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, 2021

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

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

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

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

The number of shares outstanding of the issuer's common stock, par value $0.0001 per share, as of November 22, 2021, was 148,886,141.

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

CONTENTS OF QUARTERLY REPORT ON FORM 10-Q

Summary of Material Risks Associated With Our Business

The business of Adamis Pharmaceuticals Corporation ("we," "us," "our," "Adamis," or the "company") is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "Risk Factors." These risks include, but are not limited to, the following:

- There is substantial doubt about our ability to continue as a going concern. We have incurred significant losses since our inception, anticipate that we will continue to incur losses in 2021, and may continue to incur losses in the future. We may never achieve or sustain profitability.
- Statements in this Report concerning our future plans and operations are dependent on our having adequate funding and the absence of unexpected delays or adverse developments. We may require additional financing in the future and may not be able to secure required funding, which could force us to delay, reduce or eliminate our commercialization efforts or product development programs and could cause us to cease operations.
- We may never commercialize additional product candidates that are subject to regulatory approval or earn a profit.
- Several of our potential products and technologies are in early stages of development, or have been discontinued or are suspended.
- Our development plans concerning our products and product candidates are affected by many factors, the outcome of which are difficult to predict.
- We could experience delays in the commencement or completion of clinical testing of our product candidates, which could result in increased costs and delays and adversely affect our business and financial condition. We may be required to suspend, repeat or terminate our clinical trials if trials are not well designed, do not meet regulatory requirements or the results are negative or inconclusive.
- We are subject to the risk of lawsuits or other legal proceedings.
- We are subject to substantial government regulation, which could materially adversely affect our business. We may encounter difficulties or delays in applying for or obtaining regulatory approval for our products. If we do not receive required regulatory approvals for our products, we may not be able to develop and commercialize our products or technologies.
- Even if they are approved and commercialized, our potential products may not be able to compete effectively with other products targeting similar markets.
- Our failure to adequately protect or to enforce our intellectual property rights or secure rights to third party patents or other intellectual property rights could materially harm our proprietary position in the marketplace or prevent the commercialization of our products. We may become involved in patent litigation or other intellectual property proceedings, which could result in liability for damages and have a material adverse effect on our business and financial position.
- If we determine that our intangible assets or other assets have become impaired, our total assets and financial results could be adversely affected.
- We borrowed funds pursuant to the Paycheck Protection Program. Even though our loans have been forgiven pursuant to the program, we remain subject to possible review and audit in connection with such loans.
- Our business is impacted by state and federal statutes and regulations.
- Our US Compounding Inc. subsidiary, or USC, which is registered as a human drug compounding outsourcing facility under Section 503B of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, is subject to many federal, state and local laws, regulations, and administrative practices, including, among others: federal registration as an outsourcing facility, state and local licensure, and registration requirements concerning the operation of outsourcing facilities and the compounding, labeling, marketing, sale and distribution of products from our registered outsourcing facility. . Effective as of July 30, 2021, we entered into an asset purchase agreement pursuant to which we sold and transferred certain assets of USC related to its human compounding pharmaceutical business, and we have approved a restructuring pursuant to which the remaining operations and business of USC will be wound down and wound up and assets relating to USC's business will be sold or otherwise disposed of. Nevertheless, USC and we could become involved in proceedings with the U.S. Food & Drug Administration, or FDA , or other federal or state regulatory authorities alleging non-compliance with applicable federal or state regulatory legal requirements, which could adversely affect our business, financial condition and results of operations.

- We have received a grand jury subpoena issued in connection with a criminal investigation. As we have previously disclosed, on May 11, 2021, each of the company and our USC subsidiary received a grand jury subpoena from the U.S. Attorney's Office ("USAO") for the Southern District of New York issued in connection with a criminal investigation, requesting a broad range of documents and materials relating to, among other matters, certain veterinary products sold by the company's USC subsidiary, certain practices, agreements and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC. The Audit Committee of the board of directors (the "Board") has engaged outside counsel to conduct an independent internal investigation to review these and other matters. The company has also received a request from the Securities and Exchange Commission ("SEC") that the company voluntarily provide documents and information relating to certain matters including the subject matter of the subpoena from the USAO. The Company has produced and will continue to produce and provide documents in response to the subpoena and requests. The company intends to cooperate with the USAO and SEC. At this time, the company is unable to determine what, if any, additional actions the USAO, SEC or other federal or state authorities may take, what, if any, remedies or remedial measures the USAO, SEC or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the Company's business, previously reported financial results, financial results included in this Report, or future financial results. We could receive additional requests from the USAO, SEC or other authorities, which may require further investigation. The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, result in fines, penalties, equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, future financial results. The occurrence of any of these events could have a material adverse effect on the company's business, financial condition and results of operations.

- Changes in healthcare laws could adversely affect the ability or willingness of customers to purchase our products and, as a result, adversely impact our business and financial results.

- We identified a material weakness in our internal control over financial reporting, concluded that our internal control over financial reporting was not effective and that our disclosure controls and procedures were not effective at the reasonable assurance level, and restated our unaudited condensed consolidated financial statements for the periods ended March 31, 2020, June 30, 2020, and September 30, 2020, which may lead to additional risks and uncertainties, including loss of investor confidence, legal investigations or proceedings, and negative impacts on our business, financial condition and stock price. In addition, we identified a material weakness in our internal control over financial reporting and concluded that our internal control over financial reporting was not effective as of March 31, 2021, June 30, 2021 and September 30, 2021. If we fail to effectively remediate material weaknesses in our internal control over financial reporting, it could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

- Our business depends on complex information systems, and any failure to successfully maintain these systems or implement new systems to handle our changing needs could materially harm our operations. Cybersecurity or other system failures could disrupt our business, result in liabilities, and adversely affect our business, financial condition and results of operations.

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

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

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents	$ 40,618,554	$ 6,855,355
Restricted Cash	30,000	—
Accounts Receivable, net	1,309,949	1,092,857
Inventories	2,170,888	3,115,926
Prepaid Expenses and Other Current Assets	1,999,130	1,459,983
Total Current Assets	46,128,521	12,524,121
LONG TERM ASSETS		
Intangible Assets, net	5,812,934	6,289,684
Goodwill	868,412	868,412
Fixed Assets, net	9,541,221	9,586,593
Right -of-Use Assets	1,301,741	1,543,997
Other Non-Current Assets	54,655	54,655
Total Assets	$ 63,707,484	$ 30,867,462
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable	$ 3,010,514	$ 3,491,717
Deferred Revenue, current portion	104,100	100,070
Accrued Other Expenses	3,551,863	2,524,412
Accrued Bonuses	874,595	1,047,719
Contingent Loss Liability	—	7,900,000
Lease Liabilities, current portion	509,537	494,342
Bank Loan - Building	2,018,101	2,067,213
Paycheck Protection Plan (PPP) Loans, current portion	3,383,586	2,300,253
Total Current Liabilities	13,452,296	19,925,726
LONG TERM LIABILITIES		
Deferred Revenue	800,000	850,000
Deferred Tax Liability, net	112,530	112,530
Lease Liabilities, net of current portion	845,012	1,105,219
PPP Loan, net of current portion	1,573,609	891,447
Warrant Liabilities, at fair value	244,824	4,485,000
Total Liabilities	17,028,271	27,369,922
COMMITMENTS AND CONTINGENCIES (see Note 9)		
STOCKHOLDERS' EQUITY		
Preferred Stock – Par Value $0.0001; 10,000,000 Shares Authorized; Series A-2 Convertible, no shares Issued and Outstanding at June 30, 2021 (Unaudited) and December 31, 2020, respectively.	—	—
Common Stock - Par Value $0.0001; 200,000,000 Shares Authorized; 149,409,098 and 94,365,015 Issued, 148,886,141 and 93,842,058 Outstanding at June 30, 2021 and December 31, 2020, respectively	14,941	9,437
Additional Paid-in Capital	303,620,101	233,404,968
Accumulated Deficit	(256,950,579)	(229,911,615)
Treasury Stock, at cost - 522,957 Shares	(5,250)	(5,250)
Total Stockholders' Equity	46,679,213	3,497,540
Total Liabilities and Stockholders' Equity	$ 63,707,484	$ 30,867,462

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,	
	2021 (Unaudited)	2020 (Unaudited)	2021 (Unaudited)	2020 (Unaudited)
REVENUE, net	$ 4,011,304	$ 3,926,342	$ 8,119,836	$ 8,589,552
COST OF GOODS SOLD	3,870,632	4,683,835	7,512,580	8,370,879
Gross Profit (Loss)	140,672	(757,493)	607,256	218,673
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	7,131,644	5,653,092	13,051,118	11,707,463
RESEARCH AND DEVELOPMENT	2,232,776	3,085,824	4,494,098	5,122,556
IMPAIRMENT EXPENSE - Goodwill	—	—	—	3,143,200
IMPAIRMENT EXPENSE - Long Lived Assets	9,347	—	9,347	—
IMPAIRMENT EXPENSE - Write-off of Contract Asset	—	1,750,000	—	1,750,000
Loss from Operations	(9,233,095)	(11,246,409)	(16,947,307)	(21,504,546)
OTHER INCOME (EXPENSE)				
Interest Expense	(44,947)	(32,925)	(84,272)	(71,212)
Other Income	7,886	16,621	24,089	39,676
Change in Fair Value of Warrants	(43,574)	(1,662,000)	(7,685,474)	1,365,000
Total Other Income (Expense), net	(80,635)	(1,678,304)	(7,745,657)	1,333,464
Net Loss	$ (9,313,730)	$ (12,924,713)	$ (24,692,964)	$ (20,171,082)
Basic and Diluted Loss Per Share	$ (0.06)	$ (0.18)	$ (0.18)	$ (0.29)
Basic and Diluted Weighted Average Shares Outstanding	148,886,141	73,825,491	139,228,657	70,162,628

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, 2021	**Shares**	**Amount**	**Shares**	**Amount**	**Capital**	**Shares**	**Amount**	**Deficit**	**Total**
Balance March 31, 2021	—	$ —	149,409,098	$ 14,941	$ 302,822,034	522,957	$ (5,250)	$ (247,636,849)	$ 55,194,876
Share Based Compensation	—	—	—	—	798,067	—	—	—	798,067
Net Loss	—	—	—	—	—	—	—	(9,313,730)	(9,313,730)
Balance June 30, 2021	—	$ —	149,409,098	$ 14,941	$ 303,620,101	522,957	$ (5,250)	$ (256,950,579)	$ 46,679,213
For the Three Months Ended June 30, 2020									
Balance March 31, 2020	—	$ —	74,255,245	$ 7,426	$ 219,057,654	522,957	$ (5,250)	$ (187,766,895)	$ 31,292,935
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	—	—	—	—	—	—	—	(12,924,713)	(12,924,713)
Balance June 30, 2020	1,000,000	$ 100	74,443,722	$ 7,444	$ 220,762,294	522,957	$ (5,250)	$ (200,691,608)	$ 20,072,980
For the Six Months Ended June 30, 2021									
Balance December 31, 2020, as reported	—	$ —	94,365,015	$ 9,437	$ 233,404,968	522,957	$ (5,250)	$ (229,911,615)	$ 3,497,540
Adjustment, Conversion of 2019 Warrant Liability upon Adoption of ASU 2020-06	—	—	—	—	4,830,000	—	—	(2,346,000)	2,484,000
Balance, December 31, 2020, as adjusted	—	—	94,365,015	9,437	238,234,968	522,957	(5,250)	(232,257,615)	5,981,540
Common Stock Issued, Net of Issuance Costs of $3,330,752	—	—	46,621,621	4,661	48,414,585	—	—	—	48,419,246
Exercise of Warrants	—	—	8,356,000	836	15,292,714	—	—	—	15,293,550
Issuance of Restricted Stock Units (RSUs)	—	—	66,462	7	(7)	—	—	—	—
Share Based Compensation	—	—	—	—	1,677,841	—	—	—	1,677,841
Net Loss	—	—	—	—	—	—	—	(24,692,964)	(24,692,964)
Balance June 30, 2021	—	$ —	149,409,098	$ 14,941	$ 303,620,101	522,957	$ (5,250)	$ (256,950,579)	$ 46,679,213
For the Six months Ended June 30, 2020									
Balance December 31, 2019	—	$ —	62,352,465	$ 6,235	$ 213,520,785	522,957	$ (5,250)	$ (180,520,526)	$ 33,001,244
Common Stock Issued, Net of Issuance Cost of $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 February 2020 Warrants	—	—	—	—	(1,914,000)	—	—	—	(1,914,000)
Issuance of Restricted Stock Units (RSUs)	—	—	491,257	48	(48)	—	—	—	—
Share Based Compensation	—	—	—	—	2,333,719	—	—	—	2,333,719
Net Loss	—	—	—	—	—	—	—	(20,171,082)	(20,171,082)
Balance June 30, 2020	1,000,000	$ 100	74,443,722	$ 7,444	$ 220,762,294	522,957	$ (5,250)	$ (200,691,608)	$ 20,072,980

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,	
	2021 (Unaudited)	**2020 (Unaudited)**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (24,692,964)	$ (20,171,082)
Adjustments to Reconcile Net Loss to Net		
Cash Used in Operating Activities:		
Stock Based Compensation	1,677,841	2,333,719
Acquired IPR&D	—	840,000
Provision for Bad Debts	2,904	62,457
Provision for Excess and Obsolete Inventory	867,317	1,503,399
Change in Fair Value of Warrant Liabilities	7,685,474	(1,365,000)
(Cash Payments in Excess of Lease Expense) Lease Expense in Excess of Cash Payments	(3,084)	3,374
Depreciation and Amortization	1,325,764	1,795,305
Impairment of Goodwill	—	3,143,200
Impairment of Contract Assets	—	1,750,000
Impairment of Long-Lived Assets	9,347	—
Change in Operating Assets and Liabilities		
Accounts Receivable	(219,996)	461,369
Inventories	77,721	(1,585,909)
Prepaid Expenses and Other Current Assets	(539,147)	319,867
Accounts Payable	(445,771)	204,943
Contingent Loss Liability	(7,900,000)	—
Deferred Revenue	(45,970)	527,254
Accrued Other Expenses and Bonuses	855,602	796,939
Net Cash Used in Operating Activities	(21,344,962)	(9,380,165)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of Equipment	(847,830)	(660,787)
Purchase of IPR&D	—	(250,000)
Net Cash Used in Investing Activities	(847,830)	(910,787)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from Issuance of Common Stock, net of issuance costs	51,749,998	6,726,001
Costs of Issuance of Common Stock	(3,330,752)	(492,902)
Proceeds from Exercise of Warrants	5,851,900	—
Principal Payments of Finance Leases	(1,538)	(2,224)
Proceeds of PPP Loan	1,765,495	3,191,700
Payment of Bank Loans	(49,112)	(51,056)
Net Cash Provided by Financing Activities	55,985,991	9,371,519
Increase (Decrease) in Cash & Cash Equivalents and Restricted Cash	33,793,199	(919,433)
Cash & Cash Equivalents and Restricted Cash:		
Beginning Cash & Cash Equivalents and Restricted Cash	6,855,355	8,810,636
Ending Cash & Cash Equivalents and Restricted Cash	$ 40,648,554	$ 7,891,203

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,	
	2021 (Unaudited)	**2020 (Unaudited)**
RECONCILIATION OF CASH & CASH EQUIVALENTS AND RESTRICTED CASH		
Cash & Cash Equivalents	$ 40,618,554	$ 7,891,203
Restricted Cash	30,000	—
Total Cash & Cash Equivalents and Restricted Cash	$ 40,648,554	$ 7,891,203
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash Paid for Income Taxes	$ 4,100	$ 11,300
Cash Paid for Interest	$ 62,088	$ 72,097
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES		
Series B Preferred Stock Issuance for License Agreement	$ —	$ 590,000
Decrease in Accrued Capital Expenditures	$ (36,707)	$ (207,688)

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, 2020 (the "2020 Form 10-K").

On January 30, 2020, the World Health Organization ("WHO") declared that the 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 disruptions arising from the pandemic have adversely affected certain aspects of our business. The extent and duration of the pandemic is unknown, and the future effects on our business are uncertain and difficult to predict, including in light of recent new variants of the virus. 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, our management, including the chief executive officer, who is our chief operating decision maker ("CODM"), began managing our operations as operating in two business segments: Drug Development and Commercialization which includes without limitation out-licensing the Company's FDA approved products; and Compounded Pharmaceuticals which includes the Company's registered outsourcing facility, based on changes to the way that management monitors performance, aligns strategies, and allocates resources results. We determined that each of these operating segments represented a reportable segment. These consolidated financial statements and related footnotes, including prior year financial information, are presented as if there were two reporting segments for all periods presented, to the extent described in Note 12. We are a specialty biopharmaceutical company focused on developing products in various therapeutic areas, including allergy, opioid overdose, respiratory and inflammatory disease; and a registered drug compounding outsourcing facility, which compounds sterile prescription medications and certain nonsterile preparations and compounds for human and veterinary use by patients, physician clinics, hospitals, surgery centers, vet clinics and other clients throughout most of the United States. See note 13 for a discussion of subsequent events affecting USC and our Compounded Pharmaceuticals business.

Liquidity and Capital Resources

The Company's cash and cash equivalents and restricted cash were $40,618,554 and $6,855,355 at June 30, 2021 and December 31, 2020, 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 may need additional funding in the future to help 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, 2021, 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 or other 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. 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 pandemic has had an adverse impact on the Company. 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 and other potential dilutive common stock. The effect of common stock equivalents was anti-dilutive and was excluded from the calculation of weighted average shares outstanding. Potential dilutive securities, which are not included in diluted weighted average shares outstanding for the six months ended June 30, 2021 and June 30, 2020, consist of 15,095,238 shares and 24,634,670 shares, respectively, issuable upon exercise of outstanding equity classified warrants; 6,113,866 shares and 7,238,761 shares, respectively, issuable upon exercise of outstanding options; 2,034,260 shares and 2,534,107 shares, respectively, issuable following vesting of outstanding restricted stock units; and 0 and 1,000,000, respectively, issuable upon conversion of convertible preferred stock.

Recent Accounting Pronouncement

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* which provides guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this ASU No. 2021-04 are effective for all entities for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, including interim periods within those fiscal years. The amendment currently has no impact to the Company as the effect will largely depend on the terms of written call options or financings issued or modified in the future.

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

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

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

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

Compounded Pharmaceuticals Facility Revenue Recognition

With respect to sales of prescription compounded medications by the Company's USC subsidiary, revenue arrangements consist of a single performance obligation which is satisfied at the point in time when goods are delivered to the customer. The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer which is the price reflected in the individual customer's order. Additionally, the transaction price for medication sales is adjusted for estimated product returns that the Company expects to occur under its return policy. The estimate is based upon historical return rates, which has been immaterial. The standard payment terms are 2%/10 and Net 30. The Company does not have a history of offering a broad range of price concessions or payment term changes, however, when the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value method. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. Variable consideration is not a significant component of the transaction price for sales of medications by USC.

Drug Development and Commercialization Revenue Recognition

Sandoz

See Note 5 to our consolidated financial statements in the 2020 Form 10-K for information relating to our exclusive distribution and commercialization agreement dated as of July 1, 2018 with Sandoz Inc. (the “Sandoz Agreement”), which was terminated pursuant to a termination agreement entered into on May 11, 2020.

USWM

The Company has determined that there are two performance obligations in its exclusive distribution and commercialization agreement (the "USWM Agreement") with USWM, LLC ("USWM" or "US WorldMeds"): (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 terms of 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; and (3) commercial milestone payments. Items (2) and (3) are royalties generated from the exclusive right to distribute and commercialize SYMJEPI and ZIMHI in the United States; these are considered sales-based royalties of intellectual property and recognized as they occur.

Practical Expedients

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

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, 2021 and 2020.

	Three Months Ended June 30		Six Months Ended June 30	
	2021	2020	2021	2020
Drug Development & Commercialization:				
Outsourced Manufacturing	$ 1,275,474	$ 721,435	$ 2,608,153	$ 1,228,719
Compounded Pharmaceuticals:				
Sterile	$ 1,654,686	$ 1,982,506	$ 3,279,697	$ 5,033,621
Non-Sterile	1,081,144	1,222,401	2,231,986	2,327,212
Total Compounded Pharmaceuticals Revenues	$ 2,735,830	$ 3,204,907	$ 5,511,683	$ 7,360,833
Total	$ 4,011,304	$ 3,926,342	$ 8,119,836	$ 8,589,552

The Company's revenues relating to its FDA approved product SYMJEPI are dependent on the USWM Agreement with USWM, which replaced Sandoz in May 2020 in connection with the above-mentioned termination of the Sandoz Agreement, and the Company's revenues relating to 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 products to such customers 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, 2021 and 2020.

	Three Months Ended June 30		Six Months Ended June 30	
	2021	2020	2021	2020
Drug Development and Commercialization:				
Distribution Channel	$ 1,275,474	$ 721,435	$ 2,608,153	$ 1,228,719
Compounded Pharmaceuticals:				
Clinics/Hospitals	$ 2,682,100	$ 3,013,030	$ 5,408,837	$ 6,940,458
Direct to Patients	53,730	191,877	102,846	420,375
Total Compounded Pharmaceuticals Revenues	$ 2,735,830	$ 3,204,907	$ 5,511,683	$ 7,360,833
Total	$ 4,011,304	$ 3,926,342	$ 8,119,836	$ 8,589,552

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, 2021 and 2020, $ 45,692 and $ 476,343 of the revenues recognized were reported as deferred revenue as of March 31, 2021 and 2020, respectively, and for the six months ended June 30, 2021 and 2020, $50,070 and $478,171 of the revenues recognized were reported as deferred revenue as of December 31, 2020 and 2019, respectively. Included in the deferred revenue balance at June 30, 2021 and December 31, 2020 was $900,000 and $ 950,000, respectively, relating to 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.

In 2018, the Company capitalized the $2.0 million fee paid to a financial advisor as an incremental cost of obtaining a contract to commercialize and distribute the Company's first FDA approved product SYMJEPI with Sandoz. On May 11, 2020, the Company entered into a termination agreement with Sandoz. As a result of entering into the termination agreement, the Company determined that its financial results for the quarter ending June 30, 2020 included the 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.

Note 3: Inventories

Inventories at June 30, 2021 and December 31, 2020 consisted of the following:

	June 30, 2021	December 31, 2020
Finished Goods	$ 1,192,893	$ 2,059,095
Work-in-Process	—	334,164
Devices & Raw Materials	977,995	722,667
Inventories	$ 2,170,888	3,115,926

Reserve for obsolescence as of June 30, 2021 and December 31, 2020 was approximately $577,000 and $446,000, respectively.

Note 4: Fixed Assets, net

Fixed assets at June 30, 2021 and December 31, 2020 are summarized in the table below:

Description	Useful Life (Years)	June 30, 2021	December 31, 2020
Building	30	$ 3,040,000	$ 3,040,000
Machinery and Equipment	3 - 7	6,109,153	5,633,265
Furniture and Fixtures	7	160,012	160,012
Automobile	5	9,500	9,500
Leasehold Improvements	7 - 15	342,330	342,330
Total Fixed Assets		9,660,995	9,185,107
Less: Accumulated Depreciation		(4,419,013)	(3,571,870)
Land		460,000	460,000
Construction In Progress - Equipment, net of impairment of $1,115,560		3,839,239	3,513,356
Fixed Assets, net		$ 9,541,221	$ 9,586,593

Depreciation expense for the three months ended June 30, 2021 and 2020 was approximately $439,000 and $396,000, respectively; and for the six months ended June 30, 2021 and 2020, depreciation expense was approximately $847,000 and $780,000, respectively.

Note 5: Intangible Assets and Goodwill

Intangible assets at June 30, 2021 and December 31, 2020 are summarized in the tables below:

June 30, 2021	Gross Carrying Value	Accumulated Amortization	Net Carrying Amount
Definite-lived Intangible assets, estimated lives in years:			
FDA 503B Registration & Compliance - USC, 10 years	$ 3,963,000	$ (2,068,466)	$ 1,894,534
Customer Relationships - USC, 10 years	5,572,000	(2,908,274)	2,663,726
Total Definite-lived Assets	9,535,000	(4,976,740)	4,558,260
Trade Name and Brand - USC, Indefinite	1,245,000	—	1,245,000
SYMJEPI Domain Name	9,674	—	9,674
Balance, June 30, 2021	$ 10,789,674	$ (4,976,740)	$ 5,812,934

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

Amortization expense for the three months ended June 30, 2021 and 2020 was approximately $238,000 and $481,000, respectively; and for the six months ended June 30, 2021 and 2020, amortization expense was approximately $477,000 and $963,000, respectively.

Estimated amortization expense of definite-lived intangible assets at June 30, 2021 for each of the five succeeding years and thereafter is as follows:

Year ending December 31,	
Remainder of 2021	$ 476,750
2022	953,500
2023	953,500
2024	953,500
2025	953,500
Thereafter	267,510
Total	$ 4,558,260

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

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

The carrying value of the Company's goodwill as of June 30, 2021 and December 31, 2020 was approximately $ 868,000 .

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

Balance, December 31, 2019	$	7,640,622
Less: March 31, 2020 Impairment		(3,143,200)
Less: December 31, 2020 Impairment		(3,629,010)
Balance, December 31, 2020	$	868,412
Balance, June 30, 2021	$	868,412

Note 6: Leases

The Company has three operating leases, one for an office space, another for an office space and manufacturing facility, and one for office equipment; and one finance lease for plant equipment. As of June 30, 2021, the leases have remaining terms between more than two years and less than five years. The operating leases do not include an option to extend beyond the life of the current term. There are no short-term leases, and the lease agreements do not require material variable lease payments, residual value guarantees or restrictive covenants.

The tables below present the operating and financing lease assets and liabilities recognized on the condensed consolidated balance sheets as of June 30, 2021 and December 31, 2020:

Right-of Use Assets	June 30, 2021	December 31, 2020
Operating Leases	$ 1,301,741	$ 1,542,130
Financing Leases	—	1,867
	$ 1,301,741	$ 1,543,997

Lease Liabilities, Current	June 30, 2021	December 31, 2020
Operating Leases	$ 509,537	$ 492,804
Financing Leases	—	1,538
	$ 509,537	$ 494,342
Lease Liabilities, Non-Current		
Operating Leases	$ 845,012	$ 1,105,219
Total Lease Liabilities	$ 1,354,549	$ 1,599,561

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, 2021 and December 31, 2020 are:

June 30, 2021	**Operating**	**Financing**
Weighted Average Remaining Lease Term	2.59 Years	—
Weighted Average Discount Rate	4.34%	—

December 31, 2020	**Operating**	**Financing**
Weighted Average Remaining Lease Term	3.85 Years	0.42 Years
Weighted Average Discount Rate	4.29%	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, 2021:

Year Ending December 31,	**Operating**
Remainder of 2021	$ 275,106
2022	562,615
2023	543,577
2024	28,320
2025	23,600
Undiscounted Future Minimum Lease Payments	1,433,218
Less: Difference between undiscounted lease payments and discounted lease liabilities	78,669
Total Lease Liabilities	$ 1,354,549
Short-Term Lease Liabilities	$ 509,537
Long-Term Lease Liabilities	$ 845,012

Operating lease expense for the three months ended June 30, 2021 and 2020 was approximately $136,000 and $128,000, respectively; and for the six months ended June 30, 2021 and 2020 operating lease expense was approximately $271,000 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, 2021 and 2020 was approximately $1,000 and $1,000, respectively; and for the six months ended June 30, 2021 and 2020, amortization expense related to our financing leases was approximately $2,000 and $2,000, respectively. Interest expense related to the financing leases for the three months ended June 30, 2021 and 2020 was approximately $1 and $45, respectively; and for the six months ended June 30, 2021 and 2020, interest lease expense related to financing leases was approximately $10 and $100 , 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 $137,000 and $127,000 for the three months ended June 30, 2021 and 2020, respectively, and approximately $274,000 and $254,000 for the six months ended June 30, 2021 and 2020, respectively. Cash paid for amounts included in the measurement of financing lease liabilities were approximately $400 and $1,000 for the three months ended June 30, 2021 and 2020, respectively, and approximately $1,600 and $2,000 for the six months ended June 30, 2021 and 2020, respectively.

Note 7: Debt

Building Loan

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

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

As of June 30, 2021 and December 31, 2020, the outstanding principal balance owed on the applicable note was approximately $2,018,000 and $2,067,000, respectively. The loan currently bears an interest of 6.00% per year. Interest expense for the three months ended June 30, 2021 and 2020 was approximately $30,000 and $31,000, respectively. Interest expense for the six months ended June 30, 2021 and 2020 was approximately $61,000 and $70,000 respectively.

On July 8, 2021, the Company paid in full the building loan, and there is no outstanding balance under the building loan.

First Draw Paycheck Protection Program Loan

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

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

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, the Company may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by the Company during a specified period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 60% of the loan amount is used for eligible payroll costs; the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week or 24-week period will qualify for forgiveness.

In December 2020, the Company submitted an application for the forgiveness of our PPP Loan. In August 2021, the Company received notification through the Bank that as of August 5, 2021, the PPP Loan, including principal and interest thereon, has been fully forgiven by the SBA and that the remaining PPP Loan balance is zero. The Company will recognize the amount forgiven as other income for the quarter in which the Company received the notification.

Second Draw PPP Loan

On March 15, 2021, the Company entered into a Note (the "PPP2 Note") in favor of the Bank, in the principal amount of $1,765,495 relating to funding under a Second Draw loan (the "Second Draw Loan") pursuant to the terms of the PPP, the CARES Act, and the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act enacted in December 2020. Under the terms of the PPP2 Note and Second Draw Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. If any payment on the PPP2 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 term of the PPP2 Note is five years, unless sooner provided in connection with an event of default under the PPP2 Note. The Company may prepay the Second Draw Loan at any time prior to maturity with no prepayment penalties. Under the PPP, the proceeds of the Second Draw Loan may be used to pay payroll and make certain covered interest payments, lease payments and utility payments. The Company may apply for forgiveness of some or all of the Second Draw Loan pursuant to the PPP. In order to obtain full or partial forgiveness of the Second Draw Loan, the borrower must timely request forgiveness, must provide satisfactory documentation in accordance with applicable SBA guidelines, and must satisfy the criteria for forgiveness under the PPP and applicable SBA requirements. If the Company timely applies for forgiveness, payments will be deferred in accordance with the CARES Act, as modified by the Paycheck Protection Program Flexibility Act of 2020, and we will not be obligated to make any payments of principal or interest before the date on which the SBA remits the loan forgiveness amount to the Bank or notifies the Bank that no loan forgiveness is allowed; and the Bank will then notify us of remittance by SBA of the loan forgiveness amount or notify us that the SBA determined that no loan forgiveness is allowed and the date that our first payment is due. Interest will accrue during the deferral period. There is no assurance that the Company will obtain forgiveness of the Second Draw Loan in whole or in part. Our PPP loans and applications for forgiveness of loan amounts are 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 or otherwise. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return or repay the full amount of the applicable 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 the Second Draw Loan is not forgiven in accordance with the terms of the PPP, the Company will be obligated to make monthly payments of principal and interest to repay the Second Draw Loan in full prior to the maturity date. If it is determined that the Company was ineligible to receive the Second Draw Loan, the Company may be required to repay the Second Draw Loan in its entirety and/or be subject to additional penalties. Should the Company apply for and receive forgiveness of some or all of the PPP2 Loan, the amount forgiven would be recognized as other income upon formal notice of forgiveness. If we do not submit a loan forgiveness application to the Bank within 10 months after the end of our applicable covered period, as defined under the PPP and applicable regulations and guidance issued by the SBA or the U.S. Department of Treasury, then we must begin paying principal and interest after that period. The PPP2 Note contains customary events of default relating to, among other things, payment defaults, breaches of representations, warranties or covenants, defaults on other loans with the Bank, failure to disclose material fact or making materially false or misleading representations to the Bank or SBA, certain defaults on other loan agreements or agreements with creditors, bankruptcy or insolvency events, certain change of control events, material adverse changes or events, certain events that the Bank believes may materially affect the Company's ability to pay the PPP2 Note, and certain other events. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Company, or filing suit and obtaining judgment against the Company.

In September 2021, the Company submitted an application for the forgiveness of our Second Draw PPP Loan. In October 2021, the Company received notification through the Bank that as of September 28, 2021, the Second Draw PPP Loan, including principal and interest thereon, has been fully forgiven by the SBA and that the remaining PPP Loan balance is zero.

Even though the PPP Loan and the Second Draw PPP Loan have been forgiven, our PPP loans and applications for forgiveness of loan amounts remain subject to review and audit by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form, including without limitation the required economic necessity certification by the Company that was part of the PPP loan application process. Accordingly, the Company is subject to audit or review by federal or state regulatory authorities as a result of applying for and obtaining the PPP Loan and Second Draw PPP Loan or obtaining forgiveness of those loans. 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 applicable 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 it is determined that the Company was ineligible to receive the PPP Loan and/or the Second Draw Loan, the Company may be required to repay the PPL Loan and Second Draw Loan in its entirety and/or be subject to additional penalties.

As of June 30, 2021 and December 31, 2020, the outstanding unpaid principal balance of the PPP loans were $4,957,195 and $3,191,700, respectively.

At June 30, 2021, the outstanding principal maturities of the amended long-term debts were as follows:

Years ending December 31,	Building Loan	First Draw PPP Loan*	Second Draw PPP Loan**	Total
Remainder of 2021	$ 2,018,101	$ 2,300,253	$ —	$ 4,318,354
2022	—	891,447	398,245	1,289,692
2023	—	—	415,914	415,914
2024	—	—	420,126	420,126
2025	—	—	424,430	424,430
Thereafter	—	—	106,780	106,780
	$ 2,018,101	$ 3,191,700	$ 1,765,495	$ 6,975,296
Short-Term Loans	$ 2,018,101	$ 3,191,700	$ 191,886	$ 5,401,687
Long-Term Loans	$ —	$ —	$ 1,573,609	$ 1,573,609

* Based on the amortization schedule provided to the Company by the lender prior to the submission of the PPP Loan forgiveness application. On August 12, 2021, the Company received notification through the Bank that the PPP Loan, including principal and interest thereon, has been fully forgiven by the SBA and that the remaining PPP Loan balance is zero effective August 5, 2021

** Based on the amortization schedule provided to the Company by the lender prior to the submission of the PPP Loan forgiveness application. In October 2021, the Company received notification through the Bank that the PPP2 Loan, including principal and interest thereon, has been fully forgiven by the SBA and that the remaining PPP2 Loan balance is zero effective September 28, 2021.

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 1 Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level 2 Inputs other than quoted prices included within Level 1 that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level 3 Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

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

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

	Fair Value Measurements at June 30, 2021			
	Total	Level 1	Level 2	Level 3
Liabilities				
2020 Warrant liability	$ 244,824	$ —	$ —	$ 244,824
Total common stock warrant liability	$ 244,824	$ —	$ —	$ 244,824

The fair value measurement of the warrants issued by the Company in February 2020 (the "2020 Warrants") are based on significant inputs that are unobservable and thus represents a Level 3 measurement. The Company's estimated fair value of the Warrant liability is calculated using the Black Scholes Option Pricing Model. Key assumptions at June 30, 2021 include the expected volatility of the Company's stock of approximately 70%, the Company's stock price at valuation date of $1.10, expected dividend yield of 0.0% and average risk-free interest rate of approximately 0.726%. 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.

	Fair Value Measurements at December 31, 2020			
	Total	Level 1	Level 2	Level 3
Liabilities				
2019 Warrant liability	$ 2,484,000	$ —	$ —	$ 2,484,000
2020 Warrant liability	2,001,000	—	—	2,001,000
Total common stock warrant liability	$ 4,485,000	$ —	$ —	$ 4,485,000

The fair value measurement of the warrants issued by the Company in August 2019 (the "2019 Warrants") and the 2020 Warrants are based on significant inputs that are unobservable and thus represents a Level 3 measurement. The Company's estimated fair value of the Warrant liability is calculated using the Black Scholes Option Pricing Model. Key assumptions December 31, 2020 include the expected volatility of the Company's stock of approximately 80% and 70% for 2019 and 2020 Warrants, respectively; the Company's stock price at valuation date of $0.49; expected dividend yield of 0.0% and; average risk-free interest rate of approximately 0.26% and 0.36% for 2019 and 2020 Warrants, respectively. The Level 3 estimates are based, in part, on subjective assumptions. During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs.

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

	2019 Warrant		2020 Warrant	
	Number of Warrants	Liability	Number of Warrants	Liability
Balance at December 31, 2020	13,800,000	$ 2,484,000	8,700,000	$ 2,001,000
Adoption of ASC 2020-06	(13,800,000)	(2,484,000)	—	—
Change in Fair Value of Warrants at date of exercise	—	—	—	7,521,150
Exercise of Warrants	—	—	(8,350,000)	(9,441,650)
Change in Fair Value, March 31, 2021	—	—	—	120,750
Change in Fair Value, June 30, 2021	—	—	—	43,574
Balance at June 30, 2021	—	$ —	350,000	$ 244,824

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

As discussed in Note 5, Intangible Assets And Goodwill, the Company performed an interim impairment assessment to test the carrying value of goodwill, all of which is related to the Compounded Pharmaceuticals reporting unit, as of March 31, 2020. As a result of the analysis, the carrying value of our reporting unit exceeded the fair value by approximately $3,143,000, which was recorded as goodwill impairment expense as of March 31, 2020. On December 31, 2020, the Company performed its annual impairment assessment and as a result of the analysis, the carrying value of our reporting unit exceeded the fair value by approximately $3,629,000, which was recorded as goodwill impairment expense on December 31, 2020. Refer to Note 5 for more information.

Note 9: Commitments and Contingencies

The Company has a production threshold commitment to a manufacturer of our SYMJEPI products where the Company would be required to pay for maintenance fees if it does not meet certain periodic purchase order minimums. Any such maintenance fees would be prorated as a percentage of the required minimum production threshold. Maintenance fees for the three months ended June 30, 2021 and 2020 were approximately $0 and $420,000, respectively. Maintenance fees for the six months ended June 30, 2021 and 2020 were approximately $0 and $840,000, respectively.

Legal Proceedings

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

Nephron

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

On May 6, 2020, Adamis and USC moved for summary judgment to dismiss the three claims that remained pending against them. In October 2020, the magistrate judge presiding over the motion delivered a Report and Recommendation recommending that the court enter an order granting the motion in part and denying the motion in part. The court adopted the recommendation of the magistrate and granted in part and denied in part the motion of Adamis and USC for summary judgment. The court denied the motion for summary judgment by Adamis and USC with respect to the plaintiffs’ claims under the DFSA and FUTSA, concluding that there were triable issues of material fact that precluded the entry of summary judgment, and granted the motion for summary judgment in favor of Adamis and USC with respect to the claim for tortious interference. In March 2021, the court granted a motion by Nephron to hold Adamis and USC in civil contempt for violation of a previous consent preliminary injunction related to the hiring by USC of an employee, and ordered that Adamis and USC compensate Nephron for certain fees and expenses in the litigation relating to the matter as well as pay a fine, in an amount to be determined. A hearing on the amount of such sanctions was held on April 6, 2021, but decisions regarding sanctions were deferred until after trial. After the hearing, the court ruled on various pre-trial motions relating to the conduct of the trial. The case was set for trial on April 19, 2021.

As previously disclosed in the 2020 Form 10-K, while we continued to believe that the claims and damages sought by the plaintiff were without merit, in light of several factors including the recent hearing and outcome of decisions concerning pre-trial motions, the legal expenses of ongoing litigation and trial, the uncertainties of litigation and jury trials, and the possibility of punitive damages and other adverse awards or sanctions, on April 9, 2021, Adamis, USC and Nephron agreed to terms of settlement of the Florida litigation as well as a related case filed by Nephron against USC, Adamis and a second USC employee in the United States District Court for the District of New Jersey alleging misappropriation of trade secrets from Nephron. Under the terms of the settlement agreement entered into by Adamis, the Nephron entities and certain other individuals (the “individual parties”), and related documents entered into by the parties thereto, on May 3, 2021, the Company paid Nephron an amount equal to $7,900,000; the Company and USC, as well as the individual parties, agreed to a permanent injunction reflecting certain terms of the settlement and pursuant to which they agreed, among other things, not to retain, access, communication, use or disclose any proprietary or confidential information of Nephron and to destroy all such information in their possession or control, subject to limited exceptions; and Nephron agreed to dismissal of or withdrawal from the lawsuits and related legal proceedings. A contingent loss liability of $7,900,000 was included in the Company's consolidated balance sheet as of December 31, 2020. Pursuant to the settlement agreement, each of the parties agreed to release each other from all existing claims that any of them may have against any of the other parties that arise from or relate to the claims and liabilities asserted in the various lawsuits and agreed not to sue any of the parties on the basis of any released claim.

Investigation

On May 11, 2021, the company and USC each received a grand jury subpoena from the U.S. Attorney's Office for the Southern District of New York ("USAO"). The USAO issued the subpoenas in connection with a criminal investigation and requested a broad range of documents and materials relating to, among other matters, certain veterinary products sold by USC, certain practices, agreements, and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC.

On May 11, 2021, the Audit Committee of the Board engaged outside counsel to conduct an independent internal investigation to review the matters brought forth in the subpoenas and certain other matters. The investigation involved, among other matters, interviews with employees and collection and review of a large number of documents. The company has taken a number of actions in response to the internal investigation, including personnel actions relating to certain USC veterinary sales employees. In addition, following the commencement of the investigation, as disclosed elsewhere in this Report the company has sold assets relating to its compounding pharmacy business, ceased selling human and veterinary compounded pharmaceutical products, is engaged in a process of winding down USC's business, and the employment of substantially all USC employees has ended or will end in connection with the winding down of that business. As a result, the company will no longer be engaged in the sale of human or veterinary compounded pharmaceutical products. The company is also considering a number of additional actions in response to the internal investigation. As of the date of this Report, we believe that the investigation initially commenced by the Audit Committee is substantially complete. However, additional issues or facts could arise or be determined, which may expand the scope, duration, or outcome of the Audit Committee's investigation. In addition to the subpoenas from the USAO, the company has also received requests from the U.S. Securities and Exchange Commission ("SEC") for the voluntary production of documents and information relating to the subject matter of the USAO's subpoenas and certain other matters. The company has produced documents and will continue to produce and provide documents in response to the subpoenas and requests. The company intends to cooperate with the USAO and the SEC. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, or other agencies, or determine what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate, what, if any, remedies or remedial measures the USAO, SEC, or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the company's business, previously reported financial results, financial results included in this Report, or future financial results.. We could receive additional requests from the USAO, SEC, or other authorities, which may require further investigation. There can be no assurance that any discussions with the SEC or USAO to resolve these matters will be successful.

The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, result in fines, penalties or equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, or future financial results. The occurrence of any of these events, or any determination that our activities were not in compliance with existing laws or regulations, could have a material adverse effect on the company's business, financial condition, and results of operations.

Jerald Hammann

On June 8, 2021, Jerald Hammann filed a complaint against the Company and each of its directors in the Court of Chancery of the State of Delaware, captioned *Jerald Hammann v. Adamis Pharmaceuticals Corporation et al.*, C.A. No. 2021-0506-PAF (the "Complaint"), seeking injunctive and declaratory relief. The Complaint alleges, among other things, that the defendants (i) violated Rule 14a-5(f) and 14a-9(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in connection with the Company's 2021 annual meeting of stockholders—which was subsequently held on July 16, 2021 (the "2021 annual meeting")—and disseminated false and misleading information in the Company's proxy materials relating to the 2021 annual meeting, (ii) violated certain provisions of the Company's bylaws relating to the 2021 annual meeting, (iii) violated section 220 of the Delaware General Corporation Law ("DGCL") in connection with a request for inspection of books and records submitted by the plaintiff, and (iv) breached their fiduciary duties of disclosure and loyalty, including relating to establishing and disclosing the date of the Company's 2021 annual meeting and to the Company's determination that a solicitation notice delivered to the Company by plaintiff was not timely and was otherwise deficient. The Complaint alleges, among other things, that plaintiff intended to initiate a proxy contest against the Company, that defendants' conduct made it difficult or impossible for plaintiff to initiate a proxy context, and that the Company's definitive proxy statement included false and misleading disclosures and omissions of material information. The Complaint sought injunctive relief (i) to prevent the Board, the Company, and their employees and agents from soliciting any stockholders pursuant to the Company's proxy statement and (ii) to prevent the defendants from interfering in the effectiveness of stockholder voting for the 2021 annual meeting. The Complaint also seeks declaratory relief (i) finding that plaintiff's solicitation notice was timely and properly submitted; (ii) directing the defendants to comply with Rules 14a-5(f) and 14a-9(a) of the Exchange Act; (iii) directing the Company to produce the materials set forth in the plaintiff's books and records request; (iv) finding that the director defendants breached their fiduciary obligations to stockholders; and (v) finding that the director defendants engaged in self-dealing. The Complaint seeks an award of fees, costs, and expenses in this action, including attorneys' and experts' fees.

On June 10, 2021, the plaintiff filed a motion for a temporary restraining order and for expedited proceedings, seeking an order enjoining the Company from printing or disseminating its proxy statement relating to the 2021 annual meeting or from convening the 2021 annual meeting on July 16, 2021. Following a hearing, on June 17, 2021, the Court determined that: (i) it did not have jurisdiction to consider the plaintiff's claims relating to alleged violations of the Exchange Act; (ii) plaintiff's claims regarding the books and records request and alleged violations of section 220 of the DGCL should be pursued in a separate proceeding, and the Court denied the plaintiff's motion to expedite the books and records claims; (iii) certain of the plaintiff's claims alleging breach of the fiduciary duty of disclosure against the individual defendants, including claims based on alleged misrepresentations and omissions in the Company's proxy statement, were not colorable; and (iv) plaintiff's claim alleging that the individual defendants violated their fiduciary duty by taking action purportedly intended to prevent the plaintiff from pursuing a proxy contest survived a low threshold of colorability, but the Court denied the plaintiff's motion for a temporary restraining order. The Court granted in part the motion to expedite the proceedings.

The case is proceeding and the parties are currently engaged in discovery. The Company believes the claims in plaintiff's Complaint are without merit, and intends to vigorously dispute them.

The Company records accruals for loss contingencies associated with legal matters when the Company determines it is probable that a loss has been or will be incurred and the amount of the loss can be reasonably estimated. Where a material loss contingency is reasonably possible and the reasonably possible loss or range of possible loss can be reasonably estimated, U.S. GAAP requires us to disclose an estimate of the reasonably possible loss or range of loss or make a statement that such an estimate cannot be made. The company has not accrued any amount in respect of the matters described under the headings "Investigation" or "Jerald Hammann," since even if it is probable that such matters may result in a material loss contingency, we cannot estimate the probable loss or the range of probable losses that we may incur. We are unable to make such an estimate because (i) with respect to the matters described under the heading "Investigation," we are unable to predict whether any proceedings will be initiated by the USAO, SEC or other authorities arising from such matters, what, if any, relief, remedies or remedial measures the USAO, SEC, or other authorities may seek if proceedings are commenced, and the duration, scope, or outcome of any such proceedings, if they are commenced, (ii) litigation and other proceedings are inherently uncertain and unpredictable, and (iii) with respect to the matters described under the heading "Jerald Hammann," the complaint seeks declaratory and injunctive relief. Because legal proceedings and investigations are uncertain and unpredictable and unfavorable results could occur, assessing contingencies is highly subjective and requires significant judgments about future events, including determining both the probability and reasonably estimated amount of a possible loss or range of loss. The amount of any ultimate loss may differ from any accruals or estimates that the Company may make.

Note 10: Common Stock

In January and February 2021, the Company issued common stock upon exercise of investor warrants. The warrant holders exercised for cash at exercise prices ranging from $0.70 to $1.15 per share. The Company received total proceeds of approximately $5,852,000 and the warrant holders received 8,356,000 shares of common stock.

On February 2, 2021, the Company completed the closing of an underwritten public offering of 46,621,621 shares of common stock at a public offering price of $1.11 per share, which included 6,081,081 shares pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds were approximately $48.4 million, after deducting approximately $3.3 million in underwriting discounts and commissions and estimated offering expenses payable by the Company.

Note 11: Stock-based Compensation, Warrants and Shares Reserved

At the Company's 2020 annual meeting of stockholders, the stockholders approved the Company's 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards, and other forms of equity compensation (collectively "stock awards"). In addition, the 2020 Plan provides for the grant of cash awards. The initial aggregate number of shares of common stock that may be issued initially pursuant to stock awards under the 2020 Plan is 2,000,000 shares. The number of shares of common stock reserved for issuance automatically increases on January 1 of each calendar year during the term of the 2020 Plan, commencing January 1, 2021, by 5.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares of common stock determined by the Company's board of directors before the start of a calendar year for which an increase applies. One of the provisions of the 2020 Plan is that no award may be granted, issued or made under the 2020 Plan until such time as the fair market value of the common stock, which is generally the closing sales price of the common stock on the principal stock market on which the common stock is traded, has been equal to or greater than $3.00 per share (subject to proportionate adjustment for stock splits, reverse stock splits, and similar events) for at least ten consecutive trading days, after which time awards may be made under the 2020 Plan without regard to any subsequent increase or decrease in the fair market value of the common stock. No awards were made pursuant to the 2020 Plan as of June 30, 2021.

On January 1, 2021, pursuant to the 2020 Equity Incentive Plan the number of shares reserved for the issuance of stock awards increased by 4,692,103 shares.

Stock Options

The following summarizes the stock option activity for the six months ended June 30, 2021 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, 2020	6,508,296	$ 4.29	5.60 years
Options Cancelled/Expired	(394,430)	3.99	—
Total Outstanding Vested and Expected to Vest as of June 30, 2021	6,113,866	$ 4.31	5.15 years
Vested at June 30, 2021	6,108,933	$ 4.31	5.15 years

Expense related to stock options for the three months ended June 30, 2021 and 2020 was approximately $5,000 and $292,000, respectively; and for the six months ended June 30, 2021 and 2020, expense related to stock options was approximately $147,000 and $722,000, respectively. As of June 30, 2021, the compensation expense related to stock options have been fully amortized.

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 6,113,866 and 6,508,296 stock options outstanding at June 30, 2021 and December 31, 2020 was $0, respectively. The aggregate intrinsic value of 6,108,933 and 6,397,703 stock options exercisable at June 30, 2021 and December 31, 2020 was $0, respectively.

The following table summarizes the RSUs outstanding at June 30, 2021:

	Number of Shares/Units	Weighted Average Grant Date Fair Value
Non-vested RSUs as of December 31, 2020	2,136,893	$ 3.64
RSUs vested during the period	(66,462)	3.04
RSUs forfeited during the period	(36,171)	3.09
Non-vested RSUs as of June 30, 2021	2,034,260	3.66

Expense related to RSUs for the three months ended June 30, 2021 and 2020 was approximately $793,000 and $823,000, respectively; and for the six months ended June 30, 2021 and 2020, expense related to RSUs was approximately $1,531,000 and $1,612,000, respectively. As of June 30, 2021, the unamortized compensation expense related to RSUs options was approximately $2,980,000. The weighted-average period in years over which the remaining unamortized expense will be recognized is 1.68 years.

The following summarizes warrants outstanding at June 30, 2021 and December 31, 2020:

June 30, 2021	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-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	13,794,000*	$	1.15	August 5, 2019	August 5, 2024
2020 Warrants	350,000**	$	0.70	February 25, 2020	September 3, 2025
Total Warrants	15,095,238				

* The Company adopted ASU 2020-06. See Note 8.

** As of June 30, 2021, the fair value of the warrant liability related to the 2020 Warrants was approximately $ 245,000. See Note 8.

December 31, 2020	Warrant Shares		Exercise Price Per Share	Date Issued	Expiration Date
Old Adamis Warrants	58,824	$	8.50	November 15, 2007	November 15, 2021
Preferred Stock Series A-1 Warrants	1,183,432	$	4.10	January 26, 2016	January 26, 2021
Preferred Stock Series A-2 Warrants	192,414	$	2.90	July 11, 2016	July 11, 2021
2016 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	September 3, 2025
Total Warrants	24,634,670				

* As of December 31, 2020, the fair value of the warrant liability related to the 2019 Warrants was $2,484,000. See Note 8.
** As of December 31, 2020, the fair value of the warrant liability related to the 2020 Warrants was $2,001,000. See Note 8.

At June 31, 2021, the Company has reserved shares of common stock for issuance following vesting of restricted stock units and upon exercise of outstanding options including options granted under the 2009 Equity Incentive Plan, and upon exercise of outstanding warrants, as follows:

Warrants	15,095,238
Restricted Stock Units (RSU)	2,034,260
2009 Equity Incentive Plan	6,113,866
Total Shares Reserved	23,243,364

Note 12: Segment Information

Commencing April 1, 2020, our management, including the chief executive officer, who is our chief operating decision maker ("CODM"), began managing our operations as operating in two business segments: Drug Development and Commercialization which includes, without limitation, out-licensing the Company's FDA approved products; and Compounded Pharmaceuticals which includes the Company's registered outsourcing facility, based on changes to the way that management monitors performance, aligns strategies, and allocates resources. Based on these changes, we determined that each of these operating segments represented a reportable segment. While the CEO is apprised of a variety of financial metrics and information, the business is principally managed and organized based upon business units. Each segment is separately managed and is evaluated primarily upon segment net loss. The Company does not report the statement of cash flow and the balance sheet information by segment because, except as noted below, the Company's CODM does not review that information. The revenues of the Drug Development and Commercialization segment for the three months and six months ended June 30, 2021 and 2020 were all from the USWM and 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, 2021 and 2020, respectively (unaudited):

	Three Months ended June 30, 2021			Three Months ended June 30, 2020		
	Drug Development and Commercialization (Unaudited)	Compounded Pharmaceuticals (Unaudited)	Consolidated (Unaudited)	Drug Development and Commercialization (Unaudited)	Compounded Pharmaceuticals (Unaudited)	Consolidated (Unaudited)
REVENUE, net	$ 1,275,474	$ 2,735,830	$ 4,011,304	$ 721,435	$ 3,204,907	$ 3,926,342
COST OF GOODS SOLD	1,796,242	2,074,390	3,870,632	1,840,402	2,843,433	4,683,835
Gross (Loss) Profit	(520,768)	661,440	140,672	(1,118,967)	361,474	(757,493)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	4,934,491	2,197,153	7,131,644	3,008,585	2,644,507	5,653,092
RESEARCH AND DEVELOPMENT	2,196,721	36,055	2,232,776	2,926,108	159,716	3,085,824
IMPAIRMENT EXPENSE -CONTRACT COSTS	—	—	—	1,750,000	—	1,750,000
IMPAIRMENT EXPENSE - CIP	—	9,347	9,347	—	—	—
Loss from Operations	$ (7,651,980)	$ (1,581,115)	$ (9,233,095)	$ (8,803,660)	$ (2,442,749)	$ (11,246,409)
OTHER INCOME (EXPENSE)						
INTEREST EXPENSE	(2,900)	(42,047)	(44,947)	(1,490)	(31,435)	(32,925)
OTHER INCOME	1,900	5,986	7,886	9,602	7,019	16,621
CHANGE IN FAIR VALUE OF WARRANT LIABILITIES	(43,574)	—	(43,574)	(1,662,000)	—	(1,662,000)
Total Other Income (Expense), net	(44,574)	(36,061)	(80,635)	(1,653,888)	(24,416)	(1,678,304)
Net Loss Before Income Taxes	$ (7,696,554)	$ (1,617,176)	$ (9,313,730)	$ (10,457,548)	$ (2,467,165)	$ (12,924,713)

	Six Months ended June 30, 2021			Six Months ended June 30, 2020		
	Drug Development and Commercialization (Unaudited)	Compounded Pharmaceuticals (Unaudited)	Consolidated (Unaudited)	Drug Development and Commercialization (Unaudited)	Compounded Pharmaceuticals (Unaudited)	Consolidated (Unaudited)
REVENUE, net	$ 2,608,153	$ 5,511,683	$ 8,119,836	$ 1,228,719	$ 7,360,833	$ 8,589,552
COST OF GOODS SOLD	3,641,480	3,871,100	7,512,580	3,573,185	4,797,694	8,370,879
Gross (Loss) Profit	(1,033,327)	1,640,583	607,256	(2,344,466)	2,563,139	218,673
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	8,452,542	4,598,576	13,051,118	6,311,817	5,395,646	11,707,463
RESEARCH AND DEVELOPMENT	4,446,464	47,634	4,494,098	4,962,840	159,716	5,122,556
IMPAIRMENT EXPENSE - GOODWILL	—	—	—	—	3,143,200	3,143,200
IMPAIRMENT EXPENSE - CONTRACT COST	—	—	—	1,750,000	—	1,750,000
IMPAIRMENT EXPENSE - CIP	—	9,347	9,347	—	—	—
Loss from Operations	$ (13,932,333)	$ (3,014,974)	$ (16,947,307)	$ (15,369,123)	$ (6,135,423)	$ (21,504,546)
OTHER INCOME (EXPENSE)						
INTEREST EXPENSE	(4,784)	(79,488)	(84,272)	(1,490)	(69,722)	(71,212)
OTHER INCOME	3,351	20,738	24,089	32,657	7,019	39,676
CHANGE IN FAIR VALUE OF WARRANT LIABILITIES	(7,685,474)	—	(7,685,474)	1,365,000	—	1,365,000
Total Other Income (Expense), net	(7,686,907)	(58,750)	(7,745,657)	1,396,167	(62,703)	1,333,464
Net (Loss) Before Income Taxes	$ (21,619,240)	$ (3,073,724)	$ (24,692,964)	$ (13,972,956)	$ (6,198,126)	$ (20,171,082)

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

	June 30, 2021	December 31, 2020
Assets		
Drug Development and Commercialization	$ 46,890,167	$ 13,027,945
Compounded Pharmaceuticals	16,817,317	17,839,517
Total Assets	$ 63,707,484	$ 30,867,462

	Three Months Ended June 30,	
	2021	2020
Capital Expenditures:		
Drug Development and Commercialization	$ 362,055	$ 260,427
Compounded Pharmaceuticals	15,310	40,807
Total Capital Expenditures	$ 377,365	$ 301,234

	Six Months Ended June 30,	
	2021	2020
Capital Expenditures:		
Drug Development and Commercialization	$ 795,812	$ 319,513
Compounded Pharmaceuticals	15,311	133,587
Total Capital Expenditures	$ 811,123	$ 453,100

	Three Months Ended June 30,	
	2021	2020
Depreciation and Amortization:		
Drug Development and Commercialization	$ 368,960	$ 565,882
Compounded Pharmaceuticals	309,643	312,223
Total Depreciation and Amortization	$ 678,603	$ 878,105

	Six Months Ended June 30,	
	2021	2020
Depreciation and Amortization:		
Drug Development and Commercialization	$ 696,867	$ 1,171,452
Compounded Pharmaceuticals	628,897	623,853
Total Depreciation and Amortization	$ 1,325,764	$ 1,795,305

Note 13: Subsequent Events

Full Payment of Building Loan

On July 8, 2021, the Company repaid to Arvest Bank, as lender, the full remaining outstanding principal and interest balance of $2,028,191 owed under the Company's outstanding building and real property loan relating to USC's building and real property, the maturity date of which was in August 2021. Following such payment, the Company does not have any outstanding indebtedness under any of the loan agreements that were assumed by the Company in connection with its previous acquisition of USC.

US Compounding, Inc. Agreement

On July 30, 2021, the Company and its wholly-owned USC subsidiary entered into an Asset Purchase Agreement (the "USC Agreement") effective as of July 30, 2021 (the "Effective Date") with Fagron Compounding Services, LLC d/b/a Fagron Sterile Services (the "Purchaser"), providing for the sale and transfer by USC and the purchase by the Purchaser, effective as of the Effective Date, of certain assets of USC related to its human compounding pharmaceutical business (the "Business"), including certain customer information and information on products sold to such customers by USC (together, the "Book of Business"), including related formulations, know-how, and expertise regarding the compounding of pharmaceutical preparations, clinical support knowledge and other data and certain other information relating to the customers and products (collectively, the "Assets"). After the Effective Date, Purchaser may use the Book of Business to secure customers for its products and services and may otherwise use the Book of Business. Pursuant to the USC Agreement, the Purchaser will not assume any liabilities of USC, and the transaction does not include the sale or transfer of any USC equipment, buildings or real property, or any products, information, agreements, relationships or other assets relating to the veterinary business of USC.

The USC Agreement provides that the consideration payable by the Purchaser to the Company for the Assets sold and transferred will consist of the following amounts: (i) a payment of $107,500 on the Effective Date; and (ii) monthly payments in an amount equal to (a) two (2.0) times the amount actually collected by Purchaser or its affiliates for sales of products or services made to certain identified customers included in the Book of Business during the 12-month period following the Effective Date (the "Payment Term"), and (b) a lower multiple of the amount actually collected by Purchaser or its affiliates for sales of products or services made to certain other customers included in the Book of Business. The Company estimated the variable consideration at approximately $6,385,000. In addition, to the extent that such product or service is supplied by USC pursuant to the supply arrangement provided for by the USC Agreement (the "Supply Agreement"), the Purchaser agreed to reimburse USC for the cost of such product or service, as set forth in the Supply Agreement. The USC Agreement provides that during the Payment Term, the Purchaser will maintain the Book of Business and use commercially reasonable efforts to maximize the consideration payable to the Company and collect amounts outstanding related to sales of products or services made to customers included in the Book of Business. However, the USC Agreement does not provide for any minimum purchase price consideration to the Company or USC. Accordingly, there is no assurance as to the amount of purchase price consideration that the Company or USC may ultimately receive as a result of the transactions contemplated by the USC Agreement. Certain of the customers included in the Book of Business may decide to not purchase products or to reduce their purchases of products from Purchaser after the Effective Date, and Purchaser may, in good faith, decide not to change its product mix from those products offered by Purchaser as of the Effective Date and may decide not to carry all of the products offered and sold by USC as part of the Business prior to the Effective Date.

The USC Agreement includes certain restrictive covenants of the Company and USC, including noncompetition provisions, pursuant to which, for a period of five years from the Effective Date (the "Restricted Period") and subject to certain exceptions, the Company and USC have agreed, among other matters, not to solicit any Business from any customers included in the Book of Business or engage in certain other activities. Each of the USC Agreement and the Supply Agreement includes standard indemnification provisions, and a number of other covenants and agreements of the parties concerning the transactions contemplated by the USC Agreement and the Supply Agreement, including concerning cooperation and assistance, confidentiality, non-disparagement and the transfer of information and documents, compliance with laws, and personnel matters. The USC Agreement includes indemnification provisions pursuant to which the Company and USC agreed to indemnify the Purchaser and certain related parties against losses incurred by such indemnified parties arising or resulting from certain matters including breach of the USC Agreement by USC and third party claims relating to product sales to customers by USC before the Effective Date.

In connection with the transaction, the Company will pay a fee to a financial advisor of $700,000, and may pay an additional amount depending on the total consideration received by the Company, in connection with advisory services relating to the transaction.

Plan for the Remaining Operations, Business and Assets of USC

In light of a number of factors including the sale of assets to the Purchaser pursuant to the USC Agreement, the Board approved a restructuring process of winding down and winding up the remaining operations and business of USC and selling, transferring or disposing of the remaining assets of USC. The restructuring and winding down includes, without limitation, the termination of USC's veterinary business and USC sales to veterinary customers; the termination of employment of all or substantially all employees engaged in the USC business (except as determined to be necessary or appropriate in connection with the Company's and USC's performance of their obligations under the USC Agreement and the transactions contemplated thereby, or in connection with resolving matters relating to the winding down of USC's business), and providing such notices and making such payments to such employees as the officers of the Company determine are necessary or appropriate, including as maybe required by law or as maybe provided for pursuant to any retention agreement, severance agreement, incentive agreement, or other written agreement with such employees; the sale or other disposition from time to time of the remaining equipment, real property, buildings and tangible and intangible assets relating to USC's business that are unrelated to the USC Agreement; the termination, assignment or other resolution of agreements with third parties relating to the USC business; making regulatory filings and taking appropriate actions with federal and state regulatory authorities in connection with the winding down and winding up of USC's business; and taking such other actions as the officers of the Company or USC (as appropriate) determine are necessary or appropriate in connection with the restructuring and the winding down and winding up of the remaining business, operations and assets of USC.

In August 2021, the Company and its wholly-owned USC subsidiary entered into an Asset Purchase Agreement effective as of August 31, 2021 with a third party buyer ("Buyer"), providing for the sale and transfer by USC of certain assets related to USC's veterinary compounded pharmaceuticals business. The sale covers the transfer of all the veterinary business customers' information belonging to USC or in USC's control and possession ("Book of Business – Veterinary") and USC's know how, information and expertise regarding the veterinary business including, but not limited to, formulations, clinical support knowledge and services, other data and studies, instruction and process, documents, and information relating to customers and other business relationships ("Business Knowledge – Veterinary"). Pursuant to the agreement, the Buyer agreed to pay the Company, for any sales of products in USC's veterinary products list or equivalent products made to the customers included in the Book of Business – Veterinary during the five-year period after the date of the agreement, an amount equal to twenty percent (20%) of the amount actually collected by Buyer on such sales during the period ending three months after the end of such five year period. The Company does not expect to receive a material amount from the variable consideration of this agreement.

The costs associated with providing termination payments to USC employees, employee salaries and incentive payments during a transition period after the effective date of the sale of the Assets, severance or other termination benefits or payments in connection with workforce reduction and termination of employment, and payments anticipated to be made pursuant to retention agreements or incentive agreements with certain employees is approximately $1.6 million. The substantial majority of the cash payments related to personnel-related restructuring charges are paid during the third and fourth quarters of 2021. The charges that the company incurred in connection with the workforce reduction and winding down of operations of USC are actual expenses. In addition, as part of the restructuring, the company and USC intend to sell or dispose of tangible assets relating to USC's business, including equipment, building and property. The company expects to incur commissions and other costs associated with the sale or other disposition of certain of such assets but is unable, at this time, to make a good faith determination of cost estimates, or ranges of cost estimates, associated with such future sales or dispositions of such tangible assets or other costs associated with the sale or disposition of such tangible assets.

As a result of the transactions contemplated by the USC Agreement and the restructuring activities described above, the Company has determined that its financial results for the quarter ending September 30, 2021, will include an impairment of certain assets relating to USC, including inventories, intangible assets, goodwill, fixed assets, and right of use assets. The company currently estimates approximately $8.2 million for the impairment charges of inventory, fixed assets, intangibles, goodwill and right of use assets. The impairment charges that the company expects to incur in connection with the matters described above are subject to a number of assumptions, and the actual amount of impairment charges may differ materially from those estimated by the company. In addition, the company may determine in the future that additional impairments of assets are appropriate in connection with the matters described above.

Forgiveness of First Draw PPP Loan

On August 12, 2021, the Company received notification through the Bank that the PPP Loan, including principal of $3,191,700 and interest thereon, has been fully forgiven by the SBA and that the remaining PPP Loan balance is zero effective August 5, 2021.

Forgiveness of Second Draw PPP Loan

In October 2021, the Company received notification through the Bank that as of September 28, 2021, the Second Draw PPP Loan, including principal of $1,765,495 and interest thereon, has been fully forgiven by the SBA and that the remaining Second Draw PPP Loan balance is zero.

Inventory Derecognition

In the third quarter of 2021, approximately $776,000 of certain inventory returned to a supplier was derecognized. In exchange for the return of inventory, the supplier provided fixed and variable consideration totaling approximately $445,000. The consideration partially offsets the inventory derecognition which resulted in a $330,000 loss for the three and nine months ended September 30, 2021. The Company expects to receive the variable consideration over the course of the next one to two years. The variable amount was based on the Company's estimates and is subject to change as more information comes to light, which would result in adjustments to the loss originally recorded.

Regulatory

In October 2021, following the sale in July 2021 of certain assets of USC relating to USC's human compounding pharmaceutical business and the Company's approval of a restructuring process of winding down and winding up the remaining operations and business of USC and selling or disposing of the remaining assets of USC, the company entered into a Consent Order with the Arkansas State Board of Pharmacy to resolve an ongoing administrative proceeding before the pharmacy board, pursuant to which USC agreed to surrender its Arkansas retail pharmacy permit and wholesaler/outsourcer permit effective October 31, 2021, to pay a civil penalty of $75,000 relating to violations of various Arkansas pharmacy laws and regulations and to pay $75,000 in investigative costs of the pharmacy board.

FDA Approval of ZIMHI

On October 18, 2021, the issued a press release announcing that the FDA has approved the Company's ZIMHI ™ (naloxone HCL Injection, USP) 5 mg/0.5 mL product. ZIMHI is a high-dose naloxone injection product FDA-approved for the treatment of opioid overdose. The approval was pursuant to the FDA's review of the Company's New Drug Application ("NDA"), which was resubmitted to the FDA in May 2021, pursuant to the Food, Drug & Cosmetic Act, as amended.

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 actions relating to our products and product candidates; 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; the impact of broad-based business or economic disruptions, including relating to the COVID-19 pandemic, on our ongoing business and prospects; our expectations concerning the outcome of proceedings discussed in this Report under Item 1 of Part II of this Report under the caption "Legal Proceedings"; 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 have or are able to obtain sufficient funding to support such activities and continue our operations and planned activities. As discussed elsewhere in this Report, we may require additional funding to continue operations, and there are no assurances that such funding will be available. Failure to timely obtain required funding would adversely affect and could delay or prevent our ability to realize the results contemplated by such forward-looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Because factors referred to elsewhere in this Report and in our Annual Report on Form 10-K for the year ended December 31, 2020 (sometimes referred to as the "2020 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 2020 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 2020 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," "the company" and "the Company" refer to Adamis Pharmaceuticals Corporation, a Delaware corporation, and its subsidiaries.

Investors and others should note that we may announce material information to our investors using our website (www.adamispharmaceuticals.com), SEC filings, press releases, public conference calls and webcasts, as well as social media and blogs. We use these channels as a means of disclosing material non-public information and making disclosures pursuant to Regulation FD, and to communicate with our members and the public about our company. It is possible that the information we post on our website or social media and blogs could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on our website social media channels and blogs listed on our investor relations website.

General

Company Overview

Adamis Pharmaceuticals Corporation ("we," "us," "our," "Adamis" or the "company") is a specialty biopharmaceutical company focused on developing and commercializing products in various therapeutic areas, including allergy, opioid overdose, respiratory and inflammatory disease. Our products and product candidates in the allergy, respiratory, and opioid overdose markets include: SYMJEPI™ (epinephrine) Injection 0.3mg, which was approved by the U.S. Food and Drug Administration, or FDA, in 2017 for use in the emergency treatment of acute allergic reactions, including anaphylaxis, for patients weighing 66 pounds or more; SYMJEPI (epinephrine) Injection 0.15mg which was approved by the FDA in September 2018, for use in the treatment of anaphylaxis for patients weighing 33-65 pounds; ZIMHI™ (naloxone HCL Injection, USP) 5 mg/0.5 mL, which was approved by the FDA in October 2021 for the treatment of opioid overdose; and Tempol, an investigational drug. In June 2020, we entered into a license agreement with a third party to license rights under patents, patent applications and related know-how of the licensor relating to Tempol. The exclusive license includes the worldwide use under the licensed patent rights and related rights for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection, as well as the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. We have commenced Phase 2/3 clinical trial start-up activities to examine the safety and efficacy of Tempol in COVID-19 patients early in the infection, and on September 2, 2021, we announced the initiation of patient dosing in the trial. Our goal is to create low cost therapeutic alternatives to existing treatments. Consistent across all specialty pharmaceuticals product lines, we intend to submit NDAs under Section 505(b)(2), of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, or Section 505(j) Abbreviated New Drug Applications, or ANDAs, to the FDA, whenever possible, in order to potentially reduce the time to market and to save on costs, compared to those associated with Section 505(b)(1) NDAs for new drug products.

Our US Compounding Inc. subsidiary, or USC, which we acquired in April 2016 and which is registered as a human drug compounding outsourcing facility under Section 503B of the FDCA and the U.S. Drug Quality and Security Act, or DQSA, provides prescription compounded medications, including compounded sterile preparations and nonsterile compounds, to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. USC's product offerings broadly include, among others, corticosteroids, hormone replacement therapies, hospital outsourcing products, and injectables. In July 2021, we sold certain assets relating to USC's human compounding pharmaceutical business and approved a restructuring process to wind down the remaining USC business and sell, liquidate or otherwise dispose of the remaining USC assets. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer selling compounded pharmaceutical or veterinary products.

SYMJEPI (epinephrine) Injection

On June 15, 2017, the FDA approved our SYMJEPI (epinephrine) Injection 0.3mg product for the emergency treatment of allergic reactions (Type I) including anaphylaxis. SYMJEPI (epinephrine) Injection 0.3mg is intended to deliver a dose of epinephrine, which is used for emergency, immediate administration in acute anaphylactic reactions to insect stings or bites, allergic reaction to certain foods, drugs and other allergens, as well as idiopathic or exercise-induced anaphylaxis for patients weighing 66 pounds or more. On September 27, 2018, the FDA approved our lower dose SYMJEPI (epinephrine) Injection 0.15mg product, for the emergency treatment of allergic reactions (Type I) including anaphylaxis in patients weighing 33 to 66 pounds.

In July 2018, we entered into a Distribution and Commercialization Agreement, or the Sandoz Agreement, with Sandoz Inc., or Sandoz, to commercialize both of our SYMJEPI products. In January 2019, we announced that Sandoz had launched SYMJEPI (epinephrine) 0.3 mg Injection in the U.S. market, initially available in the institutional setting. On July 9, 2019, we announced the full launch (institutional and retail) by Sandoz of both dose forms of the SYMJEPI injection products.

On May 11, 2020, we announced that we entered into an agreement, or the Termination Agreement, with Sandoz to terminate the Sandoz Agreement and simultaneously announced that we entered into an exclusive distribution and commercialization agreement, or the USWM Agreement, with USWM, LLC, or USWM or US WorldMeds, for the United States commercial rights for the SYMJEPI products, as well as for our ZIMHI product. Under the terms of the USWM Agreement, we appointed USWM as the exclusive distributor of SYMJEPI in the United States and related territories, or the Territory, effective upon the termination of the Sandoz Agreement, and of the ZIMHI product if approved by the FDA for marketing, and granted USWM an exclusive license under our patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the products in the Territory, in partial consideration of an initial payment of $1,000,000 by USWM and potential additional regulatory and commercial based milestone payments. There can be no assurances that any of these milestones will be met or that any milestone payments will be paid to us. We retain rights to the intellectual property subject to the USWM Agreement and to commercialize both products outside of the Territory. In addition, we may continue to use the licensed intellectual property (excluding certain of the licensed trademarks) to develop and commercialize other products (with certain exceptions), including products that utilize our Symject™ syringe product platform.

The USWM Agreement provides that, after deducting the supply price and subject to certain other deductions and adjustments, including an allocation for USWM sales and distribution expenses from net sales of the products, USWM will pay to us 50% of the net profit from net sales, as each such term is defined in the USWM Agreement, of the product in the Territory to third parties, determined on a quarterly basis. We will be the supplier of the products to USWM, and USWM will order and pay us a supply price for quantities of products ordered. The agreement does not include minimum payments to us by USWM, minimum requirements for sales of product by USWM or, with certain exceptions, minimum purchase commitments by USWM.

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. A CRL is issued by the FDA's Center for Drug Evaluation and Research when it has completed its review of a file and questions remain that preclude the approval of the NDA in its current form. The CRL stated that the FDA determined that it could not approve the NDA in its present form and provided recommendations needed for resubmission. In December 2019, we provided responses to the FDA to the comments included in the CRL and subsequently held 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. On May 15, 2020, we resubmitted to the FDA the NDA for ZIMHI. On November 13, 2020, we received a second CRL from the FDA regarding the resubmitted NDA. We submitted responses to the deficiencies identified in the CRL and held a Type A meeting with the FDA to discuss the CRL and the company's responses, and on May 13, 2021, we resubmitted the NDA for ZIMHI to the FDA. On October 18, 2021, we issued a press release announcing that the FDA had approved ZIMHI for the treatment of opioid overdose. The company's commercial partner USWM has indicated that it is preparing for a commercial launch of ZIMHI anticipated to be in the first quarter of 2022.

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, which had been converted into an equal number of shares of our common stock.

Tempol is a redox cycling nitroxide that promotes the metabolism of many reactive oxygen species and improves nitric oxide bioavailability. It has been studied extensively in animal models of oxidative stress and inflammation. Overall, Tempol acts as both a super-oxide dismutase mimetic and also has demonstrated anti-inflammatory, anticoagulant activity and antiviral activity. Inflammation and oxidative stress occur in various disease states including COVID-19. Both inflammatory cytokines and reactive oxygen species (ROS) from cells of the immune system called macrophages and neutrophils damage the lung in Acute Respiratory Distress Syndrome (ARDS). Many published articles describing animal models of ARDS show Tempol caused a decrease in lung inflammation and preserved lung pathology associated with acute and chronic lung injury. In animal models, Tempol has been shown to decrease proinflammatory cytokines (cytokine storm), and through its antioxidant activity has been shown to decrease the harmful effects of ROS. In addition, Tempol has been shown to decrease platelet aggregation, a problem observed in many COVID-19 patients. More recently, Tempol has been shown to have antiviral activity against the virus that causes COVID-19 in-vitro and may have synergy with the antiviral Remdesivir.

In July 2020, we submitted to the FDA a pre-IND package which provided a protocol for a Phase 2/3 study examining Tempol in COVID-19 patients, and the FDA provided comments regarding the prospective use of Tempol in a randomized placebo controlled trial. In January 2021, we submitted an IND to the FDA for the investigational use of Tempol for the treatment of COVID-19. On February 22, 2021, we announced that the FDA notified the company that the agency had completed the safety review of the IND and concluded that the company may proceed with the proposed clinical investigation and trial described in the IND. The goal of the study titled, "A Phase 2/3, Adaptive, Randomized, Double-Blind, Placebo-Controlled Study to Examine the Effects of Tempol (MBM-02) on Preventing COVID-19 Related Hospitalization in Subjects with COVID-19 Infection," is to examine the safety and activity of Tempol in COVID-19 patients early in the infection. In addition to safety, the study will examine markers of inflammation and the rate of hospitalization for patients taking Tempol versus placebo early in COVID-19 infection. On June 11, 2021, we announced that clinical trial start-up activities were underway, that the company was carrying out those activities with a large clinical research organization, that commenced activities included site identification and initiation, data base production, vendor management, and the establishment of an independent data safety monitoring board of infectious disease experts, who will review the safety and efficacy of the trial, and that clinical trial drug product and placebo have also been obtained. On September 2, 2021, we announced the initiation of patient dosing in the trial. Our trial requires individuals with moderate COVID-19 symptoms to be unvaccinated and have co-morbidities such as heart disease, as those patients typically have worse outcomes, requiring hospitalization. We have experienced enrollment challenges primarily as a result of the decrease in COVID-19 infections and increased immunizations in the United States. To mitigate this challenge, we are in the process of undertaking the steps required to open new sites across the U.S., and enrollment rates may also be affected by any increase in COVID-19 during this coming winter. New site activation requires multiple steps and can take many weeks to complete. In addition, we intend to consider sites outside of the United States in geographic locations where vaccination rates are lower, and COVID19 rates are higher. Absent unexpected developments, the company intends to announce the interim analysis of interim results for the clinical trial after 50 eligible subjects have completed day 21of the trial protocol and the appropriate analysis has been performed and reviewed by the Data Safety Monitoring Board (DSMB).

On January 28, 2021, we announced that in collaboration with the Human Immune Monitoring Center at Stanford University we conducted a study to investigate the effects of Tempol on immune cells from COVID-19 patients, and that preliminary data from that study showed that Tempol decreased cytokines from stimulated cells from COVID-19 patients. On August 24, 2021, we announced that an article reporting on the study and study results was published in the peer reviewed journal *Clinical Immunology*. In March 2021, we announced that in studies conducted at Galveston National Laboratory, University of Texas Medical Branch, hamsters challenged with the virus that causes COVID-19 (SARS-CoV-2) showed decreased inflammation in the lungs when treated with Tempol compared to controls. We intend to continue to explore the availability of government and/or non-government funding to help support study the efficacy of Tempol as a therapeutic treatment for COVID-19. We also continue to explore options regarding the funding and design of a clinical study to examine the effects of Tempol for other clinical indications including, but not limited to, the treatment of methamphetamine use disorder, and are engaged in additional activities intended to support an IND to begin such a study.

US Compounding, Inc. Agreement

On July 30, 2021, the Company and its wholly-owned USC subsidiary entered into an Asset Purchase Agreement (the "USC Agreement") effective as of July 30, 2021 (the "Effective Date") with Fagron Compounding Services, LLC d/b/a Fagron Sterile Services (the "Purchaser"), providing for the sale and transfer by USC and the purchase by the Purchaser, effective as of the Effective Date, of certain assets of USC related to its human compounding pharmaceutical business (the "Business"), including certain customer information and information on products sold to such customers by USC (together, the "Book of Business"), including related formulations, know-how, and expertise regarding the compounding of pharmaceutical preparations, clinical support knowledge and other data and certain other information relating to the customers and products (collectively, the "Assets"). After the Effective Date, Purchaser may use the Book of Business to secure customers for its products and services and may otherwise use the Book of Business. Pursuant to the USC Agreement, the Purchaser will not assume any liabilities of USC, and the transaction did not include the sale or transfer of any USC equipment, buildings or real property, or any products, information, agreements, relationships or other assets relating to the veterinary business of USC.

The USC Agreement provides that the consideration payable by the Purchaser to the Company for the Assets sold and transferred will consist of the following amounts: (i) a payment of $107,500 on the Effective Date; and (ii) monthly payments in an amount equal to (a) two (2.0) times the amount actually collected by Purchaser or its affiliates for sales of products or services made to certain identified customers included in the Book of Business during the 12-month period following the Effective Date (the "Payment Term"), and (b) a lower multiple of the amount actually collected by Purchaser or its affiliates for sales of products or services made to certain other customers included in the Book of Business. In addition, to the extent that such product or service is supplied by USC pursuant to the supply arrangement provided for by the USC Agreement (the "Supply Agreement"), the Purchaser agreed to reimburse USC for the cost of such product or service, as set forth in the Supply Agreement. The USC Agreement provides that during the Payment Term, the Purchaser will maintain the Book of Business and use commercially reasonable efforts to maximize the consideration payable to the Company and collect amounts outstanding related to sales of products or services made to customers included in the Book of Business. However, the USC Agreement does not provide for any minimum purchase price consideration to the Company or USC. Accordingly, there is no assurance as to the amount of purchase price consideration that the Company or USC may ultimately receive as a result of the transactions contemplated by the USC Agreement. Certain of the customers included in the Book of Business may decide to not purchase products or to reduce their purchases of products from Purchaser after the Effective Date, and Purchaser may, in good faith, decide not to change its product mix from those products offered by Purchaser as of the Effective Date and may decide not to carry all of the products offered and sold by USC as part of the Business prior to the Effective Date.

The USC Agreement includes certain restrictive covenants of the Company and USC, including noncompetition provisions, pursuant to which, for a period of five years from the Effective Date (the "Restricted Period") and subject to certain exceptions, the Company and USC have agreed, among other matters, not to solicit any Business from any customers included in the Book of Business or engage in certain other activities. Each of the USC Agreement and the Supply Agreement includes standard indemnification provisions, and a number of other covenants and agreements of the parties concerning the transactions contemplated by the USC Agreement and the Supply Agreement, including concerning cooperation and assistance, confidentiality, non-disparagement and the transfer of information and documents, compliance with laws, and personnel matters. The USC Agreement includes indemnification provisions pursuant to which the Company and USC agreed to indemnify the Purchaser and certain related parties against losses incurred by such indemnified parties arising or resulting from certain matters including breach of the USC Agreement by USC and third party claims relating to product sales to customers by USC before the Effective Date. In connection with the transaction, the Company accrued a $700,000 liability for a transaction fee payable to a financial advisor of $700,000 as of September 30, 2021.

Plan for the Remaining Operations, Business and Assets of USC

In light of a number of factors including the sale of assets to the Purchaser pursuant to the USC Agreement, the Board approved a restructuring process of winding down the remaining operations and business of USC and selling, transferring or disposing of the remaining assets of USC. The restructuring and winding down includes, without limitation, the termination of USC's veterinary business and USC sales to veterinary customers; the termination of employment of all or substantially all employees engaged in the USC business (except as determined to be necessary or appropriate in connection with the Company's and USC's performance of their obligations under the USC Agreement and the transactions contemplated thereby, or in connection with resolving matters relating to the winding down of USC's business), and providing such notices and making such payments to such employees as the officers of the Company determine are necessary or appropriate, including as maybe required by law or as maybe provided for pursuant to any retention agreement, severance agreement, incentive agreement, or other written agreement with such employees; the sale or other disposition from time to time of the remaining equipment, real property, buildings and tangible and intangible assets relating to USC's business that are unrelated to the USC Agreement; the termination, assignment or other resolution of agreements with third parties relating to the USC business; making regulatory filings and taking appropriate actions with federal and state regulatory authorities in connection with the winding down and winding up of USC's business; and taking such other actions as the officers of the Company or USC (as appropriate) determine are necessary or appropriate in connection with the restructuring and the winding down and winding up of the remaining business, operations and assets of USC. In August 2021, the company and USC entered into an asset purchase agreement with a third party buyer providing for the sale and transfer by USC of certain customer information and other assets related to USC's veterinary compounded pharmaceuticals business, in consideration for the payment to the company by the buyer of a percentage of amounts actually collected by the buyer on sales of certain veterinary products to veterinary customers covered by the agreement over the five year period after the date of the agreement.

Going Concern and Management's Plan

The financial statements included elsewhere herein for the six months ended June 30, 2021, and our financial statements for the year ended December 31, 2020 and 2019, were prepared under the assumption that we would continue our operations as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. However, as of June 30, 2021, we had cash and cash equivalents and restricted cash of approximately $40.6 million, an accumulated deficit of approximately $257.0 million, and liabilities of approximately $17.0 million. We have incurred substantial recurring losses from operations, have used, rather than provided, cash in our continuing operations, and are dependent on additional financing to fund operations. These conditions raise substantial doubt about our ability to continue as a going concern. The financial statements included elsewhere herein do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. In January and February 2021, the company issued common stock upon exercise of investor warrants, and the company received a total of approximately $5,852,000 and the warrant holders received 8,356,000 shares of common stock. On February 2, 2021, the company completed the closing of an underwritten public offering of 46,621,621 shares of common stock at a public offering price of $1.11 per share, which included 6,081,081 shares pursuant to the full exercise of the over-allotment option granted to the underwriters, resulting in net proceeds of approximately $48.4 million. In March 2021, we received approximately $1.8 million of debt funding that we obtained under the Second Draw Loan pursuant to the terms of the PPP, the CARES Act, and the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act enacted in December 2020. However, we may need additional funding in the future to continue operations, satisfy our obligations, including any expenses that may arise in the future relating to matters in Part II, Item 1 - Legal Proceedings, 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, 2021, 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 the future from debt or equity financing, sales of assets, sales or out-licenses of intellectual property, products, product candidates or technologies, or from a business combination or a similar transaction, after expenditure of our existing cash resources 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, consideration that we may receive from the Purchaser pursuant to our asset purchase agreement relating to certain assets of USC and sale of other assets used in the USC business, 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, 2021 and 2020

Revenues. Consolidated revenues were approximately $4,011,000 and $3,926,000 for the three months ended June 30, 2021 and 2020, respectively. Consolidated revenues increased approximately $85,000 in the second quarter of 2021 compared to the comparable period of 2020.

Revenues of our Drug Development and Commercialization business conducted by Adamis were approximately $1,275,000 and $721,000 for the three months ended June 30, 2021 and 2020, respectively. Revenue relating to the sales of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg increased approximately $554,000 primarily due to the sales and marketing initiatives of our new distribution partner, USWM, when compared with the comparable 2020 period.

Revenues of our Compounded Pharmaceuticals business conducted through USC were approximately $2,736,000 and $3,205,000 for the three months ended June 30, 2021 and 2020, respectively. The decline was primarily due to a decline in sale of USC's human products resulting primarily from restrictions on outpatient surgery and other medical procedures due to the COVID-19 pandemic, and to a lesser extent a decline in sales of veterinary products. The COVID-19 outbreak has adversely affected revenues from sales of USC products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products, and will likely continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted. Moreover, COVID-19 has restricted USC from utilizing traditional sales and marketing efforts, such as regular sales visits to customers, in generating revenues.

Cost of Goods Sold. Consolidated cost of goods sold was approximately $3,871,000 and $4,684,000 for the three months ended June 30, 2021 and 2020, 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 (loss) percentage for three months ended June 30, 2021 was approximately 4% compared to approximately (19%) for the three months ended June 30, 2020.

Cost of goods sold of our Drug Development and Commercialization business conducted by Adamis was approximately $1,796,000 and $1,840,000 for the three months ended June 30, 2021 and 2020, respectively. The gross loss percentage for the three months ended June 30, 2021 was approximately 41% compared to approximately 155% for the three months ended June 30, 2020. Cost of goods sold for the second quarter of the 2021 period compared to the comparable period of 2020 decreased primarily due to the decrease of approximately $374,000 for depreciation, maintenance fees and other related expenses associated with the production of SYMJEPI, offset by increases of approximately $330,000 in direct materials largely driven by increased sales of SYMJEPI.

Cost of goods sold of our Compounded Pharmaceuticals business conducted through USC was approximately $2,075,000 and $2,844,000 for the three months ended June 30, 2021 and 2020, respectively. The gross margin percentage for the three months ended June 30, 2021 was approximately 24% compared to approximately 11% for the three months ended June 30, 2020. Materials costs, compensation and other employee benefits, product devices, testing, freight, and other related expenses decreased approximately $769,000 due to the reduction in consumer demand for certain USC products as a result of the COVID-19 pandemic.

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, 2021 and 2020 were approximately $7,132,000 and $5,653,000, respectively.

SG&A expenses of our Drug Development and Commercialization business conducted by Adamis for the three months ended June 30, 2021 and 2020 were approximately $4,935,000 and $3,009,000, respectively. The increase was primarily attributable to an increase in professional fees of approximately $2,346,000, partially offset by an approximately $243,000 decrease in depreciation and amortization as a result of the write-off of the DPI intangible asset in the fourth quarter of 2020 that eliminated amortization expense in future periods, and a decrease of approximately $177,000 of compensation related expenses largely attributed to decreased stock compensation expenses as a result of the completion of vesting of a significant amount of option grants through February 2021.

SG&A expenses of our Compounded Pharmaceuticals business conducted through USC for the three months ended June 30, 2021 and 2020 were approximately $2,197,000 and $2,644,000, respectively. Approximately $200,000 of the decrease in SG&A expenses for second quarter of 2021 compared to the second quarter in 2020 year was attributable to decreases in selling expenses primarily due to the reduction of commission payments, marketing expenses and other related expenses as a direct effect of the reduction in revenue, approximately $68,000 of the decrease was due to reductions in professional fees and consulting expenses, approximately $55,000 of the decrease was attributable to a reduction in bad debt expense. Additionally, there was an approximately $124,000 decrease attributable to lower expense for licensing and permits, property taxes, and other administrative items.

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. Consolidated research and development expenses were approximately $2,233,000 and $3,086,000 for the three months ended June 30, 2021 and 2020, respectively.

Research and development expenses of our Drug Development and Commercialization business conducted by Adamis were approximately $2,197,000 and $2,926,000 for the three months ended June 30, 2021 and 2020, respectively. Approximately $656,000 of the decrease in R&D expenses for the three months ended June 30, 2021, compared to the comparable 2020 period was related to decreased development spending on Tempol, SYMJEPI, ZIMHI, and other projects. In addition, wages, benefits, and other compensation expenses for research and development employees decreased approximately $73,000 during the three months ended June 30, 2021, compared to the comparable 2020 period, largely attributed to decreased stock compensation expenses as a result of the completion of vesting of a significant amount of option grants through February 2021.

Research and development expenses of our Compounded Pharmaceuticals business conducted through USC were approximately $36,000 and $160,000 for the three months ended June 30, 2021 and 2020, respectively. USC's R&D expenses for the three months ended June 30, 2021, compared to the comparable 2020 period, decreased due to the reduction of new product testing.

Impairment Expense, Contract Costs. Impairment expenses of contract costs for the three months ended June 30, 2021 and 2020 were approximately $0 and $1,750,000, respectively. As a result of entering into the Termination 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.

Impairment Expense, Construction in Progress. Impairment expenses of construction in progress for the three months ended June 30, 2021 and 2020 were approximately $9,000 and $0, respectively. In the second quarter of 2021, USC determined that certain in-process development costs related to its website design no longer had value and was thus impaired.

Other Expense. Other Income (Expenses) consists primarily of interest income, interest expense, and changes to the fair value of warrant liabilities. Other income (expense) for the three months ended June 30, 2021 and 2020 was approximately $81,000 and $1,678,000, respectively. The decrease in other income (expense) during the three-month period in 2021, compared to the same period in 2020, was primarily due to the decrease of other expense of approximately $1,618,000 associated with the change in fair value of warrants, a decrease of approximately $9,000 in other income, and an increase of interest expense of approximately $12,000.

Six Months Ended June 30, 2021 and 2020

Revenues. Consolidated revenues were approximately $8,120,000 and $8,590,000 for the six months ended June 30, 2021 and 2020, respectively. Consolidated revenues decreased approximately $470,000 in the first six months of 2021 compared to the comparable period of 2020.

Revenues of our Drug Development and Commercialization business conducted by Adamis were approximately $2,608,000 and $1,229,000 for the six months ended June 30, 2021 and 2020, respectively. Revenue relating to the sales of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg increased approximately $1,379,000 primarily due to the sales and marketing initiatives of our new distribution partner, USWM, when compared with the comparable 2020 period.

Revenues of our Compounded Pharmaceuticals business conducted through USC were approximately $5,512,000 and $7,361,000 for the six months ended June 30, 2021 and 2020, respectively. The decline was primarily due to a decline in sale of USC's human products resulting primarily from restrictions on outpatient surgery and other medical procedures due to the COVID-19 pandemic, and to a lesser extent a decline in sales of veterinary products. The COVID-19 outbreak has adversely affected revenues from sales of USC products, in part due to reductions or cancellations of elective surgeries and reduction in office visits to physicians' offices, healthcare facilities or clinics by patients, and the resulting decreased demand by USC's customers for certain of USC's products, and will likely continue to adversely affect revenues from sales of USC products for a period of time which cannot be predicted. Moreover, COVID-19 has restricted USC from utilizing traditional sales and marketing efforts, such as regular sales visits to customers, in generating revenues.

Cost of Goods Sold. Consolidated cost of goods sold was approximately $7,513,000 and $8,371,000 for the six months ended June 30, 2021 and 2020, 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 six months ended June 30, 2021 was approximately 7% compared to approximately 3% for the six months ended June 30, 2020.

Cost of goods sold of our Drug Development and Commercialization business conducted by Adamis was approximately $3,642,000 and $3,573,000 for the six months ended June 30, 2021 and 2020, respectively. The gross loss percentage for the six months ended June 30, 2021 was approximately 40% compared to approximately 191% for the six months ended June 30, 2020. Cost of goods sold for the quarter ended June 30, 2021 compared to the comparable period of 2020 increased approximately $855,000 in direct materials costs, which was largely due to increased sales of SYMJEPI, partially offset primarily by a decrease of approximately $786,000 for depreciation, maintenance fees and other related expenses associated with the production of SYMJEPI.

Cost of goods sold of our Compounded Pharmaceuticals business conducted through USC was approximately $3,871,000 and $4,798,000 for the six months ended June 30, 2021 and 2020, respectively. The gross margin percentage for the six months ended June 30, 2021 was approximately 30% compared to approximately 35% for the six months ended June 30, 2020. Materials costs, compensation and other employee benefits, product devices, testing, freight, and other related expenses decreased approximately $927,000 due to the reduction in consumer demand for certain USC products as a result of the COVID-19 pandemic.

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 six months ended June 30, 2021 and 2020 were approximately $13,051,000 and $11,707,000, respectively.

SG&A expenses of our Drug Development and Commercialization business conducted by Adamis for the six months ended June 30, 2021 and 2020 were approximately $8,452,000 and $6,312,000, respectively. The increase was primarily attributable to professional fees of approximately $2,933,000, partially offset by an approximately $486,000 decrease in depreciation and amortization as a result of the write-off of the DPI intangible asset in the fourth quarter of 2020 that eliminated amortization expense in future periods, a decrease of approximately $270,000 of compensation related expenses largely attributed to decreased stock compensation expenses as a result of the completion of vesting of a significant amount of option grants through February 2021, and an approximately $37,000 decrease for other administrative expenses.

SG&A expenses of our Compounded Pharmaceuticals business conducted through USC for the six months ended June 30, 2021 and 2020 were approximately $4,599,000 and $5,395,000, respectively. Approximately $525,000 of the decrease in SG&A expenses for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 was attributable to decreases in selling expenses primarily due to the reduction of commission payments, marketing expenses and other related expenses as a direct effect of the reduction in revenue, approximately $94,000 of the decrease was attributable to a reduction of G&A employee compensation expenses, approximately $60,000 of the decrease was attributable to a reduction in bad debt expense, and approximately $117,000 of the decrease was attributable to lower licensing and permits expenses, property tax expense, and other administrative expenses.

Research and Development Expenses. Our research and development costs are expensed as incurred. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as an asset and are expensed when the research and development activities are performed. Consolidated research and development expenses were approximately $4,494,000 and $5,123,000 for the six months ended June 30, 2021 and 2020, respectively.

Research and development expenses of our Drug Development and Commercialization business conducted by Adamis were approximately $4,446,000 and $4,963,000 for the six months ended June 30, 2021 and 2020, respectively. Approximately $218,000 of the decrease in R&D expenses for the six months ended June 30, 2021, compared to the comparable 2020 period was related to decreased development spending on Tempol, ZIMHI, and other projects. In addition, wages, benefits, and other compensation expenses for research and development employees decreased approximately $299,000 during the six months ended June 30, 2021, compared to the comparable 2020 period, largely attributed to decreased stock compensation expenses as a result of the completion of vesting of a significant amount of option grants through February 2021.

Research and development expenses of our Compounded Pharmaceuticals business conducted through USC were approximately $48,000 and $160,000 for the six months ended June 30, 2021 and 2020, respectively. USC's R&D expenses for the six months ended June 30, 2021, compared to the comparable 2020 period, decreased due to the reduction of new product testing.

Impairment Expense, Goodwill. Impairment expenses of goodwill for the six months ended June 30, 2021 and 2020 were approximately $0 and $3,143,000, respectively. In light of 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 quarter of 2020.

Impairment Expense, Contract Costs. Impairment expenses of contract costs for the six months ended June 30, 2021 and 2020 were approximately $0 and $1,750,000, respectively. As a result of entering into the Termination Agreement with Sandoz, 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.

Impairment Expense, Construction in Progress. Construction in progress impairment expenses for the six months ended June 30, 2021 and 2020 were approximately $9,000 and $0, respectively. In the second quarter of 2021, USC determined that certain in-process development costs related to its website design no longer had value and was thus impaired.

Other Income (Expense). Other Income (Expenses) consists primarily of interest income, interest expense, and changes to the fair value of warrant liabilities. Other income (expense) for the six months ended June 30, 2021 and 2020 was approximately ($7,746,000) and $1,333,000 respectively. The decrease in other income (expense) during the six-month period in 2021, compared to the same period in 2020, was primarily due to the increase of other expense of approximately $9,050,000 associated with the change in fair value of warrants, a decrease of approximately $16,000 in other income, and an increase of interest expense of approximately $13,000.

Liquidity and Capital Resources

We have incurred net losses of approximately $24.7 million and $20.2 million for the six months ended June 30, 2021 and 2020, respectively. Since inception, and through June 30, 2021, we have an accumulated deficit of approximately $257.0 million. Since inception and through June 30, 2021, we have financed operations principally through debt financing and through public and private issuances of common stock, preferred stock and warrants. In January and February 2021, the company issued common stock upon exercise of investor warrants, the company received a total of approximately $5,852,000 and the warrant holders received 8,356,000 shares of common stock. On February 2, 2021, the company completed the closing of an underwritten public offering of 46,621,621 shares of common stock at a public offering price of $1.11 per share, which included 6,081,081 shares pursuant to the full exercise of the over-allotment option granted to the underwriters, resulting in net proceeds of approximately $48.4 million.

However, we may need additional funding in the future 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, studies and trials to develop our product candidates, including without limitation relating to our Tempol 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.

As of June 30, 2021, we had cash, cash equivalents and restricted cash of $40,648,554. Total assets were approximately $63.7 million and $30.9 million as of June 30, 2021 and December 31, 2020 respectively. Current assets exceeded current liabilities by approximately $32.7 million as of June 30, 2021.

Net cash used in operating activities for the six months ended June 30, 2021 and 2020, was approximately $21.3 million and $9.4 million, respectively. Net cash used in operating activities increased primarily due to the increase in operating losses and the payment of contingent loss liability in 2021 as compared to 2020.

Net cash used in investing activities was approximately $848,000 and $911,000 for six months ended June 30, 2021 and 2020, respectively. The net cash used in investing activities decreased primarily due to the purchase of in process research and development license during the six months ended June 30, 2020 compared to the six months ended June 30, 2021.

Net cash provided in financing activities was approximately $56.0 million and $9.4 million for the six months ended June 30, 2021 and 2020, respectively. Net cash flows provided by financing activities increased for the period ended June 30, 2021 primarily due to the issuance of common stock, exercise of warrants and Second Draw Loan under the PPP, generating net proceeds of approximately $56.0 million, offset by payment of loans and finance leases of approximately $51,000. In the six months ended of 2020, net cash used in financing activities consisted of issuance of common stock and the initial draw of PPP Loan, generating net proceeds of approximately $9.4 million, offset by payment of loans and finance leases of approximately $53,000.

Loan Agreements

In connection with our acquisition of USC in 2016, we assumed approximately $5,722,000 principal amount of debt obligations under two loan agreements and related loan documents relating to the building, real property and equipment that certain third parties agreed to transfer to the company or USC in connection with the merger transaction, as well as the two loan agreements to which USC is a party, a working capital loan and an equipment loan, and related loan documents evidencing loans previously made to USC, and we agreed to become an additional co-borrower under the loan agreement and related documents, such documents as amended referred to as the "Loan Documents." The lender in all of the Loan Documents was First Federal Bank and/or its successor Bear State Bank (together with Arvest Bank, as successor in interest to Bear State Bank, referred to as "Lender" or the "Bank"). All amounts owed under the working capital loan and the equipment loan have previously been paid and there are no outstanding balances under those Loan Documents, and the working capital loan has not been renewed or extended. Periodic interest and principal payments under the building loan agreement are approximately $19,000 per month, with a final payment of all outstanding amounts due and payable in August 2021. At June 30, 2021, our aggregate indebtedness under the building loan agreement was approximately $2,018,000, which we paid in full in July 2021. There is no outstanding balance under the building loan or any of the other Loan Documents.

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, or the CARES Act, and administered by the SBA. The unsecured loan, or the PPP Loan, is evidenced by a promissory note of the company, or the PPP Note, to Arvest Bank, the Lender. Under the terms of the PPP Note and the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP Note is two years, unless sooner provided in connection with an event of default under the PPP Note. To the extent the loan amount is not forgiven under the PPP, we are obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the PPP Note (or later if a timely loan forgiveness application has been submitted), until the maturity date. The CARES Act and the PPP provide a mechanism for a borrower to apply for forgiveness of up to the full amount borrowed. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by us during the eight-week or 24-week period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments, provided that at least 60% of the loan amount is used for eligible payroll costs; the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible costs during the covered eight-week or 24-week period will qualify for forgiveness.

In December 2020, we submitted an application for the forgiveness of our PPP Loan, and on August 12, 2021, we received notification through the Bank that the PPP Loan, including principal and interest thereon, has been fully forgiven by the SBA and that the remaining PPP Loan balance is zero. The company will recognize the amount forgiven as other income for the quarter in which the company received the notification.

On March 15, 2021, we entered into a Note, or the PPP2 Note, in favor of the Bank, in the principal amount of $1,765,495 relating to funding under a Second Draw loan, or the Second Draw Loan, pursuant to the terms of the PPP, the CARES Act, and the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act enacted in December 2020. Under the terms of the PPP2 Note and Second Draw Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. If any payment on the PPP2 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 term of the PPP2 Note is five years, unless sooner provided in connection with an event of default under the PPP2 Note. We may prepay the Second Draw Loan at any time prior to maturity with no prepayment penalties. Under the PPP, the proceeds of the Second Draw Loan may be used to pay payroll and make certain covered interest payments, lease payments and utility payments. We may apply for forgiveness of some or all of the Second Draw Loan pursuant to the PPP. In order to obtain full or partial forgiveness of the Second Draw Loan, we must timely request forgiveness, must provide satisfactory documentation in accordance with applicable SBA guidelines, and must satisfy the criteria for forgiveness under the PPP and applicable SBA requirements. If we timely apply for forgiveness, payments will be deferred in accordance with the CARES Act, as modified by the Paycheck Protection Program Flexibility Act of 2020, and we will not be obligated to make any payments of principal or interest before the date on which the SBA remits the loan forgiveness amount to the Bank or notifies the Bank that no loan forgiveness is allowed; and the Bank will then notify us of remittance by SBA of the loan forgiveness amount, or notify us that the SBA determined that no loan forgiveness is allowed and the date that our first payment is due. Interest will accrue during the deferral period. There is no assurance that we will obtain forgiveness of the Second Draw Loan in whole or in part. Our PPP loans are 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 or otherwise. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return or repay the full amount of the applicable 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 the Second Draw Loan is not forgiven in accordance with the terms of the PPP, we will be obligated to make monthly payments of principal and interest to repay the Second Draw Loan in full prior to the maturity date. If it is determined that the company was ineligible to receive the Second Draw Loan, we may be required to repay the Second Draw Loan in its entirety and/or be subject to additional penalties. Should the company apply for and receive forgiveness of some or all of the PPP2 Loan, the amount forgiven would be recognized as other income upon formal notice of forgiveness. If we do not submit a loan forgiveness application to the Bank within 10 months after the end of our applicable covered period, as defined under the PPP and applicable regulations and guidance issued by the SBA or the U.S. Department of Treasury, then we must begin paying principal and interest after that period. The PPP2 Note contains customary events of default relating to, among other things, payment defaults, breaches of representations, warranties or covenants, defaults on other loans with the Bank, failure to disclose material fact or making materially false or misleading representations to the Bank or SBA, certain defaults on other loan agreements or agreements with creditors, bankruptcy or insolvency events, certain change of control events, material adverse changes or events, certain events that the Bank believes may materially affect the company's ability to pay the PPP2 Note, and certain other events. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing by us, or filing suit and obtaining judgment against us.

On August 12, 2021, we received notification through the Bank that as August 5, 2021, the PPP Loan drawn on April 13, 2020, including principal of $3,191,700 and interest thereon, has been fully forgiven by the SBA and that the remaining PPP Loan balance is zero. In October 2021, we received notification through the Bank that as of September 28, 2021, the Second Draw PPP Loan, including principal of $1,765,495 and interest thereon, has been fully forgiven by the SBA and that the remaining PPP2 Loan balance is zero.

Even though the PPP Loan and the Second Draw PPP Loan have been forgiven, our PPP loans and applications for forgiveness of loan amounts remain subject to review and audit by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form, including without limitation the required economic necessity certification by the Company that was part of the PPP loan application process. Accordingly, the Company is subject to audit or review by federal or state regulatory authorities as a result of applying for and obtaining the PPP Loan and Second Draw PPP Loan or obtaining forgiveness of those loans. 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 applicable 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 it is determined that the Company was ineligible to receive the PPP Loan and/or the Second Draw Loan, the Company may be required to repay the PPL Loan and Second Draw Loan in its entirety and/or be subject to additional penalties.

As noted above under the heading "Going Concern and Management Plan," through June 30, 2021, 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, or other factors, there can be no assurance that 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.

As disclosed elsewhere in this Report, including in Part II, Item 1, "Legal Proceedings," on May 11, 2021, each of the company and its USC subsidiary received a grand jury subpoena from the U.S. Attorney's Office for the Southern District of New York issued in connection with a criminal investigation, requesting a broad range of documents and materials relating to, among other matters, certain veterinary products sold by the company's USC subsidiary, certain practices, agreements and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC. The Audit Committee of the Board has engaged outside counsel to conduct an independent internal investigation to review these and other matters. In addition to the subpoenas from the USAO, the company has also received requests from the SEC for the voluntary production of documents and information relating to the subject matter of the USAO's subpoenas and certain other matters. The company has produced documents and will continue to produce and provide documents in response to the subpoenas and requests. The company intends to cooperate with the USAO and the SEC. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, or other agencies, or determine what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate, what, if any, remedies or remedial measures the USAO, SEC or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the company's business, previously reported financial results, financial results included in this Report, or future financial results. The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, result in fines, penalties, equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, or future financial results. The occurrence of any of these events could have a material adverse effect on the company's business, financial condition and results of operations.

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, 2020 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, 2021, 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, as of June 30, 2021, our disclosure controls and procedures were, in design and operation, not effective at the reasonable assurance level, due to the presence of a material weakness in internal control over financial reporting as described below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Changes in Internal Controls Over Financial Reporting

As required by Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded that except as described below and other than the material weakness and the remediation measures described in this Item 4, there were no changes in our internal controls over financial reporting during the quarter ended June 30, 2021 that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting as a result of the COVID-19 pandemic despite the fact that some 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.

Based on the material weakness described below, management has concluded that as of March 31, 2021, our internal control over financial reporting was not effective. We identified a weakness relating to our controls over adherence to certain company policies and procedures relating to hiring, monitoring and supervision of USC's sales personnel and the activities of such personnel, which were not strictly implemented and observed. We also identified a weakness in controls regarding inadequate oversight by senior management to ensure compliance with and adherence to company policies and procedures by USC sales personnel and to ensure performance of adequate monitoring and supervision of personnel. This control deficiency was assessed as a material weakness as of June 30, 2021.

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

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

Nephron

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

On May 6, 2020, Adamis and USC moved for summary judgment to dismiss the three claims that remained pending against them. In October 2020, the magistrate judge presiding over the motion delivered a Report and Recommendation recommending that the court enter an order granting the motion in part and denying the motion in part. The court adopted the recommendation of the magistrate and granted in part and denied in part the motion of Adamis and USC for summary judgment. The court denied the motion for summary judgment by Adamis and USC with respect to the plaintiffs' claims under the DFSA and FUTSA, concluding that there were triable issues of material fact that precluded the entry of summary judgment, and granted the motion for summary judgment in favor of Adamis and USC with respect to the claim for tortious interference. In March 2021, the court granted a motion by Nephron to hold Adamis and USC in civil contempt for violation of a previous consent preliminary injunction related to the hiring by USC of an employee, and ordered that Adamis and USC compensate Nephron for certain fees and expenses in the litigation relating to the matter as well as pay a fine, in an amount to be determined. A hearing on the amount of such sanctions was held on April 6, 2021, but decisions regarding sanctions were deferred until after trial. After the hearing, the court ruled on various pre-trial motions relating to the conduct of the trial. The case was set for trial on April 19, 2021.

As previously disclosed in the 2020 Form 10-K, while we continue to believe that the claims and damages sought by the plaintiff were without merit, in light of several factors including the recent hearing and outcome of decisions concerning pre-trial motions, the legal expenses of ongoing litigation and trial, the uncertainties of litigation and jury trials, and the possibility of punitive damages and other adverse awards or sanctions, on April 9, 2021, Adamis, USC and Nephron agreed to terms of settlement of the Florida litigation as well as a related case filed by Nephron against USC, Adamis and a second USC employee in the United States District Court for the District of New Jersey alleging misappropriation of trade secrets from Nephron. Under the terms of the settlement agreement entered into by Adamis, the Nephron entities and certain other individuals (the "individual parties"), and related documents entered into by the parties thereto, on May 3, 2021, the company paid Nephron an amount equal to $7,900,000; the company and USC, as well as the individual parties, agreed to a permanent injunction reflecting certain terms of the settlement and pursuant to which they agreed, among other things, not to retain, access, communication, use or disclose any proprietary or confidential information of Nephron and to destroy all such information in their possession or control, subject to limited exceptions; and Nephron agreed to dismissal of or withdrawal from the lawsuits and related legal proceedings. Pursuant to the settlement agreement, each of the parties agreed to release each other from all existing claims that any of them may have against any of the other parties that arise from or relate to the claims and liabilities asserted in the various lawsuits and agreed not to sue any of the parties on the basis of any released claim.

Investigation

On May 11, 2021, the company and USC each received a grand jury subpoena from the U.S. Attorney's Office for the Southern District of New York ("USAO"). The USAO issued the subpoenas in connection with a criminal investigation and requested a broad range of documents and materials relating to, among other matters, certain veterinary products sold by USC, certain practices, agreements, and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC. On May 11, 2021, the Audit Committee of the Board engaged outside counsel to conduct an independent internal investigation to review the matters brought forth in the subpoenas and certain other matters. The investigation involved, among other matters, interviews with employees and collection and review of a large number of documents. The company has taken a number of actions in response to the internal investigation, including personnel actions relating to certain USC veterinary sales employees. In addition, following the commencement of the investigation, as disclosed elsewhere in this Report the company has sold assets relating to its compounding pharmacy business, ceased selling human and veterinary compounded pharmaceutical products, is engaged in a process of winding down USC's business, and the employment of substantially all USC employees has ended or will end in connection with the winding down of that business. As a result, the company will no longer be engaged in the sale of human or veterinary compounded pharmaceutical products. The company is also considering a number of additional actions in response to the internal investigation. As of the date of this Report, we believe that the investigation initially commenced by the Audit Committee is substantially complete. However, additional issues or facts could arise or be determined, which may expand the scope, duration, or outcome of the Audit Committee's investigation. In addition to the subpoenas from the USAO, the company has also received requests from the U.S. Securities and Exchange Commission ("SEC") for the voluntary production of documents and information relating to the subject matter of the USAO's subpoenas and certain other matters. The company has produced documents and will continue to produce and provide documents in response to the subpoenas and requests. The company intends to cooperate with the USAO and the SEC. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, or other agencies, or determine what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate, what, if any, remedies or remedial measures the USAO, SEC, or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the company's business, previously reported financial results, financial results included in this Report, or future financial results.. We could receive additional requests from the USAO, SEC, or other authorities, which may require further investigation. There can be no assurance that any discussions with the SEC or USAO to resolve these matters will be successful. The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, result in fines, penalties or equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, or future financial results. The occurrence of any of these events, or any determination that our activities were not in compliance with existing laws or regulations, could have a material adverse effect on the company's business, financial condition, and results of operations.

Regulatory

In October 2021, following the sale in July 2021 of certain assets of the Company's USC subsidiary relating to USC's human compounding pharmaceutical business and the Company's approval of a restructuring process of winding down the remaining operations and business of USC and selling or disposing of the remaining assets of USC, the Company entered into a Consent Order with the Arkansas State Board of Pharmacy to resolve an ongoing administrative proceeding before the pharmacy board, pursuant to which USC agreed to surrender its Arkansas retail pharmacy permit and wholesaler/outsourcer permit effective October 31, 2021, to pay a civil penalty of $75,000 relating to violations of various Arkansas pharmacy laws and the pharmacy board's regulations, and to pay $75,000 in investigative costs of the pharmacy board.

Nasdaq Compliance

In response to the company's May 2021 Form 12b-25 disclosure that it would be unable to file in a timely manner its Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 due to the need for additional time to address matters relating to the USAO's subpoenas, Nasdaq sent the company a letter determining that the company was no longer in compliance with Nasdaq Listing Rule 5250(c)(1). We submitted a plan to regain compliance. In August, we received a notification letter from Nasdaq notifying us that because we had not filed our Quarterly Report on Form 10-Q for the period ended June 30, 2021, as well as the Form 10-Q for the period ended March 31, 2021 (together, the "Form 10-Qs"), we did not comply with NASDAQ Listing Rule 5250(c)(1). Nasdaq subsequently requested that we submit an updated plan to regain compliance, which we submitted, and Nasdaq granted an exception of up to November 22, 2021, to regain compliance. With this Report and the filing of the Form 10-Qs, the company believes it has returned to full compliance.

On June 8, 2021, Jerald Hammann filed a complaint against the Company and each of its directors in the Court of Chancery of the State of Delaware, captioned *Jerald Hammann v. Adamis Pharmaceuticals Corporation et al.*, C.A. No. 2021-0506-PAF (the "Complaint"), seeking injunctive and declaratory relief. The Complaint alleges, among other things, that the defendants (i) violated Rule 14a-5(f) and 14a-9(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in connection with the Company's 2021 annual meeting of stockholders—which was subsequently held on July 16, 2021 (the "2021 annual meeting")—and disseminated false and misleading information in the Company's proxy materials relating to the 2021 annual meeting, (ii) violated certain provisions of the Company's bylaws relating to the 2021 annual meeting, (iii) violated section 220 of the Delaware General Corporation Law ("DGCL") in connection with a request for inspection of books and records submitted by the plaintiff, and (iv) breached their fiduciary duties of disclosure and loyalty, including relating to establishing and disclosing the date of the Company's 2021 annual meeting and to the Company's determination that a solicitation notice delivered to the Company by plaintiff was not timely and was otherwise deficient. The Complaint alleges, among other things, that plaintiff intended to initiate a proxy contest against the Company, that defendants' conduct made it difficult or impossible for plaintiff to initiate a proxy context, and that the Company's definitive proxy statement included false and misleading disclosures and omissions of material information. The Complaint sought injunctive relief (i) to prevent the Board, the Company, and their employees and agents from soliciting any stockholders pursuant to the Company's proxy statement and (ii) to prevent the defendants from interfering in the effectiveness of stockholder voting for the 2021 annual meeting. The Complaint also seeks declaratory relief (i) finding that plaintiff's solicitation notice was timely and properly submitted; (ii) directing the defendants to comply with Rules 14a-5(f) and 14a-9(a) of the Exchange Act; (iii) directing the Company to produce the materials set forth in the plaintiff's books and records request; (iv) finding that the director defendants breached their fiduciary obligations to stockholders; and (v) finding that the director defendants engaged in self-dealing. The Complaint seeks an award of fees, costs, and expenses in this action, including attorneys' and experts' fees.

On June 10, 2021, the plaintiff filed a motion for a temporary restraining order and for expedited proceedings, seeking an order enjoining the Company from printing or disseminating its proxy statement relating to the 2021 annual meeting or from convening the 2021 annual meeting on July 16, 2021. Following a hearing, on June 17, 2021, the Court determined that: (i) it did not have jurisdiction to consider the plaintiff's claims relating to alleged violations of the Exchange Act; (ii) plaintiff's claims regarding the books and records request and alleged violations of section 220 of the DGCL should be pursued in a separate proceeding, and the Court denied the plaintiff's motion to expedite the books and records claims; (iii) certain of the plaintiff's claims alleging breach of the fiduciary duty of disclosure against the individual defendants, including claims based on alleged misrepresentations and omissions in the Company's proxy statement, were not colorable; and (iv) plaintiff's claim alleging that the individual defendants violated their fiduciary duty by taking action purportedly intended to prevent the plaintiff from pursuing a proxy contest survived a low threshold of colorability, but the Court denied the plaintiff's motion for a temporary restraining order. The Court granted in part the motion to expedite the proceedings.

The case is proceeding and the parties are currently engaged in discovery. The Company believes the claims in plaintiff's Complaint are without merit, and intends to vigorously dispute them.

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. The risk factors set forth below with an asterisk (*) next to the title contain substantive changes to the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020. Our business, financial condition, results of operations and future prospects could be materially and adversely affected by these risks if any of them actually occurs. In these circumstances, the market price of our common stock would likely decline. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business.

Risks Related to Our Financial Condition

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

Our consolidated financial statements are prepared using the generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, as shown in our consolidated financial statements for the year ended December 31, 2020, included in our annual report on Form 10-K for the year ended December 31, 2020, 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. Additional funding may be required to develop and commercialize our products and product candidates, conduct research, development and trials relating to our product candidates, fund our ongoing operations and satisfy our obligations and liabilities. Without obtaining additional funding if required, 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 our ability to successfully develop and commercialize products, the market acceptance and success of our products and our ability to obtain additional required funding, and there are no assurances that such funding will be available at all or will be available in sufficient amounts or on reasonable terms. Without additional funds, if required, from debt or equity financings, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions or sources, we will exhaust our resources and will be unable to continue operations. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

***We may require additional funding to continue as a going concern.**

We incurred significant net losses for the years ended December 31, 2020 and December 31, 2019 and for the quarters of 2021 reflected in the financial statements included elsewhere in this Report. The development of our business may in the future require additional capital to help fund the development and commercialization of our products and product candidates, conduct research, development and trials relating to our product candidates, fund our ongoing operations and satisfy our obligations and liabilities. 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 may limit or prevent our current ability to access capital markets. Delays in obtaining, or the inability to obtain, required funding could adversely affect our ability to develop and commercially introduce products and cause us to be unable to comply with our obligations under outstanding instruments. In addition, our previously announced sale of Assets pursuant to the USC Agreement relating to the human compounding pharmaceuticals business of our USC subsidiary, together with our previously announced restructuring process of winding down, winding up and disposing of the remaining operations, business and assets of USC, will result in the company not receiving revenues in the future from sales of products by USC, other than the consideration receivable by the company pursuant to the terms of the USC Agreement or from other agreements or arrangements relating to the sale or disposition of the remaining USC assets.

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

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

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

We have restated our unaudited condensed consolidated financial statements for the interim periods of 2020, which may lead to additional risks and uncertainties, including loss of investor confidence and negative impacts on our business, financial condition and stock price.

On April 14, 2021, we concluded that, because of a misapplication of valuation principles used to determine the amount of our non-cash warrant liabilities and the associated gain or loss recognized as a result of the change in the fair value of the warrant liabilities, relating to warrants that we issued in August 2019 (the "2019 Warrants") and February 2020 (the "2020 Warrants" and, together with the 2019 Warrants, the "Warrants"), our previous quarterly and year-to-date unaudited condensed consolidated financial statements for the periods ended March 31, 2020, June 30, 2020 and September 30, 2020 (the "Affected Periods"), should no longer be relied upon. As a result, we restated our unaudited condensed consolidated financial statements for the Affected Periods. The issues identified were all non-cash and did not impact our revenues, operating expenses, operating loss, cash and cash equivalents, assets, liquidity or cash position for the Affected Periods or the year ended December 31, 2020. As a result of the foregoing matters, we may become subject to additional risks and uncertainties, including, among others, unanticipated costs for accounting and legal fees, the increased possibility of legal proceedings, shareholder lawsuits, governmental agency investigations, and inquiries by the Nasdaq Stock Market or other regulatory bodies, which could cause investors to lose confidence in our reported financial information and could subject us to civil or criminal penalties, shareholder class actions or derivative actions. We could face monetary judgments, penalties or other sanctions that could have a material adverse effect on our business, financial condition and results of operations and could cause our stock price to decline. If any such actions occur, they will, regardless of the outcome, consume a significant amount of management's time and attention and may result in additional legal, accounting, insurance and other costs. If we do not prevail in any such proceedings, we could be required to pay substantial damages or settlement costs. In addition, the restatement and related matters could impair our reputation. Each of these occurrences could have a material adverse effect on our business, results of operations, financial condition and stock price.

****We have incurred losses since our inception, and we anticipate that we will continue to incur losses. We may never achieve or sustain profitability.***

We incurred significant net losses for the years ended December 31, 2020 and December 31, 2019 and for the quarters of 2021 reflected in the financial statements included elsewhere in this Report. We expect that these losses may continue 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 relating to our SYMJEPI and ZIMHI products or other commercialization agreements that we may enter into to become profitable at all or on a sustained basis. We expect to have quarter-to-quarter fluctuations in revenue and expenses, some of which could be significant, due in part to variations in expenses and activities relating to research, development, clinical trials, marketing and manufacturing. If our product candidates fail in clinical trials or do not gain regulatory approval, or if our products do not achieve market acceptance, we may never become profitable. As we commercialize and market products, we will need to incur expenses for product marketing and brand awareness and conduct significant research, development, testing and regulatory compliance activities that, together with general and administrative expenses, could result in substantial operating losses for the foreseeable future. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our PPP loans may be audited or reviewed by federal or state regulatory authorities.

We applied for and obtained loan funding of $3,191,700 under the PPP pursuant to the PPP Loan and PPP Note, the balance of which has been forgiven, and under the Second Draw PPP Loan and PPP2 Note in the principal amount of $1,765,495, the balance of which has also been forgiven. However, even though the PPP Loan and the Second Draw PPP Loan have been forgiven, our PPP loans and applications for forgiveness of loan amounts remain subject to future review and audit by SBA for compliance with program requirements set forth in the PPP Interim Final Rules and in the Borrower Application Form, including without limitation the required economic necessity certification by the Company that was part of the PPP loan application process. Accordingly, the Company is subject to audit or review by federal or state regulatory authorities as a result of applying for and obtaining the PPP Loan and Second Draw PPP Loan or obtaining forgiveness of those loans. 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 applicable 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 it is determined that the Company was ineligible to receive the PPP Loan and/or the Second Draw Loan, the Company may be required to repay the PPL Loan and Second Draw Loan in its entirety and/or be subject to additional penalties, which could reduce our liquidity and adversely affect our business, financial condition and results of operations.

Risk Relating to Our Business and Industry

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

Except for our SYMJEPI and ZIMHI products, we have not received regulatory approval for any drugs or products. Since our fiscal 2010 year, except for revenues from sales of compounded pharmacy formulations after our acquisition of USC in 2016 and amounts that we have received and may receive in the future pursuant to our commercialization agreements relating to our SYMJEPI and ZIMHI 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.

We have received a grand jury subpoena issued in connection with a criminal investigation.

As we have previously disclosed, on May 11, 2021, each of the company and its USC subsidiary received a grand jury subpoena from the U.S. Attorney's Office for the Southern District of New York (the "USAO") issued in connection with a criminal investigation, requesting a broad range of documents and materials relating to, among other matters, certain veterinary products sold by the company's USC subsidiary, certain practices, agreements and arrangements relating to products sold by USC, including veterinary products, and certain regulatory and other matters relating to the company and USC. The Audit Committee of the Board engaged outside counsel to conduct an independent internal investigation to review these and other matters. Additional issues or facts could arise or be determined, which may expand the scope, duration, or outcome of the investigation. In addition to the subpoena from the USAO, the Company has also received requests from the Securities and Exchange Commission ("SEC") for the voluntary production of documents and information relating to the subject matter of the USAO's subpoenas and certain other matters. The company has produced documents and will continue to produce and provide documents in response to the subpoenas and requests. The company intends to cooperate with the USAO and the SEC. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, or other agencies, or determine what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate, what, if any, remedies or remedial measures the USAO, SEC, or other federal or state authorities may seek, or what, if any, impact the foregoing matters may have on the company's business, previously reported financial results, financial results included in this Report, or future financial results. We could receive additional requests from the USAO, SEC, or other authorities, which may require further investigation. There can be no assurance that any discussions with the SEC or USAO to resolve these matters will be successful. The foregoing matters may divert management's attention, cause the company to suffer reputational harm, require the company to devote significant financial resources, subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, result in fines, penalties, equitable remedies, and affect the company's business, previously reported financial results, financial results included in this Report, or future financial results. The occurrence of any of these events could have a material adverse effect on the company's business, financial condition and results of operations.

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

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

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

Our product development plans concerning our products and product candidates, and the anticipated dates for development and introduction of products in our product pipeline, are affected by many factors, many of which are difficult to predict. Some of the factors that could affect our development plans for our products and product candidates include: general market conditions and developments in the marketplace including the introduction of potentially competing new products by our competitors; the availability of adequate funding to support product development efforts and sales and marketing efforts for approved products; the outcome of discussions with the FDA concerning the regulatory pathway for our products and the number and kind of clinical trials that the FDA will require before the FDA will consider regulatory approval of the applicable product; the time required to conduct required clinical trials and unexpected delays in the anticipated timing of the commencement, conduct or completion of clinical trials; the FDA's review and acceptance of NDAs that we may file concerning our product candidates; any unexpected difficulties in licensing or sublicensing intellectual property rights that may be required for other components of the product; patent infringement lawsuits relating to Paragraph IV certifications as part of any Section 505(b)(2) or ANDA filings; any unexpected difficulties in the ability of our suppliers to timely supply quantities for commercial launch of the product; and our ability to successfully market and sell our products or enter into commercialization arrangements with third parties to market our products.

Business or economic disruptions or global health concerns, including the COVID-19 pandemic, could harm our business.

Business or economic disruptions or global health concerns, such as the COVID-19 pandemic, could adversely affect our business. The novel strain of coronavirus and the related COVID-19 pandemic, which the World Health Organization announced in January 2020 was a global health emergency and which continued through 2020 and is continuing, has spread throughout most of the world including the United States. The outbreak has resulted in extended shutdowns of businesses in the United States and elsewhere and has had ripple effects on businesses and activities around the world.

The COVID-19 outbreak and continued spread of COVID-19, including the identification of novel strains of COVID-19, has affected and may continue to affect our operations, our customers and third parties on which we rely. Restrictions on outpatient surgeries and other medical procedures due to the COVID-19 pandemic, in part due to reductions or cancellations of elective surgeries and reductions in office visits to physicians' offices, healthcare facilities or clinics by patients, decreased demand from USC's customers for certain of USC's products and adversely affected revenues from sales of USC products, and may continue to adversely affect revenues from sales of products to customers covered by the USC Agreement. In addition, we could experience delays in obtaining products or services from our third party manufacturers or suppliers as a result of the impact of the COVID-19 pandemic on such parties. The pandemic and related matters also could result in interruptions or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines relating to our NDAs or other actions relating to our products or product candidates, or could result in delays relating to patient enrollment or the conduct of clinical trials that we undertake. The outbreak and any preventative or protective actions that we, our customers, our respective manufacturers, suppliers or other third parties with which we have business relationships, or governments may take in respect of the coronavirus and COVID-19 pandemic could disrupt our business and the business of our customers or third parties with which we have business relationships. The extent to which the COVID-19 pandemic will continue to impact our business is difficult to predict and subject to change, and will depend on future developments, which are highly uncertain and cannot be predicted, including without limitation the severity of the disease and duration of the outbreak, travel restrictions and social distancing requirements in the United States and other countries, future mutations and variations of the coronavirus, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and address its impact. Global health concerns, such as coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. In addition, a severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making purchases or payments for our products. Any of the foregoing could harm our business. In addition, the COVID-19 pandemic has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, shelter-in-place or work-from-home orders or policies, travel restrictions, social distancing and business shutdowns. The effects of such measures may negatively impact productivity of our employees and disrupt our business activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and our ability to conduct business in the ordinary course. Although we have taken precautions intended to avoid the spread of the coronavirus among our employees, it is possible that one or more members of our workforce could be diagnosed with COVID-19, which could adversely impact our operations. As of the date of this Report, we cannot presently predict the long-term impact to the scope and severity of potential business or disruptions, but if we, our customers, or any of the third parties with whom we engage, including the suppliers, manufacturers, regulators and other third parties with whom we conduct business or have business relationships, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner presently anticipated could be materially and negatively impacted.

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

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

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

Delays in the commencement or completion of clinical testing of our product candidates could result in increased costs and delay our ability to generate significant revenues.

The actual timing of commencement and completion of clinical trials can vary substantially from our anticipated timing due to factors such as funding limitations, scheduling conflicts with participating clinicians and clinical institutions, and the rate of patient enrollment. Clinical trials involving our product candidates may not commence or be completed as forecast. Delays in the commencement or completion of clinical testing could significantly impact our product development costs. We do not know whether current or planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining required funding;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- obtaining sufficient quantities of clinical trial materials for product candidates;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting participants for a clinical trial; and
- delays related to the impact of the COVID-19 pandemic.

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

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

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

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

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

Before regulatory approval for a potential product can be obtained, we must undertake clinical testing on humans to demonstrate the tolerability and efficacy of the product. We cannot assure you that we will obtain authorization to permit product candidates that are in the preclinical development phase to enter the human clinical testing phase. In addition, we cannot assure you that any authorized preclinical or clinical testing will be completed successfully within any specified time period by us, or without significant additional resources or expertise to those originally expected to be necessary. We cannot assure you that such testing will show potential products to be safe and efficacious or that any such product will be approved for a specific indication. Further, the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials. In addition, we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks.

We are subject to the risk of clinical trial and product liability lawsuits.

The testing of human health care product candidates entails an inherent risk of allegations of clinical trial liability, while the marketing and sale of approved products entails an inherent risk of allegations of product liability and associated adverse publicity. We currently maintain liability insurance. However, such insurance policies are expensive, may not provide sufficient coverage, and may not be available in the future on acceptable terms, or at all. As we conduct additional clinical trials and introduce products into the United States market, the risk of adverse events increases and our requirements for liability insurance coverage are likely to increase. We are subject to the risk that substantial liability claims from the testing or marketing of pharmaceutical products could be asserted against us in the future. There can be no assurance that we will be able to obtain or maintain insurance on acceptable terms, particularly in overseas locations, for clinical and commercial activities or that any insurance obtained will provide adequate protection against potential liabilities. An inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could inhibit our business.

Moreover, our current and future coverages may not be adequate to protect us from all of the liabilities that we may incur. If losses from liability claims exceed our insurance coverage, we may incur substantial liabilities that exceed our financial resources. In addition, a product or clinical trial liability action against us would be expensive and time-consuming to defend, even if we ultimately prevailed. If we are required to pay a claim, we may not have sufficient financial resources and our business and results of operations may be harmed. A product liability claim brought against us in excess of our insurance coverage, if any, could have a material adverse effect upon our business, financial condition and results of operations.

We do not have commercial-scale manufacturing capability, and we lack commercial manufacturing experience. We will likely rely on third parties to manufacture and supply our product candidates for which we will be seeking FDA approval.

We do not own or operate manufacturing facilities for clinical or commercial production of pharmaceutical products and product candidates, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. Accordingly, we expect to depend on third-party contract manufacturers for the foreseeable future. Any performance failure on the part of our contract manufacturers could delay clinical development, regulatory approval or commercialization of our current or future product candidates, depriving us of potential product revenue and resulting in additional losses. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our existing and potential products. Any business interruptions resulting from geopolitical actions, including war and terrorism, adverse public health developments such as the outbreak of the COVID-19 coronavirus, or natural disasters including earthquakes, typhoons, floods and fires, could adversely affect our supply chain. These risks and uncertainties are compounded in the presence of the COVID-19 pandemic. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our manufacturers or suppliers could delay shipment of any of our products, increase our cost of goods sold and result in lost sales.

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

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

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

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

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

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

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

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

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

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

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

To the extent that a Section 505(b)(2) NDA relies on published literature relating to a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, where the underlying studies were not conducted by or for the applicant and the applicant lacks a right of reference or use to the underlying data, the Section 505(b)(2) applicant must submit in its Section 505(b)(2) application a patent certification or statement with respect to any patents that are subject to the Orange Book listing requirement in connection with the previously approved product on which the applicant's application relies. Specifically, the applicant must certify for each such patent that, in relevant part, (1) the required patent information has not been filed; (2) the patent has expired; (3) the patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. Alternatively, with respect to a method of use patent, the applicant may submit a statement that the patent does not claim a use for which the applicant is seeking approval. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge the listed patents through a Paragraph IV certification or submit a statement that a method of use patent does not claim a use for which the applicant is seeking approval, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents for the previously approved product have expired. Further, the FDA will also not approve a Section 505(b)(2) NDA until any applicable non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three-year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the referenced product, has expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, unless, before the end of the 30-month period, a court determines that the patent is invalid, unenforceable or not infringed; a court enters a settlement order or consent decree stating that the patent is invalid, unenforceable, or not infringed; the patent owner or exclusive licensee consents to approval of the Section 505(b)(2) NDA; or the court enters an order of dismissal without a finding of infringement.

If we rely in our Section 505(b)(2) regulatory filings on published literature relating to a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product where the underlying studies were not conducted by or for us and we lack a right of reference or use to the underlying data, and that involves patents referenced in the Orange Book, then we will need to make the patent certifications or the Paragraph IV certification described above. If we make a Paragraph IV certification and the holder of the previously approved product that we referenced in our application initiates patent litigation within the time periods described above, then any FDA approval of our 505(b)(2) application would be delayed until the earlier of 30 months, resolution of the lawsuit, or the other events described above. Accordingly, our anticipated dates relating to review and approval of a product that was subject to such litigation would be delayed. In addition, we would incur the expenses, which could be material, involved with any such patent litigation. As a result, we may invest a significant amount of time and expense in the development of our product only to be subject to significant delay and patent litigation before our product may be commercialized, if at all.

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

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

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

Government and insurance reimbursements for healthcare expenditures play an important role for all healthcare providers, including physicians and pharmaceutical companies such as Adamis, that plan to offer various products in the United States and other countries in the future. Physicians and patients may decide not to order our products unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid, pay a substantial portion of the price of the products. Market acceptance and sales of our specialty pharmaceutical products 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 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, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

We have limited sales, marketing and distribution experience.

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

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

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

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

The markets for our SYMJEPI products and ZIMHI product, 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 competes with a number of other currently marketed epinephrine products for use in the emergency treatment of acute allergic reactions, including anaphylaxis. Our ZIMHI product will compete with a number of other currently marketed products utilizing naloxone, for the treatment of acute opioid overdose. Our Tempol product candidate for use in treatment of COVID-19, if successfully developed, approved and commercialized, will compete with a number of other current and future products and therapies for use in the treatment of COVID-19. 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. Patents and intellectual property that we own or license may not afford us the rights that we anticipate. 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. In addition, many companies have encountered difficulties in protecting and defending their intellectual property rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in either the United States or foreign jurisdictions, our business prospects could be substantially harmed. In addition, we may not have adequate cash funding to devote the resources that might be necessary to prepare or pursue patent applications, either at all or in all jurisdictions in which we might desire to obtain patents, or to maintain already-issued patents.

We may become involved in patent litigation or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications, trademarks, and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights, or that one of our trademarks or trade names infringes the third party's trademark rights; in such case, we will need to defend against such proceedings. For example, the field of generic pharmaceuticals is characterized by frequent litigation that occurs in connection with the regulatory filings under Section 505(b)(2) of the FDCA and attempts to invalidate the patent of the reference drug.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our potential competitors will be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult, and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

If we determine that our intangible assets have become impaired in the future, our total assets and earnings could be adversely affected.

Goodwill represents the purchase price of acquisitions in excess of the amounts assigned to acquired tangible or intangible assets and assumed liabilities. Goodwill and indefinite lived intangible assets are not amortized but rather are evaluated for impairment annually or more frequently, if indicators of impairment exist. Finite lived intangible assets are evaluated for impairment annually or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If the impairment evaluations for goodwill and intangible assets indicate the carrying amount exceeds the estimated fair value, an impairment loss is recognized in an amount equal to that excess. As of March 31, 2020, in light of recent events associated with the global spread of COVID-19 and other factors, we performed a goodwill impairment interim review and recorded a charge of approximately $3,143,000 for impairment of goodwill during the first quarter of 2020. As of December 31, 2020, with the continued decline in revenue during 2020 primarily attributable to the COVID-19 pandemic and other factors affecting our Compounded Pharmaceutical reporting unit, we performed a goodwill impairment review and recorded an additional charge of approximately $3,629,000 for impairment of goodwill in 2020. For the year ended December 31, 2020, total goodwill impairment charge recorded was approximately $6,772,000. In addition, as of December 31, 2020, in light of the time and costs involved in further product development efforts and competitive conditions in the relevant markets related to the Taper DPI intellectual property, and our determination not to devote any further substantial financial resources to development of this product candidate or pursue further development efforts regarding this product candidate, we recorded an impairment charge of approximately $2,913,000 for the year ended December 31,2020. . In addition, a result of the transactions contemplated by the USC Agreement and the restructuring activities relating to USC described elsewhere in this Report, the company has determined that its financial results for the quarter ending September 30, 2021, will include an impairment of certain assets relating to USC, including inventories, intangible assets, goodwill, fixed assets, and right of use assets. If in the future we determine that our intangible assets have become impaired, our total assets, financial results, and earnings could be adversely affected.

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

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

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

At December 31, 2020, we had federal and state net operating loss carryforwards, or NOLs, and credit carryforwards which, subject to certain limitations, we may use to reduce future taxable income or offset income taxes due. Insufficient future taxable income will adversely affect our ability to utilize these NOLs and credit carryforwards. Pursuant to Internal Revenue Code Section 382, the annual use of the NOLs and research and development tax credits could be limited by any greater than 50% ownership change during any three-year testing period. As noted in Note 21 of the audited consolidated financial statements appearing in the company's Annual Report on Form 10-K for the year ended December 31, 2020, 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.

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

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

Risks Related to Our Compounding Pharmacy Business

We have sold a substantial portion of the assets of USC and are engaged in a restructuring process of winding down the remaining business of USC and selling or otherwise disposing of the remaining assets of USC. There is no assurance regarding the proceeds that we may receive from the sale or disposition of any assets of USC. We may incur significant costs in connection with such restructuring and winding down activities.

As previously disclosed in our reports with the SEC and as disclosed elsewhere in this Report, pursuant to the USC Agreement we have sold and transferred certain Assets to the Purchaser relating to the human compounding pharmaceutical business of USC and have agreed to a variety of restrictive covenants preventing us from engaging in certain business and competitive activities relating to the human compounding pharmaceutical business, and we have also approved a restructuring process of winding down and winding up the remaining business of USC and selling, transferring or disposing of the remaining assets of USC. As a result, upon completion of that process we will no longer be engaged in the human or veterinary compounding pharmaceutical business. The Purchase Agreement provides for payment of consideration over time based on future sales of products by the Purchaser. There is no assurance regarding the proceeds that we may receive from the Purchase Agreement or any other sale or disposition of any other assets of USC.

We have indemnification obligations under the Purchase Agreement, and we may have indemnification obligations under other agreements relating to the sale or disposition of other USC assets, pursuant to which we may be required to indemnify, hold harmless, and pay losses, liabilities, expenses and amounts arising out of certain claims relating to the assets that are the subject of such agreements, including without limitation relating to, among other matters, our breach of the USC Agreement or other applicable agreement, third party claims relating to previous sales of products by USC to customers, or other matters. These indemnification provisions could require us to pay significant amounts to satisfy our indemnification obligations under such agreements, which would reduce the net amounts that we ultimately receive from the sale of the assets subject to such agreements.

In addition, other matters may arise in the future relating to the USC business, USC assets, or USC employees, or arising out of the restructuring, winding down and winding up activities, that could require us to pay amounts in the future. The process of winding down and winding up the remaining business of USC could require us to incur significant expenses or pay significant amounts in connection with or relating to the termination of employment of USC's employees, the disposition of remaining USC assets, or the resolution of outstanding obligations, liabilities, or current or future claims or proceedings. In addition, we could be required to pay significant fines, penalties or other amounts as a result of proceedings by federal or state regulatory authorities relating to the business and operations of USC.

The COVID-19 outbreak adversely affected sales of USC's compounded pharmacy products and may adversely affect the amount that we receive from sale of USC's assets.

The COVID-19 outbreak adversely affected revenues from sales of products by USC during 2020 and interim periods of 2021. The ongoing impact of the COVID-19 pandemic, or other factors, could adversely affect the amount that we receive in the future pursuant to the Purchase Agreement or other agreements or activities relating to the sale or disposition of USC's assets.

If a compounded drug formulation leads to patient injury or death or results in a product recall, we may be exposed to significant liabilities.

The production, labeling and packaging of compounded pharmaceutical preparations is inherently risky. We could be adversely affected if any of USC's formulations or other products 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, safety alert, or other proceedings or actions, relating to one or more of USC's products. 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, we could become subject to product and professional liability lawsuits or other proceedings, including enforcement actions by state and federal authorities or other healthcare self-regulatory bodies or product liability claims or lawsuits. In addition, such matters could result in indemnification claims by third parties to which we have sold certain assets of USC, pursuant to our agreements with such third parties relating to such sales. Any of the foregoing matters could result in a material adverse effect on 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.

The compounding pharmaceuticals business formerly conducted by USC is significantly impacted by state and federal statutes and regulations.

The compounding pharmaceuticals business formerly conducted by USC is subject to federal, state and local laws, regulations, and administrative practices, including, among others: federal registration as an outsourcing facility, state and local licensure and registration requirements concerning the operation of outsourcing facilities, and federal and state laws relating to the preparation, purchase, sale, advertisement, promotion, distribution, management, compounding, dispensing, reimbursement, marketing, and labeling of drugs that USC sells and related services as well as state pharmacy, manufacturer, wholesaler and distribution licensure and registration or permit standards; HIPAA and other laws relating to the use, disclosure and transmission of health or other personal information; the Patient Protection and Affordable Care Act, or ACA, and the Health Care and Education Reconciliation Act of 2010; statutes and regulations of the FDA and the U.S. Drug Enforcement Administration, or DEA, and states including relating to controlled substances; and state pharmacy, manufacturer, wholesaler and distribution licensure and registration or permit standards and other state laws and regulations.

The federal, state and local laws and regulations applicable to the pharmaceutical and compounding industries are subject to frequent change, whether through change in law or through interpretation. There can be no assurance that we or USC have been or are compliant in material respects with applicable federal and state regulatory requirements. 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 our business, financial condition or results of operations.

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 the company and USC, 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. Such laws and regulations are subject to change and often are uncertain in their application. There can be no assurance that USC or we 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 our business, financial condition or results of operations.

In addition, we are subject to the federal anti-kickback statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service reimbursable under a federal healthcare program, or purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under a federal healthcare program. We are also subject to state anti-kickback laws and regulations. Violations of the anti-kickback statutes can result in imprisonment, civil or criminal fines, and fines and disciplinary actions relating to our state licensure. Any violation or alleged violation of such federal or state laws could harm USC's or our reputation, customer relationships or otherwise have a material adverse effect on our business, financial condition and results of operations.

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 2019 to June 30, 2021, the market price of our common stock has fluctuated between $0.27 and $3.29. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- relatively low trading volume, which can result in significant volatility in the market price of our common stock based on a relatively smaller number of trades and dollar amount of transactions;
- the timing and results of our current and any future preclinical or clinical trials of our product candidates;
- the entry into or termination of key agreements, including, among others, key collaboration and license agreements;
- the results and timing of regulatory reviews relating to the approval of our product candidates;
- the timing of, or delay in the timing of, commercial introduction of any of our 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;
- the effects of public health crises, pandemics and epidemics, such as a the COVID-19 outbreak; or
- other potentially negative financial announcements, such as a review of any of our filings by SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC.

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

Trading of our common stock is limited.

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

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

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

Our common stock is listed on the Nasdaq Capital Market. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would have a negative effect on the price of our common stock, impair the ability to sell or purchase our common stock when persons wish to do so, and any delisting materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from the Nasdaq Capital Market could also have other negative results, including the potential loss of institutional investor interest and fewer business development opportunities. In the event of a delisting, we would attempt to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

At various times from October 2019 through September 2020, we have received notices from the Nasdaq Listing Qualifications Department of The NASDAQ Capital Market ("Nasdaq") informing us 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 notices 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), in connection with each notice we were provided an initial compliance period of 180 calendar days 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. On each such occasion, following such notice we have regained compliance with the Rule.

On May 25, 2021, we received a notification letter from Nasdaq notifying us that, because the company has not yet filed its Quarterly Report on Form 10-Q for the period ended March 31, 2021 (the "Filing" or the "Form 10-Q"), the company was no longer in compliance with NASDAQ Marketplace Rule 5250(c)(1), which requires timely filing of periodic reports with the SEC. The Notice also indicated that the company had 60 calendar days to submit a plan to regain compliance and, if Nasdaq accepts the plan, Nasdaq can grant an exception of up to 180 calendar days from the Filing's due date to regain compliance. We submitted a plan to regain compliance on July 26, 2021. On August 20, 2021, we received a notification letter (the "Notice") from Nasdaq notifying us that because we had not filed our Quarterly Report on Form 10-Q for the period ended June 30, 2021, as well as its Quarterly Report on Form 10-Q for the period ended March 31, 2021 (the "Form 10-Qs"), we did not comply with NASDAQ Marketplace Rule 5250(c)(1), which requires timely filing of periodic reports with the SEC. Nasdaq subsequently requested that we submit an updated plan to regain compliance, which we submitted, and Nasdaq granted an exception of up to November 22, 2021, to regain compliance. We have the filed the Form 10-Qs and believe that we have filed the required periodic reports with the SEC to regain compliance with the Nasdaq 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.

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, 2021, we had 148,886,141 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, 2021, we had reserved for issuance 6,113,866 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 $4.31 per share, we had outstanding restricted stock units covering 2,034,260 shares of common stock, and we had outstanding warrants to purchase 15,095,238 shares of common stock at a weighted-average exercise price of $1.28 per share. Subject to applicable vesting requirements, upon exercise of these options or warrants or issuance of shares following vesting of the restricted stock units, the underlying shares may be resold into the public market, subject in some cases to volume and other limitations or prospectus delivery requirements pursuant to registration statements registering the resale of such shares. In the case of outstanding options or warrants that have exercise prices that are below the market price of our common stock from time to time, or upon issuance of shares following vesting of restricted stock units, our stockholders would experience dilution upon the exercise of these options.

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

As of June 30, 2021, we had outstanding warrants, other than the warrants described in the next sentence, to purchase 58,824 shares of common stock, at a weighted average exercise price of $8.50 per share. As of June 30, 2021, 13,794,000 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants, at an exercise price of $1.15 per share, that we issued in connection with our underwritten public offering of common stock and warrants in August 2019; 350,000 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants, at an exercise price of $0.70 per share, that we issued in connection with our private placement of warrants in February 2020 and 892,414 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 192,414 shares at an exercise price of $2.90 per share in our July 2016 Series A-2 Convertible Preferred transaction; and warrants to purchase 700,000 shares at an exercise price of $2.98 per share in our August 2016 registered direct offering of common stock and warrants.

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

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

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

We identified material weaknesses in our internal control over financial reporting. If we fail to effectively remediate identified material weaknesses, it could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner. If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, if we fail to effectively remediate identified material weaknesses, or if we discover other material weaknesses or deficiencies in our internal controls over financial reporting, our business and financial condition could be materially and adversely affected and our stock price could decline.

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any material changes and weaknesses identified through such evaluation. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and our business and financial condition could be adversely affected. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could decline significantly.

As disclosed in the company's Annual Report on Form 10-K for the year ended December 31, 2020, management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020, and as a result of this assessment identified a material weakness in internal control over financial reporting as of that date. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of December 31, 2020, and our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2020. The material weakness resulted in a misstatement of our warrant liabilities and the related gain or loss recognized as a result of the change in the fair value of the warrant liabilities, and related misstatements in, our unaudited condensed consolidated financial statements, for the periods ended March 31, June 30, and September 30, 2020. See Note 4 of the Notes to the consolidated financial statements included in the company's Annual Report on Form 10-K for the year ended December 31, 2020 for additional information. We believe the material weakness has been remediated as of March 31, 2021. In addition, we identified a material weakness in our internal control over financial reporting and concluded that our internal control over financial reporting was not effective as of March 31, 2021, June 30, 2021 and September 30, 2021.

Any failure to effectively remediate the identified material weakness or otherwise maintain adequate internal controls over financial reporting could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, and legal proceedings by stockholders or regulatory authorities, which could result in a material adverse effect on our business. We could face monetary judgments, penalties or other sanctions that could have a material adverse effect on our business, financial condition and results of operations and could cause our stock price to decline. Failure to timely file required reports with the SEC results in loss of eligibility to utilize short form registration statements on Form S-3 or Form S-4 and prospectuses outstanding under previous registration statements not being current, which may impair our ability to obtain capital in a timely fashion to execute our business strategies, issue shares to effect an acquisition, or subject us to legal claims from stockholders or warrant holders. Inadequate internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We intend to take certain remedial actions intended to address the identified material weakness in our internal control over financial reporting. However, we can give no assurance that such measures will remediate the material weakness identified or that any additional material weaknesses or restatements of financial results will not arise in the future. In the future, our management may determine that our disclosure controls and procedures are ineffective or that there are one or more material weaknesses in our internal controls over financial reporting, resulting in a reasonable possibility that a material misstatement to the annual or interim financial statements would not have been prevented or detected. Accordingly, a material weakness increases the risk that the financial information we report contains material errors. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Efforts to correct any material weaknesses or deficiencies that may be identified could require significant financial resources to address. Moreover, if remedial measures are insufficient to address the deficiencies that are determined to exist, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements could contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, and we could become subject to class action litigation or investigations or proceedings from regulatory authorities. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. Any of these matters could adversely affect our business, reputation, revenues, results of operations, financial condition and stock price.

General Risk Factors

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

Our success will be dependent upon the efforts of our management team and staff, including Dennis J. Carlo, Ph.D., our chief executive officer. The employment of Dr. Carlo may be terminated at any time by either us or Dr. Carlo. We currently do not have key person life insurance policies covering any of our executive officers or key employees. If key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly recruited. There is competition for qualified personnel in all functional areas, which makes it difficult to attract and retain the qualified personnel necessary for the operation of our business. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. If we are unable to attract new employees and retain existing key employees, the development and commercialization of our product candidates could be delayed or negatively impacted. In addition, any staffing interruptions resulting from geopolitical actions, including war and terrorism, adverse public health developments such as the COVID-19 pandemic, or natural disasters including earthquakes, typhoons, floods and fires, could have an adverse effect on our business.

We may experience difficulties in managing growth.

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

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

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

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

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

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

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

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

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

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

Information concerning our sales of unregistered securities during the quarter ended June 30, 2021, 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.

10.1	Settlement Agreement between the Company, US Compounding Inc., Nephron Pharmaceuticals Corporation, Nephron S.C., Inc., Nephron Sterile Compounding Center, LLC and certain other parties. +*
10.2	Asset Purchase Agreement effective as of July 30, 2021, by and among the Registrant, US Compounding, Inc. and Fagron Compounding Services, LLC. (1)*+
10.3	Supply Agreement Addendum by and among the Registrant, US Compounding, Inc. and Fagron Compounding Services, LLC. (1)+
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

(1) Incorporated by reference to exhibits filed with the Report on Form 8-K filed by the Company on August 5, 2021.

* 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.

\+ Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the Registrant customarily and actually treats the information contained in such portions as private or confidential and such information is not material.

SIGNATURES

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

ADAMIS PHARMACEUTICALS, INC.

Date: November 22, 2021

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

Date: November 22, 2021

By: /s/ David C. Benedicto
David C. Benedicto
Chief Financial Officer

Exhibit 10.1

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is both not material and is the type that the Registrant treats as private or confidential.

SETTLEMENT AGREEMENT

This Settlement Agreement **("Agreement")** is entered into among Nephron Pharmaceuticals Corporation, Nephron S.C., Inc., and Nephron Sterile Compounding Center, LLC **("Nephron"** or **"Plaintiff'),** and U.S. Compounding, Inc. **("U.S. Compounding"),** Adamis Pharmaceuticals Corporation **("Adamis"),** Jennifer Shelly Hulsey **("Hulsey"),** and Jessica Ingrid Lane **("Lane")** (together hereinafter **"Defendants").** Nephron and Defendants are collectively hereinafter referred to as the "Parties".

RECITALS

WHEREAS, Nephron Pharmaceuticals Corporation is a corporation organized and existing under and by virtue of the laws of the State of Florida with its principal place of business located at 4121 SW 34th Street, Orlando, Florida, 32811;

WHEREAS, Nephron S.C., Inc. is a corporation organized and existing under and by virtue of the laws of the State of South Carolina with its principal place of business located at 4500 12th Street Extension, West Columbia, South Carolina, 29172;

WHEREAS, Nephron Sterile Compounding Center, LLC a corporation with its principal place of business located at 4500 12th Street Extension, West Columbia, South Carolina, 29172;

WHEREAS, U.S. Compounding, Inc. is a corporation organized and existing under and by virtue of the laws of the State of Arkansas with its principal place of business located at 1270 Don's Lane, Conway, Arkansas, 72032;

WHEREAS, Adamis Pharmaceuticals Corporation is a California corporation that is the parent corporation of U.S. Compounding with its principal place of business located at 11682 El Camino Real, Suite 300, San Diego, California, 92130;

WHEREAS, Shelly Hulsey is a natural person domiciled in the State of Kansas;

WHEREAS, Jessica Lane is a natural person domiciled in the State of New Jersey;

WHEREAS, on September 21, 2018, Nephron commenced litigation in the United States District Court for the Middle District of Florida (the **"Florida Court"),** styled *Nephron Pharmaceuticals Corporation, Nephron S.C., Inc., and Nephron Sterile Compounding Center, LLC v. Jennifer Shelly Hulsey and U.S. Compounding, Inc. d/b/a U.S. Compounding Pharmacy, originally assigned case number 6:18-cv-1573-ORL-31-KRS and ultimately assigned case number 6:18-cv-01573-GAP-LRH (the* ***"Florida Lawsuit"),*** *alleging, without limitation, that Hulsey and* U.S. Compounding collectively misappropriated certain trade secrets from Nephron;

WHEREAS, on March **1 , 2019,** Nephron filed a second amended complaint in the Florida Lawsuit, adding Adamis as a defendant, and alleging various claims against Hulsey, U.S. Compounding, and Adamis including, without limitation, that they collectively misappropriated certain trade secrets from Nephron;

WHEREAS, on July **1 , 2019,** Nephron filed a third amended complaint in the Florida Lawsuit, alleging various claims against Hulsey, U.S. Compounding, and Adamis including, without limitation, that Hulsey, U.S. Compounding, and Adamis collectively misappropriated certain trade secrets from Nephron;

WHEREAS, on October **10, 2019,** Hulsey filed for Chapter **13** bankruptcy in her individual capacity in the United States Bankruptcy Court for the District of Kansas (the **"Bankruptcy Court"),** which matter is styled *In re: Hulsey,* case number **19-22173-13** (the **"Bankruptcy");**

WHEREAS, on December **19, 2019,** Nephron filed its original proof of claim in the Bankruptcy and later filed an amended proof of claim in the Bankruptcy on February **26, 2021** (the **"Proof of Claim");**

WHEREAS, on June 9, 2020, Nephron filed its Objection to Confirmation of Second Amended Chapter 13 Plan in the Bankruptcy (the **"Objection to Plan");**

WHEREAS, on January **6, 2020,** Nephron filed an adversary complaint in the Bankruptcy, styled *Nephron Pharmaceuticals Corporation, Nephron S.C., Inc., and Nephron Sterile Compounding Center, LLC v. Jennifer Shelly Hulsey,* assigned case number **20-06002** (the **"Adversary Proceeding")** in which Nephron asserted causes of action for exception to discharge under 11 U.S.C. § **523** against Hulsey arising from Nephron's allegations that Hulsey misappropriated trade secrets from Nephron;

WHEREAS, on February 26, 2020, Nephron filed a complaint in the United States District Court for the District of New Jersey (the **"New Jersey Court"),** styled *Nephron Pharmaceuticals Corporation, Nephron S.C., Inc., and Nephron Sterile Compounding Center, LLC v. Jessica Ingrid Lane, U.S. Compounding, Inc. d/b/a U.S. Compounding Pharmacy, and Adamis Pharmaceuticals Corporation,* case number 3:20-cv-02089-FLW-LHG (the **"New Jersey Lawsuit"),** alleging, without limitation, that Lane, U.S. Compounding, and Adamis collectively misappropriated certain trade secrets from Nephron;

WHEREAS, on December 16, 2020, the New Jersey Court issued an order transferring Nephron's claims against Lane individually to the United States District Court for the District of South Carolina, Columbia Division (the **"South Carolina Court"),** styled *Nephron Pharmaceuticals Corporation, Nephron S.C., Inc., and Nephron Sterile Compounding Center, LLC* Jessica Ingrid Lane, case number 3:20-cv-04356-MGL-PJG (the **"South Carolina Lawsuit");**

WHEREAS, Nephron, Adamis, U.S. Compounding, and Hulsey filed a Notice of Resolution with the Florida Court related to the Florida Lawsuit on April 9, 2021 indicating that they had reached settlement of the Florida Lawsuit;

WHEREAS, the Parties have reached a mutually agreeable settlement related to the Florida Lawsuit, the New Jersey Lawsuit, the South Carolina Lawsuit, the Proof of Claim, and the Adversary Proceeding, and desire to memorialize the terms of their settlement through this Agreement;

WHEREAS, by executing this Agreement, the Parties desire to fully and finally settle all claims and disputes between and among them which arise from or relate in any manner to the allegations made by Nephron in the Florida Lawsuit, the New Jersey Lawsuit, the South Carolina Lawsuit, the Bankruptcy, and the Adversary Proceeding;

NOW, THEREFORE, in consideration for the mutual promises, covenants, agreements, and undertakings contained herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

AGREEMENT

1. **Settlement Payment.** Adamis and/or U.S. Compounding will pay Nephron the total sum of Seven Million Nine Hundred Thousand Dollars and OO/ lOOths Cents ($7,900,000.00 USD) (the **"Settlement Payment")** on or before five o'clock p.m. EDT on the seventh calendar day following the Effective Date of this Agreement (defined below). The Settlement Payment shall be paid in the form of one lump sum payment wired to Nephron in accordance with the instructions to be provided by counsel for Nephron to counsel for Adamis and U.S. Compounding. Counsel for Adamis and U.S. Compounding shall notify counsel for Nephron the date the Settlement Payment is wired to Nephron and shall provide Nephron's counsel documentation sufficient to confirm the same. The Parties agree that the Settlement Payment shall be treated, for tax purposes, as compensatory damages paid to Nephron to resolve the Florida Lawsuit, the New Jersey Lawsuit, and the South Carolina Lawsuit.

2. **Consent Permanent Injunction; Required Declarations; Final Resolution of the Florida, South Carolina, and New Jersey Lawsuits, and the Adversary Proceeding; and Withdrawal of Proof of Claim in Bankruptcy.** The Parties agree to the entry of the Stipulation for Entry of Consent Permanent Injunction Order and Stipulated Final Judgement (the **"Injunction")** in the form attached hereto as **Exhibit A.** the terms being expressly incorporated herein by reference, in the Florida Lawsuit, and to the entry of the same in a substantially similar form in the New Jersey Lawsuit, and the South Carolina Lawsuit, to account for the appropriate parties and captions. If the Florida Court, New Jersey Court, or the South Carolina Court requests or requires any additional filing(s) or document(s) to support the entry of the Injunction as a final judgment resolving the Florida Lawsuit, the New Jersey Lawsuit, and/or the South Carolina Lawsuit and dismissing Nephron's claims with prejudice, the Parties agree to cooperate in the preparation and filing of the same by and through their counsel in a manner consistent with the terms of this Agreement.

Further, Lane agrees to submit a declaration to counsel for Nephron certifying that she has permanently and irrevocably destroyed any and all information, data, and documents, whether electronic or hard copy, that concern or relate in any manner to Nephron (hereafter **"Nephron Information"),** and that are in her custody, control, or possession, or to which she otherwise has access (whether on an electronic device or in a personal account such as, without limitation, an iCloud or an email account), and further swearing that she is no longer has custody, control, or possession of, or any access to, Nephron Information including, without limitation, copies of Nephron Information (the **"Lane Declaration").** The Lane Declaration shall include, without limitation, a sworn statement verifying that Lane has permanently deleted and destroyed any and all Nephron Information including, without limitation, copies thereof, which are or were at one time

stored in any of Lane's personal iCloud account(s). In addition, Hulsey agrees to submit a declaration to Nephron certifying that she has permanently and irrevocably destroyed any and all Nephron Information, whether electronic or hard copy, that is in her custody, control, or possession, or to which she otherwise has access (whether on an electronic device or in a personal account such as, without limitation, an iCloud or an email account), and further swearing that she is no longer has custody, control, or possession of, or any access to, Nephron Information including, without limitation, copies of Nephron Information (the **"Hulsey Declaration").** Hulsey agrees to work with Nephron to reach a mutual agreement regarding the deletion of Nephron Information from her devices and the third party devices that contain Nephron Information and that are in the possession of the forensic neutral engaged by the Parties in the Florida Litigation pursuant to the Stipulated Forensic Protocol therein.

Nephron agrees that, following: (i) its receipt of the Settlement Payment described at Paragraph 1 above; (ii) its receipt of the executed Lane Declaration and the Hulsey Declaration containing the certifications set forth above; and (iii) the entry of the Permanent Injunction by the Florida Court in the Florida Lawsuit, the New Jersey Court in the New Jersey Lawsuit, and the South Carolina Court in the South Carolina Lawsuit, it will: (i) if required by the Florida Court, the New Jersey Court, the South Carolina Court, file a stipulation of dismissal with prejudice in the Florida Lawsuit, the New Jersey Lawsuit, the South Carolina lawsuit, and the Adversary Proceeding, dismissing all of its claims asserted in each; and (ii) withdraw both its Proof of Claim and its Objection to Plan filed in the Bankruptcy. Hulsey specifically agrees to fully cooperate and take whatever steps are necessary in order to have the Bankruptcy Court lift the automatic stay for the purpose of permitting the Parties to have the Injunction entered on the docket in the Florida Court and to effectuate the terms of this Agreement.

3. **Effective Date.** This Agreement shall be effective once executed by all Parties (the **"Effective Date")** and shall be of no force and effect until such time.

4. **Mutual Releases and Covenants Not to Sue.** Upon the Effective Date, Nephron, on the one hand, and Defendants, on the other hand, shall mutually release and forever discharge each other from any and all claims, rights, actions, causes of action, suits, damages, losses, attorneys' fees, costs, expenses, payments, debts, grievances, and liabilities that were raised or that could have been raised in the Florida Lawsuit, the New Jersey Lawsuit, the South Carolina Lawsuit, and/or the Adversary Proceeding (hereinafter collectively the **"Lawsuits")** in any form, or that arise from or relate to the claims and liabilities asserted in the Lawsuits, including but not limited to related claims, cross-claims, or collateral claims, whether known or unknown, asserted or not yet asserted, vested or contingent. Hulsey, Lane, and Nephron each affirm, acknowledge, and agree that this release language is intended to and does include, without limitation, a mutual release of any and all claims, rights, actions, causes of action, suits, damages, losses, attorneys' fees, costs, expenses, payments, debts, grievances, and liabilities concerning or related in any manner to their former employment with Nephron including, without limitation, their separation therefrom. This release language is for any relief, no matter how described, including but not limited to back pay, front pay, compensatory damages, liquidated damages, punitive damages, damages for pain and suffering, emotional distress, or mental anguish, statutory damages, court costs and litigation expenses, and attorneys' fees and costs.

Also upon the Effective Date, Nephron, on the one hand, and Defendants, on the other hand, hereby absolutely, unconditionally and irrevocably, covenant and agree that they will not sue (at law, in equity, in any regulatory proceeding or otherwise) one another on the basis of any claim released pursuant to the above release. If any Party violates the foregoing covenant, the violating Party agrees to pay, in addition to such other damages that any other Party may sustain as a result of such violation, all reasonable attorneys' fees and costs incurred by such other Party as a result of such violation.

Notwithstanding the above, the releases and covenants under this paragraph do not constitute releases of any Party's ongoing obligations under this Agreement, or of any claims or causes of action arising under or resulting from a default or breach of this Agreement.

5. **Representations and Warranties of the Parties**.

(a) Each undersigned corporate Party represents and warrants that it has the full power and authority to enter into this Agreement, and that the persons executing this Agreement on each of their respective behalves are duly authorized to do so and have the necessary capacity to do so.

(b) Each undersigned individual Party represents and warrants that she has the full power and authority to enter into this Agreement, and that she the necessary capacity to do so.

(c) The Parties represent and warrant that they have, prior to entering into this Agreement, been advised in writing to consult with counsel and that they have had the provisions of this Agreement explained, reviewed, and approved by their attorneys. The Parties also acknowledge that they have been given a reasonable period of time to study, analyze, and evaluate this Agreement before signing it and has been given the opportunity to negotiate this Agreement at arm's length. The Parties therefore waive any common law or statutory rule of construction that ambiguities be construed against the drafter of this Agreement.

(d) The Parties acknowledge that they are executing this Agreement freely, knowingly, and voluntarily, that they are fully aware of the contents and effects thereof, and that the execution of this Agreement is not the result of any fraud, duress, mistake, coercion, or undue influence.

6. **Binding Effect**. This Agreement shall be binding upon each of the Parties and their respective successors-in-interest.

7. **Court Jurisdiction.** The Parties consent to the exclusive jurisdiction of the U.S. District Court for the Middle District of Florida (the **"Florida Court,"** as specified above) for purposes of the enforcement of this Agreement and the Injunction entered in the Florida Lawsuit (the **"Florida Injunction").** Any claims or causes of action, whether legal or equitable, arising out of or based upon this Agreement or the Florida Injunction, including, but not limited to, the interpretation and/or enforcement of this Agreement or the Florida Injunction, shall be commenced in the Florida Court. The Parties hereby expressly consent to the Florida Court's jurisdiction over any claims or actions arising out of the enforcement of this Agreement and/or the Florida Injunction and irrevocably waive any and all jurisdictional or other defenses to the enforceability of the Agreement and/or the Florida Injunction. The Parties consent to the exclusive jurisdiction for the U.S. District Court of New Jersey (the **"New Jersey Court,"** as specified above) for purposes of the

enforcement of the Injunction as entered in the New Jersey Lawsuit (the "New **Jersey Injunction"),** and agree that any claims or causes of action, whether legal or equitable, arising out of or based upon the New Jersey Injunction including, but not limited to, the interpretation and/or enforcement of the New Jersey Injunction, shall be commenced in the New Jersey Court. The Parties hereby expressly consent to the New Jersey Court's jurisdiction over any claims or actions arising out of the enforcement of the New Jersey Injunction and irrevocably waive any and all jurisdictional or other defenses to the enforceability of the New Jersey Injunction. The Parties consent to the exclusive jurisdiction for the U.S. District Court of South Carolina, Columbia Division (the **"South Carolina Court,"** as specified above) for purposes of the enforcement of the Injunction as entered in the South Carolina Lawsuit (the **"South Carolina Injunction"),** and agree that any claims or causes of action, whether legal or equitable, arising out of or based upon the South Carolina Injunction including, but not limited to, the interpretation and/or enforcement of the South Carolina Injunction, shall be commenced in the South Carolina Court. The Parties hereby expressly consent to the South Carolina Court's jurisdiction over any claims or actions arising out of the enforcement of the South Carolina Injunction and irrevocably waive any and all jurisdictional or other defenses to the enforceability of the South Carolina Injunction.

8. **Governing Law.** This Agreement is made pursuant to, and shall be governed by, the laws of the State of Florida and, where applicable, federal law.

9. **Integration and Amendments**. Excepting only Hulsey and Lane's obligations surviving their separation from employment with Nephron as expressly set forth in their respective Employee Confidentiality and Non-Disclosure Agreements (the **"NDAs")** that Hulsey executed on June 17, 2015, and that Lane executed on or about July 26, 2017, which obligations remain in full force and effect and are incorporated fully herein by reference, this Agreement constitutes the complete, and entire agreement and understanding of and among the Parties in relation to matters described herein and supersedes all prior oral or written agreements and/or negotiations with respect to the matters addressed herein. Any such obligations under the NDAs are in addition to, and not in lieu of, the obligations under the Injunction. Any amendment or modification to this Agreement must be in writing, signed by duly authorized representatives of the Parties hereto, and specifically state the intent of the Parties to amend and/or modify this Agreement. In the event of a conflict between the NDAs and this Agreement and/or the Injunction, this Agreement and/or the Injunction, as applicable, shall control.

10. **Severability.** If any particular paragraphs, subparagraphs, phrases, words, or other portions of this Agreement are determined by any court of competent jurisdiction to be invalid or unenforceable as written, they shall be modified as necessary to comport with the reasonable intent and expectations of the Parties, and such modification shall not affect the remaining provisions of this Agreement, or if they cannot be modified to be made valid or enforceable, then they shall be severed from this Agreement, and all remaining terms and provisions shall remain enforceable, provided that the primary purposes of this Agreement are not frustrated.

11. **Counterparts**. This Agreement may be executed by the Parties hereto in counterparts, each of which, once executed and delivered in accordance with the terms of this Agreement, will be deemed an original, with all such counterparts taken together constituting one and the same instalment. Delivery by facsimile, encrypted e-mail, or e-mail file attachment of any

such executed counterpart to this Agreement will be deemed the equivalent of the delivery of the original executed agreement or instrument.

12. **Waiver.** Any Party's failure to enforce any provision(s) of this Agreement shall not in any way be construed as a waiver of that provision(s) or prevent that party thereafter from enforcing each and every provision of this Agreement.

13. **Material Breach.** The Parties acknowledge and agree that even if any Party violates any term of this Agreement, all provisions of this Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the undersigned Parties have caused this Agreement to be duly executed as of the Effective Date set forth in this Agreement:

[SIGNATURE PAGES FOLLOW FOR EACH PARTY INDIVIDUALLY]

Nephron Pharmaceuticals Corporation, Nephron S.C., Inc., and Nephron Sterile Compounding Center, LLC

Signed:

/s/ Lou Kennedy

By: Lou Kennedy
Chief Executive Officer

U.S. Compounding, Inc.

Signed:

/s/ Robert O. Hopkins
By: Robert O. Hopkins
Its: CFO

[***]

/s/ Jennifer Shelley Hulsey

/s/ Jessica Ingrid Lane

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: November 22, 2021

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

Exhibit 31.2

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

I, David C. Benedicto, 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: November 22, 2021

By: /s/ David C. Benedicto
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, 2021 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

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

Dated: November 22, 2021

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, David C. Benedicto, as 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, 2021 (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/ DAVID C. BENEDICTO
David C. Benedicto
Chief Financial Officer

Dated: November 22, 2021

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.