UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2020

OR

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

Commission File Number: 001-36242

ADAMIS PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**82-0429727**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

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

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

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

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

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

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

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

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

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

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

The number of shares outstanding of the issuer's common stock, par value $0.0001 per share, as of August 11, 2020, was 73,920,765.

ADAMIS PHARMACEUTICALS, INC.

CONTENTS OF QUARTERLY REPORT ON FORM 10-Q

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents	$ 7,891,203	$ 8,810,636
Accounts Receivable, net	1,353,829	1,877,655
Inventories	2,143,607	2,061,097
Prepaid Expenses and Other Current Assets	607,455	1,127,322
	11,996,094	13,876,710
LONG TERM ASSETS		
Intangible Assets, net	10,164,479	11,127,562
Goodwill	4,497,422	7,640,622
Fixed Assets, net	11,340,533	11,667,416
Right -of-Use Assets	1,650,477	1,873,552
Other Non-Current Assets	54,655	1,654,655
Total Assets	$ 39,703,660	$ 47,840,517
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable	$ 4,264,909	$ 4,267,654
Deferred Revenue, current portion	542,925	115,671
Accrued Other Expenses	2,263,585	2,428,619
Accrued Bonuses	961,973	—
Lease Liabilities, current portion	459,210	444,621
Bank Loan - Building	2,102,126	2,153,182
Paycheck Protection Plan (PPP) Loan	1,235,506	—
Warrant Liabilities, at fair value	537,000	—
	12,367,234	9,409,747
LONG TERM LIABILITIES		
Deferred Revenue	900,000	800,000
Deferred Tax Liability, net	112,530	112,530
Lease Liabilities, net of current portion	1,246,722	1,480,996
PPP Loan, net of current portion	1,956,194	—
Total Liabilities	16,582,680	11,803,273
COMMITMENTS AND CONTINGENCIES (see Note 9)		
STOCKHOLDERS' EQUITY		
Preferred Stock – Par Value $.0001; 10,000,000 Shares Authorized; Series B Convertible, 1,000,000 and Zero Issued and Outstanding at June 30, 2020 (Unaudited) and December 31, 2019, respectively.	100	—
Common Stock - Par Value $.0001; 100,000,000 Shares Authorized; 74,443,722 and 62,352,465 Issued, 73,920,765 and 61,829,508 Outstanding at June 30, 2020 and December 31, 2019, respectively	7,444	6,235
Additional Paid-in Capital	226,969,294	218,350,785
Accumulated Deficit	(203,850,608)	(182,314,526)
Treasury Stock, at cost - 522,957 Shares	(5,250)	(5,250)
Total Stockholders' Equity	23,120,980	36,037,244
Total Liabilities and Stockholders' Equity	$ 39,703,660	$ 47,840,517

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020 (Unaudited)	2019 (Unaudited)	2020 (Unaudited)	2019 (Unaudited)
REVENUE, net	$ 3,926,342	$ 5,764,899	$ 8,589,552	$ 10,670,671
COST OF GOODS SOLD	4,683,835	3,665,565	8,370,879	7,291,033
Gross (Loss) Profit	(757,493)	2,099,334	218,673	3,379,638
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	5,653,092	7,000,339	11,707,463	15,021,803
RESEARCH AND DEVELOPMENT	3,085,824	2,845,745	5,122,556	5,042,260
IMPAIRMENT EXPENSE - Goodwill	—	—	3,143,200	—
IMPAIRMENT EXPENSE - Write-off of Contract Asset	1,750,000	—	1,750,000	—
Loss from Operations	(11,246,409)	(7,746,750)	(21,504,546)	(16,684,425)
OTHER INCOME (EXPENSE)				
Interest Expense	(32,925)	(22,954)	(71,212)	(46,962)
Interest Income	16,621	34,117	39,676	108,495
Total Other Income (Expense), net	(16,304)	11,163	(31,536)	61,533
Net Loss	$ (11,262,713)	$ (7,735,587)	$ (21,536,082)	$ (16,622,892)
Basic and Diluted Loss Per Share	$ (0.15)	$ (0.16)	$ (0.31)	$ (0.35)
Basic and Diluted Weighted Average Shares Outstanding	73,825,491	47,539,186	70,162,628	47,425,971

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
For the Three Months Ended June 30, 2020	**Shares**	**Amount**	**Shares**	**Amount**	**Capital**	**Shares**	**Amount**	**Deficit**	**Total**
Balance March 31, 2020	—	$ —	74,255,245	$ 7,426	$ 225,801,654	522,957	$ (5,250)	$ (192,587,895)	$ 33,215,935
Series B Convertible Preferred Stock Issued	1,000,000	100	—	—	589,900	—	—	—	590,000
Issuance of Restricted Stock Units (RSUs)	—	—	188,477	18	(18)	—	—	—	—
Share Based Compensation	—	—	—	—	1,114,758	—	—	—	1,114,758
Net Loss	—	—	—	—	—	—	—	(11,262,713)	(11,262,713)
Out of Period Adjustment (see Note 1)	—	—	—	—	(537,000)	—	—	—	(537,000)
Balance June 30, 2020	1,000,000	$ 100	74,443,722	$ 7,444	$ 226,969,294	522,957	$ (5,250)	$ (203,850,608)	$ 23,120,980
For the Three Months Ended June 30, 2019									
Balance March 31, 2019	—	$ —	47,965,371	$ 4,796	$ 201,674,571	522,957	$ (5,250)	$ (161,895,062)	$ 39,779,055
Issuance of Restricted Stock Units (RSUs)	—	—	195,695	20	(20)	—	—	—	—
Share Based Compensation	—	—	—	—	1,765,318	—	—	—	1,765,318
Net Loss	—	—	—	—	—	—	—	(7,735,587)	(7,735,587)
Balance June 30, 2019	—	$ —	48,161,066	$ 4,816	$ 203,439,869	522,957	$ (5,250)	$ (169,630,649)	$ 33,808,786
For the Six Months Ended June 30, 2020									
Balance December 31, 2019	—	$ —	62,352,465	$ 6,235	$ 218,350,785	522,957	$ (5,250)	$ (182,314,526)	$ 36,037,244
Common Stock Issued, Net of Issuance Costs of $494,902	—	—	11,600,000	1,161	6,231,938	—	—	—	6,233,099
Series B Convertible Preferred Stock Issued	1,000,000	100	—	—	589,900	—	—	—	590,000
Issuance of Restricted Stock Units (RSUs)	—	—	491,257	48	(48)	—	—	—	—
Share Based Compensation	—	—	—	—	2,333,719	—	—	—	2,333,719
Net Loss	—	—	—	—	—	—	—	(21,536,082)	(21,536,082)
Out of Period Adjustment (see note 1)	—	—	—	—	(537,000)	—	—	—	(537,000)
Balance June 30, 2020	1,000,000	$ 100	74,443,722	$ 7,444	$ 226,969,294	522,957	$ (5,250)	$ (203,850,608)	$ 23,120,980
For the Six months Ended June 30, 2019									
Balance December 31, 2018	—	$ —	47,814,315	$ 4,781	$ 199,696,656	522,957	$ (5,250)	$ (153,004,370)	$ 46,691,817
Cumulative Effect from Adoption of ASU 2016-02, Leases (Topic 842)	—	—	—	—	—	—	—	(3,387)	(3,387)
Issuance of Restricted Stock Units (RSUs)	—	—	346,751	35	(35)	—	—	—	—
Share Based Compensation	—	—	—	—	3,743,248	—	—	—	3,743,248
Net Loss	—	—	—	—	—	—	—	(16,622,892)	(16,622,892)
Balance June 30, 2019	—	$ —	48,161,066	$ 4,816	$ 203,439,869	522,957	$ (5,250)	$ (169,630,649)	$ 33,808,786

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended June 30,	
	2020 (Unaudited)	2019 (Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (21,536,082)	$ (16,622,892)
Adjustments to Reconcile Net Loss to Net		
Cash Used in Operating Activities:		
Stock Based Compensation	2,333,719	3,743,248
Acquired IPR&D	840,000	—
Provision for Bad Debts	62,457	33,956
Provision for Excess and Obsolete Inventory	1,503,399	539,758
Non-Cash Operating Lease Expense	3,374	—
Depreciation and Amortization	1,795,305	1,553,668
Impairment of Goodwill	3,143,200	—
Impairment of Contract Assets	1,750,000	—
Gain on Sale of Fixed Assets	—	(9,000)
Change in Operating Assets and Liabilities		
Accounts Receivable	461,369	(1,781,070)
Inventories	(1,585,909)	(175,212)
Prepaid Expenses and Other Current Assets	319,867	15,986
Accounts Payable	204,943	369,589
Deferred Revenue	527,254	(46,950)
Accrued Other Expenses and Bonuses	796,939	(310,903)
Net Cash Used in Operating Activities	(9,380,165)	(12,689,822)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of Equipment	(660,787)	(2,203,948)
Purchase of IPR&D	(250,000)	—
Net Cash Used in Investing Activities	(910,787)	(2,203,948)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from Issuance of Common Stock, net of issuance costs	6,233,099	—
Principal Payments of Finance Leases	(2,224)	(36,086)
Proceeds of PPP Loan	3,191,700	—
Payment of Bank Loan	(51,056)	(249,097)
Net Cash Provided by (Used in) Financing Activities	9,371,519	(285,183)
Decrease in Cash and Cash Equivalents	(919,433)	(15,178,953)
Cash and Cash Equivalents:		
Beginning Cash and Cash Equivalents	8,810,636	19,271,642
Ending Cash and Cash Equivalents	$ 7,891,203	$ 4,092,689

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended June 30,	
	2020 (Unaudited)	2019 (Unaudited)
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash Paid for Income Taxes	$ 11,300	$ 9,612
Cash Paid for Interest	$ 72,097	$ 47,011
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES		
Series B Preferred Stock Issuance for License Agreement	$ 590,000	$ —
Decrease in Accrued Capital Expenditures	$ (207,688)	$ (269,214)

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Note 1: Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission ("SEC"). Accordingly, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements reflect all adjustments (including normal recurring adjustments and the elimination of intercompany accounts) considered necessary for a fair 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 audited consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

On January 30, 2020, the World Health Organization ("WHO") declared that the recent novel coronavirus (COVID-19) outbreak was a global health emergency, which prompted national governments to begin putting actions in place to slow the spread of COVID-19. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic. The outbreak of COVID-19 has resulted in travel restrictions, quarantines, "stay-at-home" and "shelter-in-place" orders and extended shutdown of certain businesses around the world. The governmental actions and the widespread economic disruption arising from the pandemic have the potential to materially impact our business and influence our business decisions. The extent and duration of the pandemic is unknown, and the future effects on our business are uncertain and difficult to predict. The Company is continuing to monitor the events and circumstances surrounding the COVID-19 pandemic, which may require adjustments to the Company's estimates and assumptions in the future.

Segment Reporting

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic No. 280, Segment Reporting ("ASC 280"), establishes standards for the way that public business enterprises report information about operating segments in their annual consolidated financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. ASC 280 also establishes standards for related disclosures about products and services, geographic areas and major customers. The Company's business segments are based on the organization structure used by the chief operating decision maker for making operating and investment decisions and for assessing performance. Commencing April 1, 2020, the chief operating decision maker ("CODM") views the Company as operating in two business segments: Drug Development and Commercialization which includes out-licensing the Company's FDA approved products; and Compounded Pharmaceuticals which includes a registered outsourcing facility. We are a specialty biopharmaceutical Company focused on developing products in various therapeutic areas, including respiratory disease, allergy and opioid overdose; and a registered drug compounding outsourcing facility, that provides prescription compounded medications, including compounded sterile preparations and nonsterile compounds, to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. The Compounded Pharmaceuticals business also provides certain veterinary pharmaceutical products for animals.

Liquidity and Capital Resources

The Company's cash and cash equivalents were $7,891,203 and $8,810,636 at June 30, 2020 and December 31, 2019, respectively.

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

The Company has significant operating cash flow deficiencies. Additionally, the Company will need significant funding before the end of fiscal 2020 for future operations and the expenditures that it believes will be required to support commercialization of its products and conduct the clinical and regulatory activities relating to the Company's product candidates, satisfy existing obligations and liabilities, and otherwise support the Company's intended business activities and working capital needs. The preceding conditions raise substantial doubt about the Company's ability to continue as a going concern. The condensed consolidated financial statements for the six months ended June 30, 2020, were prepared under the assumption that we would continue our operations as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. Our unaudited condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty. Management's plans include attempting to secure additional required funding through equity or debt financings, sales or out-licensing of intellectual property assets, products, product candidates or technologies, seeking partnerships with other pharmaceutical companies or third parties to co-develop and fund research and development efforts, or similar transactions, and through revenues from existing agreements and sales of prescription compounded formulations. There is no assurance that the Company will be successful in obtaining the necessary funding to meet its business objectives. In addition, the COVID-19 outbreak has resulted in a severe economic downturn, has already significantly affected the financial markets of many countries and has had an adverse impact on the Company. In light of the current economic downturn that we believe affected the trading prices of our Common Stock, we determined that it was more likely than not that the fair value of our subsidiary, U.S. Compounding, Inc., or USC, was less than its carrying value, which triggered the Company to perform an interim impairment assessment as of March 31, 2020 to test the carrying value of goodwill resulting in approximately $3,143,000 of goodwill impairment charges. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all.

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 diluted weighted average shares for the three and six month periods ended June 30, 2020 and June 30, 2019 consist of outstanding warrants (24,634,670 and 2,134,670, respectively), outstanding options (7,238,761 and 8,346,058, respectively), outstanding restricted stock units (2,534,107 and 3,681,796, respectively) , and convertible preferred stock (1,000,000 and 0, respectively).

Prior Periods Reclassifications

Certain amounts in prior periods have been reclassified to conform with current period presentation related to the amortization of the cost to obtain a contract included in prepaid expenses and other current assets in the unaudited condensed consolidated statement of cash flows, and had no effect on cash used in operations or statement of cash flows for the period ended June 30, 2019. The reclassification has no effect on the consolidated balance sheet as of December 31, 2019, or the unaudited condensed consolidated statement of operations for the six months ended June 30, 2019.

Out of Period Adjustments

It was determined during the review of the second quarter 2020 financial statements that the warrants issued by the Company as part of a financing transaction in August 2019 (the "2019 Warrants") (i) are presumed to require the Company to issue registered shares when the 2019 Warrants are exercised and (ii) the agreement does not specify whether the 2019 Warrants prohibit net cash settlement or require an alternative form of share settlement if there are insufficient registered shares available to be issued upon the holder's exercise. This requires the Company to account for the 2019 warrants as liability instruments due to the assumed cash settlement based on ASC 815, Derivatives and Hedging. In accordance with Staff Accounting Bulletin ("SAB") No. 99, Materiality, and SAB No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, the Company evaluated the error and determined that the related impact was not material to results of operations or financial position for any prior annual or interim period or future annual period. The approximate fair value of the 2019 Warrants at issuance was approximately $828,000 and was approximately $276,000, $138,000 and $276,000 at December 31, 2019, March 31, 2020 and June 30,2020, respectively. We corrected this immaterial error in the three and six months ended June 30, 2020 (prior periods were not revised to reflect the immaterial errors) to reflect the fair value of the warrant liability at June 30, 2020 in the amount of $276,000. The gain on remeasurement of the warrant liability in the amount $552,000 as of December 31, 2019 was not recorded because the amount was deemed immaterial.

It was also determined that the warrants issued in February 2020 (the "2020 Warrants") contain certain clauses that may require cash settlement in certain circumstances and as of the date of issuance the Company did not have adequate authorized shares available to be issued upon the exercise of the 2020 Warrants if they are exercised in the future after they first become exercisable as described in Note 12. This requires the Company to account for the 2020 Warrants as liability instruments. The Company evaluated this error and determined that the related impact, including the cumulative impact of the 2019 Warrants above, was not material to the operating results or financial position of the Company for the three months ended March 31, 2020. The fair value of the 2020 warrants at issuance was approximately $261,000 and was approximately $174,000 and $261,000 at March 31, 2020 and June 30, 2020, respectively. To correct this immaterial error the Company recorded an out of period adjustment in the three months ended June 30, 2020 to additional paid-in capital in the amount of $261,000 and a gain of $87,000, which represents the gain due to the change in fair value of the warrants from the date of issuance to the period ended March 31, 2020.

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

Recently Adopted Accounting Pronouncement

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments – Credit Losses.* ASU No. 2016-13 is intended to provide users of financial statements with more decision-useful information about credit losses on financial instruments that are expected, but do not yet meet the "probable" threshold. This Update replaces the incurred loss impairment methodology with a methodology that reflects expected credit losses. ASU No. 2016-13 was effective for fiscal years beginning after December 15, 2019 and did not have a material impact on the Company's consolidated financial statements.

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

Note 2: Revenues

Revenue from Contracts with Customers

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

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

Adamis is a specialty biopharmaceutical company focused on developing and commercializing products in various therapeutic areas, including respiratory disease, allergy and opioid overdose. The Company's subsidiary U.S. Compounding, Inc. or USC, provides prescription compounded medications, including compounded sterile preparations and nonsterile compounds, to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. USC's product offerings broadly include, among others, corticosteroids, hormone replacement therapies, hospital outsourcing products, and injectables.

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

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

On May 11, 2020, the Company entered into an agreement (the "Termination Agreement") with Sandoz Inc. to terminate the Distribution and Commercialization Agreement dated as of July 1, 2018 (the "Sandoz Agreement") and entered into between the Company and Sandoz, following an initial transition period which has ended as a result of the execution of a transition services agreement, and reacquire rights to the SYMJEPI products. The Termination Agreement provides for the mutually agreed return to Adamis of the marketing, promotion, and distribution rights, and certain marketing and promotional materials, relating to the SYMJEPI products, and the termination of the Sandoz Agreement, supported by a transition services agreement that the Company entered into with Sandoz and USWM, concerning certain transition services, activities and arrangements relating to the SYMJEPI products. As part of the Termination Agreement, Sandoz will continue to support the products in the U.S. under the Sandoz Agreement through the end of the transition period to help reduce or minimize any potential impact to patients and customers. The Termination Agreement also provides for a future resolution of any amounts that may be payable or owed with respect to the net sales and profit sharing provisions of the Sandoz Agreement, and for survival of certain provisions of the Sandoz Agreement. As a result of entering into the Termination Agreement with Sandoz, the Company determined that its financial results for the quarter ending June 30, 2020 will include an impairment of the capitalized cost to obtain a contract of $1,750,000 reflected on its condensed consolidated balance sheet as of March 31, 2020. Included in the deferred revenue balance at June 30, 2020 and December 31, 2019 was $437,500 and $900,000, respectively, relating to the non-refundable upfront payment received from Sandoz pursuant to the Sandoz Agreement.

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

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

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

Compounded Pharmaceuticals Facility Revenue Recognition

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

Drug Development and Commercialization Revenue Recognition

Sandoz

Please see Note 4 to our consolidated financial statements in the 2019 Annual Report on Form 10-K.

USWM

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

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

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

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

Disaggregation of Revenue

Our sterile environment operations are governed by specific regulatory and quality requirements. Any deviation from these standards could result in a stoppage of operations, recall of products, and a significant reduction in revenues. The Company outsources the manufacturing of the SYMJEPI product to third party manufacturers who bear the responsibility of maintaining a suitable environment as governed by specific regulatory and quality requirements.

The following table presents the Company's revenues disaggregated by outsourced manufacturing, sterile and non-sterile regulatory environments for the three months and six months ended June 30, 2020 and 2019.

	Three Months Ended June 30		Six Months Ended June 30	
	2020	2019	2020	2019
Drug Development & Commercialization:				
Outsourced Manufacturing	$ 721,435	$ 1,119,584	$ 1,228,719	$ 1,584,573
Compounded Pharmaceuticals:				
Sterile	$ 1,982,506	$ 3,324,679	$ 5,033,621	$ 6,498,814
Non-Sterile	1,222,401	1,320,636	2,327,212	2,587,284
Total Compounded Pharmaceuticals Revenues	$ 3,204,907	$ 4,645,315	$ 7,360,833	$ 9,086,098
Total	$ 3,926,342	$ 5,764,899	$ 8,589,552	$ 10,670,671

The Company's revenues relating to its FDA approved product SYMJEPI are dependent on an exclusive distribution agreement with USWM, replacing Sandoz in May, 2020 arising from the above-mentioned termination of the Sandoz Agreement, and the Company's pharmacy formulations rely, in large part, on sales generated from clinics and hospital customers. Adverse economic conditions pose a risk that the Company's customers may reduce or cancel spending, which would impact the Company's revenues. The COVID-19 outbreak has adversely affected revenues from sales of USC products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products, and will likely continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted.

The following table presents the Company's revenue disaggregated by end market for the three months and six months ended June 30, 2020 and 2019.

	Three Months Ended June 30		Six Months Ended June 30	
	2020	2019	2020	2019
Drug Development and Commercialization:				
Distribution Channel	$ 721,435	$ 1,119,584	$ 1,228,719	$ 1,584,573
Compounded Pharmaceuticals:				
Clinics/Hospitals	$ 3,013,030	$ 4,428,879	$ 6,940,458	$ 8,473,072
Direct to Patients	191,877	216,436	420,375	613,026
Total Compounded Pharmaceuticals Revenues	$ 3,204,907	$ 4,645,315	$ 7,360,833	$ 9,086,098
Total	$ 3,926,342	$ 5,764,899	$ 8,589,552	$ 10,670,671

Deferred Revenue

Deferred Revenue are contract liabilities that the Company records when cash payments are received or due in advance of the Company's satisfaction of performance obligations. The Company's performance obligation is met when control of the promised goods is transferred to the Company's customers. For the three months ended June 30, 2020 and 2019, $476,343 and $28,248 of the revenues recognized were reported as deferred revenue as of March 31, 2020 and 2019, respectively, and for the six months ended June 30, 2020 and 2019, $478,171 and $61,246 of the revenues recognized were reported as deferred revenue as of December 31, 2019 and 2018, respectively. Included in the deferred revenue balance at June 30, 2020 and December 31, 2019 was $437,500 and $900,000, respectively, relating to the non-refundable upfront payment received from Sandoz pursuant to the Sandoz Agreement between the Company and Sandoz; and another $1.0 million included in the deferred revenue balance at June 30, 2020 was for the non-refundable upfront payment received from USWM pursuant to the USWM Agreement. On May 11, 2020, the Company entered into a termination agreement with Sandoz which resulted in the acceleration of recognition of the upfront payment from Sandoz to revenue over the transition service agreement period.

Cost to Obtain a Contract

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

The Company capitalized the $2.0 million fee paid to a financial advisor as an incremental cost of obtaining a contract to commercialize and distribute the Company's first FDA approved product SYMJEPI with Sandoz. On May 11, 2020, the Company entered into a termination agreement with Sandoz. As a result of entering into the termination agreement, the Company determined that its financial results for the quarter ending June 30, 2020 include recognition of a full $1,750,000 impairment of the capitalized cost to obtain a contract that was reflected on its condensed consolidated balance sheet as of March 31, 2020. The deferred costs were classified as current or non-current in the Company's condensed consolidated balance sheets based on the timing of when the Company expects to recognize the expense. As of June 30, 2020 and December 31, 2019, the Company had $0 and $1.8 million, respectively, of Cost to Obtain a Contract deferred costs. Deferred costs related to obtaining a contract were amortized to Selling, General and Administrative expenses with $0 and $50,000 expensed for the three months ended June 30, 2020 and 2019, respectively; and $50,000 and $100,000 expensed for the six months ended June 30, 2020 and 2019, respectively.

Note 3: Inventories

Inventories at June 30, 2020 and December 31, 2019 consisted of the following:

	June 30, 2020	December 31, 2019
Finished Goods	$ 936,491	$ 1,167,913
WIP	191,734	230,781
Raw Materials	1,015,382	662,403
Inventories	$ 2,143,607	2,061,097

Reserve for obsolescence as of June 30, 2020 and December 31, 2019 was approximately $1,464,000 and $473,000, respectively.

Note 4: Fixed Assets, net

Fixed assets at June 30, 2020 and December 31, 2019 are summarized in the table below:

Description	Useful Life (Years)	June 30, 2020	December 31, 2019
Building	30	$ 3,040,000	$ 3,040,000
Machinery and Equipment	3 - 7	5,664,801	2,437,525
Furniture and Fixtures	7	160,012	156,259
Automobile	5	9,500	9,500
Leasehold Improvements	7 - 15	342,330	342,330
Total Fixed Assets		9,216,643	5,985,614
Less: Accumulated Depreciation		(2,821,707)	(2,050,697)
Land		460,000	460,000
Construction In Progress - Equipment		4,485,597	7,272,499
Fixed Assets, net		$ 11,340,533	$ 11,667,416

Depreciation expense for the three months ended June 30, 2020 and 2019 was approximately $396,000 and $145,000, respectively; and for the six months ended June 30, 2020 and 2019, depreciation expense was approximately $780,000 and $301,000, respectively.

Note 5: Intangible Assets and Goodwill

Intangible assets at June 30, 2020 and December 31, 2019 are summarized in the tables below:

June 30, 2020	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	$ (6,310,655)	$ 3,398,045
FDA 503B Registration & Compliance - USC, 10 years	3,963,000	(1,672,166)	2,290,834
Customer Relationships - USC, 10 years	5,572,000	(2,351,074)	3,220,926
Website Design - USC, 3 years	16,163	(16,163)	—
Total Definite-lived Assets	19,259,863	(10,350,058)	8,909,805
Trade Name and Brand - USC, Indefinite	1,245,000	—	1,245,000
SYMJEPI Domain Name	9,674	—	9,674
Balance, June 30, 2020	$ 20,514,537	$ (10,350,058)	$ 10,164,479

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

Amortization expense for the three months ended June 30, 2020 and 2019 was approximately $481,000 and $499,000, respectively; and for the six months ended June 30, 2020 and 2019, amortization expense was approximately $963,000 and $1,118,000, respectively.

Estimated amortization expense of definite-lived intangible assets at June 30, 2020 for each of the five succeeding years and thereafter is as follows:

Year ending December 31,	
Remainder of 2020	$ 962,185
2021	1,924,370
2022	1,924,370
2023	1,924,370
2024	953,500
Thereafter	1,221,010
Total	$ 8,909,805

We have two operating segments and two reporting units. During the three months ended March 31, 2020 the novel coronavirus disease 2019 (“COVID-19”) spread across the globe and adversely impacted economic growth, including as a result of government mandated shut-downs, stay-at-home policies and social distancing efforts intended to mitigate the spread of the virus. In light of the current economic downturn that we believe affected the trading prices of our Common Stock, we determined that it was more likely than not that the fair value of our reporting unit was less than its carrying value, which triggered the Company to perform an interim impairment assessment to test the carrying value of goodwill, related to the Compounded Pharmaceuticals reporting unit, as of March 31, 2020.

Our quantitative assessment utilized a market-based approach and assessed guideline publicly traded companies that are similar from an investment standpoint to the Company and operating in the drug manufacturing and compounding industry in the healthcare sector. We determined our fair value using the income approach which requires Management to estimate the future cash flows related to our reporting unit and includes a Company specific risk premium to account for the increased risk to future cash flows in the current environment. As a result of the analysis, the carrying value of our reporting unit exceeded the fair value by approximately $3,143,000, which was recorded as goodwill impairment expense as of March 31, 2020. These valuation approaches utilize a variety of company and market assumptions which may change in the future and could result in additional impairment.”

The carrying value of the Company's goodwill as of June 30, 2020 and December 31, 2019 was approximately $4,497,000 and $7,641,000, respectively.

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

Balance, December 31, 2019	$	7,640,622
Less: Impairment		(3,143,200)
Balance, June 30, 2020	$	4,497,422

Note 6: Leases

The Company has two operating leases, one for an office space and another for office space and a manufacturing facility; and two finance leases for office equipment and plant equipment. As of June 30, 2020, the leases have remaining terms between one year and less than four years. The operating leases do not include an option to extend beyond the life of the current term. There are no short-term leases, and the lease agreements do not require material variable lease payments, residual value guarantees or restrictive covenants.

The tables below present the operating and financing lease assets and liabilities recognized on the condensed consolidated balance sheets as of June 30, 2020 and December 31, 2019:

Right-of Use Assets	June 30, 2020	December 31, 2019
Operating Leases	$ 1,646,370	$ 1,867,205
Financing Leases	4,107	6,347
	$ 1,650,477	$ 1,873,552

Lease Liabilities, Current	June 30, 2020	December 31, 2019
Operating Leases	$ 455,402	$ 440,127
Financing Leases	3,808	4,494
	$ 459,210	$ 444,621
Lease Liabilities, Non-Current		
Operating Leases	$ 1,246,722	$ 1,479,458
Financing Leases	-	1,538
	$ 1,246,722	$ 1,480,996
Total Lease Liabilities	1,705,932	1,925,617

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

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

The Company's weighted average remaining lease term and weighted average discount rate for operating and financing leases as of June 30, 2020 and December 31, 2019 are:

June 30, 2020	**Operating**	**Financing**
Weighted Average Remaining Lease Term	3.46 Years	0.92 Year
Weighted Average Discount Rate	3.95%	3.95%

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

The table below reconciles the undiscounted future minimum lease payments (displayed by year and in the aggregate) under non-cancelable leases with terms of more than one year to the total lease liabilities recognized on the unaudited condensed consolidated balance sheets as of June 30, 2020:

Year Ending December 31,	**Operating**	**Financing**
Remainder of 2020	$ 254,464	$ 2,326
2021	520,993	1,550
2022	534,295	-
2023	515,257	-
Undiscounted Future Minimum Lease Payments	1,825,009	3,876
Less: Difference between undiscounted lease payments and discounted lease liabilities	122,885	68
Total Lease Liabilities	$ 1,702,124	$ 3,808
Short-Term Lease Liabilities	$ 455,402	$ 3,808
Long-Term Lease Liabilities	$ 1,246,722	$ -

Operating lease expense for the three months ended June 30, 2020 and 2019 was approximately $128,000 and $128,000, respectively; and for the six months ended June 30, 2020 and 2019, operating lease expense was approximately $257,000 and $257,000, respectively. Operating lease costs are included within selling, general and administrative expenses on the condensed consolidated statements of operations.

Amortization expense related to our financing leases for the three months ended June 30, 2020 and 2019 was approximately $1,000 and $18,000, respectively; and for the six months ended June 30, 2020 and 2019, amortization expense related to our financing leases was approximately $2,000 and $34,000, respectively, in amortization. Interest expense related to the financing leases for the three months ended June 30, 2020 and 2019 was approximately $45 and $400, respectively; and for the six months ended June 30, 2020 and 2019, interest lease expense related to financing leases was approximately $100 and $1,000, respectively. Financing lease costs are included within selling, general and administrative expenses on the condensed consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities were approximately $127,000 and $130,000 for the three months ended June 30, 2020 and 2019, respectively; and $254,000 and $260,000 for the six months ended June 30, 2020 and 2019, respectively. Cash paid for amounts included in the measurement of financing lease liabilities were approximately $1,000 and $19,000 for the three months ended June 30, 2020 and 2019, respectively; and $2,000 and $37,000 for the six months ended June 30, 2020 and 2019, respectively.

Note 7: Debt

Ben Franklin Note

Biosyn, Inc., a wholly owned subsidiary of the Company, issued a note payable to Ben Franklin Technology Center of Southeastern Pennsylvania (“Ben Franklin Note”) in October 1992, in connection with funding the development of Savvy, a compound then under development to prevent the transmission of HIV/AIDS. The Ben Franklin Note was recorded at its estimated fair value of $205,000 and was assumed by the Company as an obligation in connection with its acquisition of Biosyn in 2004. The repayment terms of the non-interest bearing obligation include the remittance of an annual fixed percentage of 3.0% applied to future revenues of Biosyn, if any, until the principal balance of $777,902 (face amount) is satisfied. Under the terms of the obligation, revenues are defined to exclude the value of unrestricted research and development funding received by Biosyn from nonprofit sources. Absent a material breach of contract or other event of default, there is no obligation to repay the amounts in the absence of future Biosyn revenues. The Company accreted the discount of $572,902 against earnings using the interest rate method (approximately 46%) over the discount period of five years, which was estimated in connection with the Ben Franklin Note’s valuation at the time of the acquisition. Accounting principles generally accepted in the United States emphasize market-based measurement through the use of valuation techniques that maximize the use of observable or market-based inputs. The Ben Franklin Note’s peculiar repayment terms outlined above affects its comparability with main stream market issues and also affects its transferability. The value of the Ben Franklin Note would also be impacted by the ability to estimate Biosyn’s expected future revenues which in turn hinge largely upon future efforts to commercialize the product candidate, the results of which efforts are not known by the Company. Given the above factors and therefore the lack of market comparability, the Ben Franklin Note would be valued based on Level 3 inputs (see Note 13 to our consolidated financial statements in the 2019 Annual Report on Form 10-K). As such, management has determined that the Ben Franklin Note will have no future cash flows, as we do not believe the product will create a revenue stream in the future. As a result, the Ben Franklin Note had no fair market value at the time of the merger in April 2009 between the Company (which was then named Cellegy Pharmaceuticals, Inc.) and the corporation then-named Adamis Pharmaceuticals Corporation.

Building Loan

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

On November 10, 2016, a Loan Amendment and Assumption Agreement was entered with into the Bank. Pursuant to the agreement, as subsequently amended, the Company agreed to pay the Bank monthly payments of principal and interest which currently are approximately $23,000 per month, with a final payment due and payable in August 2020.

As of June 30, 2020 and December 31, 2019, the outstanding principal balance owed on the applicable note was approximately $2,102,000 and $2,153,000, respectively. The loan currently bears an interest of 6.00% per year.

Paycheck Protection Program Loan

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

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

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, the Company may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by the Company during the eight-week period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 60% of the loan amount is used for eligible payroll costs; the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week or 24-week period will qualify for forgiveness. No assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part. After the Company received funds pursuant to the PPP Loan, the Secretary of the Treasury and SBA issued guidance that the government will review all PPP loans of more than $2 million for which the borrower applies for forgiveness, and that all PPP loans in excess of $2 million, and other PPP loans as appropriate, will be subject to review by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form. Accordingly, the Company may be audited or reviewed by federal or state regulatory authorities as a result of filing an application for forgiveness of the PPP Loan or otherwise.

The Note may be prepaid in part or in full, at any time, without penalty. The Company may prepay 20% or less of the unpaid principal balance of the Note at any time without notice, and may prepay more than 20% of the unpaid principal balance of the Note subject to certain conditions. If any payment on the Note is more than 15 days late, the Bank may charge the Company a late fee of up to 5% of the unpaid portion of the regularly scheduled payment. The Note provides for certain customary events of default, including (i) failing to make a payment when due under the Note, (ii) failure to do anything required by the Note or any other loan document, (iii) defaults of any other loan with the Bank, (iv) failure to disclose any material fact or make a materially false or misleading representation to the Bank or SBA, (v) default on any loan or agreement with another creditor, if the Bank believes the default may materially affect the Company's ability to pay the Note, (vi) failure to pay any taxes when due, (vii) becoming the subject of a proceeding under any bankruptcy or insolvency law, having a receiver or liquidator appointed for any part of the Company's business or property, or making an assignment for the benefit of creditors, (viii) having any adverse change in financial condition or business operation that the Bank believes may materially affect the Company's ability to pay the Note, (ix) if the Company reorganizes, merges, consolidates, or otherwise changes ownership or business structure without the Bank's prior written consent, or (x) becoming the subject of a civil or criminal action that the Bank believes may materially affect the Company's ability to pay the Note. Upon the occurrence of an event of default, the Bank has customary remedies and may, among other things, require immediate payment of all amounts owed under the Note, collect all amounts owing from the Company, and file suit and obtain judgment against the Company.

As of June 30, 2020, the outstanding unpaid principal balance was $3,191,700.

At June 30, 2020, the outstanding principal maturities of the amended long-term debts were as follows:

Years ending December 31,	**Building Loan**	**PPP Loan**	**Total**
Remainder of 2020	$ 2,102,126	$ 176,080	$ 2,278,206
2021	—	2,124,173	2,124,173
2022	—	891,447	891,447
	$ 2,102,126	$ 3,191,700	$ 5,293,826
Short-Term Loans	$ 2,102,126	$ 1,235,506	$ 3,337,632
Long-Term Loans	$ —	$ 1,956,194	$ 1,956,194

Note 8. Fair Value of Financial Instruments

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

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

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

- Level I — Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level II — Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level III — Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

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

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

	Fair Value Measurements at December 31, 2019			
	Total	Level 1	Level 2	Level 3
Liabilities				
2019 Warrant liability	$ 276,000	$ —	$ —	$ 276,000
Total common stock warrant liability	$ 276,000	$ —	$ —	$ 276,000

	Fair Value Measurements at June 30, 2020			
	Total	Level 1	Level 2	Level 3
Liabilities				
2019 Warrant liability	$ 276,000	$ —	$ —	$ 276,000
2020 Warrant liability	261,000	—	—	261,000
Total common stock warrant liability	$ 537,000	$ —	$ —	$ 537,000

The fair value measurement of the 2019 and 2020 Warrants are based on significant inputs that are unobservable and thus represents a Level 3 measurement. The Company's estimated fair value of the Warrant liability is calculated using the Binomial Option Pricing Model. Key assumptions include the volatility of the Company's stock of approximately 41%, the Company's stock price at valuation date of $0.54, expected dividend yield of 0.0% and weighted average risk-free interest rate of approximately 0.26%. The Level 3 estimates are based, in part, on subjective assumptions. During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs.

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

	2019 Warrant		2020 Warrant	
	Number of Warrants	Liability (in thousands)	Number of Warrants	Liability (in thousands)
Balance at December 31, 2019	13,800,000	$ 276,000	—	$ —
2020 Warrant Liability	—	—	8,700,000	261,000
Balance at June 30, 2020	13,800,000	$ 276,000	8,700,000	$ 261,000

Note 9: Commitments and Contingencies

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

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

Fact discovery closed on March 2, 2020. Expert discovery, including regarding the alleged damages that Nephron seeks against Adamis and USC, occurred during the second quarter of 2020 and is scheduled to close near the end of August 2020. On May 6, 2020, Adamis and USC moved for summary judgment to dismiss the three claims that remain pending against them. The case is currently set for trial in January 2021. Adamis believes that Nephron’s claims are without merit and is vigorously defending against the allegations.

Note 10: Convertible Preferred Stock

June 2020 Series B Preferred Stock

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

As of June 30, 2020, the Capital Event has not occurred and the 1,000,000 shares Series B Preferred remain outstanding.

Note 11: Common Stock

On February 25, 2020, the Company completed a registered direct offering of 11,600,000 shares of common stock, pursuant to its existing shelf registration statement and a prospectus supplement and accompanying prospectus, and a concurrent private placement of warrants to purchase 8,700,000 shares of common stock, to a small number of investors. The combined purchase price for one share and 0.75 warrant was $0.58, and the aggregate gross proceeds was $6,700,000, excluding any future proceeds from the potential exercise of the warrants and before deducting placement agent fees and other offering expenses of approximately $467,000 payable by the Company. The warrants have an exercise price of $0.70 per share. The warrants are exercisable commencing on the later of (i) six months from the date of issuance or (ii) the date that the Company's stockholders approve a reverse stock split or an increase in the number of authorized shares of Common Stock of the Company in an amount sufficient to permit the exercise in full of all of the Warrants, and will expire five years after they become exercisable. The placement agent in connection with the offering and received a fee equal to 6.0% of the gross proceeds of the securities sold in the offering and reimbursement of certain out-of-pocket expenses.

Note 12: Stock-based Compensation, Warrants and Shares Reserved

Stock Options

The following summarizes the stock option activity for the six months ended June 30, 2020 below:

	2009 Equity Incentive Plan	Weighted Average Exercise Price	Weighted Average Remaining Contract Life
Total Outstanding Vested and Expected to Vest as of December 31, 2019	7,837,245	$ 4.40	6.01 years
Options Cancelled/Expired	(598,484)	5.09	—
Total Outstanding Vested and Expected to Vest as of June 30, 2020	7,238,761	$ 4.35	5.66 years
Vested at June 30, 2020	6,808,546	$ 4.43	5.53 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 7,238,761 and 7,837,245 stock options outstanding at June 30, 2020 and December 31, 2019 was $0, respectively. The aggregate intrinsic value of 6,808,546 and 6,917,685 stock options exercisable at June 30, 2020 and December 31, 2019 was $0, respectively.

Expense related to stock options for the three months ended June 30, 2020 and 2019 was approximately $292,000 and $883,000, respectively; and for the six months ended June 30, 2020 and 2019, expense related to stock options was approximately $722,000 and $2,059,000, respectively. As of June 30, 2020, the unamortized compensation expense related to stock options was approximately $674,000. The weighted-average period in years over which the remaining unamortized expense will be recognized is 0.65 years.

The following table summarizes the RSUs outstanding at June 30, 2020 and December 31, 2019:

June 30, 2020	RSU Shares	Price Per Share at Grant Date	Date of Grant
Non-Employee Board of Directors	150,000(1)	$ 8.46	May 25, 2016
Company Executives	950,000(1)	$ 3.50	March 1, 2017
Company Executives	114,071(2)	$ 2.83	February 21, 2018
Company Executives and Employees	1,320,036(3)	$ 3.09	January 30, 2019
Total RSUs	2,534,107		

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

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

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

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

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

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

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

Expense related to RSUs for the three months ended June 30, 2020 and 2019 was approximately $823,000 and $882,000, respectively; and for the six months ended June 30, 2020 and 2019, expense related to RSUs was approximately $1,612,000 and $1,684,000, respectively. As of June 30, 2020, the unamortized compensation expense related to RSUs options was approximately $6,276,000. The weighted-average period in years over which the remaining unamortized expense will be recognized is 2.32 years.

The following summarizes warrants outstanding at June 30, 2020 and December 31, 2019:

June 30, 2020	Warrant Shares		Exercise Price Per Share	Date Issued	Expiration Date
Old Adamis Warrants	58,824	$	8.50	November 15, 2007	November 15, 2021
Preferred Stock Series A-1 Warrants	1,183,432	$	4.10	January 26, 2016	January 26, 2021
Preferred Stock Series A-2 Warrants	192,414	$	2.90	July 11, 2016	July 11, 2021
2016 Common Stock, Private Placement	700,000	$	2.98	August 3, 2016	August 3, 2021
2019 Warrants	13,800,000**	$	1.15	August 5, 2019	August 5, 2024
2020 Warrants	8,700,000***	$	0.70	February 25, 2020	*
Total Warrants	24,634,670				

* These warrants will be exercisable commencing on the later of (i) six months from date of issuance or (ii) the date that the company's stockholders approve a reverse stock split or an increase in the number of authorized shares of common stock of the company in an amount sufficient to permit the exercise in full of all of the 2020 warrants, and will expire on the five year anniversary of the date on which they are first exercisable.

** As of June 30, 2020, the fair value of the warrant liability related to the 2019 Warrants was $276,000. See Note 1.

*** As of June 30, 2020, the fair value of the warrant liability related to the 2020 Warrants was $261,000. See Note 1.

December 31, 2019	Warrant Shares		Exercise Price Per Share	Date Issued	Expiration Date
Old Adamis Warrants	58,824	$	8.50	November 15, 2007	November 15, 2021
Preferred Stock Series A-1 Warrants	1,183,432	$	4.10	January 26, 2016	January 26, 2021
Preferred Stock Series A-2 Warrants	192,414	$	2.90	July 11, 2016	July 11, 2021
2016 Common Stock, Private Placement	700,000	$	2.98	August 3, 2016	August 3, 2021
2019 Warrants	13,800,000*	$	1.15	August 5, 2019	August 5, 2024
Total Warrants	15,934,670				

* As of December 31, 2019, the fair value of the warrant liability related to the 2019 Warrants was $276,000. See Note 1.

At June 30, 2020, the Company has reserved shares of common stock for issuance upon exercise of outstanding options including options granted under the 2009 Equity Incentive Plan, and warrants, and upon conversion of outstanding shares of convertible preferred stock, as follows:

Warrants	15,934,670(1)
Restricted Stock Units (RSU)	2,534,107
2009 Equity Incentive Plan	7,238,761
Total Shares Reserved	25,707,538(2)

(1) Excluding 8,700,000 warrants issued in February 2020 that have an exercise contingency; these warrants will be exercisable commencing on the later of (i) six months from date of issuance or (ii) the date that the company's stockholders approve a reverse stock split or an increase in the number of authorized shares of common stock of the company in an amount sufficient to permit the exercise in full of all of the February 2020 warrants.

(2) Excludes 1,000,000 shares of Common Stock that are issuable upon conversion of 1,000,000 outstanding shares of Series B Preferred that are not convertible into Common Stock at June 30, 2020, but which are convertible into Common Stock upon and following the occurrence of certain future events.

Note 13: Segment Information

Commencing April 1, 2020, the Company transitioned reporting from one reportable segment to two reportable segments. In accordance with ASC 280, the Company's businesses are based on the organizational structure used by the chief operating decision maker ("CODM") for making operating and investment decisions and for assessing performance. The CODM views the Company as operating in two business segments: Drug Development and Commercialization, which includes out-licensing of the Company's FDA approved products; and the Compounded Pharmaceuticals business. The Company's CODM is the Chief Executive Officer ("CEO"). While the CEO is apprised of a variety of financial metrics and information, the business is principally managed and organized based upon business units. Each segment is separately managed and is evaluated primarily upon segment net income (loss). The Company does not report balance sheet information by segment because the Company's CODM does not review that information. The revenues of the Drug Development and Commercialization segment for the three months ended and six months ended June 30, 2020 and 2019 were all from the Sandoz distribution channel.

The following tables present a summary of the Company's reporting segments for the three months and six months ended June 30, 2020 and 2019, respectively (unaudited):

	Three Months ended June 30, 2020			Three Months ended June 30, 2019		
	Drug Development and Commercialization (Unaudited)	Compounded Pharmaceuticals (Unaudited)	Consolidated (Unaudited)	Drug Development and Commercialization (Unaudited)	Compounded Pharmaceuticals (Unaudited)	Consolidated (Unaudited)
REVENUE, net	$ 721,435	$ 3,204,907	$ 3,926,342	$ 1,119,584	$ 4,645,315	$ 5,764,899
COST OF GOODS SOLD	1,840,402	2,843,433	4,683,835	1,141,028	2,524,537	3,665,565
Gross Profit	(1,118,967)	361,474	(757,493)	(21,444)	2,120,778	2,099,334
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	3,008,585	2,644,507	5,653,092	3,443,436	3,556,903	7,000,339
RESEARCH AND DEVELOPMENT	2,926,108	159,716	3,085,824	2,793,266	52,479	2,845,745
Impairment Expense - Contract Costs	1,750,000	—	1,750,000	—	—	—
Loss from Operations	$ (8,803,660)	$ (2,442,749)	$ (11,246,409)	$ (6,258,146)	$ (1,488,604)	$ (7,746,750)
OTHER INCOME (EXPENSE)						
Interest Expense	(1,490)	(31,435)	(32,925)	—	(22,954)	(22,954)
Interest Income	9,602	7,019	16,621	33,117	1,000	34,117
Total Other Income (Expense)	8,112	(24,416)	(16,304)	33,117	(21,954)	11,163
Net (Loss) Before Income Taxes	$ (8,795,548)	$ (2,467,165)	$ (11,262,713)	$ (6,225,029)	$ (1,510,558)	$ (7,735,587)

	Six Months ended June 30, 2020			Six Months ended June 30, 2019		
	Drug Development and Commercialization (Unaudited)	Compounded Pharmaceuticals (Unaudited)	Consolidated (Unaudited)	Drug Development and Commercialization (Unaudited)	Compounded Pharmaceuticals (Unaudited)	Consolidated (Unaudited)
REVENUE, net	$ 1,228,719	$ 7,360,833	$ 8,589,552	$ 1,584,573	$ 9,086,098	$ 10,670,671
COST OF GOODS SOLD	3,573,185	4,797,694	8,370,879	1,529,401	5,761,632	7,291,033
Gross Profit	(2,344,466)	2,563,139	218,673	55,172	3,324,466	3,379,638
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	6,311,817	5,395,646	11,707,463	7,255,856	7,765,947	15,021,803
RESEARCH AND DEVELOPMENT	4,962,840	159,716	5,122,556	4,989,781	52,479	5,042,260
Impairment Expense - Goodwill	—	3,143,200	3,143,200	—	—	—
Impairment Expense - Contract Costs	1,750,000	—	1,750,000	—	—	—
Loss from Operations	$ (15,369,123)	$ (6,135,423)	$ (21,504,546)	$ (12,190,465)	$ (4,493,960)	$ (16,684,425)
OTHER INCOME (EXPENSE)						
Interest Expense	(1,490)	(69,722)	(71,212)	—	(46,962)	(46,962)
Interest Income	32,657	7,019	39,676	107,495	1,000	108,495
Total Other Income (Expense)	31,167	(62,703)	(31,536)	107,495	(45,962)	61,533
Net (Loss) Before Income Taxes	$ (15,337,956)	$ (6,198,126)	$ (21,536,082)	$ (12,082,970)	$ (4,539,922)	$ (16,622,892)

The CODM is provided certain segment Cash Flow Information in connection with operating and investment decisions regularly. Accordingly, the following segment information is presented for Drug Development and Commercialization; and Compounded Pharmaceuticals.

	Three Months Ended June 30,	
	2020	2019
Capital expenditures:		
Drug Development and Commercialization	$ 260,427	$ 140,179
Compounded Pharmaceuticals	40,807	218,523
Total capital expenditures	$ 301,234	$ 358,702

	Six Months Ended June 30,	
	2020	2019
Capital expenditures:		
Drug Development and Commercialization	$ 319,513	$ 246,420
Compounded Pharmaceuticals	133,587	1,688,313
Total capital expenditures	$ 453,100	$ 1,934,733

	Three Months Ended June 30,	
	2020	2019
Depreciation and amortization:		
Drug Development and Commercialization	$ 565,882	$ 354,184
Compounded Pharmaceuticals	312,223	357,544
Total depreciation and amortization	$ 878,105	$ 711,728

	Six Months Ended June 30,	
	2020	2019
Depreciation and amortization:		
Drug Development and Commercialization	$ 1,171,452	$ 703,307
Compounded Pharmaceuticals	623,853	850,361
Total depreciation and amortization	$ 1,795,305	$ 1,553,668

Note 14: Subsequent Events

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

In connection with the building loan described in Note 7, on August 12, 2020, the Bank indicated to the Company that it has approved an extension of the loan’s maturity date to August 8, 2021. The Company expects to enter into an amendment to the loan documents with the Bank.

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

Information Relating to Forward-Looking Statements

This Quarterly Report on Form 10-Q (this "Report") includes forward-looking statements. Such statements are not historical facts, but are based on our current expectations, estimates and beliefs about our business and industry. Such forward-looking statements may include, without limitation, statements about our strategies, objectives and our future achievements; our expectations for growth; estimates of future revenue; our sources and uses of cash; our liquidity needs; our current or planned clinical trials or research and development activities; anticipated completion dates for clinical trials; product development timelines; anticipated dates for commercial introduction of products; our future products; regulatory matters; our expectations concerning the timing of regulatory approvals; anticipated dates for meetings with regulatory authorities and submissions to obtain required regulatory marketing approvals; expense, profit, cash flow, or balance sheet items or any other guidance regarding future periods; and other statements concerning our future operations and activities. Such forward-looking statements include those that express plans, anticipation, intent, contingencies, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events, and they are subject to risks and uncertainties, known and unknown, that could cause actual results and developments to differ materially from those expressed or implied in such statements. In some cases, you can identify forward-looking statements by terminology, such as "believe," "will," "expect," "may," "anticipate," "estimate," "intend," "plan," "should," and "would," or the negative of such terms or other similar expressions. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this Report. These forward-looking statements are not guarantees of future performance and concern matters that could subsequently differ materially from those described in the forward-looking statements. Actual events or results may differ materially from those discussed in this Report. In addition, many forward-looking statements concerning our anticipated future business activities assume that we are able to obtain sufficient funding in the near term and thereafter to support such activities and continue our operations and planned activities. As discussed elsewhere in this Report, we may require additional funding during 2020 to continue operations, and there are no assurances that such funding will be available. Failure to timely obtain required funding would adversely affect and could delay or prevent our ability to realize the results contemplated by such forward-looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Because factors referred to elsewhere in this Report and in our Annual Report on Form 10-K for the year ended December 31, 2019 (sometimes referred to as the "2019 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 2019 Form 10-K, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and except as may be required by applicable law, we undertake no obligation to release publicly the results of any revisions to these forward-looking statements or to reflect events or circumstances arising after the date of this Report. Important risks and factors that could cause actual results to differ materially from those in these forward-looking statements are disclosed in this Report including, without limitation, under the headings "Part II, Item 1A. Risk Factors," and "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our 2019 Form 10-K, including, without limitation, under the headings "Part I, Item 1A. Risk Factors," "Part I, Item 1. Business," and "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as in our subsequent filings with the Securities and Exchange Commission, press releases and other communications.

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

General

Company Overview

We are a specialty biopharmaceutical company focused on developing and commercializing products in various therapeutic areas, including respiratory disease, allergy and opioid overdose. Our products and product candidates in the allergy, respiratory, and opioid overdose markets include: SYMJEPI (epinephrine) Injection 0.3mg, which was approved by the U.S. Food and Drug Administration, or FDA, in 2017 for use in the emergency treatment of acute allergic reactions, including anaphylaxis, for patients weighing 66 pounds or more; SYMJEPI (epinephrine) Injection 0.15mg which was approved by the FDA in September 2018, for use in the treatment of anaphylaxis for patients weighing 33-65 pounds; a naloxone injection product candidate ("ZIMHI") based on the approved Symject™ injection device and intended for the treatment of opioid overdose for which the company submitted a New Drug Application, or NDA, in December 2018 and with respect to which the company received a Complete Response Letter, or CRL, from the FDA in November 2019 and responded to the CRL and resubmitted its NDA to the FDA in May 2020; a Beclomethasone metered dose inhaler product candidate (APC-1000) intended for the treatment of asthma for which the company submitted an Investigational New Drug application, or IND, in January 2018 and has initiated the start-up phase of Phase 3 studies which has been suspended; and a fluticasone (APC-4000) dry powder inhaler, or DPI, product candidate for the treatment of asthma. In June 2020, we entered into a license agreement with a third party to license rights under patents, patent applications and related know-how relating to Tempol, an investigational drug. The exclusive license includes the worldwide use under the licensed patent rights and related rights for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection, as well as the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. Our goal is to create low cost therapeutic alternatives to existing treatments. Consistent across all specialty pharmaceuticals product lines, we intend to submit NDAs under Section 505(b)(2), of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, or Section 505(j) Abbreviated New Drug Applications, or ANDAs, to the FDA, whenever possible, in order to potentially reduce the time to market and to save on costs, compared to those associated with Section 505(b)(1) NDAs for new drug products.

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

Commencing April 1, 2020, we transitioned from one segment to two segments. From April 2020, we will manage our operations through two businesses: Drug Development and Commercialization, which includes the out-licensing the Company's FDA approved products and the Compounded Pharmaceuticals. Information regarding revenue and operating income attributable to each of our businesses is included within Note 13 - Segment Information of the Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q.

SYMJEPI (epinephrine) Injection

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

On September 27, 2018, FDA approved our lower dose SYMJEPI (epinephrine) Injection 0.15mg, for the emergency treatment of allergic reactions (Type I) including anaphylaxis in patients weighing 33 to 65 pounds.

Our SYMJEPI (epinephrine) Injection 0.15mg and 0.3mg products allow users to administer a pre-measured epinephrine dose quickly with a device that we believe, based on human factors studies, to be intuitive to use. If the person using the auto-injector is not familiar with the function of the device and if not administered properly, there is a risk that it could misfire or be misused.

In July 2018, we entered into a Distribution and Commercialization Agreement with Sandoz Inc. (the "Sandoz Agreement") to commercialize both of our SYMJEPI products. Under the terms of the agreement, we appointed Sandoz as the exclusive distributor of SYMJEPI in the United States and related territories, or the Sandoz 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 Sandoz Territory, subject to the provisions of the agreement, in partial consideration of an upfront fee by Sandoz and potential performance-based milestone payments. In January 2019, we announced that Sandoz had launched SYMJEPI (epinephrine) 0.3 mg Injection in the U.S. market, initially available in the institutional setting. On July 9, 2019, we announced the full launch (institutional and retail) by Sandoz of both dose forms of the SYMJEPI injection products. See Note 2 to the unaudited condensed consolidated financial statements for further information about the agreement.

On May 11, 2020, we announced that we entered into an agreement (the "Termination Agreement") with Sandoz Inc. to terminate the Sandoz Agreement following an ignition transition period that ended as a result of the execution of a transition services agreement. The Termination Agreement provides for the mutually agreed return to Adamis of the marketing, promotion, and distribution rights, and certain marketing and promotional materials, relating to the SYMJEPI products, and the termination of the Sandoz Agreement, supported by a transition services agreement that we entered into with Sandoz and USWM, LLC concerning certain transition services, activities and arrangements relating to the SYMJEPI products. As part of the Termination Agreement, Sandoz will continue to support the products in the U.S. under the Sandoz Agreement through the end of the transition period to help reduce or minimize potential impacts to patients and customers. The Termination Agreement also provides for a future resolution of any amounts that may be payable or owed with respect to the net sales and profit sharing provisions of the Sandoz Agreement, and for survival of certain provisions of the Sandoz Agreement.

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

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

The USWM Agreement provides that, subject to certain adjustments, USWM will pay to us 50% of the net profit from net sales, as each such term is defined in the USWM Agreement, of the product in the Territory to third parties, determined on a quarterly basis. We will be the supplier of the products to USWM, and USWM will order and pay us a supply price for quantities of products ordered.

ZIMHI (naloxone) Injection

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

On December 31, 2018, we filed an NDA with the FDA relating to our higher dose naloxone injection product, ZIMHI, for the treatment of opioid overdose. On November 22, 2019, we received a Complete Response Letter, or CRL, from the FDA regarding our NDA for ZIMHI. The CRL stated that the FDA determined that it could not approve the NDA in its present form and provided recommendations needed for resubmission. A CRL is issued by the FDA's Center for Drug Evaluation and Research when it has completed its review of a file and questions remain that preclude the approval of the NDA in its current form. The questions raised by the FDA related generally to Chemistry, Manufacturing and Controls (CMC). No other clinical safety or efficacy issues were raised. In December 2019, we provided responses to the FDA to the comments included in the CRL. In February 2020, we had a Type A meeting with the FDA to discuss the company's response to the CRL and the process and timeline for resubmission of the NDA to the FDA. At the meeting, the company obtained concurrence from the agency on the Chemistry, Manufacturing and Controls, or CMC, information required for resubmission of the NDA, including additional information involving extractables and leachables testing from the syringe and glassware. On May 15, 2020, the company resubmitted to the FDA the NDA for ZIMHI. The resubmitted NDA was intended to address the issues raised by the FDA in the CRL. The FDA has indicated that it considers the company's resubmitted NDA as a complete, class 2 response to the CRL and has provided a user fee goal date under the Prescription Drug User Fee Act, or PDUFA, for a response by the FDA by November 15, 2020. However, the FDA's review processes can extend beyond, and in some cases significantly beyond, anticipated completion dates due to the timing of the FDA's review process, FDA requests for additional data, information, materials or clarification, difficulties scheduling an advisory committee meeting, FDA workload issues, extensions resulting from the submission of additional information or clarification regarding information already in the submission within the last three months of the target PDUFA date, or other reasons. As a result, the dates FDA review and action regarding our resubmitted NDA for ZIMHI or any other NDA that we may resubmit, or of regulatory approval, if obtained, and commercial introduction of our products could be delayed beyond our expectations. The development of an intramuscular injection of naloxone for the treatment of opioid overdose will require commercial scale manufacturing subject to review and approval by the FDA.

On May 11, 2020, we entered into an exclusive distribution and commercialization agreement with USWM for the United States commercial rights for the SYMJEPI products, as well as for the company's ZIMHI product candidate.

Tempol (APC400)

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

Tempol is a redox cycling nitroxide that promotes the metabolism of many reactive oxygen species, or ROS, and improves nitric oxide bioavailability. It has been studied extensively in animal models of oxidative stress and inflammation. Overall, Tempol acts as both a super-oxide dismutase mimetic and also has anti-inflammatory activity. Inflammation and oxidative stress occur in various disease states including COVID-19. In July 2020, we submitted to the FDA a pre-IND package which provided a detailed protocol for a Phase II study examining Tempol in COVID-19 patients, and the FDA has provided comments regarding the prospective use of Tempol in a randomized placebo controlled trial. Adamis intends to proceed to the next step of preparing and submitting an IND to the FDA for Tempol, and to apply for funding pursuant to certain government programs to enable and support the necessary trials to determine the efficacy of Tempol as a therapeutic treatment for COVID-19.

Asthma; APC-1000 Metered Dose Inhaler

Our APC-1000 product candidate is a steroid hydrofluoroalkane, or HFA, metered dose inhaler product, intended for the treatment of asthma. Our product candidate, if developed and approved for marketing, will target a small niche within the larger market for respiratory products. We estimate that the annual global sales of prescription steroid HFA and similar products were approximately $3.0 billion in 2019, of which we intend to target a subset of that market.

In January 2018, we submitted an IND application to the FDA to begin Phase 3 efficacy studies for a new formulation of APC-1000. We received approval from the agency to proceed with the Phase 3 studies, and in December 2018, we initiated the start-up phase of the phase 3 studies of APC-1000. However, we have delayed the continuation of the start-up phase and start of patient enrollment for the studies, and have suspended the study, and have suspended the studies, in light of, among other factors, the availability of adequate funding to continue and complete the studies. The timing of enrollment for, and the pace of conduct, progress, and completion of, such studies, and our decisions concerning such matters, are affected by a number of factors, including without limitation the availability of adequate funding, the absence of unexpected regulatory issues or delays, the time period required to enroll a sufficient number of patients in the study, and the time required to complete and analyze the results of the studies. As discussed elsewhere in this Report, we will require additional funding in 2020 to continue all of our anticipated product development activities, and product development times are subject to a number of risks and uncertainties, which can delay the actual development time beyond our estimates.

Asthma; Fluticasone

Our first product candidate utilizing the DPI technology platform, APC-4000, will deliver Fluticasone Propionate (fluticasone) as a dry powder formulation for the treatment of asthma. Fluticasone belongs to the family of medicines known as corticosteroids or steroids. It works by preventing certain cells in the lungs and breathing passages from releasing substances that cause asthma symptoms. APC-4000 is designed to deliver the same active ingredient as GlaxoSmithKline's Flovent® Diskus® for the treatment of asthma. We estimate that Flovent® Diskus® generated more than $469 million in U.S. sales and $802 million in global sales in 2019, based on GSK's publicly announced results. We conducted proof of concept studies with the DPI for APC-4000 in 2018 and 2019. In considering development and commercialization alternatives for APC-4000, we may seek to enter into development or commercialization agreements, license agreements, or other strategic agreements with third parties relating to development, commercialization and marketing of this product candidate.

Going Concern and Management's Plan

The financial statements included elsewhere herein for the three and six months ended June 30, 2020, and our financial statements for the year ended December 31, 2019 and 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. However, as of June 30, 2020, we had cash and cash equivalents of approximately $7.9 million, an accumulated deficit of approximately $203.9 million, and liabilities of approximately $16.6 million. We have incurred substantial recurring losses from operations, have used, rather than provided, cash in our continuing operations, and are dependent on additional financing to fund operations. These conditions raise substantial doubt about our ability to continue as a going concern. The financial statements included elsewhere herein do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. In February 2020, we completed a registered direct offering of common stock, and a concurrent private placement of warrants, resulting in estimated net proceeds of approximately $6.2 million. In April 2020, we secured an approximately $3.2 million Paycheck Protection Program, or PPP, loan provided for by the Coronavirus Aid, Relief and Economic Security Act and administered by the U.S. Small Business Administration, or SBA. However, we anticipate that we will need additional funding before the end of fiscal 2020 to continue operations, satisfy our obligations, fund the future expenditures that we believe will be required to support commercialization of our products and conduct the clinical and regulatory work to develop our product candidates.

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 six months ended June 30, 2020, were prepared under the assumption that we would continue our operations as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. 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. Without additional funds in 2020 from debt or equity financing, sales of assets, sales or out-licenses of intellectual property, products, product candidates or technologies, or from a business combination or a similar transaction, after expenditure of our existing cash resources and revenues from existing agreements and sales of prescription compounded formulations, we would exhaust our resources and be unable to continue operations.

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

Results of Operations

Three Months Ended June 30, 2020 and 2019

Revenues. Consolidated revenues were approximately $3,926,000 and $5,765,000 for the three months ended June 30, 2020 and 2019, respectively. Consolidated revenues decreased approximately $1,839,000 in the second quarter of 2020 compared to the comparable period of 2019.

Revenues of our Drug Development and Commercialization business conducted by Adamis were approximately $721,000 and $1,120,000 for the three months ended June 30, 2020 and 2019, respectively. Revenue relating to the sales of SYMJEPI (epinephrine) Injection .3mg and .15mg decreased approximately $399,000 primarily due to matters relating to the transition of commercialization and marketing rights to the SYMJEPI products from Sandoz to USWM.

Revenues of our Compounded Pharmaceuticals business conducted through USC were approximately $3,205,000 and $4,645,000 for the three months ended June 30, 2020 and 2019, respectively. Restrictions on outpatient surgery and other medical procedures due to the COVID-19 pandemic resulted in a decline in sales of USC's products of approximately $1,440,000. The COVID-19 outbreak has adversely affected revenues from sales of USC products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products, and will likely continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted. USC has added certain products to its product offerings, including hand sanitizer products, and certain pharmaceutical products that are in short supply but are not listed on FDA's Drug Shortage List, some of which may be used in connection with treatment of acutely ill COVID-19 patients, although the COVID-19 outbreak could result in shortages or delays in our ability to obtain supplies relating to certain of these products.

Cost of Goods Sold. Consolidated cost of goods sold was approximately $4,684,000 and $3,666,000 for the three months ended June 30, 2020 and 2019, respectively. Our cost of goods sold includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, shipping and handling costs, the write-off of obsolete inventory and other related expenses. The gross margin percentage for the three months ended June 30, 2020 was approximately (19)% compared to approximately 36% for the three months ended June 30, 2019.

Cost of goods sold of our Drug Development and Commercialization business conducted by Adamis was approximately $1,840,000 and $1,141,000 for the three months ended June 30, 2020 and 2019, respectively. The gross margin percentage for the three months ended June 30, 2020 was approximately (155)% compared to approximately (2)% for the three months ended June 30, 2019. Cost of goods sold for the second quarter of the 2020 period compared to the comparable period of 2019 increased primarily due to the increase of approximately $699,000 in direct materials, depreciation, maintenance fees and other related expenses associated with the production of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg.

Cost of goods sold of our Compounded Pharmaceuticals business conducted through USC was approximately $2,844,000 and $2,525,000 for the three months ended June 30, 2020 and 2019, respectively. The gross margin percentage for the three months ended June 30, 2020 was approximately 11% compared to approximately 46% for the three months ended June 30, 2019. Obsolete inventory at the USC outsourcing facility increased approximately $875,000 due to the reduction in consumer demand for certain USC products as a result of the COVID-19 pandemic. This amount was partially offset due to the decrease of approximately $556,000 in materials costs, compensation and other employee benefits, product devices, testing, freight, and repairs and maintenance as a result of the elimination of a second production shift at the USC outsourcing facility and the ceasing of sales of certain formulations at the USC outsourcing facility.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses consist primarily of depreciation and amortization, professional fees which include legal, accounting and audit fees, consulting and employee compensation. Consolidated SG&A expenses for the three months ended June 30, 2020 and 2019 were approximately $5,653,000 and $7,000,000, respectively.

SG&A expenses of our Drug Development and Commercialization business conducted by Adamis for the three months ended June 30, 2020 and 2019 were approximately $3,009,000 and $3,443,000, respectively. The decrease was primarily attributable to decreases in wages, benefits and other compensation expenses, patent expenses, consulting, outside services, professional fees, depreciation, selling and other related expenses of approximately $681,000. These amounts were partially offset by increases in professional fees and insurance expenses of approximately $247,000.

SG&A expenses of our Compounded Pharmaceuticals business conducted through USC for the three months ended June 30, 2020 and 2019 were approximately $2,644,000 and $3,557,000, respectively. The decrease was primarily attributable to decreases in wages, benefits and other compensation expenses, selling, professional fees, and consulting expenses of approximately $913,000.

Research and Development Expenses. Research and development, or R&D, costs are expensed as incurred. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as an asset and are expensed when the research and development activities are performed. Consolidated research and development expenses were approximately $3,086,000 and $2,846,000 for the three months ended June 30, 2020 and 2019, respectively.

Research and development expenses of our Drug Development and Commercialization business conducted by Adamis were approximately $2,926,000 and $2,793,000 for the three months ended June 30, 2020 and 2019, respectively. The increase in R&D expenses for the three months ended June 30, 2020, compared to the comparable 2019 period was primarily due to an increase of approximately $1,136,000 in development costs of Adamis products and product candidates, including Tempol and SYMJEPI. The increase was partially offset by a decrease of approximately $1,003,000 in development costs attributed to other Adamis product candidates, wages, benefits and other compensation expenses for research and development employees, consulting and recruitment expenses.

Research and development expenses of our Compounded Pharmaceuticals business conducted through USC were approximately $160,000 and $53,000 for the three months ended June 30, 2020 and 2019, respectively. USC's R&D expenses for the three months ended June 30, 2020, compared to the comparable 2019 period, increased approximately $107,000 due to the testing of new products.

Impairment Expense. Impairment expenses for the three months ended June 30, 2020 and 2019 were approximately $1,750,000 and $0, respectively. As a result of entering into the Termination Agreement described above providing for the termination of the Sandoz Agreement with Sandoz, our financial results for the three months ending June 30, 2020, included an impairment of the Adamis capitalized cost to obtain a contract of $1,750,000. For further information, see Note 2 to the unaudited condensed consolidated financial statements included elsewhere in this Report.

Other Income (Expense). Other Income (Expenses) consists primarily of interest income and interest expense. Other income (expense) for the three months ended June 30, 2020 and 2019 was approximately ($16,000) and $11,000, respectively. The decrease in other income and increase in other expense during the three-month period in 2020, compared to the same period in 2019, was primarily due to the decrease of approximately $17,000 in interest income and an increase of debt related expense of approximately $10,000.

Six Months Ended June 30, 2020 and 2019

Revenues. Consolidated revenues were approximately $8,590,000 and $10,671,000 for the six months ended June 30, 2020 and 2019, respectively. Consolidated revenues decreased approximately $2,081,000 in the first six months of 2020 compared to the comparable period of 2019.

Revenues of our Drug Development and Commercialization business conducted by Adamis were approximately $1,229,000 and $1,585,000 for the six months ended June 30, 2020 and 2019, respectively. Revenue relating to the sales of SYMJEPI (epinephrine) Injection .3mg and .15mg decreased approximately $356,000 primarily due to matters relating to the transition of commercialization and marketing rights to the SYMJEPI products from Sandoz to USWM.

Revenues of our Compounded Pharmaceuticals business conducted through USC were approximately $7,361,000 and $9,086,000 for the six months ended June 30, 2020 and 2019, respectively. Restrictions on outpatient surgery and other medical procedures due to the COVID-19 pandemic resulted in a decline in sales of USC's products of approximately $1,609,000. Approximately $191,000 of the decrease in revenues was due to the ceasing of sales of certain USC non-sterile formulations and products. These amounts were partially offset by an increase of approximately $75,000 in sales of USC's veterinary products. The COVID-19 outbreak has adversely affected revenues from sales of USC products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products, and will likely continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted. USC has added certain products to its product offerings, including hand sanitizer products, and certain pharmaceutical products that are in short supply but are not listed on FDA's Drug Shortage List, some of which may be used in connection with treatment of acutely ill COVID-19 patients, although the COVID-19 outbreak could result in shortages or delays in our ability to obtain supplies relating to certain of these products.

Cost of Goods Sold. Consolidated cost of goods sold was approximately $8,371,000 and $7,291,000 for the six months ended June 30, 2020 and 2019, respectively. Our cost of goods sold includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, shipping and handling costs, the write-off of obsolete inventory and other related expenses. The gross margin percentage for the six months ended June 30, 2020 was approximately 3% compared to approximately 32% for the six months ended June 30, 2019.

Cost of goods sold of our Drug Development and Commercialization business conducted by Adamis was approximately $3,573,000 and $1,529,000 for the six months ended June 30, 2020 and 2019, respectively. The gross margin percentage for the six months ended June 30, 2020 was approximately (191)% compared to approximately 3% for the six months ended June 30, 2019. Cost of goods sold for the six-month 2020 period compared to the six-month period of 2019 increased primarily due to an increase of approximately $2,044,000 in direct materials, depreciation, maintenance fees and other related expenses associated with the production of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg.

Cost of goods sold of our Compounded Pharmaceuticals business conducted through USC was approximately $4,798,000 and $5,762,000 for the six months ended June 30, 2020 and 2019, respectively. The gross margin percentage for the six months ended June 30, 2020 was approximately 35% compared to approximately 37% for the six months ended June 30, 2019. Obsolete inventory and other materials costs increased approximately $407,000 at the USC outsourcing facility and this amount was partially offset by a decrease of approximately $1,371,000 in wages, benefits and other compensation expenses, consulting services, product devices, testing, freight, repairs and maintenance and other related expenses as a result of the elimination of a second shift at the USC outsourcing facility and the ceasing of sales of certain formulations at the USC outsourcing facility.

Selling, General and Administrative Expenses. SG&A expenses consist primarily of depreciation and amortization, professional fees which include legal, accounting and audit fees, consulting and employee compensation. Consolidated SG&A expenses for the six months ended June 30, 2020 and 2019 were approximately $11,707,000 and $15,022,000, respectively.

SG&A expenses of our Drug Development and Commercialization business conducted by Adamis for the six months ended June 30, 2020 and 2019 were approximately $6,312,000 and $7,256,000, respectively. The decrease was primarily attributable to decreases in wages, benefits and other compensation expenses of approximately $658,000, approximately $400,000 in patent expenses, and approximately $444,000 in consulting, outside services, depreciation, selling and other related expenses. These amounts were partially offset by increases in professional fees and insurance expenses of approximately $558,000.

SG&A expenses of our Compounded Pharmaceuticals conducted through USC for the six months ended June 30, 2020 and 2019 were approximately $5,395,000 and $7,766,000, respectively. The decrease was primarily attributable to decreases in wages, benefits and other compensation expenses of approximately $695,000, approximately $622,000 in selling expenses, approximately $519,000 of operational expenses relating to the ceasing of sales of certain USC products, approximately $510,000 in professional fees and consulting expenses, and approximately $229,000 in depreciation, repairs and maintenance, and other related expenses. These amounts were partially offset by increases of approximately $204,000 in licenses, permits, bad debt expense and other related administrated expenses.

Research and Development Expenses. Our research and development costs are expensed as incurred. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as an asset and are expensed when the research and development activities are performed. Research and development expenses were approximately $5,123,000 and $5,042,000 for the six months ended June 30, 2020 and 2019, respectively.

Research and development expenses of our Drug Development and Commercialization business conducted by Adamis were approximately $4,963,000 and $4,989,000 for the six months ended June 30, 2020 and 2019, respectively. R&D expenses of Adamis increased for the six months ended June 30, 2020, compared to the comparable 2019 period was primarily due to an increase of approximately $979,000 in development costs of our product candidate, Tempol and other product candidates. These amounts were partially offset by a decrease of approximately $1,005,000 in development costs attributed to other product development expenses, compensation, consulting, and recruiting.

Research and development expenses of our Compounded Pharmaceuticals business conducted through USC were approximately $160,000 and $53,000 for the six months ended June 30, 2020 and 2019, respectively. R&D expenses of USC for the six months ended June 30, 2020, compared to the comparable 2019 period, increased approximately $107,000 due to the testing of new products.

Impairment Expense. Impairment expenses for the six months ended June 30, 2020 and 2019 were approximately $4,893,000 and $0, respectively. As described in Note 5 to the condensed consolidated financial statements included elsewhere herein, in light of recent events associated with the global spread of COVID-19 and other factors, the Company performed a goodwill impairment review as of March 31, 2020, and recorded a charge of approximately $3,143,000 for impairment of goodwill during the first three months of 2020. As a result of entering into the Termination Agreement described above providing for the termination of the Sandoz Agreement, our financial results for the six months ending June 30, 2020, included an impairment of the Adamis capitalized cost to obtain a contract of $1,750,000. For further information, see Note 2 to the condensed consolidated financial statements included elsewhere in this Report.

Other Income (Expense). Other Income (Expenses) consists primarily of interest income and interest expense. Other income (expense) for the six months ended June 30, 2020 and 2019 was approximately ($32,000) and $62,000, respectively. The decrease in other income and increase in other expense during the six-month period in 2020, compared to the same period in 2019, was primarily due to the decrease of approximately $69,000 in interest income and an increase of debt related expense of approximately $25,000.

Liquidity and Capital Resources

We have incurred net losses of approximately $21.5 million and $16.6 million for the six months ended June 30, 2020 and 2019, respectively. Since inception, and through June 30, 2020, we have an accumulated deficit of approximately $203.9 million. Since inception and through June 30, 2020, we have financed operations principally through debt financing and through public and private issuances of common stock and preferred stock. In February 2020, we completed a registered direct offering of 11,600,000 shares of common stock, and a concurrent private placement of warrants to purchase 8,700,000 shares of common stock, to a small number of accredited institutional investors, resulting in estimated net proceeds of approximately $6.2 million.

In April 2020, we secured an approximately $3.2 million Paycheck Protection Program (PPP) loan provided for by the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") and administered by the SBA. The unsecured loan (the "PPP Loan") is evidenced by a promissory note of the company (the "PPP Note"), to Arvest Bank, the Lender. Under the terms of the PPP Note and the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP Note is two years, unless sooner provided in connection with an event of default under the PPP Note. To the extent the loan amount is not forgiven under the PPP, we are obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the PPP Note, until the maturity date. The CARES Act and the PPP provide a mechanism for a borrower to apply for forgiveness of up to the full amount borrowed. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by the Company during the eight-week or 24-week period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 60% of the loan amount is used for eligible payroll costs; the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week or 24-week period will qualify for forgiveness. There is no assurance that we will apply for or be granted forgiveness of some or all of the amount of the PPP Loan. After the CARES Act was passed and we applied for and obtained the PPP Loan, the SBA issued new guidance that, among other things, questioned whether a public company with substantial market value and access to capital markets would qualify to participate in the PPP and be able to make the required certification that current economic uncertainty makes the loan request necessary to support the ongoing operations of the applicant. Subsequently, the Secretary of the Treasury and SBA has issued guidance that the government will review all PPP loans of more than $2 million for which the borrower applies for forgiveness, and that all PPP loans in excess of $2 million, and other PPP loans as appropriate, will be subject to review by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form. Should we be audited or reviewed by federal or state regulatory authorities as a result of filing an application for forgiveness of the PPP Loan or otherwise, such audit or review could result in the diversion of management's time and attention and legal and reputational costs. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return or repay the full amount of the PPP Loan and could be subjected to fines or penalties, which could reduce our liquidity and adversely affect our business, financial condition and results of operations.

We will need significant additional funding before the end of fiscal 2020 to satisfy our obligations and fund the future expenditures that we believe will be required to support commercialization of our products and conduct the clinical and regulatory work to develop our product candidates. We may finance future cash needs primarily through proceeds from equity or debt financings, loans, share of profits anticipated to be received relating to sales in the U.S. of our SYMJEPI products, sales of assets, out-licensing transactions, and/or collaborative agreements with corporate partners, and from revenues from our sale of compounded pharmacy formulations.

Total assets were approximately $39.7 million and $47.8 million as of June 30, 2020 and December 31, 2019, respectively. As of June 30, 2020, current liabilities exceed current assets by approximately $0.4 and as of December 31, 2019, current assets exceed current liabilities by approximately $4.5 million.

Net cash used in operating activities for the six months ended June 30, 2020 and 2019, was approximately $9.4 million and $12.7 million, respectively. Net cash used in operating activities decreased, as compared to 2019, primarily due to the increases in accounts receivable, deferred revenue and accrued expenses; and although there was an increase in operating losses for the first six months of 2020, it was offset by the non-cash impairment charges.

Net cash used in investing activities was approximately $0.9 million and $2.2 million for the six months ended June 30, 2020 and 2019, respectively. The net cash used in investing activities decreased primarily due to the reduction in purchases of additional equipment during the six months ended June 30, 2020 compared to the six months ended June 30, 2019.

Net cash provided (used) in financing activities was approximately $9,372,000 and ($285,000) for the six months ended June 30, 2020 and 2019, respectively. Net cash flows provided by financing activities increased for the period ended June 30, 2020 due to the issuance of common stock and warrants generating net proceeds of approximately $6,233,000 and the proceeds of the PPP loan of approximately $3,192,000, partially offset by payment of loans and finance leases of approximately $53,000. In the six months ended June 30, 2019, net cash used in financing activities of approximately $285,000 consisted of principal payments of finance leases and USC's building and equipment loans.

As noted above under the heading "Going Concern and Management Plan," through June 30, 2020, Adamis has incurred substantial losses. The availability of any required additional funding cannot be assured. If we do not obtain required additional equity or debt funding, our cash resources could be depleted and we could be required to materially reduce or suspend operations. Even if we are successful in obtaining required additional funding to permit us to continue operations at the levels that we desire, substantial time may pass before we obtain regulatory marketing approval for any additional specialty pharmaceutical products and begin to realize revenues from sales of such additional products, and during this period Adamis could require additional funds. No assurance can be given as to the timing or ultimate success of obtaining any required future funding. The company will be required to devote additional cash resources, which could be significant, in order to continue development and commercialization of our product candidates and to support our other operations and activities. As a result of the COVID-19 pandemic and actions taken to slow its spread, credit and financial markets have experienced material volatility, unemployment rates have materially increased, credit and financial markets have deteriorated, and economic growth has declined. There can be no assurance that further deterioration in credit and financial markets will not occur, which would make it more difficult, or more costly or dilutive, to obtain any necessary debt or equity financing.

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, 2019 have not significantly changed.

Recent Accounting Pronouncements

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

Off Balance Sheet Arrangements

At June 30, 2020, Adamis did not have any off balance sheet arrangements.

ITEM 3. Quantitative and Qualitative Disclosure of Market Risk

Not required.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Internal Controls

There has been no change during the quarter ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the impact of the COVID-19 pandemic on our internal controls to reduce or minimize the impact on their design and operating effectiveness.

PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

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

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

Fact discovery closed on March 2, 2020. Expert discovery, including regarding the alleged damages that Nephron seeks against Adamis and USC, occurred during the second quarter of 2020 and is scheduled to close near the end of August 2020. On May 6, 2020, Adamis and USC moved for summary judgment to dismiss the three claims that remain pending against them. The case is currently set for trial in January 2021. Adamis believes that Nephron's claims are without merit and is vigorously defending against the allegations.

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

There is substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing.

Our consolidated financial statements are prepared using the generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, as shown in our consolidated financial statements for the year ended December 31, 2019, included in our annual report on Form 10-K for the year ended December 31, 2019, and in the financial statements accompanying this Report, we have sustained substantial recurring losses from operations. In addition, we have used, rather than provided, cash in our continuing operations. We will need significant funding to continue operations, satisfy our obligations and fund the future expenditures that will be required to conduct the clinical and regulatory work to develop our product candidates. Without obtaining additional capital, it would be unlikely for us to continue as a going concern. The above conditions raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be unable to continue in existence. Uncertainty concerning our ability to continue as a going concern, among other factors, may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent, among other factors, on the market acceptance and success of our products and our ability to obtain additional required funding, and there are no assurances that such funding will be available at all or will be available in sufficient amounts or on reasonable terms. Without additional required funds from debt or equity financings, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions or sources, we will exhaust our resources and will be unable to continue operations. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

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

We incurred a net loss of approximately $21.5 million and $29.3 million for the six months ended June 30, 2020 and the year ended December 31, 2019, respectively, and a net loss of approximately $39.0 million for the year ended December 31, 2018. At June 30, 2020, and December 31, 2019, we had cash and cash equivalents of approximately $7.9 million and $8.8 million, respectively, accounts receivable of approximately $1.4 million and $1.9 million, respectively, and liabilities of approximately $16.6 million and $11.8 million, respectively. The development of our business will require additional capital in 2020 and the future to help fund the development and commercialization of our products and product candidates and conduct research and development of other product candidates, as well as to fund capital expenditures and our ongoing operations at USC and satisfy our obligations and liabilities. In addition to product revenues, we have historically relied upon sales of our equity or debt securities to fund our operations. We currently have no available balance in our credit facility or committed sources of capital, and a number of factors limit or prevent our current ability to access capital markets. Delays in obtaining required funding could adversely affect our ability to develop and commercially introduce products and cause us to be unable to comply with our obligations under outstanding instruments.

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

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

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

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

Our common stock is listed on the Nasdaq Capital Market. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would have a negative effect on the price of our common stock and would impair the ability to sell or purchase our common stock when persons wish to do so.

On October 11, 2019, we received a notice from the Nasdaq Listing Qualifications Department of The NASDAQ Capital Market ("Nasdaq") that, because the closing bid price of our common stock had been below $1.00 per share for 30 consecutive business days, we no longer complied with the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) (the "Rule") requires listed securities to maintain a minimum bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The Notice had no immediate effect on the listing or the trading of our common stock on The Nasdaq Capital Market. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), we were provided an initial compliance period of 180 calendar days, or until April 8, 2020, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. The Company received additional communications from Nasdaq in April 2020 that ultimately extended the deadline to regain compliance to December 21, 2020.

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

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 $21.5 million and $29.3 million for the six months ended June 30, 2020 and the year ended December 31, 2019, respectively, and a net loss of approximately $39.0 million for the year ended December 31, 2018. From inception through June 30, 2020, we have an accumulated deficit of approximately $203.9 million. We expect that these losses may increase as we continue our research and development activities, seek regulatory approvals for our product candidates and seek to commercialize any approved products. These losses will cause, among other things, our stockholders' equity and working capital to decrease. Any future earnings and cash flow from operations of our business are dependent on our ability to further develop our products and on revenue and profitability from sales of products.

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

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

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

On May 15, 2020, we resubmitted to the FDA our NDA relating to our ZIMHI product, responding to matters raised in the FDA's previous CRL regarding our original NDA for ZIMHI and matters discussed in our Type A meeting with the FDA concerning the CRL. However, there are no assurances that the FDA will regard our resubmission as satisfactorily responding to the matters raised in the earlier CRL or in the Type A meeting, that the FDA will not issue another CRL, or that the FDA will not require additional studies or information. Receipt of an additional CRL or other adverse action by the FDA concerning our resubmitted NDA could result in significant additional time and expense before our ZIMHI NDA is approved, if approved at all, and marketing of ZIMHI could commence, which could have a material adverse effect on our business, financial condition or results of operations.

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

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

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

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. In addition, development of some of our potential products candidates has been discontinued or suspended. Many of our potential products will require significant additional research and development before any commercial introduction. There can be no assurance that any future research, development or clinical trial efforts will result in viable products or meet efficacy standards. Future clinical or preclinical results may be negative or insufficient to allow us to successfully market our product candidates. Obtaining needed data and results may take longer than planned or may not be obtained at all. Any such delays or setbacks could have a material adverse effect on our ability to achieve our financial goals.

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

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

Our product development plans concerning our allergy and respiratory products and product candidates, including APC-1000, APC-4000 and APC-6000, are affected by many factors, many of which are difficult to predict. Some of the factors that could affect our development plans for our products and product candidates include: general market conditions and developments in the marketplace including the introduction of potentially competing new products by our competitors; the availability of adequate funding to support product development efforts and sales and marketing efforts for approved products; the outcome of discussions with the FDA concerning the number and kind of clinical trials that the FDA will require before the FDA will consider regulatory approval of the applicable product; the outcome of discussions with the FDA concerning the regulatory approval pathway of the applicable product; the FDA's review and acceptance of NDAs that we may file concerning our product candidates; any unexpected difficulties in licensing or sublicensing intellectual property rights that may be required for other components of the product patent infringement lawsuits relating to Paragraph IV certifications as part of any Section 505(b)(2) or ANDA filings; any unexpected difficulties in the ability of our suppliers to timely supply quantities for commercial launch of the product; and unexpected delays or difficulties in assembling and deploying an adequate sales force to market the product if we decide to market a product ourselves rather than seek a commercialization partner.

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

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

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

Business or economic disruptions or global health concerns, including the recent COVID-19 pandemic, could harm our business and increase our costs and expenses.

Broad-based business or economic disruptions could adversely affect our ongoing business and research, development and commercial activities and could include disruptions to the productivity of our employees working remotely or their ability to travel on matters relating to the Company's business activities. The novel strain of coronavirus and the related COVID-19 pandemic in December 2019 and 2020 has spread throughout most of the world including the United States. As of the date of this Report, this outbreak has resulted in extended shutdowns of businesses in the United States and elsewhere and has had ripple effects on businesses and activities around the world. We could experience delays in obtaining products or services from our third party manufacturers or suppliers as a result of the impact of the COVID-19 pandemic on such parties. In addition, the pandemic and related matters could result in interruptions or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines relating to our NDAs or other actions relating to our products or product candidates. The outbreak and any preventative or protective actions that we, our customers, our respective manufacturers, suppliers or other third parties with which we have business relationships, or governments may take in respect of the coronavirus and COVID-19 outbreak could disrupt our business and the business of our customers or third parties with which we have business relationships. The extent to which the COVID-19 pandemic will continue to impact our business is difficult to predict and subject to change, and will depend on future developments, which are highly uncertain and cannot be predicted, including without limitation the severity of the disease and duration of the outbreak, travel restrictions and social distancing requirements in the United States and other countries, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and address its impact. Global health concerns, such as coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. In addition, the COVID-19 outbreak has resulted in a severe economic downturn and has already significantly affected the financial markets of many countries. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making purchases or payments for our products. Any of the foregoing could harm our business. In addition, the effects of applicable shelter-in-place orders and work from home policies may negatively impact productivity of our employees and disrupt our business activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and our ability to conduct business in the ordinary course. Although we have taken precautions intended to avoid the spread of the coronavirus among our employees, it is possible that one or more members of our workforce could be diagnosed with COVID-19, which could adversely impact our operations. As of this report, we cannot presently predict the long-term impact to the scope and severity of potential business shutdowns or disruptions, but if we, our customers, or any of the third parties with whom we engage, including the suppliers, manufacturers, regulators and other third parties with whom we conduct business or have business relationships, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner presently anticipated could be materially and negatively impacted.

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;
- recruiting participants for a clinical trial; and
- delays related to the impact of the COVID-19 pandemic.

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

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

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

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

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

Before regulatory approval for a potential product can be obtained, we must undertake clinical testing on humans to demonstrate the tolerability and efficacy of the product. We cannot assure you that we will obtain authorization to permit product candidates that are in the preclinical development phase to enter the human clinical testing phase. In addition, we cannot assure you that any authorized preclinical or clinical testing will be completed successfully within any specified time period by us, or without significant additional resources or expertise to those originally expected to be necessary. For example, we have suspended additional clinical trials relating to our APC-1000 product candidate. 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 products and product candidates, we do not have any experience in drug formulation or manufacturing, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. Accordingly, we expect to depend on third-party contract manufacturers for the foreseeable future. Any performance failure on the part of our contract manufacturers could delay clinical development, regulatory approval or commercialization of our current or future product candidates, depriving us of potential product revenue and resulting in additional losses. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our existing and potential products. Any business interruptions resulting from geopolitical actions, including war and terrorism, adverse public health developments such as the outbreak of the COVID-19 coronavirus, or natural disasters including earthquakes, typhoons, floods and fires, could adversely affect our supply chain. These risks and uncertainties are compounded in the presence of the COVID-19 pandemic. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our manufacturers or suppliers could delay shipment of any of our products, increase our cost of goods sold and result in lost sales.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have limited sales, marketing and distribution experience.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our patents also may not afford protection against competitors with similar technology. We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our products or by covering the same or similar technologies that may affect our ability to market or license our product candidates. Many companies have encountered difficulties in protecting and defending their intellectual property rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in either the United States or foreign jurisdictions, our business prospects could be substantially harmed. In addition, 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. As of March 31, 2020, in light of recent events associated with the global spread of COVID-19 and other factors, we performed a goodwill impairment interim review and recorded a charge of approximately $3,143,000 for impairment of goodwill during the first quarter of 2020. 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. In addition, any staffing interruptions resulting from geopolitical actions, including war and terrorism, adverse public health developments such as the outbreak of the COVID-19 coronavirus, or natural disasters including earthquakes, typhoons, floods and fires, could have an adverse effect on our business.

We may experience difficulties in managing growth.

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

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

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

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, 2019, we had federal and state net operating loss carryforwards, or NOLs, and credit carryforwards which, subject to certain limitations, we may use to reduce future taxable income or offset income taxes due. Insufficient future taxable income will adversely affect our ability to utilize these NOLs and credit carryforwards. Pursuant to Internal Revenue Code Section 382, the annual use of the NOLs and research and development tax credits could be limited by any greater than 50% ownership change during any three-year testing period. As noted in Note 20 to the consolidated financial statements appearing in our annual report on Form 10-K for the year ended December 31, 2019, our existing NOLs are subject to limitations arising from previous ownership changes, and if we undergo additional ownership changes, our ability to use our NOLs could be further limited by Section 382 of the Code. As a result of these limitations, we may be materially limited in our ability to utilize our NOLs and credit carryforward.

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

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

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

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

Risks Related to Our Compounding Pharmacy Business

Our Inability to Successfully Manage USC's Operations Could Adversely Affect Our Operations; Need for Additional Financing.

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

USC could receive additional Form 483 inspectional observations 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.

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

Following the August 2015 Form 483 observations, and prior to our acquisition of USC, USC temporarily suspended production of sterile products and voluntarily recalled certain lots of sterile product. USC determined there was no evidence that any compounded sterile products were defective, but decided to voluntarily recall all sterile product that remained within expiry and temporarily halt sterile production. USC responded to the August 2015 Form 483 observations and took a number of corrective actions, including enhancing quality control and production systems. Approximately around the time of its acquisition by Adamis, USC resumed production and sale of its sterile products. In July 2016, USC received Form 483 observations following FDA inspections of its outsourcing facility, noting inspectional observations of a number of observed deficiencies relating to USC's facility and practices. USC responded in writing to the inspectional observations in July 2016 and provided supplemental responses to FDA in April 2017. In October 2017, USC received a Warning Letter referencing the August 2015 and July 2016 Form 483 inspectional observations. USC provided a written response to the FDA that further described the completed corrective actions that were taken in response to the inspectional observations. In November 2018, FDA responded to the 2017 Warning Letter Response submitted by USC and indicated it would look for evidence of corrective action and further clarification of policies and procedures on a future inspection. USC was inspected by FDA in the early part of 2019, with a Form 483 issued to site management in February 2019. USC duly responded to the inspectional observations in writing to the FDA in March 2019, and provided an initial update in April 2019 and a comprehensive update of completed corrective actions and milestones in August 2019.

Following the suspension and voluntary recall in 2015, state pharmacy regulatory agencies in certain states initiated inquiries or took other actions regarding sales of USC products in such states. All of these state matters have been resolved; however, future proceedings by the FDA or state regulatory agencies alleging violation of applicable federal or state laws or regulations, could require significant time and financial resources, and an adverse outcome in one or more of these proceedings could adversely affect USC's business, results of operations and financial condition. The suspension of sterile production and voluntary product recall had an adverse effect on USC's revenues, income, and financial condition for calendar years 2015 and 2016 and adversely affected its relationships with certain of its customers that established relationships with other suppliers during USC's suspension of sterile production.

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

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

Formulations prepared and dispensed by compounding pharmacies contain ingredients purchased from FDA-registered suppliers, but the finished compounded drug products are not themselves approved by the FDA. The drug products available through branded and generic drug companies have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. In addition, certain compounding pharmacies have been the subject of widespread negative media coverage in recent years, and the actions of these pharmacies have resulted in increased scrutiny of compounding pharmacy activities from the FDA and state governmental agencies. For example, the FDA has in the past requested that a number of compounding pharmacies conduct a recall of all non-expired, purportedly sterile drug products and cease sterile compounding operations due to lack of sterility assurance, and additional compounding pharmacies have suspended sterile production or voluntarily recalled certain sterile compounding products after an FDA inspection of the relevant facilities. As a result, some physicians may be hesitant to prescribe, and some patients may be hesitant to purchase and use, these compounded formulations. Other reasons physicians may be unwilling to prescribe or patients may be unwilling to use USC's compounded formulations could include the following, among others: applicable law limits our ability to discuss the efficacy or safety of USC's formulations with potential users to the extent applicable data is available; our compounded preparations are primarily sold on a cash-pay basis and reimbursement may or may not be available from third-party payors, including the government Medicare and Medicaid programs; or ordering physicians or their delegates may be unwilling or logistically unable to provide attestation of clinical need as required by FDA pursuant to guidance documents published in 2018. Any failure by physicians, patients, or third-party payors, to accept compounded formulations could substantially limit USC's market and cause its and our business and operations to suffer. An incident similar to the fungal meningitis outbreak in 2012, which was caused by a compounding pharmacy, could cause USC's customers to reduce their use of outsourced compounded medications significantly or even stop using outsourced compounded medications altogether. States have in the past enacted, and could in the future enact, regulations prohibiting or restricting the use of outsourcing compounded medication service providers in response to such incidents. Such prohibitions or restrictions on outsourced compounded preparations by states, or reduced customer demand as a result of an incident with compounded medication providers, could have a material adverse effect on USC's and our business, results of operations and financial condition.

In addition, in 2017, a lawsuit was filed by a pharmaceutical company, Endo International plc, alleging that FDA has improperly enforced DQSA related to its interim draft guidance on compounding from bulk drug ingredients. In September 2019, Endo withdrew this lawsuit based on the FDA's evaluation that outsourcing facilities should not be able to compound drugs products that contain vasopressin, the basis of Endo's complaint. FDA has indicated it intends to take similar action relative to nine other bulk drug substances, including ephedrine sulfate. Ephedrine sulfate represents a portion of USC's hospital outsourcing business, which could result in a loss of revenue resulting from affected USC products. USC is working proactively with industry stakeholders and regulatory authorities regarding the FDA's guidance and actions, and believes that the impact on USC and other 503B outsourcing facilities of the regulatory expectations regarding bulk substances will depend in part on how the guidance is implemented, interpreted, and applied over time.

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

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

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

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.

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

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

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

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

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

Currently, USC is paid directly by most of its customers and does not submit large amounts of claims for reimbursement through Medicare, Medicaid or other third-party payors, although its customers may choose to seek available reimbursement opportunities to the extent that they exist. Many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are increasingly attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. The continued efforts of health maintenance organizations, managed care organizations, government programs (such as Medicare, Medicaid and other federal and state-funded programs) and other third-party payors to limit reimbursements to USC's customers may adversely impact our financial results. Further, HIPAA, the Patient Protection and Affordable Care Act ("PPACA") and the Health Care and Education Reconciliation Act of 2012 (collectively referred to as the "Health Reform Law"), may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivably adversely affect USC's business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may cease to be available for USC's products or may not be sufficient to allow USC to sell products on a competitive basis and at desirable price points. If government and other third-party payors do not provide adequate coverage and reimbursement levels for USC's formulations, the market acceptance for USC's formulations may be limited. We expect cost pressures from third party payors to continue, and USC's customers have limited bargaining power to counter payor demands for reduced reimbursement rates. If USC's customers increasingly insource pharmaceutical preparations or use alternative third-party providers due to these pressures, USC's and our business, results of operations and financial condition may be materially adversely impacted.

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

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

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

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

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

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

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

In 2018, the FDA published a number of draft guidance materials that could have a substantial impact on USC's business. In March 2018, the FDA published the draft guidance "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503 of the Federal Food, Drug, & Cosmetic Act." The FDA also updated its interim lists of bulk drug substances on several occasions in 2018. In March 2019, the FDA issued final guidance and moved to formally remove two substances from the interim list that permitted their use; while the specific substances at issue in FDA's March 2019 guidance were not of material importance to USC, FDA has announced its intent to take similar action regarding nine other bulk drug substances, including ephedrine sulfate, that represent a portion of USC's hospital outsourcing business, which could result in a loss of revenue resulting from affected USC products. USC is working proactively with industry stakeholders and regulatory authorities regarding the FDA's guidance and actions, and believes that the impact on USC and other 503B outsourcing facilities of the regulatory expectations regarding bulk substances will depend in part on how the guidance is implemented, interpreted and applied over time.

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

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

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

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

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

USC's success depends upon its ability to provide timely, reliable and consistent services and products to its customers. Natural disasters or other catastrophic events, including tornadoes, hurricanes, blizzards and other weather conditions, terrorist attacks, power and data interruptions, fires as well as logistical or delivery disruptions could disrupt USC's or its suppliers' and vendors' operations and impede USC's ability to provide services and deliver products to customers, which could adversely impact USC's and our results of operations. For example, USC's CSPs have expiration dates, and USC's compounded preparations must remain under specified storage conditions, including some items that must remain refrigerated or frozen or those that are sensitive to excessive heat. Any disruption or delay in delivery may cause spoilage and the need to retrieve and replace products. In the event that USC experiences a temporary or longer term interruption in its ability to deliver services or products, USC's and our revenues could be reduced, USC's reputation could be damaged and USC's and our business could be materially and adversely affected. For example, USC's suspension of sterile product production during portions of the second half of 2015 and the first quarter of 2016 adversely affected its relationships with some of its customers and sales personnel, and resulted in revenues in 2016 that were below our expectations. In addition, any continuing disruption in either USC's or our computer systems or telephone system could adversely affect USC's or our ability to receive and process customer orders and ship products on a timely basis, and could adversely affect USC's or our relations with customers, potentially resulting in reduction in orders or loss of customers.

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

As we have previously disclosed in our SEC filings, in connection with our acquisition of USC and the transactions contemplated by the merger agreement relating to the USC acquisition, we assumed approximately $5,722,000 principal amount of debt obligations under two loan agreements and related loan documents relating to the building, real property and equipment that certain third parties agreed to transfer to the company or USC in connection with the merger, as well as the two loan agreements to which USC is a party, a working capital loan and an equipment loan, and related loan documents evidencing loans previously made to USC, and we agreed to become an additional co-borrower under the Loan Documents. The lender in all of the Loan Documents was First Federal Bank and/or its successor Bear State Bank, and/or Arvest Bank, as successor in interest to Bear State Bank, referred to as Lender or the Bank. We have previously entered into amendments of these loan agreements with the Bank, or the Amended Loan Documents. We are required to make current periodic interest and principal payments under the Amended Loan Documents, in an amount of approximately $23,000 per month; the amount of required interest payments is subject to change depending on future changes in interest rates.

The Amended Loan Documents with the Bank include a variety of representations, warranties and covenants that we are required to comply with. If we do not comply with the provisions of such agreements and documents and the Bank declares an event of default, the Bank would be entitled to accelerate the maturity date of the loans, the principal and accrued interest would become due and payable, and the Bank could elect to exercise its remedies as a secured creditor under the loan documents and applicable law. At June 30, 2020, our aggregate indebtedness under the Amended Loan Documents was approximately $2,102,000.

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

In addition, in April 2020, we received $3,191,700 in loan funding from the Paycheck Protection Program (the "PPP"), established pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and administered by the U.S. Small Business Administration ("SBA"). The unsecured loan (the "PPP Loan") is evidenced by a promissory note of the Company (the "PPP Note"), in the principal amount of $3,191,700, to Arvest Bank, the Lender. Under the terms of the PPP Note and the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP Note is two years, unless sooner provided in connection with an event of default under the PPP Note. To the extent the loan amount is not forgiven under the PPP, the Company is obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the PPP Note, until the maturity date. The CARES Act and the PPP provide a mechanism for a borrower to apply for forgiveness of up to the full amount borrowed. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by the Company during the eight-week period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least certain specified percentages of the loan amount is used for eligible payroll costs; the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week period will qualify for forgiveness. There is no assurance that we will apply for or be granted forgiveness of some or all of the amount of the PPP Loan. After the CARES Act was passed and we applied for and obtained the PPP Loan, the SBA issued new guidance that, among other things, questioned whether a public company with substantial market value and access to capital markets would qualify to participate in the PPP and be able to make the required certification that current economic uncertainty makes the loan request necessary to support the ongoing operations of the applicant. Subsequently, the Secretary of the Treasury and SBA has issued guidance that the government will review all PPP loans of more than $2 million for which the borrower applies for forgiveness, and that all PPP loans in excess of $2 million, and other PPP loans as appropriate, will be subject to review by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form.. Should we be audited or reviewed by federal or state regulatory authorities as a result of filing an application for forgiveness of the PPP Loan or otherwise, such audit or review could result in the diversion of management's time and attention and legal and reputational costs. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return or repay the full amount of the PPP Loan and could be subject to fines or penalties, which could reduce our liquidity and adversely affect our business, financial condition and 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, prohibitions on wholesaling or reselling, and how FDA treats the compounding of animal drugs from a 503B registered outsourcing facility. 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, 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 Memorandum of Understanding ("MOU") with each state setting forth limits on interstate compounding. The final draft of the MOU presented by the FDA in May 2020 proposed that interstate shipments of compounded drug units in excess of 50% of all compounded and non-compounded units dispensed or distributed by a 503A facility per month will trigger increased federal oversight, potential state investigation, and adverse event reporting requirements regarding prescriptions compounded in their respective states and dispensed or distributed out of state. The FDA stated in the final MOU that the document does not apply to outsourcing facilities or to veterinary drug products. Section 503A facilities in states that do not sign the MOU will be prohibited from distributing more than 5% of their compounded drugs out of state. As of the date of this Report, in part due to a reorganization of state government, USC does not know when the Arkansas State Board of Pharmacy, or its umbrella organization the Department of Health, will make a decision regarding the MOU. If the final MOU is not signed by the state of Arkansas, where USC is located, then interstate shipments of compounded preparations from a 503A facility will be limited to quantities not greater than 5% of total prescriptions dispensed or distributed by the 503A facility (the 5% rule).The FDA has announced a 365-day period for states to agree to the finalized MOU, after which it will begin to enforce the 5% rule. Even though the MOU is designated as "final," the finalized MOU must first be reviewed and approved by the federal Office of Management and Budget before it is presented to the states for signature and execution. As of the date of this Report, we believe that the MOU is currently under review by OMB. FDA enforcement of either the 5% rule or the final MOU requirements could limit any interstate sales from a 503A facility. To the extent that USC's operations include sale of products pursuant to Section 503A, the limitations outlined above could apply to a portion of USC's business.

In January 2018, the FDA published a statement outlining its compounding priorities for 2018 (the "2018 Compounding Plan") which provided an overview of the key priorities the FDA plans to focus on in 2018 in connection with compounding regulations. Included in the 2018 Compounding Plan were references to forthcoming regulations on compounding from bulk drug substances, determination of clinical need, and a revised memorandum of understanding between the FDA and State Boards of Pharmacy setting forth limits on interstate compounding under Section 503A of the FDCA. In keeping with this 2018 Compounding Plan, in March 2018 the FDA issued a draft guidance proposing a framework for determining the clinical need sufficient to permit an outsourcing facility to compound from bulk drug substances ("Bulks Guidance"), and in May 2020 the FDA issued a revised final MOU ("Revised Final MOU"). As with other FDA regulations and guidance, this guidance and MOU potentially could limit the number and type of products USC is permitted to compound as well as interstate shipping of compounded medications thereby adversely affecting sales of our compounded medications. The Bulks Guidance received numerous comments, and final guidance was published in March 2019 relating to the method by which the FDA will evaluate bulk drug substances for inclusion/exclusion on the final bulk substances lists. With the exception of two substances that have been excluded, the final bulk substances lists have not been developed and no timeline is currently available for which the lists are expected to be finalized. Until then, the interim bulk substances lists are effective, and USC does not compound with bulk drug substances not on the interim list as approved for use. We believe that the impact on USC and other 503B outsourcing facilities of the regulatory expectations regarding bulk substances will depend in part on how the guidance is implemented, interpreted and applied over time.

In November 2019, FDA issued a draft Guidance for Industry #256: Compounding Animal Drugs from Bulk Drug Substances (the "Draft GFI #256"). This guidance describes the FDA's policy regarding the compounding of animal drugs from bulk substances and limits the circumstances in which a compounder may use bulk substances to compound animal medication. Industry comments to the Draft GFI #256 are due by October 15, 2020. As with other FDA regulations and guidance, when finalized, this guidance could limit the number and type of products USC is permitted to compound for animal use.

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

In the future, we may not be able to satisfy applicable federal and state licensing and other requirements for USC's pharmacy business in a timely manner or at all, changes to federal and state pharmacy regulations may restrict compounding operations or make them more costly, we may be unable to achieve a sufficient physician and patient customer base to sustain our pharmacy operations, or market acceptance of compounding pharmacies generally may be curtailed or delayed.

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

USC's 503B outsourcing facility operations must continually adhere to (i) applicable cGMP requirements, which are issued and enforced by the FDA through regulations and guidance and interpreted and enforced through its inspection programs, and (ii) sterile product requirements under applicable state law, such as General Chapter <797> ("USP <797>"), published by the U.S. Pharmacopeia or USP Convention, a scientific standard-setting organization, which have been codified in many states and which have historically been enforced by applicable state boards of pharmacy through inspection programs but are also enforceable by the FDA. In complying with applicable cGMPs and USP <797>, we must expend time, money and effort in production, record-keeping, and quality control to ensure that USC's products and services meet applicable specifications and requirements. Revisions to USP <797> have been proposed by USP, but postponed for the foreseeable future and current USP <797> remains in effect. In July 2014, the FDA issued draft guidance for cGMPs for human drug compounding outsourcing facilities, such as USC's. This draft guidance was revised in December 2018. USC has assessed this revised draft guidance and is implementing pertinent improvements or changes to its processes, procedures, policies, or facility to achieve the expected level of compliance. Because this cGMP draft guidance has not been finalized and may be significantly changed prior to being made final, we may need to expend substantial additional resources to comply with the final applicable cGMPs, along with any additional modifications over time.

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

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

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

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

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

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

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

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

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

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

The healthcare industry is changing rapidly as consumers, governments, medical professionals and the pharmaceutical industry examine ways to broaden medical coverage while controlling the increase in healthcare costs. Such changes could include changes to make the government's Medicare reimbursement programs more restrictive, which could limit or curtail the potential for USC's formulations to obtain eligibility for reimbursement from such payors, or changes to expand the reach of HIPAA or other health privacy laws, which could make compliance with these laws costlier and more burdensome. Further, the Health Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could adversely affect USC's or our business. Any changes to laws and regulations affecting the healthcare industry could impose significant additional costs on USC's and our operations in order to maintain compliance or could otherwise negatively affect USC's or our business, financial conditions or results of operations.

Risks Related to Our Common Stock

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

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

The price of our common stock may be volatile.

The market price of our common stock may fluctuate substantially. For example, from January 2018 to June 30, 2020, the market price of our common stock has fluctuated between $0.27 and $5.10. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

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

- our filing for protection under federal bankruptcy laws;
- a negative outcome in any litigation or potential legal proceeding;
- effect of public health crises, pandemics and epidemics, such as the coronavirus COVID-19 outbreak; or
- other potentially negative financial announcements, such as a review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC.

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

Trading of our common stock is limited.

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

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.

There is no assurance that we will be able to maintain compliance with NASDAQ continued listing standards, and Nasdaq has the ability to suspend trading in our common stock or remove our common stock from listing on the Nasdaq Capital Market for a variety of reasons under its continued listing standards. Any delisting from Nasdaq could result in further reductions in the market prices of our common stock, substantially limit the liquidity of our common stock, and materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from the Nasdaq Capital Market could also have other negative results, including the potential loss of institutional investor interest and fewer business development opportunities. In the event of a delisting, we would attempt to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

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, exercise of outstanding warrants, issuance of shares following vesting of outstanding restricted stock units, and sale of the shares issuable upon conversion of such notes, exercise of such warrants or vesting of such restricted stock units, or other events that cause stockholders to sell shares, could place downward pressure on the trading price of our stock. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock. If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our common stock in the public market, the market price of our common stock could decline. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

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

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

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

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

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

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

As of June 30, 2020, we had 73,920,765 shares of common stock issued and outstanding, substantially all of which we believe may be sold publicly, subject in some cases to volume and other limitations, provisions or limitations in registration rights agreements, or prospectus-delivery or other requirements relating to the effectiveness and use of registration statements registering the resale of such shares.

As of June 30, 2020, we had reserved for issuance 7,238,761 shares of our common stock issuable upon the exercise of outstanding stock options under our equity incentive plans at a weighted-average exercise price of $4.35 per share, we had outstanding restricted stock units covering 2,534,107 shares of common stock, and we had outstanding exercisable warrants to purchase 15,934,670 shares of common stock at a weighted-average exercise price of $1.50 per share, excluding the 8,700,000 warrants issued in February 2020 that are not currently exercisable as of the date of this Report, see Note 12 to the consolidated financial statements included elsewhere herein. 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. In addition, there are 1,000,000 shares of Series B Preferred outstanding which are convertible into 1,000,000 shares of Common Stock following the occurrence of certain future events.

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

As of June 30, 2020, we had outstanding warrants, other than the warrants described in the next sentence, to purchase 58,824 shares of common stock, at an exercise price of $8.50 per share. As of June 30, 2020, 8,700,000 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants, after the date that such warrants first become exercisable, at an exercise price of $0.70 per share, that we issued in a private placement transaction in February 2020; and 15,875,846 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants that we issued in the following transactions: warrants to purchase 1,183,432 shares at an exercise price of $4.10 per share in our January 2016 Series A-1 Convertible Preferred Stock transaction; warrants to purchase 192,414 shares at an exercise price of $2.90 per share in our July 2016 Series A-2 Convertible Preferred transaction; 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; and warrants to purchase 13,800,000 shares of our common stock at an exercise price of $1.15 per share in our August 2019 underwritten public offering of common stock and warrants.

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

Based on the number of outstanding shares of our common stock held by our stockholders as of June 30, 2020, our directors, executive officers and their respective affiliates owned approximately 1.2% of our outstanding shares of common stock and based on a Schedule 13G filed February 28, 2020, our largest stockholder owned approximately 7.9% of the outstanding shares of our common stock as of such date. As a result, those stockholders have the ability to exert a significant degree of influence with respect to the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. The interests of these persons may not always coincide with our interests or the interests of our other stockholders. This concentration of ownership could harm the market price of our common stock by (i) delaying, deferring or preventing a change in corporate control, (ii) impeding a merger, consolidation, takeover or other business combination involving us, or (iii) discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

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

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

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. In the future, our management may determine that our disclosure controls and procedures are ineffective or that there are one or more material weaknesses in our internal controls over financial reporting, resulting in a reasonable possibility that a material misstatement to the annual or interim financial statements would not have been prevented or detected. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Efforts to correct any material weaknesses or deficiencies that may be identified could require significant financial resources to address. Moreover, if remedial measures are insufficient to address the deficiencies that are determined to exist, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements could contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, and we could become subject to class action litigation. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. We can give no assurance that any material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or adequate disclosure controls and procedures or circumvention of these controls. In addition, controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could decline. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, the Nasdaq Stock Market or other regulatory authorities.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

Information concerning our sales of unregistered securities during the quarter ended June 30, 2020, has previously been reported in reports on Form 8-K that we filed during that quarter.

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.

3.1	Certification of Designation. (1)
3.2	Bylaws of the Company. (2)
4.1	Description of the Registrant's Common Stock. (5)
10.1*+	Termination and Transfer Agreement between Sandoz Inc. and the Company.
10.2*+	Transition Service Agreement between USWM, LLC, the Company and Sandoz Inc. dated May 11, 2020.
10.3*+	License Agreement between the Company and Matrix Biomed, Inc.
10.4**	Adamis Pharmaceuticals Corporation Bonus Plan. (3)
10.5	Promissory Note dated April 10, 2020. (4)
10.6*	Distribution and Commercialization Agreement between the Company and USWM, LLC.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the SEC.

** Represents a compensatory plan or arrangement.

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

(1) Incorporated by reference to Exhibit 3.1 filed with the Report on Form 8-K filed with the Commission on June 6, 2020.

(2) Incorporated by reference to Exhibit 3.1 filed with the Report on Form 8-K filed with the Commission on June 22, 2020.

(3) Incorporated by reference to Exhibit 10.1 filed with the Report on Form 8-K filed with the Commission on June 22, 2020.

(4) Incorporated by reference to Exhibit 10.1 filed with the Report on Form 8-K filed with the Commission on April 15, 2020.

(5) Incorporated by reference to Exhibit 4.6 filed with the Report on Form 8-K filed with the commission on June 22, 2020.

SIGNATURES

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

ADAMIS PHARMACEUTICALS, INC.

Date: August 17, 2020

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

Date: August 17, 2020

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

Exhibit 10.1

***** Certain identified information has been omitted from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed. Such omitted information is indicated by brackets ("[…***…]" in this exhibit. *****

TERMINATION AND TRANSFER AGREEMENT

This Termination and Transfer Agreement (this "**Agreement**") is made and entered into as of May 11, 2020 (the "**Effective Date**") by and between Adamis Pharmaceuticals Corporation ("**Adamis**"), 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. ("**Sandoz**") with an address at 100 College Road, West Princeton, NJ 08540. Sandoz and Adamis may each be referred to herein as a "**Party**" or, collectively, as the "**Parties**."

WHEREAS, the Parties previously entered into a Distribution and Commercialization Agreement effective as of July 1, 2018 (the "**Commercialization Agreement**");

WHEREAS, the Parties desire to terminate the Commercialization Agreement on the Termination Date (defined herein) and enter into this Agreement to provide for the transition of certain materials and activities to Adamis on or prior to the Termination Date; and

WHEREAS, all capitalized terms used but not defined herein shall have the meanings ascribed to them in the Commercialization Agreement.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Termination. Notwithstanding anything to the contrary contained in the Transition Services Agreement, the Commercial Agreement is hereby terminated, effective as of the Termination Date.

2. Transfer. During the period beginning on the date hereof and ending on [***] (the "**Termination Date**"), the Parties shall use Commercially Reasonable Efforts to transition to Adamis [***] (the "**Transfer Period**"). Without limiting the generality of the foregoing, during the Transfer Period:

(a) Upon the date hereof Sandoz shall provide to Adamis [***].

(b) Sandoz shall use Commercially Reasonable Efforts to transfer to Adamis ownership and control of all Marketing Materials produced as of the Effective Date and before the Termination Date by or on behalf of Sandoz, its Affiliates and relating to the Products and any other materials, as set forth on Exhibit A. "**Marketing Materials**" includes all marketing materials relating to the Products including, without limitation, [***]. Adamis agrees that it or its designee shall [***].

(c) Prior to the Termination Date, Sandoz and Adamis, or Adamis' designee, will use commercially reasonable efforts to enter into a Transition Services Agreement for the post termination period. The Transition Services Agreement shall address such issues as [***]. If, for any reason, the parties are unable to reach agreement on and execute the Transition Services Agreement prior to the Termination Date, the terms of the Commercialization Agreement shall remain in full force and effect until the date that the Transition Services Agreement is executed by the parties thereto, and the Termination Date shall be extended until such date. During any such extension Sandoz shall not be required to [***] and will continue to [***]. Notwithstanding the foregoing, should the Parties be unable to reach agreement on and execute the Transition Services Agreement within [***] of the Effective Date of this Agreement, then the Commercialization Agreement shall be terminated [***] with no further obligations of either Party to negotiate further.

3. Consequences of Termination. Notwithstanding anything to the contrary contained in the Commercialization Agreement:

(a) On the Termination Date, the licenses granted to Sandoz under the Commercialization Agreement shall immediately terminate and be of no further force and effect, except as needed to provide services under the Transition Services Agreement and as set forth therein.

(b) Sandoz hereby assigns to Adamis all right, title, and interest in and to the Marketing Materials created or controlled by Sandoz for the Products subject to the requirements of section 2(b).

(c) Post Termination True-Up: [***] after the Termination Date, Sandoz shall perform a "true-up" reconciliation of the items comprising deductions from Net Sales. The reconciliation shall be based on [***]. Sandoz shall provide Adamis with a written report of such reconciliation. If the foregoing reconciliation report shows either an underpayment or an overpayment between the Parties, the Party owing the payment to the other Party shall pay the amount of the difference to the other Party within [***] after the date of delivery of such report. This provision shall survive expiration or termination of this Agreement in accordance with the terms hereof.

(d) Notwithstanding anything to the contrary contained in the Commercialization Agreement, only the following provisions of the Commercialization Agreement shall survive the termination of the Commercialization Agreement: [***].

All other provisions of the Commercialization Agreement that do not expressly survive termination pursuant to Section 3(c) hereof shall terminate.

4. Mutual Release. Except for those Claims covered by the surviving indemnities set forth in [***]:

(a) Adamis hereby releases and discharges Sandoz and any and all of its parent companies, subsidiaries, affiliates, predecessors, and/or successors, and any and all past or present directors, officers, representatives, principals, employees, insurers and attorneys, assigns of any of the foregoing, from any and all claims, demands, liabilities, actions, rights, obligations, and causes of actions of any nature, whether accrued or unaccrued, discovered or undiscovered, asserted or unasserted, direct or indirect, whether arising in law or at equity, in any way arising out of or relating to or in connection with any Commercialization Agreement, the Products and any obligations of Sandoz under the Commercialization Agreement, which they ever had, now have, or ever shall have; provided, however, that nothing contained herein shall be construed to release any claims that Adamis may have against Sandoz for breach of this Agreement.

(b) Sandoz hereby releases and discharges Adamis and any and all of its parent companies, subsidiaries, affiliates, predecessors, and/or successors, and any and all past or present directors, officers, representatives, principals, employees, insurers and attorneys, assigns of any of the foregoing, from any and all claims, demands, liabilities, actions, rights, obligations, and causes of actions of any nature, whether accrued or unaccrued, discovered or undiscovered, asserted or unasserted, direct or indirect, whether arising in law or at equity, in any way arising out of or relating to or in connection with any Commercialization Agreement, the Products, and any obligations of Adamis under the Commercialization Agreement, which they ever had, now have, or ever shall have; provided, however, that nothing contained herein shall be construed to release any claims that Sandoz may have against Adamis for breach of this Agreement or against Adamis or any third party for a breach of the Transition Services Agreement.

5. Entire Agreement; Amendments. This Agreement, the Commercialization Agreement and the Schedules, Appendices and Exhibits hereto and thereto constitute the entire agreement of the Parties with respect to the subject matter hereof and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral. In the event of any conflict between the terms of this Agreement and the Commercialization Agreement, this Agreement shall control. This Agreement may be amended or modified only by a written instrument duly executed by authorized representatives of both Parties hereto.

6. Waivers. No delay or failure on the part of a Party in exercising or enforcing any right under this Agreement shall impair or be construed as a waiver of any such right, or be construed as a waiver of any default, or shall affect the right of such Party thereafter to enforce each and every provision of this Agreement in accordance with its terms, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All waivers must be in writing and shall be effective only to the extent specifically set forth in writing, and no course of dealing among the Parties shall be deemed a waiver hereunder.

7. Severability. If any provision of this Agreement is found to be unenforceable, the remainder shall be enforced as fully as possible and the unenforceable provision shall be deemed modified to the limited extent required to permit its enforcement in a manner most closely representing the intention of the parties as expressed herein.

8. Successors and Assigns. Neither Party may assign this Agreement without the prior written consent of the other Party, except that this Agreement and all of its rights and obligations may be assigned by either Party in connection with a Change in Control, or in connection with the sale of all or substantially all of the assets to which this Agreement relates. Any purported assignment in violation of this Section shall be null and void and of no effect. No assignment will release either Party from responsibility for the performance of any accrued obligation of such Party hereunder. This Agreement will be binding upon and enforceable against the successor to or any permitted assignee of either of the Parties.

9. Notices. All communications, notices, instructions and consents provided for herein or in connection herewith shall be given in accordance with Section 16.5 of the Commercialization Agreement to the applicable address set forth above.

10. Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, including all matters of construction, validity and performance, in each case without reference to any conflict of law rules that might lead to the application of the laws of any other jurisdiction.

11. Exclusive Jurisdiction. Adamis and Sandoz agree to irrevocably submit to the exclusive jurisdiction of (a) the state courts of New York County, New York, U.S.A., or (b) 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 US. registered mail or recognized international courier service to such Party's respective address set forth herein 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. Counterparts; Electronic Signatures. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

ADAMIS PHARMACEUTICALS CORP.	**SANDOZ INC.**
By: /s/ Dennis J. Carlo	By: /s/ Karen McDonnell
Name: Dennis J. Carlo	Name: Karen McDonnell
Title: Chief Executive Officer	Title: VP & General Counsel

Exhibit 10.2

***** Certain identified information has been omitted from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed. Such omitted information is indicated by brackets ("[…***…]" in this exhibit. *****

TRANSITION SERVICES AGREEMENT

BETWEEN

USWM, LLC,

ADAMIS PHARMACEUTICALS CORPORATION,

AND

SANDOZ INC.

June 1, 2020

TRANSITION SERVICES AGREEMENT

This Transition Services Agreement (the "Agreement") is entered into as of June 1, 2020 (the "Effective Date"), by and between Adamis Pharmaceuticals Corporation, a Delaware corporation, with an office located at 11682 El Camino Real, Suite #300, San Diego, CA 92130 ("Adamis"), USWM, LLC, a Delaware limited liability company, with an office at [***] ("USWM") and Sandoz Inc., a Colorado corporation, with offices at 100 College Road West, Princeton, New Jersey 08540 ("Sandoz"). Adamis, USWM and Sandoz are each referred to individually as a "Party" and together as the "Parties".

RECITALS

WHEREAS, USWM and Adamis are parties to that certain Distribution and Commercialization Agreement dated as of May 11, 2020, pursuant to which USWM agreed, *inter alia*, to purchase certain Products from Adamis for distribution and commercialization.

WHEREAS, Sandoz and Adamis are parties to that certain Termination and Transfer Agreement, dated May 11, 2020 (as such agreement may be amended from time to time, the "Termination Agreement"), terminating the Distribution and Commercialization Agreement between the Parties, dated July 1, 2018 (the "Commercialization Agreement") with a termination effective on the date hereof.

WHEREAS, the Termination Agreement provides, among other things, that Sandoz and Adamis, or Adamis' designee, will use commercially reasonable efforts to enter into a Transition Services Agreement to address certain rights with respect to [***] (the "Distribution Products") following the Effective Date and during the applicable Transition Term.

WHEREAS, in order to ensure business continuity and to facilitate an effective transition of the Distribution Products to Adamis, Adamis and USWM desire to receive from Sandoz certain services and support in the Territory for a specified period beginning on the Effective Date and continuing for the Transition Term for each Service as set forth in the Transition Services Schedule.

WHEREAS, the services and support described in this Agreement are in addition to those actions required under the Termination Agreement.

NOW, THEREFORE, in consideration of the foregoing and the covenants and agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

ARTICLE I
DEFINITIONS

The capitalized terms used in this Agreement shall have the meanings as defined in this ARTICLE I.

"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.

"Agreement" shall have the meaning set forth in the preamble to this Agreement.

"Applicable Laws" means all laws, ordinances, rules and regulations applicable to the Parties' activities under this Agreement, 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 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; and (c) cGMP, as may be amended from time-to-time.

"Termination Agreement" shall have the meaning set forth in the recitals.

"Adamis" shall have the meaning set forth in the preamble to this Agreement.

"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.

"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 the manufacture, processing or supply of the Distribution Products pursuant to this Agreement.

"Claim" means any claim, action, suit, demand or other legal assertion or proceeding brought by a Third Party against an indemnified party under this Agreement related to any Liability.

"Designated Representative" shall have the meaning set forth in Section 3.1.

"Distribute", "Distribution" and "Distributing" means, with respect to the Distribution Products, to market, have marketed, distribute, have distributed, offer to sell, sell, commercialize, have commercialized and otherwise exploit the Distribution Products in the Territory during the Term.

"Distribution Network" shall have the meaning set forth in the Transition Services Schedule.

"Distribution Products" shall have the meaning set forth in the recitals.

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

"Force Majeure Event" shall have the meaning set forth in Section 12.1.

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

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

"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 Services contemplated by this Agreement.

"Net Sales" shall have the meaning set forth in the Transition Services Schedule.

"Party" and "Parties" shall have the meaning set forth in the preamble to this Agreement.

"Post-Transition Term True-Up" has the meaning set forth the Transition Services Schedule.

"Product Business" means the operation and activities of the business specifically relating to the Distribution services conducted by or on behalf of Sandoz for the Distribution Products in the Territory during the Term.

"Profit" shall have the meaning set forth in the Transition Services Schedule.

"Quality Agreement" shall have the meaning set forth in the Transition Services Schedule.

"Representative(s)" shall have the meaning set forth in Section 6.3(c).

"Sandoz" shall have the meaning set forth in the preamble to this Agreement.

"Service(s)" shall have the meaning set forth in ARTICLE II.

"Term" shall have the meaning set forth in ARTICLE IV.

"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.

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

"Supply Price" means, with respect to a Distribution Product, the price set forth opposite the name of such product as more fully set forth on Annex B attached hereto.

"Transition Services Schedule" shall have the meaning set forth in ARTICLE II.

"Transition Term" shall have the meaning set forth in the Transition Services Schedule.

"USWM" shall have the meaning set forth in the preamble of this Agreement.

ARTICLE II
TRANSITION SERVICES SCHEDULE

Subject to the terms and conditions of this Agreement, beginning on the Effective Date and continuing until the end of the applicable Transition Term, Sandoz, either directly or indirectly through one or more of its Affiliates (or Third Parties, subject to the requirements of ARTICLE IX), shall provide to Adamis and USWM services described in the schedule attached hereto as Annex A (the "Transition Services Schedule"), in accordance with ARTICLE III, to ensure business continuity and to facilitate an effective transition of [***] (collectively, the "Services"). For the avoidance of doubt, this Agreement applies only to Services with respect to the Territory and not to any other country of the world. The Transition Services Schedule includes the following information: [***]. The contact information for the group or personnel providing the Service will be specified during the Term. The Transition Services Schedule shall be considered part of this Agreement and is incorporated herein by reference.

ARTICLE III
SERVICES

3.1 Services Generally; Appointment of Sandoz as Distributor.

(a) Sandoz shall provide, or cause to be provided, to Adamis and USWM the Services described herein and in the Transition Services Schedule until expiration of the applicable Transition Term, in order to [***] and facilitate the transition of the activities related to the Product Business to Adamis and USWM for each Service upon the conclusion of the applicable Transition Term for such Service. The personnel providing Services shall be qualified for the applicable assigned tasks. Each Party shall appoint one or more designated representatives to oversee and coordinate the implementation of each Service (the "Designated Representative"); provided, however, that in the absence of such specific designation, the Designated Representative for Adamis and USWM shall be [***]. Each Party shall have the right from time to time, by written notice to the other Party (including by e-mail), to change the Designated Representative listed in the Transition Services Schedule. The Designated Representative shall be responsible for coordinating the Services, as specified in the Transition Services Schedule.

(b) During the Term, subject to the rights and conditions of this Agreement, Adamis and USWM hereby grant Sandoz the exclusive right to [***]. Notwithstanding the foregoing, during the Term, Adamis and USWM shall not be permitted to [***].

3.2 Service Limitations.

(a) The Parties expressly acknowledge and agree that the obligation of Sandoz to provide transitional services following the Effective Date is limited to the Services set forth in the Transition Services Schedule and services set forth in Annex C and there exists no obligation on the part of Sandoz or any of its Affiliates to provide any other transitional or other services to Adamis and USWM.

(b) Except as provided in the Transition Services Schedule, the Services will be available for purposes of [***].

(c) Nothing in this Agreement shall require Sandoz to obtain any additional licenses, systems, personnel or operations to provide or comply with the obligations set forth in this Agreement.

(d) Notwithstanding anything to the contrary in this Agreement, Adamis and USWM acknowledge and agree that the Services shall not be resold or transferred; provided that Adamis may assign its rights hereunder in accordance with Section 14.9.

3.3 Exceptions to Obligations. The sole exceptions to the obligations of Sandoz to provide the Services as contemplated hereby are to the extent (a) Sandoz cannot provide specified Services due to a Force Majeure Event, as determined under ARTICLE XII or (b) providing the Services would be prohibited by Applicable Law.

ARTICLE IV
TERM

The term of this Agreement shall commence on the Effective Date and shall remain in effect until the expiration of the Transition Term as set forth in the Transition Services Schedule unless earlier terminated under ARTICLE VII (the "Term").

ARTICLE V
COMPENSATION

5.1 Payment for Sandoz Services. In consideration for the Services, Adamis and USWM agree that Sandoz shall be permitted to [***]. Adamis and USWM shall be responsible for the payment of [***].

5.2 Accounts and Records. Sandoz shall keep accounts and records of all activities carried out, and all costs and expenses incurred, in the performance of its obligations under this Agreement consistent with the ordinary course and past practice of Sandoz. Sandoz shall maintain, and shall provide as requested by Adamis and USWM, documentation and information reasonably requested by Adamis and USWM to support [***].

5.3 Audit. Beginning on the Effective Date and during the Term and for [***] thereafter, Adamis and USWM shall have the right, within [***] after receipt by Sandoz of written request from Adamis or USWM, to have an independent certified public accounting firm inspect Sandoz and/or its Affiliates (as applicable) records with respect to [***] for the sole purpose of determining [***]. Sandoz shall permit such independent certified public accounting firm to have reasonable confidential access, during normal business hours and upon having given reasonable prior written notice, to such records of Sandoz and/or its Affiliates (as applicable) as may be reasonably necessary to [***]. Except as otherwise provided herein, the audit shall be conducted at USWM or Adamis' expense, as applicable. In the event that an examining auditor concludes any incorrect calculation of [***], the auditor will specify such incorrect calculation [***] in a written report, along with the information on which such conclusion is based. This report will be shared promptly with Sandoz. Sandoz shall remit any corresponding underpayments or reimburse any corresponding overpayment to the underpaid or overcharged Party within [***] of the date of such report. Further, if the audit for an audited period shows an underpayment or an overcharge by any Party for that period in excess of over both [***] and [***] of the amounts properly determined, Sandoz 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.

ARTICLE VI
GENERAL OBLIGATIONS; STANDARD OF CARE; INDEMNIFICATION

6.1 Performance Standards. Sandoz shall provide or cause the Services to be provided to the Adamis and USWM, (i) [***] (taking into account [***]; and (ii) in accordance with Applicable Laws. Unless otherwise specified in the Transition Services Schedule or otherwise mutually agreed by the Parties in writing, Sandoz shall perform Services [***] (taking into account [***]. Adamis and USWM shall provide commercially reasonable resources and timely decisions, approvals and acceptances in order that Sandoz may provide the Services [***] (taking into account [***].

6.2 Responsibility for Errors; Delays. Except for damages arising out of [***], subject to the remedies detailed in this Agreement (including Article XI), Sandoz' sole responsibility to Adamis and USWM with respect to errors, omissions and delays of the Services, or failure to provide the Services, is as follows:

(a) for errors or omissions in Services, to furnish correct information, payment and/or adjustment in the Services, at no additional cost or expense; provided, that Adamis or USWM shall promptly advise Sandoz of any such error or omission of which it becomes aware after having used commercially reasonable efforts to detect any such errors or omissions in the Services furnished by Sandoz; provided, further, that Sandoz' obligation with respect to ensuring compliance with this Section 6.2(a) by its Affiliates and/or subcontractors will be limited to using its commercially reasonable efforts to assure compliance with this Section 6.2(a) by its Affiliates and/or subcontractors; and

(b) for failure of Sandoz to deliver any Service, to use commercially reasonable efforts to remedy or make the Services available and/or to resume performing the Services as promptly as reasonably practicable.

6.3 Good Faith Cooperation; Confidentiality.

(a) Subject to the terms and conditions contained herein, during the Term, the Parties will use good faith efforts to cooperate with each other to provide the Services contemplated hereby and, if necessary for the provision of such Services, shall use commercially reasonable efforts to exchange information and perform reconciliations and adjustments required to ensure business continuity and to facilitate an effective transition of the Distribution Products to Adamis and USWM, in each case subject to appropriate and customary confidentiality restrictions as the providing Party may request.

(b) The Parties will maintain, in accordance with their standard document retention procedures, documentation supporting the information relevant to [***], and will use their commercially reasonable efforts to cooperate with each other in making such information available as needed in the event of a tax audit.

(c) For purposes of this Agreement, "Confidential Information" means, with respect to a Party, all confidential and proprietary 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), and all non-public information of the other Party, 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. The Receiving Party shall (i) treat as confidential all Confidential Information of the other Party or its Affiliates that comes to the receiving Party's knowledge through this Agreement, and (ii) not use the Disclosing Party's Confidential Information, or permit it to be accessed or used, for any purpose other than to exercise its rights or perform its obligations under this Agreement. The Parties hereby acknowledge that any such Confidential Information may be used solely if and as required to perform or receive Services and other assistance pursuant to this Agreement. The Receiving Party shall restrict access to Confidential Information to those of its Affiliates and any directors, officers, employees, agents or representatives (each, a "Representative" and collectively, the "Representatives") of such Party or its Affiliates as are directly involved in the performance or receipt of the Services or other assistance pursuant to this Agreement (who may include attorneys, accountants and other consultants employed by a Party in connection with the performance or receipt of the Services or other assistance under this Agreement), it being understood that they shall be informed by the Receiving Party of the confidential nature of any Confidential Information and shall be bound by obligations of confidentiality and non-use at least as great in scope as those contained herein. Each Party shall be liable for any breach of this Agreement by any of its Representatives. The Receiving Party shall take such steps to prevent disclosure of such Confidential Information to any Third Party (except to the extent that such disclosure is necessary to provide the Services under the terms of this Agreement) as it would take in protecting its own Confidential Information and shall not use any portion of such Confidential Information for any purpose not authorized herein.

6.4 Indemnification. Each Party shall indemnify and hold the other Parties harmless from and against any Liability paid or payable by such Parties to a Third Party as a result of any Claim that results from, arises out of or is based on the negligence or willful misconduct of the indemnifying Party its officers, directors, agents, servants and employees in the performance under to this Agreement.

ARTICLE VII
TERMINATION

7.1 Termination. This Agreement shall terminate automatically upon expiration or termination of the Term. This Agreement may be terminated, in whole or in part, at any time:

(a) by the mutual consent of Adamis, USWM and Sandoz;

(b) by either Adamis, USWM, or Sandoz (provided that the terminating Party is not then in material breach of any covenant or other agreement contained herein), by written notice to the other Party, if there shall have been a material breach of any of the provisions of this Agreement by the other Party; provided, however, that a Party may only terminate the Agreement under this clause (b) if (i) such breach has not been waived by the terminating Party in writing and (ii) such breach has not been cured within [***] following the terminating Party's written notice of such breach (provided, that, if such breach cannot reasonably be cured within [***] and the breaching Party is diligently proceeding to cure such breach, such Party's cure period shall be extended for such period of time as may be reasonably required, up to [***] in the aggregate); or

(c) by either Party, by written notice to the other Party, upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if such Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] after the filing thereof.

7.2 Survival. ARTICLE V, ARTICLE X, ARTICLE XI, ARTICLE XIII, ARTICLE XIV and Sections 6.2 and this 7.2 shall survive termination of this Agreement. Notwithstanding the foregoing, in the event of any termination with respect to one or more, but less than all, Services, this Agreement shall continue in full force and effect with respect to any Services under that portion of the Transition Services Schedule not terminated.

ARTICLE VIII
REPRESENTATIONS AND WARRANTIES

8.1 Authorization. Each Party hereby represents and warrants that (a) it has the requisite power and authority to execute and deliver this Agreement and to perform the transactions contemplated hereby, (b) all corporate action on the part of such Party necessary to approve or to authorize the execution and delivery of this Agreement and the performance of the transactions contemplated hereby to be performed by it has been duly taken, (c) this Agreement is a legal, valid and binding agreement of such Party, enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors' rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing), regardless of whether considered in a proceeding in equity or at law.

8.2 No Breach or Conflict. Each Party hereby represents and warrants that (a) its execution and delivery of this Agreement and its and its Affiliates' performance of its obligations hereunder does not and shall not conflict with, result in a breach of, constitute a default under, or require the consent of any Third Party under, any license, sublicense, lease, contract, agreement, or instrument to which it or any of its Affiliates is bound, and (b) it has obtained all Third Party consents, authorizations and approvals from any Third Party licensor or contractual counterparty or any other Third Party that is necessary to perform its obligations hereunder.

8.3 Compliance with Applicable Law. Each Party hereby represents and warrants that it shall perform its obligations under this Agreement in a manner that complies with all Applicable Laws.

8.4 Compliance with Good Manufacturing Practices. Sandoz hereby represents and warrants that it shall manufacture and store the Distribution Products in a manner that complies with cGMP.

ARTICLE IX
SUBCONTRACTORS

Subject to Section 3.1, any Party hereto may engage a Third Party or an Affiliate to perform all or any portion of its duties under this Agreement provided that: (a) any such Third Party agrees in writing to be bound by confidentiality obligations and (b) the Party so engaging a Third Party remains responsible for the performance of each such Third Party or Affiliate, and the compliance of each such Third Party and Affiliate with all applicable provisions of this Agreement.

ARTICLE X
INTELLECTUAL PROPERTY

The Parties do not anticipate that this Agreement or the performance of Services will affect the ownership of the intellectual property rights of either Party.

ARTICLE XI
LIMITATION OF LIABILITY; INDEMNIFICATION

11.1 Limitation of Liability. NO PARTY SHALL BE LIABLE TO OR OTHERWISE RESPONSIBLE TO ANY OTHER PARTY HERETO OR ANY AFFILIATE OF ANY OTHER PARTY HERETO FOR ANY INCIDENTAL, SPECIAL, CONSEQUENTIAL, INDIRECT, EXEMPLARY OR PUNITIVE DAMAGES THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF, WHETHER SUCH DAMAGES OR OTHER RELIEF ARE SOUGHT BASED ON BREACH OF CONTRACT, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER LEGAL OR EQUITABLE THEORY AND WHETHER OR NOT THE PARTY WAS AWARE OR ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING SHALL NOT APPLY TO (A) DAMAGES RESULTING FROM A PARTY'S FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, OR (B) THE PARTIES' RESPECTIVE INDEMNIFICATION OBLIGATIONS SET FORTH IN THE TERMINATION AGREEMENT.

11.2 Exclusive Remedy. Except as set forth in Section 6.2 of this Agreement, the sole and exclusive remedy for any and all Claims arising under, out of, or related to this Agreement and the transactions contemplated hereby shall be the rights of indemnification set forth in Section 6.4 of this Agreement only, and no Person will have any other entitlement, remedy or recourse, whether in contract, tort or otherwise, it being agreed that all of such other remedies, entitlements and recourse are expressly waived and released by the Parties hereto to the fullest extent permitted by Applicable Law.

ARTICLE XII
FORCE MAJEURE

12.1 Force Majeure Event. Neither Party nor any of its Affiliates (nor any Person acting on its or their behalf) shall bear any responsibility or liability for any losses arising out of any delay, inability to perform or interruption of its performance of obligations under this Agreement due to events beyond the reasonable control of such Party or its Affiliates (or any Person acting on its or their behalf) for a Force Majeure Event (as defined below). In such event, the obligations hereunder of Sandoz in providing the impacted Service or performing its obligations under this Agreement, and the obligation of Adamis to pay for the same, shall be postponed for such time as its performance is suspended or delayed on account thereof but only to the extent that the Force Majeure Event prevents the affected Party (or its affected Affiliate(s)) from performing its duties and obligations hereunder. During the duration of the Force Majeure Event, the affected Party shall use all commercially reasonable efforts to avoid or remove such Force Majeure Event and shall use all commercially reasonable efforts to resume its performance under this Agreement with the least practicable delay. A "Force Majeure Event" means any event which is beyond the reasonable control of the Party affected, including the following events: earthquake, storm, flood, fire or other acts of nature, epidemic, war, riot, public disturbance, strike or lockouts, government actions, terrorist attack or the like.

ARTICLE XIII
GOVERNING LAW

13.1 Governing Law; English Language. This Agreement shall be governed, interpreted and construed in accordance with the substantive laws of the State of Delaware, U.S.A., without regard to its conflict of laws principles. In the event any translation of this Agreement is prepared for convenience or for any other purpose, the provisions of the English version shall prevail.

13.2 Arbitration. Any disputes arising out of or in connection with this Agreement shall be resolved by final and binding arbitration before a panel of one arbitrator with relevant industry experience. The arbitration proceeding shall be administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("**AAA**"), and the panel of arbitrators shall be selected in accordance with such rules. The arbitration and all associated discovery proceedings and communications shall be conducted in English, and the arbitration shall be held in a reasonable location to be selected by the Party against whom arbitration is compelled. The legal place of arbitration shall be New York, NY, USA. The language of the arbitration shall be English.

ARTICLE XIV
MISCELLANEOUS

14.1 Expenses. Except as otherwise specified in this Agreement or the Transition Services Schedule, all costs and expenses, including fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement and the transactions contemplated hereby or thereby will be paid by the Party incurring such costs and expenses.

14.2 No Third Party Beneficiaries. Except as specifically provided herein, this Agreement is not intended to confer upon any Person other than the Parties hereto any rights or remedies hereunder.

14.3 Entire Agreement. This Agreement, the Termination Agreement, the other Ancillary Agreements and the Transition Services Schedule hereto constitute the entire agreement among, and supersede all prior agreements and understandings, both written and oral, between or among the Parties with respect to the subject matter hereof. Notwithstanding the above, nothing in this Agreement shall be deemed to modify or otherwise amend the rights and obligations of the Parties in the Termination Agreement and to the extent there is deemed to be a conflict between this Agreement and the Termination Agreement, the provisions of the Termination Agreement, as applicable, shall control. In the event of any conflict between the terms of this Agreement and the Annexes hereto, the terms of the Annexes shall govern.

14.4 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original but all of which, taken together, shall constitute one and the same instrument. PDF and facsimile signatures shall constitute original signatures. The Parties agree that any 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.

14.5 Headings. The headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement.

14.6 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 (a) on the date delivered, if personally delivered, (b) on the date sent by telecopier with automatic confirmation by the transmitting machine showing the proper number of pages were transmitted without error, (c) on the Business Day after being sent by Federal Express or another recognized overnight mail service which utilizes a written form of receipt for next day or next Business Day delivery or (d) three (3) Business Days after mailing, if mailed by U.S. 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 Adamis, to:

Adamis Pharmaceuticals Corporation
11682 El Camino Real, Suite 300
San Diego, California 92130
Attention: President and CEO

If to USWM, to:

USWM, LLC
[***]
[***]
Attn: [***]

With a copy to (which shall not constitute notice)

USWM, LLC
[***]
[***]
Attn: [***]
Tel: [***]
Email: [***]

If to Sandoz to:

Sandoz Inc.
[***]
[***]
Attention: President

With a copy (which shall not constitute notice) to:

Sandoz Inc.
[***]
[***]
Attention: [***]

14.7 Amendments and Waivers. This Agreement may only be amended by an instrument in writing signed on behalf of each of the Parties. By an instrument in writing, Adamis and USWM, on the one hand, or Sandoz, on the other hand, may waive compliance by the other Party with any term or provision of this Agreement that such other Party was or is obligated to comply with or perform. The failure of any Party to assert a right hereunder or to insist upon compliance with any term of condition of this Agreement shall not constitute a waiver of that right or excuse for a similar failure to perform any such term or condition by the other Party.

14.8 Severability. Should any part or provision of this Agreement be held unenforceable or in conflict with Applicable Law, the invalid or unenforceable part or provision shall, provided that it does not affect the essence of this Agreement, be replaced with a revision which accomplishes, to the greatest extent possible, the original commercial purpose of such part or provision in a valid and enforceable manner, and the balance of this Agreement shall remain in full force and effect and binding upon the Parties hereto.

14.9 Binding Effect; Assignment. The terms and provisions hereof shall inure to the benefit of, and be binding upon the Parties and their respective successors and permitted assigns. No Party shall assign, encumber or otherwise transfer this Agreement or any part of it to any third party, without the prior written consent of the other Party which consent will not be unreasonably withheld; provided, however, that notwithstanding the foregoing, no such consent shall be required in the event of any assignment or transfer of this Agreement by either Party (a) to any of its Affiliates, or (b) to any successor in interest to such Party's business, whether by merger, sale of assets or otherwise; in the event of which a Party shall only be required to give written notice of such assignment or transfer to the other Party but will not be required to obtain the consent of the other Party. In the case of any sale, assignment, divestiture or other transfer, the assigning Party shall remain liable for the full and timely performance of the transferee.

14.10 Further Assurances and Actions. Each of the Parties, upon the request of the other Party and without further consideration, will do, execute, acknowledge and deliver, or cause to be done, executed, acknowledged or delivered, any and all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement and the Termination Agreement. Sandoz and Adamis agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement and the Termination Agreement. If requested, each Party shall confirm receipt of any notice that it receives by any of the methods of delivery described in Section 14.6.

14.11 Relationship between the Parties. The relationship between the Parties established under this Agreement is that of independent contractors, and neither Party shall be deemed an employee, agent, partner or joint venturer of or with the other. Employees of Sandoz involved in the provision of Services under this Agreement shall remain employees of Sandoz and Sandoz will be solely responsible for any employment-related taxes, insurance premiums or other employment benefits applicable to such employees.

14.12 Interpretation. For purposes of this Agreement, (a) the words "include," "includes" and "including" shall be deemed to be followed by the words "without limitation," (b) the word "or" is not exclusive and (c) the words "herein," "hereof," "hereby," "hereto" and "hereunder" refer to this Agreement as a whole. Unless the context otherwise requires, references herein: (i) to clauses or annexes mean the clauses of, and annexes to, this Agreement, (ii) to an agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof, and (iii) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. This Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the Party drafting an instrument or causing any instrument to be drafted. The annexes referred to herein shall be construed with, and be an integral part of, this Agreement to the same extent as if they were set forth herein.

14.13 Specific Performance. The Parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that the Parties shall be entitled to seek specific performance of the terms hereof.

[Signature Page Follows]

IN WITNESS WHEREOF, each Party has caused this Agreement to be executed on its behalf by its duly authorized representatives on the day and year first above written.

ADAMIS PHARMACEUTICALS CORPORATION

By: /s/ Dennis J. Carlo
Name: Dennis J. Carlo
Title: Pres/CEO
Date: 6/1/2020

USWM, LLC

By: /s/ H. Lee Warren, Jr.
Name: J. Lee Warren, Jr.
Title: COO
Date: 6/1/2020

SANDOZ INC.

By: /s/ Sheila Frame
Name: Sheila Frame
Title: VP Marketing, Market Access, and Patent Access
Date: 02-Jun-20

ANNEX A

TRANSITION SERVICES SCHEDULE

1. **Distribution Services**.

Transition Term: For the period beginning on the Effective Date and ending on [***] (the "Transition Term"). The Transition Term may be extended for an additional [***] through prior written notice by Adamis and/or USWM to Sandoz provided [***].

Description: Subject to Section 3.1(b) of this Agreement and the transactions contemplated in the Termination Agreement, Sandoz or its Affiliates shall [***]; provided, that, notwithstanding anything to the contrary in this Agreement, Sandoz shall not [***] (i) [***] or (ii) [***]. Sandoz or its Affiliates shall [***]. Sandoz and USWM shall [***]. The Parties shall be permitted to [***]. At the conclusion of the Transition Term Sandoz may [***].

Distribution Products: List provided on Annex B.

Cost: During the Transition Term, subject to Section 3.1(b), Adamis, USWM and/or their respective Affiliates and designees are not authorized to [***]. As such, Sandoz or its Affiliates shall [***]. Sandoz shall [***], where [***] is calculated as follows [***]:

a) [***];

b) [***]; and

c) [***].

"[***]" means, for each applicable calendar quarter during the Term, [***].

With respect to the calculation of [***]: (i) [***]; and (ii) [***]. For clarity, within sixty (60) days following the end of each [***], [***] shall pay [***]. A written summary of [***] shall be provided by [***] to [***] within [***] following the end of [***].

Additional Costs: [***] shall bear [***], including but not limited [***] for (a) [***]; and (b) [***].

"Post Transition Term True-Up": [***] after the end of the Term, Sandoz shall perform a "true-up" reconciliation of the items comprising [***] (the "Post-Transition Term True-Up"). The reconciliation shall be based on [***]. Sandoz shall provide USWM with a written report of such reconciliation. If the foregoing reconciliation report shows either an underpayment or an overpayment between the Parties, the Party owing the payment to the other Party shall pay the amount of the difference to the other Party within [***] after the date of delivery of such report. This provision shall survive expiration or termination of this Agreement in accordance with the terms hereof.

Transition Term Orders: Except as otherwise set forth herein, USWM shall be responsible for [***]. [***] shall [***] and [***] shall [***]. The [***] shall be issued to [***] prior to [***]. For the avoidance of doubt, other than with respect to [***], [***] shall not [***]. For purposes of clarity, with respect to [***] (i) [***] shall only be responsible for the invoice associated with 9,000 units from batch EP0035, and (ii) [***] shall be responsible for [***].

Quality Agreement: The Quality Agreement between the parties shall remain in full force and effect until [***].

Labelling; Packaging: The Parties acknowledge and agree that [***]. Notwithstanding the foregoing, [***] shall make any changes during [***] to [***]; provided, that [***] shall [***]. For the avoidance of doubt, [***] shall be under no obligation to [***].

Designated Representatives:

Sandoz Representative: [***]

Adamis Representative: [***]

USWM Representative: [***]

Exhibit 10.3

***** Certain identified information has been omitted from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed. Such omitted information is indicated by brackets ("[…***…]" in this exhibit. ******

LICENSE AGREEMENT

This License Agreement ("**Agreement**") is entered into by and between Matrix Biomed, Inc. ("**Licensor**"), a Delaware corporation having a place of business at 2301 Dupont Drive, Suite 420, Irvine, California 92612, and Adamis Pharmaceuticals ("**Licensee**"), a Delaware corporation having a principal place of business at 11682 El Camino Real, Suite 300, San Diego, California 92130. Licensor and Licensee may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

RECITALS

A. Licensor has built a portfolio of intellectual property for the use of the drug Tempol for [***] ("**Tempol**") in various.

B. Licensor will license patents and know-how that relate to using the drug Tempol for COVID-19 infection, respiratory syncytial virus infection, influenza infection, and asthma, as well as a therapeutic for radiation-induced dermatitis.

C. Licensee is a specialty biopharmaceutical company focused on developing and commercializing pharmaceutical products.

D. Licensee wishes to acquire a world-wide, exclusive*, license to the Licensed Patents and Related Know How (as defined below) solely for the purpose of developing, producing and selling Licensed Products within the Licensed Field of Use (as defined below).

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Definitions. As used in this Agreement, the following terms shall have the meanings set forth below:

1.1 "Affiliate" means any person or entity that owns or controls, is owned or controlled by, or is under common control with the Licensee, where, for purposes of this definition, the term "control" means the possession, direct or indirect, or the powers to direct or cause the direction of the management and policies of an entity, whether through ownership of voting securities, by contract or otherwise.

1.2 "Claim" shall, unless otherwise specified, mean an issued claim in any of the patents licensed hereunder which read on the Licensed Product, which claim has not lapsed, been disclaimed, cancelled or become abandoned and which claim has not been declared invalid or unenforceable by a final decision of a court of competent jurisdiction or other appropriate body of competent jurisdiction and which decision is not subject to appeal or reversal by a higher court or body.

1.3 “Confidential Information” means all information concerning the business and proprietary affairs of a Party which a reasonable person would understand to be confidential, including, without limitation, product specifications, data, know-how, formulae, compositions, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current, and planned research and development, current and planned manufacturing or distribution methods and processes, market studies, business plans, computer software and programs (including object code and source code), computer software and database technologies, systems, structures and architectures (and related processes, formulae, composition, devices, inventions, discoveries, concepts, ideas, designs, methods and information); provided, however, that Confidential Information shall not include (a) information that is in the public domain at the time it is disclosed to a receiving Party or enters the public domain through no fault of a receiving Party; (b) information lawfully obtained by a receiving Party from a third party not in breach of any obligation of confidentiality or non-use to a disclosing Party; (c) information already known to a receiving Party at the time of disclosure by a disclosing Party as shown by contemporaneous documentation acknowledging same; and (d) information furnished to others by a Party intended not to have restriction on disclosure.

1.4 “Effective Date” means the date this Agreement has been signed by all Parties hereto.

1.5 “IND” means Investigational New Drug application relating to the use of Tempol in the Licensed Field of Use that is owned or controlled by Licensor.

1.6 “Insolvent” and “Insolvency” means the inability of a person to pay their debts as such debts become due in the ordinary course of business.

1.7 “Licensed Field of Use” means the use of the drug Tempol for COVID-19 infection, respiratory syncytial virus infection, and influenza infection, asthma, as well as a therapeutic for radiation-induced dermatitis.

1.8 “Licensed Patent(s)” means (i) the patent and patent application listed on Exhibit A, hereto, for using the drug Tempol for the License Field of Use, as defined in Section 1.7; and (ii) any patents licensed from [***] pursuant to [***] attached hereto as Exhibit B, for [***].

1.9 “Licensed Product(s)” shall mean any product, device, system, apparatus, kit, component, method, procedure, application, process or service the manufacture, use, sale, offer for sale, commercialization, exploitation, disposition, practice or import which is the subject of the licenses granted in this Agreement within the Licensed Field of Use or utilizes the Related Know How.

1.10 “Licensed Territory” means the world.

1.11 "Net Sales" means the gross invoice sales price or other gross consideration received from the Sale of Licensed Products by Licensee, less (a) sales, transfer, and all other taxes or excises; (b) returns and refunds; (c) discounts, allowances and/or rebates; and (d) commissions paid to selling agents. For clarity, Net Sales does not include Licensed Products that are Otherwise Disposed Of.

1.12 "Non-affiliate" shall mean any person or entity that is not otherwise the Licensee or an Affiliate.

1.13 "Otherwise Disposed Of" means not Sold, but delivered to others without receipt of any consideration such as when product is distributed for use in research, product development, clinical or other experimental non-commercial trials.

1.14 "Prosecution Matters" mean those steps taken in an effort to have a patent registration issued by the relevant registration authority, including, without limitation, the drafting and filing of the initial application and the drafting and filing of any responses to office actions or other communications from the relevant registration authority.

1.15 "Regulatory Body" means a governmental body such as the United States Food and Drug Administration or other legally-recognized entity that must approve or otherwise license the manufacture, use, testing or sale of a Licensed Product in any jurisdiction in the Licensed Territory.

1.16 "Related Know How" shall mean Licensor's unpatented know how, technical data, Trade Secrets, or other information of any kind, owned or licensed by Licensor, which is directly within the Licensed Field of Use, but which is not the subject of an issued patent within the Licensed Patents.

1.17 "Sale" or "Sold" means to sell or lease for consideration Licensed Products.

1.18 "Tempol" means [***].

1.19 "Trade Secrets" means data, formulae, compositions, processes, graphs, samples, forms, inventions and ideas, existing vendor and supplier lists or prospective vendor and supplier lists, pricing and cost data, market studies, business plans, computer software and programs (including object code and source code), database technologies, systems, structures and architectures (and related processes, formulae, composition, improvements, devices, inventions, discoveries, concepts, ideas, designs, methods and information), and any other information, however documented.

2. Term and Termination.

2.1 Term. This Agreement shall become effective as of the Effective Date. Unless terminated earlier in accordance with this Section 2, this Agreement shall terminate on the expiration of the last to expire of the patents licensed herein, or if later on the abandonment of the last to be abandoned patent application licensed herein (such period of time from the Effective Date until the date of termination being referred to herein as the "**Term**"). For the purpose of this Agreement, "abandonment" is defined with reference to 37 C.F.R. Sections 1.135, 1.138 or any applicable equivalent foreign patent provisions.

2.2 Termination by Licensor. In addition to its rights to enforce the provisions of any other Section of this Agreement, Licensor shall have the right, at its option, to terminate this Agreement, in accordance with the procedures set forth in Section 2.5, on the occurrence of any one or more of the following events after delivery to Licensee of a written notice specifying such event and the passage of the applicable cure periods specified herein or in the absence of specified cure periods, the failure to remedy such breach within [***] of notice thereof:

2.2.1 On the material breach of or default of this Agreement by Licensee; or

2.2.2 If Licensee fails to [***].

2.2.3 For purposes of Section 2.2.1, a material breach or default of this Agreement shall include, but not be limited to, each of the following: (i) Licensee attempts to [***]; (ii) or failure by Licensee to [***].

2.3 Termination by Licensee.

2.3.1 In addition to its rights to enforce the provisions of any other Section of this Agreement, Licensee shall have the right, at its option, to terminate this Agreement, in accordance with the procedures set forth in Section 2.5, on Licensor's material breach and Licensor's failure to remedy any such material breach within [***] after written notice thereof by Licensee.

2.3.2 In addition, without limiting the forgoing and notwithstanding anything to the contrary, including Section 2.5 below, Licensee may within its sole discretion terminate this Agreement at any time without cause or for its own convenience upon providing [***] written notice to Licensor. Upon such a termination for convenience or without default, the Licensee may cease the payment of any future payments or fees under this Agreement; provided, however, that Licensee shall remain liable for any pre-termination obligations under this Agreement.

2.4 Termination Upon Licensee Failing to [***]. Licensee hereby covenants and agrees that it shall [***]. In the event of any breach under this Section 2.4 [***] provided, however, that Licensee shall remain liable for any pre-termination obligations under this Agreement.

2.5 Exercise of Rights by Terminating Party. With the exception for Section 2.4 herein, the Party terminating this Agreement (the "**Terminating Party**") may exercise its right of termination, only after giving all notices described herein and the expiration of all cure periods, if any, by giving the other Party, or its trustees, receivers or assigns, as the case may be (the "**Non-Terminating Party**"), [***] prior written notice of such Terminating Party's election to terminate (unless a shorter or longer period is specified in a provision of this Agreement). Such notice shall include a brief description of the basis for such termination, but any inadequacy in the description claimed by the Non-Terminating Party will not be cause to deny a termination. On expiration of such period, this Agreement shall automatically terminate, unless the Non-Terminating Party has elected to pursue the resolution of any controversy in accordance with Section 11 hereof within the applicable cure period, in which event the question of whether the Terminating Party is entitled to terminate this Agreement shall be determined by the dispute resolution process as provided in Section 11 and this Agreement shall not be terminated by the Terminating Party until such process has finally determined that the Terminating Party is entitled to terminate this Agreement.

2.6 Effect of Termination. Upon termination of this Agreement by either Party or due the expiration of the Term, all license rights granted hereunder will terminate and all rights to use the drug Tempol in the Licensed Field of Use will revert back to Licensor.

3. Licenses.

3.1 License Grants. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee, an exclusive* royalty-free license under the Licensed Patents and Related Know-How, solely within the Licensed Field of Use, in order to make, have made, use, offer to sell, sell, import, manufacture, practice and otherwise exploit, dispose of and commercialize the Licensed Products solely within the Licensed Field of Use in the Licensed Territory.

Licensor will solely own any and all patents and patent applications related to Tempol that are now existing or derived from work under this Agreement. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee, an exclusive royalty-free license to any patent and patent applications derived from work under this Agreement and an exclusive royalty-free license in the Related Know-How to the extent not otherwise within the scope of the exclusive grant to the patent and patent applications derived from work under this Agreement, in order to make, have made, use, offer to sell, sell, import, manufacture, practice and otherwise exploit, dispose of and commercialize the Licensed Products solely within the Licensed Field of Use in the Licensed Territory.

*As used herein "exclusive" excludes [***].

3.2 Sublicensing. The Licensee may not sublicense the license it is granted hereunder without the express written consent of the Licensor, which may be withheld or granted in its sole discretion. Any sublicense of this license granted hereunder must be pursuant to a separate written agreement signed by both the Licensor and the Licensee.

4. Initial Obligations of the Parties.

4.1 Licensee.

4.1.1 Cash License Fee. In consideration for this license Licensee shall pay Licensor a onetime, non-refundable upfront payment (the "**Cash License Fee**") of Two Hundred Fifty Thousand U.S. Dollars ($250,000.00) payable upon execution of this Agreement by both Parties. The date Licensor receives the Cash License Fee is the "**Effective Date**". The Cash License Fee is not refundable, not creditable, and not an advance against any fees, royalties, or other monies required to be paid under the terms of this Agreement.

4.1.2 Stock License Fee. On the Effective Date Adamis will issue Matrix One Million (1,000,000) shares of its Series B Convertible Preferred Stock, with standard restrictive legends (the "**Stock Fee**"). The rights and preferences of the Series B Preferred Stock are set forth on Exhibit C, and such shares will be converted into shares of Adamis common stock. The Company will make all reasonable efforts necessary to ensure a Capital Event occurs no later than [***].

The Stock Fee is not refundable, not creditable, and not an advance any fees, royalties, or other monies required to be paid to Matrix under the terms of this Agreement.

4.1.3 Payment of Expenses by Licensee. Licensee will be responsible for funding the preclinical and clinical development related to the use of the drug Tempol for the Licensed Field of Use under the license granted by this Agreement (the "**Company Expenses**").

4.2 Licensor. Within [***] of receipt of the License Fee; Licensor shall provide the Licensee with Good Manufacturing Practice (GMP) Tempol for preclinical and/or clinical studies within the Field of Use. The Licensee will have immediate access to the information in the IND and all required regulatory documents within the Field of Use and will be able to reference all such filings and materials and any data referenced therein.

Licensee will purchase GMP-grade Tempol necessary for any preclinical or clinical work, as well as for any use in any Licensed Products, exclusively from the Licensor. The cost of the drug will be [***]. If Licensor becomes unable to provide GMP grade Tempol to Licensee for any purpose under this Agreement or licensee can produce Tempol more cost effectively, then Licensee has the right to manufacture, or have manufactured, GMP grade Tempol using a third party of their choosing. In the event Licensee is required to use a third-party manufacturer for GMP-grade Tempol under this Section, then Licensor agrees to provide Licensee with any know-how, trade secrets or other technical assistance required or useful to manufacture GMP grade Tempol.

Licensor will transfer for Licensee's future clinical trials for [***] for [***] patients [***], enough GMP-grade Tempol to conduct a clinical trial for [***], at a total cost of [***] to be paid by Licensee [***].

5. Government Approvals; Conduct of Studies. Except as set forth in Section 6 herein, Licensee will be responsible for the filings, costs and other matters related to establishing compliance of the Licensed Products with all current and future laws, statutes, rules and regulations of any Regulatory Body. Without limiting the generality of the foregoing, all studies, research and testing done by or on behalf of Licensee or Licensor, its Affiliates under this Agreement shall be performed in compliance with any applicable federal, state or local laws, rules, policies and regulations governing the conduct of the studies, research and testing.

6. Joint Research and Development Steering Committee. Licensor and Licensee shall form a Steering Committee that will meet and confer regularly, but no less than [***], to discuss technical, regulatory, clinical and business issues related to the development, testing and approval of Licensed Products. The Licensor and Licensee shall each appoint [***].

At each Steering Committee meeting the participants shall review [***]. All material decisions related to the testing and development of a Licensed Product under the terms of this Agreement must be approved by [***] including, but not limited to, decisions related to [***]. Meetings can be held in person, telephonically or by teleconference; meeting notices must be given no less than [***] in advance. At least [***] Steering Committee members must be present for a quorum to exist, however, all votes taken when less than all members are present must be [***].

As part of the expenses related to the development of the drug Tempol within the Licensed Field of Use, all members of the Steering Committee will receive compensation for all travel expenses.

7. Prosecution, Infringement and Enforcement.

7.1 Prosecution and Maintenance of Licensed Patents in the United States. Licensor shall have the sole right to file, prosecute and maintain all Licensed Patents and Licensor Patents and patent applications for Licensed Patents and Licensor Derived Patents in the United States and worldwide.

7.2 Infringement and Enforcement Actions.

7.2.1 Each Party shall notify the other Party of any suspected infringement(s) of the patents licensed hereunder or Related Know-How and shall inform the other Party of any evidence of such infringement(s).

7.2.2 [***] shall control any litigation, claim, action or proceeding it initiates, including the selection of counsel. [***] may retain additional counsel of its own selection and at its own expense to observe the litigation and to advise or assist [***]. [***] and its counsel will cooperate with and seek the input of [***] in such matters.

7.2.3 [***] may settle with an infringer without the prior approval of [***] (with such approval not to be unreasonably withheld or delayed) if such settlement would prejudice the rights of [***].

7.2.4 Each Party will provide the other with reasonable cooperation in any and all litigation matters or other claim, action or proceedings arising from or relating to the licensed and licensable patents and Related Know How subject to this Agreement.

8. Confidentiality.

8.1 Protected Information. Each Party shall regard and preserve as confidential all Trade Secrets and other Confidential Information pertaining to the other Party that has been or may be obtained by a Party by reason of this Agreement. Except in accordance with this Agreement, a Party shall not disclose, use for its own benefit or purpose, deliver, reproduce or in any way allow any Trade Secrets or Confidential Information to be delivered to, or used by, any third party without the specific written direction or written consent of a duly authorized representative of the disclosing Party. During or after the termination of this Agreement, no Party shall publish, release or otherwise make available to any third party any information describing any Trade Secret, or for a period of [***] other Confidential Information without prior specific written authorization of the Disclosing Party. Except as required by this Agreement, a Party shall not appropriate, retain or copy any Confidential Information or Trade Secrets of another Party.

8.2 Compelled Disclosure. In the event a receiving Party is required by legal process or applicable law (such as the Federal or California's Freedom of Information Acts or other similar "sunshine" acts or provisions) to disclose such Trade Secrets or Confidential Information, a receiving Party shall provide the disclosing Party with prompt notice of such request or requirement in order to enable the disclosing Party (a) to seek an appropriate protective or other remedy; or (b) to consult with the receiving Party with respect to the disclosing Party's taking steps to resist or narrow the scope of such request or legal process. The receiving Party that is subject to the disclosure request or requirement shall always seek to disclose only that portion of the disclosed information that is legally required to be disclosed.

9. Royalty Payments.

9.1 Minimum Annual Royalty Payment. There is no minimum annual royalty or other minimum annual payment due Licensor by Licensee under this Agreement.

9.2 Profit Sharing. The Parties shall divide Profits from the sales of Licensed Products(s) equally. As used herein Profit is defined as Net Sales less reasonable costs incurred by Licensee for manufacturing, marketing and distribution of Licensed Products, either directly or through an intermediary. [***] expenses shall include, but are not limited to the costs for [***]. Payments to the Licensor shall be made quarterly beginning [***] and shall include [***].

9.3 Books and Records. The Licensee will keep books and records accurately showing all payments due the Licensor and all Licensed Products developed, manufactured, used, offered for Sale, imported, Sold, and/or otherwise exploited under the terms of this Agreement, and provide such reports to the Licensor quarterly. The books and records will also include detailed entries for [***] incurred by [***], with sufficient detail to ensure all [***] were directly related [***]. Such books and records will be preserved for at least [***] after the date of the payment to which they pertain and will be open to examination by representatives or agents of the Licensor during regular business hours to determine their accuracy and assess the Licensee's compliance with the terms of this Agreement. The fees and expenses of performing the examination will be paid by the Licensor. If, however, an error in Profits of more than [***] of [***] is discovered or any other material term of this Agreement is discovered to have been breached, the Licensee shall bear the cost of the examination. The Licensee shall remit any underpayment to the Licensor within [***] days of the examination results; likewise, the Licensor shall remit any overpayments to Licensee within [***] of the examination results.

10. Mutual Indemnification. Licensee and Licensor shall indemnify and hold each other and its officers, directors, agents and employees harmless from and against any and all costs, expenses, settlements and judgments, including reasonable attorneys' fees, and costs and expenses incidental thereto (an "**Action**") which may be suffered by, accrued against, charged to or recoverable from the indemnified party or any of its officers, directors, agents or employees, arising out of any personal injuries, death or tangible property damage liability claim related to the manufacture, distribution or use of any Licensed Product or the practicing of the Licensed Patents, except to the extent such claim arises out of a breach of this Agreement by each Party or out of the gross negligence or willful misconduct of each Party, its officers, directors, employees or agents.

11. Dispute Resolution.

11.1 Negotiation. In the event of any dispute arising out of or in connection with this Agreement, as a condition precedent to any further action brought by either Licensor or Licensee against the other, the aggrieved party ("**Aggrieved Party**") shall give the other party (the "**Non-Aggrieved Party**") written notice of the matter which the Aggrieved Party considers to be in dispute. The notice will describe the issue in dispute in reasonable detail to apprise the Non-Aggrieved Party about the issue in dispute. Within [***] of the receipt of the notice ("**Notice Date**") delivered in accordance with the notice provisions of this Agreement, Chief Executive Officer of Licensor and the Chief Executive Officer of Licensee will meet (either telephonically or in person) in an attempt to resolve the dispute. The parties to this Agreement agree that they will make reasonable effort to resolve the dispute within [***] of the Notice Date so as to avoid arbitration as herein provided. If the dispute is not fully settled by negotiation among the parties as provided in this section within [***], then the condition precedent to arbitration shall be deemed satisfied and the dispute (to the extent not resolved) may be submitted to arbitration as herein provided. For clarity, any documents, discussions and partial settlements exchanged or agreed upon in the negotiations for settlement of the dispute may be admitted or provided to the arbitrators as evidence or statement of facts and position in any arbitration.

11.2 Arbitration. This Agreement shall be governed by and construed in accordance with the laws of the State of California, without regard to the application of principles of conflicts of law. Any disputes between the parties relating to this Agreement shall be resolved by binding arbitration before the American Arbitration Association in Los Angeles pursuant to its Commercial Arbitration Rules, then in effect.

Notwithstanding anything to the contrary in the Rules, the Licensee and Licensor agree that the place of arbitration will be in the Los Angeles County, California and each waives any objection to that venue for the arbitration for any action that arises out of the arbitration. The choice of law used in the interpretation of this Agreement shall be governed by the general laws of the United States with respect to any intellectual property issues and any other issues under this Agreement and, to the extent that such United States law is not clearly defined or is not applicable, then by the laws of the State of California.

12. Export Controls. Licensor and Licensee will each comply with all applicable United States or foreign export or import laws and regulations in connection with the licensing of any of the patents and patentable technology and Related Know How, Sale of the Licensed Products or sub-license of any technology or technical data relating to the Licensed Products.

13. Assignment. This Agreement, including its rights and obligations, may not be assigned by a Party without the prior written consent of the Licensor, which consent will be in the sole discretion of Licensor. Notwithstanding the foregoing prohibition, Licensee may, without the consent of Licensor, merge into, consolidate with, or transfer substantially all of its assets, business or stock to any entity, so long as the successor-surviving entity in any such merger, consolidation, reorganization or transfer, assumes in writing the Licensee's obligations of this Agreement. Such merger, consolidation, reorganization or transfer shall not constitute a breach of this Article or default under this Agreement.

14. Miscellaneous.

14.1 Severability. The Parties agree that if any part, term, or provision of this Agreement shall be found illegal or in conflict with any valid controlling law, the validity of the remaining provisions shall not be affected thereby.

14.2 Survival. Sections 2, 8, 9, 10, 11 and 14 shall survive expiration or termination of this Agreement.

14.3 Notices. All notices under this Agreement shall be deemed to have been fully given when done in writing, with reference to this Agreement, and when (a) delivered personally; (b) five (5) days after having been sent by United States mail, registered or certified, return receipt requested, postage prepaid; or (c) one (1) day after deposit with a nationally recognized commercial overnight carrier, with written verification of receipt. Communications or notices by other means such as e-mail shall only be effective when received and the sending or notifying party shall have the burden of proving receipt of such communication. All communications will be sent to the addresses or facsimile numbers set forth below or to such other address as may be designated by a Party by giving written notice to the other Party.

If to Licensor:

Matrix Biomed, Inc.
2301 Dupont Drive
Irvine, CA 92612
Tel: [***]
E-mail: [***]

with a copy to (which shall not constitute notice hereunder):

[***]
Attn: [***]
Fax: [***]
E-mail: [***]

If to Licensee:

Adamis Pharmaceuticals, Inc.
11682 El Camino Real, Suite 300
San Diego, CA 92130
Attn: Dr. Dennis J. Carlo, President
Tel: (858) 997-2400
E-mail: [***]

with a copy to (which shall not constitute notice hereunder):

[***]
Attn: [***]
Fax: [***]
E-mail: [***]

14.4 Public Statements. Neither Party will issue any news release, publicity, advertising or other form of public announcement relating to this Agreement without the prior written approval of the other Parties which approval shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, Licensee may make any required public announcement without the prior written approval of any other Party which relates to its business, the terms of this Agreement, and the patents and Related Know How subject to this Agreement as required by law or determined to be in the best interests of the Licensee to comply with any and all disclosure laws applicable to the Licensee.

14.5 Entire Agreement, Amendment. This Agreement, along with the referenced Research Agreement and other agreements referred to herein, represents the entire understanding between the Parties, and supersedes all other agreements, express or implied, among the Parties concerning the subject matter hereof. A provision of this Agreement may be altered or amended only by a writing signed by the Parties.

14.6 Waiver. No waiver by a Party of any breach of this Agreement, no matter how long continuing or how often repeated, shall be deemed a waiver of any subsequent breach thereof, nor shall any delay or omission on the part of a Party to exercise any right, power, or privilege hereunder be deemed a waiver of such right, power or privilege.

14.7 No Agency. The relationship among the Parties is that of independent contractors. Except as otherwise stated herein, neither Party shall be deemed to be an agent of the other in connection with the exercise of any rights hereunder, and neither shall have any right or authority to assume or create any obligation or responsibility on behalf of the other.

14.8 Construction. This Agreement shall not be construed more strictly against a Party than any other by virtue of the fact that it may have been prepared by counsel for one of the Parties, it being recognized that all Parties have contributed substantially and materially to the preparation of this Agreement.

14.9 Counterparts. This Agreement may be executed simultaneously in more than one (1) counterpart, and each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. The Agreement will be considered executed when original signatures have been exchanged or when signatures have been exchanged via facsimile or electronic transmission, including, without limitation, signatures delivered in portable document format (.pdf).

14.10 Headings. The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

[SIGNATURES ON FOLLOWING PAGE]

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

"**LICENSOR**"

Matrix Biomed, Inc.
a Delaware corporation

By: /s/ Allyn Burroughs
Allyn Burroughs, Chairman

"**LICENSEE**"

Adamis Pharmaceuticals, Inc.
a Delaware corporation

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

[SIGNATURE PAGE TO LICENSE AGREEMENT]

EXHIBIT A

TEMPOL PATENT AND PATENT APPLICATION

[***]

Exhibit 10.6

***** Certain identified information has been omitted from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed. Such omitted information is indicated by brackets ("[…***…]" in this exhibit. *****

DISTRIBUTION AND COMMERCIALIZATION AGREEMENT

This Distribution and Commercialization Agreement (the "**Agreement**") is made effective as of the Effective Date (as defined herein) 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, California 92130 **("Company")** and USWM, LLC, a limited liability company organized under the laws of Delaware, with an office at [***] ("**USWM**"). Company and USWM may hereafter be referred to collectively as the "**Parties**" and individually as a "**Party**".

WHEREAS, Company, pursuant to the terms of this Agreement, would like to manufacture and supply Products (as defined below) to USWM for distribution and commercialization in the Territory (as defined below); and

WHEREAS, USWM, pursuant to the terms of this Agreement, would like to purchase the Products from Company for distribution and commercialization in the Territory.

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. DEFINITIONS. In this Agreement, the following words shall have the following meanings:

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. **"Accrued Losses"** means, for any particular Calendar Quarter(s) occurring after the quarter in which Profitability has been reached, the amount by which the calculation of "Net Profit" for the Calendar Quarter (or Calendar Quarters, if and to the extent there are Accrued Losses in more than one (1) Calendar Quarter) is less than zero dollars ($0.00).

1.3. **"Additional Costs"** means, for any applicable Calendar Quarter, the total costs, inclusive of (i) [***], (ii) [***], (iii) [***], and (iv) [***]; in each case, only to the extent not overlapping with any amount deducted in the calculation of Net Sales.

1.4. **"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, but only for the period of time the Person first identified in this Section 1.3 controls, is controlled by, or is under common control, with the respective 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.

1.5. **"API"** means the compound epinephrine and/or naloxone, as applicable, and as further described in the Specifications.

1.6. **"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: (i) all applicable federal, state and local laws and regulations of the Territory; (ii) the Act; and (iii) cGMP.

1.7. "**Bankruptcy Code**" means the United States Bankruptcy Code (Title 11 of the United States Code).

1.8. **"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.

1.9. **"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.

1.10. "**Books and Records**" means the books and records maintained by the Parties relating to the Products in the Territory and/or the obligations hereunder in sufficient detail, in accordance with GAAP (to the extent applicable) and in accordance with the terms of this Agreement.

1.11. "**Business**" means, whether by Company or a Third Party, the development, sale, marketing, manufacturing, distribution and commercialization of the Products.

1.12. **"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.

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

1.14. **"Certificate of Analysis" "Certificate of Compliance**" and **"Certificate of Release"** (collectively the **"Certificates"**) means a document or documents signed and dated by a duly authorized representative of Company certifying that the Product Conforms to the Specifications as set forth in the Quality Agreement and/or was prepared in compliance with cGMP, and in accordance with Section 3.11.1.

1.15. **"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.

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

1.17. **"Commercialize"** or **"Commercialization"** means the activities for general management, legal, compliance, finance, regulatory, quality, medical affairs, marketing, sales, sales management, pricing, promotion, and distribution of the Products.

1.18. **"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 is anticipated that the level of effort may change over time, reflecting changes in the status of such Party and its circumstances, including, without limitation, the market for the Products. "**Commercially Reasonable**" shall have the correlative meaning.

1.19. **"Company Indemnified Parties"** means Company, 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.

1.20. **"Competitive Entry"** means an event in which prior to the Company receiving Regulatory Approval, another drug-device combination product obtains regulatory clearance to begin marketing that [***], that could also be reasonably expected to compete favorably against the Product in the Territory.

1.21. **"Components"** means, collectively, and without limitation, all container closure components (syringes, stoppers, etc.), raw materials, excipients, device parts, and all Labels, necessary to Manufacture the Products in accordance with the NDAs, the Drug Master Files, and the Specifications for the Products.

1.22. **"Confidential Information"** means all confidential, trade secret, proprietary or nonpublic information of a Party, including, without limitation, 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.

1.23. **"Conforming"** or **"Conform"** means that the Product (a) conforms, in all respects, 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.

1.24. **"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.

1.25. **"Develop"** or **"Development"** means any activities related to the development of the Products, 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 Products 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 Products in accordance with the Specifications and Applicable Laws, and any post-Launch stability testing.

1.26. "**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.

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

1.28. **"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). Notwithstanding the foregoing, the effective date with respect to USWM's rights to the SYMJEPI product shall be the effective date of the termination of the Sandoz Commercial and Distribution Agreement to which Company is a party.

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

1.30. "**Force Majeure Event**" means an event impacting a Party due to causes beyond such Party's reasonable control, including without limitation, acts of God, pandemics or epidemics, national or regional emergency, any actions of governmental authorities or agencies, government order or law, embargoes or blockades in effect on or after the Effective Date, war, hostilities between nations (whether war is declared or not), terrorist threats or acts, civil commotions, riots or other civil unrest, national industry strikes, lockouts, sabotage, labor stoppages or slowdowns or other industrial disturbances, shortage of adequate power or transportation facilities, 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 impacted Party.

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

1.32. **"GAAP"** means Generally Accepted Accounting Principles, as generally and consistently applied by USWM, and as may be updated or revised from time to time by a decision of the Financial Accounting Standards Board or related accredited accounting entity.

1.33. **"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.

1.34. **"Labels"** means any package, packaging material, labels, package inserts, instructions for use documents, patient prescribing information and medication guides, as may be applicable, designed for use with the Products, pursuant to the terms of this Agreement, in accordance with Applicable Laws, that is approved by the FDA.

1.35. **"Labeling"** means the act of preparing the Product with approved Labels (packaging in approved and serialized, as applicable, shipping containers, boxes, cartons, applying approved prescribing inserts, etc.), pursuant to the terms of this Agreement, in accordance with Applicable Laws.

1.36. **"Latent Defect"** means any adulteration, contamination of or other latent defect in any Product that is not readily detectible upon visible inspection.

1.37. **"Launch"** means the first commercial sale of Product in the Territory by USWM or its Affiliates to a Third Party (including without limitation, a wholesale, chain or retail pharmacy level) after receipt of the Launch Quantity. For purposes of this definition, "first commercial sale" shall exclude sales for test marketing, clinical-trial purposes or compassionate use.

1.38. **"Launch Quantity"** means a mutually agreed quantity of Product Delivered by Company to USWM in advance of a Launch.

1.39. **"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 of the Products developed, made, sold, marketed or otherwise distributed by the Parties.

1.40. **"Licensed IP"** means the Licensed Know-How and the Licensed Patents any intellectual property rights Controlled by Company or its Affiliates that Company reasonably determines are necessary or useful for the Manufacture or Commercialization of the Products in the Territory.

1.41. **"Licensed Know-How"** means Know-How Controlled by Company that is necessary or useful for the Manufacture and Commercialization of the Products in the Territory.

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

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

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

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

1.46. **"Marketing Year"** means any calendar year during which the Products are Commercialized in the Territory. The first Marketing Year for a Product shall be the calendar year in which its Launch occurs.

1.47. **"NDA"** means either new drug application 207534 (SYMJEPI) or 212854 (ZIMHI) filed by Company with the FDA, as may be amended or supplemented.

1.48. **"Net Profit"** means the amount (which shall not be less than zero dollars ($0.00)) calculated for a given Calendar Quarter equal to Net Sales of the Products less the sum of (i) the Supply Price of Products sold by USWM in such Calendar Quarter, and (ii) Additional Costs for the Products sold in such Calendar Quarter. Prior to [***]. Upon [***]. Notwithstanding the foregoing, if and to the extent [***], then [***]. The costs of (i) and (ii) in this definition shall be calculated in accordance with GAAP, to the extent applicable to such cost or calculation.

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

1.50. **"Net Sales"** means the net sales recorded by USWM or any of its Affiliates for sales of Product in the Territory to Third Parties as determined in accordance with GAAP as consistently applied. The deductions booked on an accrual basis by USWM and its Affiliates under GAAP to calculate the recorded net sales from gross sales consist of, without limitation, the following applied consistently:

(i) normal trade and cash discounts;

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

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

(iv) rebates and chargebacks to customers and Third Parties (including, without limitation, group purchasing organizations, 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 GAAP.

There shall be no double-counting in determining the foregoing deductions. With respect to the calculation of Net Sales: (i) 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 USWM and its Affiliates shall be disregarded for purposes of calculating Net Sales; and (ii) 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 GAAP 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 [***].

1.51. **"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.

1.52. **"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.

1.53. "**Product" or "Products"** means the applicable definition set forth on Schedule D attached hereto.

1.54. **"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 Products, and including claims by or on behalf of users of the Products (including spouses, family members and personal representatives of such users) relating to the use, sale, distribution or purchase of the Products sold by or on behalf of USWM in the Territory.

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

1.56. **"Profitability"** means the first Calendar Quarter in which a Net Profit is greater than zero (0).

1.57. **"Quality Agreement"** means the Quality Agreement that will govern the production of the Products and that will be executed by and between USWM and Company in connection with this Agreement.

1.58. **"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 Products (including post-approval changes, pricing and Third Party reimbursement approvals, and Label 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 Products as the context may require within the Territory.

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

1.60. **"Regulatory Filing"** means any filing made with a Regulatory Authority.

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

1.62. **"Specifications"** means (i) with respect to the SYMJEPI 0.3mg Product, [***], and (ii) with respect to the SYMJEPI 0.15mg Product, [***]. In either case of (i) or (ii) in this Section 1.62, "Specifications" shall also include the criteria set forth in the applicable Regulatory Approval required for USWM's acceptance of the respective Product from Company.

1.63. "**Supply Price**" means the amount Company shall invoice USWM as described in Schedule E attached hereto.

1.64. **"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, but excluding in all cases [***]. For the avoidance of doubt, [***] does not include [***].

1.65. **"Third Party" and the correlative term "Third Parties"** means any Person or Persons other than a Party or any of its Affiliates.

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

Definition	**Section**
AAA	12.4
Accelerated Net Profit Share Payments	6.2.3
At Fault Recall	5.3.2
Audited Party	6.5.2
Auditing Party	6.5.2
Branded Pharma Fee	6.3
Commercial Efforts	Schedule F
Commercial Plan	4.1
Commercial Milestone Payments	Schedule C
Commercialization Plan	4.1
Company Elected Increase	4.2.4
Delivery	3.6.1
Dispute	12.3
[***]	[***]
Encumbrance	7.5.4
Failure to Supply	11.2.2(a)
Firm Commitment	3.2
Firm Order	3.4
Indemnitee	8.3
Indemnitor	8.3
Infringement Action	11.2.2(b)
Initial Term	11.1
JPT	4.2.1
Milestone Payments	6.1
Near-Term Milestone Payments	6.1
Net Profit Share Payments	6.2.2
OPDP	4.5.2
Order Confirmation	3.4
Other Agreements	3.5.1
Other Products	3.5.1
Pharmacovigilance Agreement	5.4
Product Changes	3.12.3
Promotional Materials	4.5.1
Purchase Order	3.3
Quarterly Payment Date	6.2.2

Definition	Section
Quarterly Report	6.2.2
Renewal Term	11.1
Rolling Forecast	3.2
Sales and Distribution Allocation	Schedule F
Sales Taxes	6.4
Sandoz	3.5.1
Term	11.1
USWM Legal Expenses	2.6.3

2. EXCLUSIVE DISTRIBUTORSHIP; EXCLUSIVITY.

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

2.2. **Supply of Product for Distributorship.** As provided in Section 3, Company shall supply (or have supplied) to USWM, and USWM shall purchase from Company, its requirements of the Products for sale by USWM 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 (including, without limitation, Section 12.9), Company hereby grants to USWM a fully paid and exclusive (even as to Company), non-transferable and non-sublicenseable (except with the prior written consent of Company to any such transfer or sublicense, such consent not to be unreasonably withheld, denied, conditioned, or delayed; provided however, that such consent shall not be required to the extent the license is transferred or sublicensed to an Affiliate of USWM) license under the Licensed IP for USWM to market, sell, offer for sale, and otherwise Commercialize the Products in the Territory under this Agreement.

2.3.2. Company shall update the listing of Licensed Patents set forth in Schedule A on or before [***], so as to include information with respect to [***]. If Company plans to [***], Company shall notify USWM in writing at least [***] in advance of [***]. Following such notice, USWM will have the right, in its sole discretion, to [***]. Effective as of [***], such [***] shall [***].

2.4. **Licensed Trademarks.** Subject to the terms and conditions of this Agreement (including, without limitation, Section 12.9), Company hereby grants to USWM a fully-paid, non-transferable and non-sublicenseable (except with the prior written consent of Company to any such transfer or sublicense, such consent not to be unreasonably withheld, denied, conditioned, or delayed; provided however, that such consent shall not be required to the extent the license is transferred or sublicensed to an Affiliate of USWM) license to use the Licensed Trademarks only to market, sell, offer for sale and otherwise Commercialize the Products in the Territory under this Agreement, which shall be exclusive (even as to Company). USWM and its Affiliates shall display the Licensed Trademarks on all Products and on or in all packaging, promotion, and advertising materials to the extent practicable in a form and manner substantially in accordance with the Trademark Usage Guidelines attached hereto in Schedule H and otherwise in compliance with all Applicable Laws. At the reasonable request of Company from time to time, USWM will provide copies of packaging, Labels, advertising, promotional and other material of USWM or its Affiliates referencing the Licensed Trademark to allow Company to confirm compliance with the foregoing. In the event that Company has a reasonable objection, made in good faith, to the Licensed Trademark practices of USWM or reasonably believes in good faith that USWM is not complying with the Schedule H guidelines, following an inspection in accordance with the preceding sentence, as its sole remedy therefor, Company shall provide written notice to USWM of such objection in reasonable detail to facilitate cure by USWM, and USWM shall use all Commercially Reasonable Efforts to cure and remedy the objection. Approval of any particular practices, or use of any Licensed Trademark, once given by Company, shall continue in effect with respect to such practices, or use, and any practices or use substantially consistent therewith, without need for further approval.

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

2.5.1. Company shall be responsible for the preparation, registration, filing, prosecution and maintenance of the Licensed Trademarks, at its sole cost and expense using reasonable care and skill and using counsel reasonably acceptable to USWM.

2.5.2. Company shall prepare, file and prosecute any and all patent applications and maintain any and all patents within the Licensed Patents. 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. Company shall use all reasonable care and skill and shall use counsel reasonably acceptable to USWM in performing its obligations pursuant to this Section 2.5.2.

2.5.3. In performing its obligations under Sections 2.5.1 and 2.5.2, Company shall:

a) keep USWM reasonably informed of the filing and progress of all material aspects of the prosecution of such trademark or patent application and the issuance of patents from any such patent application or the registration of any such trademark;

b) provide USWM with a copy of such material patent application or trademark application, amendments thereto, and other related correspondence to and from patent and trademark offices, and, to the extent reasonably practicable, permit USWM an opportunity to offer its comments thereon before making a material submission to a patent and trademark office and Company shall consider in good faith USWM's comments;

c) consult with USWM concerning any decisions that could reasonably be expected to materially affect the scope or enforcement of any issued claims or the potential abandonment of such patent application, patent, trademark application or trademark; and

d) notify USWM in writing of any material changes in the scope or status of such patent, patent application, trademark, or trademark application.

2.6. **Enforcement of Licensed IP and Licensed Trademarks.**

2.6.1. If either Party believes or becomes aware of (a) any suspected infringement of any Licensed IP or Licensed Trademark by a Third Party in the Territory or (b) a Third Party allegation that any Licensed IP or Licensed Trademark is invalid or unenforceable, including the receipt of a notice of certification filed pursuant to the Hatch-Waxman Act claiming that any of the Licensed IP is invalid, unenforceable or that no infringement will arise from the manufacture, use or sale of the Product or a Competing Product by a Third Party, or (c) Third Party allegation that the Product, or its use, development, manufacture, or sale infringes a Third Party's intellectual property rights in the Territory, such Party shall notify the other Party within [***] of forming such belief or awareness and provide the other Party with all details of such infringement, claim, or notice, as applicable, that are known or possessed by such Party.

2.6.2. [***] shall have the first right, but not the obligation, to bring an Infringement Action to enforce any Licensed IP or Licensed Trademark, defend any declaratory judgment action concerning any Licensed IP or Licensed Trademark, and take any other lawful action reasonably necessary to protect, enforce, or defend any Licensed IP or Licensed Trademark, and control the conduct thereof, and attempt to resolve any claims relating to any Licensed IP or Licensed Trademark, including by (a) prosecuting or defending any *inter partes* review, post-grant review, covered business method patent review, opposition, derivation, interference, declaratory judgment, federal district court, state court, US Patent and Trademark Office, US International Trade Commission, or other proceeding of any kind, and (b) taking any other lawful action that [***] believes is reasonably necessary to protect, enforce, or defend any Licensed IP or Licensed Trademark. [***] has the right to prosecute or defend any such proceeding in [***] own name or, if required by applicable law or otherwise necessary or desirable for such purposes, in the name of [***], and may join [***] as a party. [***] shall have the right to control the conduct thereof and be represented by counsel of its own choice therein. Notwithstanding the foregoing, if [***] does not bring an action with respect to any commercially significant Third Party infringement within [***] of [***] or earlier notifies [***] in writing of [***], then [***] shall have the right, but not the obligation, to bring such an action and to control the conduct thereof.

2.6.3. Subject to the subsequent sentence, in the event a Party undertakes the enforcement or defense of any Licensed IP or Licensed Trademark in accordance with Section 2.6.2: (a) such Party will [***]; (b) the other Party shall provide all reasonable cooperation and assistance, at the enforcing Party's expense, including [***]; (c) in the event [***] undertakes the enforcement or defense, any recovery, damages, or settlement derived from such suit, action, or other proceeding will be [***]; (d) in the event [***] undertakes the enforcement or defense, any recovery, damages, or settlement derived from such suit, action, or other proceeding will be [***]; and (e) such Party may settle any such suit, action, or other proceeding, whether by consent order, settlement, or other voluntary final disposition, without the prior written approval of the other Party, provided that [***] shall not settle any such suit, action, or other proceeding in a manner that [***] without [***] prior written consent [***]. Notwithstanding the foregoing, in the event (i) [***] undertakes the enforcement or defense of any Licensed IP or Licensed Trademark in accordance with Section 2.6.2, and (ii) such enforcement or defense results in a final judgment or settlement [***] exceeds [***], then [***] shall be deducted from [***].

2.6.4. If any suit, action, or other proceeding alleging invalidity or non-infringement of any Licensed IP or Licensed Trademark is brought against [***] or any Affiliate, [***], at its option, will have the right, within [***] after commencement of such suit, action, or other proceeding, to [***].

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 utilize any Licensed IP or Licensed Trademarks to conduct activities for which it is responsible as contemplated by this Agreement, [***].

2.8. **Reserved Rights.** Company hereby expressly reserves all rights under the Licensed IP and Licensed Trademarks that are not expressly granted to USWM 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 Products outside of the Territory, and (b) the Licensed IP to research, develop, make, have made, import, use, sell, offer for sale, distribute, promote, market, and otherwise commercialize any and all products other than the Products (including any product other than the Products that use any syringe to administer products) worldwide, provided, however, that the Company's reservation of rights in this Section 2.8(b) does not apply with respect to any products sold in the Territory containing epinephrine or naloxone (but does apply to [***]), and (c) the Licensed IP and Licensed Trademarks to Manufacture, have Manufactured and supply the Products for USWM and its Affiliates pursuant to this Agreement and to make, have made, package and have packaged the Products in the Territory for Company and its Affiliates and licensees for use outside the Territory. If (i) the Company uses the Licensed IP to develop and Commercialize, or permit the Licensed IP to be used to develop and Commercialize any products containing epinephrine or naloxone in [***], or (ii) the Company or any of its Affiliates, directly or indirectly (e.g., by partnering with any Third Party), develops or Commercializes any products containing epinephrine or naloxone in [***], then the Company agrees to [***]. Further, the Company retains the right to reference and use, and grant to Company's Affiliates and licensees (and their sublicensees) the right to reference and use, all Regulatory Approvals for the Products 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 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. USWM hereby covenants and agrees that during the Term it shall not (and cause its Affiliates not to), either itself or through a Third Party, market, promote, sell or actively offer for sale the Products outside of the Territory. Without limiting the generality of the foregoing, with respect to countries outside of the Territory, USWM shall not (i) engage in any advertising activities relating to the Products 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 (ii) actively or intentionally solicit orders from any prospective purchaser of the Products for distribution outside of the Territory. To the extent permitted by Applicable Law, if USWM receives any order from a prospective purchaser of the Products in or for a country outside of the Territory, USWM shall immediately refer that order to Company and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the Products under such order. If USWM is actually aware that a customer or distributor has actively engaged itself or through a Third Party in the sale or distribution of the Products outside of the Territory, then USWM shall, [***], unless otherwise agreed in writing by the Parties.

2.10.2. 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 Products in the Territory. Without limiting the generality of the foregoing, Company shall not (i) engage in any advertising activities relating to the Products 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 (ii) actively or intentionally solicit orders from any prospective purchaser of the Products for distribution in the Territory. To the extent permitted by Applicable Law, if Company (or its Affiliates, licensees and subcontractors) receives any order from a prospective purchaser of the Products in or for the Territory, Company shall immediately refer that order to USWM. If Company is actually aware that a customer or distributor has actively engaged itself or through a Third Party in the sale or distribution of the Products in or for the Territory, then Company shall [***].

3. MANUFACTURING AND SUPPLY SERVICES.

3.1. **Overview.**

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

3.1.2. Except as expressly provided in Sections 3.2, 3.3 and 3.5, USWM makes no guarantee or commitment, directly or indirectly, that USWM will purchase any minimum quantity of the Products under this Agreement, and 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 Company will use the Product Manufacturers to Manufacture and supply (including making available to USWM for shipping) the Products to USWM and its Affiliates under this Agreement. As of the Effective Date, the Third Parties listed in Schedule G are the Product Manufacturers. If Company desires to delegate such Manufacturing and supply obligations to a Product Manufacturer other than a Third Party that is listed in Schedule G [***] at any time during the Term, then Company shall [***]. For purposes of clarity, except in the case of [***], it shall be deemed reasonable for [***], if such delegation could [***]. Company shall be responsible for performance of Company's obligations hereunder to the extent performed on Company's behalf by such subcontractor as if Company were itself performing such activities. The Parties acknowledge and agree that the terms "Company shall" or "Company will" or the like, shall be deemed to be followed by the words "or the Product Manufacturer, as a subcontractor of Company, will" or "or the Product Manufacturer, as a subcontractor of Company, shall" or "Company shall require that the Product Manufacturer shall" or the like, with respect to Company's Manufacturing and supply obligations herein.

3.1.4. Company shall be responsible for all sourcing of all Components used in the Manufacture and Processing of the Products (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.

3.2. **Rolling Forecast.** By the later to occur of (i) [***] after [***], or (ii) [***] prior to [***], USWM shall submit to Company a rolling [***] forecast of Product that USWM intends to order from Company (the "**Rolling Forecast**") for such period commencing on the Launch. The first [***] 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. On or about the [***], USWM shall provide Company with an updated Rolling Forecast of both the revised Firm Commitment and the non-binding good faith estimate.

3.3. **Purchase Order.** USWM shall provide purchase orders to Company concurrently with the submission of each Rolling Forecast which collectively represent the quantity of the Products USWM would like Company to deliver to USWM during the Firm Commitment (**"Purchase Order"**). Each Purchase Order shall specify: (a) USWM's internal purchase order number, (b) the desired Batch quantity, and (c) the desired date for Delivery.

3.4. **Firm Order.** Company shall supply to USWM those quantities of Products ordered by USWM pursuant to any accepted Firm Order within the Firm Commitment. Company shall confirm to USWM each Purchase Order, including quantity, pricing and date for Delivery, in writing (**"Order Confirmation"**) within [***] after receipt (or within [***] after receipt for a Purchase Order in excess of the Firm Commitment). Each Order Confirmation shall either confirm the delivery date requested in the Purchase Order or provide reasonable alternative date for Delivery. Company may reject any Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement; provided, however, that Company shall [***] to supply USWM with quantities of the Products which are in excess of the quantities specified in the Firm Commitment, subject to [***]. For clarity, Company will not be considered in breach or default of this Agreement if it does not supply quantities of the Products which are in excess of [***]. USWM shall have [***] following the receipt of an Order Confirmation, or such longer period as mutually agreed by the Parties, to cancel a Purchase Order; thereafter the Purchase Order, under the terms of the Order Confirmation, shall constitute a binding contact (**"Firm Order"**). Each Firm Order shall be considered a binding, non-cancellable commitment upon Company to produce and deliver such quantities of the Products on the date for Delivery described there and upon USWM to purchase and pay for such Products; however, 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 Purchase Order, Order Confirmation, Firm Order or similar form or invoice or acknowledgment shall be void and have no force or effect. Product shall be delivered to USWM no more than [***] from [***].

3.5. **Packaging; NDC.** Except (i) as may otherwise be agreed by the Parties in writing, and/or (ii) as set forth in Section 3.5.1, Company shall supply USWM with the Products packaged in USWM's trade dress under USWM's NDC labeler code. Company shall cooperate with USWM as required to support USWM obtaining its own NDC labeler codes for the Products. USWM shall supply to Company information and materials regarding USWM's trade dress and NDC labeler codes and any standards and instructions for Product packaging that USWM requests in sufficient time to permit Manufacturing and supply of the Products in accordance with this Agreement. USWM acknowledges that a failure by USWM to provide the requirements for Labels including, but not limited to, USWM trademarks, trade names, packaging graphics, serialization codes and NDC numbers, within the timeframe specified by Company could delay the Delivery of the Launch Quantity. USWM shall be responsible at its sole cost for ensuring that all such information, materials, standards and instructions comply with Applicable Laws. Company shall provide USWM with all documentation regarding the Products reasonably requested by USWM to allow USWM to complete a country of origin evaluation pursuant to Applicable Laws.

3.5.1. **Other Agreements.** To the extent that the Parties enter in one or more agreements ("**Other Agreements**") with Sandoz Inc. (**"Sandoz"**) concerning activities relating to the past, present or future commercialization, distribution, marketing or sale of [***] ("**Other Products**"), as between USWM and Company, (i) [***], and (ii) [***].

3.6. **Delivery Terms.**

3.6.1. Company or the Product Manufacturer shall deliver the Product ExWorks (Incoterms2010) in accordance with the delivery date determined according to Section 3.4 (**"Delivery"**). For the avoidance of doubt, Company shall not be responsible for the Products in transit, including any cost of insurance or other transport fees for the Products, or any risks associated with transit, storage and handling. Company shall provide delivery information [***]; however, USWM shall be [***], in accordance with the terms of the Quality Agreement.

3.6.2. If the requested quantity of the Products cannot be delivered on the delivery date determined according to Section 3.4, Company shall notify USWM within [***] of becoming aware of such delivery issue.

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

3.8. **Storage.** Company shall maintain and store all Product in accordance with the Specifications and Good Manufacturing Practices at all times, pending Delivery to USWM. Company's actual out of pocket costs incurred to comply with this Section 3.8 shall be [***].

3.9. **Serialization and Coding.** Company shall implement Product serialization and coding in accordance with Applicable Laws. USWM and Company will work together to align on implementation. USWM acknowledges that a failure by USWM to provide the requirements for serialization including, but not limited to, GTIN, bar codes, bulk serialization numbers and links between Product Manufacturer and USWM's third-party logistics (3PL) provider, within the timeframe specified by Company could delay the Delivery of the Products. 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 Products to meet the regulations in the Territory shall be borne by Company or its Product Manufacturer.

3.10. **Inspection and Acceptance.**

3.10.1. Company shall test and inspect each Batch of Product for compliance with the Specifications prior to the release and shipment thereof to USWM. Company shall provide a Certificate of Analysis, Certificate of Conformance, Certificate of Release or other Certificate with each shipment of each Batch of Product. The Certificate(s) must evidence that the Product conforms to [***].

3.10.2. USWM, or a qualified Third Party designated by USWM, may, but is not obligated to, test and inspect the Products after receipt of each Batch of Product. USWM may reject any shipment (or portion thereof) of Product if it does not Conform based on such inspection by written notification to Company within [***] of [***]. USWM shall be deemed to have accepted the Product if USWM fails to give written notice of rejection within [***] of [***], except in the case of [***] in which case such written notice of rejection must be provided within [***]. The written notice of rejection shall be given to 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, Company shall notify USWM in writing within [***] of receipt of such notice from USWM whether Company disagrees with the rejection and, if Company does not provide such written notice within such [***] period, Company will be deemed to agree with such rejection. If 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 Company to USWM, 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 USWM's claim, Company shall, at USWM's request, promptly provide USWM 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, USWM shall return, destroy, or cause to be destroyed any rejected Product to Company at Company's expense to an address that Company shall designate within [***] of the agreement or Third Party laboratory determination regarding rejection, as applicable, and Company, at USWM's request, will promptly provide USWM with a credit or refund of the Supply Price for the rejected Product if USWM has already paid Company for such rejected Product or will promptly provide replacement Product to USWM subject to USWM's payment of the Supply Price for replacement Product unless USWM has already paid Company for such rejected Product, together with [***]. If Company, however, does not agree with USWM's claim of non-compliance with the Specifications or other defect, USWM shall not be obligated to return the rejected Product to 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, USWM 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 USWM shall pay Company the Supply Price for such Batch and for any replacement Product (for purposes of clarity, USWM's payment of the Supply Price for such Batch shall not be a duplicative payment).

3.11. **Supply Price and Payment.**

3.11.1. Solely to the extent otherwise included in the Supply Price (as the term is defined in Section 1.63 hereto), Company shall send an invoice to USWM covering such Firm Order. The Supply Price shall be invoiced in U.S. dollars.

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

3.11.3. The Supply Price may be adjusted based on (i) [***], (ii) [***], and (iii) [***] upon [***] prior written notice to USWM; provided, however, that Company shall provide USWM reasonable documentation [***], and USWM may audit such [***] pursuant to Section 3.13.

3.11.4. During the Term, Company shall [***] to [***].

3.12. **Specifications & Quality.**

3.12.1. Company shall cause the Product Manufacturer to Manufacture the Products in strict conformity with the Specifications. Further, 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 Products.

3.12.2. Within [***], USWM and Company (and/or the Product Manufacturer, as applicable) shall enter into a mutually agreeable Quality Agreement relating to the Products. Company shall maintain a current Quality Agreement and quality control system compliant with the Regulatory Authority for the Products to be delivered hereunder. Such a system shall include [***]. Each Batch of Product to be supplied to USWM hereunder shall be subject to a quality control inspection by Company in accordance with Company's then current quality assurance standards and the approved Regulatory Filings. 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 Products.

3.12.3. [***] modifications, changes, additions or deletions to the (1) [***]; (2) [***]; (3) [***]; (4) [***]; (5) [***]; (6) [***]; (7) [***]; or (8) [***], which Company intends to carry out (hereinafter, "**Product Changes**"), must be evaluated and documented by [***]. Prior to implementation of any material Product Change, and in any event, within [***] from [***], Company agrees to provide reasonable notice to USWM in writing of such change and Company shall consider in good faith any input timely provided by USWM regarding any Product Changes. Reasonable notice applies in (1) circumstances in which [***], and (2) circumstances where [***]. In such circumstances, following reasonable notice, USWM shall be informed of [***]. If appropriate and upon considering in good faith timely input provided by USWM, Company shall [***].

3.12.4. Company is responsible for storing and maintaining retention samples of each Batch of Product produced for USWM for [***] in accordance with Good Manufacturing Practices and the terms of the Quality Agreement. Company will take measures to ensure that the quantity of retention samples shall be of sufficient quantity [***].

3.12.5. Company shall be responsible for the testing and generation of stability data for the Products in accordance with the cGMP and ICH guidelines.

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

3.12.7. Records which include the information relating to the Manufacturing, packaging and quality operations for each Batch of Product shall be prepared by Company for each lot at the time such operations occur. Such records shall be prepared in accordance with Applicable Laws and Company's standard operating procedures. Company shall keep Batch Records, and all associated batch documentation (i.e., deviations, testing data, testing results, Batch release documentation, etc.), for each Batch of Product until the later of (i) the period of time required by Applicable Law, or (ii) [***].

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

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

3.13.2. On reasonable prior notice, Company shall allow employees or authorized representatives of USWM 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 Products, 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), Company shall (i) upon request, provide USWM and/or its Affiliates with the report of the audits carried out by or on behalf of Company of any such subcontractor or any other documents and information necessary for USWM to verify compliance of such subcontractors with Applicable Laws and this Agreement; and (ii) use [***] to cause [***].

3.13.3. USWM 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 the Products. Product failures shall include [***]. USWM shall notify Company in writing in advance of the audit and thereafter, with Company's reasonable assistance, the Product Manufacturer and USWM shall mutually determine the timing of the audit.

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

3.14. **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 Products in accordance with the Specifications, cGMP and Applicable Laws, and thereafter Company will use [***] to ensure that the Manufacturing Facility shall maintains any and all such Regulatory Approvals.

4. COMMERCIALIZATION.

4.1. **Commercialization.** USWM shall Commercialize the Products in the Territory in accordance with Applicable Law and shall use [***], including [***], to Commercialize the Products 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 from Company and [***] representatives from USWM. [***].

4.2.2. **Purposes.** The purpose of JPT meetings will be to discuss the Launch and Commercialization of the Products according to the applicable provisions of this Agreement, including planned Commercial Efforts, improvements to [***], as well as [***]. Additionally, the JPT shall discuss and approve the Sales and Distribution Allocation for the future Marketing Year.

4.2.3. **Disputes.** The JPT will operate [***]. The decisions made and the actions taken by the JPT will be made with the interests of both Parties duly considered in good faith. Subject to the terms of this Agreement and Applicable Law, the decisions of the JPT will be made in accordance with the discretion and business judgement of the members thereof. [***].

4.2.4. **Limited Authority.** For purposes of clarity, the failure of the JPT in [***] will not be deemed to constitute a breach of this Agreement by either Party. In no case shall the JPT have any authority to (i) [***], (ii) [***], (iii) [***], and/or (iv) [***].

4.2.5. **Company Elected Increase.** If the JPT is unable to [***], the Company may elect, at its sole discretion, to [***].

4.2.6. **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 [***] days after each meeting, [***].

4.3. **Sales and Distribution; Returns.** USWM shall be responsible for handling all returns, recalls, order processing, invoicing and collection, distribution, and/or receivables for the Products Commercialized by USWM in the Territory pursuant to this Agreement. The cost of any recall shall be allocated pursuant to Section 5.3. USWM shall book all sales of the Products in the Territory.

4.4. **Pricing.** The JPT will discuss pricing strategy in general, however, USWM will have final discretion in determining the pricing, terms of sale, marketing, and selling decisions for the Products in the Territory.

4.5. **Advertising and Promotional Materials.**

4.5.1. Excepting for such advertising and Promotional Materials, if any, which are provided to USWM by the Company, USWM shall prepare and produce all Promotional Materials for Commercialization of the Products in the Territory. In relation to the Products, USWM 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 Products for sale in the Territory. USWM shall own all right, title and interest in and to any and all such Promotional Materials it develops, including all applicable copyrights, trademarks (other than the Licensed Trademarks, which are licensed to USWM under Section 2.4), program names and domain names for Products to be sold by USWM in the Territory. For purposes of this Agreement, **"Promotional Materials"** means all sales, marketing, and advertising materials as defined in the Act for the Products to be sold by USWM in the Territory.

4.5.2. USWM 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 Company's delegation of such responsibility for the Products to be sold by USWM in the Territory to USWM. USWM shall provide Company with a copy of each such filing promptly after submission thereof. For the avoidance of doubt, USWM 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 the FDA) or as otherwise required by, or permitted under, Applicable Laws. USWM shall promptly, but in any case, within three (3) Business Days of receipt, provide Company with complete copies of all material correspondence relating to Promotional Materials for the Products with Regulatory Authorities, including OPDP.

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

4.6. **Medical Information.** USWM shall determine procedures for responding in a consistent manner to medical information requests on the Products in the Territory. USWM 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 Products in the Territory; provided, that, Company shall cooperate with and assist USWM upon USWM's reasonable request with regards to such activities.

5. REGULATORY MATTERS.

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

5.1.1. Except as otherwise mutually agreed by the Parties, Company will be responsible for all regulatory and registration activities for the Products in the Territory at Company's sole cost and expense (except as set forth in Section 4.5.2), including, but not limited to, being solely responsible for interacting with FDA for the purpose of obtaining and maintaining the Regulatory Approval for the Products. Except as otherwise mutually agreed by the Parties, Company shall be responsible for conducting all nonclinical and clinical studies; device design and testing; chemistry, manufacturing and controls related activities, and manufacturing process validations 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, encompassing both registration and post-marketing commitment/ requirement activities. At each meeting of the JPT, Company will present and discuss the status of all of the registration and/or post-marketing commitment/requirement activities that Company has performed or caused to be performed pursuant to this Section 5.1.1 since the last meeting of the JPT. Company shall perform any work necessary in response to FDA deficiencies connected with initial registration, application supplement, or post-marketing commitment/requirement and Company shall keep USWM informed of the status of all such activities on a regular basis.

5.1.2. In addition to the requirements set forth in 5.1.1, Company shall provide USWM with written notice of meetings with the FDA regarding the Products. Company shall consider in good faith any input timely provided by USWM regarding regulatory activities relating to the Products in the Territory and will promptly update USWM on the results of such regulatory activities. Upon request, Company shall promptly provide to USWM complete copies of all material correspondence with Regulatory Authorities regarding the Products.

5.1.3. 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 USWM without the prior written authorization of USWM. 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 USWM and its agents relating to Company.

5.2. **Regulatory Costs.** Company shall be responsible for paying all regulatory fees that are payable to a Regulatory Authority relating to the Products, including, without limitation, the PDUFA program user fee for the Products (and any other similar or related fees required by similar laws, rules or regulations, including any annual fees owed to any Regulatory Authority with respect to the Products).

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 Company shall be responsible for providing proper notification of a Product recall or Product withdrawal to the applicable Regulatory Authority(ies). With respect to the Products Commercialized by USWM 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) USWM reasonably determines, after reasonable, good faith discussion with Company, that Product should be recalled or retrieved, USWM shall promptly notify Company of such event and both Parties shall cooperate in relation to the recall. USWM shall be responsible for the final recall decision, communication to the public, and the logistic process regarding returned goods.

5.3.2. [***] shall be responsible for administering any recall and [***] shall bear the cost of a recall and shall reimburse [***] for [***], in each case including [***], unless the recall is determined to be caused by [***], in which event [***] shall bear the cost of that recall and shall reimburse [***] for [***].

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 Products and for ensuring compliance with reporting requirements of Regulatory Authorities (the "**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement shall provide, among other things, that Company shall (at its sole cost) be, or shall cause a Third Party to be, responsible for maintaining the safety database for the Products and reporting safety-related information to the FDA; provided, that, Company shall be responsible for performance of Company's obligations under the Pharmacovigilance Agreement to the extent performed on Company's behalf by such Third Party as if 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.** USWM 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 Products sold by USWM 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 Products under state, federal or other health care programs and to list the Products under such agreements as appropriate. USWM shall be responsible for categorizing the Products under federal, state and local government pricing or reimbursement programs in the Territory. USWM shall respond to all state and federal regulations on pricing transparency. In connection with the foregoing, Company will promptly provide USWM with any information and supporting documentation with respect to the Products, which is within 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. **Milestone Payments.** During the Term, USWM will make: (a) the one-time, non-refundable, non-creditable Near-Term Milestone Payments, and (b) the one-time, non-refundable, non-creditable Commercial Milestone Payments, both set forth on Schedule B and Schedule C, respectively (collectively the "**Milestone Payments**") to the Company upon successful completion of the corresponding milestone events. 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 Quarterly Report referenced in Section 6.2.2 below, and the Company shall thereafter issue an invoice to USWM for the applicable Milestone Payment. Milestone Payments shall be due as described in Schedule B and Schedule C.

6.2. **Net Profit Sharing.**

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

6.2.2. **Net Profit Share Payments.** All Net Profit Share allocation payments made by USWM to Company will be made on a quarterly basis. Within [***] after the end of an applicable Calendar Quarter, USWM shall provide Company with a report showing units sold, Net Sales, deductions from Net Sales, the Net Profit Share allocations and [***] ("**Quarterly Report**"). Within [***] after the end of the applicable Calendar Quarter (such date, the "**Quarterly Payment Date**"), USWM shall provide Company with a cash payment equal to the Net Profit Share stated in the latest Quarterly Report.

6.2.3. **Accelerated Net Profit Share Payments.** In the absence of [***], beginning with [***], USWM shall pay [***] to the Company as defined in Schedule B until [***]. After such [***], the [***] will revert to [***]. If [***] precedes [***], then no Accelerated Net Profit Share Payments shall be due, however, [***].

6.2.4. **[***] Reports.** In addition to the quarterly reports described in Section 6.2.2, within [***] after [***], USWM shall provide Company with a report (in Microsoft excel format or any other format reasonably agreed to by the Parties) that includes (i) [***], and (ii) [***].

6.3. **Branded Prescription Drug Fees.** By means of [***], the Parties shall [***] any applicable Annual Branded Prescription Drug Fees owed with regard to the Products, 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**"). Each [***], USWM shall [***]. Such amount is subjected to [***].

6.4. **Taxes.** All amounts payable by USWM to 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 Products, the execution or performance of this Agreement or otherwise. If any payment under this Agreement by USWM to Company is subject to withholding tax under Applicable Law, USWM shall have the right to withhold any and all such taxes, which shall be paid to the appropriate taxing authority for the account of Company and such payments to Company shall be net of the applicable withholding taxes. USWM shall provide to 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 Company to USWM hereunder for the supply of the Products is exclusive of any sales, use, value added, or similar tax customarily borne by a purchaser ("**Sales Taxes**"). If Company has a legal obligation to collect or charge Sales Taxes, [***] 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 [***] prior written notice and no more than [***] for each category of costs or revenues, a Party (**"Audited Party"**) will permit its Books and Records for the prior calendar year to be examined for any cost, expense, Supply Price, 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 [***] of the date of such report, provided, that if a Party disputes the conclusion of the auditor, the Parties will attempt to resolve the dispute according to Section 12.3. 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.** Notwithstanding USWM's obligations to meet the Commercial Efforts set by the JPT, Company acknowledges that USWM makes no further representation, warranty or covenant, either express or implied, that (a) USWM will succeed in Commercializing the Products in the Territory, (b) the Products will achieve any particular sales level, or (c) achievement of any Commercialization Plan guarantees the achievement of any particular future sales level within any given period of time, if at all.

7. REPRESENTATIONS AND WARRANTIES.

7.1. **Corporate Power.** Each Party hereby represents and warrants that such Party is duly organized, validly existing, and in good standing 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 throughout the term of this Agreement. Each Party hereby represents and warrants that the execution of this Agreement by its representative whose signature is set forth at the end hereof has been duly authorized by all necessary organizational action of the Party.

7.3. **Binding Obligation.** Each Party hereby represents and warrants that this Agreement, when executed, is a legal and valid obligation binding upon it and is enforceable against that Party 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.** Company represents, warrants and covenants to USWM that (i) it has complied, and is now complying, with all Applicable Laws applicable to the conduct of the Business as currently conducted or the ownership and use of the Products, and (ii) it shall, at all times, comply with all Applicable Laws in its performance of its obligations pursuant to this Agreement. USWM represents, warrants and covenants to Company that it shall, at all times during the term of this Agreement, comply with all Applicable Laws in its performance of its obligations pursuant to this Agreement.

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

7.5.1. The Licensed Patents listed on Schedule A represent all Patents that Company or its Affiliates Control that are necessary or useful for the Manufacture or Commercialization of the Products in the Territory for the duration of the term of this Agreement. As of the Effective Date, to Company's knowledge, all of the Licensed IP and the Licensed Trademarks are valid and enforceable.

7.5.2. Company is, and shall remain for the Term of this Agreement, the sole and exclusive owner of the entire right, title and interest in and to the Licensed IP and the Licensed Trademarks.

7.5.3. Company has, and shall continue to have for the Term of this Agreement, the right to the Licensed IP and the Licensed Trademarks to grant the licenses to USWM that are granted hereunder.

7.5.4. Company has not granted, and will not grant during the Term, to any Third Party any license, lien, option, encumbrance, or other contingent or non-contingent right, title or interest in or to the Licensed IP or Licensed Trademark(s) (each, an **"Encumbrance"**) that conflicts with the licenses granted to USWM hereunder or would materially impair USWM's rights hereunder regarding the Licensed IP or Licensed Trademark(s). For avoidance of doubt, Company may grant an Encumbrance in or to the Licensed IP or Licensed Trademark(s) to a lender or other similar Third Party (in either case, solely to the extent such Third Party is not in the business of developing or commercializing pharmaceutical products) provided that such Encumbrance does not materially impair USWM's rights hereunder regarding the Licensed IP or Licensed Trademark(s).

7.5.5. As of the Effective Date, Company has not received any notice that has not been resolved from a Third Party alleging that (i) the practice of the Licensed IP or the Licensed Trademark(s) infringes or may infringe such Third Party's intellectual property right, or (ii) Development or Manufacturing of the Products by Company infringes or misappropriates the intellectual property rights of any Third Party.

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

7.5.7. As of the Effective Date, there is no settled, pending, or unresolved 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 Company's knowledge, threatened against Company in connection with the Products or any of the Licensed IP or Licensed Trademark(s) licensed to USWM hereunder, in each of the above cases which would reasonably be expected to impair, restrict or prohibit the ability of USWM or Company to perform its obligations and enjoy the benefits of this Agreement.

7.5.8. Company has complied in all material respects with all Applicable Laws in connection with the prosecution of the Licensed IP, including any disclosure requirements of the United States Patent and Trademark Office, and has timely paid all filing and renewal fees payable with respect thereto.

7.5.9. Company is in material compliance with all agreements (i) with the Product Manufacturers, and (ii) with all other Third Parties applicable to this Agreement. To the best of its knowledge, Company is not aware of any threatened material breach or termination to any of the foregoing contracts.

7.5.10. Each Product delivered to USWM will be conveyed with good title, free and clear of all encumbrances.

7.5.11. As of the Effective Date, the estimated Supply Prices for each Product set forth in Schedule E are accurate and otherwise consistent with the terms and conditions of Company's agreements (i) with the Product Manufacturers, and (ii) with all other applicable Third Parties.

7.6. **Additional USWM Representations and Warranties.**

7.6.1. In the performance of its obligations and activities under or contemplated by this Agreement, USWM shall comply and shall use [***] to 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 USWM) to comply with all Applicable Laws, including without limitation Applicable Laws regarding corruption, bribery, kickbacks, ethical business conduct, fraud and money laundering.

7.7. **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 PRODUCTS.

8. INDEMNIFICATION; LIABILITY.

8.1. **Company Indemnification.** Company shall indemnify, defend and hold USWM Indemnified Parties harmless from and against any Liability paid or payable by USWM Indemnified Parties to a Third Party as a result of any Claim that results from, arises out of or is based upon: (a) the inaccuracy or breach of any of the representations, warranties, covenants, obligations or agreements made by Company in this Agreement, the Pharmacovigilance Agreement, or the Quality Agreement; (b) the negligence or willful misconduct of Company, its Affiliates, officers, directors, agents, and employees relating to this Agreement; (c) the Development, Processing or Manufacturing of the Products by or on behalf of 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 USWM from any of USWM's customers as a result of Company's failure to provide the Products in accordance with this Agreement unless caused by any negligent action or omission of USWM, (f) any infringement of the Intellectual Property Rights of a Third Party; in each case, except to the extent to, or for matters for, which USWM would be required to indemnify Company Indemnified Parties under Section 8.2, or (g) the conduct or operation of the Business or other ownership, use or license of the Products before, or in respect of periods preceding, the Effective Date.

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

8.3. **Prompt Notice Required.** A Company Indemnified Party or USWM Indemnified Party, as applicable (the **"Indemnitee"**) seeking indemnification pursuant to this Section 8 shall give prompt notice (but in any event no later than as reasonably practicable after such Indemnitee becomes aware of such Third Party claim in order to allow the Indemnitor to attempt to resolve the claim with the respective Third Party) of the matter which may give rise to such claim to the Party against whom indemnification may be sought (the **"Indemnitor"**); 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 denied, withheld, conditioned or delayed.

8.4. **Indemnitor May Settle.** The Indemnitor shall at its expense, have the right to control, through counsel satisfactory to the Indemnitee (such satisfaction of Indemnitee shall not be unreasonably denied, withheld, conditioned or delayed), 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. Any defense arguments and proceedings 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 Claims and/or Liabilities against 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 denied, withheld, conditioned 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 denied, withheld, conditioned 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 FULLEST EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OTHER PERSON FOR 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 SECTION 10.

9. INSURANCE.

9.1. **Parties' Insurance.** Each Party, at its sole cost, at all times during [***], maintain the insurance coverages with the minimum limits as set forth below. Notwithstanding the foregoing, to the extent USWM [***] USWM shall use [***]. 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 Party at its sole cost. Within [***], each Party shall provide the other Party with proof of insurance demonstrating its compliance with the obligations of this Section 9.

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 [***]; and

d. **Product Liability Insurance**, including **Products/Completed Operations** insurance, of not less than [***], and [***] in the aggregate.

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

9.1.2. By requiring Parties to maintain insurance, neither Party represents that coverage and limits required will be adequate to fund all Liabilities for which Parties may be liable. The limits of insurance coverage shall not affect or limit the liability or indemnity obligations of the Parties stated elsewhere in this Agreement or as required by Applicable Law.

9.1.3. All required insurance coverage of Parties will be maintained without interruption during the Term of this Agreement.

9.2. **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 Section 10, any Confidential Information of the other Party, without first having obtained the furnishing Party's prior 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 Law 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, in both cases, the Party disclosing such information shall, if practicable, promptly notify the other Party in advance of any required or necessary disclosure 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, (b) provide the other Party with a copy of the proposed disclosure in sufficient time to allow reasonable opportunity to comment thereon, and (c) disclose only that portion of the Confidential Information that, in the opinion of its legal counsel, must be disclosed pursuant to Applicable Law.

10.3. **Use of Information.** Each Party shall only use, and direct each of its Affiliates to only 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 including 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 mutually 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, prior to any such disclosure. Either Party may make, such reasonable 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 and shall reasonably consider input from the other Party concerning such 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 Section 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 may not be a sufficient remedy for any breach of this Section 10. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Section 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 Launch of the first Product in the Territory pursuant to this Agreement (the **"Initial Term"**). This Agreement shall thereafter be automatically renewed for consecutive five (5) year renewal terms (each a **"Renewal Term"**) unless this Agreement is otherwise (i) terminated by mutual prior written agreement by Parties (either with respect to the ZIMHI Product or the SYMJEPI Product individually, or both Products collectively), or (ii) terminated by a Party as permitted under this Agreement. The **"Term"** means the Initial Term and, if applicable, the Renewal Term.

11.2. **Termination.**

11.2.1. **Termination for Cause.** Subject to the terms of this Section 11.2.1, 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. Notwithstanding the foregoing, the Parties agree that the [***] notice and cure period herein may be extended if the breaching Party is [***] to cure the specified breach. 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. A Party may terminate this Agreement pursuant to this Section 11.2.1 (i) with respect to the ZIMHI Product or the SYMJEPI Product individually to the extent the uncured breach arises pursuant to an obligation concerning a Product individually, or (ii) with respect to both Products collectively to the extent the uncured breach arises pursuant to obligations concerning both Products collectively.

11.2.2. **USWM Termination.**

a. Failure to Supply. If at any time during the Term, (a) Company is unable to deliver Product pursuant to a Firm Order for a period longer than [***] after the applicable delivery date set forth in the respective Firm Order for causes within Company's control, or (b) if the Company is unable to supply, or arrange to make available for shipment the Launch Quantity within [***] of the Regulatory Approval for causes within Company's control; then, in either case (each such occurrence a "**Failure to Supply**"), USWM may, upon [***] prior written notice to Company that a Failure to Supply has occurred, request in such notice that Company exercise, and Company shall, at Company's sole cost and expense, [***] to (i) evaluate, contract, and qualify a mutually agreeable alternate manufacturing facility to manufacture and supply all of USWM's requirements of Product(s) in the Territory, (ii) transfer sufficient know-how to the alternate manufacturing facility in order to enable the facility to manufacture the Product(s) in accordance with the terms of this Agreement, and (iii) ensure that the alternate manufacturing facility is contractually obligated to use commercially reasonable efforts to be approved by the applicable Regulatory Authority to manufacture commercial quantities of the Product(s) and is brought up to production readiness as soon as reasonably possible following USWM's written notice specified above. In the event an alternate manufacturing facility is utilized to supply Products under this Agreement, such facility shall be deemed a "Manufacturing Facility" for purposes of this Agreement. Subject to Company [***], the Parties may mutually agree to terminate this Agreement (either with respect to the ZIMHI Product or the SYMJEPI Product individually, or both Products collectively). Notwithstanding anything in this Section 11.2.2(a), in the event that a Failure to Supply arises by the willful act or omission of Company (and not for other reasons including without limitation acts or omissions of third parties beyond the reasonable control of Company or acts or omissions relating to [***] taken in good faith by Company), USWM may, in its sole discretion, elect to terminate this Agreement (either with respect to the ZIMHI Product or the SYMJEPI Product individually, or both Products collectively, as the case may be) at the end of such [***] notice period, and Company shall pay to USWM within [***] of the [***] an amount equal to [***]. In the event that either (i) Company fails to [***], or (ii) supply of the affected Product(s) fails to resume within [***] from [***], USWM may, in its sole discretion, elect to terminate this Agreement (either with respect to the ZIMHI Product or the SYMJEPI Product individually, or both Products collectively) unless supply of the affected Product(s) resumes during such [***] notice period and, in the event that USWM elects to terminate this Agreement (either with respect to the ZIMHI Product or the SYMJEPI Product individually, or both Products collectively, as the case may be) Company shall pay to USWM within [***] of the effective date of termination an amount equal to [***] of (a) [***], or (b) [***]. For purposes of clarity, the remedies available to USWM pursuant to this Section 11.2.2(a) are in addition to any other remedies available to USWM under this Agreement, including without limitation, USWM's indemnification rights pursuant to Section 8.1. Notwithstanding the foregoing, USWM shall not be entitled to exercise the remedies in this Section 11.2.2(a) upon a Failure to Supply as a result of a Force Majeure event in accordance with Section 12.10.

b. Infringement Action. From the Effective Date through a period of [***] following [***], USWM may, upon [***] prior written notice to Company, terminate this Agreement (either with respect to the ZIMHI Product or the SYMJEPI Product individually, or both Products collectively, as the case may be) if [***] that prevents either (i) [***], or (ii) [***]. In the event that USWM terminates this Agreement (either with respect to the ZIMHI Product or the SYMJEPI Product individually, or both Products collectively, as the case may be) pursuant to this Section 11.2.2(b), Company shall pay to USWM within [***] of [***] an amount equal to [***] plus the greater of (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 Products in the Territory.

c. Regulatory Approval. If, as it relates to the ZIMHI Product, Regulatory Approval has not been achieved within [***], USWM, in its sole discretion, may elect to either (i) upon [***] prior written notice to Company, terminate this Agreement only with respect to the ZIMHI Product individually, or (ii) [***].

11.2.3. **Termination by the Company.**

a. Failure to Launch. Subject to the terms of this Section 11.2.3(a), upon [***] prior written notice to USWM, Company shall have, at its sole discretion, the right to terminate this Agreement if within [***] (or such longer period as agreed in writing by the Parties) after both (i) [***], and (ii) [***], USWM fails to Launch the Product in the Territory, provided such failure is for causes within USWM's control. Company may terminate this Agreement pursuant to this Section 11.2.3(a) only with respect to the ZIMHI Product or the SYMJEPI Product individually to the extent USWM fails to Launch each of the Products individually on the terms and subject to the conditions otherwise set forth in this Section 11.2.3(a).

b. Commercial Efforts. Subject to the terms of this Section 11.2.3(b), upon [***] prior written notice to USWM, Company may terminate this Agreement in part or in its entirety if (i) USWM fails to [***] for [***], and (ii) such failure by USWM remains uncured at the end of such notice period; provided such failure is for causes within USWM's reasonable control. Notwithstanding the foregoing, the Parties agree that the [***] notice and cure period herein may be extended if USWM is [***] to cure the specified failure. Company may terminate this Agreement pursuant to this Section 11.2.3(b) only with respect to the ZIMHI Product or the SYMJEPI Product individually to the extent USWM fails to meet [***] for [***] as such [***] are determined with respect to each of the Products individually, and on the terms and subject to the conditions otherwise set forth in this Section 11.2.3(b).

11.2.4. **Bankruptcy.** To the extent permitted under Applicable Law, a Party may terminate this Agreement (either with respect to the ZIMHI Product or the SYMJEPI Product individually, or both Products collectively) effective immediately with written notice if the other Party shall be adjudicated bankrupt, shall be dissolved or shall have a receiver appointed for substantially all of its property. All rights and licenses granted by Company under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, rights and licenses to "intellectual property" as such term is used in, and interpreted under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights, elections, and protections under the Bankruptcy Code, and all other bankruptcy, insolvency, and similar laws with respect to this Agreement and the subject matter hereof. Without limiting the generality of the foregoing, Company acknowledges and agrees that, if Company or its estate shall become subject to any bankruptcy or similar proceeding, (i) subject to USWM's rights of election under Section 365(n) of the Bankruptcy Code, all rights, licenses, and privileges granted to USWM under this Agreement will continue subject to the respective terms and conditions hereof, and will not be affected, even by Company's rejection of this Agreement, (ii) USWM shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any and all such intellectual property and embodiments of intellectual property, which if not already in USWM's possession, shall be promptly delivered to USWM or its designee, and (iii) Company shall undertake [***] to ensure USWM's access to Company's contracts with the Product Manufacturers, in both instances of (ii) and (iii) to the extent needed to allow USWM to make or have made and continue to Commercialize any Product under this Agreement, and such, if not already in its possession, shall be promptly delivered to USWM by Company, unless the Company elects to continue, and does in fact continue to perform all of its obligations under this Agreement. All [***] incurred by USWM to [***] may be deducted by USWM from [***]. Notwithstanding the foregoing, if USWM (or any administrator, receiver, liquidator, trustee appointed over all or any parts of its assets, or similar entity) selects to continue, and does in fact continue to perform all of its obligations under this Agreement, then Company shall not be entitled to terminate this Agreement pursuant to this Section 11.2.4.

11.2.5. **Effects of Termination.**

a. Except (i) to the extent this Agreement is terminated solely with respect to a Product individually (in which case the Parties' rights and obligations pursuant to this Agreement with regard to such non-terminated Product shall be unaffected by this Section 11.2.5(c)), and (ii) 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, including any owed and payable outstanding liabilities.

b. Except to the extent this Agreement is terminated solely with respect to a Product individually (in which case the Parties' rights and obligations pursuant to this Agreement with regard to such non-terminated Product shall be unaffected by this Section 11.2.5(b)), in the event of expiration or termination of this Agreement by (i) Company pursuant to Section 11.2.1 (Termination for Cause), Section 11.2.3(a) (Failure to Launch), Section 11.2.3(b) (Commercial Efforts), or Section 11.2.4 (Bankruptcy), or (ii) USWM pursuant to Section 11.2.1 (Termination for Cause), Section 11.2.2(a) (Failure to Supply), Section 11.2.2(b) (Infringement Action), or Section 11.2.4 (Bankruptcy), all licenses and rights granted by Company to USWM will terminate, and 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.

c. Except to the extent this Agreement is terminated solely with respect to a Product individually (in which case the Parties' rights and obligations pursuant to this Agreement with regard to such non-terminated Product shall be unaffected by this Section 11.2.5(c)), in the event of early termination of this Agreement for any reason other than termination by Company pursuant to Section 11.2.1 (Termination for Cause), Section 11.2.3(a) (Failure to Launch) or Section 11.2.4 (Bankruptcy), USWM and its Affiliates shall have the right, in USWM's sole discretion, to continue, to the extent that USWM and its Affiliates continue to have Product inventory, to fulfill orders received from customers for the Products in the Territory until up to [***] after the effective date of termination of this Agreement. For Product sold by USWM or its Affiliates after the effective date of termination, USWM shall continue to make payments to Company in accordance with Section 6, as applicable.

11.2.6. **Non-Exclusive Remedy.** Subject to Section 8.6, the 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.

12. GENERAL.

12.1. **Interpretation.** The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. The definitions of the terms herein apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to always be followed by the phrase "without limitation." Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws herein will be construed as referring to such laws and any rules or regulations promulgated thereunder as from time to time enacted, repealed or amended, (c) any reference herein to any person will be construed to include the person's successors and assigns, (d) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference herein to the words "mutually agree" or "mutual written agreement" will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party's sole discretion, except as expressly provided in this Agreement, (f) as applied to a Party, the word "will" shall be construed to have the same meaning and effect as the word "shall," and (g) all references herein without a reference to any other agreement to Articles, Sections, or Exhibits will be construed to refer to Articles, Sections, and Exhibits of or to this Agreement.

12.2. **Exclusivity.** During the Term of this Agreement, except (i) as contemplated by this Agreement, including but not limited to (X) [***] and (Y) [***], (ii) as contemplated under Other Agreements, or (ii) upon the prior written consent of the other Party, the Company agrees not to, directly or indirectly, and [***].

12.3. **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 [***] after delivery of such notice of dispute, the USWM 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 [***] after such meeting, then, subject to Section 12.4, each Party reserves its right to any and all remedies available under law or equity with respect to any other dispute.

12.4. **Jurisdiction.** Any Dispute that is not resolved under Section 12.3 within the time periods described in such section shall be resolved by final and binding arbitration before a panel of one arbitrator with relevant industry experience. The arbitration proceeding shall be administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("**AAA**"), and the panel of arbitrators shall be selected in accordance with such rules. The arbitration and all associated discovery proceedings and communications shall be conducted in English, and the arbitration shall be held in a reasonable location to be selected by the Party against whom arbitration is compelled. The location selected by such Party shall not be located in a state in which the respective selecting Party is domiciled. The arbitrator shall, reasonably promptly after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the arbitrator shall be final and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction. Either Party may apply for interim injunctive relief with the arbitrator until the arbitration award is rendered or the controversy is otherwise resolved. The arbitrator shall be authorized to award compensatory damages, but shall not be authorized (i) to award noneconomic damages, (ii) to award punitive damages or any other damages expressly excluded under this Agreement, or (iii) to reform, modify or materially change this Agreement or any other agreements contemplated hereunder; provided, however, that the damage limitations described in subsections (i) and (ii) of this sentence will not apply if such damages are statutorily imposed. Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of AAA and the arbitrator; provided, however, the arbitrator shall be authorized to determine whether a Party is the prevailing Party, and at the arbitrator's discretion, to award to that prevailing Party reimbursement for its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), and/or the fees and costs of the AAA and the arbitrator. Subject to the foregoing provisions, the Company and USWM agree to irrevocably submit to the jurisdiction of the federal and state courts for the judicial district in which the underlying arbitration occurred, for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby, and agrees that services of any process may be made in the manner provided in this Agreement for delivery of notices. 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 such courts. Each Party hereto agrees that any such proceeding shall be conducted solely in the English language.

12.5. **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 12.5.

12.6. **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 Delaware, 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.

12.7. **Remedies.** Except as otherwise provided herein, any and all other remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one (1) remedy will not preclude the exercise of any other remedy, provided, that a party shall not be entitled to more than one recovery, without duplication, for the same liability, loss or damage.

12.8. **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 (i) 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); (ii) 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; (iii) 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 (iv) is on any of the FDA Clinical Investigator enforcement lists, including, but not limited to, the (a) Disqualified/Totally Restricted List, (b) Restricted List, and (c) 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.

12.9. **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 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 (i) an assignment or transfer to an Affiliate of the assigning Party, (ii) 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, or (iii) a transfer or sale of all or substantially all of the assets directly related to one (1) or more business units of such Party 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 12.9 shall be void.

12.10. **Force Majeure.** No Party shall be liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement (except for any obligations to make payments of amounts invoiced hereunder), when and to the extent such failure is caused by or results from a Force Majeure Event. The Party claiming a Force Majeure Event shall notify the other Party with notice of the Force Majeure Event as soon as practicable, which notice shall reasonably identify such obligations under this Agreement and the extent to which performance thereof will be affected, including the period of time the occurrence is expected to continue. In such event, the Parties shall meet promptly (either in person or telephonically, as the situation may dictate) 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 Commercial Reasonable Efforts to minimize the loss or inconvenience suffered by the Parties.

12.11. **Entire Agreement.** This Agreement, including any schedules or exhibits hereto, and the subsequent 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.

12.12. **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.

12.13. **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 the other Party.

12.14. **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.

12.15. **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 or email 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 USWM:

USWM, LLC
[***]
Attn: [***]

Tel: [***]
Email: [***]

With a copy to:

USWM, LLC
[***]
[***]
Attn: [***]
Tel: [***]
Email: [***]

If to Company:

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

12.16. **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.

12.17. **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.

12.18. **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 are to Sections of this Agreement, unless otherwise indicated.

12.19. **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.

12.20. **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.

12.21. **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.

12.22. **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 set forth in this Section 12.22, Section 5.3, Sections 6.5 (for [***] following the calendar year in which termination or expiration occurs), 6.6, 7, 9.1.3 (for [***] following termination or expiration occurs), 11.2.5 and 11.2.6 and Section 1, Sections 8, 10 and 12 (other than 12.1) and any right, obligation, or required performance of the Parties in this Agreement which, by its express terms or nature and context is intended to survive termination or expiration of this Agreement, will survive any such termination or expiration.

[*signature page follows*]

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

USWM, LLC

By: /s/ P. Breckinridge Jones, Sr. Date: _____
NAME: P. Breckinridge Jones, Sr.
Title: CEO

ADAMIS PHARMACEUTICALS CORPORATION

By: /s/ Dennis J. Carlo Date: _____
NAME: Dennis J. Carlo, Ph.D.
Title: President and CEO

[SIGNATURE PAGE TO DISTRIBUTION AND COMMERCIALIZATION AGREEMENT]

SCHEDULE A

Licensed Patents and Licensed Trademarks

Licensed Patents:

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

Licensed Trademarks:

“SYMJEPI” (registered trademark no. 5853281)

“ZIMHI” (pending US TM application no. 88281598)

Domain Names:

SYMJEPI.com

ZIMHI.com

SCHEDULE B

Near-Term Milestone Payments and Net Profit Share

Near-Term Milestone Payments

Milestone	Amount Payable
(i) Within [***]	US$ [***]
(ii) Within [***]	US$ [***]
(iii) [***]	US$ [***]

Net Profit Share

Subject to the terms of the Agreement, including without limitation, Section 6.2.2 (Net Profit Share Payments) and Section 6.3 (Branded Prescription Drug Fees), USWM shall pay Company [***] of the Net Profits. USWM shall retain the remaining [***] of the Net Profits.

Accelerated Net Profit Share

Subject to the terms of the Agreement, including without limitation, Section 6.2.2 (Net Profit Share Payments), Section 6.2.3 (Accelerated Net Profit Share Payments) and Section 6.3 (Branded Prescription Drug Fees), in addition to the Net Profit Share Payment USWM shall pay Company an Accelerated Net Profit Share equal to [***]. After such limit is reached, Net Profit Allocation would revert to the Net Profit Share defined above. For purposes of clarity, the payment of Accelerated Net Profit Share will end upon the date on which [***].

For the avoidance of doubt, the cumulative total of Near-Term Milestone Payments and Accelerated Net Profit Share Payments shall not exceed a total of US$ [***].

SCHEDULE C

Commercial Milestone Payments and Net Profit Share

Commercial Milestone Payments

Milestones	**Amount Payable**
(i) On [***], upon the initial achievement of [***] (1)	US$ [***]
(ii) On [***], upon the initial achievement of [***] (1)	US$ [***]
(iii) On [***], upon the initial achievement of [***] (1)	US$ [***]
(iv) On [***], upon the initial achievement of [***] (1)	US$ [***]
(v) On [***], upon the initial achievement of [***] (1)	US$ [***]

(1) If there is [***] and therefore no [***], the combined Net Sales of the Products (SYMJEPI and ZIMHI) will then be counted toward the achievement of the above Commercial Milestones. For the avoidance of doubt, the cumulative Commercial Milestone Payments shall not exceed a total of US$ [***].

SCHEDULE D

Products

"**Product**" or **"Products"** means the Company's injection product containing epinephrine in 0.3mg/0.3mL, 0.15mg/0.3mL, and any other strength, as approved by the FDA under NDA number 207534, as amended, and/or any the Company's injection product containing naloxone in 5mg/0.5 mL, and any other strength, pending FDA approval under NDA number 212854, as amended, in finished, packaged form that is distributed by USWM under the Licensed Trademarks SYMJEPI and ZIMHI pursuant to their respective NDAs, in each case, in the Territory, under USWM NDC numbers, pursuant to this Agreement.

SCHEDULE E

Supply Price

The Supply Price shall be [***] Company's actual cost for Product without any Company markup or allocation of Company overhead. The Supply Price shall include [***]. The following is an estimate of Third Party costs under the current Product Manufacturer agreements.

SYMJEPI

Primary Assembly – the primary assembly, which includes [***], will be conducted at [***]. Pursuant to the supply agreement, [***] sources all material and components required to complete the primary assembly and [***] cost is determined by [***]. The approximate current cost of primary assembly at [***] is [***] and [***] and [***] for batches of [***] and [***], respectively. The approximate direct cost of shipping the filled syringes from [***] to [***] for [***] and [***] batches of [***] and [***], respectively.

Final Assembly – the final assembly, which includes [***], will be performed at [***]. The cost of final assembly varies based on [***]

The estimated annual capacity for [***] is [***]) doses and [***] is at least [***]) doses. Presently, the [***] dose is assembled on [***] and the [***] dose is assembled on [***]; however, the Company, at its sole expense and cost (e.g., not to be included in the Supply Price), plans to [***].

By way of example, if a [***] unit batch of SYMJEPI was assembled on the [***] when the forecasted combined annual volume was [***], the estimated total cost would be [***].

ZIMHI

Primary Assembly – the primary assembly, which includes [***], will be conducted at [***]. The cost of primary assembly includes [***]. Pursuant to the supply agreement, [***] will source all material (except API) and components required to complete the primary assembly and [***] cost will be determined by [***]. The total cost of primary assembly, including [***] is estimated to be [***] and [***] per [***] for batches of [***] and [***], respectively. The approximate direct cost of shipping [***] from [***] to [***] for final assembly is [***] and [***] per syringe for batches of [***] and [***], respectively.

Final Assembly – the final assembly, which includes [***], will also be performed at [***] and the cost of final assembly is [***]. [***] has been [***]; however, the Company, at [***], plans to [***].

By way of example, [***] unit batch of SYMJEPI was assembled on the [***] when the forecasted combined annual volume was [***], the estimated total cost would be [***].

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

SCHEDULE F

Commercial Efforts and Sales and Distribution Allocation

"**Commercial Efforts**" as described in this Agreement shall mean the specific activities involved in USWM's Commercial Efforts for each Product and could [***]. More generally, such activities would include [***]: [***]. Commercial Efforts for a given Marketing Year would include, but not be limited to, [***]:

1) [***];

2) [***];

3) [***]; and

4) [***].

The allocation of cost for these functions via [***] would be determined [***] and would be [***].

Notwithstanding anything in this Agreement to the contrary, USWM shall not be deemed to be in breach of its Commercial Efforts obligations under this Agreement so long as USWM actually [***].

"Sales and Distribution Allocation" as described in this Agreement shall mean [***] including, without limitation, (i) [***], (ii) [***], and (iii) [***].

The Parties acknowledge and agree that, with respect to [***], commencing as of [***], the allocation of shared sales expenses will be allocated [***].

The Company shall have the right to reasonably audit USWM's Books and Records for purposes of verifying the Commercial Efforts and the calculation of the Sales and Distribution Allocation under this Agreement (for purposes of clarity, any such audit described herein shall be limited to only include those records of USWM that are applicable to/for verifying USWM's Commercial Efforts performance and the calculation of the Sales and Distribution Allocation pursuant to this Agreement). Such audits may be requested no more than [***] per [***] period during the Term and once during the [***] period following [***]. Such audits shall be limited to USWM's Books and Records which are relevant for verifying the Commercial Efforts and/or the calculation of the Sales and Marketing Allocation, and for no earlier than [***] immediately preceding such audit. Any such right to audit shall be exercised only on at least [***] advance written notice.

SCHEDULE G

Approved Product Manufacturer

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

[***]

[***]

[***]

SCHEDULE H

Licensed Trademarks Usage Guidelines

Pursuant to the Distribution and Commercialization Agreement dated May 11, 2020, 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 (**"Licensor"**) and USWM, LLC a limited liability company organized under the laws of Delaware, with an office at [***] ("**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 Usage Guidelines and the Agreement, the terms contained in these 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.

[***]

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 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: August 17, 2020

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 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: August 17, 2020

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

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

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

(1) the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

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

Dated: August 17, 2020

This certification is being furnished to the SEC with this Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

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

(1) the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

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

Dated: August 17, 2020

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.