UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____to _____

Commission File Number: 001-36242

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 Number)**

11682 El Camino Real, Suite 300, San Diego, CA 92130
(Address of principal executive offices, including zip code)

(858) 997-2400
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADMP	NASDAQ Capital Market

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

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

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth company ☐

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

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

The number of shares outstanding of the issuer's common stock, par value $0.0001 per share, as of August 6, 2019, was 61,438,109.

ADAMIS PHARMACEUTICALS, INC.

CONTENTS OF QUARTERLY REPORT ON FORM 10-Q

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents	$ 4,092,689	$ 19,271,642
Accounts Receivable, net	2,902,280	1,155,166
Inventories, net	2,914,486	3,279,032
Prepaid Expenses and Other Current Assets	2,062,427	2,078,413
	11,971,882	25,784,253
LONG TERM ASSETS		
Security Deposits	54,655	54,655
Intangible Assets, net	12,101,441	13,210,596
Goodwill	7,640,622	7,640,622
Fixed Assets, net	11,501,412	9,867,921
Right -of-Use Assets	2,119,113	—
Other Non-Current Assets	1,700,000	1,800,000
Total Assets	$ 47,089,125	$ 58,358,047
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable	$ 4,271,095	$ 4,170,720
Deferred Revenue	964,296	1,011,246
Accrued Other Expenses	2,487,182	2,340,095
Accrued Bonuses	959,868	1,448,505
Lease Liabilities, current portion	445,401	—
Bank Loans - Building and Equipment	2,334,037	2,583,134
	11,461,879	11,553,700
LONG TERM LIABILITIES		
Deferred Tax Liability, net	112,530	112,530
Lease Liabilities, net of current portion	1,705,930	—
Total Liabilities	13,280,339	11,666,230
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred Stock – Par Value $.0001; 10,000,000 Shares Authorized; Series A-2 Convertible, Zero and Zero Issued and Outstanding at June 30, 2019 (Unaudited) and December 31, 2018, respectively.	—	—
Common Stock - Par Value $.0001; 100,000,000 Shares Authorized; 48,161,066 and 47,814,315 Issued, 47,638,109 and 47,291,358 Outstanding at June 30, 2019 and December 31, 2018, respectively	4,816	4,781
Additional Paid-in Capital	203,439,869	199,696,656
Accumulated Deficit	(169,630,649)	(153,004,370)
Treasury Stock, at cost - 522,957 Shares and 522,957 at June 30, 2019 and December 31, 2018, respectively	(5,250)	(5,250)
Total Stockholders' Equity	33,808,786	46,691,817
Total Liabilities and Stockholders' Equity	$ 47,089,125	$ 58,358,047

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019 (Unaudited)	2018 (Unaudited)	2019 (Unaudited)	2018 (Unaudited)
REVENUE, net	$ 5,764,899	$ 3,920,566	$ 10,670,671	$ 7,099,800
COST OF GOODS SOLD	3,665,565	2,394,394	7,291,033	4,457,557
Gross Profit	2,099,334	1,526,172	3,379,638	2,642,243
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	7,000,339	6,362,931	15,021,803	12,836,746
RESEARCH AND DEVELOPMENT	2,845,745	4,835,634	5,042,260	7,084,702
Loss from Operations	(7,746,750)	(9,672,393)	(16,684,425)	(17,279,205)
OTHER INCOME (EXPENSE)				
Interest Expense	(22,954)	(51,435)	(46,962)	(102,103)
Interest Income	34,117	21,457	108,495	60,566
Total Other Income (Expense), net	11,163	(29,978)	61,533	(41,537)
Net (Loss)	$ (7,735,587)	$ (9,702,371)	$ (16,622,892)	$ (17,320,742)
Basic and Diluted (Loss) Per Share	$ (0.16)	$ (0.29)	$ (0.35)	$ (0.52)
Basic and Diluted Weighted Average Shares Outstanding	47,539,186	33,389,600	47,425,971	33,389,505

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)

	Common Stock		Additional	Treasury Stock		Accumulated	
	Shares	Amount	Paid-In Capital	Shares	Amount	Deficit	Total
Balance at December 31, 2018	47,814,315	$ 4,781	$199,696,656	(522,957)	$ (5,250)	$(153,004,370)	$46,691,817
Cumulative effect from adoption of Topic 842 (1)	—	—	—	—	—	(3,387)	(3,387)
Issuance of RSU's	151,056	15	(15)	—	—	—	—
Share Based Compensation	—	—	1,977,930	—	—	—	1,977,930
Net (Loss)	—	—	—	—	—	(8,887,305)	(8,887,305)
Balance March 31, 2019	47,965,371	4,796	201,674,571	(522,957)	(5,250)	(161,895,062)	39,779,055
Issuance of RSU's	195,695	20	(20)	—	—	—	—
Share Based Compensation	—	—	1,765,318	—	—	—	1,765,318
Net (Loss)	—	—	—	—	—	(7,735,587)	(7,735,587)
Balance June 30, 2019	48,161,066	$ 4,816	$203,439,869	(522,957)	$ (5,250)	$(169,630,649)	$33,808,786

	Common Stock		Additional	Treasury Stock		Accumulated	
	Shares	Amount	Paid-In Capital	Shares	Amount	Deficit	Total
Balance at December 31, 2017	33,696,950	$ 3,369	$153,546,932	(307,540)	$ (5,229)	$(113,997,588)	$39,547,484
Share Based Compensation	—	—	1,517,657	—	—	—	1,517,657
Net (Loss)	—	—	—	—	—	(7,618,371)	(7,618,371)
Balance March 31, 2018	33,696,950	3,369	155,064,589	(307,540)	(5,229)	(121,615,959)	33,446,770
Common Stock Issued for Exercised Options	720	1	(1)	—	—	—	—
Share Based Compensation	—	—	1,654,421	—	—	—	1,654,421
Net (Loss)	—	—	—	—	—	(9,702,371)	(9,702,371)
Balance June 30, 2018	33,697,670	$ 3,370	$156,719,009	(307,540)	$ (5,229)	$(131,318,330)	$25,398,820

(1) The Company adopted Accounting Standards Update ("ASU") 2016-02, *Leases*. Refer to the recent accounting pronouncements footnote for further details.

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended June 30, 2019 (Unaudited)	2018 (Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (Loss)	$ (16,622,892)	$ (17,320,742)
Adjustments to Reconcile Net (Loss) to Net		
Cash (Used in) Operating Activities:		
Stock Based Compensation	3,743,248	3,172,078
Provision for Bad Debts	33,956	84,350
Provision for Excess and Obsolete Inventory	539,758	2,805,609
Depreciation and Amortization Expense	1,453,668	1,544,003
Gain on Sale of Fixed Assets	(9,000)	(758)
Change in Assets and Liabilities		
(Increase) Decrease in:		
Accounts Receivable - Trade	(1,781,070)	(499,578)
Inventories	(175,212)	(3,590,891)
Prepaid Expenses and Other Current Assets	15,986	83,139
Other Non-Current Assets	100,000	—
Increase (Decrease) in:		
Accounts Payable	369,589	1,227,391
Deferred Revenue	(46,950)	7,317
Accrued Other Expenses and Bonuses	(310,903)	87,765
Net Cash (Used) in Operating Activities	(12,689,822)	(12,400,317)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of Equipment	(2,203,948)	(1,270,486)
Net Cash (Used) in Investing Activities	(2,203,948)	(1,270,486)
CASH FLOWS FROM FINANCING ACTIVITIES		
Principal Payment of Finance Leases	(36,086)	—
Payment of Bank Loans	(249,097)	(239,840)
Net Cash (Used) in Financing Activities	(285,183)	(239,840)
(Decrease) in Cash and Restricted Cash	(15,178,953)	(13,910,643)
Cash, Cash Equivalents and Restricted Cash:		
Beginning Cash, Cash Equivalents and Restricted Cash	19,271,642	18,332,702
Ending Cash, Cash Equivalents and Restricted Cash	$ 4,092,689	$ 4,422,059

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended June 30, 2019 (Unaudited)	2018 (Unaudited)
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and Cash Equivalents	$ 4,092,689	$ 3,406,331
Restricted Cash	—	1,015,728
Total Cash, Cash Equivalents and Restricted Cash	$ 4,092,689	$ 4,422,059
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash Paid for Income Taxes	$ 9,612	$ 8,650
Cash Paid for Interest	$ 47,011	$ 108,796
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES		
Increase (Decrease) in Accrued Capital Expenditures	$ (269,214)	$ 1,017,300

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Note 1: Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission ("SEC"). Accordingly, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements reflect all adjustments (including normal recurring adjustments and the elimination of intercompany accounts) considered necessary for a fair presentation of all periods presented. The results of operations of Adamis Pharmaceuticals Corporation ("the Company") for any interim periods are not necessarily indicative of the results of operations for any other interim periods or for a full fiscal year. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Liquidity and Capital Resources

The Company's cash and cash equivalents were $4,092,689 and $19,271,642 at June 30, 2019 and December 31, 2018, respectively.

The Company prepared the condensed consolidated financial statements assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. In preparing these condensed consolidated financial statements, consideration was given to the Company's future business as described below, which may preclude the Company from realizing the value of certain assets.

The Company has significant operating cash flow deficiencies. Additionally, the Company will need significant funding for future operations and the expenditures that it believes will be required to support commercialization of its products and conduct the clinical and regulatory activities relating to the Company's product candidates, satisfy existing obligations and liabilities, and otherwise support the Company's intended business activities and working capital needs. The preceding conditions raise substantial doubt about the Company's ability to continue as a going concern. The condensed consolidated financial statements included elsewhere herein for the three and six months ended June 30, 2019, 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. Our unaudited condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty. Management's plans include attempting to secure additional required funding through equity or debt financings, sales or out-licensing of intellectual property assets, products, product candidates or technologies, 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 existing agreements and sales of prescription compounded formulations. There is no assurance that the Company will be successful in obtaining the necessary funding to meet its business objectives.

Basic and Diluted (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. Except as noted below, the effect of common stock equivalents was anti-dilutive and was excluded from the calculation of weighted average shares outstanding. Potential dilutive securities, which are not included in dilutive weighted average shares for the three and six month periods ended June 30, 2019 and June 30, 2018 consist of outstanding equity classified warrants (2,134,670 and 3,166,995, respectively), outstanding options (8,346,058 and 9,352,243, respectively), and outstanding restricted stock units (3,681,796 and 1,642,212, respectively).

Prior Periods Reclassifications

Certain amounts in prior periods have been reclassified to conform with current period presentation related to the reserve for inventory obsolescence in the condensed consolidated statement of cash flows and had no effect on cash used in operations or statement of cash flows for the periods ended June 30, 2019 and June 30, 2018. The reclassification has no effect on the condensed consolidated balance sheet as of June 30, 2019 and December 31, 2018, or the condensed consolidated statement of operations for the three months and six months ended June 30, 2019 and June 30, 2018.

Recently Adopted Accounting Pronouncement

In February 2016, the Financial Accounting Standards Board ("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 lessees 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 was effective for the Company for the year ending December 31, 2019. We reported our financial information for fiscal years ending before December 31, 2018 under the Topic 840 lease accounting standard. The Company applied the modified retrospective transition method and elected the transition option to use the effective date of January 1, 2019 as the date of initial application. The Company recognized the cumulative effect of the transition adjustment as of the effective date and will not 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 as classified 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 used the incremental borrowing rate based on the total lease term and total minimum rental payments. The Company completed its identification of leases which comprised 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 recognized right-of-use ("ROU") assets and leasing liabilities on its condensed consolidated balance sheets of approximately $2 million. The adoption had no significant impact on the Company's condensed consolidated statement of operations.

Note 2: Revenues

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 we expect to be entitled in exchange for transferring goods or services to a customer. This principle is applied using the following 5-step process:

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

Adamis is a specialty biopharmaceutical company focused on developing and commercializing products in the therapeutic areas of respiratory disease and allergy. Our subsidiary U.S. Compounding, Inc. or USC 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.

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

Effective July 1, 2018 (the "Effective Date"), Adamis signed an exclusive distribution and commercialization agreement with Sandoz, Inc. ("Sandoz"). This agreement grants Sandoz the exclusive rights to market, sell and distribute the Company's SYMJEPI™ epinephrine pre-filled syringe injectable products ("Products") throughout the United States only. There is currently no distributor for markets outside the United States. The Company generates revenue from this agreement by manufacturing and supplying Sandoz with Products. The Company's performance obligation is to manufacture and supply the Products to Sandoz.

The initial term for the agreement with Sandoz began on the Effective Date and shall continue for a period of 10 years from the first launch of Product in the United States, unless terminated earlier in accordance with its terms. The term will automatically renew for one year terms after the initial 10-year term and subsequent renewal terms, unless terminated by either party. The revenue arrangement consists of a single performance obligation, which is satisfied at the point in time when the Product is delivered to the carrier, as control, title and risk of loss is passed on to Sandoz upon delivery of the products to the carrier.

The Company has the following payment considerations with Sandoz: (1) Fixed consideration. One-time milestone payment, which grants Sandoz the material right for the distribution and commercialization of the Product in the United States market only. This one-time milestone payment is a non-refundable up-front fee. Revenue from this up-front fee is recognized over the initial 10-year term of the contract, which is substantially the expected customer life. The period of recognition is subject to adjustment if the expected customer life changes; and (2) Variable considerations which are recognized upon satisfaction of the performance obligation, comprised of the following:

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

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

(iii) Commercial milestone payments that are payable upon the Company's successful achievement of certain milestone events specified under the agreement. There are five commercial milestone events, based on certain revenue thresholds from Products sold over the term. The variable consideration from milestone payments is estimated using the most likely amount method, subject to constraint.

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

With respect to sales of prescription compounded medications by our USC subsidiary, revenue arrangements consist of a single performance obligation which is satisfied at the point in time when goods are delivered to the customer. The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer.

The contracts between the Company and the customers provide that 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 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 regarding sales of medications by USC, and does not have a history of offering a broad range of price concessions or payment term changes. The Company believes a significant reversal in the amount of cumulative revenue recognized from such contracts is neither 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 regarding sales of medications by USC.

Disaggregation of Revenue

As operations under a sterile environment is covered by Section 503B of the U.S. Food, Drug & Cosmetic Act, as amended, 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 to minimize the likelihood of this occurrence. The Company outsources the manufacturing of the SYMJEPI product to third party manufacturers who bear the responsibility of maintaining a suitable environment as governed by specific regulatory and quality requirements.

The following table presents the Company's revenues disaggregated by outsourced manufacturing, sterile and non-sterile regulatory environments for the three months and six months ended June 30, 2019 and 2018.

	Three Months Ended June 30		Six Months Ended June 30	
	2019	2018	2019	2018
Outsourced Manufacturing	$ 1,119,584	$ —	$ 1,584,573	$ —
Sterile	3,324,679	2,111,509	6,498,814	3,882,245
Non-Sterile	1,320,636	1,809,057	2,587,284	3,217,555
Total	$ 5,764,899	$ 3,920,566	$ 10,670,671	$ 7,099,800

The Company's revenues relating to its FDA approved product SYMJEPI are dependent on an exclusive distribution agreement with Sandoz and the Company's pharmacy formulations rely, in large part, on sales generated from clinics and hospital customers. Adverse economic conditions pose a risk that the Company's customers may reduce or cancel spending, which would impact the Company's revenues.

The following table presents the Company's revenue disaggregated by end market for the three months and six months ended June 30, 2019 and 2018.

	Three Months Ended June 30		Six Months Ended June 30	
	2019	2018	2019	2018
Distribution Channel - Sandoz	$ 1,119,584	$ —	$ 1,584,573	$ —
Clinics/Hospitals	4,428,879	3,365,302	8,473,072	6,117,912
Direct to Patients	216,436	555,264	613,026	981,888
Total	$ 5,764,899	$ 3,920,566	$ 10,670,671	$ 7,099,800

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 three months ended June 30, 2019 and 2018, $28,248 and $12,043 of the revenues recognized were reported as deferred revenue as of March 31, 2019 and 2018, respectively, and for the six months ended June 30, 2019 and 2018, $61,246 and $14,758 of the revenues recognized were reported as contract liabilities as of December 31, 2018 and 2017, respectively. Included in the deferred revenue at June 30, 2019 and December 31, 2018 was $950,000 and $1.0 million, respectively, relating to the non-refundable upfront payment received from Sandoz pursuant to the Agreement between the Company and Sandoz.

Cost to Obtain a Contract

The Company capitalizes costs related to contracts that would have not been incurred if the contract was not obtained and the Company expects to recover such costs. The deferred costs, reported in the prepaid expenses and other current assets and other non-current assets on the Company's Condensed Consolidated Balance Sheets, will be amortized over the economic benefit period of the contract.

The Company capitalized the $2.0 million fee paid to a financial advisor as an incremental cost of obtaining a contract to commercialize and distribute the Company's first FDA approved product SYMJEPI with Sandoz. The costs were deferred and will be amortized over the economic benefit period estimated to be approximately 10 years from date of product launch, based on the contract term. The period of recognition is subject to adjustment in future periods if the expected customer life changes. The deferred costs were classified as current or non-current in the Company's condensed consolidated balance sheets based on the timing of when the Company expects to recognize the expense. As of June 30, 2019 and December 31, 2018, the Company had $1,900,000 and $2.0 million, respectively, of deferred costs related to obtaining a contract with $100,000 and $50,000 amortized to Selling, General and Administrative expenses during the six months and three months ended June 30, 2019, respectively.

Practical Expedients

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

Note 3: Inventories

Inventories at June 30, 2019 and December 31, 2018 consisted of the following:

	June 30, 2019	December 31, 2018
Finished Goods	$ 1,296,494	$ 1,320,738
Raw Material	417,853	527,308
Devices	1,200,139	1,430,986
	$ 2,914,486	$ 3,279,032

Reserve for obsolescence as of June 30, 2019 and December 31, 2018 was approximately $225,000 and $526,000, respectively.

Note 4: Fixed Assets

Fixed assets at June 30, 2019 and December 31, 2018 are summarized in the table below:

Description	Useful Life (Years)	June 30, 2019	December 31, 2018
Building	30	$ 3,040,000	$ 3,040,000
Machinery and Equipment	3 - 7	2,473,988	2,244,744
Furniture and Fixtures	7	126,654	126,654
Automobile	5	9,500	9,395
Leasehold Improvements	7 - 15	284,037	284,037
Total Fixed Assets		5,934,179	5,704,830
Less: Accumulated Depreciation		(1,869,895)	(1,578,049)
Land		460,000	460,000
Construction In Progress - Equipment		6,977,128	5,281,140
Fixed Assets, net		$ 11,501,412	$ 9,867,921

Depreciation expense for the three months ended June 30, 2019 and 2018 was approximately $145,000 and $154,000, respectively; and for the six months ended June 30, 2019 and 2018, depreciation expense was approximately $301,000 and $306,000, respectively.

Note 5: Intangible Assets and Goodwill

Intangible assets at June 30, 2019 and December 31, 2018 are summarized in the tables below:

June 30, 2019	Gross Carrying Value	Accumulated Amortization	Net Carrying Amount
Definite-lived Intangible assets, estimated lives in years:			
Patents, Taper DPI Intellectual Property, 10 years	$ 9,708,700	$ (5,339,785)	$ 4,368,915
Transition Services Agreement, 1 year	194,200	(194,200)	—
FDA 503B Registration & Compliance - USC, 10 years	3,963,000	(1,275,866)	2,687,134
Non-compete Agreement - USC, 3 years	1,639,000	(1,639,000)	—
Customer Relationships - USC, 10 years	5,572,000	(1,793,874)	3,778,126
Website Design - USC, 3 years	25,163	(12,571)	12,592
Total Definite-lived Assets	21,102,063	(10,255,296)	10,846,767
Trade Name and Brand - USC, Indefinite	1,245,000	—	1,245,000
SYMJEPI Domain Name	9,674	—	9,674
Balance, June 30, 2019	$ 22,356,737	$ (10,255,296)	$ 12,101,441

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 - USC, 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 - USC, 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

Amortization expense for the three months ended June 30, 2019 and 2018 was approximately $499,000 and $619,000, respectively; and for the six months ended June 30, 2019 and 2018, amortization expense was approximately $1,118,000 and $1,238,000, respectively.

Estimated amortization expense of definite-lived intangible assets at June 30, 2019 for each of the five succeeding years and thereafter is as follows:

Year ending December 31,	
Remainder of 2019	$ 966,379
2020	1,927,370
2021	1,927,370
2022	1,926,768
2023	1,924,370
Thereafter	2,174,510
Total	$ 10,846,767

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 June 30, 2019 and December 31, 2018 was approximately $7,641,000.

Note 6: Leases

The Company has two operating leases, one for an office space and another for an office space and manufacturing facility; and two finance leases for an office equipment and plant equipment. As of June 30, 2019, the leases have remaining terms between four months and less than five years. The operating leases do not include an option to extend beyond the life of the current term. There are no short-term leases, and the lease agreements do not require material variable lease payments, residual value guarantees or restrictive covenants.

The tables below present the operating and financing lease assets and liabilities recognized on the condensed consolidated balance sheets as of June 30, 2019:

Right-of Use Assets	June 30, 2019
Operating Leases	$ 2,083,901
Financing Leases	35,212
	$ 2,119,113

Lease Liabilities, Current	June 30, 2019
Operating Leases	$ 412,424
Financing Leases	32,977
	$ 445,401
Lease Liabilities, Non-Current	
Operating Leases	$ 1,702,123
Financing Leases	3,807
	$ 1,705,930
Total Lease Liabilities	$ 2,151,331

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

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

The Company's weighted average remaining lease term and weighted average discount rate for operating and financing leases as of June 30, 2019 are:

June 30, 2019	Operating	Financing
Weighted Average Remaining Lease Term	4.44 Years	.65 Years
Weighted Average Discount Rate	3.95%	3.95%

The table below reconciles the undiscounted future minimum lease payments (displayed by year and in the aggregate) under non-cancelable leases with terms of more than one year to the total lease liabilities recognized on the unaudited condensed consolidated balance sheets as of June 30, 2019:

June 30, 2019	Operating	Financing
Remainder of 2019	$ 235,229	$ 31,180
2020	508,056	4,651
2021	520,993	1,550
2022	534,295	—
2023	515,257	—
Undiscounted Future Minimum Lease Payments	2,313,830	37,381
Less: Difference between undiscounted lease payments and discounted lease liabilities	199,283	597
Total Lease Liabilities	$ 2,114,547	$ 36,784

Operating lease expense was approximately $128,000 and $257,000 for the three months and six months ended June 30, 2019. Operating lease costs are included within selling, general and administrative expenses on the condensed consolidated statements of operations.

Financing lease costs for the three months and six months ended June 30, 2019 included approximately $18,000 and $34,000, respectively, in right-of-use asset amortization and approximately $400 and $1,000, respectively, of interest expense. Financing lease costs are included within selling, general and administrative expenses on the condensed consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities were approximately $260,000 for the six months ended June 30, 2019. Cash paid for amounts included in the measurement of financing lease liabilities were approximately $37,000 for the six months ended June 30, 2019.

Note 7: Debt

Ben Franklin Note

Biosyn, Inc., a wholly owned subsidiary of the Company, issued a note payable to Ben Franklin Technology Center of Southeastern Pennsylvania ("Ben Franklin Note") in October 1992, in connection with funding the development of Savvy, 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 the Company 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. The Company 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 8). As such, management has determined that the Ben Franklin Note will have no future cash flows, as we do not believe the product will create a revenue stream in the future. As a result, the Ben Franklin 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 ("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. 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 was no gain or loss upon extinguishment of the debt. The Adamis Working Capital Line was not renewed and the account was closed as of December 31, 2018. 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 June 30, 2019 and December 31, 2018, the loan balance on the Adamis Working Capital Line of credit was $0. Interest expense related to the loan for the three months ended June 30, 2019 and 2018 was approximately $0 and $24,000, respectively; and for the six months ended June 30, 2019 and 2018, interest expense was approximately $0 and $47,000, respectively.

Loans Assumed from Acquisition of USC:

Building Loan

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

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 June 30, 2019 and December 31, 2018, the outstanding principal balance owed on the applicable note was approximately $2,199,000 and $2,249,000, respectively. The loan currently bears an interest of 3.75% per year. Interest expense for the three month periods ended June 30, 2019 and 2018 was approximately $21,000 and $22,000, respectively; and for the six month periods ended June 30, 2019 and 2018, interest expense was approximately $42,000 and $44,000, 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 formulations, and Lender consented to such assignment. The outstanding unpaid principal balance under the applicable note that was consolidated, as described below, 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 June 30, 2019 and December 31, 2018, the outstanding unpaid principal balance was approximately $135,000 and $334,000, respectively. Interest expense for the three months ended June 30, 2019 and 2018 was approximately $2,000 and $6,000, respectively; and for the six months ended June 30, 2019 and 2018, interest expense was approximately $5,000 and $12,000, respectively.

Loan Amendment, Forbearance and Assumption Agreement

In connection with the Company's acquisition of USC in April 2016, 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 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.

The notes included in the USC Loan Documents 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 June 30, 2019, the Company was not in breach of any of the debt covenants or subjective acceleration clauses.

At June 30, 2019, the outstanding principal maturities of the amended long-term debts were as follows:

Years ending December 31,	Building Loan	Equipment Loan	Total
Remainder of 2019	$ 2,199,297	$ 134,740	$ 2,334,037

Note 8: 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 than 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 Condensed Consolidated Balance Sheets for cash and cash equivalents, accounts receivable, inventory, accounts payable, notes payable, accrued liabilities and other payables approximate their fair values due to their short-term nature.

Note 9: 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 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.

Litigation with Belcher Pharmaceuticals

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 sought 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. On December 28, 2018, Belcher filed a reissue application for one of the Patents-in-Suit seeking to amend the asserted claims and correct an improper benefit claim. On March 29, 2019, the parties agreed to stay the litigation at the District Court pending the outcome of the reissue application and the Company's petition for *inter partes* review, filed with the U.S. Patent and Trademark Office in April 2019, to challenge the validity of the remaining Patent-in-Suit. 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.

On July 24, 2019, the Company announced that Adamis and Belcher Pharmaceuticals, LLC ("Belcher") agreed to settle all previously filed litigation between the parties, including the case filed by Adamis in the United States District Court for the Middle District of Florida in which Adamis was seeking a declaratory judgment of non-infringement of certain patents in which Belcher claimed rights, relating to certain methods of preparing epinephrine solutions ("Patent Case"), and the *inter partes* review proceeding filed by Adamis in the United States Patent and Trademark Office requesting a formal review of the validity of certain aspect of Belcher's patents ("IPR"). Under the terms of the settlement agreement, Adamis agreed to voluntarily withdraw both the Patent Case and IPR and Belcher agreed to provide Adamis a worldwide, non-exclusive, fully paid-up, royalty-free license relating to Belcher's patents for Adamis' epinephrine injection product, SYMJEPI, and agreed not to make future claims of infringement relating to Adamis' naloxone injection product candidate, ZIMHI™. The parties agreed to file requests of voluntary dismissal in the Florida court and USPTO, as appropriate.

Litigation with kaléo Inc.

On May 21, 2019, the Company announced that on May 20, 2019, it received notice that it had been named and served as a defendant in a lawsuit filed by kaléo Inc. in the United States District Court for the District of Delaware regarding Adamis' higher dose naloxone injection product candidate, ZIMHI, for the treatment of opioid overdose, for which Adamis has previously submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) that is being reviewed by the agency. The complaint alleges, among other things, that the company's product candidate infringes patents purportedly held by kaléo relating to its naloxone auto-injector product. The action was filed under the provisions of the Hatch-Waxman Act in response to Adamis' Paragraph IV certification regarding the kaléo patents as part of the company's NDA process, and results in an automatic stay of any final approval by the FDA of Adamis' NDA.

On June 21, 2019, the Company filed two motions in the United States District Court for the District of Delaware in response to kaléo's patent infringement lawsuit relating to ZIMHI. The first was a motion to disqualify Cooley LLP as counsel to kaléo based on, among other things, conflicts of interest and violation of applicable ethical rules. The second was a motion to dismiss the entire lawsuit for lack of subject matter jurisdiction. Adamis filed an amendment to its original new drug application ("NDA") removing any reference to kaléo's EVZIO® product, which Adamis contends prevents kaléo from claiming infringement under the Hatch-Waxman Act. On the same day, Adamis filed a separate lawsuit in the United States District Court for the Eastern District of Virginia against kaléo, Inc. for cybersquatting under 15 U.S.C. § 1125(d), unfair competition under 15 U.S.C. § 1125(a), and common law unfair competition and trademark infringement for kaléo's use of Adamis' SYMJEPI trademark. With this lawsuit, Adamis is seeking injunctive relief to prevent kaléo from using Adamis' SYMJEPI trademark and damages for kaléo's past use of Adamis' SYMJEPI trademark in commerce.

On July 18, 2019, the Company announced that Adamis and kaléo Inc. agreed to settle all previously announced litigation between the parties, including the case filed by kaléo in the United States District Court for the District of Delaware in which kaléo claimed specified aspects of Adamis' ZIMHI naloxone product infringed certain kaléo-owned patents, and the case filed by Adamis in the United States District Court for the Eastern District of Virginia in which Adamis claimed specified actions by kaléo infringed Adamis' SYMJEPI trademark. As part of the resolution of the current litigation, kaléo agreed not to bring future action against Adamis relating to ZIMHI so long as Adamis does not reference kaléo's product in a future filing with the FDA, and Adamis agreed not to bring future action against kaléo for acts that occurred prior to the settlement date.

Other

The Company has a production threshold commitment to a manufacturer of our SYMJEPI Products where the Company would be required to pay for maintenance fees if it does not meet certain periodic purchase order minimums. Any such maintenance fees would be prorated as a percentage of the required minimum production threshold. The Company believes that the production thresholds will be met in the succeeding periods, or if not that the fees will not be material, as they are prorated based on actual production.

Note 10: Stock Option Plans, Shares Reserved and Warrants

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

On January 30, 2019, the Company granted options to purchase 90,000 shares of common stock to the non-employee directors of the Company under the 2009 Plan with an exercise price of $3.09 per share. The options will vest over a period of one year. These options were valued using the Black-Scholes option pricing model, 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 2.6%, which resulted in a calculated fair value of approximately $152,000.

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

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

The following summarizes the stock option activity for the six months ended June 30, 2019 below:

	2009 Equity Incentive Plan	Weighted Average Exercise Price	Weighted Average Remaining Contract Life
Outstanding Options as of December 31, 2018	9,298,101	$ 4.40	7.92 years
Options Granted	90,000	3.09	9.59 years
Options Cancelled/Expired	(1,042,043)	4.34	—
Outstanding Options as of June 30, 2019	8,346,058	$ 4.38	6.89 years
Exercisable at June 30, 2019	6,551,706	$ 4.72	6.46 years

The aggregate intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money options) of the 8,346,058 and 9,298,101 stock options outstanding at June 30, 2019 and December 31, 2018 was $0, respectively. The aggregate intrinsic value of 6,551,706 and 6,130,337 stock options exercisable at June 30, 2019 and December 31, 2018 was $0, respectively.

The following summarizes warrants outstanding at June 30, 2019 and December 31, 2018:

June 30, 2019	Warrant Shares	Exercise Price Per Share	Date Issued	Expiration Date
Old Adamis Warrants	58,824	$ 8.50	November 15, 2007	November 15, 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	2,134,670			

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			

The following table summarizes the RSUs outstanding at June 30, 2019 and December 31, 2018:

June 30, 2019	RSU Shares	Price Per Share at Grant Date	Date of Grant
Non-Employee Board of Directors	350,000(1)	$ 8.46	May 25, 2016
Company Executives	950,000(1)	$ 3.50	March 1, 2017
Company Executives	228,141(2)	$ 2.83	February 21, 2018
Company Executives and Employees	2,153,655(3)	$ 3.09	January 30, 2019
Total RSUs	3,681,796		

(1) The RSUs will fully vest on the seventh anniversary of the date of grant if the recipient has provided continuous service or upon change of control or upon death or disability.

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

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

December 31, 2018	RSU Shares	Price Per Share at Grant Date	Date of Grant
Non-Employee Board of Directors	350,000(1)	$ 8.46	May 25, 2016
Company Executives	950,000(1)	$ 3.50	March 1, 2017
Company Executives	342,212(2)	$ 2.83	February 21, 2018
Total RSUs	1,642,212		

(1) The RSUs will fully vest on the seventh anniversary of the date of grant if the recipient has provided continuous service or upon change of control or upon death or disability.

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

Expense related to RSUs for the three months ended June 30, 2019 and 2018 was approximately $882,000 and $305,000, respectively; and for the six months ended June 30, 2019 and 2018, expense related to RSUs was approximately $1,684,000 and $563,000, respectively.

At June 30, 2019, the Company has reserved shares of common stock for issuance upon exercise of outstanding options and warrants, convertible preferred stock shares and options granted under the 2009 Equity Incentive Plan, as follows:

Warrants	2,134,670
Restricted Stock Units (RSU)	3,681,796
2009 Equity Incentive Plan	8,346,058
Total Shares Reserved	14,162,524

Note 11: Subsequent Events

Litigation with Belcher Pharmaceuticals

On July 24, 2019, the Company announced that Adamis and Belcher Pharmaceuticals, LLC ("Belcher") agreed to settle all previously filed litigation between the parties, including the case filed by Adamis in the United States District Court for the Middle District of Florida in which Adamis was seeking a declaratory judgment of non-infringement of certain patents in which Belcher claimed rights, relating to certain methods of preparing epinephrine solutions ("Patent Case"), and the *inter partes* review proceeding filed by Adamis in the United States Patent and Trademark Office requesting a formal review the validity of certain aspect of Belcher's patents ("IPR"). Under the terms of the settlement agreement, Adamis agreed to voluntarily withdraw both the Patent Case and IPR and Belcher agreed to provide Adamis a worldwide, non-exclusive, fully paid-up, royalty-free license relating to Belcher's patents for Adamis' epinephrine injection product, SYMJEPI, and agreed not to make future claims of infringement relating to Adamis' naloxone injection product candidate, ZIMHI. The parties agreed to file requests of voluntary dismissal in the Florida court and USPTO, as appropriate.

Litigation with kaléo Inc.

On July 18, 2019, the Company announced that Adamis and kaléo Inc. agreed to settle all previously announced litigation between the parties, including the case filed by kaléo in the United States District Court for the District of Delaware in which kaléo claimed specified aspects of Adamis' ZIMHI naloxone product infringed certain kaléo-owned patents, and the case filed by Adamis in the United States District Court for the Eastern District of Virginia in which Adamis claimed specified actions by kaléo infringed Adamis' SYMJEPI trademark. As part of the resolution of the current litigation, kaléo agreed not to bring future action against Adamis relating to ZIMHI so long as Adamis does not reference kaléo's product in a future filing with the FDA, and Adamis agreed not to bring future action against kaléo for acts that occurred prior to the settlement date.

Financing

On August 5, 2019, the Company completed the closing of an underwritten public offering of 13,800,000 shares of common stock, and warrants ("Warrants") to purchase up to 13,800,000 shares of common stock, which included 1,800,000 shares and Warrants to purchase up to 1,800,000 shares pursuant to the full exercise of the over-allotment option granted to the underwriters. The exercise price of the Warrants is $1.15 per share, and the Warrants are exercisable for five years. Each share of common stock was sold together with a warrant to purchase one share of common stock for a combined public offering price of $1.00 per unit. Estimated net proceeds were approximately $12.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. Raymond James & Associates, Inc. acted as the sole book-running manager for the offering, and Maxim Group LLC acted as lead 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 prospectus supplement and an accompanying prospectus relating to the offering.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Information Relating to Forward-Looking Statements

This Quarterly Report on Form 10-Q (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 Report. In addition, many forward-looking statements concerning our anticipated future business activities assume that we are able to obtain sufficient funding in the near term and thereafter to support such activities and continue our operations and planned activities. As discussed elsewhere in this Report, we may require additional funding during 2019 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 and in our Annual Report on Form 10-K for the year ended December 31, 2018 (sometimes referred to as the "2018 Form 10-K") that we previously filed with the Securities and Exchange Commission, including without limitation the "Risk Factors" section in this Report and in the 2018 Form 10-K, 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 Report including, without limitation, under the headings "Part II, Item 1A. Risk Factors," and "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our 2018 Form 10-K, including, without limitation, under the headings "Part I, Item 1A. Risk Factors," "Part I, Item 1. Business," and "Part II, 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.

Unless the context otherwise requires, the terms "we," "our," and "the Company" refer to Adamis Pharmaceuticals Corporation, a Delaware corporation, and its subsidiaries.

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, and opioid overdose markets include: SYMJEPI (epinephrine) Injection 0.3mg, which was approved by the U.S. Food and Drug Administration, or FDA, in 2017 for use in the emergency treatment of acute allergic reactions, including anaphylaxis; SYMJEPI (epinephrine) Injection 0.15mg which was approved by the FDA in September 2018, for use in the treatment of anaphylaxis for patients weighing 33-65 pounds; a naloxone injection product candidate ("ZIMHI") based on the approved Symject™ injection device and intended for the treatment of opioid overdose for which the company submitted a New Drug Application, or NDA, in December 2018 which was accepted for review by the FDA in March 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.

SYMJEPI (epinephrine) Injection

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 for patients weighing 66 pounds or more.

On September 27, 2018, FDA approved our lower dose SYMJEPI (epinephrine) Injection 0.15mg, for the emergency treatment of allergic reactions (Type I) including anaphylaxis in patients weighing 33 to 65 pounds. In July 2018, we entered into a Distribution and Commercialization Agreement with Sandoz Inc., a division of Novartis AG, to commercialize both of our SYMJEPI products. Under the terms of the agreement, we appointed Sandoz as the exclusive distributor of SYMJEPI in the United States and related territories, 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. 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.

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, initially available in the institutional setting. On July 9, 2019, we announced the full launch (institutional and retail) by Sandoz of both dose forms of the SYMJEPI injection products. See Note 2 to the financial statements for further information about the agreement.

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 subset of that market.

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. In January 2018, we submitted an IND application to the FDA to begin Phase 3 efficacy studies for a new formulation of 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. However, we have delayed the continuation of the start-up phase and start of patent enrollment for the studies in light of, among other factors, the availability of adequate funding to continue and complete the studies. The timing of enrollment for, and the pace of conduct, progress, and completion of, such studies, and our decisions concerning such matters, are affected by a number of factors, including without limitation the availability of 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, we may require additional funding to continue all of our anticipated product development activities, and product development times are subject to a number of risks and uncertainties, which can delay the actual development time beyond our estimates.

ZIMHI (naloxone) Injection

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

As announced in December 2018, the Company filed an NDA relating to its higher dose naloxone injection product, ZIMHI, for the treatment of opioid overdose. On March 14, 2019, the Company received notice from the FDA that it had determined the NDA was sufficiently complete to permit a substantive review, and the agency 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. In June 2019, the Company amended the NDA to remove any reference to the EVZIO® product and withdrew the associated Paragraph IV certification relating to that product. As a result, Narcan injectable (NDA 016636) now remains as the sole Reference Listed Drug and, because there are no Orange Book listed patents for NDA 016636, no patent certification is required. The Company is conducting additional studies comparing the Company's product and a relevant comparator and will submit the results to the FDA when completed. The Company is currently exploring commercialization options for the Naloxone product and is engaged in discussions with potential commercialization and marketing partners.

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.

Other

We previously were pursuing development of a fast-disintegrating sublingual tablet containing tadalafil (APC-8000), a drug used for treating erectile dysfunction.

On December 28, 2018, we filed an NDA for a fast-disintegrating sublingual version of tadalafil 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. After reviewing and considering the FDA's comments, we have determined that the information, data and deliverables that the agency would require for a resubmitted NDA to be deemed complete would require significant additional time and resources to complete. For that reason and to prioritize our financial resources among our activities, products and product candidate pipeline, we have determined not to devote significant resources to further development work on APC-8000.

Recent Developments

On August 5, 2019, the Company completed the closing of an underwritten public offering of 13,800,000 shares of common stock, and warrants ("Warrants") to purchase up to 13,800,000 shares of common stock, which included 1,800,000 shares and Warrants to purchase up to 1,800,000 shares pursuant to the full exercise of the over-allotment option granted to the underwriters. The exercise price of the Warrants is $1.15 per share, and the Warrants are exercisable for five years. Each share of common stock was sold together with a warrant to purchase one share of common stock for a combined public offering price of $1.00 per unit. Estimated net proceeds were approximately $12.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. Raymond James & Associates, Inc. acted as the sole book-running manager for the offering, and Maxim Group LLC acted as lead 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 prospectus supplement and an accompanying prospectus relating to the offering.

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 June 30, 2019, we had cash of approximately $4.1 million, an accumulated deficit of approximately $169.6 million, and liabilities of approximately $13.3 million. As described above, in August 2019, we completed a public offering of common stock and Warrants, resulting in estimated net proceeds of approximately $12.7 million. We could require significant funding in the future to continue operations, 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. Such additional funding, if required, may not be available, may not be available on reasonable terms, and, in the case of equity funding, could result in significant additional dilution to our stockholders. If we do not obtain required additional equity or debt funding, our cash resources would 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 unaudited condensed consolidated financial statements included elsewhere herein for the six months ended June 30, 2019, 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 unaudited condensed 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 unaudited condensed consolidated 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 funds in 2019 from debt or equity financing, sales of assets, sales or out-licenses of intellectual property, products, product candidates or technologies, or from a business combination or a similar transaction, after expenditure of our existing cash resources and revenues from existing agreements and sales of prescription compounded formulations, we would exhaust our resources and be unable to continue operations.

Our management intends to attempt to secure additional required funding through equity or debt financings, sales or out-licensing of intellectual property assets, products, product candidates or technologies, 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 existing agreements and sales of prescription compounded formulations. However, there can be no assurance that we will be able to obtain required funding. If we are unsuccessful in securing sufficient funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures, delay development or commercialization of some or all of our products and reduce the scope of our operations. 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.

Results of Operations

Three Months Ended June 30, 2019 and 2018

Revenues. Revenues were approximately $5,765,000 and $3,921,000 for the three months ended June 30, 2019 and 2018, respectively. Revenues increased by approximately $1,844,000 in the three months ended June 30, 2019 compared to the comparable period of 2018. Approximately $724,000 of the increase in revenues was due to the increase in sales of USC's sterile pharmaceutical formulations resulting in part from an increase in production capacity in order to meet product demand and marketing personnel efforts. The increase in revenue for the three-month period 2019 was impacted by approximately $1,120,000 of outsourced manufacturing revenue relating to sales of SYMJEPI (epinephrine) Injection 0.3mg and .15mg. There was no revenue relating to sales of that product for the three months ended June 30, 2018.

Cost of Goods Sold. Cost of goods sold was approximately $3,666,000 and $2,394,000 for the three months ended June 30, 2019 and 2018, respectively. Our cost of goods sold includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, shipping and handling costs, the write-off of obsolete inventory and other related expenses. The gross margin percentage for the three months ended June 30, 2019 was approximately 36% compared to approximately 39% for the three months ended June 30, 2018. The cost of goods sold for the three-month 2019 period compared to the three-month period of 2018 increased primarily due to the increase of approximately $1,052,000 in direct materials, and supplies; primarily caused by an increase in production of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg. Approximately $220,000 of the increase was due to the increase in compensation, consulting services and other employee benefits as a result of new hires related to the increase in production and added shifts at USC.

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 three months ended June 30, 2019 and 2018 were approximately $7,000,000 and $6,363,000, respectively. SG&A expenses increased by approximately $637,000 for the three-month period in 2019 year compared to the same period in 2018, primarily due to increases in sales commissions, facility costs, legal expenses and patent expenses of approximately $637,000.

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 $2,846,000 and $4,836,000 for the three months ended June 30, 2019 and 2018, respectively. The decrease in research and development expenses for the three months ended June 30, 2019, compared to the 2018 period was primarily due to a decrease of approximately $278,000 in development costs of our product candidates, including SYMJEPI (epinephrine) Injection products, APC-4000 and APC-8000. The decrease was partially offset by an increase of approximately $267,000 in development costs attributed to the APC-1000, ZIMHI (naloxone) Injection and general research and development consulting and other related development expenses. Compensation for research and development employees increased by approximately $258,000 for the three months ended June 30, 2019, compared to the 2018 three-month period, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with equity compensation and other employee benefits. Write-offs related to obsolete SYMJEPI inventory that is expected to expire before resale decreased approximately $2,237,000 for the three months ended June 30, 2019 compared to the same period in 2018.

Other Income (Expense). Other Income (Expense) consists of interest expense and interest income. Other income and expense for the three months ended June 30, 2019 and 2018 was approximately $11,000 and ($30,000), respectively. The decrease in other expenses in the three months ended June 30, 2019, compared to the comparable period of 2018 was primarily due to a decrease in debt related expense (Interest Expense) of approximately $28,000 and an increase of interest income of approximately $13,000 for the three months ended June 30, 2019.

Six Months Ended June 30, 2019 and 2018

Revenues. Revenues were approximately $10,671,000 and $7,100,000 for the six months ended June 30, 2019 and 2018, respectively. Revenues increased by approximately $3,571,000 in the first six months of 2019 compared to the comparable period of 2018. Approximately $1,986,000 of the increase in revenues reflected an increase in sales of USC's sterile pharmaceutical formulations resulting in part from an increase in production capacity in order to meet product demand and marketing personnel efforts. The increase in revenue for the six-month period 2019 was also impacted by approximately $1,585,000 of outsourced manufacturing revenue relating to sales of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg. There was no revenue relating to sales of that product for the six months ended June 30, 2018.

Cost of Goods Sold. Cost of goods sold was approximately $7,291,000 and $4,458,000 for the six months ended June 30, 2019 and 2018, respectively. Our cost of goods sold includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, shipping and handling costs, the write-off of obsolete inventory and other related expenses. The gross margin percentage for the six months ended June 30, 2019 was approximately 32% compared to approximately 37% for the six months ended June 30, 2018. The cost of goods sold for the six-month 2019 period compared to the six-month period of 2018 increased primarily due to the increase of approximately $890,000 in compensation, consulting services and other employee benefits as a result of new hires related to the increase in production and added shifts at USC. Approximately $1,943,000 of the increase was due to an increase in direct materials, supplies and obsolete inventory; primarily caused by an increase in production of SYMJEPI (epinephrine) Injection 0.3mg and .15mg.

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 six months ended June 30, 2019 and 2018 were approximately $15,022,000 and $12,837,000, respectively. Compensation expense for SG&A employees increased by approximately $787,000 for the six-month period in 2019 year compared to the same period in 2018, primarily due to new hires, increase in sales commissions related to the increase in sales, increases in salary expenses and bonus accruals, and expenses associated with equity compensation and other employee benefits. Approximately $975,000 of the increase for the six-month period in 2019 compared to the same period in 2018 was primarily due to the PDUFA fees for the SYMJEPI (epinephrine) Injection 0.15mg approved in September 2018; expenses related to certain of our product candidates; and outside services and professional fees related to business development, legal and other related services. Approximately $423,000 of the increase for the first six months of 2019 compared to the same period of 2018 was due to increases in patent expenses primarily related to our product candidates and SYMJEPI (epinephrine) Injection; and increases in rent expense, supplies, 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 $5,042,000 and $7,085,000 for the six months ended June 30, 2019 and 2018, respectively. The decrease in research and development expenses for the six months ended June 30, 2019, compared to the 2018 period was primarily due to a decrease of approximately $1,469,000 in development costs of our product candidates, including ZIMHI (naloxone) Injection, APC-4000 and APC-8000, including approximately $970,000 of refunded filing fees for an NDA for APC-8000 filed in December 2018. The decrease was partially offset by an increase of approximately $882,000 in development costs attributed to the APC-1000 product candidate and the SYMJEPI (epinephrine) Injection products, which includes additional maintenance and validation costs of its assembly lines; and general research and development consulting and other related expenses. Compensation for research and development employees increased by approximately $668,000 for the six months ended June 30, 2019, compared to the 2018 six-month period, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with equity compensation and other employee benefits. Write-offs related to obsolete SYMJEPI inventory that is expected to expire before resale decreased approximately $2,124,000 for the six months ended June 30, 2019 compared to the same period in 2018.

Other Income (Expense). Other Income (Expense) consists of interest expense and interest income. Other income and expense for the six months ended June 30, 2019 and 2018 was approximately $62,000 and ($42,000), respectively. The decrease in other expenses in the six months ended June 30, 2019, compared to the comparable period of 2018 was primarily due to a decrease in debt related expense (Interest Expense) of approximately $55,000 and an increase of interest income of approximately $48,000 for the six months ended June 30, 2019.

Liquidity and Capital Resources

We have incurred net losses of approximately $16.6 million and $17.3 million for the six months ended June 30, 2019 and 2018, respectively. Since inception, and through June 30, 2019, we have an accumulated deficit of approximately $169.6 million. Since inception and through June 30, 2019, we have financed operations principally through debt financing and through public and private issuances of common stock and preferred stock. As described above, in August 2019, we completed a public offering of common stock and Warrants, resulting in estimated net proceeds of approximately $12.7 million. If our existing cash together with revenues in future quarters are not sufficient to cover our expenses, we may require additional funding 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 expect to finance future cash needs primarily through proceeds from equity or debt financings, sales or out-licensing or intellectual property assets, products, product candidates or technologies, seeking partnerships with other pharmaceuticals companies or third parties to co-develop and fund research and development efforts, or similar transactions, and through revenues from existing agreements and sales of prescription compounded formulations.

Total assets were approximately $47.1 million and $58.4 million as of June 30, 2019 and December 31, 2018, respectively. As of June 30, 2019, current assets exceed current liabilities by approximately $510,000 and as of December 31, 2018, current assets exceed current liabilities by approximately $14.2 million.

Net cash used in operating activities for the six months ended June 30, 2019 and 2018, was approximately $12.7 million and $12.4 million, respectively. Net cash used in operating activities increased primarily due to the increase in operating losses, increases in accounts receivable and decrease in accounts payable, and primarily reduced by the increase in inventory purchases, as compared to 2018.

Net cash used in investing activities was approximately $2.2 million and $1.3 million for the six months ended June 30, 2019 and 2018, respectively. The net cash used in investing activities increased primarily due to the purchase of additional equipment.

Net cash used in financing activities was approximately $285,000 and $240,000 for the six months ended June 30, 2019 and 2018, respectively. Net cash used in financing activities consisted of principal payments of finance leases and USC's building and equipment loans.

As noted above under the heading “Going Concern and Management Plan,” through June 30, 2019, Adamis had incurred substantial losses. The availability of any required additional funding cannot be assured. If we do not obtain required additional equity or debt funding, our cash resources could be depleted and we could be required to materially reduce or suspend operations. Even if we are successful in obtaining required additional funding to permit us to continue operations at the levels that we desire, substantial time may pass before we obtain regulatory marketing approval for any additional specialty pharmaceutical products and begin to realize revenues from sales of such additional products, and during this period Adamis could require additional funds. No assurance can be given as to the timing or ultimate success of obtaining any required future funding. 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 unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company's critical accounting policies and estimates previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018 have not significantly changed. Refer to Note 1 to the accompanying financial statements of this Quarterly Report on Form 10-Q for the additional policy adopted during the three months ended June 30, 2019.

Recent Accounting Pronouncements

Recent accounting pronouncements are disclosed in Note 1 to the accompanying financial statements of this Quarterly Report on Form 10-Q.

Off Balance Sheet Arrangements

At June 30, 2019, Adamis did not have any off balance sheet arrangements.

ITEM 3. Quantitative and Qualitative Disclosure of Market Risk

Not required.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Internal Controls

There has been no change during the quarter ended June 30, 2019 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. 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 (the "Patent Case") 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. On December 28, 2018, Belcher filed a reissue application for one of the Patents-in-Suit seeking to amend the asserted claims and correct an improper benefit claim. On March 29, 2019, the parties agreed to stay the litigation at the District Court pending the outcome of the reissue application and the company's forthcoming petition for *inter partes* review, filed with the U.S. Patent and Trademark Office in April 2019, to challenge the validity of the remaining Patent-in-Suit (the "IPR").

On July 24, 2019, the Company announced that the Company and Belcher agreed to settle all previously filed litigation between the parties, including the Patent Case and the IPR. Under the terms of the settlement agreement, the Company agreed to voluntarily withdraw both the Patent Case and IPR and Belcher agreed to provide the Company a worldwide, non-exclusive, fully paid-up, royalty-free license relating to Belcher's patents for the Company's epinephrine injection product, SYMJEPI, and agreed not to make future claims of infringement relating to the Company's naloxone injection product candidate, ZIMHI. The parties agreed to file requests of voluntary dismissal in the Florida court and USPTO, as appropriate.

On May 20, 2019, the Company received notice that it had been named and served as a defendant in a lawsuit filed by kaléo Inc. in the United States District Court for the District of Delaware regarding the Company's higher dose naloxone injection product candidate for the treatment of opioid overdose, ZIMHI, for which the Company has previously submitted an NDA to the FDA and which is being reviewed by the agency. The complaint alleges, among other things, that the Company's product candidate infringes patents purportedly held by kaléo relating to its naloxone auto-injector product. On June 21, 2019, the Company filed a motion to dismiss the lawsuit for lack of subject matter jurisdiction, in light of an amendment filed by the Company to its original NDA removing any reference to kaléo's EVZIO® product, which the Company contended contends prevented kaléo from claiming infringement under the Hatch-Waxman Act. On the same day, the Company filed a separate lawsuit in the United States District Court for the Eastern District of Virginia against kaléo for cybersquatting under 15 U.S.C. § 1125(d), unfair competition under 15 U.S.C. § 1125(a), and common law unfair competition and trademark infringement for kaléo's use of Adamis' SYMJEPI trademark.

On July 18, 2019, the Company announced that the Company and kaléo agreed to settle all previously announced litigation between the parties, including the cases described above. As part of the resolution of the litigation, kaléo agreed not to bring future action against the Company relating to ZIMHI so long as the Company does not reference kaléo's product in a future filing with the FDA, and the Company agreed not to bring future action against kaléo for acts that occurred prior to the settlement date.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q 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 if required, 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 funding to continue as a going concern.

We incurred net losses of approximately $39.0 million and $16.6 million for the year ended December 31, 2018 and the six months ended June 30, 2019, respectively, and a net loss of approximately $25.5 million for the year ended December 31, 2017. At June 30, 2019, we had cash and cash equivalents of approximately $4.1 million, accounts receivable of approximately $2.9 million and liabilities of approximately $13.3 million. In August 2019, we completed a public offering of common stock and warrants, resulting in estimated net proceeds of approximately $12.7 million. The development of our business may require additional funds to help fund the development and commercialization of our products and 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. In addition to product revenues, we have historically relied upon sales of our equity or debt securities to fund our operations. We currently have no available balance in our credit facility or committed sources of capital. Delays in obtaining required funding could adversely affect our ability to develop and commercially introduce products and cause us to be unable to comply with our obligations under outstanding instruments.

Our ability to obtain financing if required will be subject to a number of factors, including 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 Report concerning our future plans and operations are dependent on our ability to secure adequate funding and the absence of unexpected delays or adverse developments. We may not be able to secure required funding.

The statements contained in this Report concerning future events or developments or our future activities, such as concerning current or planned clinical trials, anticipated research and development activities, anticipated dates for commencement of clinical trials, anticipated completion dates of clinical trials, anticipated meetings with the FDA or other regulatory authorities concerning our product candidates, anticipated dates for submissions to obtain required regulatory marketing approvals, anticipated dates for commercial introduction of products, 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 and $16.6 million for the year ended December 31, 2018 and the six months ended June 30, 2019, respectively, and a net loss of approximately $25.5 million for the year ended December 31, 2017. From inception through June 30, 2019, we have an accumulated deficit of approximately $169.6 million. We expect that these losses could increase as we continue our research and development activities, seek regulatory approvals for our product candidates and 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 or other commercialization agreements that we may enter into to become profitable at all or on a sustained basis. We expect to have quarter-to-quarter fluctuations in revenue and expenses, some of which could be significant, due in part to variations in expenses and activities relating to research, development, clinical 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 and amounts that we may receive pursuant to our commercialization agreement with Sandoz, 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 ZIMHI (naloxone) Injection, APC-1000 and APC-4000, 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: the availability of adequate funding to support product development efforts and sales and marketing efforts for approved products; general market conditions and developments in the marketplace including the introduction of potentially competing new products by our competitors; 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, approval of applications may be delayed by several years, or may require us to expend more resources than we may have available. It is also possible that additional studies may not suffice to make applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval.

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

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

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

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

We submitted a Section 505(b)(2) NDA regulatory filing to the FDA in connection with our approved SYMJEPI products, we submitted Section 505(b)(2) NDA regulatory filings to the FDA in connection with our ZIMHI (naloxone) Injection product candidate, and we 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. We provided such a Paragraph IV certification in connection with our NDA filing with the FDA in December 2018 relating to our ZIMHI (naloxone) Injection product candidate, and following the FDA's acceptance for filing and review of the NDA in March 2019, we provided such a notice. 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. As of the date of this Report, such 45-day period has not expired with respect to our ZIMHI NDA and we have not received notice of the filing of a patent infringement lawsuit relating to our ZIMHI product candidate.

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 relating to review and approval of a product that was subject to such litigation would be delayed. In addition, we would incur the expenses, which could be material, involved with any such patent litigation. As a result, we may invest a significant amount of time and expense in the development of our product only to be subject to significant delay and patent litigation before our product may be commercialized, if at all.

In addition, even if we submit a Section 505(b)(2) application, such as we may submit for other future products, that relies on 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.

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

The markets for our SYMJEPI 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, 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 acquire 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 carry forwards 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 in the 2018 Form 10-K, 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; Need for Additional Financing.

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 Form 483 inspectional observations, 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.

Human drug compounding outsourcing facilities have historically been subject to FDA inspections on an irregular basis and are now subject to FDA inspections on a risk-based schedule in accordance with DQSA Section 503B(b)(4). Observations by the FDA of potentially violative conditions during inspections are required to be reported to facility management at the close of the inspection on 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, July 2016, and February 2019, USC received Form 483 inspectional observations following FDA inspections of its outsourcing facility, noting inspectional observations of a number of observed potential deficiencies relating to USC's facility and practices.

Following the August 2015 Form 483 observations, and prior to our acquisition of USC, USC temporarily suspended production of sterile products and voluntarily recalled certain lots of sterile product. USC determined there was no evidence that any compounded sterile products were defective, but decided to voluntarily recall all sterile product that remained within expiry and temporarily halt sterile production. USC responded to the August 2015 Form 483 observations and took a number of corrective actions, including enhancing quality control and production systems**.** Approximately around the time of its acquisition by Adamis, USC resumed production and sale of its sterile products. In July 2016, USC received 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. USC was inspected by FDA in the early part of 2019, with a Form 483 issued to site management in February 2019. USC duly responded to the inspectional observations in writing in March 2019 and has provided timely updates to FDA on progress of corrective actions.

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 human drug compounding 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 the medications compounded and distributed by USC, but rather FDA establishes standards for manufacturing processes controls to ensure drug quality. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed. Drugs available through branded and generic drug companies have been approved for marketing and sale by the FDA and are subject to many more requirements than drugs compounded in outsourcing facilities. In addition, some compounding pharmacies have been the subject of widespread negative media coverage in 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 ingredients purchased from FDA-registered suppliers, but the finished compounded drug products 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. 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 June 30, 2019, our aggregate indebtedness under the Amended Loan Documents was approximately $2,334,000.

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

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

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

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

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

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

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

Participants in the healthcare industry, including USC and its suppliers and customers, are subject to a variety of federal, state, and local laws and regulations. Laws and regulations in the healthcare industry are extremely complex and, in many instances, industry participants do not have the benefit of significant regulatory or judicial interpretation. Though certain of these healthcare laws and regulations are not directly applicable to USC or us, they may be applicable to USC's customers, third-party vendors, and other supply chain partners. For example, the 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 June 30, 2019, the market price of our common stock has fluctuated between $1.25 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;
- our ability to successfully expand sales of our compounded pharmacy medications;
- 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;
- 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 June 30, 2019, we had 47,638,109 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 June 30, 2019, 8,346,058 shares of common stock were 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 3,681,796 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 or issuance of shares following vesting of the restricted stock units, the underlying shares may be resold into the public market, subject in some cases to volume and other limitations or prospectus-delivery requirements pursuant to registration statements registering the resale of such shares. In the case of outstanding options or warrants that have exercise prices that are below the market price of our common stock from time to time, or upon issuance of shares following vesting of restricted stock units, our stockholders would experience dilution upon the exercise of these options.

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

As of June 30, 2019, we had outstanding warrants, other than the warrants described in the next sentence, to purchase 58,824 shares of common stock, at a weighted average exercise price of $8.50 per share. As of June 30, 2019, 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 June 30, 2019, our directors, executive officers and their respective affiliates owned approximately 1.5% 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 control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

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

31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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

SIGNATURES

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

ADAMIS PHARMACEUTICALS, INC.

Date: August 08, 2019

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

Date: August 08, 2019

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

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 Quarterly Report on Form 10-Q 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 quarterly 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 we 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 quarterly report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting disclosure 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 quarterly 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 data; 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: August 08, 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 Quarterly Report on Form 10-Q 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 quarterly 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 we 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 quarterly report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting disclosure 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 quarterly 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 data; 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: August 08, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 (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: August 08, 2019

This certification is being furnished to the SEC with this Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and 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.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Robert O. Hopkins, as 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 (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: August 08, 2019

This certification is being furnished to the SEC with this Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and 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.