sandoz will pay to us 50% of the net profit from net sales, as each such term is defined in the agreement, of the product in the Territory to third parties, determined on a quarterly basis. We were the supplier of the product to Sandoz, and Sandoz ordered and paid us a supply price for quantities of products ordered. We were responsible for all manufacturing and, prior to Sandoz paying us the supply price, the component and supply costs related to manufacturing and supplying the product to Sandoz. 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 following an initial transition period that ended as a result of the execution of a transition services agreement. The Termination Agreement provided for the mutually agreed return to us 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 we entered into with Sandoz and USWM, LLC concerning certain transition services, activities and arrangements relating to the SYMJEPI products. As part of the Termination Agreement, Sandoz agreed to support the products in the U.S. under the Sandoz Agreement through the end of the transition period to help reduce or minimize potential impacts to patients and customers. The Termination Agreement also provided for a future resolution of 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.

On May 11, 2020, we 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 the company's ZIMHI product candidate. 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 regulatory and commercial based milestone payments totaling up to $26 million, if all of 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 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. Commencing in July 2020, USWM began promoting the SYMJEPI products through its field sales force.

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. We anticipate that it could take many months in order to obtain the required registration and approvals.

ZIMHI (naloxone) Injection 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 CRL from the FDA regarding our NDA for ZIMHI. The CRL stated that the FDA determined that it could not approve the NDA in its present form and provided recommendations needed for resubmission. 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 questions raised by the FDA related generally to Chemistry, Manufacturing and Controls (CMC). No other clinical safety or efficacy issues were raised. In December 2019, we provided responses to the FDA to the comments included in the CRL. In February 2020, we had a Type A meeting with the FDA to discuss our response to the CRL and the process and timeline for resubmission of the NDA to the FDA. At the meeting, we obtained concurrence from the agency on the CMC information required for resubmission of the NDA, including additional information involving extractables and leachables testing from the syringe and glassware. On May 15, 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. The deficiencies and questions raised in the CRL related generally to new CMC issues. We submitted responses to the deficiencies identified in the CRL and held a Type A meeting with the FDA to discuss the CRL and the company's responses, and obtained input from the agency concerning the resubmission of the NDA. With the input from the meeting, the company intends to resubmit the NDA for ZIMHI to the FDA. The company expects to resubmit the NDA within approximately 45 days from the date of this Report absent unexpected delays, although there can be no assurance regarding the date that our NDA will be resubmitted. At the Type A meeting, the FDA did not provide any specific timeline for review of a resubmitted NDA. If the matters raised in the CRL cannot be resolved with the FDA division that sent the CRL, we may appeal the matter within the agency through a Formal Dispute Resolution process. There can be no assurances regarding the timing or outcome of our resubmission of the NDA to the FDA or the FDA's review of any resubmitted NDA relating to the ZIMHI product, the timing or outcome of any Formal Dispute Resolution process that we may decide to initiate, whether the FDA will regard our responses to the CRL and a resubmitted NDA as satisfactory, whether the FDA will require additional actions, information or trials after review of a resubmitted NDA or issue another CRL, the timing, costs or outcome of any additional actions that may be required following any resubmission of the NDA, or that the product will be able to compete successfully in the market if approved and launched. The development of an intramuscular injection of naloxone for the treatment of opioid overdose will require commercial scale manufacturing subject to review and approval by the FDA.

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 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 company was notified by the FDA 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. We currently anticipate that the trial will begin in the second quarter of 2021. 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, 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. 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 the treatment of radiation induced dermatitis and are engaged in additional formulation and development and GMP manufacturing processes intended to support an IND to begin such a study.

Going Concern and Management Plan

The financial statements included elsewhere herein for the year ended December 31, 2020, 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, 2020, we had cash and cash equivalents of approximately $6.9 million, an accumulated deficit of approximately $229.9 million, and liabilities of approximately $27.4 million. We have incurred substantial recurring losses from 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. 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. In January and February 2021, the Company issued common stock upon exercise of investor warrants. The Company received total 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. Net proceeds were approximately $48.6 million, after deducting approximately $3.2 million in underwriting discounts and commissions and estimated offering expenses payable by the Company.

Our management intends to attempt to secure additional required funding, if required, through equity or debt financing, sales or out-licensing of product candidates or intellectual property assets, revenues from sales of compounded sterile formulations, share of profits received relating to sales in the U.S. of our 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 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, if required. 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 2021 is expected to be used to satisfy existing 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 fund a number of projects, which may include, without limitation, some or all of the following:

- continue development and commercialization of our ZIMHI (naloxone) product candidate;
- 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;
- hire additional management, sales, research, development and clinical personnel; and
- help fund the operations and capital expenditures of USC.

Results of Operations

Our consolidated results of operations are presented for the year ending December 31, 2020 and for the year ending December 31, 2019.

Years Ended December 31, 2020 and 2019

Revenues. Consolidated revenues were approximately $16,527,000 and $22,114,000 for the year ended December 31, 2020 and 2019, respectively. Consolidated revenues decreased approximately $5,587,000 in year 2020 compared to the comparable period of 2019.

Revenues of our Drug Development and Commercialization business conducted by Adamis were approximately $2,777,000 and $3,763,000 for the years ended December 31, 2020 and 2019, respectively. Revenue relating to the sales of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg decreased approximately $986,000 primarily due to decreased sales, and sales and marketing and other matters relating to the transition of commercialization and marketing rights to the SYMJEPI products from Sandoz to USWM.

Revenues of our Compounded Pharmaceuticals business conducted through USC were approximately $13,751,000 and $18,351,000 for the years ended December 31, 2020 and 2019, respectively. Restrictions on outpatient surgery and other medical procedures due to the COVID-19 pandemic resulted in a decline in sales of USC's products of approximately $4,995,000. These amounts were partially offset by an increase of approximately $395,000 in sales of USC's veterinary products. The COVID-19 outbreak has adversely affected revenues from sales of USC products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products, and will likely continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted. Moreover, COVID-19 has restricted USC from utilizing traditional sales and marketing efforts, such as regular sales visits to customers, in generating revenues. USC has added to its product catalog certain drugs that may from time to time appear on the FDA's Drug Shortage List, some of which may be used in connection with the treatment of acutely ill COVID-19 patients, although the COVID-19 outbreak could result in shortages or delays in our ability to obtain supplies relating to certain of these products.

Cost of Goods Sold. Consolidated cost of goods sold was approximately $14,894,000 and $15,479,000 for the years ended December 31, 2020 and 2019, respectively. 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. The gross margin percentage for the years ended December 31, 2020 was approximately 10% compared to approximately 30% for the years ended December 31, 2019.

Cost of goods sold of our Drug Development and Commercialization business conducted by Adamis was approximately $6,327,000 and $5,057,000 for the years ended December 31, 2020 and 2019, respectively. The gross loss percentage for the year ended December 31, 2020 was approximately 128% compared to approximately 34% for the year ended December 31, 2019. Cost of goods sold for the 2020 year compared to the 2019 year increased primarily due to an increase of approximately $1,270,000 in direct materials, depreciation, maintenance fees and other related expenses associated with the production of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg.

Cost of goods sold of our Compounded Pharmaceuticals business conducted through USC was approximately $8,567,000 and $10,422,000 for the years ended December 31, 2020 and 2019, respectively. The gross margin percentage for the year ended December 31, 2020 was approximately 38% compared to approximately 43% for the year ended December 31, 2019. Expenses relating to wages,

benefits and other compensation expenses, consulting services, product devices, testing, freight, repairs and maintenance and other related expenses as a result of the elimination of a second shift at the USC outsourcing facility and the ceasing of sales of certain formulations at the USC outsourcing facility decreased approximately $3,055,000, which was partially offset by an increase of approximately $1,200,000 of charges for obsolete inventory.

Selling, General and Administrative ("SG&A") Expenses. SG&A expenses consist primarily of depreciation and amortization, professional fees which include legal, accounting and audit fees, consulting and employee compensation. Consolidated SG&A expenses for the years ended December 31, 2020 and 2019 were approximately $30,581,000 and $25,288,000, respectively.

SG&A expenses of our Drug Development and Commercialization business conducted by Adamis for the years ended December 31, 2020 and 2019 were approximately $20,090,000 and $11,271,000, respectively. The increase was attributable to increases in professional fees and insurance expenses of approximately $1,631,000, approximately $7,900,000 in contingency loss accrual related to the Nephron case, as discussed in Note 15, and compensation and related expenses of approximately $272,000. These amounts were partially offset by decreases in approximately $492,000 in patent expenses, approximately $311,000 in selling expenses, and approximately $181,000 in consulting, outside services and other related expenses.

SG&A expenses of our Compounded Pharmaceuticals business conducted through USC for the years ended December 31, 2020 and 2019 were approximately $10,491,000 and $14,016,000, respectively. Approximately $1,784,000 of the decrease in SG&A expenses for the 2020 year compared to the 2019 year was attributable to decreases in selling expenses primarily due to the reduction of commission payments, marketing expenses and other related expenses as a direct effect of the reduction in revenue, approximately $896,000 of the decrease was attributable to decreases in wages, benefits and other compensation expenses, approximately $519,000 of the decrease was attributable to operational expenses relating to the ceasing of sales of certain USC products, approximately $318,000 of the decrease was attributable to depreciation, repairs and maintenance, and other related expenses, and approximately $261,000 of the decrease was attributable to decreases in professional fees and consulting expenses. These amounts were partially offset by increases of approximately $253,000 in licenses, permits, bad debt expense and other related administrative expenses.

Research and Development Expenses. Our 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. Research and development expenses were approximately $8,281,000 and $10,376,000 for the years ended December 31, 2020 and 2019, respectively.

Research and development expenses of our Drug Development and Commercialization business conducted by Adamis were approximately $8,040,000 and $10,293,000 for the years ended December 31, 2020 and 2019, respectively. R&D expenses of Adamis decreased for the year ended December 31, 2020, compared to the comparable 2019 period was primarily due to a net decrease of approximately $4,056,000 in development costs of our product candidates, including ZIMHI, APC-1000, SYMJEPI and other product candidates. R&D miscellaneous expenses decreased by approximately $105,000. These amounts were partially offset by an increase of approximately $1,763,000 in development costs primarily attributed to APC-400, and other product candidates, including the $590,000 fair value of the preferred stock issued to Matrix Biomed Inc. upon execution of the licensing agreement related to APC-400, and an increase of approximately $145,000 for wages, benefits, and other compensations expenses.

Research and development expenses of our Compounded Pharmaceuticals business conducted through USC were approximately $241,000 and $83,000 for the years ended December 31, 2020 and 2019, respectively. R&D expenses of USC for the year ended December 31, 2020, compared to the comparable 2019 period, increased approximately $158,000 due to the testing of new products.

Impairment Expense Goodwill. Impairment expense of goodwill for the years ended December 31, 2020 and 2019 was approximately $6,772,000 and $0, respectively. As described in Note 10 to the consolidated financial statements included elsewhere herein, in light of recent events associated with the global spread of COVID-19 and other factors, we performed a goodwill impairment review as of March 31, 2020, and recorded a charge of approximately $3,143,000 for impairment of goodwill during the first three months 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 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.

Impairment Expense Contract Costs. Impairment expense of contract costs for the years ended December 31, 2020 and 2019 was approximately $1,750,000 and $0, respectively. As a result of entering into the Termination Agreement described above providing for the termination of the Sandoz Agreement, our financial results for the year ending December 31, 2020, included an impairment of the Adamis capitalized cost to obtain a contract of $1,750,000. For further information, see Note 5 to the consolidated financial statements included elsewhere in this Report.

Impairment Expense – Long Lived Assets . Impairment expense of long-lived assets for the years ended December 31, 2020 and 2019 was approximately $1,116,000 and $0, respectively. In light of the delay in putting the Construction In Progress – Equipment assets into service and the continued effect of the COVID-19 pandemic as of December 31, 2020, the Company recorded an impairment charge of approximately $1,116,000. See Note 9 to the consolidated financial statements included elsewhere in this Report.

Impairment Expense Intangibles. Impairment expense of intangibles for the years ended December 31, 2020 and 2019 was approximately $2,913,000 and $0, respectively. The impairment expense was primarily due to the impairment of the Taper DPI intellectual property, as a result of the Company's determination not to pursue further development efforts regarding the product candidate related to this intangible. For further information, please see Note 10 to the consolidated financial statements included elsewhere in this Report.

Impairment Expense Inventories. Impairment expenses of inventories for the years ended December 31, 2020 and 2019 were approximately $0 and $322,000, respectively. The 2019 impairment expense was attributable to the inventories damaged during a flood at the USC facility.

Other Income (Expense). Other Income (Expenses) consists primarily of interest income, interest expense, and changes to the fair value of warrant liabilities. Other income (expense) for the years ended December 31, 2020 and 2019 was approximately $389,000 and $1,847,000, respectively. The decrease in other income and increase in other expense during the twelve-month period in 2020, compared to the same period in 2019, was primarily due to the decrease of approximately $1,329,000 for the change in fair value of warrants, a decrease of approximately $92,000 in interest/other income and an increase of interest expense of approximately $37,000.

Liquidity and Capital Resources

We have incurred net losses of approximately $49.4 million and $27.5 million for the years ended December 31, 2020 and 2019, respectively. Since our inception, June 6, 2006, and through December 31, 2020, we have an accumulated deficit of approximately $229.9 million. Since inception and through December 31, 2020, 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 $210.4 million in debt and equity financing transactions, consisting of approximately $26.7 million in debt financing and approximately $183.7 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 $48.3 million.

In April 2020, we secured an approximately $3.2 million Paycheck Protection Program (PPP) loan provided for by the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") and administered by the SBA. The unsecured loan (the "PPP Loan") is evidenced by a promissory note of the company (the "PPP Note"), to Arvest Bank, the Lender. Under the terms of the PPP Note and the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP Note is two years, unless sooner provided in connection with an event of default under the PPP Note. To the extent the loan amount is not forgiven under the PPP, we are obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the PPP 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 a borrower to apply for forgiveness of up to the full amount borrowed. 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 the eight-week or 24-week 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, we submitted an application for the forgiveness of the full amount of the PPP Loan, and as such will not be required to make any payments of principal or interest on the PPP Loan before the date on which the SBA remits the loan forgiveness amount on our loan to our Lender (or notifies our Lender that no forgiveness amount is allowed). There is no assurance that we will be granted forgiveness of some or all of the amount of the PPP Loan. After the CARES Act was passed and we applied for and obtained the PPP Loan, the SBA issued new guidance that, among other things, questioned whether a public company with substantial market value and access to capital markets would qualify to participate in the PPP and be able to make the required certification that current economic uncertainty makes the loan request necessary to support the ongoing operations of the applicant. Subsequently, the Secretary of the Treasury and SBA has issued guidance that the government will review all PPP loans of more than $2 million for which the borrower applies for forgiveness, and that all PPP loans in excess of $2 million, and other PPP loans as appropriate, will be subject to review by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form. Should we be audited or reviewed by federal or state regulatory authorities as a result of filing an application for forgiveness of the PPP Loan or otherwise, such audit or review could result in the diversion of management's time and attention and legal and reputational costs. 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 PPP Loan and could be subjected to fines or penalties, which could reduce our liquidity and adversely affect our business, financial condition and results of operations.

On March 15, 2021, we entered into a Note, or the PPP2 Note, in favor of Arvest Bank as lender, or the Bank, in the principal amount of $1,765,495 relating to funding under a Second Draw loan, or 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. We 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. We 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, we 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 we timely apply for forgiveness, p ayments 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 in 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. No assurance is provided that we will obtain forgiveness of the PPP Loan in whole or in part. If the Second Draw Loan is not forgiven in accordance with the terms of the PPP, we will be obligated to make monthly payments of principal and interest to repay the Second Draw Loan in full prior to the maturity date. If we do not submit a loan forgiveness application to the Bank within 10 months after the end of our applicable covered period, as defined under the PPP and applicable regulations and guidance issued by the SBA or the U.S. Department of Treasury, then we must begin paying principal and interest after that 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, bankruptcy or insolvency events, certain change of control events, material adverse changes or events, and certain other events. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing by us, or filing suit and obtaining judgment against us.

Net cash used in operating activities for the years ended December 31, 2020 and 2019, was approximately $20.9 million and $19.9 million, respectively. Net cash used in operating activities increased, as compared to 2019, primarily due to the increases in inventory purchases and prepaid expenses, and a reduction in accounts payable. Although there was an increase in operating losses in

2020, it was offset by the impairment expenses described above.

Net cash used in investing activities was approximately $0.9 million and $2.9 million for the years ended December 31, 2020 and 2019, respectively. The net cash used in investing activities decreased primarily due to the reduction in purchases of additional equipment during the year months ended December 31, 2020 compared to the year months ended December 31, 2019.

Net cash provided by financing activities was approximately $19.9 million and $12.3 million for the years ended December 31, 2020 and 2019, respectively. Net cash flows provided by financing activities increased for the period ended December 31, 2020 primarily due to higher proceeds from issuance of common stock and the proceeds of the PPP loan.

Loan Agreements

In connection with our acquisition of USC and the transactions contemplated by the merger agreement relating to the USC acquisition, 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, referred to as Lender or the Bank. In November 2016, we entered into amendments of our loan agreements with the Bank. The balances of the USC working capital line, building loan and equipment loan were due and payable on February 28, 2018, August 9, 2020 and October 1, 2019, respectively. There was no outstanding balance on the USC Working Capital Line at its maturity date, and that agreement has not currently been renewed or extended. In addition, amounts owed under the equipment loan have been previously paid and there is no outstanding balance under those loan documents. Periodic interest and principal payments under the building loan agreement are approximately $19,000 per month. We also entered into a loan and security agreement with the Lender, referred to as the Adamis Working Capital Line, pursuant to which we borrowed $2,000,000 to provide working capital to USC, subject to the terms and conditions of the loan agreement. Our obligations under the Adamis Working Capital Line were satisfied in full in July 2018, and there is no outstanding balance under the Adamis Working Capital Line, which has been terminated.

At December 31, 2020, our aggregate indebtedness under the building loan agreement was approximately $2,067,000. The building loan matures in August 2021 and a final payment of all outstanding amounts will be due and payable on the maturity date. The building loan agreement included in the amended Loan Documents with the Bank include a variety of representations, warranties and covenants that we are required to comply with. If we do not comply with the provisions of such agreements and documents and the Bank declares an event of default, the Bank would be entitled to accelerate the maturity date of the loans, the principal and accrued interest would become due and payable, and the Bank could elect to exercise its remedies as a secured creditor under the loan documents and applicable law.

Our ability to make scheduled payments on our indebtedness depends in part on our future performance and ability to raise additional capital if required, which is subject to economic, financial, competitive and other factors, some of which are beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, attempting to restructure our debt or obtaining additional capital through sales of equity or incurrence of additional debt on terms that may be onerous or highly dilutive to our stockholders. Our ability to engage in any of these activities would depend on the capital markets and our financial condition at such time, and we may not be able to do so when needed, on desirable terms or at all, which could result in a default on our debt obligations. Additionally, the building loan included in the Loan Documents contains various restrictive covenants, including, among others, our obligation to deliver to the Bank certain financial and other information, our obligation to comply with certain notice and insurance requirements, and our inability, without the Bank's prior consent, to dispose of certain of our assets, incur certain additional indebtedness, enter into certain merger, acquisition or change of control transactions, pay certain dividends or distributions on or make certain repurchases of our capital stock or incur any lien or other encumbrance on our assets, subject to certain permitted exceptions. Any failure by us to comply with any of these covenants, subject to certain cure periods, or to make all payments under the debt instruments when due, would cause us to be in default under the applicable debt instrument. In the event of any such default, the Bank may be able to foreclose on the assets that secure the debt or declare all borrowed funds, together with accrued and unpaid interest, immediately due and payable, thereby potentially causing all of our available cash to be used to pay our indebtedness or forcing us into bankruptcy or liquidation if we do not then have sufficient cash available. Any such event or occurrence could severely and negatively impact our business, financial conditions or results of operations.

For additional information concerning our debt and equity financing transactions, and our loan agreements, see Notes 11, 12, 13, 16 and 17 accompanying our financial statements included elsewhere herein.

As noted above under the heading "Going Concern and Management Plan," through December 31, 2020, we have incurred substantial losses. The availability of any required additional funding cannot be assured. In addition, an adverse outcome in legal proceedings in which we are involved could adversely affect our liquidity and financial position. See Note 15 accompanying our financial statements included elsewhere herein. If in the future we are not able to obtain additional equity or debt funding that might be required, 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. 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.

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.

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.

We performed an impairment analysis as of December 31, 2020 and 2019, and no impairment of goodwill or acquired intangibles was identified. The COVID-19 pandemic and the related significant market decline, including the market price of the common stock of Adamis, may constitute a triggering event that requires an assessment of the company's goodwill and other intangible assets as of March 31, 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 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 year ended December 31, 2020, total goodwill impairment charge recorded was approximately $6,772,000.

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 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 Construction In Progress - Equipment ("CIP") are primarily for the expansion of USC's operations and will 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 residual value of the assets.

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.

Off Balance Sheet Arrangements

At December 31, 2020, we did not have any off balance sheet arrangements.

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 not effective at the reasonable assurance level as of December 31, 2020, 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 2020 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, 2020. 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 material weakness described below, management has concluded that as of December 31, 2020, our internal control over financial reporting was not effective.

We determined that our controls over the accounting for financial instruments were not operating effectively to allow management to timely identify errors related to the recording of transactions. Specifically, we did not have sufficient technical resources to appropriately identify errors relating to the both the accounting evaluation for financial instruments and the accuracy of the inputs and assumptions used in the Company's valuation models for the measurement of liability classified warrants. This control deficiency has been assessed as a material weakness as of December 31, 2020.

Notwithstanding the material weakness described above, our management has concluded that our audited consolidated financial statements included in this Report are fairly stated in all material respects in accordance with U.S. GAAP for each of the periods presented herein.

We intend to address the weaknesses identified above by adopting additional procedures with respect to the determination in our future financial statements of warrant liabilities and the valuation of options, warrants or other instruments. While we have processes to identify and appropriately apply applicable accounting requirements, we plan to enhance these processes to better evaluate our assumptions and understanding of the accounting standards that apply to our consolidated financial statements, and in particular that apply to our warrants and other derivative instruments. Our plans at this time include increased communication among our personnel and third party professionals with whom we consult regarding complex accounting applications.

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 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, 2020 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

The Board of Directors of the Company has determined that the Company's 2021 annual meeting of stockholders will be held July 16, 2021 (the "2021 Annual Meeting"). The time and location of the 2021 Annual Meeting, and the matters to be considered, will be as set forth in the Company's definitive proxy statement for the 2021 Annual Meeting to be filed with the SEC.

Because the expected date of the 2021 Annual Meeting represents a change of more than 30 calendar days from the date of the anniversary of the Company's 2020 annual meeting of stockholders, the Company is informing stockholders of this change and the updated deadlines for stockholders to submit proposals intended for inclusion in our proxy statement or nominations for director or proposals for consideration at the 2021 Annual Meeting in accordance with the rules and regulations of the SEC and the Company's Bylaws. Accordingly, to be timely, stockholders wishing to submit proposals intended to be considered for inclusion in our proxy statement relating to the 2021 Annual Meeting, must ensure that proper notice is received by the Company at its offices no later than the close of business on April 20, 2021, which we consider a reasonable time before we will begin printing and mailing proxy materials. Any proposal intended to be considered for inclusion in our proxy statement must comply with Rule 14a-8 of Regulation 14A of the proxy rules of the SEC. The submission of a stockholder proposal does not guarantee that it will be included in the Company's proxy materials. In addition, to be timely, stockholders wishing to nominate a candidate for director or to propose other business at the 2021 Annual Meeting, must ensure that proper notice is received by the Company at its offices no later than the close of business on April 25, 2021, which is the 10^{th} day following the day on which public announcement of the date of the 2021 Annual Meeting is first made by us. The Company's bylaws specify requirements relating to the content of the notice that stockholders must provide, and any such notices must be received in writing at the following address: Adamis Pharmaceuticals Corporation, 11682 El Camino Real, Suite 300, San Diego, CA 92130, Attention: Corporate Secretary. The notice must comply with the procedures and include the information required by the Company's Bylaws.

Other Matters

See Part I, Item 3, "Legal Proceedings," above, for a description of the Company's terms of agreement to settle certain legal proceedings and the terms of the settlement, which description is incorporated herein by reference.

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 ACCOUNTING 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 dated August 19, 2014		8-K	08/20/14
4.4	Form of Amended and Restated Warrant dated January 26, 2016		8-K	01/26/16
4.5	Form of Common Stock Purchase Warrant		8-K	08/01/19
4.6	Description of the Registrant's Capital Stock	X		
4.7	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 Restricted Stock Unit Agreement*		10-K	03/30/17
10.5	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
10.12	Executive Employment Agreement between the Company and Dennis J. Carlo dated December 31, 2015*		10-K	03/23/16
10.13	Executive Employment Agreement between the Company and David J. Marguglio dated December 31, 2015*		10-K	03/23/16
10.14	Executive Employment Agreement between the Company and Robert O. Hopkins dated December 31, 2015*		10-K	03/23/16
10.15	Executive Employment Agreement between the Company and Karen K. Daniels dated December 31, 2015*		10-K	03/23/16
10.16	Executive Employment Agreement between the Company and Thomas H. Moll, Ph.D. dated December 31, 2015*		10-K	03/23/16
10.17	Product Development and Contract Manufacturing Agreement dated November 1, 2010, between the Company and Beximco Pharmaceuticals Ltd.		10-Q	02/14/11
10.18	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

10.19	Lease Agreement dated April 1, 2014, between the Registrant and Pacific North Court Holdings, L.P.		10-KT	03/26/15
10.20	First Amendment to Lease between the Registrant and Pacific North Court Holdings, L.P.	X		
10.21	Purchase Agreement dated August 19, 2014 by and between the Company and Sio Partners QP LP and Sio Partners Offshores, Ltd.		8-K	08/20/14
10.22	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
10.23	Form of Warrant dated January 26, 2016		8-K	01/26/16
10.24	Purchase Agreement		8-K	01/26/16
10.25	Registration Rights Agreement dated as of January 26, 2016		8-K	01/26/16
10.26	Business Loan Agreement dated July 14, 2014, between First Federal Bank and U.S. Compounding, Inc., and related loan documents		10-Q	08/15/16
10.27	Business Loan Agreement between 4 HIMS, LLC and First Federal Bank dated August 8, 2014, and related loan documents		10-Q	08/15/16
10.28	Business Loan Agreement between Tribute Labs, LLC and First Federal Bank dated March 21, 2014, and related loan documents		10-Q	08/15/16
10.29	Loan Amendment, Forbearance and Assumption Agreement between the Company and Bear State Bank, N.A.		10-Q	08/15/16
10.30	Loan Amendment and Assumption Agreement and related Agreements and Instruments dated as of November 3, 2016		10-K	03/30/17
10.31	September 2016 Loan Amendment and Consolidation Agreement among Bear State Bank, N.A., U.S. Compounding, Inc., Tribute Labs, LLC, and the Company		10-K	03/30/17
10.32	Amendment to Loan Agreement dated as November 3, 2016 between Bear State Bank, N.A., and the Company		10-K	03/30/17
10.33	September 2016 Amendment to Commercial Line of Credit Agreement and Note		10-K	03/30/17
10.34	Loan Release Agreement dated as of November 14, 2016		10-K	03/30/17
10.35	Form of Common Stock Purchase Warrant dated January 26, 2016		8-K	01/26/16
10.36	Amended and Restated Common Stock Purchase Warrant dated August 19, 2014		8-K	01/26/16
10.37	Purchase Agreement dated January 26, 2016		8-K	01/26/16
10.38	Amended and Restated Registration Rights Agreement dated January 26, 2016		8-K	01/26/16
10.39	Form of Joinder Agreement and General Release dated March 28, 2016		8-K	03/29/16
10.40	Loan and Security Agreement by and between the Company and Bear State Bank, N.A., dated March 28, 2016		8-K	03/29/16
10.41	Common Stock Purchase Warrant dated March 28, 2016		8-K	03/29/16
10.42	Purchase Agreement dated July 11, 2016		8-K	07/12/16
10.43	Registration Rights Agreement dated July 11, 2016		8-K	07/12/16
10.44	Form of Common Stock Purchase Warrant dated July 11, 2016		8-K	07/12/16
10.45	Form of Common Stock Purchase Warrant dated August 3, 2016		8-K	07/29/16
10.46	Placement Agency Agreement between Maxim Group LL and the Company dated July 29, 2016		8-K	07/29/16
10.47	Form of Securities Purchase Agreement dated July 29, 2016		8-K	07/29/16
10.48	Compensation Committee Authorization Regarding Discretionary Payments		8-K	02/27/18
10.49	2019 Bonus Plan*		8-K	2/5/2019
10.50	Executive Employment Agreement between the Company and Ronald B. Moss, M.D., dated as of February 28, 2017.*		10-K	03/30/17
10.51	March 2017 Amended and Restated Line of Credit Promissory Note		10-K	03/30/17
10.52	March 2017 Amendment to Loan and Security Agreement between the Company and Bear State Bank		10-K	03/30/17
10.53	March 2018 Amendment to Loan and Security Agreement		10-K	12/31/2017
10.54	March 2018 Amended and Restated Line of Credit Promissory Note		10-K	12/31/2017
10.55	June 2018 Amendment to Loan and Security Agreement and Warrant		10-Q	08/19/18
10.56	Underwriting Agreement dated August 2, 2018		8-K	08/02/18
10.57	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
10.58	Placement Agency Agreement between Maxim Group LLC and the Company dated February 20, 2020		8-K	02/21/20
10.59	Form of Securities Purchase Agreement dated February 21, 2020		8-K	02/21/20
10.60	Underwriting Agreement dated January 29, 2021		8-K	01/29/21
10.61	Underwriting Agreement dated September 18, 2020		8-K	09/18/20
10.62	August 2020 Amendment to Loan Amendment and Assumption Agreement		8-K	09/15/20
10.63	Amended Promissory Note		8-K	09/15/20
10.64	2020 Equity Incentive Plan *		8-K	08/24/20
10.65	Adamis Pharmaceuticals Corporation Bonus Plan *		8-K	06/22/20
10.66	Promissory Note		8-K	04/15/20
10.67	Form of Warrant		8-K	02/21/20
10.68	Termination and Transfer Agreement between Sandoz Inc. and the Company ***+		10-Q	08/17/20
10.69	Transition Service Agreement ***+		10-Q	08/17/20
10.70	License Agreement between the Company and Matrix Biomed, Inc. ***+		10-Q	08/17/20

10.71	Distribution and Commercialization Agreement between the Company and USWM, LLC***		10-Q	08/17/20
10.72	Lease Agreement between the Company and Oil States Energy Services, LLC, as amended +	X		
10.73	Promissory Note dated March 15, 2021	X		
21.1	Subsidiaries of the Registrant	X		
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm	X		
23.2	Consent of Mayer Hoffman McCann P.C., 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	XBRL Instance Document			
101.SCH	XBRL Taxonomy Extension Schema Document			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document			

\+ 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 portions of this exhibit (indicated by "[***]") have been omitted as the registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the registrant if publicly disclosed.

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: April 15, 2021

Power of Attorney

Each person whose signature appears below constitutes and appoints each of Dennis J. Carlo and Robert O. Hopkins, 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	April 15, 2021
Principal Financial Officer and Principal Accounting Officer:		
/s/ ROBERT O. HOPKINS Robert O. Hopkins	Senior Vice President, Finance, Chief Financial Officer and Secretary	April 15, 2021
Directors:		
/s/ DAVID J. MARGUGLIO David J. Marguglio	Director	April 15, 2021
/s/ RICHARD C. WILLIAMS Richard C. Williams	Chairman	April 15, 2021
/s/ ROSHAWN A. BLUNT	Director	April 15, 2021

Roshawn A. Blunt		
/s/ HOWARD C. BIRNDORF Howard C. Birndorf	Director	April 15, 2021

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

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DECEMBER 31, 2020 AND 2019

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 sheet of Adamis Pharmaceuticals Corporation (the "Company") as of December 31, 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for the year 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, 2020, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited the adjustments described in Note 4 (c) that were applied to revise the 2019 consolidated financial statements to correct an error. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2019 consolidated financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2019 financial statements taken as a whole.

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 audit. 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 audit 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were 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 matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Fair Value of Goodwill at Compounded Pharmaceuticals reporting unit

As described in Note 3, 10, and 14 to the consolidated financial statements, the Company's goodwill balance as of December 31, 2020 was $868,418 and is allocated to the Compound Pharmaceuticals reporting unit. The Company reviews goodwill for impairment at least annually as of December 31 or more frequently if an event occurs indicating potential impairment. During the first quarter of 2020, the Company identified a triggering event relating the economic impact of COVID-19 affecting the Company's stock price and the Company performed an interim fair value measurement of goodwill, which resulted in the recognition of goodwill impairment expense of $3,143,000. In addition, the Company performed its annual review for goodwill impairment as of December 31, 2020 and determined an additional goodwill impairment expense of $3,629,000. The Company utilized a combination of a market-based approach and income approach to measure the fair value of this reporting unit. The market-based approach requires management to make significant estimates and assumptions using market multiple assumptions for comparable companies. The income approach requires management to make significant estimates and assumptions relating to estimated future cash flows and discount rates.

We identified the determination of the fair value of goodwill for the Compounded Pharmaceutical reporting unit as a critical audit matter. The principal considerations for our determination are the inherent uncertainties relating to the management's estimates and assumptions in determining fair value under both the market-based approach and the income approach. These estimates and assumptions require significant management judgment due to their highly subjective nature. Changes in these assumptions could have a significant impact on the fair value of the reporting unit and goodwill. Auditing these elements involved especially challenging auditor judgment in evaluating the reasonableness of management's estimates and assumptions, including the extent of specialized skill or knowledge needed.

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

- Evaluating the reasonableness of management's judgments in determining comparable companies under the market-based approach.

- Evaluating the reasonableness of management's judgments and assumptions used to estimate future cash flows through (i) assessing the projected revenues and operating costs against historical performance, (ii) evaluating whether the assumptions used are consistent with the general economic and market conditions, including expectations derived from industry reports, (iii) evaluating the impact of alternative assumptions on the measurement and comparing to management's estimate and (iv) testing the mathematical accuracy of management's valuation model.

- Comparing the Company's estimated fair value of the reporting unit to the fair value of purchase consideration in the non-binding letter of intent.

- Utilizing personnel with specialized knowledge and skill in valuation to assist in: (i) evaluating the appropriateness of the methodologies and the valuation models utilized by management to determine the fair value of the reporting unit, (ii) assessing the reasonableness of certain assumptions incorporated into the valuation models including terminal growth rates, discount rates, and (iii) comparing market multiples in management's valuation model to comparable companies' trading multiples as of the valuation date.

Impairment of Long-Lived Assets

As described in Notes 3, 9 and 14 to the consolidated financial statements, the Company's consolidated fixed assets included construction in progress – equipment of $3,513,356 as of December 31, 2020. Management evaluates its long-lived assets, by asset group, for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be fully recoverable ("triggering events"). An impairment is recorded when the carrying value of the asset group exceeds its estimated undiscounted future cash flows. As a result of triggering events identified during the year ended December 31, 2020, management reviewed the construction in progress – equipment asset group for recoverability. The Company determined the carrying value was not fully recoverable and recorded a $1,116,000 impairment charge.

We identified the valuation of the long-lived assets for the construction in progress – equipment asset group as a critical audit matter. The principal considerations for our determination was the significant judgment required by management when estimating the fair value of the asset group. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address this matter, including the degree of auditor judgment.

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

- Evaluating the reasonableness of significant assumptions used by management to estimate the fair value of the asset group, including assessing the equipment's condition and remaining useful lives through physical observation to evaluate the appropriate discount from original cost.

- Comparing management's estimate of fair value to published market data for similar assets in the asset group.

/s/ BDO USA, LLP

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

San Diego, California

April 15, 2021

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Adamis Pharmaceuticals Corporation and Subsidiaries:

Opinion on the Financial Statements

We have audited, before the effects of the adjustments for the correction of the error more fully described in Note 4, the accompanying consolidated balance sheet of Adamis Pharmaceuticals Corporation and Subsidiaries (the "Company") as of December 31, 2019, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements") (the 2019 financial statements before the effects of the adjustments discussed in Note 4 are not presented herein). In our opinion, the financial statements, before the effects of the adjustments described in Note 4, present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review, or apply any procedures to the adjustments more fully described in Note 4 and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by the successor auditor.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring losses from operations and is dependent on additional financing to

fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2 to the financial statements. The financial statements 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.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the 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 audit 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 financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Mayer Hoffman McCann P.C.

We served as the Company's auditor from 2007 to 2020.
San Diego, California
March 30, 2020, except as it relates to Note 22, as to which the date is October 5, 2020.

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019, Revised
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents	$ 6,855,355	$ 8,810,636
Accounts Receivable, net	1,092,857	1,877,655
Inventories	3,115,926	2,061,097
Prepaid Expenses and Other Current Assets	1,459,983	1,127,322
	12,524,121	13,876,710
LONG TERM ASSETS		
Intangible Assets, net	6,289,684	11,127,562
Goodwill	868,412	7,640,622
Fixed Assets, net	9,586,593	11,667,416
Right-of-Use Assets	1,543,997	1,873,552
Other Non-Current Assets	54,655	1,654,655
Total Assets	$ 30,867,462	$ 47,840,517
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable	$ 3,491,717	$ 4,267,654
Deferred Revenue, current portion	100,070	115,671
Accrued Other Expenses	2,524,412	2,428,619
Accrued Bonuses	1,047,719	—
Contingent Loss Liability	7,900,000	—
Lease Liabilities, current portion	494,342	444,621
Bank Loans - Building, current portion	2,067,213	2,153,182
Paycheck Protection Plan (PPP) Loan, current portion	2,300,253	—
	19,925,726	9,409,747
LONG TERM LIABILITIES		
Deferred Revenue, net of current portion	850,000	800,000
Deferred Tax Liability, net	112,530	112,530
Lease Liabilities, net of current portion	1,105,219	1,480,996
PPP Loan, net of current portion	891,447	—
Warrant Liabilities, at fair value	4,485,000	3,036,000
Total Liabilities	27,369,922	14,839,273
COMMITMENTS AND CONTINGENCIES, see Note 17		
STOCKHOLDERS' EQUITY		
Preferred Stock - Par Value $0.0001; 10,000,000 Shares Authorized; Series A-1 and Series A-2 convertible, no shares Issued and Outstanding at December 31, 2020 and December 31, 2019, respectively.	—	—
Common Stock - Par Value $0.0001; 200,000,000 Shares Authorized; 94,365,015 and 62,352,465 Issued, 93,842,058 and 61,829,508 Outstanding at December 31, 2020 and December 31, 2019, respectively.	9,437	6,235
Additional Paid-in Capital	233,404,968	213,520,785
Accumulated Deficit	(229,911,615)	(180,520,526)

Treasury Stock, at cost - 522,957 Shares at December 31, 2020 and December 31, 2019.	(5,250)	(5,250)
Total Stockholders' Equity	3,497,540	33,001,244
Total Liabilities and Stockholders' Equity	$ 30,867,462	$ 47,840,517

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, 2020	Year Ended December 31, 2019, Revised
REVENUE, net	$ 16,527,397	$ 22,113,869
COST OF GOODS SOLD	14,893,822	15,478,815
Gross Profit	1,633,575	6,635,054
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	30,580,740	25,287,568
RESEARCH AND DEVELOPMENT	8,280,750	10,375,991
IMPAIRMENT EXPENSE - Goodwill	6,772,210	—
IMPAIRMENT EXPENSE - Contract Asset	1,750,000	—
IMPAIRMENT EXPENSE - Construction in Progress	1,115,560	—
IMPAIRMENT EXPENSE - Intangibles	2,912,610	—
IMPAIRMENT EXPENSE - Inventories	—	322,106
Loss from Operations	(49,778,295)	(29,350,611)
OTHER INCOME (EXPENSE)		
Interest Expense	(159,628)	(123,258)
Other Income	84,008	175,772
Change in Fair Value of Warrant Liabilities	465,000	1,794,000
Total Other Income (Expense), net	389,380	1,846,514
Loss Before Income Taxes	(49,388,915)	(27,504,097)
Income Tax Expense	(2,174)	(8,672)
Net Loss	$ (49,391,089)	$ (27,512,769)
Basic & Diluted Loss Per Share:		
Basic & Diluted Loss Per Share	$ (0.64)	$ (0.52)
Basic & Diluted Weighted Average Shares Outstanding	77,569,745	53,263,918

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, 2018	—	$ —	47,814,315	$ 4,781	$199,696,656	522,957	$ (5,250)	$(153,004,370)	$ 46,691,817
Common Stock Issued, net of issuance cost of $1,012,130	—	—	13,800,000	1,380	12,786,490	—	—	—	12,787,870
Cumulative effect from adoption of ASU 2016-02, Leases (Topic 842)	—	—	—	—	—	—	—	(3,387)	(3,387)
Issuance of Restricted Stock Units (RSUs)	—	—	738,150	74	(74)	—	—	—	—
Issuance of 2019 Warrants	—	—	—	—	(4,830,000)	—	—	—	(4,830,000)

Share Based Compensation	—	—	—	—	5,867,713	—	—	—	5,867,713
Net (Loss), Revised	—	—	—	—	—	—	—	(27,512,769)	(27,512,769)
Balance December 31, 2019, Revised	—	$ —	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 (RSUs)	—	—	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

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, 2020	Year Ended December 31, 2019, Revised
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (49,391,089)	$ (27,512,769)
Adjustments to Reconcile Net Loss to Net		
Cash Provided by (Used in) Operating Activities:		
Stock Based Compensation	4,420,172	5,867,713
Purchased IPR&D	840,000	—
Provision for Bad Debts	46,866	22,660
Provision for Excess and Obsolete Inventory	2,360,503	871,066
Change in Fair Value of Warrant Liability	(465,000)	(1,794,000)
Non-Cash Operating Lease Expense	3,669	18,460
Depreciation and Amortization Expense	3,606,996	2,944,516
Impairment of Inventory	—	322,106
Impairment of Goodwill	6,772,210	—
Impairment of Contract Asset	1,750,000	—
Impairment of Construction in Progress	1,115,560	—
Impairment of Intangibles	2,912,610	—
Gain on Sale of Fixed Assets	—	(9,000)
Change in Operating Assets and Liabilities:		
Accounts Receivable	737,932	(745,149)
Inventories	(3,415,332)	24,763
Prepaid Expenses and Other Current Assets	(532,661)	951,091
Accounts Payable	(726,708)	574,510
Contingent Loss Liability	7,900,000	—
Deferred Revenue	34,399	(95,575)
Accrued Other Expenses and Bonuses	1,128,513	(1,326,060)
Net Cash Used in Operating Activities	(20,901,360)	(19,885,668)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of Equipment	(696,214)	(2,866,418)
Purchase of IPR&D License	(250,000)	—
Net Cash Used in Investing Activities	(946,214)	(2,866,418)

CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from Issuance of Common Stock	18,228,000	13,800,000
Costs of Issuance of Common Stock	(1,436,787)	(1,012,130)
Principal Payments of Finance Leases	(4,651)	(66,838)
Proceeds of PPP Loan	3,191,700	—
Payments of Bank Loan	(85,969)	(429,952)
Net Cash Provided by Financing Activities	19,892,293	12,291,080
Decrease in Cash and Cash Equivalents	(1,955,281)	(10,461,006)
Cash:		
Beginning, Cash and Cash Equivalents	8,810,636	19,271,642
Ending, Cash and Cash Equivalents	$ 6,855,355	$ 8,810,636

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, 2020	Year Ended December 31, 2019, Revised
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash Paid for Income Taxes	$ 9,401	$ 9,001
Cash Paid for Interest	$ 135,827	$ 106,784
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES		
Decrease in Accrued Capital Expenditures	$ (34,230)	$ (477,576)
Series B Preferred Stock Issuance for License Agreement	$ 590,000	—

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

Notes to the Consolidated Financial Statements

NOTE 1: NATURE OF BUSINESS

The company formerly named Adamis Pharmaceuticals Corporation, or Old Adamis, was founded in June 2006 as a Delaware corporation. Effective April 1, 2009, 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 (the "Company," "Adamis Pharmaceuticals" or "Adamis"), and Old Adamis survived as a wholly-owned subsidiary and changed its corporate name to Adamis Corporation. The Company has three wholly-owned subsidiaries: Adamis Corporation; U.S. Compounding, Inc.; and Biosyn, Inc.

On April 11, 2016, the Company completed its acquisition of U.S. Compounding, Inc., an Arkansas corporation ("USC"), pursuant to the terms of the Agreement and Plan of Merger dated March 28, 2016 (the "Merger Agreement") and entered into by and among the Company, USC and Ursula MergerSub Corp., an Arkansas corporation and a wholly owned subsidiary of the Company ("MergerSub"). Pursuant to the terms of the Merger Agreement, MergerSub merged with and into USC (the "Merger"), with USC surviving as a wholly owned subsidiary of the Company.

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.

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 operations, has used, rather than provided, cash in the Company's continuing operations, and is dependent on additional financing to fund operations. As of December 31, 2020, the Company had cash and cash equivalents of approximately $6.9 million, an accumulated deficit of approximately $ 229.9 million, and liabilities of approximately $ 27.4 million. These conditions raise substantial doubt about the Company's ability to continue as a going concern. 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 from sales of compounded sterile formulations, 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.

The COVID-19 outbreak has adversely affected revenues from sales of USC products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products, and will likely continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted. Moreover, COVID-19 has restricted USC from utilizing traditional sales and marketing efforts, such as regular sales visits to customers, in generating revenues, and the COVID-19 outbreak could result in shortages or delays in our ability to obtain supplies relating to certain of these products.

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.

Segment Information

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic No. 280, Segment Reporting ("ASC 280"), establishes standards for the way that public business enterprises report information about operating segments in their annual consolidated financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. ASC 280 also establishes standards for related disclosures about products and services, geographic areas and major customers. The Company's business segments are based on the organization structure used by the chief operating decision maker for making operating and investment decisions and for assessing performance. Commencing April 1, 2020, our management, including the chief executive officer, who is our chief operating decision maker ("CODM"), began managing our operations as operating in two business segments: Drug Development and Commercialization which includes without limitation out-licensing the Company's FDA approved products; and Compounded Pharmaceuticals which includes the Company's registered outsourcing facility, based on changes to the way that management monitors performance, aligns strategies, and allocates resources results. We determined that each of these operating segments represented a reportable segment. These consolidated financial statements and related footnotes, including prior year financial information, are presented as if there were two reporting segments for all periods presented, to the extent described in Note 22. We are a specialty biopharmaceutical company focused on developing products in various therapeutic areas, including allergy, opioid overdose, respiratory and inflammatory disease; and a registered drug compounding outsourcing facility, which compounds 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.

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, 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, 2020 and 2019 was approximately $120,000 and $99,000, respectively.

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 - 30 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.

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 of the Company. In performing the Company's goodwill impairment tests during 2020, the Company compares the fair value of a reporting unit with its carrying amount. Impairment, if any, is recognized for the amount by which the carrying amount exceeds the reporting unit's fair value.

During the three months ended March 31, 2020, COVID-19 spread across the globe and adversely impacted economic growth, including as a result of government mandated shut-downs, stay-at-home policies and social distancing efforts intended to mitigate the spread of the virus. We believe the economic downturn as a result of COVID-19 affected the trading prices of our common stock, and we determined that it was more likely than not that the fair value of our reporting unit was less than its carrying value, which triggered the Company to perform an interim impairment assessment to test the carrying value of goodwill, all of which is related to the Compounded Pharmaceuticals reporting unit, as of March 31, 2020. In the three months ended March 31, 2020, approximately $3,143,000 impairment of goodwill was recorded. We also performed our annual impairment testing related to our Compounded Pharmaceuticals reporting unit as of December 31, 2020. Due to the continuous decline in revenue caused by the COVID-19 pandemic and other factors affecting our Compounded Pharmaceutical reporting unit, the results of the annual impairment test indicated that the estimated fair value of the reporting unit was less than its carrying value. Thus, our Compounded Pharmaceutical reporting unit recorded an additional charge of approximately $3,629,000 for the impairment of goodwill in 2020. For the year ended December 31, 2020, total goodwill impairment charge recorded was approximately $6,772,000.

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. 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 10.

The Construction In Progress - Equipment are primarily for the expansion of USC's operations and will 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 residual value of the assets.

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.

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, 2020 and 2019, the Company incurred approximately $8.3 million and $10.4 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.

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, 2020 and 2019 consist of outstanding warrants (24,634,670 shares and 15,934,670 shares, respectively), outstanding options (6,508,296 shares and 7,837,245 shares, respectively), and outstanding restricted stock units (2,136,893 shares and 3,090,397 shares, respectively).

	For the Years Ended December 31,	
	2020	2019, Revised
Loss per Share - Basic & Diluted		
Numerator for basic & diluted loss per share	$ (49,391,089)	$ (27,512,769)
Denominator for basic & diluted loss per share	77,569,745	53,263,918
Loss per common share - basic & diluted	$ (0.64)	$ (0.52)

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments – Credit Losses.* ASU No. 2016-13 is intended to provide users of financial statements with more decision-useful information about credit losses on financial

instruments that are expected, but do not yet meet the “probable” threshold. This Update replaces the incurred loss impairment methodology with a methodology that reflects expected credit losses. ASU No. 2016-13 was effective for fiscal years beginning after December 15, 2019 and did not have a material impact on the Company’s consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies when transactions between participants in a collaborative arrangement are within the scope of the FASB’s new revenue standard (Topic 606). Such guidance clarifies revenue recognition and financial statement presentation for transactions between collaboration participants. ASU 2018-18 is effective for the Company in the first quarter of 2020, with early adoption permitted. The standard requires retrospective application to the date we adopted Topic 606, January 1, 2018. The adoption had no significant impact on the Company’s consolidated financial statements.

Recent Accounting Pronouncements

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 amendments in this Update are effective for public business entities that meet the definition of a Securities and Exchange Commission (SEC) filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company plans to adopt ASU 2020-06 early. The early adoption is expected to affect warrants and warrants liabilities as noted below.

The Company has issued and outstanding Warrants that contain certain clauses that may require cash settlement in in certain circumstances. As of December 31, 2020, the Company has included Warrant Liabilities of $4,485,000, of which $2,484,000 pertaining to the 2019 Warrants will be adjusted to equity upon early adoption in January 2021.

NOTE 4: RESTATEMENTS, REVISIONS AND RECLASSIFICATIONS

(a) It was determined during the review of the second quarter 2020 financial statements that the warrants issued by the Company as part of a financing transaction in August 2019 and February 2020 should be recorded as liability instruments. The Company booked an out of period adjustment in second quarter of 2020 related to the errors in 2019 and the first quarter of 2020. However, in connection with the Company’s preparation of its financial statements for the year ended December 31, 2020, the Company re-assessed certain matters relating to its determination of the amount of warrant liabilities, and the associated gain or loss recognized as a result of the change in the fair value of the warrant liabilities, related to the outstanding Warrants as of December 31, 2019 and periods ended March 31, 2020, June 30, 2020 and September 30, 2020. The Company concluded that certain of the valuation principles, estimates, and methods used to determine the valuation of the warrants for the year ended December 31, 2019 and periods ended March 31, 2020, June 30, 2020 and September 30, 2020 were not in accordance with ASC 820 – “Fair Value Measurement and Disclosures,” primarily because of the applicability of the Black-Scholes option-pricing model to determine the fair value of the warrants and because the Company’s calculation incorporated the estimated exercise behavior of its warrant holders by applying an early exercise multiple, rather than using the full contractual exercise term of the warrants as an input for determining the fair value of the warrants. The impact of this error on previously issued annual financial statements is discussed in (b) and (c) and the impact of this error on the unaudited interim financial statements for the periods ended March 31, June 30, and September 30, 2020 is discussed in (d).

(b) In accordance with Staff Accounting Bulletin (“SAB”) No. 99, Materiality and SAB 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, the Company evaluated the impact of the error on the 2019 financial statements and determined that the impact was not material to results of operations or financial position. We corrected this immaterial error, as disclosed below, by adjusting other income and net income for the year ended December 31, 2019 and warranty liability, additional paid in capital and equity as of December 31, 2019.

(c) Changes made to the financial statements for the year ended December 31, 2019 due to the effect of the warrant errors are as follows:

	Consolidated Balance Sheet		
	As Previously Reported	Adjustments	As Revised
As of December 31, 2019			
Warrant liabilities, at fair value	$ —	$ 3,036,000	$ 3,036,000
Total Liabilities	$ 11,803,273	$ 3,036,000	$ 14,839,273
Additional paid in capital	$ 218,350,785	$ (4,830,000)	$ 213,520,785
Accumulated deficit	$ (182,314,526)	$ 1,794,000	$ (180,520,526)
Total stockholders’ equity	$ 36,037,244	$ (3,036,000)	$ 33,001,244

	Consolidated Statement of Operations		
	As Previously Reported	Adjustments	As Revised
For the year ended December 31, 2019			
Change in fair value of warrant liabilities	$ —	$ 1,794,000	$ 1,794,000
Total Other Income (Expense), net	$ 52,514	$ 1,794,000	$ 1,846,514
Net Loss	$ (29,306,769)	$ 1,794,000	$ (27,512,769)

Basic and Diluted Loss Per Share	$ (0.55)	$ 0.03	$ (0.52)

	Consolidated Statement of Shareholders' Equity		
	As Previously Reported	Adjustments	As Revised
For the year ended December 31, 2019			
Additional paid-in capital	$ 218,350,785	$ (4,830,000)	$ 213,520,785
Accumulated deficit	$ (182,314,526)	$ 1,794,000	$ (180,520,526)
Total shareholders' equity	$ 36,037,244	$ (3,036,000)	$ 33,001,244

	Consolidated Statement of Cash Flows		
	As Previously Reported	Adjustments	As Revised
For the year ended December 31, 2019			
Net income (loss)	$ (29,306,769)	$ 1,794,000	$ (27,512,769)
Change in fair value of warrant liability	$ —	$ (1,794,000)	$ (1,794,000)

(d) Impact on interim financial statements (unaudited):

In accordance with SAB 99 and SAB 108, the Company evaluated the impact of the error related to warrant classification, valuation and presentation on the 2020 quarterly financial statements as of and for the periods ended March 31, 2020, June 30, 2020 and September 30, 2020 and determined that the impact was material to results of operations and financial position. Accordingly, the Company has restated its previously issued financial statements. The Company has corrected errors in warrant classification, measurement and presentation. The Company's previously filed quarterly reports on Form 10-Q for the periods affected by the restatements, have not been amended. Accordingly, investors should no longer rely upon the Company's previously released financial statements for quarterly periods ended March 31, 2020, June 30, 2020 and September 30, 2020, and any earnings releases or other communications relating to these periods.

The following tables set forth the effects of the restatement on the affected line items within our previously reported unaudited condensed consolidated financial statements of the affected periods.

Condensed Consolidated Balance Sheet
Unaudited

		September 30, 2020	June 30, 2020	March 31, 2020
Warrant Liabilities, at Fair Value	As Previously Reported	$ 1,161,000	$ 537,000	$ —
	Adjustments	$ 6,924,000	$ 3,048,000	$ 1,923,000
	As Restated	$ 8,085,000	$ 3,585,000	$ 1,923,000
Current Liabilities	As Previously Reported	$ 12,976,779	$ 12,367,234	$ 10,586,976
	Adjustments	$ (1,161,000)	$ (537,000)	$ 0
	As Restated	11,815,779	$ 11,830,234	$ 10,586,976
Total Liabilities	As Previously Reported	$ 16,517,447	$ 16,582,680	$ 12,063,556
	Adjustments	$ 6,924,000	$ 3,048,000	$ 1,923,000
	As Restated	$ 23,441,447	$ 19,630,680	$ 13,986,556
Additional Paid-in Capital	As Previously Reported	$ 238,726,680	$ 226,969,294	$ 225,801,654
	Adjustments	$ (6,207,000)	$ (6,207,000)	$ (6,744,000)
	As Restated	$ 232,519,680	$ 220,762,294	$ 219,057,654
Accumulated Deficit	As Previously Reported	$ (211,335,806)	$(203,850,608)	$(192,587,895)
	Adjustments	$ (717,000)	$ 3,159,000	$ 4,821,000
	As Restated	$ (212,052,806)	$(200,691,608)	$(187,766,895)
Total Stockholders' Equity	As Previously Reported	$ 27,395,042	$ 23,120,980	$ 33,215,935
	Adjustments	$ (6,924,000)	$ (3,048,000)	$ (1,923,000)
	As Restated	$ 20,471,042	$ 20,072,980	$ 31,292,935

Condensed Consolidated Statement of Operations - YTD
Unaudited

		Nine Months Ended September 30, 2020	Six Months Ended June 30, 2020
Change in Fair Value of Warrant Liabilities	As Previously Reported	$ (624,000)	$ —
	Adjustments	$ (2,511,000)	$ 1,365,000
	As Restated	$ (3,135,000)	$ 1,365,000
Total Other Income (Expense), net	As Previously Reported	$ (677,537)	$ (31,536)
	Adjustments	$ (2,511,000)	$ 1,365,000
	As Restated	$ (3,188,537)	$ 1,333,464
Net Loss	As Previously Reported	$ (29,021,280)	$ (21,536,082)

	Adjustments	$ (2,511,000)	$ 1,365,000
	As Restated	$ (31,532,280)	$ (20,171,082)
Basic and Diluted Loss Per Share	As Previously Reported	$ (0.40)	$ (0.31)
	Adjustments	$ (0.04)	$ 0.02
	As Restated	$ (0.44)	$ (0.29)

Condensed Consolidated Statement of Operations - Three months ended
Unaudited

		September 30, 2020	June 30, 2020	March 31, 2020
Change in Fair Value of Warrant Liabilities	As Previously Reported	$ (624,000)	$ —	$ —
	Adjustments	$ (3,876,000)	$ (1,662,000)	$ 3,027,000
	As Restated	$ (4,500,000)	$ (1,662,000)	$ 3,027,000
Total Other Income (Expense), net	As Previously Reported	$ (646,001)	$ (16,304)	$ (15,232)
	Adjustments	$ (3,876,000)	$ (1,662,000)	$ 3,027,000
	As Restated	$ (4,522,001)	$ (1,678,304)	$ 3,011,768
Net Loss	As Previously Reported	$ (7,485,198)	$(11,262,713)	$(10,273,369)
	Adjustments	$ (3,876,000)	$ (1,662,000)	$ 3,027,000
	As Restated	$ (11,361,198)	$(12,924,713)	$ (7,246,369)
Basic and Diluted Loss Per Share	As Previously Reported	$ (0.10)	$ (0.15)	$ (0.15)
	Adjustments	$ (0.05)	$ (0.02)	$ 0.04
	As Restated	$ (0.15)	$ (0.17)	$ (0.11)

Condensed Consolidated Statement of Shareholders' Equity - YTD
Unaudited

		September 30, 2020	June 30, 2020	March 31, 2020
Additional Paid-in Capital	As Previously Reported	$ 238,726,680	$ 226,969,294	$ 225,801,654
	Adjustments	$ (6,207,000)	$ (6,207,000)	$ (6,744,000)
	As Restated	$ 232,519,680	$ 220,762,294	$ 219,057,654
Accumulated Deficit	As Previously Reported	$ (211,335,806)	$ (203,850,608)	$ (192,587,895)
	Adjustments	$ (717,000)	$ 3,159,000	$ 4,821,000
	As Restated	$ (212,052,806)	$ (200,691,608)	$ (187,766,895)
Total Shareholders' Equity	As Previously Reported	$ 27,395,042	$ 23,120,980	$ 33,215,935
	Adjustments	$ (6,924,000)	$ (3,048,000)	$ (1,923,000)
	As Restated	$ 20,471,042	$ 20,072,980	$ 31,292,935

Condensed Consolidated Statement of Cash Flows
Unaudited

		Nine Months Ended September 30, 2020	Six Months Ended June 30, 2020	Three Months Ended March 31, 2020
Net Loss	As Previously Reported	$ (29,021,280)	$ (21,536,082)	$ (10,273,369)
	Adjustments	$ (2,511,000)	$ 1,365,000	$ 3,027,000
	As Restated	$ (31,532,280)	$ (20,171,082)	$ (7,246,369)
Change in Fair Value of Warrant Liabilities	As Previously Reported	$ 624,000	$ —	$ —
	Adjustments	$ 2,511,000	$ (1,365,000)	$ (3,027,000)
	As Restated	$ 3,135,000	$ (1,365,000)	$ (3,027,000)

Other Prior Periods Reclassifications

Certain amounts in prior periods have been reclassified to conform with current period presentation related to the amortization of the cost to obtain a contract included in prepaid expenses and other current assets in the audited consolidated statement of cash flows, and had no effect on cash used in operations or statement of cash flows for the period ended December 31, 2019. The reclassification has no effect on the consolidated balance sheet as of December 31, 2019, or the consolidated statement of operations for the year ended December 31, 2019.

Deferred revenue in prior periods has been adjusted to reflect short-term and long-term portion of the liability. This adjustment had no effect on the total liability or loss for any period presented.

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, provides 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.

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 HCl 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.

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.

Drug Development and Commercialization Revenue Recognition

Sandoz

Effective July 1, 2018, Adamis signed an exclusive distribution and commercialization agreement with Sandoz. This agreement grants 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 generates revenue from this agreement by manufacturing and supplying Sandoz with Products. The Company's performance obligation is 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, create 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 is 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 has 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 is a non-refundable up-front fee and is considered a material right. Revenue from this up-front fee is recognized as the option to distribute is exercised, which is substantially the expected customer life, estimated as 10 years. The period of recognition is subject to adjustment if the expected customer life changes; and (2) considerations which are 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 is obligated to pay Adamis for Products ordered based on a supply pricing arrangement plus additional cost of shipping and distribution. This fixed consideration does 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 requires 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 includes sales-based royalties in the form of commercial milestone payments that are payable upon successful achievement of certain milestone events specified under the agreement. There are five commercial milestone events, based on certain revenue thresholds from Products sold over the term. The variable consideration from milestone payments is 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.

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.

Disaggregation of Revenue

Our sterile environment operations are governed by specific regulatory and quality requirements. Any deviation from these standards could result in a stoppage of operations, recall of products, and a significant reduction in revenues. 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 following table presents the Company's revenues disaggregated by outsourced manufacturing, sterile and non-sterile regulatory environments for the years ended December 31, 2020 and 2019.

	For the Years Ended December 31,	
	2020	2019
Drug Development & Commercialization:		
Outsourced Manufacturing	$ 2,776,587	$ 3,762,967
Compounded Pharmaceuticals:		
Sterile	9,164,938	13,495,344
Non-Sterile	4,585,872	4,855,558
Total Compounded Pharmaceuticals Revenues	13,750,810	18,350,902

Total	$ 16,527,397	$ 22,113,869

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, and the Company's pharmacy formulations rely, in large part, on sales generated from clinics and hospital customers. Adverse economic conditions pose a risk that the Company's customers may reduce or cancel spending, which would impact the Company's revenues. The COVID-19 outbreak has adversely affected revenues from sales of USC products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products, and will likely continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted.

The following table presents the Company's revenue disaggregated by end market for the years ended December 31, 2020 and 2019.

	For the Years Ended December 31,	
	2020	2019
Drug Development & Commercialization:		
Distribution Channel	$ 2,776,587	$ 3,762,967
Compounded Pharmaceuticals:		
Clinics/Hospitals	13,162,264	17,247,663
Direct to Patients	588,546	1,103,239
Total Compounded Pharmaceuticals Revenues	13,750,810	18,350,902
Total	$ 16,527,397	$ 22,113,869

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, 2020 and 2019, $915,671 and $111,246 of the revenues recognized were reported as deferred revenue as of December 31, 2019 and 2018, respectively. Included in the deferred revenue balance at December 30, 2020 and December 31, 2019 was $0 and $900,000, respectively, relating to the non-refundable upfront payment received from Sandoz pursuant to the Sandoz Agreement; and $950,000 included in the deferred revenue balance at December 31, 2020 was for the non-refundable upfront payment received from USWM pursuant to the USWM Agreement. 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 quarter ending June 30, 2020 include recognition of a full $1,750,000 write-off of the capitalized cost to obtain a contract that was reflected on its condensed consolidated balance sheet as of March 31, 2020. The deferred costs were classified as current or non-current in the Company's condensed consolidated balance sheets based on the timing of when the Company expects to recognize the expense. As of December 31, 2020 and 2019, the Company had $0 and $1.8 million, respectively, of Cost to Obtain a Contract deferred costs. Deferred costs related to obtaining a contract were amortized to Selling, General and Administrative expenses with $50,000 and $200,000 expensed for the years ended December 31, 2020 and 2019, respectively.

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 two customers that have a balance greater than 10% of the accounts receivables at December 31, 2020 and 2019.

	December 31, 2020	December 31, 2019
Customer A	—	30%
Customer B	48%	—

The Company had one customer that accounted for more than 10% of total sales for the years ended December 31, 2020 and 2019.

	December 31, 2020	December 31, 2019
Customer A	11%	17%

For the years ended December 31, 2020 and 2019 Customer A had approximately $ 1.8 million and $3.8 million of total sales for the year, 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 one vendor that had a balance of greater than 10% of trade accounts payables at December 31, 2020 and 2019.

	December 31, 2020	December 31, 2019
Vendor A	15%	21%

The Company had two vendors that accounted for more than 10% of total purchases for the years ended December 31, 2020 and 2019.

	December 31, 2020	December 31, 2019
Vendor A	10%	13%
Vendor B	11%	less than 10%

Vendor A had approximately $2.7 million and $3.9 million of total purchases for the years ended December 31, 2020 and 2019, respectively. Vendor B accounted for approximately $2.8 million of total purchases for the year ended December 31, 2020. The Company has minimal or no exposure to the elimination of Vendor A or Vendor B, 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, 2020 and December 31, 2019 consisted of the following:

	December 31, 2020	December 31, 2019
Finished Goods	$ 2,059,095	$ 1,158,637
Work-in-process	334,164	360,609
Devices	722,667	541,851
	$ 3,115,926	$ 2,061,097

Reserve for obsolescence as of December 31, 2020 and December 31, 2019 was approximately $446,000 and $473,000, respectively. The Company recorded an impairment charge of approximately $ 322,000 for the year ended December 31, 2019 due to inventories damaged due to flooding of the USC facility.

NOTE 8: PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2020 and December 31, 2019:

	December 31, 2020	December 31, 2019
Prepaid Insurance	$ 234,489	$ 193,613
Prepaid - Research and Development	562,832	137,727
Other Prepaid	649,577	792,542
Other Current Assets	13,085	3,440
	$ 1,459,983	$ 1,127,322

NOTE 9: FIXED ASSETS

Fixed assets at December 31, 2020 and December 31, 2019 are summarized in the table below:

Description	Useful Life (Years)	December 31, 2020	December 31, 2019
Building	30	$ 3,040,000	$ 3,040,000
Machinery and Equipment	3 - 7	5,633,265	2,437,525
Furniture and Fixtures	7	160,012	156,259
Automobile	5	9,500	9,500
Leasehold Improvements	7 - 15	342,330	342,330
Total Fixed Assets		9,185,107	5,985,614
Less: Accumulated Depreciation		(3,571,870)	(2,050,697)
Land		460,000	460,000
Construction In Progress - Equipment		3,513,356	7,272,499
Fixed Assets, net		$ 9,586,593	$ 11,667,416

For the years ended December 31, 2020 and 2019, depreciation expense was approximately $1,627,000 and $598,000, respectively. The increase in 2020 depreciation expense was primarily due to the assembly line for the Company's SYMJEPI (epinephrine) Injection 0.3 mg and 0.15 mg products, which was placed into service in January of 2020 and additions to fixed assets of approximately $662,000 were primarily due the upgrades made to said assembly line. The disposals of fixed assets for the years ended December 31, 2020 and 2019 were approximately $106,000 and $126,000, respectively. The CIP - Equipment are primarily for the expansion of USC's operations and will 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 - Equipment 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.

NOTE 10: INTANGIBLE ASSETS AND GOODWILL

Intangible assets at December 31, 2020 and December 31, 2019 are summarized in the table below:

December 31, 2020	Gross Carrying Value	Accumulated Amortization	Impairment	Net Carrying Amount
Definite-lived Intangible assets, estimated lives in years:				
Patents, Taper DPI Intellectual Property, 10 years	$ 9,708,700	$ (6,796,090)	$ (2,912,610)	$ —
FDA 503B Registration & Compliance, 10 years	3,963,000	(1,870,316)	—	2,092,684
Customer Relationships, 10 years	5,572,000	(2,629,674)	—	2,942,326
Website Design, 3 years	16,163	(16,163)	—	—
Total Definite-lived Assets	19,259,863	(11,312,243)	(2,912,610)	5,035,010
Trade Name and Brand, Indefinite	1,245,000	—		1,245,000
SYMJEPI Domain Name	9,674	—		9,674
Balance, December 31, 2020	$ 20,514,537	$ (11,312,243)	$ (2,912,610)	$ 6,289,684

December 31, 2019	Gross Carrying Value	Accumulated Amortization	Net Carrying Amount
Definite-lived Intangible assets, estimated lives in years:			
Patents, Taper DPI Intellectual Property, 10 years	$ 9,708,700	$ (5,825,220)	$ 3,883,480
FDA 503B Registration & Compliance, 10 years	3,963,000	(1,474,015)	2,488,985
Non-compete Agreement, 3 years	1,639,000	(1,639,000)	—
Customer Relationships, 10 years	5,572,000	(2,072,475)	3,499,525
Website Design, 3 years	16,163	(15,265)	898
Total Definite-lived Assets	20,898,863	(11,025,975)	9,872,888
Trade Name and Brand, Indefinite	1,245,000	—	1,245,000
SYMJEPI Domain Name	9,674	—	9,674
Balance, December 31, 2019	$ 22,153,537	$ (11,025,975)	$ 11,127,562

Amortization expense for years ended December 31, 2020 and 2019 was approximately $1,925,000 and $2,083,000, respectively. 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, as of December 31, 2020, we have determined that 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 for the year ended December 31,2020.

Estimated amortization expense of definite-lived intangible assets at December 31, 2020 for each of the five succeeding years and thereafter is as follows:

Year ending December 31,	
2021	$ 953,500
2022	953,500
2023	953,500
2024	953,500
2025	953,500
Thereafter	267,510

Total	$ 5,035,010

We have two operating segments and two reporting units. During the three months ended March 31, 2020, COVID-19 spread across the globe and adversely impacted economic growth, including as a result of government mandated shut-downs, stay-at-home policies and social distancing efforts intended to mitigate the spread of the virus. In light of the current economic downturn, that we believe affected the trading prices of our common stock, we determined that it was more likely than not that the fair value of our reporting unit was less than its carrying value. This triggered the Company to perform an interim impairment assessment to test the carrying value of goodwill, all of which is related to the Compounded Pharmaceuticals reporting unit, as of March 31, 2020. We also performed our annual impairment testing related to our Compounded Pharmaceuticals reporting unit as of December 31, 2020. The results of the annual impairment test indicated that the estimated fair value of the reporting unit was less than its carrying value. This was primarily due to a decline in projected net cash flows as a result of the continued impact of COVID-19 on revenue and related cash flows.

For both the interim and annual impairment assessments, the Company utilized a combination of the market-based approach and income approach to determine the fair value of our Compounded Pharmaceuticals business segment. Our quantitative assessments utilized a market-based approach and assessed guideline publicly traded companies operating in the drug manufacturing and compounding industry in the healthcare sector that are similar from an investment standpoint to the Company. The income approach required management to estimate the future cash flows related to our reporting unit and included an adjustment to the discount rate for a company specific risk premium to account for the increased risk to future cash flows in the current environment. As a result of these analyses, the carrying value of our reporting unit exceeded the fair value by approximately $3,143,000 and $3,629,000 as of March 31, 2020 and December 31, 2020, respectively. The difference between the carrying values and fair values which were recorded as goodwill impairment expense in their respective periods. No impairment charge was recorded for the year ended December 31, 2019. These valuation approaches utilize a variety of company and market assumptions which may change in the future and could result in additional impairment.

The carrying value of the Company's goodwill as of December 31, 2020 and December 31, 2019 was approximately $ 868,000 and $7,641,000, respectively.

The change in the carrying amount of goodwill consisted of the following activity:

Balance, December 31, 2019	$ 7,640,622
Less: March 31, 2020 Impairment	(3,143,200)
Less: December 31, 2020 Impairment	(3,629,010)
Balance, December 31, 2020	$ 868,412

NOTE 11: LEASES

The Company has three operating leases, one for an office space, another for an office space and manufacturing facility, and one for office equipment; and one finance lease for plant equipment. As of December 31, 2020, the leases have remaining terms between less than one year and less than five 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 previously entered into a lease agreement to occupy approximately 7,525 square feet leased premises with a term commencing December 1, 2014 (as amended, the "Lease") and expiring on November 30, 2018. Average rent expense is approximately $23,000 per month, with a deposit of $ 170,000 which was paid in November 2014. In December 2017, $ 42,500 of the deposit was applied to rent and the balance of deposit as of December 31, 2018 was $42,500 which rolled as deposit to the amended lease. The base rent expense over the life of the lease was approximately $1,119,000.

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 an additional 3,457 square feet of certain office space within the property. Total annual rent expense for the years ended December 31, 2020 and 2019 was approximately $354,000, respectively.

On November 22, 2017, the Company has 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. The agreement, as amended, provides for an initial base rent of $12,155 per month for the first 12 months, a base rent commencing on January 1, 2019 of $10,000 per month for the succeeding 12 months and increasing annually to $ 10,824 for the 12 months ending December 31, 2023.

The tables below present the operating and financing lease assets and liabilities recognized on the condensed consolidated balance sheets as of December 31, 2020 and December 31, 2019:

Right-of Use Assets	December 31, 2020	December 31, 2019
Operating Leases	$ 1,542,130	$ 1,867,205

Financing Leases	1,867	6,347
	$ 1,543,997	$ 1,873,552

Lease Liabilities, Current	December 31, 2020	December 31, 2019
Operating Leases	$ 492,804	$ 440,127
Financing Leases	1,538	4,494
	$ 494,342	$ 444,621
Lease Liabilities, Non-Current		
Operating Leases	$ 1,105,219	$ 1,479,458
Financing Leases	-	1,538
	1,105,219	1,480,996
Total Lease Liabilities	$ 1,599,561	$ 1,925,617

The amortizable lives of operating and financing leased assets are limited by the expected lease term.

The Company's leases generally do not provide an implicit rate, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring operating and financing 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, 2020 and 2019 are:

December 31, 2020	Operating	Financing
Weighted Average Remaining Lease Term	3.85 Years	0.42 Year
Weighted Average Discount Rate	4.29%	3.95%

December 31, 2019	Operating	Financing
Weighted Average Remaining Lease Term	3.96 Years	1.42 Years
Weighted Average Discount Rate	3.95%	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, 2020:

December 31, 2020	Operating	Financing
2021	$ 549,313	$ 1,550
2022	562,615	—
2023	543,577	—
2024	28,320	—
2025	23,600	—
Undiscounted Future Minimum Lease Payments	1,707,425	1,550
Less: Difference between undiscounted lease payments and discounted lease liabilities	109,402	12
Total Lease Liabilities	$ 1,598,023	$ 1,538
Short-Term Lease Liabilities	$ 492,804	$ 1,538
Long-Term Lease Liabilities	$ 1,105,219	$ —

Operating lease expense was approximately $516,000 and $514,000 for the years ended December 31, 2020 and 2019. Operating lease costs are included within selling, general and administrative expenses on the consolidated statements of operations.

Amortization expense related to our financing leases for the years ended December 31, 2020 and 2019, amortization expense related to our financing leases was approximately $4,500 and $67,000, respectively. Interest expense related to the financing leases for the years for the years ended December 31, 2020 and 2019 was approximately $160 and $1,400, respectively. Financing 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 $ 513,000 and $495,000 for the years ended December 31, 2020 and 2019, respectively. Cash paid for amounts included in the measurement of financing lease liabilities were approximately $5,000 and $68,000 for the years ended December 31, 2020 and 2019, respectively.

NOTE 12: ACCRUED OTHER EXPENSES

Accrued other expenses at December 31, 2020 and December 31, 2019:

	December 31, 2020	December 31, 2019

Accrued Commissions	$ 181,925	$ 447,550
Accrued Expenses	1,410,696	1,211,364
Accrued PTO	534,939	403,702
Accrued Salaries	247,595	242,884
Accrued Sales Taxes	76,152	119,224
Accrued State Tax	1,445	3,895
Deferred Social Security	71,660	—
	$ 2,524,412	$ 2,428,619

NOTE 13: DEBT

Building Loan

In connection with the closing of the acquisition of USC by the Company in April 2016 and the agreements relating to the transaction, an entity of which certain then-current or former officers, or stockholders, of USC were members, agreed to sell to the Company, the building and property owned by the entity on which USC's offices are located, in consideration of the Company being added as an additional "borrower" and assuming the obligations under the loan agreement, promissory note and related loan documents that the entity and certain other parties previously entered into with First Federal Bank 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").

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

As of December 31, 2020 and 2019, the outstanding principal balance owed on the applicable note was approximately $ 2,067,000 and $2,153,000, respectively. The loan currently bears an interest of 6.00% per year and interest expense for the years ended December 31, 2020 and 2019 was approximately $136,000 and $117,000, respectively.

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. No assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part. After the Company received funds pursuant to the PPP Loan, the Secretary of the Treasury and SBA issued guidance that the government will review all PPP loans of more than $2 million for which the borrower applies for forgiveness, and that all PPP loans in excess of $2 million, and other PPP loans as appropriate, will be subject to review by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form. Accordingly, the Company may be audited or reviewed by federal or state regulatory authorities as a result of filing an application for forgiveness of the PPP Loan or otherwise. 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 PPP 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. In December 2020, the Company submitted an application for the forgiveness of our PPP Loan. Should the Company qualify for ultimate forgiveness of the loan, the amount would be recognized as other income upon formal notice of forgiveness. If, despite the good-faith belief that given the Company's circumstances all eligibility requirements for the PPP loan were satisfied, it is later determined that the Company was ineligible to receive the PPP loan, it may be required to repay the PPP loan in its entirety and/or be subject to additional penalties. As of the date of this Report, we have not received a determination from SBA regarding our PPP Loan forgiveness application.

The Note may be prepaid in part or in full, at any time, without penalty. The Company may prepay 20% or less of the unpaid principal balance of the Note at any time without notice, and may prepay more than 20% of the unpaid principal balance of the Note subject to certain conditions. If any payment on the Note is more than 15 days late, the Bank may charge the Company a late fee of up to 5% of the unpaid portion of the regularly scheduled payment. The Note provides for certain customary events of default, including (i) failing to make a payment when due under the Note, (ii) failure to do anything required by the Note or any other loan document, (iii) defaults of any other loan with the Bank, (iv) failure to disclose any material fact or make a materially false or misleading representation to the Bank or SBA, (v) default on any loan or agreement with another creditor, if the Bank believes the default may materially affect the Company's ability to pay the Note, (vi) failure to pay any taxes when due, (vii) becoming the subject of a proceeding under any bankruptcy or

insolvency law, having a receiver or liquidator appointed for any part of the Company's business or property, or making an assignment for the benefit of creditors, (viii) having any adverse change in financial condition or business operation that the Bank believes may materially affect the Company's ability to pay the Note, (ix) if the Company reorganizes, merges, consolidates, or otherwise changes ownership or business structure without the Bank's prior written consent, or (x) becoming the subject of a civil or criminal action that the Bank believes may materially affect the Company's ability to pay the Note. 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.

As of December 31, 2020, the outstanding unpaid principal balance was $ 3,191,700.

At December 31, 2020, the outstanding principal maturities of the amended long-term debts were as follows:

Years ending December 31,	Building Loan	PPP Loan*	Total
Remainder of 2021	$ 2,067,213	$ 2,300,253	$ 4,367,466
2022	—	891,447	891,447
Total	$ 2,067,213	$ 3,191,700	$ 5,258,913
Short-Term Loans	$ 2,067,213	$ 2,300,253	$ 4,367,466
Long-Term Loans	$ —	$ 891,447	$ 891,447

* Based on the amortization schedule provided to the Company by the lender prior to the submission of the PPP Loan forgiveness application.

NOTE 14: 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, 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 2019 and 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 average volatility of the Company's stock of approximately 70%, 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 0.285%. The Company applied a Discount for Lack of Marketability ("DLOM") on certain of the measurement periods during the year but the restrictions limiting the exercise of the warrants were eliminated as of December 31,2020 and no DLOM was applied as of December 31,2020. 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	Number of Warrants	Liability
		(in thousands)		(in thousands)
Balance at December 31, 2018	—	—	—	—
2019 Warrant Issuance	13,800,000	4,830,000	—	—
Change in Fair Value, December 31, 2019		(1,794,000)	—	—
Balance at December 31, 2019, Revised	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

The Company has certain assets, such as goodwill, that are measured at fair value on a non-recurring basis and are adjusted to fair value only when the carrying values are more than the fair values. Based on market data of companies operating in the compounding and generic drug manufacturing industry, for the March 31, 2020 and December 31, 2020 goodwill impairment analysis, the Company used a discount rate of 26.5% and 17.3%, respectively, for the income approach calculation which includes a Company specific risk premium to account for the increased risk to future cash flows in the current environment. The categorization of the framework used to price the assets is considered Level 3, due to the subjective nature of the unobservable inputs used to determine the fair value.

As discussed in Note 10, Intangible Assets And Goodwill, the Company performed an interim impairment assessment to test the carrying value of goodwill, all of which is related to the Compounded Pharmaceuticals reporting unit, as of March 31, 2020. As a result of the analysis, the carrying value of our reporting unit exceeded the fair value by approximately $3,143,000, which was recorded as goodwill impairment expense as of March 31, 2020. On December 31, 2020, the Company performed its annual impairment assessment and as a result of the analysis, the carrying value of our reporting unit exceeded the fair value by approximately $3,629,000, which was recorded as goodwill impairment expense on December 31, 2020. Refer to Note 10 for more information.

The CIP - Equipment are primarily for the expansion of USC's operations and will 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 residual value of the assets. See Note 9.

NOTE 15: 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.

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 settlements 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.

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. Because litigation is inherently unpredictable and unfavorable results could occur, assessing contingencies is highly subjective and requires significant judgments about future events, including determining both the probability and 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.

As a result of the above matters, the Company has determined that liabilities associated with legal contingencies relating to the above Legal proceedings are probable and can be reasonably estimated, and has accrued $7,900,000 as of December 31, 2020, which is included in accrued liabilities in the consolidated balance sheet in the financial statements included in this Report.

NOTE 16: LICENSING AGREEMENTS

Viral Therapies

On July 28, 2006, the Company entered into a nonexclusive, royalty free license agreement with an entity for the technology used to research and develop new viral therapies, and an exclusive royalty-bearing license requiring a small percentage of revenue received by the Company on future products developed and sold with a payment cap of $10,000,000. The Company paid the entity an initial license fee and granted one of the entity's officers the right to purchase 1,000,000 shares of common stock of the Company at price of $ 0.001 pursuant to a separate stock purchase agreement.

Adamis has the right to terminate the agreement if it is determined that no viable product can come from the technology and either party may terminate the license agreement in the event of a material breach of the agreement by the other party that has not been cured or corrected within 90 days of notice of the breach. The Company does not currently intend to devote resources to the development of this technology and may consider terminating the agreement.

Influenza Vaccine

On September 22, 2006, the Company entered into an agreement with an entity to manufacture an influenza vaccine for the Company. The agreement requires the Company to pay $70,000 upon commencement of the project, followed by monthly payments based upon services performed until the project is complete. No product has been manufactured and no payments have been made as of December 31, 2020. If the project begins, the total payments will aggregate $283,420. The project has an open ended start time. Adamis may terminate the agreement upon notice to the other party, other than reimbursing the other party for non-cancellable materials and supplies ordered, and work in progress, through the date of the termination. The Company does not currently intend to devote resources to the development of this technology and may consider terminating the agreement.

3M License and Asset Acquisition Agreement

On August 1, 2013, the Company entered into an agreement to initially license and, with an additional closing payment fully acquire from 3M Company and 3M Innovative Properties Company ("3M"), certain intellectual property and assets relating to 3M's Taper Dry Powder Inhaler (DPI) technology under development for the treatment of asthma and chronic obstructive pulmonary disease, for total cash consideration of $10 million. The intellectual property includes patents, patent applications and other intellectual property relating to the Taper assets. The Company granted back to 3M a license to the intellectual property assets outside of the dry powder inhalation field.

The Company hired an independent valuation specialist to assist management with its determination of the fair value of the tangible and intangible assets acquired to be used in research and development. Management is responsible for the estimates and valuations. The work performed by the independent valuation specialist has been considered in management's estimates of fair value reflected below.

In addition to the patents and intellectual property, the Company also acquired a transition services agreement outlined in the asset purchase agreement, which provides the buyer certain knowledge transfer rights related to the Taper technology.

The following table summarizes the fair values of the identifiable assets acquired on December 27, 2013:

Description	
Taper DPI Intellectual Property	$ 9,708,700
Equipment	97,100
3M Transition Services Agreement	194,200

	$ 10,000,000

The values listed above were determined using the cost savings and discounted cash flow methods. Value is estimated based on the cost savings attributable to the asset being appraised which in this case was the transition service agreement. As with most income-based valuation methods, the cost (or royalty) savings method are generally estimated on an after tax basis and discounted using an after tax discount rate. The cost savings method was used to value the transition services agreement. Discounted cash flow analysis involves projecting monetary benefits directly associated with an asset and factoring them to reflect present value at a rate that considers the risk and rate of return associated with the subject asset. In the application of this approach, the value of the asset is considered to be the sum of the present values of the future cash flows received over the expected life of the asset. The Company applied the discounted cash flow method to estimate the fair value of the acquired intellectual property (patents and unpatented technology associated with the taper dry powder inhaler IP). In regards to the Taper DPI, the Company calculated the after-tax net income, or cash flow related to the technology and discounted the future income with a discount rate of 26.5%, a 5.0% premium over the weighted average cost of capital. 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 for the year ended December 31, 2020. The Taper DPI intellectual property has zero book value as of December 31, 2020. See Note 10.

NOTE 17: 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, 2020 and 2019 were approximately $746,000 and $958,000, respectively.

For information concerning contingencies relating to legal proceedings, see Note 15 of the notes to the consolidated financial statements.

Ben Franklin Note

Biosyn (a wholly owned subsidiary of the Company and previously a wholly owned subsidiary of Cellegy) 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 Ben Franklin Note was recorded at its estimated fair value of $ 205,000 and was assumed by Cellegy as an obligation in connection with its acquisition of Biosyn in 2004. 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.

Accounting principles generally accepted in the United States emphasize market-based measurement through the use of valuation techniques that maximize the use of observable or market-based inputs. 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 14). 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 had no fair market value at the time of the merger in April 2009 between the Company (which was then named Cellegy Pharmaceuticals, Inc.) and the corporation then-named Adamis Pharmaceuticals Corporation.

NOTE 18: CAPITAL STRUCTURE

On August 5, 2019, the Company completed the closing of an underwritten public offering of 13,800,000 shares of common stock, and warrants to purchase up to 13,800,000 shares of common stock, which included 1,800,000 shares and warrants to purchase up to 1,800,000 shares pursuant to the full exercise of the over-allotment option granted to the underwriters. The exercise price of the warrants is $1.15 per share, and the equity classified warrants are exercisable for five years. Each share of common stock was sold together with a warrant to purchase one share of common stock for a combined public offering price of $1.00 per unit. Net proceeds were approximately $12.8 million, after deducting underwriting discounts and commissions and offering expenses of approximately $ 1.0 million payable by the Company. The securities were issued by the Company pursuant to a “shelf” registration statement on Form S-3 that the Company previously filed with the Securities and Exchange Commission, and a prospectus supplement and an accompanying prospectus relating to the offering.

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 September 29, 2020, the Company received a notice from the Listing Qualifications Department of The Nasdaq Stock Market ("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 and 5810(c)(3)(A), the Company has a period of 180 calendar days from the date of notification, or until March 29, 2021, to regain compliance. If at any time before March 29, 2021, 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. 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.

On February 9, 2021, the Company received a letter from Nasdaq notifying the Company that as a result of the closing bid price of the Company's common stock having been at $1.00 per share or greater for at least ten consecutive business days, the Company has regained compliance with Nasdaq's minimum bid price requirement under Nasdaq's Marketplace Rule 5550(a)(2) for continued listing on The NASDAQ Capital Market, and the matter is now closed.

NOTE 19: CONVERTIBLE PREFERRED STOCK

January 2016 Series A-1 Preferred Stock

On January 26, 2016, the Company completed a private placement transaction with a small number of accredited investors pursuant to which the Company issued 1,183,432 shares of Series A-1 Convertible Preferred Stock ("Series A-1 Preferred") and warrants to purchase up to 1,183,432 shares of common stock or Series A-1 Preferred. The shares of Series A-1 Preferred and warrants were sold in units, with each unit consisting of one share and one warrant, at a purchase price of $4.225 per unit. The Series A-1 Preferred is convertible into shares of common stock at an initial conversion rate of 1-for-1 (subject to stock splits, reverse stock splits and similar events) at any time at the discretion of the investor. The exercise price of the warrants is $4.10 per share, and the warrants are exercisable at any time over the five-year term of the warrants. If the Company grants, issues or sells any Common Stock equivalents pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then a holder of Series A-1 Preferred or warrants will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of Common Stock acquirable upon conversion of the Series A-1 Preferred or exercise of the warrants (without regard to any limitations on conversion). If the Company declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of Common Stock, then a holder of Series A-1 Preferred or warrants is entitled to participate in such distribution to the same extent as if the holder had held the number of shares of Common Stock acquirable upon complete conversion of the Series A-1 Preferred or exercise of the warrants (without regard to any limitations on conversion). Gross proceeds to the Company were approximately $5,000,000 excluding transactions costs, fees and expenses. In accordance with the transaction agreements, the Company filed a registration statement with the SEC, which has been declared effective, to register the resale from time to time of shares of common stock underlying the Series A-1 Preferred and the warrants. The January 2016 warrants include call provisions that are generally similar to the 2014 warrants. The exercise price of the January 2016 warrants is $4.10 per share, and accordingly 250% of such exercise price is $10.25 per share. The warrants to purchase 1,183,432 shares remain outstanding as of December 31, 2020.

For the period ended December 31, 2016, the investors converted 1,183,432 shares of Series A-1 Preferred into an equal number of shares of common stock, with no shares of Series A-1 Preferred Shares remaining outstanding.

July 2016 Series A-2 Preferred Stock

On July 11, 2016, the Company completed a private placement transaction with a small number of accredited investors pursuant to which the Company issued 1,724,137 shares of Series A-2 Convertible Preferred Stock ("Series A-2 Preferred") and warrants to purchase up to 1,724,137 shares of common stock or Series A-2 Preferred. The shares of Series A-2 Preferred and warrants were sold in units, with each unit consisting of one share and one warrant, at a purchase price of $2.90 per unit. The Series A-2 Preferred is convertible into shares of common stock at an initial conversion rate of 1-for-1 (subject to stock splits, reverse stock splits and similar events) at any time at the discretion of the investor. The exercise price of the warrants is $2.90 per share, and the warrants are exercisable at any time over the five year term of the warrants. If the Company grants, issues or sells any Common Stock equivalents pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then a holder of Series A-2 Preferred or warrants will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of Common Stock acquirable upon conversion of the Series A-2 Preferred or exercise of the warrants (without regard to any limitations on conversion). If the Company declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of Common Stock, then a holder of Series A-2 Preferred or warrants is entitled to participate in

such distribution to the same extent as if the holder had held the number of shares of Common Stock acquirable upon complete conversion of the Series A-2 Preferred or exercise of the warrants (without regard to any limitations on conversion). Gross proceeds to the Company were approximately $5,000,000 excluding transactions costs, fees and expenses. In accordance with the transaction agreements, the Company filed a registration statement with the SEC, which has been declared effective, to register the resale from time to time of shares of common stock underlying the Series A-2 Preferred and the warrants. The July 2016 warrants include call provisions that are generally similar to the 2014 warrants. The exercise price of the July 2016 warrants is $2.90 per share, and accordingly 250% of such exercise price is $7.25 per share. For the period ended December 31, 2017, the investors have exercised July 2016 warrants to acquire 1,531,723 shares of common stock. As of December 31, 2020, 192,414 warrants remaining outstanding.

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 is 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 is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is 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 are not entitled to receive any dividends paid on shares of the Common Stock, and no other dividends are 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 20: 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.

The Company has a 2009 Equity Incentive Plan (the “2009 Plan”). The 2009 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 2009 Plan provides for the grant of performance cash awards. The initial aggregate number of shares of common stock that may be issued initially pursuant to stock awards under the 2009 Plan was 411,765 shares. The number of shares of common stock reserved for issuance automatically increases on January 1 of each calendar year, from January 1, 2010 through and including January 1, 2019, by the lesser of (a) 5.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year or (b) 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. On November 3, 2014, the number of shares reserved for issuance under the 2009 Plan increased by 1,000,000. On May 25, 2016, upon the approval of the Company’s stockholders at the annual meeting of stockholders, the number of shares reserved for issuance increased by 4,500,000. The 2009 Plan terminated effective February 2019 and no new awards may be made under the 2009 Plan. Outstanding options awarded under the 2009 Plan will remain outstanding and continue to be governed by the provisions of the 2009 Plan.

On January 30, 2019, the Company granted options to purchase 90,000 shares of common stock to the non-employee directors of the Company under the 2009 Plan with an exercise price of $3.09 per share. The options will vest over a period of one year. These options were valued using the Black-Scholes option pricing model under the following assumptions: volatility of approximately 56% using the Company's volatility blended with other peer companies, applying the simplified method for calculating the expected term of six years, dividend rate of 0.0 % and risk-free interest rate of approximately 2.6%, which resulted in a calculated fair value of approximately $152,000.

On January 30, 2019, the Company awarded Restricted Stock Units (“RSUs”) covering 2,349,350 shares of common stock to the officers and employees of the Company under the 2009 Plan; as of the date of grant, the market price of the common stock was $3.09 per share. These RSUs vest in equal amounts each quarter on the determined date over a period of three years from grant date provided that the recipient has continued to provide services to the Company, or earlier upon the occurrence of certain events including a Change in Control of the Company (as defined in the 2009 Plan), or earlier upon the recipient’s separation from service to the Company by reason of death or disability (as defined in the 2009 Plan). The calculated fair value of the RSUs was approximately $7,259,000.

On January 30, 2019, the Company awarded RSUs covering 36,985 shares of common stock to an employee of the Company under the 2009 Plan; as of the date of grant, the market price of the common stock was $3.09 per share. These RSUs were vested in full at grant date. The calculated fair value of the RSUs was approximately $114,000 and expensed immediately.

During the quarter ended September 30, 2019, the Company granted SARs with respect to a total of 290,000 reference units of common stock to certain non-employee directors and non-executive employees of the Company, with initial reference prices ranging from $0.74 to $0.97 per SAR. 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).

Stock Options

The following summarizes the stock option activity for the year ended December 31, 2020 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, 2019	7,837,245	$ 4.40	6.01 years
Options Canceled/Expired	(1,328,949)	4.95	—
Total Outstanding Vested and Expected to Vest as of December 31, 2020	6,508,296	$ 4.29	5.60 years
Vested as of December 31, 2020	6,397,703	$ 4.31	5.57 years

Stock based compensation expense for the years ended December 31, 2020 and 2019 was approximately $ 1,230,000 and $5,868,000, respectively. As of December 31, 2020, unrecognized compensation expense related to these stock options was approximately $147,000 and will be recorded as compensation expense in 0.17 year.

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 6,508,296 and 7,837,245 stock options outstanding at December 31, 2020 and 2019 was $0, respectively. The aggregate intrinsic value of 6,397,703 and 6,917,685 stock options exercisable at December 31, 2020 and 2019 was $0, respectively.

Restricted Stock Units

The following summarizes the RSU activity for the year ended December 31, 2020 below:

	Number of Shares/Unit	Weighted Average Grant Date Fair Value
Non-vested RSUs as of December 31, 2019	3,090,397	$ 3.46
RSUs vested during the period	(864,163)	3.06
RSUs forfeited during the period	89,341	3.09
Non-vested RSUs as of December 31, 2020	2,136,893	$ 3.64

Expense related to RSUs, included in the stock based compensation above, for the years ended December 31, 2020 and 2019 was approximately $3,190,000 and $2,597,000, respectively. The recorded expense related to RSUs for the year ended December 31, 2019 was reduced due to the termination of two non-employee members of the board of directors during the year ended December 31, 2019. The Company accounts for forfeiture as they occur and reduces the compensation cost at the time of forfeiture. As of December 31, 2020, unrecognized compensation expense related to these RSUs was approximately $4,622,000 and will be recorded as compensation expense in 3.17 year.

December 31, 2019	RSUs	Price Per Share at Grant Date	Date of Grant
Non-Employee Board of Directors	150,000(1)	$ 8.46	May 25, 2016
Company Executives	950,000(1)	$ 3.50	March 1, 2017
Company Executive	228,141(2)	$ 2.83	February 21, 2018
Company Executives and Employees	1,762,256(3)	$ 3.09	January 30, 2019
Total RSUs	3,090,397		

(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 annually over a period of three years if the recipient has provided continuous service or upon change of control or upon death or disability.

(3) 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.

Cash-settled Stock Appreciation Rights

The following table summarizes cash-settled SARS outstanding at December 31, 2020:

	Number of Units	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Total Outstanding Vested and Expected to Vest as of December 31, 2019	290,000	$ 0.82	6.7 Years
Granted	—	0.00	—
Total Outstanding Vested and Expected to Vest as of December 31, 2020	290,000	$ 0.82	5.7 Years
Vested as of December 31, 2020	141,943	$ 0.81	5.7 Years

The Company had a liability, which is included in accrued other expenses in the consolidated balance sheets, associated with its SARs of approximately $32,000 and $18,000 at December 31, 2020 and December 31, 2019, respectively. These SARs were valued using the Black-Scholes option pricing model, the expected volatility was approximately 63%, the term was seven years, the dividend rate was 0.0% and the risk-free interest rate was approximately 0.47%, which resulted in a calculated fair value of approximately $ 63,000. The fair value of these liability awards will be remeasured at each reporting period until the date of settlement. Increases and decreases in stock-based compensation expense are recognized over the vesting period, or immediately for vested awards. For the years ended December 31, 2020 and 2019, the Company recognized compensation expense related to these awards of $14,000 and $18,000, respectively.

Warrants

The following table summarizes warrants outstanding at December 31, 2020 and December 31, 2019:

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 14.

*** As of December 31, 2020, the fair value of the warrant liability related to the 2020 Warrants was $ 2,001,000. See Note 14.

December 31, 2019	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 Common Stock, Private Placement	700,000	$ 2.98	August 3, 2016	August 3, 2021
2019 Warrants	13,800,000*	$ 1.15	August 5, 2019	August 5, 2024
Total Warrants	15,934,670			

* As of December 31, 2019, the fair value of the warrant liability related to the 2019 Warrants was $ 3,036,000. See Note 4.

Shares Reserved

At December 31, 2020, the Company has reserved shares of common stock for issuance upon exercise of outstanding options and warrants, and vesting of RSUs, as follows:

Warrants	24,634,670
RSU	2,136,893
2009 Equity Incentive Plan	6,508,296
Total Shares Reserved	33,279,859

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 during the year ended December 31, 2020.

NOTE 21: INCOME TAXES

Net operating losses and tax credit carryforwards as of December 31, 2020 are as follows:

	Amount	Expiration Years
Net operating losses, federal (Post December 31, 2017)	$ 79,888,707	N/A
Net operating losses, federal (Pre January 1, 2018)	86,660,717	2028 - 2038
Net operating losses, state	63,031,411	2030 - 2040
Tax credits, federal	2,774,230	2037 - 2040
Tax credits, state	1,844,036	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.

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, 2020 and 2019, the Company reassessed its need for valuation allowance and decreased the valuation allowance because a portion of the indefinite lived taxable temporary difference was determined to be a future source of taxable income. This reassessment resulted in a tax expense of $2,000 and $9,000, respectively.

The expense for income taxes from operations consists of the following for the years ended December 31, 2020 and 2019:

	December 31, 2020	December 31, 2019
Current	$ 2,000	$ 9,000
Deferred	10,528,000	7,428,000
Total	10,530,000	7,437,000
Change in Valuation Allowance	(10,528,000)	(7,428,000)
Tax Expense	$ 2,000	$ 9,000

At December 31, 2020 and December 31, 2019 the significant components of the deferred tax assets from operations are summarized below:

	December 31, 2020	December 31, 2019
Deferred Tax Assets		
Net Operating Losses Carryforwards	$ 38,796,000	$ 32,621,000
Tax Credits	4,618,000	3,805,000
Stock Compensation	2,511,000	1,689,000
Accrued Expenses	2,259,000	172,000
Other	139,000	134,000
Total Deferred Tax Assets	48,323,000	38,421,000
Valuation Allowance	(47,908,000)	(36,989,000)
	$ 415,000	$ 1,432,000
Deferred Tax Liabilities		
Intangibles	$ (464,000)	$ (1,373,000)
Fixed Assets	(63,000)	(171,000)
Total Deferred Tax Liabilities	(527,000)	(1,544,000)
Net Deferred Tax Liability	$ (112,000)	$ (112,000)

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, 2020 and December 31, 2019 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 do not expect to be utilized by deferred tax liabilities.

The following table reconciles the Company's losses from operations before income taxes for the year ended December 31, 2020 and December 31, 2019.

	December 31, 2020		December 31, 2019	
Federal Statutory Rate	$ (10,337,000)	21.00%	$ (5,776,000)	21.00%
State Income Tax, net of Federal Tax	3,000	(0.01%)	7,000	(0.02%)
Other Permanent Differences	1,762,000	(3.58%)	(140,000)	0.51%
Research and Development Credits	(422,000)	0.85%	(652,000)	2.37%
Change in Valuation Allowance	8,996,000	(18.27%)	6,570,000	(23.89%)
Expected Tax Expense	$ 2,000	(0.01%)	$ 9,000	(0.03%)

Interest and penalties related to uncertain tax positions are recognized as a component of income tax expense. For the tax year ended December 31, 2020 and 2019, the Company recognized no interest or penalties.

NOTE 22: SEGMENT INFORMATION

Commencing April 1, 2020, our management, including the chief executive officer, who is our chief operating decision maker (“CODM”), began managing our operations as operating in two business segments: Drug Development and Commercialization which includes, without limitation, out-licensing the Company’s FDA approved products; and Compounded Pharmaceuticals which includes the Company’s registered outsourcing facility, based on changes to the way that management monitors performance, aligns strategies, and allocates resources. Based on these changes, we determined that each of these operating segments represented a reportable segment. While the CEO is apprised of a variety of financial metrics and information, the business is principally managed and organized based upon business units. Each segment is separately managed and is evaluated primarily upon segment net loss. The Company does not report the statement of cash flow and the balance sheet information by segment because, except as noted below, the Company’s CODM does not review that information. Goodwill recorded in the Compounded Pharmaceuticals business segment which was related to the acquisition of USC in April 2016 was approximately $7,641,000. The revenues of the Drug Development and Commercialization segment for years ended December 31, 2020 and 2019 were all from the distribution channel relating to the Company's SYMJEPI products.

The following tables present a summary of the Company’s reporting segments for the years ended December 31, 2020 and 2019, respectively:

	Year ended December 31, 2020			Year ended December 31, 2019, Revised		
	Drug Development and Commercialization	Compounded Pharmaceuticals	Consolidated	Drug Development and Commercialization	Compounded Pharmaceuticals	Consolidated
REVENUE, net	$ 2,776,587	$ 13,750,810	$ 16,527,397	$ 3,762,967	$ 18,350,902	$ 22,113,869
COST OF GOODS SOLD	6,326,971	8,566,851	14,893,822	5,056,956	10,421,859	15,478,815
Gross Profit	(3,550,384)	5,183,959	1,633,575	(1,293,989)	7,929,043	6,635,054
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	20,089,660	10,491,080	30,580,740	11,271,407	14,016,161	25,287,568
RESEARCH AND DEVELOPMENT	8,039,776	240,974	8,280,750	10,293,109	82,882	10,375,991
Impairment Expense - Goodwill	—	6,772,210	6,772,210	—	—	—
Impairment Expense – Construction In Progress	—	1,115,560	1,115,560	—	—	—
Impairment Expense - Contract Asset	1,750,000	—	1,750,000	—	—	—
Impairment Expense - Intangible	2,912,610	—	2,912,610	—	—	—
Impairment Expense – Inventories	—	—	—	—	322,106	322,106
Loss from Operations	$ (36,342,430)	$ (13,435,865)	$(49,778,295)	$ (22,858,505)	$ (6,492,106)	$(29,350,611)
OTHER INCOME (EXPENSE)						
Interest Expense	(4,921)	(154,707)	(159,628)	—	(123,258)	(123,258)
Interest Income	38,319	45,689	84,008	173,938	1,834	175,772
Change in Fair Value of Warrant Liabilities	465,000	—	465,000	1,794,000	—	1,794,000
Total Other Income (Expense)	498,398	(109,018)	389,380	1,967,938	(121,424)	1,846,514
Net Loss Before Income Taxes	$ (35,844,032)	$ (13,544,883)	$(49,388,915)	$ (20,890,567)	$ (6,613,530)	$(27,504,097)

The CODM is provided certain segment cash flow and balance sheet information in connection with operating and investment decisions regularly. Accordingly, the following segment information is presented for Drug Development and Commercialization, and Compounded Pharmaceuticals.

	December 31, 2020	December 31, 2019
Assets		
Drug Development and Commercialization	$ 13,027,945	$ 20,388,803
Compounded Pharmaceuticals	17,839,517	27,451,714
Total Assets	$ 30,867,462	$ 47,840,517

	Years Ended December 31,	
	2020	2019
Capital expenditures:		
Drug Development and Commercialization	$ 515,652	$ 538,362
Compounded Pharmaceuticals	146,331	1,859,479
Total capital expenditures	$ 661,983	$ 2,397,841

	Years Ended December 31,	
	2020	2019
Depreciation and amortization:		
Drug Development and Commercialization	$ 2,329,094	$ 1,431,418
Compounded Pharmaceuticals	1,277,902	1,513,098
Total depreciation and amortization	$ 3,606,996	$ 2,944,516

NOTE 23: SUBSEQUENT EVENTS

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 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 $48.6 million, after deducting approximately $3.2 million in underwriting discounts and commissions and estimated offering expenses payable by the Company.

Letter of Intent Regarding US Compounding Inc.

On January 26, 2021, the Company announced that it had entered into a non-binding letter of intent with a potential buyer for sale of substantially all of the assets of the Company's US Compounding Inc. subsidiary. Under the terms described in the letter of intent, the buyer would agree to acquire substantially all of the assets of US Compounding in exchange for a total gross consideration that could range from approximately $10-$20 million, before transaction fees and expenses and other potential post-closing adjustments.

If a transaction is negotiated, reflected in definitive agreements entered into by the parties, and completed, the proposed purchase price consideration includes a combination of a cash payment at the closing of the transaction, a promissory note representing portion of the purchase price payable at a future date, and potential future performance-based milestone payments over a period of years. The amount and structure of consideration could change as a result of subsequent negotiations, due diligence or other factors.

Any definitive agreement would be subject to approval by the respective parties, including approval by the Company's board of directors, and would likely include a number of customary provisions, including without limitation representations and warranties of USC and the Company, restrictive covenants and indemnification provisions.

The closing of a transaction would be contingent on the satisfaction of closing conditions which might include, among other things: (i) the receipt of required governmental, regulatory, and third-party consents and approvals, (ii) buyer obtaining required licenses, permits, registrations, or other approvals from the necessary state boards of pharmacy and other state and federal governmental authorities, and (iii) other customary closing conditions.

The letter of intent is non-binding other than with respect to certain customary confidentiality and exclusivity provisions. There can be no assurances that the parties will negotiate and enter into definitive transaction agreements or concerning the final terms that might be included in any definitive agreements, whether a transaction will be completed, concerning the timing of closing of any such transaction or concerning the amount of consideration that the Company might receive at the closing or over time from any such transaction.

Second Draw PPP Loan

On March 15, 2021, the Company entered into a Note (the "PPP2 Note") in favor of Arvest Bank (the "Bank"), the lender, 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 in 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. No assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part. If the Second Draw Loan is not forgiven in accordance with the terms of the PPP, the Company will be obligated to make monthly payments of principal and interest to repay the Second Draw Loan in full prior to the maturity date. Should the Company qualify for ultimate forgiveness of the loan, the amount would be recognized as other income upon formal notice of forgiveness. If, despite the good-faith belief that given the Company's circumstances all eligibility requirements for the PPP loan were satisfied, it is later determined that the Company was ineligible to receive the PPP loan, it may be required to repay the PPP loan in its entirety and/or be subject to additional penalties. If we do not submit a loan forgiveness application to the Bank within 10 months after the end of our applicable covered period, as defined under the PPP and applicable regulations and guidance issued by the SBA or the U.S. Department of Treasury, then we must begin paying principal and interest after that 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, bankruptcy or insolvency events, certain change of control events, material adverse changes or events, and certain other events. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Company, or filing suit and obtaining judgment against the Company.

Nephron Litigation

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 settlements 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 15 of the Notes to the consolidated financial statements included elsewhere herein for additional information.