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 September 30, 2018

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)

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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

Indicate by check mark whether the registrant 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 November 9, 2018, was 47,291,358.

ADAMIS PHARMACEUTICALS, INC.
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ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018	December 31, 2017
ASSETS	(Unaudited)	
CURRENT ASSETS		
Cash	$ 32,034,584	$ 17,323,241
Restricted Cash	—	1,009,461
Accounts Receivable, net	1,195,959	830,090
Inventories, net	3,218,678	1,824,558
Prepaid Expenses and Other Current Assets	1,252,007	474,180
Total Current Assets	37,701,228	21,461,530
LONG TERM ASSETS		
Security Deposits	54,655	54,655
Intangible Assets, net	13,829,619	15,686,687
Goodwill	7,640,622	7,640,622
Fixed Assets, net	9,203,278	6,559,664
Other Non-Current Assets	1,800,000	—
Total Assets	$ 70,229,402	$ 51,403,158
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable	$ 3,457,149	$ 2,919,120
Deferred Revenue	1,014,707	14,758
Accrued Other Expenses	3,396,259	2,300,672
Accrued Bonuses	1,343,493	1,069,021
Bank Loans - Line of Credit	—	2,000,000
Bank Loans - Building and Equipment, current portion	2,672,033	483,992
Total Current Liabilities	11,883,641	8,787,563
LONG TERM LIABILITIES		
Deferred Tax Liability, net	485,002	485,002
Building and Equipment Loans, net of current portion	34,026	2,583,109
Total Liabilities	12,402,669	11,855,674
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Common Stock - Par Value $.0001; 100,000,000 Shares Authorized; 47,814,315 and 33,696,920 Issued, 47,291,358 and 33,389,380 Outstanding at September 30, 2018 and December 31, 2017, Respectively	4,781	3,369
Additional Paid-in Capital	198,020,815	153,546,932
Accumulated Deficit	(140,193,613)	(113,997,588)
Treasury Stock, at cost - 522,957 and 307,540 Shares at September 30, 2018 and December 31, 2017, Respectively	(5,250)	(5,229)
Total Stockholders' Equity	57,826,733	39,547,484
	$ 70,229,402	$ 51,403,158

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		Nine Months Ended	
	September 30, 2018	**September 30, 2017**	**September 30, 2018**	**September 30, 2017**
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
REVENUE, net	$ 3,832,935	$ 3,388,221	$ 10,932,736	$ 10,231,426
COST OF GOODS SOLD	2,300,432	2,092,270	6,757,989	5,638,283
Gross Profit	1,532,503	1,295,951	4,174,747	4,593,143
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	6,534,746	5,747,572	19,371,492	16,975,376
RESEARCH AND DEVELOPMENT	3,908,408	1,248,187	10,993,111	3,943,934
LOSS ON IMPAIRMENT OF FIXED ASSETS	—	96,346	—	96,346
Loss from Operations	(8,910,651)	(5,796,154)	(26,189,856)	(16,422,513)
OTHER INCOME (EXPENSE)				
Interest Expense	(30,653)	(52,635)	(132,755)	(179,540)
Interest Income	66,020	39,710	126,586	48,975
Inducement Expense for Exercise of Warrants	—	(960,230)	—	(960,230)
Total Other Income (Expense), net	35,367	(973,155)	(6,169)	(1,090,795)
Net (Loss)	$ (8,875,284)	$ (6,769,309)	$ (26,196,025)	$ (17,513,308)
Basic and Diluted (Loss) Per Share:				
Basic and Diluted (Loss) Per Share	$ (0.21)	$ (0.21)	$ (0.72)	$ (0.66)
Basic and Diluted Weighted Average Shares Outstanding	42,085,852	31,509,050	36,320,142	26,651,249

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2018	**2017**
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (Loss)	$ (26,196,025)	$ (17,513,308)
Adjustments to Reconcile Net (Loss) to Net		
Cash (Used in) Operating Activities:		
Stock Based Compensation	4,859,453	4,502,093
Inducement Expense for Exercise of Warrants	—	960,230
Provision for Bad Debts	98,710	73,384
Depreciation and Amortization Expense	2,320,148	2,318,417
Loss on Impairment of Fixed Assets	—	96,346
(Gain) on Sale of Fixed Assets	(758)	—
Change in Assets and Liabilities:		
(Increase) Decrease in:		
Accounts Receivable - Trade	(464,579)	(269,198)
Inventories	(1,394,120)	(54,021)
Prepaid Expenses and Other Current Assets	(777,827)	17,131
Other Non-Current Assets	(300,000)	—
Increase (Decrease) in:		
Accounts Payable	603,119	(400,290)
Deferred Revenue	999,949	(17,088)
Accrued Other Expenses and Bonuses	(129,941)	400,315
Net Cash (Used in) Operating Activities	(20,381,871)	(9,885,989)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of Equipment	(3,171,026)	(1,456,841)
Purchase of Intangibles	—	(25,837)
Net Cash (Used in) Investing Activities	(3,171,026)	(1,482,678)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from Issuance of Common Stock, net of issuance cost	37,619,759	16,036,134
Proceeds from Exercise of Warrants, net of exercise cost	—	16,766,650
(Payments) of Bank Loans	(364,980)	(2,212,583)
Net Cash Provided by Financing Activities	37,254,779	30,590,201
Increase in Cash and Restricted Cash	13,701,882	19,221,534
Cash and Restricted Cash:		
Beginning	18,332,702	5,095,760
Ending	$ 32,034,584	$ 24,317,294

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2018	**2017**
	(Unaudited)	(Unaudited)
RECONCILIATION OF CASH AND RESTRICTED CASH		
Cash	$ 32,034,584	$ 23,312,476
Restricted Cash	—	1,004,818
Total Cash and Restricted Cash	$ 32,034,584	$ 24,317,294
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash Paid for Income Taxes	$ 8,650	$ 13,645
Cash Paid for Interest	$ 156,149	$ 182,823
SUPPLEMENTAL DISCLOSURE OF NON-CASH OPERATING, FINANCING AND INVESTING ACTIVITIES		
Increase in Contract Costs and Other Non-Current Assets	$ 1,500,000	$ —
Decrease in Accrued Capital Expenditures	$ (65,090)	$ —
Exercise of Warrants for Payment of Working Capital Line	$ 1,996,062	$ —
Acquisition of Treasury Shares in Connection with Warrant Exercise	$ 21	$ —

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 statement 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 consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Inventories

Inventories are valued at the lower of cost or net realizable value ("NRV"). The cost of inventories is determined using the first-in, first-out ("FIFO") method. Inventories consist of compounding formulation raw materials, currently marketed products, and device supplies. A reserve for obsolescence is recorded monthly based on a review of inventory for obsolescence.

Liquidity and Capital Resources

The Company's cash balance was $32,034,584 and $18,332,702 at September 30, 2018 and December 31, 2017, respectively. The December 31, 2017 cash balance includes approximately $1.0 million in restricted cash held by the Bear State Bank, N.A. as collateral for a $2.0 million working capital line.

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 may require additional 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. Management's plans include attempting to secure additional required funding through equity or debt financings, sales or out-licensing of intellectual property assets, seeking partnerships with other pharmaceutical companies or third parties to co-develop and fund research, development or commercialization efforts, or similar transactions. 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 as of September 30, 2018 and September 30, 2017 consist of outstanding equity classified warrants (2,166,995 and 3,189,052, respectively), outstanding options (9,339,037 and 6,598,817, respectively), and outstanding restricted stock units (1,642,212 and 1,300,000, respectively).

Recently Adopted Accounting Pronouncements

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

The Company evaluated the impact that adoption of this new standard will have on its consolidated financial statements and determined that the timing of revenue recognition and amount of revenue recognized is not materially impacted under the new standard. Accordingly, it did not have a material quantitative impact on the Company's revenue recognition relating to sales of compounded pharmacy formulations and other pharmacy products by U.S. Compounding, Inc. ("USC"), a subsidiary. The Company also determined that the modified retrospective adoption will have no impact on either the timing or amount of prior period revenues. As a result, any comparative information has not been restated. Refer to Note 2 for further details.

In March 2018, the FASB issued ASU No. 2018-05, Income Taxes (Topic 740): *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* which allowed SEC registrants to record provisional amounts in earnings for the year ended December 31, 2017 due to the complexities in accounting for the enactment of the Tax Cuts and Jobs Act (TCJA). The Company recognized the estimated income tax effects of the TCJA in its 2017 Consolidated Financial Statements in accordance with SEC Staff Accounting Bulletin No. 118 ("SAB No. 118"). At December 31, 2017, the Company remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The remeasurement of the net deferred tax liability resulted in a provision benefit of $339,000 recorded through continuing operations.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842). The amendments under this pronouncement will change the way all leases with a duration of one year or more are treated. Under this guidance, lessees will be required to capitalize virtually all leases on the balance sheet as a right-of-use asset and an associated financing lease liability or capital lease liability. The right-of-use asset represents the lessee's right to use, or control the use of, a specified asset for the specified lease term. The lease liability represents the lessee's obligation to make lease payments arising from the lease, measured on a discounted basis. Based on certain characteristics, leases are classified as financing leases or operating leases. Financing lease liabilities, those that contain provisions similar to capitalized leases, are amortized like capital leases are under current accounting, as amortization expense and interest expense in the statement of operations. Operating lease liabilities are amortized on a straight-line basis over the life of the lease as lease expense in the statement of operations. This update is effective for annual reporting periods, and interim periods within those reporting periods, beginning after December 15, 2018. In July 2018 the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases and ASU 2018-11, Leases (Topic 842), Targeted Improvements, which provided additional implementation guidance on the previously issued ASU. The Company is currently assessing the impact of adopting this guidance on its consolidated financial statements.

In June 2018, the FASB issued Accounting Standards Update No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Non employee Share-Based Payment Accounting.* This update simplifies the accounting for non employee share-based payment transactions by expanding the scope of Topic 718, Compensation-Stock Compensation, to include share-based payment transactions for acquiring goods and services from non-employees. The guidance is effective for annual periods beginning after December 15, 2018, and interim periods within that reporting period. The Company is currently evaluating the updated standard but does not expect that adopting this guidance will have a material effect on its consolidated financial statements.

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

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

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

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

Currently, the Company's revenues are entirely attributed to its USC subsidiary. The only performance obligation identified with the Company's sales arrangements is the delivery of the products, so revenue is recognized upon delivery of the promised goods to the customers. Revenue is measured at the point control transfers and represents the amount of consideration the Company expects to receive in exchange for transferring the goods. USC is a registered drug compounding outsourcing facility under Section 503B of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, and provides prescription compounded medications to humans and animals, including compounded sterile preparations or CSPs, and non-sterile compounds to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States.

Disaggregation of Revenue

As operations under a sterile environment are covered by Section 503B of the FDCA, and the U.S. Drug Quality and Security Act, USC's 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 following table presents the Company's revenues disaggregated by sterile and non-sterile regulatory environments for the three months and nine months ended September 30, 2018 and 2017.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Sterile	$ 2,296,278	$ 2,104,213	$ 6,178,524	$ 6,323,125
Non-Sterile	1,536,657	1,284,008	4,754,212	3,908,301
Total	$ 3,832,935	$ 3,388,221	$ 10,932,736	$ 10,231,426

The revenues of the Company's pharmacy formulations rely, in large part, on sales generated from clinics/hospitals. Adverse economic conditions pose a risk that the Company's customers may reduce or cancel spending, which would impact the Company's revenue.

The following table presents the Company's revenue disaggregated by end market for the three months and nine months ended September 30, 2018 and 2017.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Clinics/Hospitals	$ 3,494,871	$ 3,035,913	$ 9,612,784	$ 9,080,547
Direct to Patients	338,064	352,308	1,319,952	1,150,879
Total	$ 3,832,935	$ 3,388,221	$ 10,932,736	$ 10,231,426

Distribution and Commercialization Agreement

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

The Agreement provides that Sandoz will pay to the Company 50% of the Net Profit from Net Sales, as each such term is defined in the Agreement, of the product in the Territory to third parties, determined on a quarterly basis. The Company will be the supplier of the product to Sandoz, and Sandoz will order and pay the Company a supply price for quantities of products ordered. The Company will be responsible for all manufacturing, component and supply costs related to manufacturing and supplying the product to Sandoz. The Company is responsible for component sourcing and regulatory compliance in the supply chain and for testing of lots of product.

Sandoz has agreed to use commercially reasonable efforts to commercialize the product, subject to various conditions and to the other provisions of the Agreement. The Agreement does not include minimum payments to the Company by Sandoz, minimum requirements for sales of product by Sandoz or, with certain exceptions, minimum purchase commitments by Sandoz. Under the Agreement, Sandoz has sole discretion in determining pricing, terms of sale, marketing, and selling decisions relating to the product. As of September 30, 2018, the Symjepi product has not been commercially launched.

Deferred Revenue

Deferred Revenue are contract liabilities that the Company records when cash payments are received or due in advance of the Company's satisfaction of performance obligations. The Company's performance obligation is met when control of the promised goods is transferred to the Company's customers. For the three months ended September 30, 2018 and 2017, $22,075 and $10,937 of the revenues recognized were reported as deferred revenue as of June 30, 2018 and 2017, respectively, and for the nine months ended September 30, 2018 and 2017, $14,758 and $54,478 of the revenues recognized were reported as deferred revenue as of December 31, 2017 and 2016, respectively. The increase in deferred revenue as of September 30, 2018 was primarily due to a payment received from Sandoz Inc., pursuant to the Agreement between the Company and Sandoz.

Cost to Obtain a Contract

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

The Company capitalized the $2.0 million fee payable to Jefferies as an incremental cost of obtaining a contract to commercialize and distribute the Company's first FDA approved product Symjepi™ with Sandoz, Inc. Of the $2.0 million fee, $500,000 was paid and $1.5 million was accrued as of September 30, 2018. The costs were deferred and will be amortized over the economic benefit period of approximately 10 years from date of product launch. The deferred costs were classified as current or non-current based on the timing of when the Company expects to recognize the expense. The current and non-current portions of the deferred costs were $200,000 included in prepaid expenses and other current assets and $1.8 million included in other non-current assets, respectively, in the Company's condensed consolidated balance sheets.

Practical Expedients

The Company pays commissions on certain sales once the customer payment has been received, which are accrued at the time of the sale. The Company generally expenses sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses.

Note 3: Acquisition of U.S. Compounding

On April 11, 2016, the Company acquired the net assets and assumed the principal debt obligations of U.S. Compounding, Inc. in a merger transaction (the "Merger") pursuant to which the Company acquired USC and USC continued as a wholly owned subsidiary of the Company. The acquisition is accounted for using the purchase method of accounting. USC is registered as a drug compounding outsourcing facility under Section 503B of the FDCA and the U.S. Drug Quality and Security Act, and provides prescription compounded medications, including compounded sterile preparation and certain nonsterile drugs, to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. USC also provides certain veterinary pharmaceutical drugs for animals. The total consideration for the transaction was $15,967,942.

Note 4: Inventories

Inventories, net of reserves, at September 30, 2018 and December 31, 2017 consisted of the following:

	September 30, 2018	December 31, 2017
Finished Goods	$ 1,236,633	$ 256,050
Raw Material	778,148	560,828
Devices	1,203,897	1,007,680
	$ 3,218,678	$ 1,824,558

Reserve for obsolescence as of September 30, 2018 and December 31, 2017 was approximately $194,000 and $795,000, respectively. During the nine months ended September 30, 2018 and 2017, approximately $3,421,000 and $263,000, respectively, of inventory was written off. The 2018 write off includes approximately $3,262,000 of Symjepi™ inventory.

Note 5: Fixed Assets

Fixed Assets at September 30, 2018 and December 31, 2017 are summarized in the table below:

Description	Useful Life (Years)	September 30, 2018	December 31, 2017
Building	30	$ 3,040,000	$3,040,000
Machinery and Equipment	3 - 7	2,214,306	1,525,643
Furniture and Fixtures	7	126,654	126,654
Automobile	5	9,395	9,395
Leasehold Improvements	7 - 15	284,037	284,037
Total Fixed Assets		5,674,392	4,985,729
Less: Accumulated Depreciation		(1,422,461)	(959,380)
Land		460,000	460,000
Construction In Progress - Equipment		4,491,347	2,073,315
Fixed Assets, net		$ 9,203,278	$6,559,664

Depreciation expense for the three months ended September 30, 2018 and 2017 was approximately $157,000 and $139,000, respectively; and for the nine months ended September 30, 2018 and 2017, depreciation expense was approximately $463,000 and $462,000, respectively.

Note 6: Intangible Assets and Goodwill

Intangible assets at September 30, 2018 and December 31, 2017 are summarized in the tables below:

September 30, 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	$ (4,611,632)	$ 5,097,068
Transition Services Agreement, 1 year	194,200	(194,200)	—
FDA 503B Registration & Compliance - USC, 10 years	3,963,000	(978,641)	2,984,359
Non-compete Agreement - USC, 3 years	1,639,000	(1,349,140)	289,860
Customer Relationships - USC, 10 years	5,572,000	(1,375,975)	4,196,025
Website Design - USC, 3 years	16,163	(8,530)	7,633
Total Definite-lived Assets	21,093,063	(8,518,118)	12,574,945
Trade Name and Brand - USC, Indefinite	1,245,000	—	1,245,000
Symjepi™ Domain Name	9,674	—	9,674
Balance, September 30, 2018	$ 22,347,737	$ (8,518,118)	$ 13,829,619

December 31, 2017	Gross Carrying Value	Accumulated Amortization	Net Carrying Amount
Definite-lived Intangible assets, estimated lives in years:			
Patents, Taper DPI Intellectual Property, 10 years	$ 9,708,700	$ (3,883,480)	$ 5,825,220
Transition Services Agreement, 1 year	194,200	(194,200)	—
FDA 503B Registration & Compliance - USC, 10 years	3,963,000	(681,416)	3,281,584
Non-compete Agreement, 3 years	1,639,000	(939,389)	699,611
Customer Relationships, 10 years	5,572,000	(958,074)	4,613,926
Website Design, 3 years	16,163	(4,491)	11,672
Total Definite-lived Assets	21,093,063	(6,661,050)	14,432,013
Trade Name and Brand - USC, Indefinite	1,245,000	—	1,245,000
Symjepi™ Domain Name	9,674	—	9,674
Balance, December 31, 2017	$ 22,347,737	$ (6,661,050)	$ 15,686,687

Amortization expense for the three months ended September 30, 2018 and 2017 was approximately $619,000 and $619,000, respectively; and for the nine months ended September 30, 2018 and 2017, amortization expense was approximately $1,857,000 and $1,856,000, respectively.

Estimated amortization expense of definite-lived intangible assets at September 30, 2018 for each of the five succeeding years and thereafter is as follows:

Year ending December 31,	
Remainder of 2018	$ 619,023
2019	2,083,034
2020	1,925,267
2021	1,924,370
2022	1,924,370
Thereafter	4,098,881
Total	$ 12,574,945

Goodwill recorded at the acquisition of USC was approximately $7,641,000 including the deferred tax liability of approximately $5,416,000 through acquisition goodwill. The carrying value of the Company's goodwill as of September 30, 2018 and December 31, 2017 was approximately $7,641,000.

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 (refer to 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 Note had no fair market value at the time of the merger in April 2009 between the Company (which was then named Cellegy Pharmaceuticals, Inc.) and the corporation then-named Adamis Pharmaceuticals Corporation.

Working Capital Line of Credit

On March 28, 2016, the Company entered into a loan and security agreement (sometimes referred to as the "Adamis Working Capital Line") with Bear State Bank, N.A. (the "Lender" or the "Bank"), pursuant to which the Company may borrow up to an aggregate of $2,000,000 to provide working capital to USC, subject to the terms and conditions of the loan agreement. Interest on amounts borrowed under the Adamis Working Capital Line accrues at a rate equal to the prime interest rate, as defined in the agreement. Interest payments are required to be made quarterly. As amended, the entire outstanding principal balance, and all accrued and unpaid interest and all other sums payable pursuant to the loan documents, were due and payable on June 1, 2018. The Company's obligations under the loan agreement were secured by certain collateral, including without limitation its interest in amounts that it has loaned to USC, and a warrant that the Company issued to the Bank to purchase up to 1,000,000 shares of the Company's common stock at an exercise price equal to par value per share. The warrant was exercisable only if the Company is in default under the loan agreement or related loan documents, the Lender delivers a notice to the Company and the Company does not cure the default within the applicable cure period. If the warrant became exercisable, then Lender may exercise the warrant in whole or in part, from time to time, to acquire warrant shares in a number that the Lender believes will, upon sale of such shares, be sufficient to cure or pay off the Company's obligations due to the Lender under the loan documents. Under the terms of the Warrant, the Lender agreed that following any exercise of the warrant, Lender will use its best efforts to sell as promptly as reasonably practicable following such exercise, the shares of common stock acquired by the Lender upon such exercise, and that all of the net proceeds from such sales of warrant shares will be applied in satisfaction of the Company's obligations under the loan documents. On June 28, 2018, the Company and the Lender amended the warrant and the loan and security agreement to provide that effective as of June 1, 2018, if the Company has not paid in full all amounts that are required to be paid to the Lender under the loan documents on or before the maturity date of the loan, then the Lender may exercise the Warrant, in whole or in part, to acquire a number of warrant shares as described above. In July 2018, the Lender delivered a notice of exercise of the warrant and sold warrant shares in an amount sufficient to satisfy substantially all of the outstanding principal balance of the loan. Refer to Note 10. The Company paid the remaining principal and accrued unpaid interest, and there is no outstanding balance under the Adamis Working Capital Line. In addition, the Lender released the Company's $1.0 million restricted Certificate of Deposit that had served as additional collateral for the Adamis Working Capital Line, and the amount is no longer restricted cash.

As of September 30, 2018 and December 31, 2017, the loan balance on the Adamis Working Capital Line of credit was $0 and $2,000,000, respectively. Interest expense related to the loan for the three months ended September 30, 2018 and 2017 was approximately $4,000 and $22,000, respectively; and for the nine months ended September 30, 2018 and 2017, interest expense was approximately $51,000 and $61,000, respectively.

Loans Assumed from Acquisition of USC:

Building Loan

In connection with the closing of the Merger and the transactions contemplated by the related merger agreement, 4 HIMS, LLC, an entity of which Eddie Glover, the chief executive officer of USC, and certain other former stockholders of USC are members, agreed to sell to the Company, the building and property owned by 4 HIMS on which USC's offices are located, in consideration of the Company being added as an additional "borrower" and assuming the obligations under the loan agreement, promissory note and related loan documents that 4 HIMS and certain other parties previously entered into with the Lender (the "4 HIMS Loan Documents").

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

As of September 30, 2018 and December 31, 2017, the outstanding principal balance owed on the applicable note was approximately $2,274,000 and $2,347,000, respectively. The loan currently bears an interest of 3.75% per year. Interest expense for the three months period September 30, 2018 and 2017 was approximately $22,000 and $23,000, respectively; and for the nine months ended September 30, 2018 and 2017, interest expense was approximately $66,000 and $68,000, respectively.

USC Working Capital Loan

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

On November 10, 2016, the Company and Lender agreed to amend the USC Working Capital Loan Documents to provide that the personal property securing the Borrower's obligations under the loan documents will also secure the Borrower's obligations under the other USC Loan Documents with the Lender. In addition, a new financial covenant replaced the previous financial covenants, providing that USC will, at all times during the term of the loan, maintain a "Cash Flow Coverage Ratio" of not less than 1.2:1. "Cash Flow Coverage Ratio" is defined as: (i) net income plus non-cash expense items including, but not limited to, depreciation expense, amortization expense and option expense for the month in which the measurement date occurs times 12; divided by (ii) the cash required for payments of interest for the prospective twelve (12) month period and current maturities of principal on all outstanding debt to any person or entity, including without limitation to debt by the Company to the Lender. The Cash Flow Coverage Ratio will be measured on the last day of each December, March, June and September, commencing on December 31, 2017. Under the amendment, in lieu of compliance with the foregoing covenant, Borrower has the option, at the time of each quarterly measuring period, of making a principal reduction in the amount of $250,000.

In addition, pursuant to the amendment, Borrower and Lender agreed that certain other financial covenants set forth in the loan agreement included in the 4 HIMS Loan Documents, the loan agreement included in the Tribute Loan Documents, and the loan agreement included in the USC Equipment Loan Agreement, as well as the original USC Working Capital Loan Agreement described above, are waived for the remainder of the term of the respective loans. The amended loan had a maturity date of September 30, 2017. In May 2017, the Company paid the remaining balance of the USC Working Capital Loan. In November 2017, the Company agreed with the Lender to extend the term of the USC Working Capital Loan agreement to February 28, 2018. There was no outstanding balance on the USC Working Capital Line at its maturity date, and that agreement has not currently been renewed or extended.

As of September 30, 2018 and December 31, 2017, the outstanding unpaid principal balance was $0. Interest expense for the three months ended September 30, 2018 and 2017 was approximately $0 and $0, respectively; and for the nine months ended September 30, 2018 and 2017, interest expense was approximately $0 and $29,000, 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 was $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 September 30, 2018 and December 31, 2017, the outstanding unpaid principal balance was approximately $432,000 and $720,000, respectively. Interest expense for the three months ended September 30, 2018 and 2017 was approximately $5,000 and $8,000, respectively; and for the nine months ended September 30, 2018 and 2017, interest expense was approximately $16,000 and $27,000, respectively.

Loan Amendment, Forbearance and Assumption Agreement

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

Pursuant to the Loan Amendment Agreement, Adamis was added as a "Borrower" and co-borrower under the loan agreements and related loan documents between USC (and certain other entities) and Lender (the "USC Loan Documents"), and assumed all of the rights, duties, liabilities and obligations as a Borrower and a party under the USC Loan Documents, jointly and severally with the current borrower or borrowers under each of the USC Loan Documents. As part of the Loan Amendment Agreement, the parties also agreed that the real and personal property securing each of the USC Loans will also secure each of the other USC Loans, as well as the Adamis Working Capital Line of $2.0 million. Except as expressly set forth in the Loan Amendment Agreement, as amended, the terms and provisions set forth in the USC Loan Documents were not modified and remain in full force and effect.

The notes evidencing the foregoing loans from the Lender 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 September 30, 2018, the Company believes that it is in compliance in all material respects with all the loan covenants.

At September 30, 2018, the outstanding principal maturities of the amended long-term debts were as follows:

Years ending December 31,	**Building Loan**	**Equipment Loan**	**Total**
Remainder of 2018	$ 24,754	$ 98,036	$ 122,790
2019	2,249,514	333,755	2,583,269
Total	$ 2,274,268	$ 431,791	$ 2,706,059

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, accounts payable, notes payable, accrued liabilities and other payables approximate their fair values due to their short-term nature.

Note 9: Legal Matters

As of the end of the quarter to which this Report on Form 10-Q relates, we are not a party to any legal proceedings that we believe, individually or in the aggregate, are expected to have a material adverse effect on our business, financial condition 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.

Note 10: Common Stock

On June 28, 2018, the Company and the Lender amended the Adamis Working Capital Line loan and security agreement and warrant disclosed in Note 7 above. In July 2018, the Lender delivered a notice of exercise of the warrant to acquire 699,978 shares of common stock and sold shares with proceeds in an amount sufficient to satisfy substantially all of the outstanding principal balance of the loan, and the remaining 215,417 shares were returned to the Company as treasury stock. Refer to Note 7.

On August 6, 2018, the Company completed the closing of an underwritten public offering of 13,416,667 shares of common stock at a public offering price of $3.00 per share, which included 1,750,000 shares pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds were approximately $37.6 million, after deducting approximately $2,630,000 in underwriting discounts and commissions and estimated offering expenses payable by the Company. Raymond James & Associates, Inc. acted as the sole book-running manager for the offering, B. Riley FBR acted as lead manager for the offering, and H.C. Wainwright & Co. and Maxim Group LLC acted as co-managers 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.

Note 11: Stock Option Plans, Shares Reserved and Warrants

The following table summarizes the stock option activity for the nine months ended September 30, 2018:

	2009 Equity Incentive Plan	Weighted Average Exercise Price	Weighted Average Remaining Contract Life
Balance as of December 31, 2017	6,726,594	$ 5.05	8.17 years
Options Granted	2,905,789	$ 3.01	9.43 years
Options Exercised	(4,166)	$ 3.35	—
Options Canceled/Expired	(289,180)	$ 5.78	—
Balance as of September 30, 2018	9,339,037	$ 4.39	8.15 years
Vested and Exercisable at September 30, 2018	5,511,795	$ 5.01	7.01 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 9,339,037 and 6,726,594 stock options outstanding at September 30, 2018 and December 31, 2017 was approximately $2,199,000 and approximately $2,980,000, respectively. The aggregate intrinsic value of 5,511,795 and 3,835,992 stock options exercisable at September 30, 2018 and December 31, 2017 was approximately $645,000 and $1,009,000, respectively.

The following table summarizes warrants outstanding at September 30, 2018:

	Warrant Shares	Exercise Price Per Share	Date Issued	Expiration Date
Old Adamis Warrants	58,824	$ 8.50	November 15, 2007	November 15, 2018
Underwriter Warrants	28,108	$ 7.44	December 12, 2013	December 12, 2018
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 Private Placement	700,000	$ 2.98	August 3, 2016	August 3, 2021
Total Warrants	2,166,995			

The following table summarizes the RSUs outstanding at September 30, 2018:

	RSUs	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 September 30, 2018 and 2017 was approximately $308,000 and $225,000, respectively; and for the nine months ended September 30, 2018 and 2017, expense related to RSUs was approximately $871,000 and $594,000, respectively.

At September 30, 2018, the Company has reserved shares of common stock for issuance upon exercise of outstanding options and warrants, vesting of RSUs and options and other awards that may be granted in the future under the 2009 Equity Incentive Plan, as follows:

Warrants	2,166,995
RSU	1,642,212
2009 Equity Incentive Plan	9,409,867
Total Shares Reserved	13,219,074

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 to support such activities and continue our operations and planned activities. As discussed elsewhere in this Report, we may require additional funding to continue operations, and there are no assurances that such funding, if required, 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, 2017 (sometimes referred to as the "2017 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 2017 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 update any forward-looking statements or to reflect events or circumstances arising after the date on which the statement is made or of this Report, or to reflect the occurrence of unanticipated events. 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 2017 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 primarily focused on developing and commercializing products in various therapeutic areas, including respiratory disease and allergy. Our current products and product candidates in development 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 is intended for use in the treatment of anaphylaxis for patients weighing 33-65 pounds; a naloxone injection product candidate (APC-6000) utilizing our approved Symject™ injection device used for our epinephrine product, intended for the treatment of opioid overdose; a beclomethasone hydrofluoroalkane, or HFA, metered dose inhaler product candidate (APC-1000) intended for the treatment of asthma; a fluticasone dry powder inhaler, or DPI, product candidate (APC-4000) for the treatment of asthma; and a tadalafil sublingual product candidate (APC-8000) for the treatment of erectile dysfunction. Our goal is to create low cost therapeutic alternatives to existing treatments. Consistent across all specialty pharmaceuticals product lines, we intend to submit New Drug Applications, or NDAs, under Section 505(b)(2), or Section 505(j) Abbreviated New Drug Applications, or ANDAs, to the FDA, whenever possible, in order to potentially reduce the time to market and to save on costs, compared to those associated with Section 505(b)(1) NDAs for new drug products. In July 2018, we entered into a distribution and commercialization agreement with Sandoz Inc., a division of Novartis AG, to commercialize the Symjepi product. Under the terms of the agreement, we appointed Sandoz as the exclusive distributor of Symjepi in the United States and related territories.

Our subsidiary U.S. Compounding, Inc., or USC, which we acquired in April 2016 and which is registered as a drug compounding outsourcing facility under Section 503B of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, and the U.S. Drug Quality and Security Act, or DQSA, provides prescription compounded medications, including compounded sterile preparations and nonsterile compounds, to patients, animals, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. USC's product offerings broadly include, among others, corticosteroids, hormone replacement therapies, hospital outsourcing products, injectables, urological preparations, ophthalmic preparations, and topical compounds for pain and men's and women's health products. USC's compounded formulations are often offered as alternatives to drugs approved by the FDA.

Recent Developments

Epinephrine Injection USP 1:1000 0.3mg Pre-filled Single Dose Syringe

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

On September 27, 2018, FDA approved our lower dose version (0.15mg) of Symjepi™ (epinephrine) Injection, for the emergency treatment of allergic reactions (Type I) including anaphylaxis. The Symjepi™ (epinephrine) Injection 0.3mg product, which was approved by the FDA in June 2017, is designed for patients weighing 66 pounds or greater. The lower dose Symjepi™ (epinephrine) Injection 0.15mg product candidate is intended for patients weighing 33 to 66 pounds.

Distribution and Commercialization Agreement

On July 1, 2018, we announced that we had entered into a Distribution and Commercialization Agreement (the "Agreement") with Sandoz Inc., a division of Novartis AG, to commercialize our Symjepi™ product for the emergency treatment of allergic reactions (Type I) including anaphylaxis. Under the terms of the Agreement, we appointed Sandoz as the exclusive distributor of Symjepi in the United States and related territories ("Territory"), in all fields including both the retail market and other markets, and granted Sandoz an exclusive license under our patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the product in the Territory, subject to the provisions of the Agreement, in partial consideration of an upfront fee by Sandoz and potential performance-based milestone payments. As part of the Agreement, Sandoz has commercial rights to our Symjepi Epinephrine Injection USP Injection (0.3mg/0.3mL) Injection pre-filled single dose syringe product, as well as the lower dose Symjepi (epinephrine) Injection 0.15mg product, which was approved by the FDA in September 2018 and is intended for use in the treatment of anaphylaxis for patients weighing 33-65 pounds and for which we submitted a supplemental new drug application to the FDA on November 27, 2017. We retain rights to the intellectual property subject to the Agreement and to commercialize both products outside of the Territory, but have granted Sandoz a right of first negotiation regarding such territories. In addition, we may continue to use the licensed intellectual property (excluding certain of the licensed trademarks) to develop and commercialize other products (with certain exceptions), including products that utilize our Symject syringe product platform.

The Agreement provides that Sandoz will pay to us 50% of the Net Profit from Net Sales, as each such term is defined in the Agreement, of the product in the Territory to third parties, determined on a quarterly basis. We will be the supplier of the product to Sandoz, and Sandoz will order and pay us a supply price for quantities of products ordered. We will be responsible for all manufacturing, component and supply costs related to manufacturing and supplying the product to Sandoz. We are responsible for component sourcing and regulatory compliance in the supply chain and for testing of lots of product.

Sandoz has agreed to use commercially reasonable efforts to commercialize the product, subject to various conditions and to the other provisions of the Agreement. The Agreement does not include minimum payments to us by Sandoz, minimum requirements for sales of product by Sandoz or, with certain exceptions, minimum purchase commitments by Sandoz. Under the Agreement, Sandoz has sole discretion in determining pricing, terms of sale, marketing, and selling decisions relating to the product. Jefferies LLC acted as sole financial advisor to us in connection with the transaction. We agreed to pay Jefferies a fee of $2.0 million, $500,000 of which was paid in September 2018 with the balance payable in November 2018.

*Naloxone Injection (*APC-6000)

We intend to develop a naloxone injection product candidate utilizing the same Symject™ device approved for our epinephrine product. 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.

According to statistics published by the Centers for Disease Control and Prevention (CDC), in 2017 drug overdoses resulted in approximately 72,000 deaths in the United States – greater than 195 deaths per day. Drug overdoses are now the leading cause of death for Americans under 50, and the proliferation of more powerful synthetic opioids, such as fentanyl and its analogues, could result in future increases in the number of deaths resulting from opioid overdoses. Repeat dosing of the commonly utilized dose of naloxone has been noted in some studies as suggesting the need for a higher dosage product.

We are considering the appropriate development, trial and regulatory pathway for our naloxone injection product candidate. As we have previously disclosed, in December 2017 we submitted an IND to the FDA to begin testing of the drug compound naloxone in human patients, and we began testing in human patients in April 2018. A pharmacokinetic study has been completed and we are analyzing the results of the study. Assuming no unexpected regulatory issues or delays, we are working towards a goal of filing an NDA relating to our APC-6000 product by the end of 2018. However, the timing of any NDA filing could be affected by several factors, including without limitation unexpected regulatory issues or delays, and the time required to analyze the results of the study and the results of the study. As a result, there can be no assurances concerning the timing of completion of analysis of the study results or the filing of an NDA relating to APC-6000. The development of an intramuscular injection of naloxone for the treatment of opioid overdose will require commercial scale manufacturing subject to review and approval by FDA.

Tadalafil (APC-8000)

We are currently in IND development work for our APC-8000 product candidate, which is a fast-disintegrating sublingual tablet containing tadalafil. Tadalafil (Cialis®) is a drug used for treating erectile dysfunction, or ED, pulmonary hypertension and benign prostatic hyperplasia, or BPH. Tadalafil is in a class of drugs called phosphodiesterase-5, or PDE5, inhibitors which includes, among others, sildenafil (Viagra®) and vardenafil (Levitra®). All three of these oral tablets are FDA approved and clinically indicated for the treatment of ED. Tadalafil and sildenafil are also indicated for pulmonary hypertension, but among PDE5 drugs, only tadalafil is approved for the treatment of BPH. We estimate that annual sales of Cialis in the United States in 2017 were approximately $1.4 billion, based on publicly available information.

Our initial goal in development and clinical testing of APC-8000 will be to demonstrate comparability to Cialis® and additional benefits of a rapidly acting sublingual formulation. In the fourth quarter of 2018 we conducted a test of a sublingual tadalafil tablet product candidate in human patients and are analyzing the results of the test. If the analysis of the results of the testing is positive, we intend to file an NDA with the FDA before the end of 2018. However, the timing of completion of any studies relating to APC-8000 could be affected by a number of factors, including, without limitation, completion of product development, unexpected regulatory issues or delays, the results of the studies, the time required to complete and analyze the results of the studies, and FDA guidance concerning the regulatory pathway for the product. As a result, there are no assurances concerning the results of trials or the filing of an NDA relating to APC-8000 within the time periods that we currently anticipate, or at all. The development of APC-8000 will require commercial scale manufacturing subject to review and approval by FDA.

As described above and in our previous filings with the SEC, we are engaged in product development activities regarding a number of product candidates in our pipeline. For the fourth quarter of 2018, we expect an increase in our research and development spending and expenses due to advancement of our product pipeline development activities, which may include FDA filing fees for NDAs for our naloxone (APC-6000) and sublingual tadalafil (APC-8000) product candidates if those NDAs are filed before the end of 2018, fees and costs associated with initiating a Phase 3 trial for our beclomethasone HFA (APC-1000) product candidate, and other spending and expenses relating to clinical trials relating to our pipeline product candidates, related regulatory expenses and other development expenses.

Going Concern and Management's Plan

Our independent registered public accounting firm has included a “going concern” explanatory paragraph in its report on our consolidated financial statements for the years ended December 31, 2017 and 2016 indicating that we have sustained substantial losses from continuing 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 September 30, 2018, we had a cash balance of approximately $32.0 million, an accumulated deficit of approximately $140.2 million, and liabilities of approximately $12.4 million. As noted below under the heading “Liquidity and Capital Resources” appearing elsewhere herein, in August 2018, we completed an underwritten public offering of shares of common stock resulting in estimated net proceeds, after underwriting discounts and estimated offering expenses, of approximately $37.6 million. We could require additional 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. Any such additional funding that might be required may not be available, may not be available on reasonable terms, and could result in significant additional dilution to our stockholders. If we do not obtain any required additional funding, our cash resources could 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 condensed consolidated financial statements included elsewhere herein for the nine months ended September 30, 2018, were prepared under the assumption that we would continue our operations as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. In preparing these 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. If we are not able to obtain additional funding if required in the future in the future 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 we could exhaust our resources and be unable to continue operations.

Our management intends to attempt to secure any 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 sales of compounded sterile formulations. However, there can be no assurance that we will be able to obtain any sources of funding if required. If we are unsuccessful in securing any required 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 did 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

Nine Months Ended September 30, 2018 and 2017

Revenues. Revenues were approximately $10,933,000 and $10,231,000 for the nine months ended September 30, 2018 and 2017, respectively. The increase in revenues for the nine months ended September 30, 2018 compared to the comparable period of 2017 reflected an increase in sales of USC's compounded and non-compounded pharmaceutical formulations resulting in part from price increases; increase in production capacity in order to meet product demand; and marketing personnel efforts.

Cost of Goods Sold. Cost of goods sold was approximately $6,758,000 and $5,638,000 for the nine months ended September 30, 2018 and 2017, respectively. Our cost of goods sold includes direct and indirect costs to manufacture formulations, including active pharmaceutical ingredients, personnel costs, packaging, storage, shipping and handling costs, the write-off of obsolete inventory and other related expenses. The cost of goods sold increased at a greater proportional rate than the increase in revenue for the nine months ended September 30, 2018 compared to the comparable period of 2017, primarily due to an increase in compensation of approximately $896,000 as a result of new hires, increases in salaries and bonus accruals, expenses associated with stock options grants and other employee benefits. Approximately $224,000 of the increase for the nine-month period of 2018 compared to the same period of 2017 was due to an increase in contract labor, direct materials and other production related costs.

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 nine months ended September 30, 2018 and 2017 were approximately $19,371,000 and $16,975,000, respectively. Compensation expense for SG&A employees increased by approximately $1,462,000 for the nine months ended September 30, 2018, compared to the comparable period of 2017, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with stock option grants and other employee benefits. Approximately $228,000 of the increase in the nine-month period of 2018 compared to the same period of 2017 was due to the fees under the Prescription Drug User Fee Act, or PDUFA. Approximately $219,000 of the increase in the nine-month period of 2018 period compared to the same period of 2017 was due to increases in patent fees. Approximately $487,000 of the increase in the nine-month period of 2018 compared to the same period of 2017 was due to increases in accounting, audit and other professional fees, depreciation, selling expenses, IT consulting expenses, taxes, travel expenses 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 $10,993,000 and $3,944,000 for the nine months ended September 30, 2018 and 2017, respectively. The increase in research and development expenses for the nine months ended September 30, 2018, compared to the comparable period of the prior year was due in part to an increase of approximately $4,024,000 in development costs of our product candidates. This amount was partially offset by a decrease of approximately $534,000 in development costs primarily attributable to Symjepi™ (epinephrine) and the APC-1000 product candidate. Compensation expense for Research and Development employees increased by approximately $1,037,000 for the nine months ended September 30, 2018, compared to the comparable period of 2017, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with stock options grants and other employee benefits. Research and development costs for the nine months ended September 30, 2018, also included a reserve of approximately $2,522,000 relating to Symjepi™ inventory that is expected to expire before its sale. We expect that research and development spending and expenses in the fourth quarter of 2018 will increase as a result of various clinical trials relating to our pipeline product candidates, related regulatory expenses and other development expenses.

Impairment Expense. Impairment expenses for the nine months ended September 30, 2018 and 2017 were approximately $0 and $96,000. The impairment expense was attributable to assets damaged during a flood at an off-site facility at USC.

Other Income (Expense). Other Income (Expense) consists of interest expense and interest income. Other expense for the nine months ended September 30, 2018 and 2017 was approximately $6,000 and $1,091,000, respectively. The decrease in other expenses in the nine months ended September 30, 2018, compared to the comparable period of 2017 was primarily due to approximately $960,000 in expenses incurred for the nine month period ended September 30, 2017, relating to inducement to exercise warrants, and $125,000 in debt related expenses after offsetting the recorded interest income from deposits. The reduction in debt related expenses as of September 30, 2018 was primarily due to the payoff of our working capital lines of approximately $1.4 million and $2.0 million made in May 2017 and July 2018, respectively.

Three Months Ended September 30, 2018 and 2017

Revenues. Revenues were approximately $3,833,000 and $3,388,000 for the three months ended September 30, 2018 and 2017, respectively. The increase in revenues for the three months ended September 30, 2018 compared to the comparable period of 2017 reflected an increase in sales of USC's compounded and non-compounded pharmaceutical formulations resulting in part from price increases; increase in production capacity in order to meet product demand; and marketing personnel efforts.

Cost of Goods Sold. Cost of goods sold was approximately $2,300,000 and $2,092,000 for the three months ended September 30, 2018 and 2017, respectively. Our cost of goods sold includes direct and indirect costs to manufacture formulations, including active pharmaceutical ingredients, personnel costs, packaging, storage, shipping and handling costs, the write-off of obsolete inventory and other related expenses. The cost of goods sold increased in dollar amount but at a lower proportional rate than the increase in revenue from the three months ended September 30, 2018 compared to the comparable period of 2017, primarily due to efficiencies in production.

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 September 30, 2018 and 2017 were approximately $6,535,000 and $5,748,000, respectively. Compensation expense for SG&A employees increased by approximately $409,000 for the three months ended September 30, 2018, compared to the comparable period of 2017, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with stock options grants and other employee benefits. SG&A expenses for the third quarter of 2018 compared to the comparable period of 2017 also increased by approximately $76,000 in patent expenses. Approximately $96,000 of the increase in the three-month period of 2018 compared to the same period of 2017 was due to the fees under the PDUFA. Approximately $206,000 of the increase in SG&A expenses for the third quarter of 2018 period compared to the same period of 2017 was due to increases in accounting, audit and other professional fees, depreciation, selling expenses, IT consulting expenses, taxes, travel expenses 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 $3,908,000 and $1,248,000 for the three months ended September 30, 2018 and 2017, respectively. The increase in research and development expenses for the three months ended September 30, 2018, compared to the comparable period of the prior year was due in part to an increase of approximately $2,455,000 in development costs of our product candidates. This amount was partially offset by a decrease of approximately $134,000 in development costs primarily attributable to the APC-1000 and APC 5000 product candidates. Compensation expense for Research and Development employees increased by approximately $339,000 for the three months ended September 30, 2018, compared to the comparable period of 2017, primarily due to new hires, increases in salary expenses and bonus accruals, and expenses associated with stock options grants and other employee benefits. We expect that research and development spending and expenses in the fourth quarter of 2018 will increase as a result of various clinical trials relating to our pipeline product candidates, related regulatory expenses and other development expenses.

Impairment Expense. Impairment expenses for the three months ended September 30, 2018 and 2017 were approximately $0 and $96,000. The impairment expense is attributable to assets damaged during a flood at an off-site facility at USC.

Other Income (Expense). Other Income (Expense) consists of interest expense and interest income. Other income (expense) for the three months ended September 30, 2018 and 2017 was approximately $35,000 and $(973,000), respectively. The decrease in other expenses in the three months ended September 30, 2018, compared to the comparable period of 2017 was primarily due to approximately $960,000 in expenses incurred for the three month period ended September 30, 2017, relating to inducement to exercise warrants, and $48,000 in debt related expenses after offsetting interest income from deposits. The reduction in debt related expenses as of September 30, 2018 was primarily due to the payoff of our working capital lines of approximately $1.4 million and $2.0 million made in May 2017 and July 2018, respectively.

Liquidity and Capital Resources

We have incurred net losses of approximately $26.2 million and $17.5 million for the nine months ended September 30, 2018 and 2017, respectively. Since inception, and through September 30, 2018, we have an accumulated deficit of approximately $140.2 million. Since inception and through September 30, 2018, we have financed operations principally through debt financing, through private and public issuances of common stock and preferred stock. On August 6, 2018, we completed the closing of an underwritten public offering of 13,416,667 shares of common stock at a public offering price of $3.00 per share, which included 1,750,000 shares pursuant to the full exercise of the over-allotment option granted to the underwriters, resulting in estimated net proceeds of approximately $37.6 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. However, in the future 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 attempt to secure any additional required funding primarily 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 sales of compounded pharmacy formulations.

Total assets were approximately $70.2 million and $51.4 million as of September 30, 2018 and December 31, 2017, respectively. Current assets exceed current liabilities by approximately $25.8 million at September 30, 2018.

Net cash used in operating activities for the nine months ended September 30, 2018 and 2017, was approximately $20.4 million and $9.9 million, respectively. Net cash used in operating activities increased primarily due to the decrease in gross profit and the increase in operating expenses.

Net cash used in investing activities was approximately $3,171,000 and $1,483,000 for nine months ended September 30, 2018 and 2017, respectively. The net cash used in investing activities increased primarily due to the acquisition of new equipment.

Net cash provided by financing activities was approximately $37.2 million and $30.6 million for the nine months ended September 30, 2018 and 2017, respectively. Net cash flows provided by financing activities increased for the period ended September 30, 2018 due to the issuance of common stock generating net proceeds of approximately $37.6 million, partially offset by the payment of loans of approximately $0.4 million; in 2017, capital raised from issuance of common stock and warrant exercises totaled approximately $32.8 million and payment of bank loans amounted to approximately $2.2 million.

As noted above under the heading “Going Concern and Management Plan,” through September 30, 2018, Adamis had incurred substantial losses. The availability of any required additional funding cannot be assured. If we do not obtain additional equity or debt funding if required in the future, our cash resources would be depleted and we would be required to materially reduce or suspend operations. Even if we are successful in obtaining any required additional funding, substantial time may pass before we obtain regulatory marketing approval for any additional products and begin to realize revenues from sales of specialty pharmaceutical products, and during this period Adamis could require additional funds. No assurance can be given as to the timing or ultimate success of obtaining future funding if required. 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, 2017 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 September 30, 2018.

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 September 30, 2018, 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 Over Financial Reporting

There has been no change during the quarter ended September 30, 2018 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

Information regarding certain material pending legal proceedings to which the Company is a party can be found in the description of legal proceedings contained in the Company's most recent Annual on Report on Form 10-K for the year ended December 31, 2017, and is incorporated herein by reference. As of the end of the quarter to which this Report on Form 10-Q relates, we are not a party to any legal proceedings that we believe, individually or in the aggregate, are expected to have a material adverse effect on our business, financial condition or results of operations. We are and may become involved in or subject to routine litigation, claims, disputes, proceedings and investigations in the ordinary course of business, including without limitation claims relating to matters such as commercial, employment, alleged infringement of third party intellectual property rights, or other claims. Any such matters could divert management time and attention from the Company, could involve significant amounts of legal fees and other fees and expenses, or could negatively affect our financial condition, cash flows or results of operations.

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, 2017, 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, 2017, 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 our ability to obtain additional funding if required in the future, 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. If we could not obtain any required additional funding in the future from debt or equity financings, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions or sources, we could exhaust our resources and could be unable to continue operations, and our stockholders could likely lose most 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 $25.5 million and $26.2 million for the year ended December 31, 2017 and the nine months ended September 30, 2018, respectively, and a net loss of approximately $19.4 million for the year ended December 31, 2016. From inception through September 30, 2018, we have an accumulated deficit of approximately $140.2 million. We expect that these losses will 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 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 product, we have not received regulatory approval for any drugs or products. Since our fiscal 2010 year, except for revenues from sales of compounded pharmacy formulations after our acquisition of USC in 2016, 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 products and product candidates 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 financings; 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.

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 would 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 Symjepi™ (epinephrine) Injection 0.3mg product, and we intend to pursue Section 505(b)(2) NDA filings with the FDA in connection with our beclomethasone HFA, fluticasone DPI, naloxone injection and tadalafil product candidates. A Section 505(b)(2) NDA is a special type of NDA that enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing previously approved product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Such filings involve significant filing costs, including filing fees.

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the previously approved product on which the applicant's application relies and that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product have expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest to occur of 30 months beginning on the date the patent holder receives notice, expiration of the patent, settlement of the lawsuit, or until a court deems the patent unenforceable, invalid or not infringed.

If we rely in our Section 505(b)(2) regulatory filings on clinical trials conducted, or the FDA's prior findings of safety and effectiveness, for a previously approved drug product that involves patents referenced in the Orange Book, then we will need to make the patent certifications or the Paragraph IV certification described above. If we make a Paragraph IV certification and the holder of the previously approved product that we referenced in our application initiates patent litigation within the time periods described above, then any FDA approval of our 505(b)(2) application would be delayed until the earlier of 30 months, resolution of the lawsuit, or the other events described above. Accordingly, our anticipated dates of a product that was subject to such litigation would be delayed. In addition, we would incur the expenses, which could be material, involved with any such patent litigation. As a result, we may invest a significant amount of time and expense in the development of our product only to be subject to significant delay and patent litigation before our product may be commercialized, if at all.

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

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

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

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

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

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

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

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

In both the United States and certain foreign jurisdictions, there have been and are expected to be a number of legislative and regulatory changes to the healthcare system in ways that could impact our ability to sell our products profitably, including the Patient Protection and Affordable Care Act signed into law in the United States in March 2010. Given the enactment of these laws and other federal and state legislation and regulations relating to the healthcare system, their impact on the biotechnology and pharmaceutical industries and our business is uncertain. The U.S. Congress continues to consider issues relating to the healthcare system, and future legislation or regulations may affect our ability to market and sell products on favorable terms, which would affect our results of operations, as well as our ability to raise capital, obtain additional collaborators or profitably market our products. Such legislation or regulation may reduce our revenues, increase our expenses or limit the markets for our products. In particular, we expect to experience pricing pressures in connection with the sale of our products due to the influence of health maintenance and managed health care organizations and additional legislative proposals.

We have limited sales, marketing and distribution experience.

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

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

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

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

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

Our success will be dependent upon the efforts of our management team and staff, including Dennis J. Carlo, Ph.D., our chief executive officer. The employment of Dr. Carlo may be terminated at any time by either us or Dr. Carlo. We currently do not have key person life insurance policies covering any of our executive officers or key employees. If key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly recruited. There is competition for qualified personnel in all functional areas, which makes it difficult to attract and retain the qualified personnel necessary for the operation of our business. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. If we are unable to attract new employees and retain existing key employees, the development and commercialization of our product candidates could be delayed or negatively impacted.

We may experience difficulties in managing growth.

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

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

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

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

At December 31, 2017, we had federal net operating loss carry forwards, or NOLs, of approximately $81 million which, subject to certain limitations, we may use to reduce future taxable income or offset income taxes due. The NOLs will begin to expire in 2027. At December 31, 2017, the NOLs for state purposes were approximately $49 million, which will begin to expire in 2031. Insufficient future taxable income will adversely affect our ability to deploy these NOLs and credit carry forwards. 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. 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 carryforwards.

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

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

Outsourced compounding facilities have historically been subject to FDA inspections on an irregular basis and are now subject to FDA inspections on a risk-based schedule in accordance with DQSA Section 503B(b)(4). Observations by the FDA of potentially violative conditions during inspections are required to be reported to facility management at the close of the inspection on FDA Form 483. It is common for such reports to be provided in connection with inspections of compounding outsourcing facilities, and observations may be further followed by warning letters and other enforcement actions as the FDA deems warranted. In March 2014 and August 2015, USC received Form 483 observations following FDA inspections of its outsourcing facility, noting inspectional observations of a number of observed deficiencies relating to USC's facility and practices. Following the August 2015 Form 483 observations, USC suspended production of sterile products and voluntarily recalled all lots of sterile products aseptically compounded and packaged by USC that remained within expiry, due to the FDA's concern over a lack of sterility assurance. This was a voluntary recall and voluntary suspension of sterile production, and USC determined there was no evidence that any compounded sterile products were defective. The recall did not pertain to any non-sterile compounded products prepared by USC. USC responded to the August 2015 Form 483 observations and took a number of corrective actions, including reviewing and enhancing quality control and production systems**.** The FDA stated in a December 2015 communication that at that time it did not object to USC's resumption of production and distribution of sterile drug products. In March 2016, USC received another letter from the FDA indicating that the voluntary action was a class II recall. Class II means that the probability of serious adverse health consequences is remote. USC resumed production and sale of compounded sterile products in March - April 2016. 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, and provided additional responses to FDA in April 2017. In October 2017, USC received a warning letter from the FDA referencing the August 2015 and July 2016 Form 483 inspectional observations. USC provided a written response to the FDA that addressed completed corrective actions intended to be responsive to the inspectional observations, including relating to differential pressures, facility design, product specifications, environmental monitoring, and suspension quality.

Following the suspension of sterile production and the voluntary recall in 2015, state pharmacy regulatory agencies in certain states also initiated inquiries or took other actions regarding sales of USC products in such states, and some of those proceedings are ongoing. Resolution of these proceedings, or any 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 our business, results of operations and financial condition. We cannot predict when or if we will receive additional Form 483 observations or other communications from the FDA or state regulatory authorities regarding USC's compounding outsourcing facility, or our CSPs. USC could be subject to additional regulatory action by the FDA and civil or criminal enforcement action by the Department of Justice under the FDCA, Federal False Claims Act, or other applicable statutes, as well as related private actions, as a result of previous, current or future FDA observations. USC's suppliers and customers may negatively consider the Form 483 observations or warning Letter issued to us when deciding to award contracts or continue or renew agreements. Other state and federal regulators and agencies may also consider the Form 483 observations and warning Letter when conducting their own inspections, enforcement actions or approvals, including license renewals. Any such actions could significantly disrupt USC's business and harm its and our reputation, resulting in a material adverse effect on our business, results of operations and financial condition.

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

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

Formulations prepared and dispensed by compounding pharmacies contain FDA-approved ingredients, but are not themselves approved by the FDA. As a 503B outsourcing facility, USC's compounded formulations are not subject to the FDA approval process. 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; 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 government Medicare and Medicaid programs. 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. Although as of the date of this Report we believe that this guidance, if finalized in its current form, would not have a material adverse effect on our business, financial condition and results of operations, it could limit the number and type of products USC is permitted to compound and could adversely impact our business and revenues from sales of sterile compounded drug formulations. 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.

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

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

Many competitors that market and sell compounded preparations have longer operating histories and may have greater financial, marketing and other resources than we do. We are significantly smaller than some of such competitors, and we may lack the financial and other resources needed to develop, produce, distribute, market and commercialize any of USC's formulations or compete for market share in these sectors. These potential competitors could leverage existing resources and experience operating in industries that are subject to significant regulatory oversight in order to overcome certain barriers to entry. Consequently, competitors may be able to develop products and services competitive with, or superior to, USC's products and services. Furthermore, we may not be able to differentiate USC's compounded preparations and services from those of our competitors, successfully develop or introduce new services—on a timely basis or at all—that are less costly than those of our competitors or offer customers payment and other commercial terms as favorable as those offered by our competitors. We expect competition to intensify as technology advances, such as those in the field of robotics and automation, and consolidation continues. Also, new developments by pharmaceutical manufacturers, such as increasing the number of abbreviated new drug applications, to cover less frequently used drug formulations, could render some or most of USC's products or services obsolete. In addition, the drug products available through branded and generic drug companies with which USC's formulations compete have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. USC's compounded formulations are not required to be, and have not been, approved for marketing and sale by the FDA. As a result, some physicians may be unwilling to prescribe, and some patients may be unwilling to use, USC's formulations. The DQSA prohibits compounding facilities, both 503A and 503B, from compounding products that are considered "essentially a copy" of approved drug products offered by traditional pharmaceutical manufacturers. In January 2018, FDA published Final Guidance on what it considers to be "essentially a copy" of approved drug products. This policy added the requirement that purchasers and prescribers document on each order and prescription the specific clinical need for the compounded medication. Some purchasers and prescribers may be unwilling to complete this additional documentation, resulting in decreased demand for the compounded drug products.

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

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

Many competitors that market and sell compounded preparations have longer operating histories and may have greater financial, marketing and other resources than we do. We are significantly smaller than some of such competitors, and we may lack the financial and other resources needed to develop, produce, distribute, market and commercialize any of USC's formulations or compete for market share in these sectors. These potential competitors could leverage existing resources and experience operating in industries that are subject to significant regulatory oversight in order to overcome certain barriers to entry. Consequently, competitors may be able to develop products and services competitive with, or superior to, USC's products and services. Furthermore, we may not be able to differentiate USC's compounded preparations and services from those of our competitors, successfully develop or introduce new services—on a timely basis or at all—that are less costly than those of our competitors or offer customers payment and other commercial terms as favorable as those offered by our competitors. We expect competition to intensify as technology advances, such as those in the field of robotics and automation, and consolidation continues. Also, new developments by pharmaceutical manufacturers, such as increasing the number of abbreviated new drug applications, to cover less frequently used drug formulations, could render some or most of USC's products or services obsolete. In addition, the drug products available through branded and generic drug companies with which USC's formulations compete have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. USC's compounded formulations are not required to be, and have not been, approved for marketing and sale by the FDA. As a result, some physicians may be unwilling to prescribe, and some patients may be unwilling to use, USC's formulations. The DQSA prohibits compounding facilities, both 503A and 503B, from compounding products that are considered "essentially a copy" of approved drug products offered by traditional pharmaceutical manufacturers.

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

The production, labeling and packaging of CSPs is inherently risky. The success of USC's compounded formulations and pharmacy operations depends to a significant extent upon medical and patient perceptions of USC and us and the safety and quality of USC's products. We could be adversely affected if USC, any other compounding pharmacies or USC's formulations and technologies, are subject to negative publicity. We could also be adversely affected if any of USC's formulations or other products, any similar products sold by other companies, or any products sold by other compounding pharmacies, prove to be, or are asserted to be, harmful to patients. There are a number of factors that could result in the injury or death of a patient who receives one of USC's compounded formulations, including quality issues, manufacturing or labeling flaws, improper packaging or unanticipated or improper uses of the products, any of which could result from human or other error. Any of these situations could lead to a recall of, or safety alert relating to, one or more of USC's products. Similarly, to the extent any of the components of approved drugs or other ingredients used by USC to produce compounded formulations have quality or other problems that adversely affect the finished compounded preparations, USC's and our sales could be adversely affected. In addition, in the ordinary course of business, we may voluntarily retrieve products in response to a customer complaint. Because of our dependence upon medical and patient perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of USC's products, any similar products sold by other companies or any other compounded formulations, could have a material adverse impact on our business, results of operations and financial condition.

We could become subject to product recalls and termination or suspension of our state pharmacy licenses if laboratory testing does not identify all contaminated products or if our products otherwise cause or appear to have caused injury or harm to patients. In addition, such laboratory testing may produce false positives, which could harm our business and impact our pharmacy operations even if the impacted formulations are ultimately found to be sterile and no patients are harmed by them. If adverse events or deaths or a product recall, either voluntarily or as required by the FDA or a state board of pharmacy, were associated with one of USC's formulations or compounds, USC's and our reputation could suffer, physicians may be unwilling to prescribe USC's products or order any prescriptions from such pharmacies, we could become subject to product and professional liability lawsuits, and USC's or our state pharmacy or other required licenses could be terminated or restricted.

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

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

Currently, USC is paid directly by most of its customers and does not submit large amounts of claims for reimbursement through Medicare, Medicaid or other third-party payors, although its customers may choose to seek available reimbursement opportunities to the extent that they exist. USC works with third-party insurers, pharmacy benefit managers and buying groups to advocate that patient-specific customizable compounded formulations be available to patients at accessible prices. We plan to continue to devote time and other resources to seek reimbursement for compounded formulations. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are increasingly attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. The continued efforts of health maintenance organizations, managed care organizations, government programs (such as Medicare, Medicaid and other federal and state-funded programs) and other third party payors to limit reimbursements to USC's customers may adversely impact our financial results. Further, HIPAA and the Health Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivably adversely affect USC's business. As a result, reimbursement from Medicare, Medicaid and other third party payors may cease to be available for USC's products or may not be sufficient to allow USC to sell products on a competitive basis and at desirable price points. If government and other third party payors do not provide adequate coverage and reimbursement levels for USC's formulations, the market acceptance for USC's formulations may be limited. We expect cost pressures from third party payors to continue, and USC's customers have limited bargaining power to counter payor demands for reduced reimbursement rates. If USC's customers increasingly insource pharmaceutical preparations or use alternative third party providers due to these pressures, USC's and our business, results of operations and financial condition may be materially adversely impacted.

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

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

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

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

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

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

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

The FDA published in March 2018 updated guidance on compounding from bulk active pharmaceutical ingredients. A substantial majority of USC's compounded drug products are made from active pharmaceutical ingredients, and if finalized in its current form, the updated policy would diminish USC's ability to continue to use these materials and could adversely affect our ability to produce compounded drug products. USC would be required to change to utilizing approved drug products to produce its compounds, which could lead to increases in materials costs and decreases in production efficiency. Additionally, as the updated policy would impact all 503(B) outsourcing facilities, there is the potential for supply chain shortages of the approved drug products.

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 September 30, 2018, our aggregate indebtedness under the Amended Loan Documents was approximately $2,706,000.

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 ("Draft 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 definition of clinical need set forth in the Draft Bulks Guidance could limit the bulk substances used by our outsourcing facilities to compound, which could adversely impact our business and revenues from sales of sterile compounded drug formulations. The Draft Bulks Guidance received numerous comments, and as of the date of this Report we believe the FDA is working on responding to the comments from the industry before it finalizes the guidance. Similarly, if finalized, the Revised Draft MOU could also limit our pharmacy's interstate sales. Although the Revised Draft MOU removed any requirement that states take action against a pharmacy dispensing more than 30% of its compounded preparations interstate, it still requires that the state report to the FDA any pharmacy shipping more than 50% of its compounded products out of state. The Revised Draft MOU also changed the method of calculation: the percentage is now calculated using compounded products only. Under the Revised Draft MOU, for pharmacies that are dispensing more than 50% interstate, the FDA will analyze if the risk posed by the pharmacy's interstate dispensing practices may weigh in favor of additional federal oversight using a variety of risk factors. Moreover, if the state in which the pharmacy is located determines it will not enter into an MOU with FDA, the 5% rule will apply. In the Federal Register notice accompanying the Revised Draft MOU, the FDA continued to advise that it will not enforce the 5% limitation until some time period (it is proposing 180 days) after FDA has finalized the MOU. Nevertheless, the finalization of any MOU and the accompanying process could limit USC's ability to ship its compounded drug products interstate. The Revised Draft MOU is currently out for comment, with the comment period ending 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 (USP) Convention, a scientific standard-setting organization, which have been codified in many states and which have historically been enforced by applicable state boards of pharmacy through inspection programs but are also enforceable by the FDA. In complying with applicable cGMPs and USP <797>, we must expend time, money and effort in production, record-keeping and quality control to ensure that USC's products and services meet applicable specifications and requirements. In July 2014, the FDA issued draft guidance for cGMPs for human drug compounding outsourcing facilities, such as USC's. Because this cGMP draft guidance has not been finalized and may be significantly changed prior to being made final, we may need to expend substantial additional resources to comply with the final applicable cGMPs, along with any additional modifications over time.

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

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

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

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

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

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

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

In addition, we are subject to the federal anti-kickback statute, which prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, the referral of business or ordering of services paid for by Medicare or other federal programs. Violations of the anti-kickback statute can result in imprisonment, civil or criminal fines. Any violation or alleged violation of such federal or state laws could harm USC's or our reputation, customer relationships or otherwise have a material adverse effect on our business, financial condition and results of operations.

Such laws and regulations are subject to change and often are uncertain in their application. As controversies continue to arise in the healthcare industry, federal, state and local regulation and enforcement priorities may increase. There can be no assurance that USC, or one of its customers, third party vendors or other supply chain partners, will not be subject to scrutiny or challenge under one or more of these laws or regulations or that any such challenge would not be successful. Any such challenge, whether or not successful, could adversely affect USC's or our business, financial condition or results of operations.

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

The healthcare industry is changing rapidly as consumers, governments, medical professionals and the pharmaceutical industry examine ways to broaden medical coverage while controlling the increase in healthcare costs. Such changes could include changes to make the government's Medicare reimbursement programs more restrictive, which could limit or curtail the potential for USC's formulations to obtain eligibility for reimbursement from such payors, or changes to expand the reach of HIPAA or other health privacy laws, which could make compliance with these laws more costly and 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 1, 2015 through September 30, 2018, the market price of our common stock has fluctuated between $2.50 and $10.12. The price of our common stock that will prevail in the market after this offering may be higher or lower than the price that you have paid, depending on many factors, some of which are beyond our control and may not be related to our operating performance. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

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

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

Trading of our common stock is limited.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of September 30, 2018, we had 47,291,358 shares of common stock issued and outstanding, substantially all of which we believe may be sold publicly, subject in some cases to volume and other limitations, provisions or limitations in registration rights agreements, or prospectus-delivery or other requirements relating to the effectiveness and use of registration statements registering the resale of such shares.

As of September 30, 2018, 9,339,037 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 $4.39 per share, we had outstanding restricted stock units covering 1,642,212 shares of common stock, and we had outstanding warrants to purchase 2,166,995 shares of common stock at a weighted-average exercise price of $3.80 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 September 30, 2018, we had outstanding warrants, other than the warrants described in the next sentence, to purchase 91,149 shares of common stock, at a weighted average exercise price of $8.12 per share. As of September 30, 2018, 2,075,846 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants that we issued in the following private placement transactions: warrants to purchase 1,183,432 shares at an exercise price of $4.10 per share in our January 2016 Series A-1 Convertible Preferred Stock transaction; warrants to purchase 192,414 shares at an exercise price of $2.90 per share in our July 2016 Series A-2 Convertible Preferred transaction; and warrants to purchase 700,000 shares at an exercise price of $2.98 per share in our August 2016 registered direct offering of common stock and warrants.

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

Based on the number of outstanding shares of our common stock held by our stockholders as of December 31, 2017, our directors, executive officers and their respective affiliates owned approximately 4.1% of our outstanding shares of common stock and our largest stockholder owned approximately 4.9% of the outstanding shares of our common stock. As a result, those stockholders have the ability to exert a significant degree of influence with respect to the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. The interests of these persons may not always coincide with our interests or the interests of our other stockholders. This concentration of ownership could harm the market price of our common stock by (i) delaying, deferring or preventing a change in corporate control, (ii) impeding a merger, consolidation, takeover or other business combination involving us, or (iii) discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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.

10.1	Distribution and Commercialization Agreement between the Company and Sandoz, Inc. (+)
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.PR	XBRL Taxonomy Extension Presentation Linkbase Document

(+) Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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: November 9, 2018

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

Date: November 9, 2018

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

Exhibit [10.1]

Execution Version

[*] Designates Text Omitted and Filed Separately with the Securities and Exchange Commission. Confidential Treatment Requested Under 17 C.F.R. Sections 200.80(b)(4) and Rule 24b-2

DISTRIBUTION AND COMMERCIALIZATION AGREEMENT

This Distribution and Commercialization Agreement (the "**Agreement**") is made effective as of the Effective Date by and between Adamis Pharmaceuticals Corporation, a corporation organized under the laws of Delaware (the "**Company**"), with an office located at 11682 El Camino Real, Suite #300, San Diego, CA 92130 and Sandoz Inc., a corporation organized under the laws of Colorado, with an office at 100 College Road West, Princeton, New Jersey 08540 ("**Sandoz**"). Sandoz and the Company may hereafter be referred to collectively as the "**Parties**" and individually as a "**Party**".

WHEREAS, the Company, pursuant to the terms of this Agreement, would like to manufacture and supply Product (as defined below) to Sandoz for Sandoz to distribute Product in the Territory; and

WHEREAS, Sandoz, pursuant to the terms of this Agreement, would like to purchase Product from the Company and distribute Product in the Territory.

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the parties hereto agree as follows:

1. DEFINITIONS

1.1. "**Act**" means the Federal Food, Drug and Cosmetic Act of 1938, including any amendments thereto and all regulations promulgated thereunder or under any similar act or set of laws in the Territory.

1.2. "**Additional Costs**" means, for any applicable Calendar Quarter, the total costs for (a) **[*]**; (b) **[*]**; and (c) **[*]**; in each case, only to the extent not overlapping with any amount deducted in the calculation of Net Sales.

1.3. "**Affiliate**" means, with respect to any Person, any Person which, directly or indirectly, controls, is controlled by, or is under common control with, the specified Person. For the purposes of this definition, the term "control," as applied to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management of that Person, whether through ownership of more than fifty percent (50%) voting securities or otherwise.

1.4. "**API**" means the compound epinephrine, as further described in the Specifications.

1.5. "**Applicable Laws**" means all laws, ordinances, rules and regulations applicable to the Parties' activities under this Agreement, including, without limitation, the Manufacture, Development, or Processing of API or Product, and the obligations of each Party as the context requires, including, without limitation: (a) all applicable federal, state and local laws and regulations of the Territory; (b) the Act; and (c) cGMPs.

1.6. "**Batch**" means a specific quantity of the Product that is intended to have uniform character and quality within specified limits, and is produced according to a single Manufacturing order during the same cycle of Manufacture.

1.7. "**Batch Record**" means Batch production and control records as set forth in 21 C.F.R. § 211.188, as may be amended from time-to-time.

1.8. "**Business Day**" means any day that is not a Saturday, Sunday or other day on which commercial banks located in New York, New York are authorized or required to be closed, as the case may be.

1.9. "**Calendar Quarter**" means any of the three-month periods beginning January 1, April 1, July 1 or October 1 of any calendar year.

1.10. "**Certificate of Analysis**" means a document which is signed and dated by a duly authorized representative of the Company certifying that the Product Conforms to the Specifications and was prepared in accordance with Section 3.10.1.

1.11. "**cGMP**" or "**Good Manufacturing Practices**" means current good manufacturing practices as set forth in 21 C.F.R. Parts 210 and 211, as established by the FDA or any similar set of laws, regulations, rules, or practices in the Territory or otherwise applicable to Development, Manufacture, Processing or supply of Product pursuant to this Agreement, as may be amended from time-to-time.

1.12. "**Claim**" means any claim, action, suit, demand or other legal assertion or proceeding brought by a Third Party against any of the Sandoz Indemnified Parties and/or the Company Indemnified Parties, as the case may be, related to any Liability.

1.13. "**Commercialize**" or "**Commercialization**" means the activities for marketing, pricing, promotion, distribution, and/or selling of the Product.

1.14. "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, reasonable, diligent, good-faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances exercising reasonable business judgment, it being understood and agreed that, with respect to the Manufacture, Processing and Commercialization of the Product, such efforts shall be substantially equivalent to those efforts and resources commonly used by such Party for a product owned by it or to which it has rights, which product is at a similar stage in its product life and is of similar market potential as the Product, taking into account **[*]**. It is anticipated that the level of effort may change over time, reflecting changes in the status of the Product. "**Commercially Reasonable**" shall have the correlative meaning.

1.15. "**Company Indemnified Parties**" means the Company, the Company's Affiliates, any of their successors or assigns, and any of their respective then-current or then-former directors, officers, employees, contractors or agents.

1.16. "**Components**" means, collectively, all packaging components including the syringes for pre-fill, raw materials, excipients, and ingredients (including labels, product inserts and other Labeling for the Product), necessary to Manufacture the Product in accordance with the NDA, the Drug Master File, and the Specifications for the Product.

1.17. "**Confidential Information**" means, with respect to a Party, all Know-How, scientific information, clinical data, efficacy and safety data, formulas, methods and processes, specifications, pricing information (including discounts, rebates and other price adjustments), and other terms and conditions of sales, customer information, business plans, and all other intellectual property), which is disclosed or made available to the other Party regardless of whether such information is marked, identified as or otherwise acknowledged to be confidential at the time of disclosure to the other Party.

1.18. "**Conforming**" or "**Conform**" means that the Product conforms, in all respects, (a) to the applicable Specifications; (b) was Manufactured in accordance with cGMP and Applicable Law; and (c) is not adulterated or misbranded within the meaning of the Act or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially the same as those contained in the Act.

1.19. "**Control**" or "**Controlled**" means, with respect to any Know-How, materials, Patents or other intellectual property rights, the legal authority or right (whether by ownership, license or otherwise but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant access, a license or a sublicense of or under such Know-How, materials, Patents or other intellectual property rights to another Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.20. "**Develop**" or "**Development**" means any activities related to the development of the Product, including but not limited to, all formulation, process and method development, manufacturing, testing and release of all clinical/registration and scale-up, Product validation, and packaging related to the Product for use in the Territory, on-going Product stability testing in accordance with the Specifications and Applicable Laws, maintaining documentation of any stability testing conducted on the Product in accordance with the Specifications and Applicable Laws, and any post-Launch stability testing.

1.21. "**Domain Names**" means any internet electronic addresses, uniform resource locators and alphanumeric designations associated therewith, registered with or assigned by any domain name registrar, domain name registry or other domain name registration authority as part of an electronic address on the internet, rights in social media accounts and social media pages, and all applications for any of the foregoing.

1.22. "**Drug Master File**" or "**DMF**" means, with respect to the Product API, the drug master file or any supplement thereto, filed by the Company or its Affiliates or a Third Party with the FDA or other Regulatory Authority pursuant to the Act or other Applicable Law.

1.23. "**Effective Date**" means the date this Agreement is signed by the last Party (as indicated by the date associated with such Party's signature on the signature page to this Agreement).

1.24. "**Executive Officer**" means (a) the President of Sandoz or another officer of Sandoz designated by Sandoz, or an Affiliate of Sandoz (the "**Sandoz Executive Officer**"), and (b) the President of the Company or another officer of the Company designated by the Company (the "**Company Executive Officer**").

1.25. "**Force Majeure Event**" means an event impacting a Party due to causes beyond such Party's reasonable control, including without limitation, any actions of governmental authorities or agencies, war, hostilities between nations, civil commotions, riots, national industry strikes, lockouts, sabotage, fire, floods and acts of nature such as typhoons, hurricanes, earthquakes, or tsunamis, or by any other event or circumstance of like or different character to the foregoing beyond the reasonable control of such Party.

1.26. "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto.

1.27. "**IFRS**" means International Financial Reporting Standards, as generally and consistently applied by Sandoz.

1.28. "**[*]**" means **[*]**.

1.29. "**Know-How**" means any information or material that is confidential and proprietary, including, without limitation, ideas, concepts, discoveries, inventions, developments, improvements, know-how, trade secrets, designs, devices, equipment, process conditions, algorithms, notation systems, works of authorship, computer programs, technologies, formulas, techniques, methods, procedures, assay systems, applications, data, documentation, reports, chemical compounds, products and formulations, whether patentable or otherwise. Know-How shall also include non-Confidential Information and material to the extent such information and material first lost its confidentiality by virtue of its disclosure in an issued patent or published patent application, a filing with a Regulatory Authority or as part of a legal proceeding.

1.30. "**Label**" means any package, packaging material, or label designed for use with the Product, pursuant to the terms of this Agreement, in accordance with Applicable Laws including the package insert for such Product, that is approved by the FDA.

1.31. "**Labeling**" means applying a Label or a package insert to the Product, pursuant to the terms of this Agreement, in accordance with Applicable Laws.

1.32. "**Latent Defect**" means a defect that causes Product to fail to Conform, which defect is not discoverable upon reasonable physical inspection and testing performed pursuant to Section 3.10 but is discovered at a later time.

1.33. "**Launch**" means the first commercial sale of Product in a given format and Market in the Territory by Sandoz or its Affiliates to a Third Party, but excluding sales for test marketing, clinical-trial purposes or compassionate use.

1.34. "**Liabilities**" or "**Liability**" means all losses, costs, damages, judgments, settlements, interest, fees or expenses including, without limitation, all reasonable attorneys' fees, experts' or consultants' fees, expenses and costs, related to or arising from this Agreement or any Product developed, made, sold, marketed or otherwise distributed by the Parties.

1.35. "**Licensed IP**" means the Licensed Know-How and the Licensed Patents.

1.36. "**Licensed Know-How**" means Know-How Controlled by the Company that are necessary or useful for the Manufacture and Commercialization of the Product in the Territory.

1.37. "**Licensed Patents**" means any patents and patent applications Controlled by the Company now or in the future that are necessary or useful for Commercialization and Manufacture of the Product in the Territory. An initial list of Licensed Patents is set forth on Schedule A. Schedule A will be updated by the Company during the Term, as specified in Section 2.3.2 below.

1.38. "**Licensed Trademarks**" means the trademarks and domains listed on Schedule A and any Domain Names Controlled by the Company during the Term related to such trademark.

1.39. "**Manufacture**" or "**Manufacturing**" means the commercial synthesis, manufacture, storage, handling, production, Processing, packaging, and Labeling of Product pursuant to this Agreement.

1.40. "**Manufacturing Facility**" means the manufacturing facilities of the Product Manufacturer, or such other facility under its control that is approved by the FDA or other Regulatory Authority for manufacturing the Product.

1.41. "**NDA**" means new drug application 207534 filed by the Company with the FDA, as may be amended or supplemented.

1.42. "**Net Profit**" means the amount (which shall not be less than zero (0)) calculated for a given Calendar Quarter equal to Net Sales less (a) Supply Price that Sandoz paid for the Product sold in such Calendar Quarter, and (b) Additional Costs for the Product sold in such Calendar Quarter.

1.43. "**Net Profit Share**" means an amount equal to the percentage of Net Profits allocated to each Party as set forth on Schedule B.

1.44. "**Net Sales**" means the net sales recorded by Sandoz or any of its Affiliates for sales of Product in the Territory to Third Parties as determined in accordance with IFRS as consistently applied. The deductions booked on an accrual basis by Sandoz and its Affiliates under its IFRS to calculate the recorded net sales from gross sales consist of the following, applied consistently:

(i) normal trade and cash discounts;

(ii) amounts repaid or credited by reasons of defects, rejections, recalls or returns;

(iii) price protection and shelf stock adjustments, slotting fees and coupons;

(iv) rebates and chargebacks to customers and third parties (including, without limitation, Medicare, Medicaid, Managed Healthcare and similar types of rebates);

(v) any amounts recorded in gross revenue associated with goods provided to customers for free;

(vi) amounts provided or credited to customers through coupons and other discount programs;

(vii) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates or retroactive price reductions;

(viii) fee for service payments to customers for any non-separable services (including compensation for maintaining agreed inventory levels and providing information); and

(ix) other reductions or specifically identifiable amounts deducted for reasons similar to those listed above in accordance with IFRS.

There shall be no double-counting in determining the foregoing deductions. With respect to the calculation of Net Sales: (a) Net Sales only include the value charged or invoiced on the first arm's length sale to a Third Party and sales between or among Sandoz and its Affiliates shall be disregarded for purposes of calculating Net Sales; and (b) if a Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under IFRS are met. In the case of any sale or other disposal for value, **[*]** of any Product, or part thereof, other than **[*]** Net Sales shall be calculated **[*]**.

1.45. "**Non-U.S. Territory**" means the entire world, except the Territory.

1.46. "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

1.47. "**Process**" or "**Processing**" means the compounding, filling, producing and/or packaging of the API and raw materials to produce a Product in accordance with the applicable Specifications and the terms and conditions set forth in this Agreement.

1.48. "**Product**" means the applicable definition set forth on Schedule C attached hereto.

1.49. "**Product Liability Claim**" means any product liability claims or action asserted or filed by a Third Party, seeking damages or equitable relief of any kind, relating to personal injury, wrongful death, medical expenses, an alleged need for medical monitoring, consumer fraud or other alleged economic losses, allegedly caused by the Product, and including claims by or on behalf of users of the Product (including spouses, family members and personal representatives of such users) relating to the use, sale, distribution or purchase of the Product sold by or on behalf of Sandoz in the Territory.

1.50. "**Product Manufacturer**" means the Third Party manufacturers of the Product set forth in Schedule F attached hereto, or as otherwise agreed in writing by the Parties.

1.51. "**Quality Agreement**" means the Quality Agreement that will govern the production of Batches of the Product and that will be executed by and between Sandoz and either the Company or the Product Manufacturer in connection with this Agreement.

1.52. "**Regulatory Approval**" means the technical, medical and scientific licenses, registrations, authorizations and approvals required for the manufacture, use, storage, import, transport, marketing, promotion, selling, and placing on the market of the Product (including post-approval changes, pricing and Third Party reimbursement approvals, and Labeling approvals) by any Regulatory Authority in the Territory. This includes any authorization necessary for the Manufacture, distribution, marketing, promotion, offer for sale, use, import, export or sale of the Product as the context may require within the Territory.

1.53. "**Regulatory Authority**" means any applicable local, national or supranational government agency involved in assessing the Product or granting approvals for the marketing and sale of Product in the Territory.

1.54. "**Regulatory Filing**" means any filing made with a Regulatory Authority to obtain a Regulatory Approval.

1.55. "**[*]**" means **[*]**.

1.56. "**Sandoz Indemnified Parties**" means Sandoz, its Affiliates, any of their successors or assigns, and any of their respective then-current or then-former directors, officers, employees, contractors or agents.

1.57. "**Specifications**" means: (a) with respect to the Product having 0.3mg/0.3ml strength, **[*]**; and (b) with respect to the Product having 0.15mg/0.3ml strength, **[*]**.

1.58. "**Supply Price**" means, with respect to a Product, the applicable prices set forth on and determined in accordance with Schedule D attached hereto.

1.59. "**Territory**" means the fifty states of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the U.S. Virgin Islands and all territories and possessions of the United States of America, United States military bases and any other territories the Parties mutually agree in writing to add to this Agreement.

1.60. "**Third Party**" means any Person other than a Party or any of its Affiliates.

1.61. **Other Defined Terms**. Each of the following definitions is set forth in the Section of this Agreement indicated below:

Definition	**Section**
Agreement	Introductory Paragraph
Audited Party	6.5.2
Auditing Party	6.5.2

Definition	Section
Commercial Milestone Payment	6.1
Company	Introductory Paragraph
Company Executive Officer	1.24
Dispute	12.2
Exercise Period	2.11.1(b)
Firm Commitment	3.5
Firm Order	3.3.1
Indemnitee	8.3
Indemnitor	8.3
Initial Term	11.1
JPT	4.2.1
Material Contracts	7.5.7
Milestone Payment	6.1
Negative Amount	6.2.2
Negotiation Period	2.11.1(b)
Non-US Transaction	2.11.1
Non-US Transaction Notice	2.11.1(a)
OPDP	4.5.2
Other Product	2.11.2
Party or Parties	Introductory Paragraph
Pharmacovigilance Agreement	5.4
Promotional Materials	4.5.1
Renewal Term	11.1
ROFN Right(s)	2.11.1
Rolling Forecast	3.5
Sales Taxes	6.4
Sandoz	Introductory Paragraph
Sandoz Executive Officer	1.24
Term	11.1

2. EXCLUSIVE DISTRIBUTORSHIP; EXCLUSIVITY

2.1. **Appointment of Sandoz as Exclusive Distributor in the Territory**. Subject to the terms and conditions of this Agreement, (a) the Company hereby appoints Sandoz, and Sandoz hereby accepts, during the Term, to serve as the exclusive distributor (even as to the Company) of the Product in the Territory, and (b) the Company grants to Sandoz the exclusive right (even as to the Company) to market, sell, offer for sale, and otherwise Commercialize the Product in the Territory under the Company's NDA during the Term. Sandoz shall have the exclusive right to invoice and book all Product sales in the Territory during the Term. Sandoz shall not have the right to grant any rights as subdistributor to any Third Party except to the extent Sandoz's agreements with group purchasing organizations, wholesalers or similar entities that apply to Commercialization of the Product in the Territory contemplate such entities acting as subdistributors.

2.2. **Supply of Product for Distributorship**. As provided in Article 3, the Company shall supply (or have supplied) to Sandoz, and Sandoz shall purchase from the Company, its requirements of the Product for sale by Sandoz and its Affiliates in the Territory pursuant to Section 2.1.

2.3. **Licensed IP**.

2.3.1. Subject to the terms and conditions of this Agreement, the Company hereby grants to Sandoz an exclusive (even as to the Company), non-transferable and non-sublicenseable (except to an Affiliate of Sandoz) license under the Licensed IP for Sandoz to market, sell, offer for sale, and otherwise Commercialize the Product in the Territory under this Agreement.

2.3.2. The Company shall update the listing of Licensed Patents set forth in Schedule A on or before **[*]**, so as to include information with respect to **[*]**. The Company shall also provide Sandoz, on or before **[*]** with **[*]**.

2.4. **Licensed Trademark**. The Company hereby grants to Sandoz a fully-paid, non-transferable and non-sublicenseable (except to an Affiliate of Sandoz) license to use the Licensed Trademarks only to market, sell, offer for sale and otherwise Commercialize the Product in the Territory under this Agreement, which shall be exclusive (even as to the Company), except the license with respect to the Licensed Trademark Symject shall be non-exclusive. For clarity, the Company may use (or license to a Third Party or Affiliate) the Licensed Trademark Symject: (i) in connection with any product other than the Product in and outside the Territory; and (ii) in connection with the marketing, sale, offer for sale, and other Commercialization of the Product outside the Territory. All uses by Sandoz and its Affiliates of the Licensed Trademarks shall be in compliance with all Applicable Laws and shall be in accordance with the Licensed Trademark Usage Guidelines attached hereto in Schedule H. At the reasonable request of the Company from time to time, Sandoz will provide copies of packaging, labeling, advertising, promotional and other material of Sandoz or its Affiliates referencing the Licensed Trademark to allow the Company to confirm compliance with the foregoing.

2.5. **Licensed Trademark and Licensed Patent Filing, Prosecution, Maintenance and Costs**.

2.5.1. The Company shall be responsible for registration, filing and maintenance of the Licensed Trademarks, and shall bear all costs related thereto.

2.5.2. The Company shall prepare, file and prosecute any and all patent applications and maintain any and all patents within the Licensed Patents. The Company shall pay for all prosecution, filing and maintenance fees and all other costs for prosecution, filing and maintenance of any Licensed Patents associated with the Product in the Territory.

2.6. **Enforcement of Licensed IP and Licensed Trademarks**. Upon a Party learning of any infringement or threatened infringement of any of the Licensed IP and/or Licensed Trademarks by a Third Party in the Territory, such Party shall promptly inform the other Party in writing of any such infringement and shall supply such other Party with all evidence pertaining to such infringement in such Party's possession. In the event of any infringement or threatened infringement of any Licensed Patent by a Third Party in the Territory, **[*]**, to file an action against any such infringing Third Party or seek abatement of the infringement by such Third Party and by counsel of its own choice, and **[*]** shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. **[*]** shall recover **[*]**. In the event **[*]** does not file an action or seek abatement within: (a) **[*]** following the notice of alleged infringement; or (b) **[*]** before the time limit, if any, set forth in the Applicable Laws, whichever comes first, then **[*]** shall have the right, but not the obligation, to file an action against any such infringing Third Party or seek abatement of the infringement by such Third Party at **[*]** cost and expense and by counsel of its own choice, and **[*]** shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. **[*]** shall use **[*]** to promptly notify **[*]** in writing if **[*]** decides not to file an action or seek abatement. **[*]** shall fully cooperate with **[*]** in such action, including **[*]**, and **[*]** shall **[*]** in connection with providing such cooperation. Neither Party shall enter into any settlement or compromise of any action or proceeding under this Section 2.6 that would: (a) admit fault on the part of the other Party; (b) impose any financial obligation on the other Party; or (c) alter, diminish, or be in derogation of the other Party's rights under this Agreement, in each case, without the prior written consent of such other Party, not to be unreasonably withheld or delayed. Except for **[*]**, in each case, as set forth above, any recovery or damages realized as a result of such action or proceeding with respect to Licensed IP and/or Licensed Trademarks shall be used **[*]**.

2.7. **License of Third Parties' Rights**. In addition to the Company's obligations pursuant to Section 8.1, in the event it is necessary to obtain a license in the intellectual property rights of the Third Party in order for a Party to practice any Licensed IP or Licensed Trademarks to conduct activities for which it is responsible as contemplated by this Agreement, **[*]**.

2.8. **Reserved Rights**. The Company hereby expressly reserves all rights under the Licensed IP and Licensed Trademarks that are not expressly granted to Sandoz under this Agreement, including, without limitation, rights under: (a) the Licensed IP and Licensed Trademarks to research, develop, make, have made, import, use, sell, offer for sale, distribute, promote, market, and otherwise Commercialize the Product outside of the Territory; and (b) the Licensed IP and Licensed Trademark Symject (but excluding the other Licensed Trademarks) to research, develop, make, have made, import, use, sell, offer for sale, distribute, promote, market, and otherwise commercialize any and all products other than Products (including any product other than Products that use any syringe used to administer Products) worldwide, except in connection with any product containing epinephrine that would compete with the Product in the Territory; and (c) the Licensed IP and Licensed Trademarks to Manufacture, have Manufactured and supply Product for Sandoz and its Affiliates pursuant to this Agreement and to make, have made, package and have packaged the Product in the Territory for the Company and its Affiliates and licensees for use outside the Territory. Further, the Company retains the right to reference and use, and grant to the Company's Affiliates and licensees (and their sublicensees) the right to reference and use, all Regulatory Approvals for Product in the Territory, including the NDA and the documentation comprising the NDA, including all submissions, reports and correspondence relating to the NDA, and all data and information contained or referenced therein (including all data and information from human factors, reliability and biocompatibility studies) as may be necessary or useful (A) to perform the Company's obligations contemplated by this Agreement and (B) in connection with any of the activities described in Section 2.8(a), (b) and/or (c).

2.9. **No Implied Licenses**. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any patents, patent applications, Know-How or other intellectual property owned or Controlled by the other Party.

2.10. **Mutual Agreements**.

2.10.1. Sandoz hereby covenants and agrees that during the Term it shall not (and shall cause its Affiliates not to), either itself or through a Third Party, market, promote, sell or actively offer for sale the Product outside of the Territory. Without limiting the generality of the foregoing and subject to Section 2.11.1, with respect to countries outside of the Territory, Sandoz shall not: (a) engage in any advertising activities relating to the Product directed primarily to customers located outside of the Territory (which excludes any participation in conferences, congresses or scientific or medical meetings held throughout the world) or in the Territory for distribution outside the Territory; or (b) actively or intentionally solicit orders from any prospective purchaser of the Product for distribution outside of the Territory. To the extent permitted by Applicable Law, if Sandoz receives any order from a prospective purchaser of the Product in or for a country outside of the Territory, Sandoz shall immediately refer that order to the Company and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the Product under such order. If Sandoz is actually aware that a customer or distributor is actively engaged itself or through a Third Party in the sale or distribution of the Product outside of the Territory, then Sandoz shall: (i) **[*]**; and (ii) **[*]**, unless otherwise agreed in writing by the Parties.

2.10.2. The Company hereby covenants and agrees that during the Term it shall not (and shall cause its Affiliates, licensees and subcontractors not to), either itself or through a Third Party, market, promote, sell or actively offer for sale the Product in the Territory. Without limiting the generality of the foregoing, the Company shall not: (a) engage in any advertising activities relating to the Product directed primarily to customers located in the Territory (which excludes any participation in conferences, congresses or scientific or medical meetings held throughout the world) or outside of the Territory for distribution in the Territory; or (b) actively or intentionally solicit orders from any prospective purchaser of the Product for distribution in the Territory. To the extent permitted by Applicable Law, if the Company receives any order from a prospective purchaser of the Product in or for the Territory, the Company shall immediately refer that order to Sandoz. If the Company is actually aware that a customer or distributor is actively engaged itself or through a Third Party in the sale or distribution of the Product in or for the Territory, then the Company shall: (i) **[*]**; and (ii) use **[*]**. For clarity, in the case of termination of rights granted to Sandoz under this Agreement in **[*]**, nothing in this Section 2.10.2 shall limit or restrict activities by or on behalf of the Company with respect to Product **[*]**.

2.11. **Right of Negotiation for Product in Non-US Territory**.

2.11.1. In the event that, after the Effective Date and during the Term, the Company proposes to grant any license or similar rights (whether exclusive, semi-exclusive or otherwise) with respect to the development, supply, marketing, sale, distribution or Commercialization of the Product in any Non-US Territory ("**Non-US Transaction**"), then Sandoz shall have a first right to negotiate with the Company regarding such Non-US Transaction ("**ROFN Right(s)**") in accordance with the terms of this Section 2.11.1.

a) The Company shall provide Sandoz with a written notice (a "**Non-US Transaction Notice**") of the principal terms of a proposed Non-US Transaction prior to entering into negotiations regarding such Non-US Transaction with a Third Party.

b) Sandoz shall have a period of **[*]** in which to exercise the ROFN Right with respect to such Non-US Transaction by providing written notice to the Company. If Sandoz elects to exercise the ROFN Right within **[*]**, then **[*]** within **[*]** after **[*]**. Sandoz shall be entitled to assign all or any portion of its ROFN Rights to one or more of its Affiliates upon written notice to the Company. If Sandoz does not exercise the ROFN Right for a Non-US Transaction within **[*]**, or if Sandoz exercises the ROFN Right for a Non-US Transaction within **[*]** by the Parties do not **[*]** within **[*]**, then the Company shall have no further obligation under this Section 2.11 with regard to the territory for such Non-US Transaction and the Company will be free to negotiate and enter into agreements with one or more Third Parties with regard to such Non-US Transaction.

2.11.2. In the event that, after the Effective Date, the Company proposes to grant any license or similar rights (whether exclusive, semi-exclusive or otherwise) with respect to the development, supply, marketing, sale, distribution or Commercialization of a pre-filled syringe or auto-injector containing epinephrine as one or more of the active pharmaceutical ingredients that is not covered by the Product's NDA in the Territory or in the Non-US Territory ("**Other Product**"), then Sandoz shall have a right of first negotiation with respect to such Other Product, pursuant to the terms of Section 2.11.1 above.

2.11.3. Nothing in this Section 2.11 shall restrict or prevent the Company from negotiating or completing any transaction for the sale of all or substantially all of the business or assets of the Company, whether by merger, sale of stock, sale of assets or otherwise; provided, that any successor to the Company in such transaction shall remain subject to the Company's obligations under the ROFN Right in accordance with this Section 2.11 if the ROFN Right has not been exercised or terminated prior to consummation of such transaction.

3. MANUFACTURING AND SUPPLY SERVICES

3.1. **Overview**.

3.1.1. Subject to the terms and conditions of this Agreement, the Company shall supply to Sandoz or its designee the Product for distribution and sale by Sandoz or its Affiliates in the Territory, and the Company agrees not to supply such Product to any Third Party for sale in the Territory. Sandoz agrees that in no event shall Sandoz or its Affiliates Manufacture or have Manufactured Product, or purchase Product from any party other than the Company unless otherwise agreed in writing by the Parties. Subject to the terms and conditions of this Agreement, the Company shall be responsible for all costs related to Manufacturing and supplying the Product to Sandoz.

3.1.2. Except as expressly provided in Sections 3.3 and 3.5, Sandoz makes no guarantee or commitment, directly or indirectly, that Sandoz will purchase any minimum quantity of the Product under this Agreement, and the Company acknowledges that it will not conduct its business in reliance on any such guarantee or commitment.

3.1.3. The Parties acknowledge and agree that the Company will use a Third Party manufacturer to Manufacture and supply Product to Sandoz and its Affiliates under this Agreement. As of the Effective Date, the Third Parties listed in Schedule F are the Product Manufacturers. If the Company desires to delegate such Manufacturing and supply obligations to a Product Manufacturer other than a Third Party that is listed in Schedule F at any time during the Term, then the Company shall **[*]**. The Company shall be responsible for performance of the Company's obligations hereunder to the extent performed on the Company's behalf by such subcontractor as if the Company were itself performing such activities. The Parties acknowledge and agree that the terms "the Company shall" or "the Company will" or the like, shall be deemed to be followed by the words "or the Product Manufacturer, as a subcontractor of the Company, will" or "or the Product Manufacturer, as a subcontractor of the Company, shall" or "the Company shall require that the Product Manufacturer shall" or the like, with respect to the Company's Manufacturing and supply obligations herein.

3.2. **Product Supply Chain**. The Company shall be responsible for all sourcing of all Components used in the Manufacture and Processing of the Product (including API, excipients and primary packaging Components). The Company shall be responsible for all importation activities relating to the Product (including API, excipients, and primary packaging Components). The Company shall cause the Components to be manufactured under cGMP conditions, as required by Applicable Law, and cause the Drug Master File to be maintained in good standing with the FDA during the Term.

3.3. **Firm Orders**.

3.3.1. The Company agrees to supply to Sandoz **[*]** quantities of the Product ordered by Sandoz pursuant to one or more purchase orders issued in accordance with the terms and conditions hereof (each, as accepted by the Company in accordance with Section 3.3.2, a "**Firm Order**"). Sandoz shall issue Firm Orders to the Company for the purchase of the quantities described therein, and upon acceptance by the Company in accordance with Section 3.3.2, each Firm Order shall be considered a binding, non-cancellable commitment upon the Company to produce and deliver such quantities of Product on the delivery dates described therein and upon Sandoz to purchase and pay for such quantities of Product.

3.3.2. The Company shall confirm to Sandoz all Firm Orders, including quantities, pricing, commercial terms, and delivery dates, in writing within **[*]** after receipt (or within a reasonable period of time after receipt for orders in excess of the Firm Commitment). Any such confirmation shall either confirm the delivery date set out in the Firm Order or provide a reasonable alternative delivery date. Any Firm Orders not expressly accepted or rejected by the Company shall be deemed to have been accepted. The Company may reject any Firm Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement; provided, however, that the Company shall **[*]** to supply Sandoz with quantities of Product which are in excess of the quantities specified in the Firm Commitment, subject to **[*]**. For clarity, the Company will not be considered in breach or default if it does not supply quantities of Product which are in excess of the quantities specified in the Firm Commitment after **[*]**.

3.3.3. Sandoz shall provide each Firm Order to the Company concurrently with the submission of each Rolling Forecast, and (a) with respect to Product quantities for Launch at least **[*]** prior to the delivery date specified therein and (b) with respect to all subsequent quantities of Product, at least **[*]** prior to the delivery date specified therein. Each Firm Order shall specify: (i) purchase order number; (ii) the name and quantities of the Product to be purchased by and supplied to Sandoz; (iii) the delivery dates and shipping instructions with respect thereto; (iv) Supply Price of the Product; (v) payment terms; and (vi) any other elements necessary to ensure the timely production and delivery of the Product. Each Firm Order shall constitute a contract, and the Parties shall comply in all respects with the obligations set forth therein including, without limitation, the obligation of the Company to deliver the Product on the delivery date set forth in the Firm Order; provided, however, that except for the information specified in clauses (ii) and (iii) of this Section, the supply, purchase and sale of the Products shall be governed solely by this Agreement and any additional or contrary terms or provisions contained in any Firm Order, purchase order or similar form or invoice or acknowledgment shall be void and have no force or effect.

3.4. **Packaging; NDC**. The Company shall supply Sandoz with Product packaged in Sandoz's trade dress under Sandoz's NDC labeler code. The Company shall cooperate with Sandoz as required to support Sandoz obtaining its own NDC labeler code for the Product. At Sandoz's cost, Sandoz shall supply to the Company information and materials regarding Sandoz's trade dress and NDC labeler code and any standards and instructions for Product packaging that Sandoz requests in sufficient time to permit Manufacturing and supply of Product in accordance with this Agreement. Sandoz shall be responsible at its sole cost for ensuring that all such information, materials, standards and instructions comply with Applicable Laws. The Company shall provide Sandoz with all documentation regarding the Product reasonably requested by Sandoz to allow Sandoz to complete a country of origin evaluation pursuant to Applicable Laws.

3.5. **Rolling Forecast**. Approximately **[*]**, Sandoz shall submit to the Company a rolling **[*]** forecast of Product that Sandoz intends to order from the Company (the "**Rolling Forecast**") for such period commencing on the Launch date. The Rolling Forecast shall be updated within **[*]**. Except as otherwise provided under Section 3.3.2 with respect to quantities for Launch in the first Rolling Forecast issued by Sandoz, the **[*]** of each Rolling Forecast shall be binding on the Parties (the "**Firm Commitment**"). The remaining **[*]** of each Rolling Forecast shall be non-binding good faith estimates for planning purposes; provided, however, that **[*]** in a subsequent Rolling Forecast, as applicable, the quantities of Product specified for delivery for such **[*]** shall not exceed **[*]** of the total quantities of Product projected for delivery during the **[*]** of the Rolling Forecast delivered to the Company **[*]** prior to the then-current Rolling Forecast. For purposes of this Agreement, an "**Excess**" means the total quantity of Product requested by Sandoz in its Firm Order for **[*]** that is in excess of **[*]**. The Company shall **[*]** supply Sandoz with Excess quantities of Product as provided in Section 3.3.2, and the Company shall keep Sandoz informed of its communications with the Product Manufacturers regarding the supply of Excess quantities.

3.6. **Delivery Terms**.

3.6.1. The Company shall deliver the Product to such locations in the Territory as are designated by Sandoz in each Firm Order and in accordance with the delivery date determined according to Section 3.3.2. The place of shipment by the Company or the Product Manufacturer shall be **[*]**. All shipments of Product to Sandoz shall be made via such carrier(s) as Sandoz may direct. Title and risk of loss shall pass to Sandoz upon **[*]**. The Company shall not be responsible for Product in transit, including any cost of insurance or other transport fees for Product, or any risks associated with transit, storage and handling. The Company shall provide shipment information **[*]**. Notwithstanding the foregoing, the Company shall be responsible for ensuring that **[*]**, in accordance with the terms of the Quality Agreement.

3.6.2. If the Company is unable to deliver the requested quantity of the Product on the delivery date determined according to Section 3.3.2, the Company shall notify Sandoz as soon as possible.

3.6.3. At the time of delivery of Product to Sandoz, Product shall have a remaining shelf-life of **[*]** of the Product's **[*]**. If supplied with Product that has a shelf-life of less than **[*]**, Sandoz may return such Product to the Company for reimbursement of all costs, including return shipping and handling, unless Sandoz has agreed in writing to accept such Product prior to delivery. If requested by Sandoz, the Company will **[*]** to promptly provide **[*]**. The Company will use **[*]**.

3.7. **Documentation**. With each shipment of the Product, the Company shall, or shall cause its Product Manufacturer to, provide all documentation in the possession or control of the Company or the Product Manufacturer as is reasonably required by any Regulatory Authority from time to time in connection with the Manufacture of the Product.

3.8. **Storage**. The Company shall maintain and store all Product in accordance with the Specifications and Good Manufacturing Practices at all times, pending its shipment to Sandoz, in the Manufacturing Facility.

3.9. **Serialization and Coding**. The Company shall implement Product serialization and coding in accordance with Applicable Laws. Sandoz and the Company will work together to align on implementation timing as well as the location of the coding information on each level of packaging, including without limitation, the Product's carrying case. The cost of setting up the relevant equipment and the capability for online coding, creating unique serial numbers and its aggregations including necessary IT systems required for data storage and data exchange in order to pack the Product to meet the regulations in the Territory shall be borne by the Company or its Product Manufacturer.

3.10. **Inspection and Acceptance**.

3.10.1. The Company shall test and inspect each Batch of Product for compliance with the Specifications prior to the release and shipment thereof to Sandoz. The Company shall provide a Certificate of Analysis with each shipment of each Batch of Product. The Certificate of Analysis must evidence that the Product conforms to **[*]**.

3.10.2. Sandoz may test and inspect the Product after receipt of each Batch of Product. Sandoz may reject any shipment (or portion thereof) of Product if it does not Conform based on such inspection by written notification to the Company within **[*]** of **[*]**. Sandoz shall be deemed to have accepted the Product if Sandoz fails to give written notice of rejection within **[*]** of **[*]**, except in the case of **[*]** such written notice of rejection must be provided within **[*]**. The written notice of rejection shall be given to the Company and shall include identification of the lot number and description of the basis for rejection.

3.10.3. Following receipt of written notice of rejection of a particular Batch of Product, the Company shall notify Sandoz in writing within **[*]** of receipt of such notice from Sandoz whether the Company disagrees with the rejection and, if the Company does not provide such written notice within such **[*]** period, the Company will be deemed to agree with such rejection. If the Company provides written notice of disagreement with the rejection in accordance with the preceding sentence, the following procedures shall apply. The Parties shall review the test results and attempt to reach agreement as to whether or not the Product fails to Conform and if they fail to reach agreement within **[*]** after delivery of the written notice of disagreement provided by the Company to Sandoz, the Parties shall designate a mutually acceptable Third Party laboratory to make a determination on such matter from a sample obtained from the rejected Batch of Product. The decision of the Third Party laboratory shall be binding on all Parties hereto and all expenses related to such Third Party investigation shall be borne by the Party found to have been mistaken. Should such Third Party laboratory confirm Sandoz's claim, the Company shall, at Sandoz's request, promptly provide Sandoz with **[*]**.

3.10.4. If the Parties agree to the rejection of any Batch (or portion thereof) of Product or the Third Party laboratory confirms rejection of any Batch (or portion thereof) of Product, Sandoz shall return any rejected Product to the Company at the Company's expense to an address that the Company shall designate within **[*]** of the agreement or Third Party laboratory determination regarding rejection, as applicable, and the Company, at Sandoz's request, promptly provide Sandoz with a credit or refund of the Supply Price for the rejected Product if Sandoz has already paid the Company for such rejected Product or promptly provide replacement Product to Sandoz subject to Sandoz's payment of the Supply Price for replacement Product unless Sandoz has already paid the Company for such rejected Product, together with **[*]**. If the Company, however, does not agree with Sandoz's claim of non-compliance with the Specifications or other defect, Sandoz shall not be obligated to return the rejected Product to the Company until after a final determination is made by a Third Party laboratory that such Product does not comply with the applicable Specifications or is otherwise defective. Absent such designation of address, Sandoz shall ship rejected Product to the location of the Manufacturing Facility. If the Third Party laboratory determines that the Batch was not correctly rejected, then Sandoz shall pay the Company the Supply Price for such Batch and for any replacement Product.

3.11. **Supply Price; Payment; and**

3.11.1. The initial Supply Price for the Product is set forth on Schedule D. The Supply Price is subject to adjustment in accordance with the provisions of this Section 3.11.

3.11.2. The Supply Price may be adjusted based on **[*]** prior written notice to Sandoz, as further described **[*]**; provided, however, any **[*]** in Supply Price shall not exceed the greater of: (a) **[*]** and (b) **[*]**; provided, further that, the Company shall provide Sandoz reasonable documentation of **[*]**, and Sandoz may audit such **[*]** pursuant to Section 3.14 or Section 6.5, as applicable. **[*]**.

3.11.3. The Company will use **[*]** to **[*]**.

3.11.4. Simultaneously with the shipment of any particular Batch of Product to Sandoz, the Company shall send an invoice to Sandoz covering such Product order. Supply Price shall be invoiced in U.S. dollars. The Company shall reflect freight separately on each invoice for each total shipment.

3.11.5. Sandoz shall pay each undisputed invoice no later than **[*]** after receipt of such invoice by Sandoz. Payments by Sandoz to the Company, including, but not limited to, any final payment by Sandoz to the Company, shall not be deemed as an acknowledgement by Sandoz that the Company has performed properly or that the Company has fulfilled its contractual obligations, regardless of whether the respective payments were made with any reservation.

3.12. **Quarterly Exchange Rate and Shipping Cost Reconciliation; Annual Volume Reconciliation**.

3.12.1. Within **[*]** after the end of each Calendar Quarter during the Term, the Parties shall determine: (a) the exchange rate for converting the Euro into United States Dollars published (i) on **[*]** and (ii) by **[*]**; and (b) **[*]**. The Company shall then promptly provide Sandoz with a written report setting forth in reasonable detail **[*]**. Sandoz shall have the opportunity to review and approve such written report. If Sandoz agrees with such written report, then, Sandoz shall provide the Company with a statement setting forth in reasonable detail, any underpayment or overpayment of the Net Profit Share based on **[*]**, which statement shall accompany **[*]** for such Calendar Quarter. In the event of an underpayment to the Company, Sandoz shall include such underpayment in the payment of the Net Profit Share for such Calendar Quarter. In the event of an overpayment to the Company, Sandoz shall reduce such overpayment from the Net Profit Share payment for such Calendar Quarter, or subsequent Net Profit Share payments if needed. If the Parties are unable to resolve any dispute under this Section 3.12.1, the matter shall be referred to an independent firm or certified public accountants chosen by agreement of the Parties for resolution of such dispute. Any decision by said firm or independent certified public accounts shall be binding on the Parties.

3.12.2. Within **[*]** after the end of each calendar year during the Term, the Parties shall determine the actual quantity of Product ordered by Sandoz during the preceding calendar year. The Company shall then promptly provide Sandoz with a written report setting forth in reasonable detail the actual quantity of Product ordered by Sandoz during the preceding calendar year and the amount of any underpayment or overpayment by Sandoz during the preceding calendar year as a result of **[*]**. In the event of an underpayment to the Company, the Company shall invoice Sandoz for such underpayment, and Sandoz shall pay such invoice in accordance with the terms of Section 3.11.5. In the event of an overpayment to the Company, the Company shall, simultaneous with its written report, issue to Sandoz a credit memorandum for such overpayment. If the Parties are unable to resolve any dispute under this Section 3.12.2, the matter shall be referred to an independent firm or certified public accountants chosen by agreement of the Parties for resolution of such dispute. Any decision by said firm or independent certified public accountant shall be binding on the Parties.

3.13. **Specifications & Quality**.

3.13.1. The Company shall cause the Product Manufacturer to Manufacture the Product in strict conformity with the Specifications. Further, the Company represents that, as of the Effective Date and during the Term, the Product Manufacturer holds the required manufacturing authorization pursuant to Applicable Laws for the Manufacture of the Product.

3.13.2. Within **[*]**, Sandoz and the Company (and/or the Product Manufacturer, as applicable) shall enter into a Quality Agreement relating to the Product. The Company shall maintain a current Quality Agreement and quality control system compliant with the Regulatory Authority for the Product to be delivered hereunder. Such a system shall include **[*]**. Each Batch of Product to be supplied to Sandoz hereunder shall be subject to a quality control inspection by the Company in accordance with the Company's then current quality assurance standards. In the event a conflict arises between the Quality Agreement and this Agreement, the term contained in the Quality Agreement shall control with respect to quality-related matters relating to the Product.

3.13.3. **[*]** modifications, changes, additions or deletions to the: (a) **[*]**; (b) **[*]**; (c) **[*]**; (d) **[*]**; (e) **[*]**; (f) **[*]**; (g) **[*]**; or (h) **[*]**, which the Company intends to carry out must be evaluated and documented by **[*]**. Prior to implementation of any such change, the Company agrees to provide reasonable notice to Sandoz in writing of such change and to obtain Sandoz's prior written consent to do so, which consent shall not be unreasonably withheld or delayed. Reasonable notice applies in circumstances where a change is required as a result of changes to Applicable Law or the order of any Regulatory Authority, in which case the Parties shall cooperate in good faith to implement the applicable change as soon as reasonably practicable following provision of notice by the Company. Upon receiving Sandoz's written consent, the Company shall amend its NDA through the appropriate notification to the applicable Regulatory Authorities.

3.13.4. The Company is responsible for storing and maintaining retention samples of each Batch of Product shipped to Sandoz for **[*]**, in accordance with Good Manufacturing Practices and the terms of the Quality Agreement. The quantity of retention samples shall be of sufficient quantity required to perform all required testing.

3.13.5. The Company shall be responsible for the testing and generation of stability data for the Product in accordance with the cGMP and ICH guidelines.

3.13.6. The Company shall be responsible for confirming that all facilities (including the Manufacturing Facility), utilities, equipment and the processes utilized to Manufacture the Product are satisfactorily validated according to the guidelines of all applicable Regulatory Authorities and Applicable Laws.

3.13.7. Records which include the information relating to the Manufacturing, packaging and quality operations for each Batch of Product shall be prepared by the Company for each lot at the time such operations occur. Such records shall be prepared in accordance with Applicable Laws and the Company's standard operating procedures. The Company shall keep Batch Records for each Batch of Product for the period of time required by Applicable Law.

3.14. **Manufacture and Supply Records; Audit Rights**.

3.14.1. The Company shall maintain: (a) complete, accurate and systematic written records of the Manufacture and supply of Product in the Territory to Sandoz; and (b) records relating to quality and Manufacturing processes and control steps. Such records shall be maintained for a period of **[*]** or longer if required under Applicable Laws or the Quality Agreement.

3.14.2. On reasonable prior notice, the Company shall allow employees or authorized representatives of Sandoz and/or its Affiliates to perform an audit of any documents, records or any facility, including the Manufacturing Facility, involved in the Processing or Manufacturing of the Product, including, but not limited to, any such documents and records and facility related to the API and Product intermediates, subject to the following sentence with respect to subcontractors. In case that any subcontractor is involved (including, without limitation, any Product Manufacturer), the Company shall: (a) upon request, provide Sandoz and/or its Affiliates with the report of the audits carried out by or on behalf of the Company of any such subcontractor or any other documents and information necessary for Sandoz to verify compliance of such subcontractors with Applicable Laws and this Agreement; and (b) use **[*]** to cause **[*]** to **[*]**.

3.14.3. Sandoz shall also have the right to conduct "for-cause" audits to address significant Product or safety concerns as discovered through Product failures related to the Manufacture of Products. Product failures shall include **[*]**. Sandoz shall notify the Company in writing in advance of the audit and thereafter, with the Company's reasonable assistance, the Product Manufacturer and Sandoz shall mutually determine the timing of the audit.

3.14.4. In the event the Company's (or its Product Manufacturer's) Manufacturing, packaging, testing or storage facility(ies), including the Manufacturing Facility, producing Product is/are inspected by representatives of any Regulatory Authority in connection with the Company's (or its Third Party contractor's) Manufacture of the Product, the Company will notify Sandoz promptly upon learning of such inspection, and will, to the extent required by Applicable Laws, or to the extent permitted by Applicable Laws and the Company's agreements with its Third Party contractors, supply Sandoz with copies (redacted only for confidential information) of any correspondence or communications or portions thereof which relate to the Product.

3.15. **Manufacturing Facility**. As of the Effective Date, the Manufacturing Facility is deemed to be Catalent **[*]**. As of the Effective Date, the Manufacturing Facility has any and all Regulatory Approvals required for the Manufacture, Labeling, packaging, and exportation of the Product in accordance with the Specifications, cGMP and Applicable Laws, and thereafter the Company will use **[*]** to ensure that the Manufacturing Facility shall maintains any and all such Regulatory Approvals.

4. COMMERCIALIZATION

4.1. **Commercialization**. Sandoz shall Commercialize the Product in the Territory in accordance with Applicable Law and shall use Commercially Reasonable Efforts to Commercialize the Product in the Territory in accordance with **[*]**.

4.2. **Joint Project Team.**

4.2.1. **Formation**. Promptly after the Effective Date, the Parties will form a Joint Project Team ("**JPT**") comprised of **[*]** representatives of each of the Company and Sandoz. **[*]**.

4.2.2. **Purposes**. The JPT will discuss the Launch and Commercialization of the Product; provided however, **[*]**.

4.2.3. **Disputes**. The JPT will operate **[*]**.

4.2.4. **Meetings**. The JPT will meet in person or by teleconference on a quarterly basis, or at such other frequency as the JPT agrees. The Parties will agree upon the time and place of such meetings. Within **[*]** after each meeting, **[*]**.

4.3. **Sales and Distribution; Returns**. Sandoz shall be responsible for handling all returns, recalls, order processing, invoicing and collection, distribution, and receivables for the Product Commercialized by Sandoz in the Territory pursuant to this Agreement. Sandoz shall book all sales of the Product in the Territory.

4.4. **Pricing**. Sandoz will have independent, sole discretion to determine the pricing, terms of sale, marketing, and selling decisions for the Product in the Territory without any consultation with, input from, or prior notice to the Company.

4.5. **Advertising and Promotional Materials**.

4.5.1. Sandoz shall prepare and produce all Promotional Materials for Commercialization of the Product in the Territory. In relation to the Product, Sandoz shall determine the manner in which information will be presented and described to the medical community in any Promotional Materials or other materials related to the Product for sale in the Territory. Sandoz shall own all right, title and interest in and to any and all such Promotional Materials, including all applicable copyrights, trademarks (other than the Licensed Trademarks, which are licensed to Sandoz under Section 2.4), program names and domain names for Product to be sold by Sandoz in the Territory. For purposes of this Agreement, "**Promotional Materials**" means all Labeling, except FDA approved non-promotional Labeling, such as, Product warning labels and the Product's package insert, and advertising materials as defined in the Act for Product to be sold by Sandoz in the Territory.

4.5.2. Sandoz shall be solely responsible for developing, filing and making decisions with respect to all Promotional Materials and associated regulatory materials, including all filings and interactions with the FDA's Office of Prescription Drug Promotion ("**OPDP**"). The Parties shall jointly notify the FDA of the Company's delegation of such responsibility for Product to be sold by Sandoz in the Territory to Sandoz. Sandoz shall provide the Company with a copy of each such filing promptly after submission thereof. For the avoidance of doubt, Sandoz will retain exclusive authority and responsibility for the filing of Promotional Materials with the FDA on Form 2253 (or such other form as required by FDA) or as otherwise required by, or permitted under, Applicable Laws. Sandoz shall promptly, but in any case within three (3) Business Days of receipt, provide the Company with complete copies of all material correspondence relating to Promotional Materials for the Product with Regulatory Authorities, including OPDP.

4.5.3. **Sandoz Trademarks**. All trademarks, trade names and packaging graphics owned or licensed by Sandoz and intended to be used in connection with the Product will be chosen by Sandoz in its sole discretion. Additionally, in the event the Licensed Trademark(s) cannot be used in connection with the Commercialization of Product in the Licensed Territory because of legal, safety and/or regulatory reasons, Sandoz shall select and work with the Company to obtain regulatory acceptance for an alternative trademark or tradename for such use and shall file and register appropriate registrations for such trademark with the USPTO. Sandoz shall own such alternative trademark and all goodwill associated therewith.

4.6. **Medical Information**. Sandoz shall determine procedures for responding in a consistent manner to medical information requests on the Product in the Territory. Sandoz shall be solely responsible for responding to all medical information requests and for providing support and responding to product and medical complaints relating to the Product in the Territory; provided, that, the Company shall cooperate with and assist Sandoz upon Sandoz's reasonable request with regards to such activities.

5. REGULATORY MATTERS

5.1. **Regulatory Approval; Regulatory Authority Communications**.

5.1.1. The Company will be responsible for all regulatory and registration activities for the Product in the Territory at the Company's cost and expense (except as set forth in Section 4.5.2), including, but not limited to, being solely responsible for interacting with FDA and maintaining the Regulatory Approval for the Product. For the avoidance of doubt, with respect to the 0.15mg/0.3ml strength of the Product, which, as of the Effective Date, has not received FDA Regulatory Approval, the Company will be responsible for the registration activities for such strength in the Territory with the objective of obtaining approval for such strength in the Territory. The Company shall be responsible for conducting all clinical studies necessary for Regulatory Approval or required by a Regulatory Authority as a condition to, or in connection with the grant or maintenance of a Regulatory Approval. At each meeting of the JPT, the Company will present and discuss the status of all of the registration activities that the Company has performed or caused to be performed pursuant to this Section 5.1.1 since the last meeting of the JPT. The Company shall perform any work necessary in response to FDA deficiencies, and the Company shall keep Sandoz informed of the status of the registration activities on a regular basis. In the event the Company does not **[*]**, the Company shall [*].

5.1.2. The Company shall provide Sandoz with reasonable advance written notice (and in no event less than thirty (30) days' advance written notice whenever feasible) of meetings with the FDA regarding the Product. The Company shall consider in good faith any input timely provided by Sandoz regarding regulatory activities relating to the Product in the Territory and will promptly update Sandoz on the results of such regulatory activities. The Company shall provide to Sandoz complete copies of all material correspondence with Regulatory Authorities regarding the Product.

5.1.3. The Company acknowledges that it is not authorized to and agrees that it shall not interact directly with government agencies, entities or authorities on behalf of Sandoz without the prior written authorization of Sandoz. In the event that such interaction with government agencies, entities or authorities is authorized in writing, it is agreed that certain due diligence, additional inquiries, and potentially other agreed upon measures will be required prior to or coincident with such authorization being granted and that this Agreement may also need to be amended to include certain standard provisions including regular satisfactory reviews and updated due diligence by Sandoz and its agents relating to the Company.

5.2. **Regulatory Costs**. The Company shall be responsible for paying all regulatory fees that are payable to a Regulatory Authority relating to the Product, including the PDUFA program user fee for the product (and any other similar or related fees required by similar laws, rules or regulations), except as provided in Section 4.5.

5.3. **Product Withdrawals and Recalls**.

5.3.1. The Parties agree that each Party shall consult with the other Party and the Parties shall jointly cooperate in all recalls, but that the Company shall be responsible for providing proper notification of a Product recall or Product withdrawal to the applicable Regulatory Authority(ies). With respect to Product Commercialized by Sandoz in the Territory, in the event that: (a) any Regulatory Authority in the Territory issues a request, directive or order that Product be recalled or retrieved; (b) a court of competent jurisdiction orders that Product be recalled or retrieved; or (c) Sandoz reasonably determines, after reasonable, good faith discussion with the Company to the extent that time allows, that Product should be recalled or retrieved, Sandoz shall promptly notify the Company of such event and both Parties shall cooperate in relation to the recall. Sandoz shall be responsible for the final recall decision, communication to the public, and the logistic process regarding returned goods.

5.3.2. All reasonable costs of the Product recall and corrective actions shall be **[*]** to the extent that such costs are **[*]**. Subject to the Company's indemnification obligations under Section 8.1, the Company shall be responsible for (or reimburse Sandoz for) **[*]** to the extent caused by: (a) **[*]**; (b) **[*]**; or (c) **[*]**. To the extent the Company is responsible for **[*]**, the Company shall promptly reimburse Sandoz for **[*]**, and the Company shall be responsible for **[*]**. Subject to Sandoz's indemnification obligations under Section 8.2, Sandoz shall be responsible for **[*]** to the extent caused by: (a) **[*]**; (b) **[*]**; or (c) **[*]**. With respect to **[*]** shall allocate **[*]** based on **[*]**.

5.4. **Safety Reporting**. Within **[*]**, the Parties shall enter into a mutually agreeable, commercially reasonable pharmacovigilance agreement for the purpose of providing detailed procedures regarding the exchange of safety data and information regarding the Product and for ensuring compliance with reporting requirements of Regulatory Authorities (the "**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement shall provide, among other things, that the Company shall be, or shall cause a Third Party approved in writing by Sandoz to be, responsible for maintaining the safety database for the Product and reporting safety-related information to the FDA; provided, that, the Company shall be responsible for performance of the Company's obligations under the Pharmacovigilance Agreement to the extent performed on the Company's behalf by such Third Party as if the Company were itself performing such activities. **[*]** will be **[*]** responsible for **[*]** incurred by **[*]** related to **[*]**. In the event a conflict arises between any pharmacovigilance term in this Agreement and a term in the Pharmacovigilance Agreement, the term contained in the Pharmacovigilance Agreement shall prevail.

5.5. **Compliance with Government Pricing, Government Programs and State/Federal Pricing Transparency Regulations**. Sandoz shall be solely responsible for all federal, state and local government purchasing, pricing or reimbursement programs and private purchasing, pricing or reimbursement programs with respect to the Product sold by Sandoz pursuant to this Agreement, including taking all necessary and proper steps to execute agreements and file other appropriate reports and other documents with Regulatory Authorities and private entities necessary for coverage of the Product under state, federal or other health care programs and to list the Product under such agreements as appropriate. Sandoz shall be responsible for categorizing the Product under federal, state and local government pricing or reimbursement programs in the Territory. Sandoz shall respond to all state and federal regulations on pricing transparency. In connection with the foregoing, the Company will promptly provide Sandoz with any information and supporting documentation with respect to the Product, which is within the Company's possession or control, that is required to support all government pricing calculations including product classifications, baseline AMP value and period or state/federal regulations/legislation related to government pricing, Medicaid liabilities or pricing transparency regulations (current and future).

6. FINANCIALS

6.1. **One-Time Milestone Payments**. During the Term, subject to **[*]**, Sandoz will make: (a) the one-time, non-refundable, non-creditable milestone payment set forth on Schedule B ("**Milestone Payment**"); and (b) the one-time, non-refundable, non-creditable milestone payment(s) set forth on Schedule E ("**Commercial Milestone Payments**"); in each case, to the Company upon successful completion of the corresponding milestone events; provided however, that Sandoz shall not be obligated to make any Commercial Milestone Payment for a milestone completed after a Party's receipt of a notice of termination of this Agreement for any reason under Article 11 of this Agreement. Each Party shall promptly notify the other Party upon the occurrence of a milestone (as applicable) which may occur prior to the completion of a final report referenced in Section 6.2.2 below, and the Company shall thereafter issue an invoice to Sandoz for the applicable Milestone Payment or Commercial Milestone Payment. The Milestone Payment, and each of the Commercial Milestone Payments shall be due **[*]** following Sandoz's receipt of invoice thereof from the Company, but in no event shall such payment be due prior to **[*]**.

6.2. **Net Profit Sharing**.

6.2.1. **Net Profit Allocation Percentages**. During the Term of this Agreement, the Company will be entitled to a payment from Sandoz equal to its allocated percentage of Net Profit Share, as more fully set forth on Schedule B attached hereto. Sandoz shall retain the remaining percentage of Net Profit Share.

6.2.2. **Net Profit Share Payments**. All Net Profit Share allocation payments made by Sandoz to the Company will be made on a quarterly basis within **[*]** after the end of the applicable Calendar Quarter, such payments shall be delivered along with a report showing Net Profit, Net Sales, deductions from Net Sales and the Net Profit Share allocations. **[*]** following the end of a Calendar Quarter, Sandoz shall **[*]**. The Parties agree that if, for any applicable Calendar Quarter, Net Profit is an amount less than zero (0) (a "**Negative Amount**"), then no Net Profit Share payment will be made to the Company for such Calendar Quarter, and Sandoz shall be permitted to carry such Negative Amount from such Calendar Quarter to any subsequent Calendar Quarter(s) to offset Net Profits, if any, for such subsequent Calendar Quarter(s).

6.3. **Branded Prescription Drug Fees**. The Parties shall **[*]** any applicable Annual Branded Prescription Drug Fees owed with regard to the Product, including under Section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111-148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111-152 (124 Stat. 1029 (2010)), or any successor laws (the "**Branded Pharma Fee**"). **[*]** will accrue **[*]**. Each **[*]**, **[*]** shall **[*]**. Such **[*]** amount is subjected to **[*]**.

6.4. **Taxes**. All amounts payable by Sandoz to the Company under this Agreement are exclusive of any tax, levy or similar governmental charge that may be assessed by any jurisdiction, whether based on gross revenue, the Manufacturing, sale, storage, delivery, possession or use of the Product, the execution or performance of this Agreement or otherwise. If any payment under this Agreement by Sandoz to the Company is subject to withholding tax under Applicable Law, Sandoz shall have the right to withhold any and all such taxes, which shall be paid to the appropriate taxing authority for the account of the Company and such payments to Company shall be net of the applicable withholding taxes. Sandoz shall provide to the Company appropriate proof of payment of any and all taxes so withheld. The Parties agree to cooperate to minimize any withholding taxes (including providing each other with any exemption certificates or other documentation establishing that no taxes are due, or such taxes are due at a reduced rate). Additionally, all charges made by the Company to Sandoz hereunder for the supply of Product is exclusive of any sales, use, value added or similar tax customarily borne by a purchaser ("**Sales Taxes**"). If the Company has a legal obligation to collect or charge Sales Taxes, an amount equal to such taxes will be invoiced to, and paid by, Sandoz and **[*]**. Other than as provided in this Section 6.4, each Party shall be responsible for its own taxes, including but not limited to any tax, fee, assessment or other charge based on or measured by the capital or net income, or any other tax imposed by any jurisdiction.

6.5. **Financial Records; Audits**.

6.5.1. During the Term, the Parties shall maintain complete and accurate books and records for the purpose of determining the amounts paid or payable pursuant to this Agreement. Such books and records shall be kept for such period of time required by Applicable Laws, but no less than at least **[*]**. Such records shall be subject to inspection in accordance with Section 6.5.2.

6.5.2. Upon **[*]** written notice, a Party ("**Audited Party**") will permit its books and records for the prior calendar year to be examined for any cost, expense, Net Sales or Net Profit for which it may owe a payment to the other Party **[*]**, during normal business hours, by an independent auditor appointed by the other Party ("**Auditing Party**") and reasonably acceptable to the Audited Party, and at the Auditing Party's expense (and the Auditing Party shall not compensate such auditor on a contingent fee basis), to the extent necessary to verify the accuracy of the amounts paid by the Audited Party to the Auditing Party pursuant to this Agreement. Any information received as a result of such inspection will be maintained as the Audited Party's Confidential Information. In the event that an examining auditor concludes any underpayment or overcharging by any Party, the auditor will specify such underpayment or overcharging in a written report, along with the information on which such conclusion is based. This report will be shared promptly with the Audited Party. The underpaying or overcharging Party shall remit such underpayment or reimburse such overpayment to the underpaid or overcharged Party within **[*]**, provided, that if a Party disputes the conclusion of the auditor, the Parties will attempt to resolve the dispute according to Section 12.2. Further, if the audit for an audited period shows an underpayment or an overcharge by any Party for that period in excess of **[*]** of the amounts properly determined, the underpaying or overcharging Party, as the case may be, shall reimburse the applicable underpaid or overcharged Party conducting the audit, for its respective audit fees and reasonable out-of-pocket costs in connection with such audit, which reimbursement shall be made within **[*]** after receiving appropriate invoices and other support for such audit-related costs.

6.6. **Disclaimer**. The Company acknowledges that Sandoz makes no representation, warranty or covenant, either express or implied, that (a) Sandoz will succeed in Commercializing the Product in the Territory, (b) the Product will achieve any particular sales level, or (c) achievement of any Commercialization milestone or plan guarantees the achievement of any particular future sales level or Commercialization milestone within any given period of time, if at all. The Company acknowledges that the milestone triggers are not a measure of either Party's expectations (minimum or otherwise) with respect to the potential performance of the Product or the payments that the Company may receive from Sandoz as a result of the Commercialization of the Product in the Territory under this Agreement, and are not intended to be used and will not be used as a measure of damages under any circumstances.

7. REPRESENTATIONS AND WARRANTIES

7.1. **Corporate Power**. Each Party hereby represents and warrants that such Party is duly organized and validly existing under the laws of its jurisdiction of formation and organization and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

7.2. **Due Authorization**. Each Party hereby represents and warrants that such Party is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder.

7.3. **Binding Obligation**. Each Party hereby represents and warrants that this Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over it.

7.4. **Compliance with Applicable Laws**. The Company represents, warrants and covenants to Sandoz that it shall, at all times, comply with all Applicable Laws in its performance of its obligations pursuant to this Agreement. Sandoz represents, warrants and covenants to the Company that it shall, at all times, comply with all Applicable Laws in its performance of its obligations pursuant to this Agreement.

7.5. **Additional Company Representations and Warranties**. The Company hereby represents and warrants that:

7.5.1. All Licensed Patents existing as of the Effective Date are listed on Schedule A, and the Licensed Patents listed on Schedule A represent all Patents that the Company or its Affiliates Control that are necessary or useful for the Manufacture or Commercialization of the Product in the Territory. As of the Effective Date, to the best of the Company's knowledge, all of the Licensed IP and the Licensed Trademarks are valid and enforceable.

7.5.2. The Company has the right to the Licensed IP and the Licensed Trademarks to grant the licenses to Sandoz that are granted in Sections 2.3 and 2.4.

7.5.3. The Company has not granted, and will not grant during the Term, rights to any Third Party under the Licensed IP or Licensed Trademark(s) that conflict with the licenses granted to Sandoz in Sections 2.3 and 2.4.

7.5.4. As of the Effective Date, it has not received any notice from a Third Party alleging that: (a) the practice of the Licensed IP or the Licensed Trademark(s) infringes or may infringe such Third Party's intellectual property right; or (b) Development or Manufacturing of the Product by the Company infringes or misappropriates the intellectual property rights of any Third Party.

7.5.5. As of the Effective Date, there is no actual or, to the best of the Company's knowledge, threatened infringement by a Third Party of any of the Licensed IP or the Licensed Trademark(s) licensed to Sandoz hereunder.

7.5.6. As of the Effective Date, there is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the best of the Company's knowledge, threatened against the Company in connection with the Product or any of the Licensed IP or Licensed Trademark(s) licensed to Sandoz hereunder.

7.5.7. Except for the agreements listed on Schedule G (the "**Material Contracts**"), the Company has no other material agreements with a Third Party relating to the supply of finished formulation of the Product, and the Company has provided Sandoz with access to true, correct and complete (except for redacted financials) copies of the Material Contracts.

7.5.8. Each Material Contract is in full force and effect as of the Effective Date. During the Term, the Company will use **[*]** to maintain the Material Contracts in full force and effect and perform its obligations thereunder during the term thereof. The Company will keep Sandoz informed of any material development pertaining to any Material Contract that would reasonably be expected to have a material adverse effect on Sandoz's rights under this Agreement. During the Term, the Company shall not, without the prior written approval of Sandoz: (a) amend any provision of any Material Contract in a manner that would reasonably be expected to have a material adverse effect on Sandoz's rights under this Agreement; or (b) make any election or exercise any right or option to terminate in whole or in part any Material Contract to the extent such election or exercise would reasonably be expected to have a material adverse effect on Sandoz's rights under this Agreement. During the Term, the Company shall promptly provide Sandoz with written notice of any alleged, threatened, or actual breach of any Material Contract of which it becomes aware. As of the Effective Date, none of the Company, its Affiliates or any Third Party is in breach of any Material Contract.

7.5.9. The Company has provided Sandoz with access to true, correct and complete copies of: (a) **[*]**; and (b) **[*]** impact on the ability of Sandoz to Commercialize the Product in the Territory pursuant to this Agreement.

7.5.10. All Product supplied by the Company to Sandoz hereunder shall Conform to the Specifications as of the date of delivery, and the Manufacturing, packaging, Labeling, storage, disposal and handling of all Product by the Company prior to delivery to Sandoz shall comply with the applicable current Regulatory Approvals, Good Manufacturing Practices and Applicable Law. Until the Product expiration date, the Product shall be free from defects in materials and manufacture and shall continue to Conform to the Specifications (except for defects attributable to any materials supplied by Sandoz, including artwork, advertising and labeling). Subject to the Company's indemnification obligations under Section 8.1, the sole remedy for non-compliance with this Section 7.5.10 shall be refund or replacement of rejected Product, as set forth in Section 3.9.

7.5.11. As of the Effective Date, the Company has conducted Development of the Product in accordance with all Applicable Laws.

7.6. **Company Conduct**.

7.6.1. Sandoz promotes the societal and environmental values of the United Nations Global Compact to its external suppliers and uses its influence where possible to encourage their adoption. Sandoz expects suppliers with whom it works to comply with the law and to adhere to ethical business practices set out in the Novartis Supplier Code. The Company shall: (a) comply with the Novartis Supplier Code (and any published updates) which can be viewed and downloaded from https://www.novartis.com/about-us/corporate-responsibility/resources-news/codes-policies-guidelines (you may request a copy free of charge from Novartis); (b) allow Sandoz (or its nominated Third Party experts) adequate access for the purposes of auditing compliance with these standards and provide information and documentation on reasonable request to Sandoz and its Affiliates to allow Sandoz and its Affiliates to verify compliance with the Novartis Supplier Code in the form requested; (c) to rectify identified non-compliances with the Novartis Supplier Code (where capable of remedy) and report remediation progress to Novartis on request; and (d) ensure that where the Company's Affiliates and/or permitted Third Party subcontractors/agents of the Company, which have been pre-approved by Sandoz, that such Affiliates and/or Third Party subcontractors/agents also comply with the above requirements relating to the Novartis Supplier Code.

7.6.2. The Company shall train any representative who is involved with the performance of services to Sandoz on anti-corruption and anti-bribery at its own expense. Such training shall include the provisions of the applicable anti-corruption and anti-bribery laws and the standards set out in the Novartis Global Anti-Bribery Policy.

7.6.3. The Company acknowledges and agrees that the Novartis Supplier Code forms an integral part of this Agreement and understands that failure to adhere to these standards and/or obstructing/refusing Sandoz's audit rights as stated in the Novartis Supplier Code shall constitute a material breach of this Agreement and entitle Novartis to immediately terminate the Agreement by written notice without compensation.

7.7. **Sandoz Conduct**. In the performance of its obligations under this Agreement, Sandoz shall comply and shall cause its employees and contractors and those of its Affiliates that are engaged in Commercialization of the Product in the Territory (but not any other Affiliates of Sandoz) to comply with all Applicable Laws regarding corruption, bribery, kickbacks, ethical business conduct, fraud and money laundering.

7.8. **Disclaimer**. Except as expressly set forth in this Agreement, NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, AS TO DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, OR ANY OTHER MATTER CONCERNING THE COMMERCIAL UTILITY OF THE PRODUCT.

8. INDEMNIFICATION; LIABILITY

8.1. **Company Indemnification**. The Company shall indemnify and hold the Sandoz Indemnified Parties harmless from and against any Liability paid or payable by the Sandoz Indemnified Parties to a Third Party as a result of any Claim that results from, arises out of or is based upon: (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement, the Pharmacovigilance Agreement, or the Quality Agreement; (b) the negligence or willful misconduct of the Company, its officers, directors, agents, and employees relating to this Agreement; (c) the Development, Processing or Manufacturing of the Product by or on behalf of the Company pursuant to this Agreement; (d) any Product Liability Claim involving a failure to warn claim, a Product manufacturing defect (i.e., non-Conforming Product) or a Product design defect; (e) any failure to supply penalties incurred by Sandoz from any of Sandoz's customers as a result of the Company's failure to provide Product in accordance with this Agreement unless caused by any negligent action or omission of Sandoz, or (f) any actual or alleged infringement of the Intellectual Property Rights of a Third Party resulting from the Commercialization of the Product by Sandoz in accordance with the terms of this Agreement, where **[*]** as contemplated by **[*]**; in each case, except to the extent to, or for matters for, which Sandoz would be required to indemnify Company Indemnified Parties under Section 8.2.

8.2. **Sandoz Indemnification**. Sandoz shall indemnify and hold the Company Indemnified Parties harmless from and against any Liability paid or payable by the Company Indemnified Parties to a Third Party as a result of any Claim that results from, arises out of or is based on: (a) any breach of any of the representations, warranties, covenants or agreements made by Sandoz in this Agreement; (b) the negligence or willful misconduct of Sandoz, its officers, directors, agents, servants and employees relating to this Agreement; or (c) the Commercialization of Product by or on behalf of Sandoz or its Affiliates; in each case, except to the extent to, or for matters for, which the Company would be required to indemnify Sandoz Indemnified Parties under Section 8.1.

8.3. **Prompt Notice Required**. No claim for indemnification hereunder shall be valid unless notice of the matter which may give rise to such claim is given in writing by the applicable Company Indemnified Party or Sandoz Indemnified Party (the "**Indemnitee**") to the Party against whom indemnification may be sought (the "**Indemnitor**") as soon as reasonably practicable after such Indemnitee becomes aware of such claim; provided, however, that the failure to notify the Indemnitor shall not relieve it from any liability that it may have to the Indemnitee otherwise unless the Indemnitor demonstrates that the defense of the underlying Claim has been materially prejudiced by such failure to provide timely notice. Such notice shall request indemnification and describe the Liability and Claim giving rise to the request for indemnification, and provide relevant details thereof. The Indemnitor shall notify the Indemnitee no later than thirty (30) days from such notice of its intention to assume the defense of any such Claim. If the Indemnitor fails to give the Indemnitee notice of its intention to defend any such Claim as provided in this Section 8.3, the Indemnitee involved shall have the right to assume the defense thereof with counsel of its choice, at the Indemnitor's expense, and defend, settle or otherwise dispose of such Claim with the consent of the Indemnitor, not to be unreasonably withheld or delayed.

8.4. **Indemnitor May Settle**. The Indemnitor shall at its expense, have the right to control, through counsel reasonably satisfactory to the Indemnitee, any Claim or Liability which is or may be brought in connection with all matters for which indemnification is provided hereunder, including without limitation the right to settle or defend. In such event the Indemnitee of the Claim or Liability in question and any successor thereto shall permit Indemnitor's counsel and independent auditors, to the extent relevant, full and free access to its books and records and otherwise fully cooperate with the Indemnitor in connection with such Claim or Liability; provided, however, that (i) the Indemnitee shall have the right fully to participate in such defense at its own expense; (ii) the Indemnitor's counsel and independent auditors shall not disclose any Confidential Information of the Indemnitee to the Indemnitor without the Indemnitee's consent, except as permitted pursuant to Section 10.2; and (iii) access shall only be given to the books and records that are relevant to the Claim or Liability at issue. The defense by the Indemnitor of any such actions shall not be deemed a waiver by the Indemnitee of its right to assert a claim with respect to the responsibility of the Indemnitor with respect to the Claim or Liability in question. The Indemnitor shall have the right to settle or compromise any Claim against the Indemnitee without the consent of the Indemnitee provided that the terms thereof: (a) provide for the unconditional release of the Indemnitee; (b) require the payment of compensatory monetary damages by Indemnitor only; and (c) expressly state that neither the fact of settlement nor the settlement agreement shall constitute, or be construed or interpreted as, an admission by the Indemnitee of any issue, fact, allegation or any other aspect of the Claim being settled. In all other cases, the Indemnitee and Indemnitor must agree to enter into any proposed settlement, which shall not be unreasonably withheld or delayed. No Indemnitee shall pay or voluntarily permit the determination of any Liability which is subject to any such Claim while the Indemnitor is negotiating the settlement thereof or contesting the matter, except with the prior written consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed.

8.5. **Assistance**. Each Party shall use Commercially Reasonable Efforts to provide all relevant information in its possession and reasonable assistance to the other Party as necessary to enable the other Party to defend any Claim. Nothing herein shall prevent the Indemnitee from retaining counsel of its choice, at such Indemnitee's expense, to monitor the defense, trial, or settlement of a Claim, and the Indemnitor and its counsel shall reasonably cooperate with such Indemnitee counsel.

8.6. **LIMITATION OF LIABILITY**. TO THE EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT EXCEPT TO THE EXTENT THAT A PARTY IS SOLELY SEEKING REIMBURSEMENT FOR SUCH DAMAGES PAID TO A THIRD PARTY AND SUCH REIMBURSEMENT IS COVERED BY THE INDEMNIFICATION PROVISIONS OF THIS AGREEMENT; AND PROVIDED THAT THIS SECTION 8.6 SHALL NOT BE CONSTRUED TO LIMIT A PARTY'S RIGHT TO SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES FOR THE OTHER PARTY'S BREACH OF ARTICLE 10.

9. INSURANCE

9.1. **Company Insurance**. The Company, at its sole cost, at all times during **[*]**, the insurance coverages with the minimum limits as set forth below. Insurance shall be purchased from insurance companies licensed to do business within the state or country where any Manufacturing work is being performed and rated A.M. Best A-VIII or better. It is also understood and agreed that any deductibles associated with the insurance coverage set forth below shall be assumed by the Company at its sole cost.

a. **Statutory Workers' Compensation** insurance, including occupational disease, as required by the State(s) in which workers are located;

b. **Employer's Liability** insurance in the amount of **[*]**;

c. **Commercial General Liability** insurance, including Contractual Liability, with a combined single limit of not less than **[*]**; and

d. **Product Liability Insurance**, including **Products/Completed Operations** insurance, of not less than **[*]**, and **[*]** in the aggregate. This policy must be maintained in full force and effect for **[*]**.

9.1.1. All insurance coverage required of the Company will be primary and not concurrent or excess over any insurance or self-insurance program carried by Sandoz, and will have no recourse to any self-insured program or insurance program carried by Sandoz.

9.1.2. By requiring the Company to maintain insurance, Sandoz does not represent that coverage and limits required will be adequate to fund all Liabilities for which the Company may be liable. The limits of insurance coverage shall not affect or limit the liability or indemnity obligations of the Company stated elsewhere in this Agreement or as required by Applicable Law.

9.1.3. All required insurance coverage of the Company will be maintained without interruption during the term of this Agreement plus an additional **[*]** following the termination of this Agreement by Sandoz or the Company.

9.1.4. The Company will waive, and will cause its insurers to waive, all rights of recovery, under subrogation or otherwise, against Sandoz at all tiers.

9.1.5. Before the commencement of any services pursuant to this Agreement, the Company will provide Sandoz with one or more certificates of insurance on forms acceptable to Sandoz, completed by a duly authorized representative of the Company's insurer(s). Such certificate(s) will (i) certify that the insurance coverages set forth above are in full force and effect, (ii) provide that such insurance coverages will not be cancelled, non-renewed, or materially changed through issuance of other policy(ies) of insurance or otherwise until Sandoz has received **[*]** written notice of such cancellation, non-renewal or material changes, and (iii) name Sandoz and its employees, directors, officers, subcontractors, representatives and agents as additional insureds, for services performed under or incidental to this Agreement.

9.2. **Sandoz Insurance**. Without prejudice to any rights or remedies the Company may have under this Agreement or otherwise at law generally, Sandoz shall (at its sole cost and expense) maintain a program of insurance or self-insurance that is customary of companies in the same or similar business.

9.3. **Maintenance Covenant**. Each Party represents, warrants and covenants that nothing has or will be done or be omitted to be done that may result in any of the said insurance policies being or becoming void, voidable or unenforceable during the Term or any Renewal Term of this Agreement.

10. CONFIDENTIALITY

10.1. **Obligations**. Each Party acknowledges that it may receive Confidential Information of the other Party in the performance of this Agreement. Each Party shall safeguard and hold such information received by it from the other Party in confidence by using such reasonable precautions as it normally takes with its own confidential and proprietary information, but in no event less than a reasonable degree of care, and each Party shall limit disclosure of the furnishing Party's information to those employees and consultants of the receiving Party and its Affiliates who are informed of and understand the confidential nature thereof and are bound by non-disclosure and non-use obligations no less restrictive than those set forth in this Agreement. To the extent that such employees or consultants take an action, or fail to take an action, that would constitute a breach of such confidentiality or non-use obligations by such employee or contractor (as if such employee or contractor were a party to this Agreement), it will constitute a breach of such obligations as if a Party had taken, or failed to take, such action itself. Each receiving Party shall not, directly or indirectly, disclose, publish or use for the benefit of any Third Party or itself, except in exercising its rights and carrying out its duties hereunder or as otherwise provided in this Article 10, any Confidential Information of the other Party, without first having obtained the furnishing Party's written consent to such disclosure or use. This restriction shall not apply to any information within the following categories: (i) information that is known to the receiving Party or its Affiliates prior to the time of disclosure to it, to the extent evidenced by written records or other competent proof; (ii) information that is independently developed by employees, agents, or independent contractors of the receiving Party or its Affiliates without reference to or reliance upon the information furnished by the disclosing Party, as evidenced by written records or other competent proof; (iii) information disclosed at any time to the receiving Party or its Affiliates by a Third Party that has a right to make such disclosure; or (iv) any other information that is or becomes part of the public domain through no fault or negligence of the receiving Party.

10.2. **Required Disclosures**. The receiving Party shall also be entitled to disclose the other Party's Confidential Information (i) that is required to be disclosed in compliance with applicable laws or regulations (including, without limitation, to comply with SEC, NASDAQ, NYSE or similar stock exchange disclosure requirements) or by order of any governmental body or a court of competent jurisdiction, or (ii) as may be necessary or appropriate in connection with the enforcement of this Agreement; provided, however, that the Party disclosing such information shall promptly notify the other Party and shall use Commercially Reasonable Efforts to obtain confidential treatment of such information by the agency or court or other disclosee, and that, in the case of disclosures under (i), shall (a) provide the other Party with prompt prior notice of the proposed disclosure such that the other Party may seek a protective order or other appropriate remedy, and (b) provide the other Party with a copy of the proposed disclosure in sufficient time to allow reasonable opportunity to comment thereon.

10.3. **Use of Information**. Each Party shall use, and direct each of its Affiliates to use, any Confidential Information obtained by it from the other Party or their respective Affiliates, pursuant to this Agreement or otherwise, solely in connection with the transactions contemplated hereby.

10.4. **Return of Information**. Upon the earlier of expiration or termination of this Agreement, the receiving Party shall, if requested by the disclosing Party, return or destroy all Confidential Information of the disclosing Party and copies and extracts thereof; provided, that the receiving Party shall not be required to return or destroy any electronic copy of Confidential Information created pursuant to its standard electronic backup and archival procedures. Notwithstanding the foregoing, the receiving Party may retain one copy of any Confidential Information of the disclosing Party to the extent required to defend or maintain any litigation relating to this Agreement, comply with legal or regulatory requirements or established document retention policies, or to demonstrate compliance with this Agreement. Notwithstanding the return or destruction of the Confidential Information (or the retention of any Confidential Information pursuant to the preceding sentence) the Parties shall continue to be bound by its obligations of confidentiality and non-use hereunder. Each Party's obligations of confidentiality and non-use shall extend during the Term and for a period of **[*]** from the expiration or termination of this Agreement.

10.5. **Publicity**. The Parties may agree to issue a joint press release substantially, in a form agreed by the Parties, as of the Effective Date or as promptly as practicable following the Effective Date. Each agrees to consult with the other Party reasonably and in good faith with respect to the text and timing of any publicity, news release or public announcement, written or oral, whether to the public, the press, stockholders or otherwise, referring to the terms or existence of this Agreement, the subject matter to which it relates, the performance under it or any of its specific terms and conditions, and to obtain the other Party's written consent, prior to any such disclosure, except a Party may not unreasonably withhold, condition or delay consent to, and either Party may make, such announcements or disclosures to securities exchanges or other applicable agencies as it determines, based on advice of the legal counsel for the Party making such announcement, are required by Applicable Law, including United States securities laws, rules or regulations, or market disclosure. Each Party shall provide the other Party with advance notice of legally required disclosures. Each Party may make any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements made in accordance with this Section 10.5 and which do not reveal non-public information about the other Party.

10.6. **Filing of this Agreement**. The Parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the U.S. Securities and Exchange Commission or any stock exchange or governmental authority on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that, each Party will ultimately retain control over what information to disclose to the U.S. Securities and Exchange Commission or any stock exchange or other governmental authority, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the U.S. Securities and Exchange Commission or any stock exchange or other governmental authority on which securities issued by a Party or its Affiliate are traded.

10.7. **Prior Non-Disclosure Agreement**. As of the Effective Date, the terms of this Article 10 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

10.8. **Equitable Relief**. Given the nature of the Confidential Information and the irreparable harm that a Party may suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this Article 10. In addition to all other remedies, a Party shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 10.

11. TERM AND TERMINATION

11.1. **Term**. The term of this Agreement shall begin on the Effective Date and, unless otherwise terminated as permitted under this Agreement, shall continue for a period of ten (10) years from the first Launch of the Product in the Territory pursuant to this Agreement (the "**Initial Term**"). This Agreement shall thereafter be automatically renewed for consecutive one (1) year renewal terms (each a "**Renewal Term**") unless terminated in accordance with the terms hereof or a Party provides notice of non-renewal to the other Party at least **[*]** in advance of **[*]** that such Party does not wish to renew this Agreement, in which case this Agreement shall expire on the last day of the Initial Term or such Renewal Term, as the case may be. The "**Term**" means the Initial Term and, if applicable, the Renewal Term.

11.2. **Termination**.

11.2.1. **Termination for Cause**. A Party may terminate this Agreement for any breach of a material provision of this Agreement by the other Party **[*]** in the case of payment breach) after written notice to the other Party containing details of such breach if the breach remains uncured at the end of such notice period. With respect to a default or breach of this Agreement, failure of a Party to provide notice to the defaulting or breaching Party as required by this Section 11.2.1 shall not constitute a waiver of the right to give such notice with respect to any subsequent default or breach.

11.2.2. **Sandoz Termination**.

a. Commercial Viability. Upon **[*]** prior written notice to the Company, Sandoz shall have **[*]** the right to terminate this Agreement either in its entirety or **[*]**, if Sandoz determines that **[*]**.

b. Product Viability. Sandoz may terminate this Agreement upon **[*]** prior written notice to the Company if, with respect to the Product, there is a withdrawal of the Product from the Territory due to (i) any decision, judgment, ruling or other requirement of the FDA, (ii) the issuance of a voluntary recall by FDA, or (iii) mutual written agreement of the Parties of material safety of the Product.

c. Failure to Supply. Sandoz may, upon **[*]** prior written notice to the Company, terminate this Agreement if the Company is unable to supply, or arrange for the supply of the Product to Sandoz pursuant to a Firm Order, and such inability to supply lasts for **[*]**, unless **[*]**.

d. Infringement Action. Sandoz may, upon **[*]** prior written notice to the Company, terminate this Agreement if **[*]** that prevents either (i) **[*]** or (ii) **[*]**. For purposes of this Agreement, "**Infringement Action**" any claim of infringement or potential infringement of Third Party intellectual property rights in connection with the marketing, development, manufacture, production, use, importation, offer for sale, or sale of the Product in the Territory.

e. Quality. Sandoz may, upon **[*]** prior written notice to the Company, terminate this Agreement if, at any time during the Term, any supplier of Components (including API, excipients and primary and secondary packaging Components) and/or the Product Manufacturer(s) either (i) **[*]** and Company is unable to effect corrective action that is satisfactory to Sandoz or its designated auditor within **[*]**, or (ii) fails to maintain an approved Product NDA.

f. Product Clearance. Beginning on **[*]**, Sandoz may, upon **[*]** written notice to the Company, terminate this Agreement if **[*]**.

11.2.3. **Termination by the Company**.

a) Termination of Rights **[*]**. Upon **[*]** prior written notice to Sandoz, the Company shall have, at its sole discretion, the right to terminate this Agreement with respect to **[*]** if: (a) **[*]**, Sandoz fails to **[*]**, or (b) if **[*]** following the receipt of **[*]** (or such longer period as agreed in writing by the Parties, such agreement not to be unreasonably withheld, conditioned or delayed), Sandoz fails to **[*]**.

b) Termination of this Agreement. Upon **[*]** prior written notice to Sandoz, the Company may terminate this Agreement in its entirety if Sandoz fails to **[*]** within **[*]**, provided **[*]**

11.2.4. **Bankruptcy**. To the extent permitted under Applicable Law, a Party may terminate this Agreement effective immediately with written notice if the other Party shall file for bankruptcy, shall be adjudicated bankrupt, shall file a petition under insolvency laws, shall be dissolved or shall have a receiver appointed for substantially all of its property. All rights and licenses granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of the Company, Sandoz shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property Controlled by the Company to the extent needed to allow Sandoz to make or have made and continue to market and sell any Product under this Agreement, and such, if not already in its possession, shall be promptly delivered to Sandoz by the Company, unless the Company elects to continue, and continues to perform all of its obligations under this Agreement.

11.2.5. **Effects of Termination**.

a. Except as expressly set forth in this Agreement, upon expiration or termination of this Agreement for any reason, neither Party shall have any obligation to make any payments to the other, except for amounts accrued prior to expiration or termination.

b. In the event of expiration or termination of this Agreement by (i) the Company pursuant to Section 11.2.1 (Termination for Cause), Section 11.2.3(b) (Termination of this Agreement), or Section 11.2.4 (Bankruptcy) or (ii) Sandoz pursuant to Section 11.2.1 (Termination for Cause), Section 11.2.2 (Sandoz Termination) or Section 11.2.4 (Bankruptcy), (i) all licenses and rights granted by Company to Sandoz will terminate and (ii) each Party will promptly return to the other Party all materials and records in its possession or control containing Confidential Information of the other Party. In addition, in the event of termination of this Agreement by Sandoz pursuant to **[*]**, the Company shall **[*]**.

c. In the event of early termination of this Agreement for any reason other than termination by the Company pursuant to Section 11.2.1 (Termination for Cause), Section 11.2.3(b) (Termination of this Agreement) or Section 11.2.4 (Bankruptcy), Sandoz and its Affiliates shall have the right, in Sandoz's sole discretion, to continue, to the extent that Sandoz and its Affiliates continue to have Product inventory, to fulfill orders received from customers for Product in the Territory until up to **[*]** after the effective date of termination of this Agreement. For Product sold by Sandoz or its Affiliates after the effective date of termination, Sandoz shall continue to make payments to the Company in accordance with Article 6, as applicable.

d. In the event Sandoz or the Company issues a notice of partial termination of this Agreement, pursuant to Section 11.2.2(a) (Commercial Viability) or Section 11.2.3(a) (Termination of Rights **[*]**), respectively, then the Company and Sandoz, during the notice period (unless the Parties agree to extend such period of time, such agreement not to be unreasonably withheld, conditioned or delayed), shall negotiate a commercially reasonable amendment to this Agreement, to account for **[*]**, such amendment to have an effective date as of the effective date of such partial termination. All other rights to Product **[*]** shall continue in effect in accordance with the terms of this Agreement.

11.2.6. **Non-Exclusive Remedy**. Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including, without limitation, the Parties' ability to receive legal damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.

11.2.7. **Damages; Set-Off**. Without limiting Section 11.2.6, if a Party alleges that the other Party has breached any provision of this Agreement and claims in good faith that it is entitled to receive damages with respect to any such breach (whether or not the alleging Party terminates this Agreement pursuant to Section 11.2.1 (Termination for Cause)), then (a) if there is no Dispute regarding such breach or damages or, if there is a Dispute regarding such breach or damages, while such Dispute is pending resolution pursuant to Sections 12.2, 12.3 and 12.4, as applicable, the alleging Party will have the right to deduct such claimed damages from amounts otherwise payable hereunder by the alleging Party to the other Party and (b) where there is a Dispute regarding such breach or damages, (i) the alleging Party will have the right to deduct any damages to which the alleging Party is determined to be entitled in such Dispute from amounts otherwise payable hereunder by the alleging Party to the other Party to the extent such damages have not been previously deducted hereunder or otherwise paid to the alleging Party by the other Party, and (ii) if the alleging Party is determined not to be entitled to damages in such Dispute or to be entitled to damages in such Dispute that are less than the amounts previously deducted hereunder by the alleging Party, then the alleging Party shall promptly pay the other Party any amounts of claimed damages previously deducted by the alleging Party hereunder that exceed the damages (if any) to which the alleging is determined to be entitled in such Dispute.

12. GENERAL

12.1. **Exclusivity**. During the Term of this Agreement, except as contemplated by this Agreement, the Company agrees not to, directly or indirectly, and Sandoz agrees not to directly conduct, participate in or sponsor the Commercialization of any pharmaceutical composition that: (a) either (i) is or will be approved for the Territory under a drug application by way of 21 U.S.C. §355(b)(1) or (b)(2) or (ii) is AB-rated to the Product and approved under an abbreviated new drug application by way of 21 U.S.C. §355(j); and (b) is comprising an injectable formulation having epinephrine as an active ingredient; and (c) is indicated for the emergency treatment of allergic reactions, including anaphylaxis; provided, however, such restriction shall not apply **[*]** in the event the Company exercises its rights under Section 11.2.3(a) or Sandoz exercises its right under Section 11.2.2(a).

12.2. **Informal Dispute Resolution**. Unless otherwise expressly provided for herein, any disputes arising out of or in connection with this Agreement ("**Dispute**") shall be identified in writing and presented to the other Party. Within fourteen (14) days after delivery of such notice of dispute, the Sandoz Executive Officer and the Company Executive Officer shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the dispute in good faith. All reasonable requests for information made by one Party to another shall be honored. All negotiations pursuant to this clause are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If such Executive Officers cannot resolve such dispute within fourteen (14) days after such meeting, then, subject to Section 12.3, each Party reserves its right to any and all remedies available under law or equity with respect to any other dispute.

12.3. **Jurisdiction**. The Company and Sandoz agree to irrevocably submit to the exclusive jurisdiction of (i) the state courts of New York County, New York, U.S.A., or (ii) the United States District Court for the Southern District of New York, U.S.A., for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the Southern District of New York, U.S.A. or, if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the state courts of New York County, New York, U.S.A. Each Party further agrees that service of any process, summons, notice or document by U.S. registered mail or recognized international courier service to such Party's respective address set forth in Section 12.14 of this Agreement shall be effective service of process for any action, suit or proceeding in New York with respect to any matters to which it has submitted to jurisdiction in this Agreement. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in (i) the state courts of New York County, New York, U.S.A., or (ii) the United States District Court for the Southern District of New York, U.S.A., and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum (e.g., under the doctrine of forum non conveniens or pursuant to 28 U.S.C. § 1404(a)). Each Party hereto agrees that any such proceeding shall be conducted solely in the English language.

12.4. **Waiver of Jury Trial**. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE IT HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE EITHER OF SUCH WAIVERS; (II) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF SUCH WAIVERS; (III) IT MAKES SUCH WAIVERS VOLUNTARILY; AND (IV) IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS CLAUSE 12.4.

12.5. **Governing Law**. This Agreement and any and all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, U.S.A. applicable to agreements made and to be performed entirely in such state, without giving effect to the conflict of law principles thereof. The Parties expressly agree that the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement or any Party's performance hereunder.

12.6. **Convictions, Exclusion, Debarment, Etc.** Neither Party nor any person employed by or under contract to such Party now or in the future in connection with any activities contemplated by this Agreement: (a) has been convicted of an offense related to any Federal or State healthcare program, including (but not limited to) those within the scope of 42 U.S.C. § 1320a-7(a); (b) has been excluded, suspended or is otherwise ineligible for Federal or State healthcare program participation, including (but not limited to) persons identified on the General Services Administration's List of Parties Excluded from Federal Programs or the HHS/OIG List of Excluded Individuals/Entities; (c) has been debarred from or under any Federal or State healthcare program (including, but not limited to debarment under Section 306 of the Federal Food, Drug and Cosmetic Act (21 USC 335a); or (d) is on any of the FDA Clinical Investigator enforcement lists, including, but not limited to, the (i) Disqualified/Totally Restricted List, (ii) Restricted List and (iii) Adequate Assurances List. Each Party further agrees that if, at any time after execution of this Agreement, it becomes aware that it has or any Person who participated, or is participating, in the performance of any activities contemplated by this Agreement has become or is in the process of being charged, convicted, debarred, excluded, proposed to be excluded, suspended or otherwise rendered ineligible, or is on an enforcement list, such Party will immediately notify the other Party in writing.

12.7. **Assignment or Transfer of Interest**. This Agreement shall be binding upon and inure to the benefit of the successors or permitted assigns of each of the Parties and may not be assigned or transferred by a Party (other than to an Affiliate provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate) without the prior written consent of the other, except that such consent shall not be required on the part of either Party in connection with a transfer or sale of all or substantially all of the business of that Party to which this Agreement relates, to a Third Party, whether by merger, sale of stock, sale of assets or otherwise; provided, however, that in the event of such a transaction (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the Parties to this Agreement) shall not be included in the technology licensed hereunder or otherwise subject to this Agreement. Any attempted assignment that does not comply with the terms of this Section 12.7 shall be void.

12.8. **Force Majeure**. Provided that such failure is cured as soon as is practicable after its occurrence, the failure of the Company or Sandoz to perform any of its obligations under this Agreement, other than the payment of amounts invoiced, shall not subject the Company or Sandoz to any liability, if such failure is caused or occasioned by a Force Majeure Event. The Party claiming Force Majeure Event shall notify the other Party with notice of the Force Majeure Event as soon as practicable, but in no event later than fourteen (14) days after its occurrence, which notice shall reasonably identify such obligations under this Agreement and the extent to which performance thereof will be affected. In such event, the Parties shall meet promptly to determine an equitable solution to the effects of any such Force Majeure Event, and the Party affected by the Force Majeure Event shall use all reasonable efforts to minimize the loss or inconvenience suffered by the Parties.

12.9. **Entire Agreement**. This Agreement, including any schedules or exhibits hereto, and the pharmacovigilance agreement and Quality Agreement to be executed by the Parties pursuant to this Agreement, contains the entire agreement and understanding between the Parties relating to the subject matter hereof, and shall supersede all prior or contemporaneous agreements and understandings, oral or written, relating to the subject matter hereof and any inconsistent terms of any subsequent invoice, purchase order or similar document. Neither Party shall be liable or bound to the other Party in any manner by any representations, warranties or covenants relating to such subject matter except as specifically set forth herein.

12.10. **Amendments and Waiver**. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the Parties. By an instrument in writing a Party may waive compliance by another Party with any term or provision of this Agreement that such other Party was or is obligated to comply with or perform. Any failure of a Party to enforce at any time, or for any time period, any of the provisions of this Agreement shall not be deemed or construed to be a waiver of such provisions or a waiver of any right of such Party thereafter to enforce each and every such provision on any succeeding occasion or breach thereof.

12.11. **Nature of Relationship**. In making and performing this Agreement, the Parties are acting, and intend to be treated, as independent entities and nothing contained herein shall be deemed or implied to create an independent contractor, agency, distributorship, joint venture or partnership relationship among the Parties hereto. Except as otherwise expressly provided herein, no Party may make any representation, warranty or commitment, whether express or implied, on behalf of or incur any charges or expenses for, or in the name of, any other Party.

12.12. **Further Actions and Documents**. Each Party agrees to execute, acknowledge and deliver all such further instruments, and to do all such further acts, as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

12.13. **Notices**. All notices and other communications required or permitted to be given or made pursuant to this Agreement shall be in writing signed by the sender and shall be deemed duly given (i) on the date delivered, if personally delivered, (ii) on the date sent by telecopier with automatic confirmation by the transmitting machine showing the proper number of pages were transmitted without error, (iii) on the Business Day after being sent by FedEx or another recognized overnight mail service which utilizes a written form of receipt for next day or next Business Day delivery, or (iv) five (5) Business Days after mailing, if mailed by United States postage-prepaid certified or registered mail, return receipt requested, in each case addressed to the applicable Party at the address set forth below; provided, that a Party may change its address for receiving notice by the proper giving of notice hereunder:

If to Sandoz:

Sandoz Inc.
[*]
[*]
Attn: **[*]**
Tel: **[*]**
Fax: **[*]**

If to the Company:

Adamis Pharmaceuticals Corporation
11682 El Camino Real, Suite 300
San Diego, CA 92130
Attn: President & CEO
Tel: (858) 997-2400
Fax: **[*]**

With a copy to:

Sandoz Inc.
[*]
[*]
Attn: **[*]**
Tel: **[*]**
Fax: **[*]**

With a copy to:

[*]
[*]
[*]
Attn: **[*]**
Tel: **[*]**
Fax: **[*]**

12.14. **Counterparts; Facsimile/PDF Signature**. This Agreement may be executed by the exchange of faxed executed copies, certified electronic signatures or executed copies delivered by electronic mail in Adobe Portable Document Format or similar format, and any signature transmitted by such means for the purpose of executing this Agreement shall be deemed an original signature for purposes of this Agreement. The parties agree that the electronic signatures appearing on this Agreement are the same as handwritten signatures for the purposes of validity, enforceability and admissibility pursuant to the Electronic Signatures in Global and National Commerce (ESIGN) Act of 2000 and Uniform Electronic Transactions Act (UETA) model law or similar applicable laws. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original as against any Party whose signature appears thereon, but all of which together shall constitute one and the same instrument.

12.15. **Severability**. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstances, is held invalid, illegal or unenforceable in any respect for any reason, the Parties shall negotiate in good faith with a view to the substitution therefore of a suitable and equitable solution in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; provided, however, that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions contained herein shall not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties hereto shall be enforceable to the fullest extent permitted by law.

12.16. **Headings**. The captions or headings of the Sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and are not part of the agreement of the Parties and shall have no effect on the meaning of the provisions hereof. All references in this Agreement to Sections or Articles are to Sections or Articles of this Agreement, unless otherwise indicated.

12.17. **Expenses**. Each Party will pay all of its own fees and expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation and execution of this Agreement and the arrangements contemplated hereby.

12.18. **Third Party Rights**. Nothing in this Agreement will be deemed to create any Third Party beneficiary rights in or on behalf of any other Person.

12.19. **Performance through Affiliates**. Notwithstanding anything to the contrary contained herein, each Party may discharge any obligations and exercise any right hereunder, or performance hereunder, through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

12.20. **Survival**. Expiration or termination of this Agreement shall not relieve the Parties of any rights or obligation accruing prior to such expiration or termination. In addition, the Parties' respective rights and obligations under the following Sections and Articles (and all associated definitions) shall survive the termination or expiration of this Agreement: Section 5.3, Sections 6.5 (for three (3) years following the calendar year in which termination or expiration occurs), 6.6, 7.8, 9.1.3 (for three (3) years following termination or expiration occurs), 11.2.5 and 11.2.6 and Article 1, Articles 8, 10 and 12 (other than 12.1).

[*signature page follows*]

IN WITNESS WHEREOF, each Party is signing this Agreement on the date stated opposite that Party's signature.

SANDOZ INC.

By: /s/ Carol Lynch Date: 28-June-2018
Name: Carol Lynch
Title: President Sandoz US

ADAMIS PHARMACEUTICALS CORPORATION

By: /s/ Dennis J. Carlo Date: 7/1/18
Name: Dennis J. Carlo
Title: Pres/CEO

SCHEDULE A

Licensed Patents and Licensed Trademarks

Licensed Patents:

Country	Serial No.	Filed Date	Publication/Patent No.	Status	Priority Date
US	**[*]**	**[*]**		**[*]**	**[*]**
US	29/537,278	08/24/2015	D781,569	ISSUED	08/24/2015
US	29/591,934	01/25/2017	D799,202	ISSUED	08/24/2015
US	**[*]**	**[*]**		**[*]**	**[*]**

Licensed Trademarks:

“Symjepi” (pending US TM application no. 86582421)

“Symject”

symjepi.com

SCHEDULE B

One-Time Milestone Payments and Net Profit Share

One-Time Milestone Payments

Milestone	**Amount Payable**
Upon the Effective Date of this Agreement	$**[*]** USD

Net Profit Share

Subject to the terms of the Agreement, including without limitation, **[*]**, Sandoz shall pay the Company fifty percent (50%) of the Net Profits. Sandoz shall retain the remaining fifty percent (50%) of the Net Profits.

SCHEDULE C

Product

Product

"**Product**" means epinephrine pre-filled syringe injectable device in 0.3mg/0.3ml, 0.15mg/0.3ml, and any other strength, as approved by the FDA under New Drug Application Number 207534, as amended, in finished, packaged form that is distributed by Sandoz under the Licensed Trademark Symjepi™ or as an authorized generic version distributed by Sandoz pursuant to the NDA, in each case, in the Territory, under Sandoz NDC numbers, pursuant to this Agreement.

SCHEDULE D

Supply Price

The initial Supply Price is in the table below:

Annual Quantity of Product*	**[*]**	**[*]**	**[*]**	**[*]**	**[*]**
[*] Batches	$**[*]**	$**[*]**	$**[*]**	$**[*]**	$**[*]**
[*] Batches	$**[*]**	$**[*]**	$**[*]**	$**[*]**	$**[*]**

*Note: Quantities are in individual units of pre-filled syringe with device. In addition, **[*]**. This means, for example, that **[*]**.

☐ The Supply Price set forth above is comprised of the following:

- o **[*]**.

[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	

- o **[*]**.
- o **[*]**.

[*]	**[*]**	**[*]**	**[*]**	**[*]**	**[*]**
[*]	**$[*]**	**$[*]**	**$[*]**	**$[*]**	**$[*]**

The Company will **[*]**. The Company shall maintain complete and accurate written records of all costs relating to Product and will make these records available to Sandoz as requested in accordance with this Agreement.

SCHEDULE E

[*] Commercial Milestone Payments

One-time Commercial Milestones		**One-time Commercial Milestone Payment Amount**
[*]	**[*]***	$**[*]**
[*]	**[*]***	$**[*]**
[*]	**[*]***	$**[*]**
[*]	**[*]***	$**[*]**
[*]	**[*]***	$**[*]**

* **[*]**

[*].

SCHEDULE F

Approved Product Manufacturer

Catalent **[*]** located at **[*]**

[*]

SCHEDULE G

Material Contracts

[*]

[*]

[*]

[*]

SCHEDULE H

Licensed Trademark Usage Guidelines

Pursuant to the Distribution and Commercialization Agreement by and between Adamis Pharmaceuticals Corporation, a corporation organized under the laws of Delaware, with an office located at 11682 El Camino Real, Suite #300, San Diego, CA 92130 (the "**Licensor**") and Sandoz Inc., a corporation organized under the laws of Colorado, with an office at 100 College Road West, Princeton, New Jersey 08540 ("**Licensee**") (the "**Agreement**") and to create and maintain strong trademark protection, Licensee should follow these guidelines when using any Licensed Trademarks in print and electronic materials. In the event a conflict arises between these Licensed Trademark Usage Guidelines and the Agreement, the terms contained in these Licensed Trademark Usage Guidelines shall control with respect to matters relating to the usage of the Licensed Trademarks. Any capitalized terms used but not defined herein shall have the meaning ascribed to them in the Agreement.

[*].

Status of Licensed Marks

June 2018

Mark	Country	Status
SYMJEPI	United States	Pending Application
[*]	**[*]**	**[*]**

SCHEDULE I

[*]

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 annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial 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: November 9, 2018

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 annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial 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: November 9, 2018

By: /s/ Robert O. Hopkins
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 September 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

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

Dated: November 9, 2018

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 September 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

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

Dated: November 9, 2018

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.