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, 2018

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of the chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 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, 2018, was $102,637,530.

At March 15, 2019, the Company had 47,291,358 shares outstanding.

Documents Incorporated by Reference: Portions of the registrant's proxy statement for its 2019 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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Information Relating to Forward-Looking Statements

This Annual Report on Form 10-K (this "Report") includes forward-looking statements. 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. In some cases, you can identify forward-looking statements by terminology, such as "believe," "will," "expect," "may," "anticipate," "estimate," "intend," "plan," "should," and "would," or the negative of such terms or other similar expressions. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this Report. These forward-looking statements are not guarantees of future performance and concern matters that could subsequently differ materially from those described in the forward-looking statements. Actual events or results may differ materially from those discussed in this Annual Report on Form 10-K. In addition, many forward-looking statements concerning our anticipated future business activities assume that we are able to obtain sufficient funding to support such activities and continue our operations and planned activities. As discussed elsewhere in this Report, we may require additional funding to continue operations, and there are no assurances that such funding will be available. 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. Because factors referred to elsewhere in this Report, including without limitation the "Risk Factors" section on this Report, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and except as may be required by applicable law, we undertake no obligation to release publicly the results of any revisions to these forward-looking statements or to reflect events or circumstances arising after the date of this Report. 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.

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.

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 the therapeutic areas of respiratory disease and allergy. Our products and product candidates in the allergy, respiratory, opioid overdose and erectile dysfunction or ED 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 33-65 pounds; a naloxone injection product candidate (APC-6000) based on the approved Symject™ injection device and intended for the treatment of opioid overdose for which the company submitted a New Drug Application, or NDA, in December 2018 which was accepted for review by the FDA in March 2019; a fast-disintegrating sublingual tablet containing tadalafil (APC-8000), a drug used for treating ED, for which the company submitted an NDA for ED in December 2018 which was the subject of a refusal to file letter from the FDA in February 2019; 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 and has initiated the start-up phase of Phase 3 studies; and a fluticasone (APC-4000) dry powder inhaler, or DPI, product candidate for the treatment of asthma. 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.

To achieve our goals and support our overall strategy, we may need to raise a substantial amount of funding and make significant investments in, among other things, new 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
Naloxone Injection (APC-6000)	Opioid Overdose	Submitted NDA, December 2018
Tadalafil (APC-8000)	Erectile Dysfunction or ED	Submitted NDA, December 2018 (1)
Metered Dose Inhaler Product		
Beclomethasone (APC-1000)	Asthma	Phase 3, December 2018
Dry Powder Inhaler Product		
Fluticasone (APC-4000)	Asthma	Phase 3 ready (2)

(1) On February 26, 2019, we received a refusal to file letter from the FDA, indicating that upon its preliminary review, the submitted NDA was not sufficiently complete to permit a substantive review. The FDA requested that we supplement and include in any resubmitted NDA additional stability data and additional dissolution data for both the clinical and registration batches.

(2) Represents the next anticipated development or regulatory stage for the product candidate that we may pursue following completion of product development, assuming that we have the financial resources to pursue any of these opportunities. There are no assurances that we will pursue these opportunities, for financial or other reasons. Following completion of product development, one or more Phase 3 trials, without previous Phase 1 or Phase 2 trials, is the anticipated next product development stage. We intend to conduct additional trials, such as pharmacokinetic, or PK, and/or dose escalation studies in connection with the Phase 3 trials.

Anaphylaxis; Epinephrine Pre-Filled Syringe

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 in patients weighing 66 pounds and greater. 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.

On September 27, 2018, FDA approved our lower dose version (0.15mg) of Symjepi™ (epinephrine) Injection, for the emergency treatment of allergic reactions (Type I) including anaphylaxis in patients weighing 33 to 66 pounds.

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 2018 were more than $1.5 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. As discussed elsewhere in this Report, including under the headings "Business – Competition" and "Risk Factors - 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 market for prescription epinephrine products is increasingly 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, prescription epinephrine products such as our Symjepi™ (epinephrine) Injection 0.3mg and lower dose version 0.15mg product.

Our Symjepi™ (epinephrine) Injection 0.3mg product will 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 the 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.

In July 2018, we entered into a Distribution and Commercialization Agreement with Sandoz Inc., a division of Novartis AG, 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, or the Territory, 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 Territory, subject to the provisions of the agreement, in partial consideration of an upfront fee by Sandoz and potential performance-based milestone payments. As part of the agreement, Sandoz has commercial rights to our Symjepi™ (epinephrine) Injection 0.3 mg product, as well as the lower dose Symjepi™ (epinephrine) Injection 0.15mg product. We retain rights to the intellectual property subject to the agreement and to commercialize both products outside of the Territory, but have granted Sandoz a right of first negotiation regarding such territories. 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 agreement provides 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 will be the supplier of the product to Sandoz, and Sandoz will order and pay us a supply price for quantities of products ordered. We will be responsible for all manufacturing and, prior to Sandoz paying the supply price, the component and supply costs related to manufacturing and supplying the product to Sandoz. We are responsible for component sourcing and regulatory compliance in the supply chain and for testing of lots of product.

Sandoz has agreed to use commercially reasonable efforts to commercialize the product, subject to various conditions and to the other provisions of the agreement. The agreement does not include minimum payments to us by Sandoz, minimum requirements for sales of product by Sandoz or, with certain exceptions, minimum purchase commitments by Sandoz. Under the agreement, Sandoz has sole discretion in determining pricing, terms of sale, marketing, and selling decisions relating to the product.

On January 16, 2019, we announced that Sandoz had launched Symjepi™ (epinephrine) 0.3 mg Injection in the U.S. market. Symjepi™ will be rolled out via a phased launch and will initially be available in the institutional setting, an established channel where Sandoz has a significant experience and knowledge, followed by anticipated introduction into the retail market. We also anticipate that Sandoz will launch the lower dose Symjepi™ 0.15 mg Injection product in the U.S. markets.

Opioid Overdose

*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 2017 drug overdoses resulted in approximately 70,000 deaths in the United States – greater than approximately 190 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 have revealed an 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.

As we have previously disclosed, in December 2017 we submitted an IND to the FDA to begin testing of the drug compound naloxone in human patients. Testing in humans, which included a pharmacokinetic study, began in April 2018. On December 31, 2018, we filed an NDA with the FDA relating to our APC-6000 product which provides a higher dose of naloxone than all products currently approved in the U.S. for the treatment of opioid overdose. On March 14, 2019, we announced that the FDA had accepted the submitted NDA for review and indicated that it had completed its filing review and had determined that the NDA was sufficiently complete to permit a substantive review. The FDA further provided a target agency action date of October 31, 2019. However, the FDA's review processes can extend beyond, and in some cases significantly beyond, anticipated completion dates due to the timing of the FDA's review process, FDA requests for additional data, information, materials or clarification, difficulties scheduling an advisory committee meeting, FDA workload issues, extensions resulting from the submission of additional information or clarification regarding information already in the submission within the last three months of the target PDUFA date, or other reasons. As a result, the dates of regulatory approval, if obtained, and commercial introduction of our product could be delayed beyond our expectations. 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.

Tadalafil (APC-8000)

Tadalafil (Cialis®) is in a class of drugs called phosphodiesterase-5, or PDE5, inhibitors which includes, among others, sildenafil (Viagra®) and vardenafil (Levitra®). All of these oral tablets are FDA approved and clinically indicated for the treatment of ED. Tadalafil and sildenafil are also indicated for pulmonary hypertension, but among PDE5 drugs, only tadalafil is approved for the treatment of BPH. We estimate that annual sales of Cialis in the United States in 2018 were approximately $2.5 billion, based on publicly available information.

On December 28, 2018, we filed an NDA for fast-disintegrating sublingual version of tadalafil (APC-8000) with the FDA. On February 26, 2019, we received a refusal to file letter from the FDA, indicating that upon its preliminary review, the FDA determined that the submitted NDA was not sufficiently complete to permit a substantive review. The FDA requested that we supplement and include in any resubmitted NDA (i) longer real-time (versus accelerated) stability data and (ii) additional dissolution data for both the clinical and registration batches. The agency indicated that it would refund 75% of the total user fee that we submitted with the NDA. We continue to evaluate the FDA's comments, and we may seek immediate guidance from the FDA, including requesting a Type A meeting, to discuss the letter with the agency and seek additional guidance concerning information, data and specific deliverables that the agency would require for a resubmitted NDA to be deemed complete. We cannot provide any assurances concerning the amount of time or costs that may be associated with the activities and data that may be required to enable a resubmission of the NDA. If Adamis resubmits the NDA, there can be no assurances concerning the acceptance of the NDA, the review time by FDA or the FDA's response to any resubmitted NDA.

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 (CDC) reporting on findings from 2016, the number of people in the U.S. with asthma is approximately 26.5 million and growing. We estimate that global sales of asthma and bronchospasm prescription products were in excess of approximately $8.1 billion in 2018, 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, will target a small niche within the larger market for respiratory products. We estimate that the annual global sales of prescription steroid HFA and similar products were approximately $2.7 billion in 2018, of which we intend to target a smaller niche.

In February 2015, we announced the result of our pharmacokinetic study, or PK study, comparing our beclomethasone dipropionate HFA, 80 mcg Inhalation Aerosol, product, APC-1000, with Teva Respiratory, LLC's Qvar® (Beclomethasone Dipropionate HFA, 80 mcg Inhalation Aerosol) product. The study was a Phase I open label, randomized, single-dose, four-way crossover PK study comparing APC-1000 to Qvar. Twenty-two healthy male and female subjects who met the study inclusion criteria were enrolled. The study involved a screening period before randomization and four treatment periods each separated by a minimum of three days. Both inhalation aerosols were administered to each subject for a total dose of 320 mcg BDP (4 inhalations). Twenty-one subjects completed the study. One subject was withdrawn due to non-compliance. The purpose of this PK study was to compare the bioavailability of APC-1000 to Qvar. The results showed the extent of absorption of APC-1000 to be equivalent to Qvar. Following discussions with the FDA and additional consideration of the development pathway for the product, we decided to conduct additional development work for APC-1000.

In January 2018, we submitted an IND application to the FDA to begin Phase 3 efficacy studies for APC-1000. 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 phase 3 studies of APC-1000. We anticipate that trial enrollment will commence in 2019. The timing of enrollment and completion of such studies could be affected by a number of factors, including without limitation adequate funding, the absence of unexpected regulatory issues or delays, the time period required to enroll a sufficient number of patients in the study, and the time required to complete and analyze the results of the studies. As discussed elsewhere in this Report, product development times are subject

to a number of risks and uncertainties, which can delay the actual development time beyond our estimates.

Dry Powder Inhaler (DPI) Device Platform

In December 2013, we acquired assets relating to 3M'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 are utilizing the Taper DPI assets to develop the DPI device. We believe that, if successfully developed, the device can 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, which may include combination products. Our agreement with 3M contemplates that the microstructured carrier tape will be supplied by 3M under a separate commercial supply agreement to be negotiated with 3M.

We believe that 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. To our knowledge, there are currently no excipient-free dry powder inhalers in the U.S. market. We are continuing product development efforts concerning this platform delivery device and product candidates utilizing the device.

Asthma; Fluticasone. Our first product candidate utilizing the DPI technology platform, APC-4000, will 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. It works by preventing certain cells in the lungs and breathing passages from releasing substances that cause asthma symptoms. APC-4000 is designed to deliver the same active ingredient as GlaxoSmithKline's Flovent® Diskus® for the treatment of asthma. We estimate that Flovent® Diskus® generated more than $443 million in U.S. sales and $791 million in global sales in 2018, based on GSK's publicly announced results. We conducted a proof of concept study with the DPI for APC-4000 in 2018. Assuming sufficient funding and successful development, we may conduct one or more additional proof of concept studies for APC-4000 during 2019.

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 to produce DPI and HFA products.

Our development plans concerning our allergy and respiratory products, including APC-1000 and APC-4000, and our other product candidates are affected by developments in the marketplace, including the introduction of potentially competing new products by our competitors. As a result, our product development plans could be affected by such considerations. The anticipated dates for development and introduction of products in our product pipeline will depend on a number of factors, including the availability of adequate funding to support product development efforts and, should we choose to seek commercialization partners for one or more of our products or product candidates, our success in negotiating and entering into development or commercialization agreements relating to our products. We believe that should we decide to pursue such applications, we would be required to submit data for an application for approval to market APC-1000 and APC-4000 pursuant to Section 505(b)(2) of the FDCA, although there are no assurances that this will be the case. 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.

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, see "Government Regulation—Regulation in the United States—Section 505(b)(2) New Drug Applications," 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 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 therapeutic alternatives to drugs approved by the FDA. USC also provides certain veterinary 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 located throughout most of the United States.

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 a ready-to-use, or 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.

USC's business is focused on marketing a portfolio of compounded preparations for humans and animals, including sterile injectable and non-sterile integrative therapies, in therapeutic areas such as autoimmunity, chronic infectious diseases, and endocrine and metabolic diseases. Many 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. USC's veterinary products include, without limitation, a formulation that we believe is novel, of an equine ulcer product that addresses what we believe is a significant market.

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 2018.

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. During 2019, we intend to move certain aspects of production into a new, larger facility that was in development during 2018. Initial commissioning and qualification are expected to commence in the first quarter of 2019. We believe that the new, larger facility will expand production capacity and allow for increased sales of products.

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.

Regulatory Matters. 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 FDA Form 483. It is common for such reports 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, and July 2016, USC received Form 483 observations following FDA inspections of its outsourcing facility, noting inspectional observations of a number of observed 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 Form 483 observations following FDA inspections 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.

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 these state matters 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 business, results of operations and financial condition.

The suspension of sterile production and voluntary product recall had an adverse effect on USC's revenues, income, and financial condition for calendar years 2015 and 2016 and adversely affected its relationships with certain of its customers that established relationships with other suppliers during USC's suspension of sterile production.

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 CSPs. 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.

In January 2018, FDA published a statement outlining its compounding priorities for 2018. Included in this statement were references to forthcoming regulations on compounding from bulk drug substances, determination of clinical need, and a revised memorandum of understanding between FDA and State Boards of Pharmacy setting forth limits on interstate compounding under Section 503A of the FDCA. The draft guidance documents published in 2018, which are of general application to compounding pharmacies, or other FDA regulations and guidance, potentially could limit the number and type of products USC is permitted to compound as well as interstate shipping of compounded medications, and could adversely affect sales of our compounded medications. In December 2018, FDA published a revised draft guidance on cGMP for 503B Outsourcing Facilities. USC is currently assessing this new guidance and any required improvements or changes to its processes, procedures, policies, or facility to achieve the expected level of compliance.

Other Technologies

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. No drug-related serious adverse events were observed with C31G. 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 seek regulatory approval for a C31G product, 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. In considering commercialization alternatives, 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. As a result, commercialization of the product could require, among other things, renegotiation with the former Biosyn shareholders and such third parties. Accordingly, there can be no assurances that we will pursue commercialization of or conclude a 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.

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, 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. There are potential sources of supply other than our existing suppliers, but new supplier would be required to qualify under applicable regulatory requirements.

Sales and Marketing

Our Symjepi™ (epinephrine) products will be marketed and sold in the U.S. markets by Sandoz pursuant to our commercialization agreement with Sandoz. 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 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 our marketing and commercial partner, Sandoz, a Novartis division, has launched Symjepi™ (epinephrine) 0.3 mg Injection in the US market. Symjepi™ will be rolled out via a phased launch and will initially be available in the institutional setting, an established channel where Sandoz has a significant experience and knowledge, followed by anticipated introduction into the retail market. Pursuant to our agreement with Sandoz, we are responsible for supplying the Symjepi™ products to Sandoz at a supply price for quantities of products ordered. Revenues from sales of the company's compounded pharmacy medications and compounds consist, in large part, of sales to 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 will compete against other self-administered epinephrine products, including EpiPen, EpiPen Jr., Auvi-Q and Adrenaclick. In addition, there has been market and regulatory focus during 2017 and 2018 on the prices to consumers of self-administered epinephrine products, which have exerted downward pressure on the pricing of such products. Competitors may reduce or otherwise modify the pricing of their existing products following the introduction our Symjepi™ (epinephrine) Injection 0.3mg and 0.15mg products. In addition, the company that markets the currently leading auto-injector product, EpiPen, has 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 product candidates Naloxone Injection (APC-6000) for opioid overdose and Tadalafil (APC-8000) for ED, if approved and introduced, are expected to compete with other pharmaceuticals in the markets for opioid overdose and ED, respectively. Moreover, our APC-1000 and APC-4000 products, if developed and commercialized, are expected to compete with allergy inhaler and other products offered by several companies, including without limitation GlaxoSmithKline and Teva Respiratory, LLC.

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 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. 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, 2018, the company had: (i) 17 issued patents in the United States and 13 pending applications, one of which has been allowed; (ii) 72 issued and 41 pending foreign patent applications, one of which has 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 2019 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 any 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, 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. We cannot assure you that any of our product candidates will ever obtain approval. 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 patients to determine safety, any 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 in an expanded patient population to determine efficacy and to further determine safety, usually at multiple clinical sites.

We cannot assure you that any of our current or future clinical trials will result in approval to market our 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, offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA also has established other special programs for NDAs that are intended to expedite or simplify the process for reviewing drugs or provide for approval based on surrogate endpoints. 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. 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. 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, 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. 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 and may require prior approval of promotional materials.

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 can inspect the facilities at which the product is manufactured. The FDA will not approve the submission unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical studies were conducted in compliance with GCP requirements. If the FDA determines that the processes and procedures used are not acceptable, it will outline the deficiencies in the submission and often will request additional clinical testing or information before an NDA can be approved. The FDA may also inspect one or more of the preclinical toxicology research sites to assure that the preclinical studies were conducted in compliance with GLP requirements. If the FDA determines that the studies were not performed in compliance with applicable GLP rules and regulations, the FDA may request additional preclinical testing or information before an NDA can be approved.

The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter describes all of the specific deficiencies in the submission identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, 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. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. 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, complying with FDA promotion and advertising requirements, which include, among others, restrictions on direct-to-consumer advertising, promoting biologics 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, operating restrictions and criminal prosecution.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. 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.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are 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. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Many states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, 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.

The Patient Protection and Affordable Care Act, or PPACA, enacted in 2010, imposes new reporting and disclosure requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals. In addition, pharmaceutical and device manufacturers will also be required to report and disclose 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 reforms imposed by the PPACA will significantly impact the pharmaceutical industry; however, the full effects of the law cannot be known until these provisions are implemented. In addition, although the PPACA was upheld by the U.S. Supreme Court, it is possible that the PPACA or portions thereof may be modified, challenged or repealed in the future, or that future judicial decisions, executive orders or regulatory actions could affect the impact of the law on the pharmaceutical industry.

If not preempted by federal law, several states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing various other marketing related activities. Other states require the posting of information relating to clinical studies and their outcomes. 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. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. 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 or refuse to approve a product, suspend or withdraw of an approved product from the market, 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, suspension of manufacturing, 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 biologics 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.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to a Section 505(b)(1) NDA filing or an Abbreviated NDA, or ANDA. An alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which 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 list with the FDA each patent whose claims cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug 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 clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the previously approved product on which the applicant's application relies that are listed in the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed 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. 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 one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product have expired. Further, the FDA will also not approve, as applicable, a Section 505(b)(2) NDA application until any 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 until the earliest to occur of 30 months beginning on the date the patent holder receives notice, expiration of the patent, settlement of the lawsuit, or until a court deems the patent unenforceable, invalid or not infringed. 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 after the fourth 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 few 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 0.3mg product and our lower dose 0.15 mg version, we are pursuing Section 505(b)(2) regulatory filings in connection with our naloxone injection and tadalafil products, for which we filed an NDA for each product in December 2018, and we intend to pursue a Section 505(b)(2) regulatory filing in connection with our beclomethasone HFA and fluticasone DPI product candidates, if successfully developed. Accordingly, if we rely in our regulatory filing on clinical trials conducted, or the FDA's prior findings of safety and effectiveness, for a previously approved drug product 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 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 505(b)(2) application, such as we submitted for the Symjepi™ (epinephrine) Injection 0.3mg product and as we may submit for other future products, that relies on clinical trials conducted for a previously approved product where there are no patents 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 reference another previously approved product that involves patents referenced in the Orange Book, requiring us to make the certifications 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) 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 bioequivalency 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 drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA. The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book, in a manner generally similar to the certifications that are required in connection with Section 505(b)(2) regulatory filings as described above. As with Section 505(b)(2) regulatory filings, if the applicant does not challenge the listed patents, 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) regulatory filings 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 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 no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge 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 contains previously approved active ingredients, but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which FDA cannot grant effective approval of an ANDA based on that listed drug.

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 and, to a lesser extent, Medicaid, to reimburse all or part of the cost of the product and procedure for which the product is being used. 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 drug would not be eligible for any reimbursement of the cost, and our ability to successfully market any such drug would be materially and adversely impacted.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals 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. In these markets, once marketing approval is received, pricing negotiations 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

Federal and state anti-kickback and anti-fraud and abuse laws, as well as the federal Civil False Claims Act may apply to certain drug and device research and marketing practices. The Civil False Claims Act prohibits knowingly presenting or causing to be presented a false, fictitious or fraudulent claim for payment to the United States. 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. Violations of the Civil False Claims Act can result in significant monetary penalties. The federal government is using 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 multi-million dollar settlements. The federal government may continue to devote substantial resources toward investigating healthcare providers', suppliers' and drug and device manufacturers' compliance with the Civil False Claims Act and other fraud and abuse laws. We may have to expend significant financial resources and management attention if we ever become the focus of such an investigation, even if we are not guilty of any wrongdoing.

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, privacy and security standards and other administrative simplification provisions, by covered entities which include many healthcare providers, health plans and healthcare clearinghouses. HIPAA instructs the Secretary of the Department of Health and Human Services to promulgate regulations implementing these standards in the United States. 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 Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other similar federal and state laws regarding, among other things, occupational safety, the use and handling of radioisotopes, environmental protection and hazardous substance control. Although as of the date of this Report we have not been required to take any action to correct any noncompliance, 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 products. 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 has 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.

Pharmacy Regulation

Our compounding pharmacy business conducted by USC is subject to federal, state and local laws, regulations, and administrative practices, including, among others: federal, state and local licensure and registration requirements concerning the operation of pharmacies and the practice of pharmacy; HIPAA; PPACA and the Health Care and Education Reconciliation Act of 2012, collectively referred to as the Health Reform Law; 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 the compounded formulations 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 pharmacy operations are regulated by both individual states and the federal government. Every state has laws and regulations addressing pharmacy operations, including regulations relating specifically to compounding pharmacy operations. 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, more stringent requirements on compounding pharmacies. Revisions to United States Pharmaceopeia Chapters <800> "Hazardous Drugs – Handling in Healthcare Setting," <795> "Pharmaceutical Compounding – Non-Sterile Preparations," and <797> "Pharmaceutical Compounding – Sterile Preparations" are expected to be published in July 2019 with effective dates of December 1, 2019. These new and revised chapters are incorporated by reference in most state regulations, and compliance with these revisions may require significant changes to procedures, policies, and facility design. If our pharmacy operations become subject to additional licensure requirements or, are unable to maintain their required licenses or if states place burdensome restrictions or limitations on pharmacies, USC's ability to operate in some states could be limited. At this time, there are no operating restrictions on USC's licensure in any of the states where it is licensed, and none are pending or expected in the foreseeable future. The company believes that all permits are in good standing in all material respects.

Most of the states into which USC delivers its formulations have laws and regulations that require out-of-state pharmacies to register with, or be licensed by, the boards of pharmacy or similar regulatory bodies in those states. These states generally permit the dispensing pharmacy to follow the laws of the state within which the dispensing 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 pharmacies by, among other things, requiring compliance with all laws of the states into which the out-of-state pharmacy dispenses or distributes 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.

The DQSA also contained new Section 503B of the FDCA, which established an outsourcing facility as a new form of entity that is permitted to compound large quantities of drug formulations without a prescription, thus permitting the practice of anticipatory compounding, and distribute them out of state without limitation, if the drug formulations appear on the FDA's drug shortage list or the bulk drug substances contained in the formulations appear on a list to be established by the FDA. 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 cannot predict when FDA will issue, finalize, or enforce new guidance documents that affect our business practices. Several guidance documents from FDA are currently in draft form, which does not preclude them from being enforceable by FDA, and USC cannot predict or control when Final Guidance might be issued or if any changes from draft versions will be introduced. Specifically, in December 2018, FDA published a revised draft guidance on cGMP for 503(b) Outsourcing Facilities and USC is currently assessing this new guidance and any required improvements or changes to its processes, procedures, policies, or facility to achieve the expected level of compliance. The DQSA prohibits compounding facilities, both 503A and 503B, from compounding products that are "essentially a copy" of approved drug products offered by traditional pharmaceutical manufacturers. In January 2018, the FDA published a Final Guidance on compounding from bulk ingredients and what it considers to be "essentially a copy" of approved drug products. This policy 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 decrease demand for the compounded drug products. Additionally, in January 2018, the FDA published a statement outlining its compounding priorities for 2018. Included in this statement were references to forthcoming regulations on compounding from bulk drug substances, determination of clinical need, and a memorandum of understanding between FDA and State Boards of Pharmacy. The draft guidance documents published in 2018 which are of general application to compounding pharmacies, potentially could limit the number and type of products USC is permitted to compound and interstate shipping of compounded medications, and could adversely affect sales of our compounded medications.

USC initiated actions in 2018 to separate a portion of its business activities into 503A prescriptions dispensed to individual patients and 503B compounds distributed to facilities and practitioners without a specific patient identified. In December 2016, FDA issued Final Guidance for Industry entitled "Prescription Requirement Under Section 503A of the Federal Food, Drug, & Cosmetic Act." This guidance document outlines that traditional 503A pharmacies can only dispense prescriptions pursuant to receipt of a valid prescription for a specifically identified individual patient. This December 2016 Guidance, in combination with the August 2015 Final Guidance for Industry "For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, & Cosmetic Act," and the May 2018 Guidance for Industry "Facility Definition Under Section 503B of the Federal Food, Drug, & Cosmetic Act" effectively make compounding prescriptions for individual patients impractical as a 503B Outsourcing Facility and require separate physical operations for 503A and 503B operations that are not logistically feasible in USC's existing facility. The process to open, commission, and license the new facility is expected to require additional capital expenditures in 2019.

Confidentiality, Privacy and HIPAA

USC's pharmacy operations involve the receipt, use and disclosure of confidential medical, pharmacy and other health-related information. 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 compliance with federal security regulations 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 that is not health-related.

Medicare Reimbursement

Medicare is a federally funded program that provides health insurance coverage for qualified persons age 65 or older and for some disabled persons with certain specific conditions. Currently, most of USC's formulations are sold in cash transactions and a small percentage of USC's prescriptions are billed to Medicare and other third parties prescription benefits managers. 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. Further, the Health Reform Law 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 and other 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.

To the extent that USC obtains third-party reimbursement for its compounded formulations, it may become subject to Medicare, and other publicly financed health benefit plan regulations prohibiting kickbacks, beneficiary inducement and the submission of false claims.

Food and Drug Administration

As a human drug compounding outsourcing facility, USC is registered with, and regulated by, the FDA under the FDCA. In particular, the DQSA, which sets forth standards applicable to compounding outsourcing facilities such as USC's, was enacted in November 2013, creating a new Section 503B in the FDCA, under which a compounder can voluntarily register as an outsourcing facility. USC has registered as an outsourcing facility.

In July 2014, the FDA issued a draft guidance entitled: Industry Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act. According to the FDA, this "interim guidance describes the FDA's expectations regarding compliance with cGMP requirements" for Section 503B compounding facilities. The guidance also notes that the FDA intends to promulgate more specific cGMP regulations for such facilities, but that until "final regulations are promulgated, this guidance describes the FDA's expectations" regarding outsourcing facility compliance with cGMP requirements for drugs during the interim period. In December 2018, FDA published a revised draft guidance on cGMP for 503B Outsourcing Facilities. USC is currently assessing this new guidance and any required improvements or changes to its processes, procedures, policies, or facility to achieve the expected level of compliance. We cannot predict when the guidance will be finalized. The revised guidance for 503B outsourcing facilities regarding vendor qualification and incoming raw materials testing is onerous and could increase the cost of USC's compounded medications.

In June 2016, the FDA issued guidance entitled: "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act – Guidance for Industry." According to the FDA, this guidance sets forth the FDA's interim regulatory policy concerning compounding by outsourcing facilities registered under section 503B of the FDCA using bulk drug substances. Section 503B of the FDCA includes certain restrictions on the bulk drug substances that outsourcing facilities can use in compounding and directs the FDA to develop a list of bulk drug substances that can be used in compounding under that section. The FDA is developing that list of bulk drug substances, and this guidance describes the FDA's interim regulatory policy regarding outsourcing facilities that compound human drug products using bulk drug substances while the list is being developed. In 2017, a pharmaceutical company filed suit against FDA in a federal district court alleging that the interim policy described above on compounding from bulk drug substances was an improper implementation of the 2013 Drug Quality & Security Act. In March 2018, the FDA published the draft guidance "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, & Cosmetic Act." FDA also updated its interim lists of bulk drug substances on multiple occasions in 2018. In September 2018, the FDA and the pharmaceutical company that filed the suit agreed to an additional stay of the lawsuit until December 31, 2018, pending the FDA's continued evaluation of its preliminary assessment that outsourcing facilities should not be able to compound drugs products that contain any of three specific bulk drug ingredients. On January 7, 2019, the district court entered another order staying the matter until counsel for the Federal Government notifies the Court that federal appropriations have been restored. In March 2019, the FDA issued final guidance and moved to formally remove two substances from the interim list that permitted their use, and a decision regarding a third substance is still pending. While the three specific substances at issue in FDA's updated interim list were not of material importance to USC, the potential exists for the FDA to take similar action in the future relative to other bulk drug substances that may be more significant to USC's business, without extended notice, solicitation of comments, or Administrative Procedures Act procedures, which could result in a loss of revenue resulting from any affected USC products. USC is working proactively with industry stakeholders and regulatory authorities regarding the FDA's guidance and actions, and believes 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.

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 FDA Form 483. It is common for such reports 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. As described elsewhere under the heading "Business of U.S. Compounding, Inc. – Overview – Regulatory Matters," USC has received Form 483 observations in the past following FDA facility inspections, including in 2014, 2015, and 2016. Following the August 2015 Form 483 observations, USC temporarily suspended production of sterile products and voluntarily recalled all lots of sterile products aseptically compounded and packaged by USC that remained within expiry, due to the FDA's concern over a lack of sterility assurance. Issuance of a Form 483 from FDA has the potential to result in additional regulatory restrictions from the various State Boards of Pharmacy that could limit business in those states on a temporary or permanent basis. Following the 2016 inspection, USC was issued a Form 483 listing inspectional observations. USC responded in writing in July 2016 and again in April 2017. In October 2017, FDA issued a Warning Letter to USC summarizing its concerns from the 2015 and 2016 inspections. USC provided FDA with a written response detailing corrective actions taken, including regarding differential pressures, facility design, environmental monitoring, product specifications, and suspension quality. In November 2018, FDA responded to the 2017 Warning Letter Response submitted by USC and indicated that it would look for evidence of corrective action and further clarification of policies and procedures on a future inspection.

Drug Enforcement Administration

USC maintains registrations with the DEA that enables USC to receive, manufacture, store and distribute controlled substances. Controlled substances are those drugs that appear 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 potential for abuse. Laws enforced by the DEA, as well as similar state agencies, require each location that handles controlled substances to separately register.

The CSA governs, among other things, the 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 DEA and state controlled substances regulations.

Procurement quota requirements imposed by the DEA on USC's purchases of materials containing 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 drugs for use in USC's business could adversely affect our business, financial condition and results of operations. In 2017, the DEA issued a statement indicating it would significantly decrease the procurement quotas it issued for opiates in an effort to curb the national opioid abuse crisis. This decrease could limit USC's ability to procure controlled substances and adversely impact our revenues and results of operations; however, USC works with both 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 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

As of December 31, 2018, we had 152 full-time employees and 79 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.

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 ("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 Business, Industry and Financial Condition

Our auditors have expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing.

Our audited financial statements for the year ended December 31, 2018, were prepared under the assumption that we would continue our operations as a going concern. Our independent registered public accounting firm has included a "going concern" explanatory paragraph in its report on our financial statements for the year ended December 31, 2018, indicating that we have incurred recurring losses from operations and are dependent on additional financing to fund operations, and that these factors raise substantial doubt about our ability to continue as a going concern. Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent on the market acceptance and success of our products and our ability to obtain additional funding in 2019 if required and thereafter, and there are no assurances that such funding will be available at all or will be available in sufficient amounts or on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. Without additional required funds 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 $39.0 million for the year ended December 31, 2018, and a net loss of approximately $25.5 million for the year ended December 31, 2017. At December 31, 2018, we had cash and cash equivalents of approximately $19.3 million, accounts receivable of approximately $1.2 million and liabilities of approximately $11.7 million. The development of our business may require additional capital in 2019 and the future to help fund the development of the naloxone injection, tadalafil fast-disintegrating sublingual tablet, fluticasone DPI, and beclomethasone HFA product candidates, and conduct research and development of other product candidates, as well as to fund capital expenditures and our ongoing operations at USC and satisfy our obligations and liabilities. We have historically relied upon sales of our equity or debt securities to fund our operations. We currently have no available balance in our credit facility or committed sources of capital. Delays in obtaining 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 additional financing if required will be subject to a number of factors, including market conditions, 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, at least until additional funding is obtained, 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K 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, 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 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 $39.0 million for the year ended year ended December 31, 2018, and a net loss of approximately $25.5 million for the year ended December 31, 2017. From inception through December 31, 2018, we have an accumulated deficit of approximately $153.0 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 Sandoz 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 trial, 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.

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

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

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

We are in the relatively early stage of operations and development of our current product candidates (other than our Symjepi products) and have only a limited operating history on which to base an evaluation of our business and prospects. Even if we successfully obtain additional funding, we are subject to the risks associated with early stage companies with a limited operating history, including without limitation: the 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.

The development of new pharmaceutical products is a highly risky undertaking, and there can be no assurance that any future research and development efforts we might undertake will be successful. Many of our potential products will 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 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.

The anticipated dates for development and introduction of products in our product pipeline will depend on a number of factors, including the availability of adequate funding to support product development efforts.

Our product development plans concerning our allergy and respiratory products and product candidates, including APC-1000, APC-4000, APC-6000 and APC-8000, 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 number and kind of clinical trials that the FDA will require before the FDA will consider regulatory approval of the applicable product; the outcome of discussions with the FDA concerning the regulatory approval pathway 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 unexpected delays or difficulties in assembling and deploying an adequate sales force to market the product if we decide to market a product ourselves rather than seek a commercialization partner.

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 usually 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 dramatically 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; and
- recruiting participants for a clinical trial.

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 coverage of up to a general aggregate of $3,000,000, with a $1,000,000 limit for each occurrence; and an excess liability insurance coverage of up to a general aggregate of $6,000,000, with a $4,000,000 limit for each occurrence. Such insurance policies are expensive 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 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.

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. 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 Naloxone Injection (APC-6000) and Tadalafil (APC-8000) product candidates, and we intend to pursue Section 505(b)(2) NDA filings with the FDA in connection with our beclomethasone HFA and fluticasone DPI 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 clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the previously approved product on which the applicant's application relies and that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed 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. 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 one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product have 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 until the earliest to occur of 30 months beginning on the date the patent holder receives notice, expiration of the patent, settlement of the lawsuit, or until a court deems the patent unenforceable, invalid or not infringed.

If we rely in our Section 505(b)(2) regulatory filings on clinical trials conducted, or the FDA's prior findings of safety and effectiveness, for a previously approved drug product 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 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 clinical trials conducted for a previously approved 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; and
- 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. This would 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 Patient Protection and Affordable Care Act signed into law in the United States in March 2010. 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.

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 product, 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. 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, because of funding limitations and our limited cash resources, we may not be able to devote the resources that we might otherwise desire 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, such as the litigation described elsewhere in this Report under Item 3, “Legal Proceedings,” 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. 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 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.

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.

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, 2018, 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 deploy these NOLs and credit carryforwards. Pursuant to Internal Revenue Code Section 382, the annual use of the NOLs and research and development tax credits could be limited by any greater than 50% ownership change during any three-year testing period. As noted in Note 20 to the 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 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.

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.

Risks Related to Our Compounding Pharmacy Business

Our Inability to Successfully Manage USC's Operations Could Adversely Affect Our Operations.

Our acquisition of USC represented a significant investment. Managing USC's operations requires significant attention and resources, which could reduce the likelihood of achievement of other corporate goals. There is no assurance that we will realize the benefits of the USC acquisition that we hope will be achieved.

USC could receive additional Section 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.

Outsourced compounding 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 FDA Form 483. It is common for such reports 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, and July 2016, USC received Form 483 observations following FDA inspections of its outsourcing facility, noting inspectional observations of a number of observed 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 Form 483 observations following FDA inspections 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.

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 these state matters 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 business, results of operations and financial condition. The suspension of sterile production and voluntary product recall had an adverse effect on USC's revenues, income, and financial condition for calendar years 2015 and 2016 and adversely affected its relationships with certain of its customers that established relationships with other suppliers during USC's suspension of sterile production.

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

Compounded drugs are not FDA-approved. As a 503B outsourcing facility, USC's compounded formulations are not subject to the FDA drug approval process. This means that FDA does not verify the safety, or effectiveness of compounded drugs. 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 recent years. 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; and 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. 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.

Formulations prepared and dispensed by compounding pharmacies contain FDA-approved ingredients, but are not themselves approved by the FDA. The drug products available through branded and generic drug companies have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. In addition, certain compounding pharmacies have been the subject of widespread negative media coverage in recent years, and the actions of these pharmacies have resulted in increased scrutiny of compounding pharmacy activities from the FDA and state governmental agencies. For example, the FDA has in the past requested that a number of compounding pharmacies conduct a recall of all non-expired, purportedly sterile drug products and cease sterile compounding operations due to lack of sterility assurance, and additional compounding pharmacies have suspended sterile production or voluntarily recalled certain sterile compounding products after an FDA inspection of the relevant facilities. As a result, some physicians may be hesitant to prescribe, and some patients may be hesitant to purchase and use, these compounded formulations. 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 government 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. Any failure by physicians, patients, or third-party payors, to accept compounded formulations could substantially limit USC's market and cause its and our business and operations to suffer. An incident similar to the fungal meningitis outbreak in 2012, which was caused by a compounding pharmacy, could cause USC's customers to reduce their use of outsourced compounded medications significantly or even stop using outsourced compounded medications altogether. States have in the past enacted, and could in the future enact, regulations prohibiting or restricting the use of outsourcing compounded medication service providers in response to such incidents. Such prohibitions or restrictions on outsourced compounded preparations by states, or reduced customer demand as a result of an incident with compounded medication providers, could have a material adverse effect on USC's and our business, results of operations and financial condition.

In addition, in 2017, a lawsuit was filed by a pharmaceutical company, Endo International plc, alleging that FDA has improperly enforced DQSA related to its interim draft guidance on compounding from bulk drug ingredients. In January 2018, FDA and Endo agreed to stay this lawsuit pending FDA releasing new guidance on this topic, a draft of which was published at the end of March 2018. In September 2018, the FDA and Endo agreed to an additional stay of the lawsuit until December 31, 2018, pending the FDA's continued evaluation of its preliminary assessment that outsourcing facilities should not be able to compound drugs products that contain any of three specific bulk drug ingredients. On January 7, 2019, the court entered another order staying the matter until counsel for the Federal Government notifies the Court that federal appropriations have been restored. In March 2019, the FDA issued final guidance and moved to formally remove two substances from the interim list that permitted their use, and a decision regarding a third substance is still pending. While the three specific substances at issue in FDA's updated interim list were not of material importance to USC, the potential exists for the FDA to take similar action in the future relative to other bulk drug substances that may be more significant to USC's business, without extended notice, solicitation of comments, or Administrative Procedures Act procedures, which could result in a loss of revenue resulting from any affected USC products. USC is working proactively with industry stakeholders and regulatory authorities regarding the FDA's guidance and actions, and believes 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.

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. 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. 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. The DQSA prohibits compounding facilities, both 503A and 503B, from compounding products that are considered "essentially a copy" of approved drug products offered by traditional pharmaceutical manufacturers. In January 2018, FDA published Final Guidance on what it considers to be "essentially a copy" of approved drug products. This policy 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.

Our failure to anticipate or appropriately adapt to changes or trends within the pharmaceutical industry could have a significant negative impact on our ability to compete successfully.

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. 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. 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. The DQSA prohibits compounding facilities, both 503A and 503B, from compounding products that are considered "essentially a copy" of approved drug products offered by traditional pharmaceutical manufacturers.

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 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, physicians may be unwilling to prescribe USC's products or order any prescriptions from such pharmacies, 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. USC works with third-party insurers, pharmacy benefit managers and buying groups to advocate that patient-specific customizable compounded formulations be available to patients at accessible prices. We plan to continue to devote time and other resources to seek reimbursement for compounded formulations. However, we may be unsuccessful in achieving these goals, as 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 and the Health Reform Law 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 or may not be sufficient to allow USC to sell products on a competitive basis and at desirable price points. If government and other third-party payors do not provide adequate coverage and reimbursement levels for USC's formulations, the market acceptance for USC's formulations may be limited. 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, and we expect this trend to continue. 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, and expects to continue to derive, 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 GPS, 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, some of which provide favorable terms in exchange for USC's or our commitment to purchase minimum volumes of, or in some cases all of USC's needs for, one or more drugs. 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.

In 2018, the FDA published a number of draft guidance materials that could have a substantial impact on USC's business. In March 2018, the FDA published the draft guidance "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503 of the Federal Food, Drug, & Cosmetic Act." The FDA also updated its interim lists of bulk drug substances on several occasions in 2018. In August 2018, the FDA moved to remove three bulk drug substances from the interim list that permitted their use. . In March 2019, the FDA issued final guidance and moved to formally remove two substances from the interim list that permitted their use, and a decision regarding a third substance is still pending. While the three specific substances at issue in FDA's updated interim list were not of material importance to USC, the potential exists for the FDA to take similar action in the future relative to other bulk drug substances that may be more significant to USC's business, without extended notice, solicitation of comments, or Administrative Procedures Act procedures, which could result in a loss of revenue resulting from any affected USC products. USC is working proactively with industry stakeholders and regulatory authorities regarding the FDA's guidance and actions, and believes 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.

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. For example, USC's suspension of sterile product production during portions of the second half of 2015 and the first quarter of 2016 adversely affected its relationships with some of its customers and sales personnel, and resulted in revenues in 2016 that were below our expectations. 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.

We have incurred significant indebtedness, which will require substantial cash to service and which subjects us to certain financial requirements and business restrictions.

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 USC 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 these loan agreements with the Bank, or the amended Loan Documents. We are required to make current periodic interest and principal payments under the Amended Loan Documents, in an amount of approximately $49,000 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, 2018, our aggregate indebtedness under the Amended Loan Documents was approximately $2,583,000.

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.

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 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.

The marketing and sale of compounded formulations is subject to and must comply with extensive and evolving state and federal statutes and regulations governing compounding entities. These statutes and regulations include, among other things, for certain kinds of compounding pharmacies restrictions on compounding for office use or in advance of receiving a patient-specific prescription or, for outsourcing facilities registered under Section 503B of the FDCA such as USC's registered outsourcing facility, requirements regarding preparation, such as regular FDA inspections and cGMP requirements, prohibitions on compounding drugs that are essentially copies of FDA-approved drugs, restrictions on the use of bulk active ingredients, limitations on the volume of compounded formulations that may be sold across state lines, and prohibitions on wholesaling or reselling. These and other restrictions on the activities of compounding pharmacies and outsourcing facilities may limit the market available for compounded formulations, as compared to the market available for FDA-approved drugs.

USC's pharmacy business is impacted by federal and state laws and regulations governing, among other things: the purchase, distribution, management, compounding, dispensing, reimbursement, marketing and labeling of prescription drugs and related services; FDA and/or state regulation affecting the pharmacy and pharmaceutical industries, including state pharmacy, manufacturer, wholesaler and distribution licensure and registration or permit standards; rules and regulations issued pursuant to HIPAA, and other state and federal laws related to the use, disclosure and transmission of health information; and state and federal controlled substance laws. USC's or our failure to comply with any of these laws and regulations could severely limit or curtail 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.

We are subject to significant costs and uncertainties related to compliance with the extensive regulations that govern the compounding, labeling and distribution of pharmaceutical products and services, in general, and compounded formulations, in particular. If our compounding facility fails to comply with the Controlled Substances Act, FDCA, or state statutes and regulations, USC could be required to cease operations or become subject to restrictions that could adversely affect our business.

The production, distribution, processing, formulation, packaging and labeling of pharmaceutical products and services such as USC's compounded formulations are subject to extensive regulation by federal agencies, including the FDA and the DEA. We and USC are also subject to a significant number of state and local laws and 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.

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. For example, as a result of the increased scrutiny resulting from the 2012 meningitis outbreak that was traced to a Massachusetts compounding pharmacy, in 2013 the U.S. Congress passed the DQSA, which sets forth new standards applicable to outsourcing facilities such as USC's and invites voluntary registration with the FDA. The DQSA also permits states to continue to impose separate regulatory requirements. Under the DQSA, USC has registered with the FDA as a Section 503B outsourcing facility and has implemented policies and procedures that are intended to achieve compliance with the DQSA requirements for such facilities. However, there can be no assurance that we or USC are fully compliant with these 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.

State legislatures and regulatory authorities also reacted to the fungal meningitis outbreak by imposing additional regulatory requirements on compounding activities for outsourcing compounders and reminding outsourcing compounders of regulatory requirements already in effect. 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.

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.

Further, the FDA seeks to limit, under Section 503A of the FDCA, the amount of compounded products that a pharmacy not registered as an outsourcing facility under Section 503B of the FDCA can dispense interstate. The interpretation and enforcement of this provision is dependent on the FDA entering into a standard Memorandum of Understanding ("MOU") with each state setting forth limits on interstate compounding. The draft standard MOU presented by the FDA in February 2015 would limit interstate shipments of compounded drug units to 30% of all compounded and non-compounded units dispensed or distributed by the pharmacy per month, with the excess considered by the FDA as an "inordinate amount." The FDA stated in guidance issued in February 2015 that it would not enforce interstate restrictions until after it published a final standard MOU and made it available to states for signature for some designated period of time. If the final standard MOU was released but not signed by a particular state, then interstate shipments of compounded preparations from a pharmacy located in that state and not registered as an outsourcing facility would be limited to quantities not greater than 5% of total prescription orders dispensed or distributed by the pharmacy (the 5% rule); however, we are not aware that the FDA currently enforces or has in the past enforced the 5% rule and, under current draft guidance, the FDA has stated that it would not enforce the 5% rule until a standard MOU has been made available to states for signature. The FDA originally proposed a 180-day period for states to agree to a final MOU after the final version was presented, after which it would begin to enforce the 5% rule.

In January 2018, the FDA published a statement outlining its compounding priorities for 2018 (the "2018 Compounding Plan") which provided an overview of the key priorities the FDA plans 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"), and in September 2018 the FDA issued a revised draft MOU ("Revised Draft MOU"). As with other FDA regulations and guidance, when finalized, this guidance and MOU potentially could limit the number and type of products USC is permitted to compound as well as interstate shipping of compounded medications thereby adversely affecting sales of our compounded medications. 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 lists. With the exception of two substances that have been excluded, the final lists have not been developed and no timeline is currently available for which the lists are expected to be finalized. Until then, the interim 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. Similarly, if finalized, the Revised Draft MOU could also limit our pharmacy's interstate sales. Although the Revised Draft MOU removed any requirement that states take action against a pharmacy dispensing more than 30% of its compounded preparations interstate, it still requires that the state report to the FDA any pharmacy shipping more than 50% of its compounded products out of state. The Revised Draft MOU also changed the method of calculation: the percentage is now calculated using compounded products only. Under the Revised Draft MOU, for pharmacies that are dispensing more than 50% interstate, the FDA will analyze if the risk posed by the pharmacy's interstate dispensing practices may weigh in favor of additional federal oversight using a variety of risk factors. Moreover, if the state in which the pharmacy is located determines it will not enter into an MOU with FDA, the 5% rule will apply. In the Federal Register notice accompanying the Revised Draft MOU, the FDA continued to advise that it will not enforce the 5% limitation until some time period (it is proposing 180 days) after FDA has finalized the MOU. Nevertheless, the finalization of any MOU and the accompanying process could limit USC's ability to ship its compounded drug products interstate. The Revised Draft MOU The comment period for the Revised Draft MOU ended in December 2018.

In the future, we may not be able to satisfy applicable federal and state licensing and other requirements for USC's 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.

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>, including revisions to key chapters in 2019, 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. 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 is currently assessing this new guidance and any required 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 and 2016. 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 "listed 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 controlled 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 and the DEA review 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 services, or could withdraw regulatory approval for materials that USC uses as components in its products or services. 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 PPACA was enacted in 2010, and many of the structural changes enacted by the PPACA were implemented in 2014. However, some of the applicable regulations and sub-regulatory guidance under the PPACA 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 our USC's to purchase USC products or services and, as a result, adversely impact our revenues. We cannot predict what effect, if any, the PPACA, 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 the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, the referral of business or ordering of services paid for by Medicare or other federal programs. Violations of the anti-kickback statute can result in imprisonment, civil or criminal fines. 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.

Changes in the healthcare industry that are beyond our control may have an adverse impact on our business.

The healthcare industry is changing rapidly as consumers, governments, medical professionals and the pharmaceutical industry examine ways to broaden medical coverage while controlling the increase in healthcare costs. Such changes could include changes to make the government's Medicare reimbursement programs more restrictive, which could limit or curtail the potential for USC's formulations to obtain eligibility for reimbursement from such payors, or changes to expand the reach of HIPAA or other health privacy laws, which could make compliance with these laws costlier and more burdensome. Further, the Health Reform Law 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 or our business. Any changes to laws and regulations affecting the healthcare industry could impose significant additional costs on USC's and our operations in order to maintain compliance or could otherwise negatively affect USC's or our business, financial conditions 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 2017 to December 31, 2018, the market price of our common stock has fluctuated between $2.01 and $6.45. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- relatively low trading volume, which can result in significant volatility in the market price of our common stock based on a relatively smaller number of trades and dollar amount of transactions;
- the timing and results of our current and any future preclinical or clinical trials of our product candidates;
- the entry into or termination of key agreements, including, among others, key collaboration and license agreements;
- the results and timing of regulatory reviews relating to the approval of our product candidates;
- the timing of, or delay in the timing of, commercial introduction of any of our product;
- 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;
- period-to-period fluctuations in our financial results;
- 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; 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.

Prior to the listing of our common stock on the NASDAQ Capital Market, trading of our common stock was conducted on the OTCQB. The liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also as it may be adversely affected by delays in the timing of transactions and reduction in security analysts' and the media's coverage of us, if at all.

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 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's investment will only occur if our stock price appreciates.

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, 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.

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 February 28, 2019, we had 47,291,358 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 February 28, 2019, we had reserved for issuance 9,388,101 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 $4.38 per share, we had outstanding restricted stock units covering 4,028,547 shares of common stock, and we had outstanding warrants to purchase 2,134,670 shares of common stock at a weighted-average exercise price of $3.75 per share. Subject to applicable vesting requirements, upon exercise of these options or warrants, 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, our stockholders would experience dilution upon the exercise of these options.

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

As of December 31, 2018, we had outstanding warrants, other than the warrants described in the next sentence, to purchase 63,041 shares of common stock, at a weighted average exercise price of $8.43 per share. As of December 31, 2018, 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 private placement 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 February 28, 2019, our directors, executive officers and their respective affiliates owned approximately 2.7% of our outstanding shares of common stock and our largest stockholder owned approximately 7.2% 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.

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 controls over financial reporting, our stock price could decline and raising capital could be more difficult.

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 raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal controls, 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 drop significantly.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. 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. 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 financial statements will not be prevented or detected on a timely basis. 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. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. We can give no assurance that any material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or adequate disclosure controls and procedures or circumvention of these controls. In addition, controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements. 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. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, the Nasdaq Stock Market or other regulatory authorities.

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 previously entered into a lease agreement to lease the space with a term commencing December 1, 2014 (as amended, the "Lease"). The lease has a basic term expiring four years after the commencement date, and the company has an option to extend the term of the lease for an additional three years. Average rent during the term was $23,304 per month, with a deposit of $170,000 paid in November 2014. Through December 2018, $127,500 of the deposit was applied to rent and the balance of deposit as of December 31, 2018, was $42,500.

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. Commencing on December 1, 2018 with one month free rent, base rent will initially be $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 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.

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 entered into a lease agreement for the planned expansion of the company's compounding business, to lease a building consisting of approximately 44,880 square feet located in Conway, Arkansas. The agreement provides for an initial base rent of $12,155 per month for the first 12 months and will increase to $12,895 for the 12 months ending November 30, 2020. Average rent during the term will be $12,523 per month, with a previously paid deposit of $12,155.

ITEM 3. LEGAL PROCEEDINGS

We are and may become involved in or subject to routine litigation, claims, disputes, proceedings and investigations in the ordinary course of business. Any such litigation could divert management time and attention from Adamis, could involve significant amounts of legal fees and other fees and expenses, or could have a material adverse effect on our financial condition, cash flows or results of operations.

On September 26, 2018, the company brought action against Belcher Pharmaceuticals, LLC ("Belcher") in the United States District Court for the Middle District of Florida for a declaratory judgment ("Complaint") of non-infringement of certain patents in which Belcher claims rights, relating to certain methods of preparing epinephrine solutions and treating allergic reactions using a method of preparing certain epinephrine solutions (collectively the "Patents-in-Suit"). The Complaint seeks a declaratory judgment that the company's Symjepi™ (epinephrine) Injection product ("Symjepi") does not infringe the Patents-in-Suit. On November 7, 2018, Belcher filed its Answer and Counterclaim to the Complaint and alleged that the company infringes the Patents-in-Suit as a result of the Symjepi product. Belcher's Counterclaim seeks damages and injunctive relief in conjunction with the infringement claims. The company responded to the Counterclaim by generally denying any wrongdoing and asserting the affirmative defense that the Patents-in-Suit are invalid. The parties exchanged initial disclosures and initiated discovery in January 2019. A claim construction hearing is currently scheduled for August 15, 2019. The company believes that its Symjepi product does not infringe any valid and enforceable patent held by Belcher, and that Belcher's Counterclaim is without merit. The company intends to defend against Belcher's claims and pursue all available legal remedies available to the company against Belcher.

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, 2018, we had approximately 87 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.

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, 2018, has previously been reported in reports on Form 10-Q and reports on Form 8-K that we filed during that fiscal year.

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 the therapeutic areas of respiratory disease and allergy. Our products and product candidates in the allergy, respiratory, opioid overdose and erectile dysfunction, or ED, 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 33-65 pounds; a naloxone injection product candidate (APC-6000) based on the approved Symject™ injection device and intended for the treatment of opioid overdose for which the company submitted a New Drug Application, or NDA, in December 2018 which was accepted for review by the FDA in March 2019; a fast-disintegrating sublingual tablet containing tadalafil (APC-8000), a drug used for treating ED, for which the company submitted an NDA for ED in December 2018 which was the subject of a refusal to file letter from the FDA in February 2019; a beclomethasone metered dose inhaler product candidate (APC-1000) intended for the treatment of asthma for which the company submitted an IND in January 2018 and has initiated the start-up phase of Phase 3 studies; and a fluticasone (APC-4000) dry powder inhaler, or DPI, product candidate for the treatment of asthma. 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. In July 2018, we entered into a distribution and commercialization agreement with Sandoz Inc., a division of Novartis AG, to commercialize the Symjepi product. Under the terms of the agreement, we appointed Sandoz as the exclusive distributor of Symjepi in the United States and related territories.

Our subsidiary U.S. Compounding, Inc., or USC, which we acquired in April 2016 and which is registered as a drug compounding outsourcing facility under Section 503B of the U.S. Food, Drug & Cosmetic Act, as amended, or 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, animals, 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, and topical compounds for pain and men's and women's health products. USC's compounded formulations are often 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 will need to raise a substantial amount of funding and make significant investments in, among other things, new 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., a division of Novartis AG, 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, or the Territory, 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 Territory, subject to the provisions of the agreement, in partial consideration of an upfront fee by Sandoz and potential performance-based milestone payments. As part of the agreement, Sandoz has commercial rights to our Symjepi™ (epinephrine) Injection 0.3mg product, as well as the lower dose Symjepi (epinephrine) Injection 0.15mg product. We retain rights to the intellectual property subject to the agreement and to commercialize both products outside of the Territory, but have granted Sandoz a right of first negotiation regarding such territories. 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 agreement provides 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 will be the supplier of the product to Sandoz, and Sandoz will order and pay us a supply price for quantities of products ordered. We will be 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. We are responsible for component sourcing and regulatory compliance in the supply chain and for testing of lots of product.

Sandoz has agreed to use commercially reasonable efforts to commercialize the product, subject to various conditions and to the other provisions of the agreement. The Agreement does not include minimum payments to us by Sandoz, minimum requirements for sales of product by Sandoz or, with certain exceptions, minimum purchase commitments by Sandoz. Under the agreement, Sandoz has sole discretion in determining pricing, terms of sale, marketing, and selling decisions relating to the product.

On January 16, 2019, we announced that Sandoz had launched Symjepi™ (epinephrine) 0.3 mg Injection in the U.S. market. Symjepi™ will be rolled out via a phased launch and will initially be available in the institutional setting, an established channel where Sandoz has a significant experience and knowledge, followed by anticipated introduction into the retail market. We also anticipate that Sandoz will launch the lower dose Symjepi™ 0.15 mg Injection product in the U.S. markets.

Going Concern and Management Plan

Our independent registered public accounting firm has included a "going concern" explanatory paragraph in its report on our financial statements for the years ended December 31, 2018 and 2017 indicating that we have incurred recurring losses from operations and are dependent on additional financing to fund operations, and that these conditions raise substantial doubt about our ability to continue as a going concern. As of December 31, 2018, we had cash and cash equivalents of approximately $19.3 million, an accumulated deficit of approximately $153.0 million, and liabilities of approximately $11.7 million. We anticipate that we may need additional funding during 2019 to continue operations, satisfy our obligations, fund the future expenditures that we believe will be required to support commercialization of our products and conduct the clinical and regulatory work to develop our product candidates. Such additional funding may not be available, may not be available on reasonable terms, and 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.

The above conditions raise substantial doubt about our ability to continue as a going concern. The financial statements included elsewhere herein for the year ended December 31, 2018, 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. In preparing these consolidated financial statements, consideration was given to our future business as described elsewhere herein, which may preclude us from realizing the value of certain assets. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business. Without additional required funds in 2019, from debt or equity financing, sales of assets, sales or out-licenses of intellectual property or technologies, or from a business combination or a similar transaction, we could exhaust our resources and be unable to continue operations at anticipated levels or at all.

Our management intends to attempt to secure additional required funding through equity or debt financing, sales or out-licensing of product candidates or intellectual property assets, seeking partnerships with other pharmaceutical companies or third parties to co-develop and fund research and development efforts, or similar transactions, and through revenues from sales of compounded sterile formulations. However, there can be no assurance that we will be able to obtain any sources of funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures and delay development or commercialization of some or all of our products. 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 2019 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 naloxone and tadalafil product candidates;
- continue development of our allergy and respiratory product candidates;
- continue development of the DPI product candidates;
- pursue the development of other product candidates that we may develop or acquire;
- fund clinical trials and seek regulatory approvals;
- 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, 2018 and for the year ending December 31, 2017.

Years Ended December 31, 2018 and 2017

Revenues

Revenues were approximately $15,087,000 and $13,073,000 for the years ended December 31, 2018 and 2017, respectively. Revenues increased by approximately $2,014,000 in the 2018 period compared to the comparable period of 2017. The increase in revenues for the 2018 year compared to 2017 reflected an increase in sales of USC's sterile and non-sterile pharmaceutical formulations resulting in part from price increases; increase in unit sales production capacity in order to meet product demand; and marketing personnel efforts. Although our goal is to increase revenues from sales of compounded formulations and preparations by USC, we cannot provide any assurances regarding the level of revenues and profitability in future periods from sales of compounded formulations and preparations by USC.

Cost of Goods Sold

Cost of goods sold was approximately $9,798,000 and $7,420,000 for the years ended December 31, 2018 and 2017, 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 cost of goods sold for 2018 compared to 2017 increased primarily due to the increase of approximately $1,711,000 in compensation as a result of new hires related to the increase in production, increases in salaries and bonus accruals, expenses associated with stock options grants, other employee benefits and consulting expenses. Approximately $667,000 of the increase for the year ended 2018 compared to the same period in 2017 was due to the increase in obsolete inventory expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses ("SG&A") consist primarily of depreciation and amortization, legal fees, accounting and audit fees, professional/consulting fees and employee compensation. SG&A expenses for the years ending December 31, 2018 and 2017 were approximately $25,948,000 and $22,819,000, respectively. Compensation expense for SG&A employees increased by approximately $2,001,000 for the 2018 year compared to 2017, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with equity compensation and other employee benefits. Approximately $495,000 of the increase for the 2018 year compared to 2017 was due to PDUFA fees, marketing, selling, insurance, consulting, outside services and travel expenses. Approximately $267,000 of the increase for the 2018 year compared to 2017 was due to increases in patent fees. Approximately $366,000 of the increase for the 2018 year compared to the same period of 2017 was due to increases in occupancy costs, supplies, taxes, and other related 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 $18,794,000 and $7,527,000 for the years ended December 31, 2018 and 2017, respectively. The increase in research and development expenses for the year ended December 31, 2018, compared to the 2017 year was primarily due to an increase of approximately $8,747,000 in development costs of our product candidates, including APC-1000, APC-4000, APC-6000, and APC-8000 product candidates, including approximately $2,600,000 in combined filing fees for submitting NDAs for APC-6000 and APC-8000. This amount was partially offset by a decrease of approximately $355,000 in development costs attributed to the Symjepi™ (epinephrine) Injection 0.3mg and 0.15mg products and other product candidates. Compensation for Research and Development employees, consulting, and other operating expenses increased by approximately $1,582,000 for the year ended December 31, 2018, compared to the 2017 year, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with equity compensation and other employee benefits. Research and development costs for the 2018 year also included an increase of approximately $1,293,000 of obsolete Symjepi™ inventory that is expected to expire before its sale.

Impairment Expense

Impairment expenses for the years ended December 31, 2018 and 2017 were approximately $11,000 and $96,000, respectively. The impairment expense was attributable to assets damaged at the USC facility.

Other Income (Expenses)

Other Income (Expense) consists primarily of expense on inducement to exercise warrants, interest expense and loss on asset disposal. Other income (expense) for the years ended December 31, 2018 and 2017 was approximately $88,000 and ($1,089,000), respectively. The increase in other income and decrease in other expenses in 2018, compared to 2017, was primarily due to decreases of approximately $960,000 in warrant exercise inducement expenses and approximately $74,000 in interest expenses. These amounts were partially supplemented by the increase of approximately $143,000 in interest income during the 2018 period compared to the comparable period of 2017. The decrease in expenses relating to inducement to exercise warrants was in connection with the transactions entered into by the company in the third quarter of 2017 with certain warrant holders to exercise certain warrants at a reduced exercise price. The decrease in debt related expenses for the year ended December 31, 2018, compared to the comparable period in 2017 was due to the working capital loan in the principal amount of $2.0 million and other bank loan obligations assumed in connection with the acquisition of USC in April 2016 being fully paid off.

Income Tax Benefit

The income tax benefit for the years ended December 31, 2018 and 2017 was approximately $369,000 and $339,000 respectively. The income tax benefit for 2017 reflected the remeasurement of the net deferred tax liability as part of the Tax Cuts and Jobs Act, enacted on December 22, 2017. The income tax benefit for 2018 reflected the reassessment of the company's valuation allowance related to the portion of the deferred tax asset that the company determined to be more-likely-than-not to be recognized. The reassessment resulted from the fact that the company's indefinite lived taxable temporary differences are now available as a source of future taxable income to offset NOLs generated in the current year which, under the Tax Cuts and Jobs Act, do not expire. This reassessment resulted in a provision benefit of $369,000.

Liquidity and Capital Resources

We have incurred net losses of approximately $39.0 million and $25.5 million for years ended December 31, 2018 and 2017, respectively. Since our inception, June 6, 2006, and through December 31, 2018, we have an accumulated deficit of approximately $153.0 million. Since inception and through December 31, 2018, 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 $175.1 million in debt and equity financing transactions, consisting of approximately $23.5 million in debt financing and approximately $151.6 million in equity financing transactions. We may need significant additional funding during 2019 to satisfy our obligations and fund the future expenditures that we believe will be required to support commercialization of our products and conduct the clinical and regulatory work to develop our product candidates. We may finance future cash needs primarily through proceeds from equity or debt financings, loans, share of profits anticipated to be received from Sandoz relating to sales in the U.S. of our Symjepi product, sales of assets, out-licensing transactions, and/or collaborative agreements with corporate partners, and from revenues from our sale of compounded pharmacy formulations. We have used the net proceeds from debt and equity financings for general corporate purposes, which have included funding for research and development, selling, general and administrative expenses, working capital, reducing indebtedness, pursuing and completing acquisitions or investments in other businesses, products or technologies, and for capital expenditures. Assuming adequate funding, we anticipate that we may make capital expenditures during 2019 of at least approximately $1.9 million to $2.5 million including, without limitation, expenditures relating to a new USC facility and the construction of manufacturing assembly lines for our Symjepi™ (epinephrine) Injection 0.3mg and 0.15mg products and naloxone (APC-6000) product candidate.

Net cash used in operating activities from continuing operations for the years ended December 31, 2018 and 2017 were approximately $32.7 million and $15.1 million, respectively. Net cash used in operating activities increased primarily due to the increase in operating expenses, accounts receivable, inventories and prepayments as compared to 2017.

Net cash used in investing activities was approximately $3,535,000 and $2,088,000 for years ended December 31, 2018 and 2017, respectively. The net cash used in investing activities increased primarily due to the purchase of additional equipment.

Net cash provided by financing activities was approximately $37.1 million and $30.5 million for the years ended December 31, 2018 and 2017, respectively. Net cash flows provided by financing activities increased for the period ended December 31, 2018 due to the issuance of common stock generating net proceeds of approximately $37.6 million, partially offset by the payment of loans of approximately $0.5 million; in 2017, capital raised from issuance of common stock and warrant exercises totaled approximately $32.8 million and payment of bank loans amounted to approximately $2.3 million.

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, 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 USC 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. Under the loan agreements, we are required to make current periodic interest and principal payments under the Amended Loan Documents, in an amount of approximately $57,000 per month; the amount of required interest payments is subject to change depending on future changes in interest rates. The balances of the USC Working Capital Line, Building Loan and Equipment Loan are due and payable on February 28, 2018, August 8, 2019 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. Though the maturity dates of the USC loans may be extended at later dates. We also entered into a loan and security agreement with the Lender, referred to as the Adamis Working Capital Line, pursuant to which we may borrow up to an aggregate of $2,000,000 to provide working capital to USC, subject to the terms and conditions of the loan agreement. Interest on amounts borrowed under the Adamis Working Capital Line accrues at a rate equal to the prime interest rate, as defined in the agreement. Interest payments are required to be made quarterly. As amended effective March 31, 2017, the entire outstanding principal balance, and all accrued and unpaid interest and all other sums payable pursuant to our loan agreement with the Bank, are due and payable on March 1, 2018, or sooner upon the occurrence of certain events as provided in the loan agreement and related documents. In March 2018, we agreed with the lender to extend the maturity date of this loan to June 1, 2018. Our obligations under the Adamis Working Capital Line are secured by certain collateral, including without limitation our interest in amounts that we have loaned to USC; a warrant that we issued to the Lender to purchase up to 1,000,000 shares of our common stock at an exercise price equal to par value per share, only exercisable by Lender if we are in default under the loan documents and if the Lender delivers a notice to us and we do not cure the default within the applicable cure period; and our Certificate of Deposit ("CD") with the Lender of approximately $1,000,000. Further, if at any time before the repayment of the loan, the value of the sum of (i) the amount of the funds in the CD, plus (ii) the product of: (A) the number of unexercised shares under the warrant multiplied by (B) the value of our common stock, falls below the product of (Y) 1.5 multiplied by (Z) the outstanding principal balance of the note evidencing the Adamis Working Capital Line, then following delivery of a notice from the Bank to the Company, the company will either: (1) amend the warrant or provide an additional warrant to provide Lender with rights to purchase additional shares of common stock; or (2) reduce the principal balance of the note to bring us in compliance with the requirements set forth above, and failure to comply with this requirement after notice from Lender is an event of default under the loan documents. Under the terms of the Warrant, the Lender agreed that following any exercise of the warrant, Lender will use its best efforts to sell as promptly as reasonably practicable following such exercise, the shares of common stock acquired by the Lender upon such exercise, and that all of the net proceeds from such sales of warrant shares will be applied in satisfaction of the Company's obligations under the loan documents. On June 28, 2018, the company and the Lender amended the warrant and the loan and security agreement to provide that effective as of June 1, 2018, if the company has not paid in full all amounts that are required to be paid to the Lender under the loan documents on or before the maturity date of the loan, then the Lender may exercise the Warrant, in whole or in part, to acquire a number of warrant shares as described above. In July 2018, the Lender delivered a notice of exercise of the warrant and sold warrant shares in an amount sufficient to satisfy substantially all of the outstanding principal balance of the loan. See Note 12 to the financial statements included elsewhere herein for additional information. The company paid the remaining principal and accrued unpaid interest, and there is no outstanding balance under the Adamis Working Capital Line. In addition, the Lender released the company's $1.0 million restricted Certificate of Deposit that had served as additional collateral for the Adamis Working Capital Line, and the amount is no longer restricted cash.

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 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.

For additional information concerning our debt and equity financing transactions, and our loan agreements, see Notes 10, 11, 15 and 16 accompanying our financial statements included elsewhere herein.

As noted above under the heading "Going Concern and Management Plan," through December 31, 2018, Adamis had incurred substantial losses. The availability of any required additional funding cannot be assured. If we do not obtain additional equity or debt funding in the near future, our cash resources will be depleted and we will be required to materially reduce or suspend operations. Even if we are successful in obtaining additional funding to permit us to continue operations at the levels that we desire, substantial time will pass before we obtain regulatory marketing approval for any products and begin to realize revenues from sales of specialty pharmaceutical products, and during this period Adamis will require additional funds. No assurance can be given as to the timing or ultimate success of obtaining future funding. As noted under the heading Recent Developments, the Company will be required to devote additional cash resources, which could be significant, 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 financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these 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 financial statements appearing elsewhere in this Annual Report on Form 10-K.

Segment Information. The company is engaged primarily in the discovery, development and sales of pharmaceutical, specialty biopharmaceutical and other drug products. Accordingly, the company has determined that it operates in one operating segment.

Revenue Recognition. 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 five-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

Cost of Sales. Our cost of sales includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, the write-off of obsolete inventory and other related expenses.

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 USC's history of past write-offs and collections and current credit conditions.

Inventories. Inventories are valued at the lower of cost or net realizable value. The cost of inventories is determined using the first-in, first-out ("FIFO") method. Inventories consist of compounding formulation raw materials, work-in-process, currently marketed products, and device supplies. Monthly, the company reviews the expiration dates of the raw materials, work-in-process and finished goods inventory, and a reserve for obsolescence is recorded based on the expiration dates.

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 and Other Long-Lived Assets. 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.

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, 2018 and 2017, and no impairment of goodwill or acquired intangibles was identified.

Deferred Income Taxes. Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the tax basis of such assets and liabilities. The company maintains a valuation allowance against its deferred tax assets due to the uncertainty regarding the future realization of such assets, which is based on historical taxable income, projected future taxable income and the expected timing of the reversals of existing temporary differences. Until such time as the company can demonstrate that it will no longer incur losses, or if the company is unable to generate sufficient future taxable income, it could be required to maintain the valuation allowance against its deferred tax 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.

Derivative Instruments and Hedging Activities. Derivatives are recognized as either assets or liabilities in the consolidated balance sheets and are measured at fair value. The treatment of gains and losses resulting from changes in the fair values of derivative instruments is dependent on the use of the respective derivative instrument and whether they qualify for hedge accounting.

Off Balance Sheet Arrangements

At December 31, 2018, we did not have any off balance sheet arrangements.

Recent Accounting Pronouncements

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

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

In connection with the preparation of this Annual Report on Form 10-K, an evaluation was carried out by our management, with the participation of the Principal Executive Officer and Accounting Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act) as of December 31, 2018. Disclosure controls and procedures are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms and that such information is accumulated and communicated to management, including the Principal Executive Officer and Accounting Officer, to allow timely decisions regarding required disclosures.

Based on their evaluation, our Principal Executive Officer and Accounting Officer concluded that disclosure controls and procedures were effective as of December 31, 2018.

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 Annual Report on Internal Control Over Financial Reporting" and is incorporated herein by reference. 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, 2018. 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 has concluded that our internal control over financial reporting was effective as of December 31, 2018, based on those criteria. Effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by Mayer Hoffman McCann, P.C., an independent registered public accounting firm, as stated in their report which appears elsewhere herein.

The independent registered public accounting firm that audited the consolidated financial statements that are included in this Annual Report on Form 10-K has issued an audit report on our internal control over financial reporting. The report appears below.

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Adamis Pharmaceuticals Corporation and Subsidiaries' ("Company") internal control over financial reporting as of December 31, 2018, based on criteria established in the *2013 Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO criteria). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years ended December 31, 2018 and 2017, of the Company and our report dated March 15, 2019, expressed an unqualified opinion that included explanatory paragraphs regarding the Company's change in method of accounting for revenue from contracts with customers as a result of the adoption of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, effective January 1, 2018, as well as the Company's ability to continue as a going concern.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 15, 2019

Changes in Internal Controls

There has been no change during the quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not Applicable.

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, 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
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
4.1	Amended and Restated Bylaws of the Company		S-4/A 333-155322	01/12/09
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
*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
10.6	Agreement dated as of October 8, 1996 by and among Biosyn, Inc., Edwin B. Michaels and E.B. Michaels Research Associates, Inc. (Confidential treatment has been granted with respect to portions of this agreement.)		10-K	03/31/05
10.7	Funding Agreement dated October 12, 1992, by and between Ben Franklin Technology Center of Southeastern Pennsylvania and Biosyn, Inc.		S-4/A 333-155322	01/12/09
10.8	License Agreement dated July 28, 2006, by and between Nevagen, LLC and Adamis Pharmaceuticals Corporation		S-4/A 333-155322	01/12/09
10.9	Amendment to License Agreement dated December 29, 2008, by and between Nevagen, LLC and Adamis Pharmaceuticals Corporation		S-4/A 333-155322	01/12/09
10.10	Common Stock Purchase Agreement dated as of November 10, 2010, by and between Adamis Pharmaceuticals Corporation and the Purchaser named therein (Confidential treatment has been granted for portions of this exhibit.)		8-K	11/12/10
10.11	Registration Rights Agreement dated as of November 10, 2010, by and between Adamis Pharmaceuticals Corporation and the Purchaser named therein		8-K	11/12/10
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

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference	
			Form/ File No.	Date
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	First Amendment to Common Stock Purchase Agreement dated as of June 30, 2011, by and between the Company and Eses Holdings (FZE)		10-K	07/07/11
10.19	Second Amendment to Common Stock Purchase Agreement dated as of November 10, 2011, by and between the Company and Eses Holdings (FZE)		8-K	11/21/11
10.20	Third Amendment to Common Stock Purchase Agreement dated as of January 31, 2012, by and between the Company and Eses Holdings (FZE)		10-Q	02/14/12
10.21	Securities Purchase Agreement dated as of June 11, 2012		8-K	06/15/12
10.22	10% Senior Convertible Note dated as of June 11, 2012		8-K	06/15/12
10.23	Form of Subsidiary Guarantee dated as of June 11, 2012		8-K	06/15/12
10.24	Convertible Promissory Note dated as of June 11, 2012		8-K	06/15/12
10.25	Amendment to Convertible Promissory Note dated March 26, 2014		8-K	04/01/14
10.26	Securities Purchase Agreement dated as of April 5, 2013		8-K	04/08/13
10.27	12% Convertible Debenture dated April 5, 2013		8-K	04/08/13
10.28	Subscription Agreement dated as of June 26, 2013		8-K	07/01/13
10.29	Form of Secured Convertible Notes dated June 26, 2013		8-K	07/01/13
10.30	Form of Warrants dated June 26, 2013		10-Q	11/14/14
10.31	Consent and Waiver		8-K	10/31/13
10.32	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
10.33	Lease Agreement dated April 1, 2014, between the Registrant and Pacific North Court Holdings, L.P.		10-KT	03/26/15
10.34	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
10.35	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
10.36	Form of Warrants dated June 26, 2013		10-Q	11/14/14
10.37	Form of Warrant dated January 26, 2016		8-K	01/26/16
10.38	Purchase Agreement		8-K	01/26/16
10.39	Registration Rights Agreement dated as of January 26, 2016		8-K	01/26/16
10.40	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
10.41	Business Loan Agreement between 4 HIMS, LLC and First Federal Bank dated August 8, 2014, and related loan documents		10-Q	08/15/16
10.42	Business Loan Agreement between Tribute Labs, LLC and First Federal Bank dated March 21, 2014, and related loan documents		10-Q	08/15/16
10.43	Loan Amendment, Forbearance and Assumption Agreement between the Company and Bear State Bank, N.A.		10-Q	08/15/16
10.44	Development, License and Commercialization Agreement dated as of May 9, 2016, between the Company and Watson Laboratories, Inc. [Confidential treatment has been granted for portions of this exhibit]		10-Q	08/15/16
10.45	Loan Amendment and Assumption Agreement and related Agreements and Instruments dated as of November 3, 2016		10-K	03/30/17
10.46	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
10.47	Amendment to Loan Agreement dated as November 3, 2016 between Bear State Bank, N.A., and the Company		10-K	03/30/17
10.48	September 2016 Amendment to Commercial Line of Credit Agreement and Note		10-K	03/30/17
10.49	Loan Release Agreement dated as of November 14, 2016		10-K	03/30/17
10.50	Form of Common Stock Purchase Warrant dated January 26, 2016		8-K	01/26/16
10.51	Amended and Restated Common Stock Purchase Warrant dated August 19, 2014		8-K	01/26/16
10.52	Purchase Agreement dated January 26, 2016		8-K	01/26/16
10.53	Amended and Restated Registration Rights Agreement dated January 26, 2016		8-K	01/26/16
10.54	Agreement and Plan of Merger by and among the Company, US Compounding, Inc., Ursula MergerSub Corp. and Eddie Glover dated as of March 28, 2016		8-K	03/29/16
10.55	Form of Joinder Agreement and General Release dated March 28, 2016		8-K	03/29/16
10.56	Loan and Security Agreement by and between the Company and Bear State Bank, N.A., dated March 28, 2016		8-K	03/29/16
10.57	Common Stock Purchase Warrant dated March 28, 2016		8-K	03/29/16
10.58	Purchase Agreement dated July 11, 2016		8-K	07/12/16
10.59	Registration Rights Agreement dated July 11, 2016		8-K	07/12/16
10.60	Form of Common Stock Purchase Warrant dated July 11, 2016		8-K	07/12/16
10.61	Form of Common Stock Purchase Warrant dated August 3, 2016		8-K	07/29/16
10.62	Placement Agency Agreement between Maxim Group LL and the Company dated July 29, 2016		8-K	07/29/16
10.63	Form of Securities Purchase Agreement dated July 29, 2016		8-K	07/29/16
*10.64	2017 Bonus Plan		10-K	03/30/17
10.65	Executive Employment Agreement between the Company and Eddie W. Glover dated March 28, 2016*		10-K	03/30/17
*10.66	2018 Bonus Plan		8-K	02/27/18
10.67	Compensation Committee Authorization Regarding Discretionary Payments		8-K	02/27/18
*10.68	2019 Bonus Plan		8-K	2/5/2019
10.69	Underwriting Agreement dated January 9, 2015		8-K	01/09/15
*10.70	Executive Employment Agreement between the Company and Ronald B. Moss, M.D., dated as of February 28, 2017.		10-K	03/30/17
10.71	March 2017 Amended and Restated Line of Credit Promissory Note		10-K	03/30/17
10.72	March 2017 Amendment to Loan and Security Agreement between the Company and Bear State Bank		10-K	03/30/17
10.73	March 2018 Amendment to Loan and Security Agreement		10-K	12/31/2017
10.74	March 2018 Amended and Restated Line of Credit Promissory Note		10-K	12/31/2017
10.75	June 2018 Amendment to Loan and Security Agreement and Warrant		10-Q	08/19/18
10.76	Underwriting Agreement dated August 2, 2018		8-K	08/02/18
10.77	Distribution and Commercialization Agreement between the Company and Sandoz, Inc. (Confidential treatment has been granted for portions of this exhibit)		10-Q	11/9/2018

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference Form/ File No.	Date
21.1	Subsidiaries of the Registrant		10-K	03/30/17
23.1	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			

* Represents a compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California.

ADAMIS PHARMACEUTICALS CORPORATION

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

Dated: March 15, 2019

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	March 15, 2019
Principal Financial Officer and Principal Accounting Officer:		
/s/ ROBERT O. HOPKINS Robert O. Hopkins	Vice President, Finance, Chief Financial Officer and Secretary	March 15, 2019
Directors:		
/s/ DAVID J. MARGUGLIO David J. Marguglio	Director	March 15, 2019
/s/ RICHARD C. WILLIAMS Richard C. Williams	Chairman	March 15, 2019
/s/ ROBERT B. ROTHERMEL Robert B. Rothermel	Director	March 15, 2019
/s/ WILLIAM C. DENBY, III William C. Denby, III	Director	March 15, 2019

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

TABLE OF CONTENTS

DECEMBER 31, 2018 AND 2017

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 the accompanying consolidated balance sheets of Adamis Pharmaceuticals Corporation and Subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Adoption of New Accounting Standard

As discussed in Note 3 to the financial statements, the Company changed its method of accounting for revenue from contracts with customers as a result of the adoption of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers,* effective January 1, 2018, under the modified retrospective method.

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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in the *2013 Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 15, 2019 expressed an unqualified opinion.

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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ Mayer Hoffman McCann P.C.

We have served as the Company's auditor since 2007.
San Diego, California
March 15, 2019

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents	$ 19,271,642	$ 17,323,241
Restricted Cash	—	1,009,461
Accounts Receivable, net	1,155,166	830,090
Inventories	3,279,032	1,824,558
Prepaid Expenses and Other Current Assets	2,078,413	474,180
	25,784,253	21,461,530
LONG TERM ASSETS		
Security Deposits	54,655	54,655
Intangible Assets, net	13,210,596	15,686,687
Goodwill	7,640,622	7,640,622
Fixed Assets, net	9,867,921	6,559,664
Other Non-Current Assets	1,800,000	—
Total Assets	$ 58,358,047	$ 51,403,158
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable	$ 4,170,720	$ 2,919,120
Deferred Revenue	1,011,246	14,758
Accrued Other Expenses	2,340,095	2,300,672
Accrued Bonuses	1,448,505	1,069,021
Bank Loans - Line of Credit	—	2,000,000
Bank Loans - Building and Equipment, current portion	2,583,134	483,992
	11,553,700	8,787,563
LONG TERM LIABILITIES		
Deferred Tax Liability, net	112,530	485,002
Building and Equipment Loans, net of current portion	—	2,583,109
Total Liabilities	11,666,230	11,855,674
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Common Stock - Par Value $.0001; 100,000,000 Shares Authorized; 47,814,315 and 33,696,920 Issued, 47,291,358 and 33,389,380 Outstanding at December 31, 2018 and December 31, 2017, Respectively.	4,781	3,369
Additional Paid-in Capital	199,696,656	153,546,932
Accumulated Deficit	(153,004,370)	(113,997,588)
Treasury Stock, at cost - 522,957, and 307,540 Shares at December 31, 2018 December 31, 2017, Respectively	(5,250)	(5,229)
Total Stockholders' Equity	46,691,817	39,547,484
	$ 58,358,047	$ 51,403,158

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, 2018	Year Ended December 31, 2017
REVENUE, net	$ 15,086,643	$ 13,073,259
COST OF GOODS SOLD	9,797,988	7,419,988
Gross Profit	5,288,655	5,653,271
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	25,948,062	22,819,224
RESEARCH AND DEVELOPMENT	18,793,836	7,526,784
LOSS ON IMPAIRMENT OF FIXED ASSETS	10,517	96,346
Loss from Operations	(39,463,760)	(24,789,083)
OTHER INCOME (EXPENSE)		
Interest Expense	(157,765)	(231,291)
Interest Income	245,403	102,233
Inducement Expense for Exercise of Warrants	—	(960,230)
Total Other Income (Expense)	87,638	(1,089,288)
Net (Loss) Before Income Taxes	$ (39,376,122)	$ (25,878,371)
Income Tax Benefit	369,340	339,391
Net (Loss)	$ (39,006,782)	$ (25,538,980)
Basic & Diluted (Loss) Per Share:		
Basic & Diluted (Loss) Per Share	$ (1.00)	$ (0.90)
Basic Weighted Average Shares Outstanding	39,085,490	28,349,368

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series Convertible Preferred Stock		Common Stock			Treasury Stock			
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Shares	Amount	Accumulated Deficit	Total
Balance December 31, 2016	625,013	$ 62	22,299,083	$ 2,230	$ 113,741,412	(307,540)	$ (5,229)	$ (88,458,608)	$ 25,279,867
Common Stock Issued, net of issuance cost of $1,228,368	—	—	4,928,572	493	16,021,141	—	—	—	16,021,634
Common Stock Issued for Exercised Options	—	—	2,678	—	—	—	—	—	—
Common Stock Issued for Exercised Warrants, net of issuance fees of $100,109	—	—	5,841,574	584	16,766,066	—	—	—	16,766,650
Warrant Inducement Cost	—	—	—	—	960,230	—	—	—	960,230
1:1 Conversion of Series Preferred Stock to Common Stock	(625,013)	(62)	625,013	62	—	—	—	—	—
Share Based Compensation	—	—	—	—	6,058,083	—	—	—	6,058,083
Net (Loss)	—	—	—	—	—	—	—	(25,538,980)	(25,538,980)
Balance December 31, 2017	—	$ —	33,696,920	$ 3,369	$ 153,546,932	(307,540)	$ (5,229)	$ (113,997,588)	$ 39,547,484
Common Stock Issued, net of issuance cost of $2,630,242	—	—	13,416,667	1,342	37,618,416	—	—	—	37,619,758
Common Stock Issued for Exercised Options	—	—	750	—	—	—	—	—	—
Common Stock Issued for Exercised Warrants	—	—	699,978	70	(70)	—	—	—	—
Payment of Bank Loan - Line of Credit	—	—	—	—	1,996,062	—	—	—	1,996,062
Purchase of Treasury Stock	—	—	—	—	21	(215,417)	(21)	—	—
Share Based Compensation	—	—	—	—	6,535,295	—	—	—	6,535,295
Net (Loss)	—	—	—	—	—	—	—	(39,006,782)	(39,006,782)
Balance December 31, 2018	—	$ —	47,814,315	$ 4,781	$ 199,696,656	(522,957)	$ (5,250)	$ (153,004,370)	$ 46,691,817

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, 2018	Year Ended December 31, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (Loss)	$ (39,006,782)	$ (25,538,980)
Adjustments to Reconcile Net (Loss) to Net		
Cash (Used in) Operating Activities:		
Stock Based Compensation	6,535,295	6,058,083
Inducement Expense to Exercise Warrants	—	960,230
Provision for Bad Debts	95,937	62,910
Provision for Excess and Obsolete Inventory	3,525,783	1,521,222
Depreciation and Amortization Expense	3,098,916	3,063,553
Loss on Impairment of Fixed Assets	10,517	96,346
(Gain) Loss on Sale of Fixed Assets	(758)	20,858
Deferred Tax Provision	(372,472)	(343,554)
Change in Assets and Liabilities:		
(Increase) Decrease in:		
Accounts Receivable - Trade	(421,013)	(87,628)
Inventories	(4,980,257)	(2,403,713)
Prepaid Expenses and Other Current Assets	(1,604,233)	(247,140)
Security Deposits	—	(12,155)
Other Non-Current Assets	(1,800,000)	—
Increase (Decrease) in:		
Accounts Payable	846,123	587,152
Deferred Revenue	996,488	(39,719)
Accrued Other Expenses and Bonuses	418,907	1,169,960
Net Cash (Used in) Operating Activities	(32,657,549)	(15,132,575)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of Equipment	(3,535,364)	(2,063,221)
Purchase of Intangibles	—	(25,837)
Proceeds from Sale of Equipment	—	1,100
Net Cash (Used in) Investing Activities	(3,535,364)	(2,087,958)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from Issuance of Common Stock, net of issuance cost	37,619,758	16,021,634
Proceeds from Exercise of Warrants, net of exercise cost	—	16,766,650
(Payments) of Bank Loan	(487,905)	(2,330,809)
Net Cash Provided by Financing Activities	37,131,853	30,457,475
Increase in Cash, Cash Equivalents and Restricted Cash	938,940	13,236,942
Cash:		
Beginning, Cash, Cash Equivalents and Restricted Cash	18,332,702	5,095,760
Ending, Cash, Cash Equivalents and Restricted Cash	$ 19,271,642	$ 18,332,702

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, 2018	Year Ended December 31, 2017
RECONCILIATION OF CASH AND RESTRICTED CASH		
Cash	$ 19,271,642	$ 17,323,241
Restricted Cash	—	1,009,461
Total Cash and Restricted Cash	$ 19,271,642	$ 18,332,702
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash Paid for Income Taxes	$ 5,613	$ 16,664
Cash Paid for Interest	$ 181,277	$ 216,831
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES		
Increase in Accrued Capital Expenditures	$ 405,477	$ 306,100
Exercise of Warrants for Payment of Working Capital Line	$ 1,996,062	$ —
Acquisition of Treasury Shares in Connection with Warrant Exercise	$ 21	—

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, as shown in the accompanying consolidated financial statements, the Company has sustained substantial recurring losses from operations. In addition, the Company has used, rather than provided, cash in its continuing operations. The company will need significant funding to continue operations, satisfy its obligations and fund the future expenditures that will be required to conduct the clinical and regulatory work to develop its product candidates. Without obtaining additional capital, it would be unlikely for the Company to continue as a going concern. Management intends to attempt to secure additional required funding through equity or debt financings, sales or out-licensing of product candidates or other intellectual property assets, seeking partnerships with other pharmaceutical companies or third parties to co-develop and fund research and development efforts, or similar transactions.

The above 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.

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

The Company is engaged primarily in the discovery, development and sales of pharmaceutical, biotechnology and other drug products. Accordingly, the Company has determined that it operates in one operating segment.

Accounting Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Actual results could differ from those estimates, and the differences could be material.

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.

Restricted Cash

Restricted cash refers to money that is held for a specific purpose and therefore not available to the Company for immediate or general business use. For the years ended December 31, 2018 and 2017, the Company has restricted cash of approximately $0 and $1.0 million, respectively, in the form of a certificate of deposit held by Bear State Bank as part of the collateral relating to the $2.0 million working capital line of credit.

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 USC's history of past write-offs and collections and current credit conditions. Provision for bad debts as of December 31, 2018 and 2017 was approximately $175,000 and $84,000, respectively.

Inventories

Inventories are valued at the lower of cost or net realizable value. The costs of inventories are determined using the first-in, first-out ("FIFO") method. Inventories consist of compounding formulation raw materials, work-in-process, currently marketed products, and device supplies. Monthly, the Company reviews the expiration dates of the raw materials, work-in-process and finished goods inventory, and a reserve for obsolescence is recorded based on the expiration dates. Reserve for obsolescence as of December 31, 2018 and 2017 was approximately $526,000 and $795,000, respectively.

Fixed Assets

Fixed assets are recorded at historical cost or fair value as of the date acquired, and depreciated on a straight line basis with useful lives ranging from 3-30 years.

Acquisitions

The Company has engaged in business combination activity. 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 and Other Long-Lived Assets

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 during the fourth quarter, 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 our goodwill impairment tests during 2018, the Company utilized the approach prescribed under the Accounting Standard Codification, or ASC, 350, as amended by Accounting Standard Update, or ASU, 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"), which the Company adopted on January 1, 2017. ASU 2017-04 requires that an entity perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value.

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.

The Company performed an annual impairment analysis as of December 31, 2018 and 2017, and no impairment of goodwill or other long-lived assets was identified.

Derivative Instruments and Hedging Activities

Derivatives are recognized as either assets or liabilities in the consolidated balance sheets and are measured at fair value. The treatment of gains and losses resulting from changes in the fair values of derivative instruments is dependent on the use of the respective derivative instrument and whether they qualify for hedge accounting. As of December 31, 2018 and 2017, no derivative instruments qualified for hedge accounting.

Revenue Recognition

The Company recognizes revenues 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; and (5) recognize revenue when (or as) each performance obligation is satisfied. Currently, the Company's revenues are entirely attributed to its USC subsidiary. Revenue arrangements consist of a single performance obligation of which control is transferred at a point in time, and represents the amount of consideration the Company expects to receive in exchange for transferring the goods.

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 options to purchase common stock. Stock-based compensation cost for restricted stock units ("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 recognizes stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period.

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, 2018 and 2017, we estimate that we spent approximately $18.8 million and $7.5 million, respectively, on all 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 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. At the adoption date, the Company applied the guidance to all tax positions for which the statute of limitations remained open. Upon implementation, the Company did not recognize any additional liabilities for unrecognized tax benefits. Accordingly, the adoption of the guidance had no impact on the Company's financial statements.

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 penalty accrued related to unrecognized tax benefits in its income tax expense, if any. No interest or penalties have been accrued for all 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 from the calculation of weighted average shares outstanding. Potential dilutive securities for the years ended December 31, 2018 and 2017 consist of outstanding warrants (2,138,887 and 3,189,052, respectively), outstanding options (9,298,101 and 6,726,594, respectively), and outstanding restricted stock units (1,642,212 and 1,300,000, respectively).

	For the Year Ended December 31, 2018	For the Year Ended December 31, 2017
Loss per Share - Basic & Diluted		
Numerator for basic & diluted loss per share	$ 39,006,782	$ (25,538,980)
Denominator for basic & diluted loss per share	39,085,490	28,349,368
Loss per common share - basic & diluted	$ (1.00)	$ (0.90)

Prior Periods Reclassifications

Certain amounts in prior periods have been reclassified to conform with current period presentation related to the provision for excess and obsolete inventory in the consolidated statement of cash flows. The reclassification has no effect on the consolidated balance sheet as of December 31, 2018 and 2017, or the consolidated statement of operations for the years ended December 31, 2018 and 2017.

Recently Adopted Accounting Pronouncements

Utilizing the deferred effective date of January 1, 2018, the Company adopted ASU 2014-09, *Revenue from Contracts with Customers (ASC Topic 606)*, using the modified retrospective method with the cumulative effect of the change recognized in retained earnings. The new guidance, referred to as ASC Topic 606, requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers and replaces most of the existing revenue recognition standards in U.S. GAAP. A five-step model will be utilized to achieve the core principle: (1) identify the customer contract; (2) identify the contract's performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when or as a performance obligation is satisfied.

The Company evaluated the impact that adoption of this new standard will have on its consolidated financial statements and determined that the timing of revenue recognition and amount of revenue recognized is not materially impacted under the new standard. Accordingly, it did not have a material quantitative impact on the Company's revenue recognition relating to sales of compounded pharmacy formulations and other pharmacy products by the Company's USC subsidiary. Refer to Note 4 for further details.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118,* which allowed SEC registrants to record provisional amounts in earnings for the year ended December 31, 2017 due to the complexities involved in accounting for the enactment of the TCJA. The Company recognized the estimated income tax effects of the TCJA in its 2017 Consolidated Financial Statements in accordance with SEC Staff Accounting Bulletin No. 118 ("SAB No. 118"). The provisional amounts recorded in 2017 were adjusted to final estimates in 2018 in connection with filing tax returns for 2017. Refer to Note 20 for further information regarding the impact of these provisions for both 2017 and 2018.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 *Leases* (Topic 842), also referred to as "ASC 842" or "New Lease Standard", which supersedes ASC 840 *Leases* (Topic 840), and provides principles for the recognition, measurement, presentation and disclosure of leases for both leases and lessors. The FASB has continued to clarify this guidance through the issuance of additional ASUs. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification determines whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less may be accounted for similar to existing guidance for operating leases. ASC 842 will be effective for the Company for the year ending December 31, 2019. We will continue to report financial information for fiscal years ending before December 31, 2018 under the current lease accounting standard. The Company will apply the modified retrospective transition method and elect the transition option to use the effective date of January 1, 2019 as the date of initial application. The Company will recognize the cumulative effect of the transition adjustment as of the effective date and does not expect to provide any new lease disclosures for periods before the effective date. The Company elected the package of practical expedients and did not elect the use of the hindsight practical expedient. As a result, the Company will, in effect, continue to account for existing leases in accordance with ASC 840, throughout the entire lease term, including periods after the effective date, with the exception that the Company will apply the new balance sheet recognition guidance for operating leases and apply ASC 842 for remeasurements and modifications after the transition date.

Other key practical expedients elected by the Company (as a lessee) relate to maintaining leases with an initial term of 12 months or less off the balance sheet; not separating lease and non-lease components and the use of the portfolio approach to determine the incremental borrowing rate. For transition purposes, the Company will be using the incremental borrowing rate based on the total lease term and total minimum rental payments. In connection with the adoption of ASC 842, the Company has assembled a cross-functional team supported by external consultants to evaluate the lease portfolio, systems, processes and policy change requirements. The Company completed its identification of leases which comprised of two building leases and two equipment leases. Further, the Company analyzed service contracts and parts assembly arrangements from suppliers and did not identify any material leases of production equipment. On the date of initial application, the Company anticipates that this standard will result in the recognition of right-of-use ("ROU") assets and leasing liabilities on its consolidated balance sheets of approximately $2 million. The Company does not expect a significant impact on its consolidated statement of operations.

In June 2018, the FASB issued Accounting Standards Update No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Non employee Share-Based Payment Accounting*. This update simplifies the accounting for non employee share-based payment transactions by expanding the scope of Topic 718, Compensation-Stock Compensation, to include share-based payment transactions for acquiring goods and services from non-employees. The guidance is effective for annual periods beginning after December 15, 2018, and interim periods within that reporting period. Adoption is not expected to have a significant impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. The new guidance modifies disclosure requirements related to fair value measurement. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the new guidance but does not expect that adopting this guidance will have a material effect on the consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The new guidance aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. Capitalized implementation costs related to a hosting arrangement that is a service contract will be amortized over the term of the hosting arrangement, beginning when the module or component of the hosting arrangement is ready for its intended use. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company is still currently assessing the impact of this new guidance but does not expect adoption will have a material impact on its consolidated financial statements.

NOTE 4: 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.

Currently, the Company's revenues are entirely attributed to its USC subsidiary. USC is a registered drug compounding outsourcing facility under Section 503B of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, and provides prescription compounded medications to humans and animals, including compounded sterile preparations or CSPs, and non-sterile compounds to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. The Company delivers goods on an FOB destination basis.

A contract with a customer exists 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. 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.

The contracts between the Company and the transaction price for medication sales is adjusted for estimated product returns that the Company expects to occur under its return policy based upon historical return rates, which have historically been immaterial. In rare cases when the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes.

The Company has extensive experience with the types of contracts entered with customers and does not have a history of offering a broad range of price concessions nor payment term changes. The Company believes a significant reversal in the amount of cumulative revenue recognized is not probable nor significant. The transaction price for all transactions is based on the price reflected in the individual customer's purchase order. Variable consideration has not been identified as a significant component of the transaction price for any of our transactions.

Disaggregation of Revenue

As operations under a sterile environment are covered by Section 503B of the FDCA, and the U.S. Drug Quality and Security Act, USC's sterile operations are governed by specific regulatory and quality requirements. Any deviation from these exacting standards could result in a stoppage of operations, recall of products, and a significant reduction in revenues. The Company employs rigorous quality controls and outside testing facilities in an effort to minimize the likelihood of this occurrence.

The following table presents the Company's revenues disaggregated by sterile and non-sterile regulatory environments for the twelve months ended December 31, 2018 and 2017.

	Twelve Months Ended December 31,	
	2018	2017
Sterile	$ 9,116,123	$ 7,892,224
Non-Sterile	5,970,520	5,181,035
Total	$ 15,086,643	$ 13,073,259

Revenues from sales of the Company's pharmacy formulations consist, in large part, of sales generated to clinics/hospitals. Adverse economic conditions pose a risk that the Company's customers may reduce or cancel spending, which would impact the Company's revenue. The following table presents the Company's revenue disaggregated by end market for the twelve months ended December 31, 2018 and 2017.

	Twelve Months Ended December 31,	
	2018	2017
Clinics/Hospitals	$ 13,405,933	$ 11,601,652
Direct to Patients	1,680,710	1,471,607
Total	$ 15,086,643	$ 13,073,259

Distribution and Commercialization Agreement

On July 1, 2018, the Company announced that it had entered into a Distribution and Commercialization Agreement (the "Agreement") with Sandoz Inc., a division of Novartis AG, to commercialize the Company's Symjepi™ product for the emergency treatment of allergic reactions (Type I) including anaphylaxis. Under the terms of the Agreement, the Company appointed Sandoz as the exclusive distributor of Symjepi in the United States and related territories ("Territory"), in all fields including both the retail market and other markets, and granted Sandoz 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 product in the Territory, subject to the provisions of the Agreement, in partial consideration of an upfront fee by Sandoz and potential performance-based milestone payments. As part of the Agreement, Sandoz has commercial rights to the Company's Symjepi™ (epinephrine) Injection 0.3mg product, as well as the lower dose Symjepi™ (epinephrine) Injection 0.15mg product, which was approved by the FDA in September 2018 and is intended for use in the treatment of anaphylaxis for patients weighing 33-65 pounds and for which the Company submitted a supplemental new drug application to the FDA on November 27, 2017. The Company retains rights to the intellectual property subject to the Agreement and to commercialize both products outside of the Territory, but has granted Sandoz a right of first negotiation regarding such territories. 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.

The Agreement provides that Sandoz will pay to the Company 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. The Company will be the supplier of the product to Sandoz, and Sandoz will order and pay the Company a supply price for quantities of products ordered. The Company will be responsible for all manufacturing, component and supply costs related to manufacturing and supplying the product to Sandoz. The Company is responsible for component sourcing and regulatory compliance in the supply chain and for testing of lots of product.

Sandoz has agreed to use commercially reasonable efforts to commercialize the product, subject to various conditions and to the other provisions of the Agreement. The Agreement does not include minimum payments to the Company by Sandoz, minimum requirements for sales of product by Sandoz or, with certain exceptions, minimum purchase commitments by Sandoz. Under the Agreement, Sandoz has sole discretion in determining pricing, terms of sale, marketing, and selling decisions relating to the product. As of December 31, 2018, the Symjepi product has not been commercially launched.

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, 2018 and 2017, $14,758 and $54,478 of the revenues recognized were reported as deferred revenue as of December 31, 2017 and 2016, respectively. The increase of approximately $1.0 million in deferred revenue as of December 31, 2018 was primarily due to a payment received from Sandoz Inc., pursuant to the Agreement between the Company and Sandoz.

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.

The Company capitalized a $2.0 million fee paid to an investment banking firm as an incremental cost of obtaining a contract to commercialize and distribute the Company's first FDA approved product Symjepi™ with Sandoz, Inc. The costs were deferred and will be amortized over the economic benefit period of approximately 10 years from date of product launch. The deferred costs are classified as current or non-current based on the timing of when the Company expects to recognize the expense. The current and non-current portions of the deferred costs were $200,000 included in prepaid expenses and other current assets and $1.8 million included in other non-current assets, respectively, in the Company's consolidated balance sheets.

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 sales and marketing 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; (iii) shipping and handling activities are accounted for as fulfillment costs and recorded in cost of sales.

NOTE 5: CONCENTRATIONS

Financial instruments that potentially subject the Company to credit risk consist principally of cash 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 and restricted 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.

Purchases and Accounts Payable

The Company had three vendors that had balances greater than 10% of trade accounts payable or accounted for more than 10% of total purchases for the year ended December 31, 2018. Vendor A and Vendor B had balances that accounted for 10% each of the total accounts payable at December 31, 2018 but did not account for more than 10% of total purchases for the year. Vendor C accounted for approximately 11% or $4.4 million of total purchases for the year. The Company has no exposure to the elimination of Vendor A and B, there are a number of companies which could provide the same services, and management believes, on comparable terms. Comparatively, the Company had two vendors that had balances greater than 10% of trade accounts payable or accounted for more than 10% of total purchases for the year ended December 31, 2017. Vendor E had a balance that accounted for 25% of total accounts payable at December 31, 2017 and approximately 15% or $3.2 million in total purchases for the year ended December 31, 2017. Vendor F had a balance that accounted for 12% of total accounts payable at December 31, 2017 but did not account for more than 10% of total purchases.

NOTE 6: ACQUISITION of U.S. COMPOUNDING

On April 11, 2016, the Company acquired the net assets and assumed the principal debt obligations of U.S. Compounding, Inc. in a merger transaction (the "Merger") pursuant to which the Company acquired USC and USC continued as a wholly owned subsidiary of the Company. The acquisition is accounted for using the purchase method of accounting. USC is registered as a drug compounding outsourcing facility under Section 503B of the FDCA and the U.S. Drug Quality and Security Act. The total consideration for the transaction was $15,967,942. Refer to Note 10.

NOTE 7: INVENTORIES

Inventories at December 31, 2018 and December 31, 2017 consisted of the following:

	December 31, 2018	December 31, 2017
Finished Goods	$ 1,320,738	$ 256,050
Raw Material	527,308	560,828
Devices	1,430,986	1,007,680
	$ 3,279,032	$ 1,824,558

Reserve for obsolescence as of December 31, 2018 and December 31, 2017 was approximately $526,000 and $795,000, respectively.

NOTE 8: PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2018 and December 31, 2017:

	December 31, 2018	December 31, 2017
Prepaid Insurance	$ 175,253	$ 75,592
Prepaid - Research and Development	1,308,517	—
Other Prepaid	591,203	390,569
Other Current Assets	3,440	8,019
	$ 2,078,413	$ 474,180

NOTE 9: FIXED ASSETS

Fixed assets at December 31, 2018 and December 31, 2017 are summarized in the table below:

Description	Useful Life (Years)	December 31, 2018	December 31, 2017
Building	30	$ 3,040,000	$ 3,040,000
Machinery and Equipment	3 - 7	2,244,744	1,525,643
Furniture and Fixtures	7	126,654	126,654
Automobile	5	9,395	9,395
Leasehold Improvements	7 - 15	284,037	284,037
Total Fixed Assets		5,704,830	4,985,729
Less: Accumulated Depreciation		(1,578,049)	(959,380)
Land		460,000	460,000
Construction In Progress - Equipment		5,281,140	2,073,315
Fixed Assets, net		$ 9,867,921	$ 6,559,664

For the years ended December 31, 2018 and 2017, depreciation expense was approximately $623,000 and $588,000, respectively. The additions to fixed assets of approximately $2,369,000 during 2017 were primarily due to the construction of the assembly line for our Symjepi™ (epinephrine) Injection 0.3mg product, and additional fixed assets purchased by USC. The additions to fixed assets of approximately $3,941,000 during 2018 were primarily due to the USC relocation of the 503B operations into a new facility and the construction of the assembly line for Symjepi™. For the year ended December 31, 2018, the Company recorded a loss of approximately $11,000, related to the impairment of fixed assets of approximately $15,000 with accumulated depreciation of approximately $4,000.

NOTE 10: INTANGIBLE ASSETS AND GOODWILL

Intangible assets at December 31, 2018 and December 31, 2017 are summarized in the table below:

December 31, 2018	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	$ (4,854,350)	$ 4,854,350
Transition Services Agreement, 1 year	194,200	(194,200)	—
FDA 503B Registration & Compliance, 10 years	3,963,000	(1,077,716)	2,885,284
Non-compete Agreement, 3 years	1,639,000	(1,485,721)	153,279
Customer Relationships, 10 years	5,572,000	(1,515,274)	4,056,726
Website Design, 3 years	16,163	(9,880)	6,283
Total Definite-lived Assets	21,093,063	(9,137,141)	11,955,922
Trade Name and Brand, Indefinite	1,245,000	—	1,245,000
Symjepi™ Domain Name	9,674	—	9,674
Balance, December 31, 2018	$ 22,347,737	$ (9,137,141)	$ 13,210,596

December 31, 2017	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	$ (3,883,480)	$ 5,825,220
Transition Services Agreement, 1 year	194,200	(194,200)	—
FDA 503B Registration & Compliance, 10 years	3,963,000	(681,416)	3,281,584
Non-compete Agreement, 3 years	1,639,000	(939,389)	699,611
Customer Relationships, 10 years	5,572,000	(958,074)	4,613,926
Website Design, 3 years	16,163	(4,491)	11,672
Total Definite-lived Assets	21,093,063	(6,661,050)	14,432,013
Trade Name and Brand, Indefinite	1,245,000	—	1,245,000
Symjepi™ Domain Name	9,674	—	9,674
Balance, December 31, 2017	$ 22,347,737	$ (6,661,050)	$ 15,686,687

Amortization expense for years ended December 31, 2018 and 2017 was approximately $2,476,000 and $2,475,000, respectively.

Estimated amortization expense of definite-lived intangible assets at December 31, 2018 for each of the five succeeding years and thereafter is as follows:

Year ending December 31,	
2019	$ 2,083,034
2020	1,925,267
2021	1,924,370
2022	1,924,370
2023	1,924,370
Thereafter	2,174,511
Total	$ 11,955,922

Goodwill recorded related to the acquisition of USC in 2016 was approximately $7,641,000. Goodwill is calculated as the excess of the consideration transferred over the net assets recognized and represents the future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. Goodwill is not amortized but rather evaluated for impairment annually or more frequently, if indicators of impairment exist. If the impairment evaluations for goodwill indicate the carrying amount exceeds the estimated fair value, an impairment loss is recognized in an amount equal to that excess. The carrying value of the Company's goodwill as of December 31, 2018 and 2017 was approximately $7,641,000.

The Company performs an annual impairment testing as of December 31 each year. As of December 31, 2018 and 2017, no impairment of goodwill or acquired intangibles was identified. The Company is not aware of an event or change in circumstances that would indicate the carrying value of any assets held by USC may be impaired as of the measurement date.

NOTE 11: ACCRUED OTHER EXPENSES

Accrued other expenses at December 31, 2018 and December 31, 2017:

	December 31, 2018	December 31, 2017
Accrued Commissions	$ 399,971	$ 247,197
Accrued Expenses	831,670	950,063
Accrued PTO	421,178	265,445
Accrued Salaries	572,402	345,695
Accrued Sales Taxes	77,058	480,895
Accrued State Tax	3,895	4,594
Deferred Rent	33,921	6,783
	$ 2,340,095	$ 2,300,672

NOTE 12: DEBT

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

Working Capital Line of Credit

On March 28, 2016, the Company entered into a loan and security agreement (sometimes referred to as the "Adamis Working Capital Line") with Bear State Bank, N.A. (the "Lender" or the "Bank"), pursuant to which the Company may borrow up to an aggregate of $2,000,000 to provide working capital to USC, subject to the terms and conditions of the loan agreement. Interest on amounts borrowed under the Adamis Working Capital Line accrues at a rate equal to the prime interest rate, as defined in the agreement. Interest payments are required to be made quarterly. As amended, the entire outstanding principal balance, and all accrued and unpaid interest and all other sums payable pursuant to the loan documents, were due and payable on June 1, 2018. The Company's obligations under the loan agreement were secured by certain collateral, including without limitation its interest in amounts that it has loaned to USC, and a warrant that the Company issued to the Bank to purchase up to 1,000,000 shares of the Company's common stock at an exercise price equal to par value per share. The warrant was exercisable only if the Company is in default under the loan agreement or related loan documents, the Lender delivers a notice to the Company and the Company does not cure the default within the applicable cure period. If the warrant became exercisable, then Lender may exercise the warrant in whole or in part, from time to time, to acquire warrant shares in a number that the Lender believes will, upon sale of such shares, be sufficient to cure or pay off the Company's obligations due to the Lender under the loan documents. Under the terms of the Warrant, the Lender agreed that following any exercise of the warrant, Lender will use its best efforts to sell as promptly as reasonably practicable following such exercise, the shares of common stock acquired by the Lender upon such exercise, and that all of the net proceeds from such sales of warrant shares will be applied in satisfaction of the Company's obligations under the loan documents. On June 28, 2018, the Company and the Lender amended the warrant and the loan and security agreement to provide that effective as of June 1, 2018, if the Company has not paid in full all amounts that are required to be paid to the Lender under the loan documents on or before the maturity date of the loan, then the Lender may exercise the Warrant, in whole or in part, to acquire a number of warrant shares as described above. In July 2018, the Lender delivered a notice of exercise of the warrant and sold warrant shares in an amount sufficient to satisfy substantially all of the outstanding principal balance of the loan. Refer to Note 17. The Company paid in cash the remaining principal and accrued unpaid interest, and there is no outstanding balance under the Adamis Working Capital Line. There no gain or loss upon extinguishment of the debt. In addition, the Lender released the Company's $1.0 million restricted Certificate of Deposit that had served as additional collateral for the Adamis Working Capital Line, and the amount is no longer restricted cash.

As of December 31, 2018 and 2017, the loan balance on the Adamis Working Capital Line of credit was $0 and $2,000,000, respectively. Interest expense for the years ended December 31, 2018 and 2017 was approximately $51,000 and $83,000, respectively.

Loans Assumed from Acquisition of USC:

Building Loan

In connection with the closing of the USC Merger and the transactions contemplated by the Merger Agreement, 4 HIMS, LLC, an entity of which Eddie Glover, the chief executive officer of USC, and certain other former stockholders of USC are members, agreed to sell to the Company, the building and property owned by 4 HIMS 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 4 HIMS and certain other parties previously entered into with the Lender (the "4 HIMS Loan Documents").

On November 10, 2016, a Loan Amendment and Assumption Agreement was entered with into the Bank. Pursuant to the agreement, the Company agreed to pay the Bank monthly payments of principal and interest of $15,411, with a final monthly payment and any other amounts due under the 4 HIMS Loan Document due and payable in August 2019.

As of December 31, 2018 and 2017, the outstanding principal balance owed on the applicable note was approximately $2,249,000 and $2,347,000, respectively. The loan currently bears an interest of 3.75% per year and interest expense for the years ended December 31, 2018 and 2017 was approximately $87,000 and $91,000, respectively.

USC Working Capital Loan

In connection with the Merger, Adamis agreed to be added as a Borrower and to assume the obligations as a Borrower under the USC Working Capital Loan Agreement and related promissory note and other related loan documents (the "USC Working Capital Loan Documents"). Under the USC Working Capital Loan Agreement, Lender agreed to loan funds to USC, as the "Borrower," up to an aggregate principal amount of $2,500,000, and evidenced by the USC Working Capital Note. Borrowings are limited to 80% of qualified trade accounts receivables and 50% of qualified inventories per the borrowing base agreement and are collateralized with trade accounts receivables and inventory.

On November 10, 2016, the Company and Lender agreed to amend the USC Working Capital Loan Documents to provide that the personal property securing the Loan will also secure the Borrower's obligations under the other USC Loan Documents with the Lender. In addition, a new financial covenant replaced the previous financial covenants, providing that USC will, at all times during the term of the loan, maintain a "Cash Flow Coverage Ratio" of not less than 1.2:1. "Cash Flow Coverage Ratio" is defined as: (i) net income plus non-cash expense items including, but not limited to, depreciation expense, amortization expense and option expense for the month in which the measurement date occurs times 12; divided by (ii) the cash required for payments of interest for the prospective twelve (12) month period and current maturities of principal on all outstanding debt to any person or entity, including without limitation to debt by the Company to the Lender. The Cash Flow Coverage Ratio will be measured on the last day of each December, March, June and September, commencing on December 31, 2016. Under the amendment, in lieu of compliance with the foregoing covenant, Borrower has the option, at the time of each quarterly measuring period, of making a principal reduction in the amount of Two Hundred Fifty Thousand Dollars ($250,000).

In addition, pursuant to the amendment, Borrower and Lender agreed that certain other financial covenants set forth in the loan agreement included in the 4 HIMS Loan Documents, the loan agreement included in the Tribute Loan Documents, and the loan agreement included in the USC Equipment Loan Agreement, as well as the original USC Working Capital Loan Agreement described above, are waived for the remainder of the term of the respective loans. The amended loan had a maturity date of September 30, 2017. In May 2017, the Company paid the remaining balance of the USC Working Capital Loan. In November 2017, the Company agreed with the Lender to extend the term of the USC Working Capital Loan agreement to February 28, 2018. 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.

As of December 31, 2018 and 2017, the outstanding unpaid principal balance under the USC Working Capital Loan Agreement was approximately $0. The interest rate on the loan was 3.75% per year, and interest expense for the years ended December 31, 2018 and 2017 was approximately $0 and $23,000, respectively.

Equipment Loans, Consolidated

Equipment Loan, Tribute. In connection with the Merger, Tribute Labs, LLC, a Nevada limited liability company and former related party of USC ("Tribute" or "Borrower") assigned to Adamis all of its rights under the loan agreement, promissory note and related loan documents that Tribute and certain other parties previously entered into with the Lender (the "Tribute Loan Documents"). Adamis agreed to become an additional co-borrower and to assume Borrower's obligations under the Tribute Loan Documents, in consideration of the transfer to USC of laboratory equipment owned by Tribute and used to perform testing services for USC's products, and Lender consented to such assignment. The outstanding unpaid principal balance under the applicable note that was consolidated to one equipment loan was approximately $518,000. Prior to the consolidation, the loan had an interest rate of 4.75% per year.

USC Equipment Loan. In connection with the Merger, Adamis agreed to become a Borrower and to assume the obligations as a Borrower under the USC Equipment Loan Agreement and the related USC Equipment Loan Documents. Under the USC Equipment Loan Agreement, Lender agreed to loan funds to USC, as the "Borrower," up to an aggregate principal amount of $700,000, with amounts loaned evidenced by the Commercial Line of Credit Agreement and Note (the "USC Equipment Note"). The loan is collateralized by USC's property and equipment. The outstanding unpaid principal balance under the USC Equipment Note that was consolidated to one equipment loan was approximately $635,000. The note had an interest rate of 3.25% per year.

Consolidated Equipment Loans. On November 10, 2016, the Company and the Lender agreed to the amendment and consolidation of the above USC and Tribute equipment loans. The principal amount of the consolidated loans is $1,152,890 with an interest rate of 3.75% per annum. The loan is payable in three years at an equal monthly amortization of $33,940 commencing on November 1, 2016, and continuing on the first day of each succeeding month through October 1, 2019. As of December 31, 2018 and 2017, the outstanding unpaid principal balance was approximately $334,000 and $720,000, respectively. Interest expense for the years ended December 31, 2018 and 2017 was approximately $20,000 and $34,000, respectively.

Loan Amendment, Forbearance and Assumption Agreement

In connection with our acquisition of USC in April 2016, Lender, Adamis, USC, 4 HIMS and Tribute (USC, 4 HIMS and Tribute sometimes referred to as the "Initial Loan Parties" and together with Adamis, collectively the "Loan Parties"), and certain individual guarantors, entered into a Loan Amendment, Forbearance and Assumption Agreement (the "Loan Amendment Agreement").

Pursuant to the Loan Amendment Agreement, Adamis was added as a "Borrower" and co-borrower under the loan agreements and related loan documents between USC (and certain other entities) and Lender (the "USC Loan Documents"), and assumed all of the rights, duties, liabilities and obligations as a Borrower and a party under the USC Loan Documents, jointly and severally with the current borrower or borrowers under each of the USC Loan Documents. The parties also agreed that the real and personal property securing each of the USC Loans will also secure each of the other USC Loans, as well as the Adamis Working Capital Line of $2.0 million.

Except as expressly set forth in the Loan Amendment Agreement, as amended, the terms and provisions set forth in the USC Loan Documents were not modified and remain in full force and effect. Subject to the satisfaction of all conditions precedent set forth in the Loan Amendment Agreement, the Bank consented to the transfer of the real and personal property by 4 HIMS and Tribute to Adamis and the foregoing acceptance and assumptions by Adamis. The Loan Amendment Agreement provide for a number of conditions precedent to Bank's obligations under the agreement, including without limitation: (i) satisfactory title insurance and other insurance regarding the 4 HIMS Property; (ii) satisfactory lien searches and UCC-1 financing statements; (iii) any other document and agreements required by the Bank; (iv) accuracy of the representations and warranties set forth in the Loan Amendment Agreement; and (v) certain other customary conditions.

The notes are subject to customary subjective acceleration clauses, effective upon a material impairment in collateral, a material adverse change in the Company's business or financial condition, or a material impairment in the Company's ability to repay the note. As of December 31, 2018, the Company was not in breach of any of the debt covenants.

At December 31, 2018 the principal maturities of the amended long-term debts were as follows:

For the Years Ending December 31	Building Loan	Equipment Loan	Total
2019	$ 2,249,514	$ 333,620	$ 2,583,134

NOTE 13: FAIR VALUE MEASUREMENTS

Fair value measurements adopted by the Company are based on the authoritative guidance provided by the FASB which defines fair value as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. FASB authoritative guidance establishes a fair value hierarchy, which prioritizes the inputs used in measuring fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable inputs other that Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in inactive markets; or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated with observable market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The carrying amounts reported in the Consolidated Balance Sheets for cash and cash equivalents, accounts receivable, accounts payable, notes payable, accrued liabilities and other payables approximate their fair values due to their short-term nature.

NOTE 14: LEGAL MATTERS

The Company may become involved in or subject to, routine litigation, claims, disputes, proceedings and investigations in the ordinary course of business, which in management's opinion will not have a material adverse effect on our financial condition, cash flows or results of operations. Any such litigation could divert management time and attention from Adamis, could involve significant amounts of legal fees and other fees and expenses.

On September 26, 2018, the Company brought action against Belcher Pharmaceuticals, LLC ("Belcher") in the United States District Court for the Middle District of Florida for a declaratory judgment ("Complaint") of non-infringement of certain patents in which Belcher claims rights, relating to certain methods of preparing epinephrine solutions and treating allergic reactions using a method of preparing certain epinephrine solutions (collectively the "Patents-in-Suit"). The Complaint seeks a declaratory judgment that the Company's Symjepi™ Epinephrine Injection ("Symjepi") product does not infringe the Patents-in-Suit. On November 7, 2018, Belcher filed its Answer and Counterclaim to the Complaint and alleged that the Company infringes the Patents-in-Suit as a result of the Symjepi product. Belcher's Counterclaim seeks damages and injunctive relief in conjunction with the infringement claims. The Company responded to the Counterclaim by generally denying any wrongdoing and asserting the affirmative defense that the Patents-in-Suit are invalid. The parties exchanged initial disclosures and initiated discovery on January 11, 2019. A claim construction hearing is currently scheduled for August 15, 2019. The Company believes that its Symjepi product does not infringe any valid and enforceable patent held by Belcher, and that Belcher's Counterclaim is without merit. The Company intends to defend against Belcher's claims and pursue all available legal remedies available to the Company against Belcher.

NOTE 15: 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. The Company also granted the entity a royalty-free non-exclusive license to use any improvements made on the existing technology for research purposes only. The Company and the entity have the right to sublicense with written permission of each party. In the event that the entity sublicenses or sells the improved technology to a third party, then a portion of the total payments, to be decided by mutual agreement, will be due to the Company.

The Company is obligated to make the following milestone payments to the entity based on commencement of various clinical trials and submissions of an application to the FDA for regulatory approval:

Amount	Date due
$ 50,000	Within 30 days of commencement of Phase I/II clinical trial.
$ 50,000	Within 30 days of commencement of a separate Phase II trial as required by the FDA.
$ 300,000	Within 30 days of commencement of a Phase III trial.
$ 500,000	Within 30 days of submission of a biological license application or a new drug application with the FDA.

Total milestone payments are not to exceed $900,000 and can only be paid one time and will not repeat for subsequent products. At December 31, 2018 and December 31, 2017, no milestones have been achieved.

The agreement will remain in effect as long as the patent rights remain in effect. Adamis has the right to terminate the agreement if it is determined that no viable product can come from the technology. Adamis would be required to transfer and assign all filings, rights and other information in its control if termination occurs. Adamis would retain the same royalty rights for license, or sublicense, agreements if the technology is later developed into a product.

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.

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, 2018. 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.

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.

NOTE 16: COMMITMENTS AND CONTINGENCIES

The Company may become involved in or subject to, routine litigation, claims, disputes, proceedings and investigations in the ordinary course of business, which in our opinion will not have a material adverse effect on our financial condition, cash flows or results of operations. Any such litigation could involve significant amounts of legal fees and other fees and expenses.

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 will initially be 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, 2018 and 2017 was approximately $286,000 and $280,000, respectively.

The Company has entered into a lease agreement for the planned expansion of the Company's compounding business, to lease a building consisting of approximately 44,880 square feet located in Conway, Arkansas. The agreement provides for an initial base rent of approximately $12,000 per month for the first 12 months and will increase to approximately $13,000 for the 12 months ending November 30, 2020. Average rent during the term will be approximately $13,000 per month, with a previously paid deposit of approximately $12,000.

Future minimum lease payments as at December 31, 2018 for each of the succeeding five years and thereafter are as follows:

For the Years Ending December 31,		
2019	$	490,083
2020		491,504
2021		360,145
2022		370,950
2023		349,378
	$	2,062,060

NOTE 17: CAPITAL STRUCTURE

On January 19, 2017, the Company issued 18,157 shares of common stock to an institutional investor in exchange for the cancellation of warrants to acquire 181,575 shares of common stock.

In March 2017, 625,013 shares of Series A-2 Convertible Preferred were converted into shares of common stock at a 1:1 ratio, with no shares of Series A-2 Preferred Shares remaining outstanding.

In April 2017, the Company completed the closing of an underwritten public offering of 4,928,572 shares of common stock at a public offering price of $3.50 per share. Net proceeds were approximately $16.0 million, after deducting approximately $1,228,000 in underwriting discounts and commissions and estimated offering expenses payable by the Company. Raymond James & Associates, Inc. acted as the sole book-running manager of the offering and Maxim Group LLC acted as co-manager for the offering. 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 related registration statement), and a prospectus supplement and an accompanying prospectus relating to the offering filed in April 2017.

In June 2017, the Company issued common stock upon exercise of an investor warrant. The warrant holder exercised for cash at an exercise price of $2.98 per share. The Company received a total proceeds of approximately $321,000 and the warrant holder received 107,755 shares of common stock.

In July 2017, the Company issued common stock upon exercise of investor warrants. The warrant holders exercised for cash at exercise prices ranging from $2.90 to $3.40 per share. The Company received total of approximately $2,921,000 and the warrant holders received 914,514 shares of common stock.

On July 20, 2017, the Company and certain holders of warrants issued in the Company's registered direct offering transaction in July 2016 (the "July Warrants") agreed to reduce the exercise price of the July Warrants held by such holders from $2.98 to $2.78 per share (the "July Reduced Exercise Price") in consideration for the exercise in full of the July Warrants held by such holders. The Company entered into a Warrant Repricing Letter Agreement (the "Exercise Agreement") with two holders of the July Warrants (the "Exercising Holders"), which Exercising Holders owned, in the aggregate, July Warrants exercisable for 2,765,500 shares of common stock. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their July Warrants with respect to all of the shares of common stock underlying such July Warrants for the July Reduced Exercise Price, subject to the 4.99% beneficial ownership limitations contained in the July Warrants. The Company received aggregate gross proceeds of approximately $7,688,000 from the exercise of the July Warrants by the Exercising Holders. In connection with the transaction, the Company recognized an expense for the inducement to exercise the warrants of approximately $553,000. The Company also incurred approximately $100,000 in placement agent fees, legal costs and other related fees, which have been recognized as an offset to the proceeds received from the warrant exercises.

In August 2017, the Company and certain holders of warrants issued in the Company's private placement transactions in August 2014 (the "2014 Warrants") and July 2016 (the "2016 Warrants") agreed to reduce the exercise price of the 2014 Warrants and the 2016 Warrants held by such holders from $3.40 to $3.20 per share and from $2.90 to $2.70 per share, respectively, (the "August Reduced Exercise Price") in consideration for the exercise of the 2014 Warrants and 2016 Warrants held by such holders. The Company entered into a Warrant Repricing Letter Agreement (the "Exercise Agreement") with holders of the 2014 Warrants and the 2016 Warrants (the "Exercising Holders"), which Exercising Holders owned, in the aggregate, 2014 Warrants and 2016 Warrants exercisable for 880,672 and 1,154,976 shares of common stock, respectively. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their 2014 Warrants and 2016 Warrants with respect to all of the shares of common stock underlying such 2014 Warrants and 2016 Warrants for the August Reduced Exercise Price, subject to the 4.99% beneficial ownership limitations contained in the 2014 Warrants and 2016 Warrants. The Company received aggregate gross proceeds of approximately $5,937,000 from the exercise of the 2014 Warrants and 2016 Warrants by the Exercising Holders. In connection with the transaction, the Company recognized an expense for the inducement to exercise the warrants of approximately $407,000.

On June 28, 2018, the Company and the Lender amended the Adamis Working Capital Line loan and security agreement and warrant disclosed in Note 12 above. In July 2018, the Lender delivered a notice of exercise of the warrant to acquire 699,978 shares of common stock and sold shares with proceeds in an amount sufficient to satisfy substantially all of the outstanding principal balance of the loan, and the remaining 215,417 shares were returned to the Company as treasury stock. Refer to Note 12.

On August 6, 2018, the Company completed the closing of an underwritten public offering of 13,416,667 shares of common stock at a public offering price of $3.00 per share, which included 1,750,000 shares pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds were approximately $37.6 million, after deducting approximately $2,630,000 in underwriting discounts and commissions and estimated offering expenses 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.

NOTE 18: CONVERTIBLE PREFERRED STOCK

August 2014 Series A Preferred Stock

In August 2014, the Company completed a private placement transaction with a small number of sophisticated investors pursuant to which the Company issued 1,418,439 shares of Series A Convertible Preferred Stock and warrants to purchase up to 1,418,439 shares of common stock. The shares of Series A Preferred and warrants were sold in units, with each unit consisting of one share and one warrant, at a purchase price of $3.525 per unit. The Series A 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 $3.40 per share, and the warrants are exercisable for five years. 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 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 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 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 Preferred or exercise of the warrants (without regard to any limitations on conversion). 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 Preferred and the warrants.

The warrants include call provisions giving the Company the option, subject to various conditions, to call the exercise of any or all of the 2014 warrants, by giving a call notice to the warrant holders. The Company may give a call notice only within (i) if a holder and its affiliates beneficially own 2% or less of our outstanding common stock, then 10 trading days after any 20-consecutive trading day period during which the daily volume weighted average price of the common stock (the "VWAP") is not less than 250% of the exercise price for the 2014 warrants in effect for 10 out of such 20-consecutive trading day period, and (ii) if holder and its affiliates beneficially own more than 2% of the outstanding common stock, five trading days after any 30-consecutive trading day period during which the VWAP of the common stock is not less than 250% of the exercise price then in effect for 25 out of such 30-consecutive trading day period. The exercise price of the 2014 warrants is $3.40 per share, and accordingly 250% of such exercise price is $8.50 per share. During a "call period" of 30 trading days following the date on which the call notice is deemed given and effective (with the call period being extended for one trading day for each trading day during the call period during which the VWAP is less than 225% of the exercise price then in effect during the call period), a holder may exercise the 2014 warrant and purchase the called warrant shares. Subject to the foregoing and to the other provisions of the 2014 warrants, if the holder fails to timely exercise the called 2014 warrant, the Company may cancel the unexercised called warrant (or portion thereof that was called). In July 2017, the investors have exercised 2014 warrants to acquire 1,418,439 shares of common stock, with no warrants remaining outstanding.

For the period ended December 31, 2016, the investors converted 1,418,439 shares of Series A Preferred into an equal number of shares of common stock, with no shares of Series A Preferred remaining outstanding.

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, 2018.

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. As of December 31, 2017, the investors have exercised July 2016 warrants to acquire 1,531,723 shares of common stock. As of December 31, 2018, 192,414 warrants remaining outstanding.

For the periods ended December 31, 2017 and December 31, 2016, the investors converted 625,013 shares and 1,099,124 shares, respectively, of Series A-2 Preferred into an equal number of shares of common stock, with no shares of Series A-2 Preferred Shares remaining outstanding as of December 31, 2018.

NOTE 19: STOCK OPTION PLANS, SHARES RESERVED AND WARRANTS

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 increase 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. At December 31, 2018, the aggregate balance of shares reserved for issuance under the 2009 plan was 11,335,847. On January 1, 2019, pursuant to the provisions of the 2009 Plan, 2,364,568 shares were added to the shares reserved for issuance pursuant to awards under the 2009 Plan (see Note 21).

On February 21, 2018, the Company granted options to purchase 2,400,789 shares of common stock to the officers and employees of the Company under the 2009 Equity Incentive Plan with an exercise price of $2.83 per share. The options were granted based on a guideline and not for performance during the year ended December 31, 2017 and will vest over a period of three years. These options were valued using the Black-Scholes option pricing model, the expected volatility was approximately 57% and the risk-free interest rate was approximately 2.86%, which resulted in a calculated fair value of approximately $3,764,000.

During the quarter ended March 31, 2018, the Company granted options to purchase 202,500 shares of common stock to the new hires of the Company under the 2009 Equity Incentive Plan with exercise prices ranging from $3.20 to $4.75 per share. These options will vest with respect to the one-sixth of the option shares on the date that is six months after the vesting commencement date and one thirty-sixth of the option shares thereafter on each subsequent monthly anniversary of the vesting commencement date, so that the option is exercisable in full over a period of three years. These options were valued using the Black-Scholes option pricing model, the expected volatility was approximately 57%, the term was six years, the dividend rate was 0.0 % and the risk-free interest rate was approximately 2.7%, which resulted in a calculated fair value of $420,109.

From April 4, 2018 to August 9, 2018, the Company granted options to purchase 212,500 shares of common stock to the new hires of the Company under the 2009 Equity Incentive Plan with exercise prices ranging from $3.25 to $4.35 per share. These options will vest with respect to the one-sixth of the option shares on the date that is six months after the vesting commencement date and one thirty-sixth of the option shares thereafter on each subsequent monthly anniversary of the vesting commencement date, so that the option is exercisable in full over a period of three years. These options were valued using the Black-Scholes option pricing model, the expected volatility was approximately 56%, the term was six years, the dividend rate was 0.0 % and the risk-free interest rate was approximately 2.8%, which resulted in a calculated fair value of $415,802.

On July 9, 2018, 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 $4.28 per share. The options will vest over a period of one year. These options were valued using the Black-Scholes option pricing model, the expected volatility was approximately 56%, the term was six years, the dividend rate was 0.0 % and the risk-free interest rate was approximately 2.8%, which resulted in a calculated fair value of $211,208.

During the year ended December 31, 2018, vested but unexercised options and unvested options to purchase 330,116 shares of common stock were canceled following the holders' termination of employment.

The following summarizes the stock option activity for the years ended December 31, 2018 and 2017 below:

	2009 Equity Incentive Plan	Weighted Average Exercise Price	Weighted Average Remaining Contract Life
Balance as of December 31, 2016	4,320,409	$ 6.06	7.98 years
Options Granted	2,696,750	3.54	9.26 years
Options Exercised	(8,402)	3.17	—
Options Canceled	(282,163)	6.23	—
Balance as of December 31, 2017	6,726,594	$ 5.05	8.17 years
Options Granted	2,905,789	$ 3.01	9.17 years
Options Exercised	(4,166)	3.35	—
Options Canceled	(330,116)	5.47	—
Balance as of December 31, 2018	9,298,101	$ 4.40	7.92 years
Exercisable at December 31, 2018	6,130,337	$ 4.91	6.93 years

Stock based compensation expense for the years ended December 31, 2018 and 2017 was approximately $6,535,000 and $6,058,000, respectively. As of December 31, 2018, unrecognized compensation expense related to these stock options was approximately $5.8 million and will be recorded as compensation expense over the next three years.

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 9,298,101 and 6,726,594 stock options outstanding at December 31, 2018 and 2017 was approximately $0 and $2,980,000, respectively. The aggregate intrinsic value of 6,130,337 and 3,835,992 stock options exercisable at December 31, 2018 and 2017 was approximately $0 and $1,009,000, respectively.

The Company has reserved shares of common stock for issuance upon conversion or exercise at December 31, 2018 as follows:

Warrants	2,138,887
RSU	1,642,212
2009 Equity Incentive Plan	9,298,101
Total Shares Reserved	13,079,200

The following table summarizes warrants outstanding at December 31, 2018:

	Warrant Shares	Exercise Price Per Share	Date Issued	Expiration Date
Old Adamis Warrants	58,824	$ 8.50	November 15, 2007	November 15, 2019
Underwriter Warrants	4,217	$ 7.44	January 16, 2014	January 16, 2019
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
Total Warrants	2,138,887			

On May 25, 2016, the Company issued RSUs covering of 350,000 shares of common stock to the non-employee directors of the Company under the 2009 Equity Incentive Plan. The value of the award per share is $8.46 and will vest 100% on the seventh year anniversary from grant date. The fair value of RSUs is $2,961,000. The Company recorded compensation expense, related to these RSU's, of $425,000 and $423,000 for the years ended December 31, 2018 and 2017. Unrecognized compensation expense related to these RSUs as of December 31, 2018 was $1,860,000.

On March 1, 2017, the Company issued RSUs covering 950,000 shares of common stock to officers and employees of the Company under the 2009 Equity Incentive Plan. The value of the award per share was $3.50 and will vest 100% on the seventh year anniversary from grant. The fair value of RSUs is $3,325,000. The Company recorded compensation expense, related to these RSU's, of approximately $476,000 and $396,000 for the year ended December 31, 2018 and 2017. Unrecognized compensation expense related to these RSUs as of December 31, 2018 was $2,453,000.

On February 21, 2018, the Company awarded RSUs covering 342,212 shares of common stock to certain officers of the Company under the 2009 Plan; as of the date of grant, the market price of the common stock was $2.83 per share. These RSUs vest in equal amounts each year on the anniversary 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 and Section 409A of the Internal Revenue Code of 1986, as amended), or earlier upon the recipient's separation from service to the Company by reason of death or disability (as defined in the 2009 Plan and Section 409A). The calculated fair value of the RSUs was $968,460. The Company recorded compensation expense, related to these RSU's, of approximately $277,000 for the year ended December 31, 2018. Unrecognized compensation expense related to these RSUs as of December 31, 2018 was approximately $691,000.

NOTE 20: INCOME TAXES

Net operating losses and tax credit carryforwards as of December 31, 2018 are as follows:

	Amount	Expiration Years
Net operating losses, federal (Post December 31, 2017)	$ 30,690,079	N/A
Net operating losses, federal (Pre January 1, 2018)	79,544,760	2027-2037
Net operating losses, state	48,805,225	2029-2038
Tax credits, federal	1,530,117	2036-2038
Tax credits, state	742,946	N/A

Pursuant to Internal Revenue Code Section 382, the annual use of the net operating loss carry forwards and research and development tax credits could be limited by any greater than 50% ownership change during any three year testing period. As a result of any such ownership change, portions of our net operating loss carry forwards and research and development tax credits are subject to annual limitations. The Company completed a Section 382 analysis, 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, 2018 and 2017, 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 provision benefit of $369,000 and $339,000, respectively.

The benefit for income taxes from continuing operations consists of the following for the years ended December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Current	$ 3,000	$ 4,000
Deferred	7,128,000	256,000
Total	7,131,000	260,000
Change in Valuation Allowance	(7,500,000)	(599,000)
Tax Benefit, net	$ (369,000)	$ (339,000)

At December 31, 2018 and December 31, 2017 the significant components of the deferred tax assets from continuing operations are summarized below:

	December 31, 2018	December 31, 2017
Deferred Tax Assets		
Net Operating Losses Carryforwards	$ 26,322,000	$ 20,137,400
Tax Credits	2,117,000	1,253,500
Stock Compensation	1,037,000	736,100
Accrued Expenses	586,000	651,400
Other	3,000	1,900
Total Deferred Tax Assets	30,065,000	22,780,300
Valuation Allowance	(28,338,000)	(20,838,600)
	$ 1,727,000	$ 1,941,700
Deferred Tax Liabilities		
Intangibles	$ (1,628,000)	$ (2,080,700)
Fixed Assets	(211,000)	(346,000)
Total Deferred Tax Liabilities	(1,839,000)	(2,426,700)
Net Deferred Tax Liability	$ (112,000)	$ (485,000)

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, 2018 and December 31, 2017 that a full valuation allowance would be required against of all our 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 our losses from continuing operations before income taxes for the year ended December 31, 2018 and December 31, 2017.

	December 31, 2018		December 31, 2017	
Federal Statutory Rate	$ (8,269,000)	21.00%	$ (8,800,000)	34.00%
State Income Tax, net of Federal Tax	(663,000)	1.68%	(305,000)	1.18%
Other Permanent Differences	1,962,000	(4.98%)	1,669,000	(6.45%)
Section 382 Analysis and Other	—	—	(1,657,000)	6.40%
Tax Cuts and Jobs Act	—	—	9,408,000	(36.35%)
Research and Development Credits	(899,000)	2.28%	(1,253,000)	4.84%
Change in Valuation Allowance	7,500,000	(19.04%)	599,000	(2.31%)
Expected Tax Benefit	$ (369,000)	0.94%	$ (339,000)	1.31%

Interest and penalties related to uncertain tax positions are recognized as a component of income tax expense. For the tax year ended December 31, 2018 and 2017, the Company recognized no interest or penalties.

NOTE 21: SUBSEQUENT EVENTS

On January 1, 2019, pursuant to the 2009 Equity Incentive Plan (Note 19) the number of shares reserved for the issuance of stock awards increased by 2,364,568 shares.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Prospectus constituting a part of the Registration Statements on Form S-8 (Nos. 333-159229, 333-169106, 333-175383, 333-196435, 333-201742, 333-211773, 333-218945, 333-226230, and 333-229379), on Form S-1 (Nos. 333-190798, 333-192372, and 333-192801), and on Form S-3 (Nos. 333-196976, 333-199454, 333-200447, 333-209401, 333-212880, 333-217400, 333-717908, and 333-226100) of our report dated March 15, 2019, (which includes explanatory paragraphs related to the change in the method of accounting for revenue, and the uncertainty of the Company's ability to continue as a going concern) relating to the consolidated financial statements of Adamis Pharmaceuticals Corporation and Subsidiaries (the Company), as of and for the years ended December 31, 2018 and 2017, and our report dated March 15, 2019, relating to internal control over financial reporting (which report expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting) as of December 31, 2018, which reports are included in this Annual Report on Form 10-K.

/s/ Mayer Hoffman McCann P.C.

San Diego, California

March 15, 2019

Exhibit 31.1

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

I, Dennis J. Carlo, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2019

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

Exhibit 31.2

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

I, Robert O. Hopkins, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2019

By: /s/ Robert O. Hopkins
Senior Vice President, Finance and Chief Financial Officer

Exhibit 32.1

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

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

(1) the Company's Annual Report on Form 10-K for the year ended December 31, 2018 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

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

Dated: March 15, 2019

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

Exhibit 32.2

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

The undersigned, Robert O. Hopkins, as Senior Vice President, Finance and Chief Financial Officer of Adamis Pharmaceuticals, Corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the year ended December 31, 2018 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

/s/ ROBERT O. HOPKINS
Robert O. Hopkins
Senior Vice President and Chief Financial Officer

Dated: March 15, 2019

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