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, 2022

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 August 5, 2022, was 149,983,265.

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

CONTENTS OF QUARTERLY REPORT ON FORM 10-Q

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents	$ 8,875,925	$ 23,220,770
Restricted Cash	30,045	30,023
Accounts Receivable, net	—	815,565
Receivable from Fagron	956,066	5,084,452
Inventories	440,198	418,607
Prepaid Expenses and Other Current Assets	795,839	1,313,546
Current Assets of Discontinued Operations, Note 2	4,222,542	4,320,659
Total Current Assets	15,320,615	35,203,622
LONG TERM ASSETS		
Fixed Assets, net	1,835,885	2,334,768
Right-of-Use Assets	485,761	650,460
Other Non-Current Assets	52,174	109,137
Total Assets	$ 17,694,435	$ 38,297,987
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable	$ 4,516,722	$ 3,754,010
Deferred Revenue, current portion	100,000	100,000
Accrued Other Expenses	2,145,386	2,800,241
Accrued Bonuses	529,928	535,624
Product Recall Liability	601,480	2,000,000
Lease Liabilities, Current Portion	362,434	349,871
Current Liabilities of Discontinued Operations, Note 2	1,468,368	1,683,246
Total Current Liabilities	9,724,318	11,222,992
LONG TERM LIABILITIES		
Deferred Revenue, net of current portion	700,000	750,000
Lease Liabilities, net of current portion	157,246	342,562
Warrant Liabilities, at fair value	70,728	99,655
Total Liabilities	10,652,292	12,415,209
COMMITMENTS AND CONTINGENCIES, see Note 12		
STOCKHOLDERS' EQUITY		
Preferred Stock - Par Value $0.0001; 10,000,000 Shares Authorized; no shares Issued and Outstanding at June 30, 2022 (Unaudited) and December 31, 2021, respectively.	—	—
Common Stock - Par Value $.0001; 200,000,000 Shares Authorized; 150,506,222 and 150,117,219 Issued, 149,983,265 and 149,594,262 Outstanding at June 30, 2022 (Unaudited) and December 31, 2021, respectively	15,051	15,012
Additional Paid-in Capital	303,869,991	303,958,829
Accumulated Deficit	(296,837,649)	(278,085,813)
Treasury Stock - 522,957 Shares, at cost	(5,250)	(5,250)
Total Stockholders' Equity	7,042,143	25,882,778
Total Liabilities and Stockholders' Equity	$ 17,694,435	$ 38,297,987

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
REVENUE, net	$ 39,847	1,275,474	$ 1,194,361	$ 2,608,153
COST OF GOODS SOLD	689,178	1,796,243	2,152,760	3,641,480
Gross Loss	(649,331)	(520,769)	(958,399)	(1,033,327)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	4,205,934	4,934,491	7,588,630	8,452,542
RESEARCH AND DEVELOPMENT	3,320,654	2,196,721	7,542,179	4,446,465
Loss from Operations	(8,175,919)	(7,651,981)	(16,089,208)	(13,932,334)
OTHER INCOME (EXPENSE)				
Interest Income	16,174	1,900	20,322	3,351
Interest Expense	—	(2,900)	—	(4,784)
Other Expense	(257,832)	—	(697,832)	—
Gain/(Loss) on PPP2 loan	62,583	—	(1,787,417)	—
Change in Fair Value of Warrants	19,540	(43,574)	28,927	(7,685,474)
Total Other Income (Expense), net	(159,535)	(44,574)	(2,436,000)	(7,686,907)
Net Loss from Continuing Operations	(8,335,454)	(7,696,555)	$ (18,525,208)	$ (21,619,241)
DISCONTINUED OPERATIONS				
Net Loss from Discontinued Operations before Income Taxes	(61,767)	(1,617,175)	(226,628)	(3,073,723)
Income Taxes - Discontinued Operations	—	—	—	—
Net Loss from Discontinued Operations	(61,767)	(1,617,175)	(226,628)	(3,073,723)
Net Loss Applicable to Common Stock	$ (8,397,221)	$ (9,313,730)	$ (18,751,836)	$ (24,692,964)
Basic and Diluted Loss Per Share:				
Continuing Operations	$ (0.06)	$ (0.05)	$ (0.13)	$ (0.16)
Discontinued Operations	$ —	$ (0.01)	$ —	$ (0.02)
Basic and Diluted Loss Per share	$ (0.06)	$ (0.06)	$ (0.13)	$ (0.18)
Basic and Diluted Weighted Average Shares Outstanding	149,815,683	148,886,141	149,717,104	139,228,658

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)

For the Three Months Ended June 30, 2022	Preferred Stock		Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	Shares	Amount	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance March 31, 2022	—	$ —	150,256,222	$15,026	$ 304,330,933	522,957	$ (5,250)	$ (288,440,428)	$ 15,900,281
Issuance of Common Stock upon Vesting of Restricted Stock Units (RSUs)	—	—	250,000	25	(25)	—	—	—	—
Stock Based Compensation	—	—	—	—	(460,917)	—	—	—	(460,917)
Net Loss	—	—	—	—	—	—	—	(8,397,221)	(8,397,221)
Balance June 30, 2022	—	$ —	150,506,222	$15,051	$303,869,991	522,957	$ (5,250)	$(296,837,649)	$ 7,042,143
For the Six Months Ended June 30, 2022									
Balance December 31, 2021	—	$ —	150,117,219	$ 15,012	$ 303,958,829	522,957	$ (5,250)	$ (278,085,813)	$ 25,882,778
Issuance of Common Stock upon Vesting of Restricted Stock Units (RSUs)	—	—	389,003	39	(39)	—	—	—	—
Stock Based Compensation	—	—	—	—	(88,799)	—	—	—	(88,799)
Net Loss			—	—	—	—	—	(18,751,836)	(18,751,836)
Balance June 30, 2022	—	$ —	150,506,222	$ 15,051	$ 303,869,991	522,957	$ (5,250)	$ (296,837,649)	$ 7,042,143

For Three Months Ended June 30, 2021	Preferred Stock		Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	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
Stock 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 Six Months Ended June 30, 2021									
Balance December 31, 2020	—	$ —	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 Common Stock upon Vesting of Restricted Stock Units (RSUs)	—	—	66,462	7	(7)	—	—	—	—
Stock 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

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (18,751,836)	$ (24,692,964)
Less: Loss from Discontinued Operations	226,628	3,073,723
Adjustments to Reconcile Net Loss to Net		
Cash Used in Operating Activities:		
Stock Based Compensation	(88,799)	1,677,841
Provision for Excess and Obsolete Inventory	(29,003)	414,048
Change in Fair Value of Warrant Liability	(28,927)	7,685,474
Cash Payments in Excess of Lease Expense	(8,054)	(2,665)
Depreciation Expense	712,510	696,867
Gain on Repayment of PPP2 Loan Contingent Loss Liability	62,583	—
Change in Operating Assets and Liabilities:		
Accounts Receivable	815,565	(265,870)
Receivable from Fagron	1,197,832	—
Inventories	7,412	27,665
Prepaid Expenses and Other Current & Non-Current Assets	574,670	(510,795)
Accounts Payable	532,465	9,917
Product Recall Liability	(1,398,520)	—
PPP2 Loan Contingent Loss Liability Payment	(1,850,000)	—
PPP2 Loan Contingent Loss Liability	1,787,417	—
Contingent Loss Liability	—	(7,900,000)
Deferred Revenue	(50,000)	(50,000)
Accrued Other Expenses and Bonuses	(262,764)	931,666
Net Cash Used in Operating Activities of Continuing Operations	(16,550,821)	(18,905,093)
Net Cash Used in Operating Activities in Discontinued Operations	(329,564)	(2,439,869)
Net Cash Used in Operating Activities	(16,880,385)	(21,344,962)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of Equipment	(381,167)	(847,141)
Proceeds from Receivable from Fagron	2,930,554	—
Net Cash Provided by (Used in) Investing Activities of Continuing Operations	2,549,387	(847,141)
Net Cash Provided by (Used in) Investing Activities of Discontinued Operations	—	(689)
Net Cash Provided by (Used in) Investing Activities	2,549,387	(847,830)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from Issuance of Common Stock	—	51,749,998
Costs of Issuance of Common Stock	—	(3,330,752)
Proceeds from Exercise of Warrants	—	5,851,900
Proceeds of PPP Loan	—	1,765,495
Net Cash Provided by Financing Activities of Continuing Operations	—	56,036,641
Net Cash Provided by Financing Activities of Discontinued Operations	—	(50,650)
Net Cash Provided by Financing Activities	—	55,985,991
(Decrease) Increase in Cash and Cash Equivalents and Restricted Cash	(14,330,998)	33,793,199
Cash and Cash Equivalents and Restricted Cash:		
Beginning Balance	23,250,793	6,855,355
Decrease in Cash and Restricted Cash from Discontinued Operations	(13,825)	(313,116)
Ending Balance	$ 8,905,970	$ 40,335,438

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Six Months Ended June 30,	
	2022	**2021**
RECONCILIATION OF CASH & CASH EQUIVALENTS AND RESTRICTED CASH		
Cash & Cash Equivalents	$ 8,875,925	$ 40,305,438
Restricted Cash	30,045	30,000
Total Cash & Cash Equivalents and Restricted Cash	$ 8,905,970	$ 40,335,438
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash Paid for Income Taxes	$ 3,625	$ 4,100
Cash Paid for Interest	$ —	$ 62,088
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES		
Increase in Accrued Capital Expenditures	$ 167,540	$ (36,707)

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 8 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, 2021 (the "2021 Form 10-K").

For the three and six months ended June 30, 2022 and June 30, 2021, and year ended December 31, 2021, the assets, liabilities, operations, and cash flows of the Company's subsidiary, US Compounding, Inc. ("USC"), have been separated from the comparative period amounts to conform to the current period presentation as discontinued operations as the result of the Company's decision to wind down and cease operations of USC and liquidate its remaining assets. Moreover, for the three month and six months ended June 30, 2022 and 2021, all gains and losses on disposition, impairment charges and disposal costs, along with the sales, costs and expenses and income taxes attributable to discontinued locations, have been aggregated in a single caption entitled "net loss from discontinued operations" in our consolidated statements of operations for all periods presented. See Note 2.

Going Concern

The Company's cash and cash equivalents were $8,875,925 and $23,220,770 at June 30, 2022 and December 31, 2021, respectively.

The Condensed consolidated financial statements were prepared under the assumption that the Company will 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 the Company's future business as described below, which may preclude the Company from realizing the value of certain assets.

The Company has significant operating cash flow deficiencies. Additionally, the Company will need 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 and future 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, 2022, 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, a severe or prolonged economic downturn, political disruption or pandemic, such as the COVID-19 pandemic, 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, 2022 and June 30, 2021, consist of outstanding equity classified warrants covering 14,202,824 shares and 15,095,238 shares, respectively, outstanding options covering 4,861,142 shares and 6,113,866 shares, respectively, and outstanding restricted stock units covering 650,000 shares and 2,034,260 shares, respectively.

Discontinued Operations

In accordance with ASC 205-20 *Presentation of Financial Statements: Discontinued Operations*, a disposal of a component of an entity or a group of components of an entity is required to be reported as discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results when the component/s of an entity meets the criteria in paragraph 205-20-45-10. In the period in which the component meets held-for-sale or discontinued operations criteria the major current assets, other assets, current liabilities, and noncurrent liabilities shall be reported as components of total assets and liabilities separate from those balances of the continuing operations. At the same time, the results of all discontinued operations, less applicable income taxes, shall be reported as components of net loss separate from the net loss of continuing operations. The Company disposed of a component of its business in August 2021 and met the definition of a discontinued operation as of June 30, 2022. Accordingly, the operating results of the business disposed are reported as loss from discontinued operations in the accompany unaudited condensed statements of operations for the six months and year ended June 30, 2022 and December 31, 2021.

Recent Accounting Pronouncements

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: Discontinued Operations and Assets Held for Sale

In August 2021, the Company announced an agreement with Fagron Compounding Services, LLC ("Fagron") to sell to Fagron certain assets of the Company's subsidiary, US Compounding, Inc. ("USC"), related to the Company's human compounding pharmaceutical business including certain customer information and information on products sold to such customers by USC, 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. The agreement includes fixed consideration of approximately $107,000 and variable consideration estimated at approximately $6,385,000, and the Company has recorded a gain of approximately $4,637,000 for the year ended December 31, 2021 within discontinued operations related to this asset sale to Fagron, which was the total estimated consideration net of approximately $1,856,000 of allocated costs related to USC's customer relationships intangible that was sold to Fagron. The variable consideration is tied to Fagron's sales to former USC customers over the twelve-month-period commencing on the agreement date. The Company used the expected value method to estimate Fagron's sales over the twelve-month period following the agreement date. Additionally, the Company relied on historical data and its judgement to make estimates, and as such, the total variable consideration is subject to change as more information becomes available, which would result in adjustments to the receivable from Fagron recorded at December 31, 2021. At March 31, 2022, based on the Company's evaluation, the estimated variable consideration related to the sale of certain assets to Fagron was reduced by approximately $440,000. Additionally, at June 30, 2022, based on the Company's evaluation, the estimated variable consideration related to the sale of certain assets to Fagron was further reduced by approximately $758,000, because of the lower level of sales by Fagron to covered customers in part due to certain supply and materials difficulties and increased competitive conditions. The Company recognized a total loss of approximately $1.2 million, which was included in net loss from continued operations on the Company's condensed consolidated statement of operations for the six months ended June 30, 2022, as the change occurred subsequent to the disposal of the USC business. In connection with the transaction, the Company accrued as of December 31, 2021 and paid in January 2022 a $700,000 liability for a transaction fee payable to a financial advisor which was recorded in selling, general and administrative expenses of continuing operations.

In July 2021, the Company approved a restructuring process to wind down and cease the remaining operations at USC, with the remaining USC assets to be sold, liquidated or otherwise disposed of. The Company disposed of a component of its business in August 2021 and met the definition of a discontinued operation as of September 30, 2021. Accordingly, the operating results of the business disposed are reported as loss from discontinued operations in the accompany unaudited condensed statements of operations for the three months and six months ended June 30, 2022 and 2021. As of December 31, 2021, the Company had shut down the operations of USC, terminated all of USC's employees and was engaged in the process of selling or attempting to sell or otherwise dispose of USC's remaining assets.

Discontinued operations comprise those activities that were disposed of during the period, abandoned or which were classified as held for sale at the end of the period and represent a separate major line of business or geographical area that was previously distinguished as Compounded Pharmaceuticals segment for operational and financial reporting purposes in prior reported financial statements.

Assets Held for Sale

The Company considers assets to be held for sale when management approves and commits to a plan to actively market the assets for sale at a reasonable price in relation to its fair value, the assets are available for immediate sale in their present condition, an active program to locate a buyer and other actions required to complete the sale have been initiated, the sale of the assets is expected to be completed within one year and it is unlikely that significant changes will be made to the plan. Upon designation as held for sale, the Company ceases to record depreciation and amortization expenses and measures the assets at the lower of their carrying value or estimated fair value less costs to sell. Assets held for sale are included as other current assets in the Company's consolidated balance sheets and the gain or loss from sale of assets held for sale is included in the Company's general and administrative expenses.

The major assets and liabilities associated with discontinued operations included in our consolidated balance sheets are as follows (unaudited):

Carrying amounts of major classes of assets included as part of discontinued operations (unaudited):

	June 30, 2022	December 31, 2021
Cash and Cash Equivalents	$ 24,024	$ 37,849
Accounts Receivable, net	—	693
Inventories	—	12,000
Fixed Assets, net	6,791,090	6,799,090
Other assets	8,870	72,469
Loss recognized on classification as held for sale	(2,601,442)	(2,601,442)
Total assets of the disposal group classified as held for sale in the statement of financial position	$ 4,222,542	$ 4,320,659
Carrying amounts of major classes of liabilities included as part of discontinued operations		
Accounts Payable	$ 630,819	$ 681,646
Accrued Other Expenses	53,936	133,313
Lease Liabilities	327,683	412,357
Contingent Loss Liability	410,000	410,000
Deferred Tax Liability	45,930	45,930
Total liabilities of the disposal group classified as held for sale in the statement of financial position	$ 1,468,368	$ 1,683,246

The revenues and expenses associated with discontinued operations included in our consolidated statements of operations were as follows (unaudited):

	Three Months Ended June 30,	
	2022	2021
Major line items constituting pretax profit (loss) of discontinued operations		
REVENUE, net	$ —	$ 2,735,830
COST OF GOODS SOLD	—	(2,074,390)
Gross Profit	—	661,440
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(91,911)	(2,197,153)
RESEARCH AND DEVELOPMENT	—	(36,055)
IMPAIRMENT OF LONG LIVED ASSETS	—	(9,347)
OTHER INCOME (EXPENSE)		
Interest Expense	—	(42,047)
Other Income	8,614	5,987
Gain from asset disposal	21,530	—
Loss from discontinued operations before income taxes	(61,767)	(1,617,175)
Income tax benefit	—	—
Loss from discontinued operations after income taxes	$ (61,767)	$ (1,617,175)

	Six Months Ended June 30,	
	2022	2021
Major line items constituting pretax profit (loss) of discontinued operations		
REVENUE, net	$ —	$ 5,511,683
COST OF GOODS SOLD	—	(3,871,100)
Gross Profit	—	1,640,583
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(264,383)	(4,598,575)
RESEARCH AND DEVELOPMENT	—	(47,634)
IMPAIRMENT OF LONG LIVED ASSETS	—	(9,347)
OTHER INCOME (EXPENSE)		
Interest Expense	—	(79,488)
Other Income	8,625	20,738
Gain from asset disposal	29,130	—
Loss from discontinued operations before income taxes	(226,628)	(3,073,723)
Income tax benefit	—	—
Loss from discontinued operations after income taxes	$ (226,628)	$ (3,073,723)

Discontinued Operations - Revenue

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.

Discontinued Operations - Lease

USC has two operating leases, one for an office space and one for office equipment. As of June 30, 2022, the leases have remaining terms between more than one year and less than four years. The operating leases do not include an option to extend beyond the life of the current term. There are no short-term leases, and the lease agreements do not require material variable lease payments, residual value guarantees or restrictive covenants. The Company leases a building which requires monthly base rent of $10,824 through December 31, 2023.

As part of the restructuring process to wind down and cease the operations at USC, the Company is working to cancel or transfer the leases of the discontinued operations. During the year ended December 31, 2021, the Right-of-Use assets related to the leases of approximately $448,000 were fully impaired because there is no benefit expected from the subject leases. As of June 30, 2022, and December 31, 2021 the liabilities of the discontinued operations included approximately $328,000 and $412,000 in lease liabilities, respectively.

Discontinued Operations - Restructuring Costs

As of June 30, 2022, and December 31, 2021, the outstanding liabilities related to the contract termination costs recorded in contingent loss liability of discontinued operations was approximately $410,000, reflecting estimated costs of termination of a contract between USC and a vendor. As of June 30, 2022, and December 31, 2021, the outstanding liabilities related to chemical destruction costs recorded in accounts payable of discontinued operations was approximately $0 and $3,000, respectively.

Discontinued Operations - Building Loan

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

In July 2021, the Company, in connection with the sale of certain USC assets to Fagron, paid to the lender the outstanding principal balance, accrued unpaid interest and other obligations under the Company's loan agreement, promissory note and related loan documents relating to the outstanding building loan relating to the building and property on which USC's offices are located. The land and building were included in the assets of discontinued operations.

The loan bore an interest of 6.00% per year and interest expense for the three months ended June 30, 2022 and June 30, 2021, was approximately $0 and $30,000, respectively. Interest expense for the six months ended June 30, 2022 and 2021 was approximately $0 and $61,000 respectively. The amount of interest allocated to the discontinued operations was based on the legal obligations of USC.

Note 3: Revenues

Revenue Recognition

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

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

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, provided 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 included, among others, corticosteroids, hormone replacement therapies, hospital outsourcing products, and injectables. In July 2021, the Company 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.

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.

Exclusive Distribution and Commercialization Agreement for SYMJEPI® and ZIMHI™ with US WorldMeds

On May 11, 2020 (the "Effective Date") the Company entered into an exclusive distribution and commercialization agreement (the "USWM Agreement") with USWM for the United States commercial rights for the SYMJEPI products, as well as for the Company's ZIMHI (naloxone HCI Injection, USP) 5mg/0.5mL product intended for the emergency treatment of opioid overdose. The Company's revenues relating to its FDA approved products SYMJEPI and ZIMHI are dependent on the USWM Agreement.

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

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

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

As the optional future sales of SYMJEPI and ZIMHI reflect a significant or incremental discount, they are material rights, and are accounted for as performance obligations. We allocate the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that USWM will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised or expires.

Revenues from product sales are recognized at a point in time upon delivery to USWM. Variable consideration from product sales is allocated directly to the products being sold. Under the USWM Agreement, the Company is entitled to receive various amounts and milestone payments, including regulatory milestone payments; net-profit sharing payments based on certain percentages of net profit generated from the sale of products over a given quarter; and commercial milestone payments. Payments from regulatory milestone payments were excluded from the transaction price as the Company utilizes the most likely amount method to estimate variable consideration. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. Receivable from USWM has a payment term of Net 30.

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

Product Recall

On March 21, 2022, we announced a voluntary recall of four lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes to the consumer level, due to the potential clogging of the needle preventing the dispensing of epinephrine. USWM will handle the entire recall process for the Company, with Company oversight. SYMJEPI is manufactured and tested for us by Catalent Belgium S.A. The costs of the recall and the allocation of costs of the recall, including the costs to us resulting from the recall, were estimated at approximately $2.0 million; moreover, the recall could cause the Company to suffer reputational harm, depending on the resolution of matters relating to the recall could result in the Company incurring financial costs and expenses which could be material, could adversely affect the supply of SYMJEPI products until manufacturing is resumed, and depending on the resolution of matters relating to the recall could have a material adverse effect on our business, financial condition, and results of operations.

For the period ended June 30, 2022 and December 31, 2021, a liability of approximately $0.6 million and $2.0 million, respectively, associated with the recall is reflected in the balance sheet. The estimated costs of the recall was reflected in the consolidated statement of operations for the year ended December 31, 2021 as a reduction of net sales because we expect to offer the customers a cash refund or credit. The Company may be able to be reimbursed by certain third parties for some of the costs of the recall under the terms of its manufacturing agreements or insurance policies, but there are no assurances regarding the amount or timing of any such recovery.

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, 2022 and 2021, $25,000 and $25,000 of the revenues recognized were reported as deferred revenue as of March 31, 2022 and 2021, respectively, and for the six months ended June 30, 2022 and 2021, $50,000 and $50,000 of the revenues recognized were reported as deferred revenue as of December 31, 2021 and 2020, respectively. Included in the deferred revenue balance at June 30, 2022 and December 31, 2021 was $800,000 and $850,000, respectively, relating to the non-refundable upfront payment received from USWM pursuant to the USWM Agreement.

Cost to Obtain a Contract

The Company capitalizes incremental costs of obtaining a contract with a customer if the Company expects to recover those costs and that it would not have been incurred if the contract had not been obtained. The deferred costs, reported in the prepaid expenses and other current assets and other non-current assets on the Company's consolidated balance sheets, will be amortized over the economic benefit period of the contract.

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.

Note 4: Inventories

Inventories at June 30, 2022 and December 31, 2021 consisted of the following:

	June 30, 2022	December 31, 2021
Finished Goods	$ —	$ —
Work-in-Process	—	386,610
Raw Materials	440,198	31,997
Inventories	$ 440,198	418,607

Reserve for obsolescence as of June 30, 2022 and December 31, 2021 was approximately $0 and $ 0, respectively.

Note 5: Fixed Assets, net

Fixed assets at June 30, 2022 and December 31, 2021 are summarized in the table below:

Description	Useful Life (Years)	June 30, 2022	December 31, 2021
Machinery and Equipment	3 - 5	$ 5,079,972	$ 4,522,583
Less: Accumulated Depreciation		(3,894,077)	(3,181,567)
Construction In Progress - Equipment		649,990	993,752
Fixed Assets, net		$ 1,835,885	$ 2,334,768

Depreciation expense for the three months ended June 30, 2022 and 2021 was approximately $368,000 and $369,000, respectively; and for the six months ended June 30, 2022 and 2021, depreciation expense was approximately $713,000 and $697,000, respectively.

Note 6: Leases

The Company has one operating lease for an office space. As of June 30, 2022, the lease has a remaining term of approximately 17 months. The operating lease does not include an option to extend beyond the life of the current term. There are no short-term leases, and the lease agreement does not require material variable lease payments, residual value guarantees or restrictive covenants.

The tables below present the operating lease assets and liabilities recognized on the condensed consolidated balance sheets as of June 30, 2022, and December 31, 2021:

Right-of Use Assets	June 30, 2022	December 31, 2021
Operating Lease	$ 485,761	$ 650,460

Lease Liabilities, Current Portion	June 30, 2022	December 31, 2021
Operating Lease	$ 362,434	$ 349,871
Lease Liabilities, net of current portion		
Operating Lease	157,246	342,562
Total Lease Liabilities	$ 519,680	$ 692,433

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

The Company's lease does 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, 2022 and December 31, 2021 were:

June 30, 2022	**Operating**
Weighted Average Remaining Lease Term	1.42 Years
Weighted Average Discount Rate	3.95%

December 31, 2021	**Operating**
Weighted Average Remaining Lease Term	1.92 Years
Weighted Average Discount Rate	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, 2022:

Year Ending December 31,	**Operating**
Remainder of 2022	$ 185,937
2023	349,365
Undiscounted Future Minimum Lease Payments	535,302
Less: Difference between undiscounted lease payments and discounted lease liabilities	15,622
Total Lease Liabilities	$ 519,680
Short-Term Lease Liabilities	$ 362,434
Long-Term Lease Liabilities	$ 157,246

Operating lease expense for the three months ended June 30,2022 and 2021 was approximately $88,000 and $88,000 respectively, and for the six months ended June 30, 2022 and 2021, operating lease expense was approximately $177,000 and $177,000, respectively. Operating 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 $93,000 and $90,000 for the three months ended June 30, 2022, and 2021, respectively, and approximately $185,000 and $180,000 for the six months ended June 30, 2022 and 2021, respectively.

Note 7: Debt

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 recognized the amount forgiven as other income.

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. The term of the PPP2 Note was 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. The Company applied for forgiveness of the PPP2 Loan, and 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, was fully forgiven by the SBA. The Company recognized the amount forgiven as other income in the third quarter of 2021. However, as described further in Note 9 below, in March 2022 the Company was informed that the Civil Division of the U.S. Attorney's Office for the Southern District of New York was investigating the Company's Second Draw PPP Loan and eligibility for that loan, and the Company's financial statements for the quarter ended March 31, 2022, included a $1,850,000 contingent loss liability relating to the possible repayment of the full amount of the Second Draw PPP Loan as well as accrued interest and processing fees of the lending bank. In June 2022, following the inquiry, the Company paid a total of $1,787,417 in repayment of the Second Draw PPP Loan principal and such related interest and fees.

Even though the PPP Loan has been forgiven and the Second Draw PPP Loan repaid, 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 the Company were to be audited or reviewed and receive an adverse determination or finding in such audit or review, including a determination that the Company was ineligible to receive the applicable loan, the Company could be required to return or repay the full amount of the applicable loan and could be subject to additional fines or penalties, which could reduce the Company's liquidity and adversely affect our business, financial condition and results of operations.

Note 8. Fair Value Measurement

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.

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, 2022			
	Total	**Level 1**	**Level 2**	**Level 3**
Liabilities				
2020 Warrant Liability	$ 70,728	$ —	$ —	$ 70,728

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, 2022 include the expected volatility of the Company's stock of approximately 70%, the Company's stock price at valuation date of $0.501, expected dividend yield of 0.0% and average risk-free interest rate of approximately 2.991%. 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, 2021			
	Total	**Level 1**	**Level 2**	**Level 3**
Liabilities				
2020 Warrant Liability	$ 99,655	$ —	$ —	$ 99,655

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 December 31, 2021 include the expected volatility of the Company's stock of approximately 70%, the Company's stock price at valuation date of $0.605, expected dividend yield of 0.0% and average risk-free interest rate of approximately 1.038%. 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.

Note 9: Legal Matters

We may from time to time become party to actions, claims, suits, investigations or proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, breach of contract claims, labor and employment claims and other matters. We may also become party to litigation in federal and state courts relating to opioid drugs. Any litigation could divert management time and attention from Adamis, could involve significant amounts of legal fees and other fees and expenses, or could result in an adverse outcome having a material adverse effect on our financial condition, cash flows or results of operations. 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.

Investigations

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. 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, has effectively wound down USC's business, and the employment of substantially all USC employees has ended. As a result, the Company is no longer 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 and the USAO 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. 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 as needed. Additionally, on March 16, 2022, the Company was informed that the Civil Division of the USAO ("Civil Division") was investigating the Company's Second Draw PPP Loan application and the company's eligibility for the Second Draw PPP Loan. The Audit Committee of the Board engaged outside counsel to conduct an internal inquiry into the matter. The Company intends to continue cooperating with the USAO, SEC, and Civil Division. At this time, the Company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, Civil Division, or other agencies; what, if any, proceedings the USAO, SEC, Civil Division, or other federal or state authorities may initiate; what, if any, remedies or remedial measures the USAO, SEC, Civil Division 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, Civil Division, or other authorities, which may require further investigation. There can be no assurance that any discussions with the USAO, SEC or Civil Division 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, liquidity, financial condition, and results of operations.

As a result of the investigation by the Civil Division, the Company's financial statements for the first quarter of 2022 included a $1,850,000 contingent loss liability relating to the possible repayment of the full amount of the Second Draw PPP Loan as well as accrued interest and processing fees of the lending bank. In June 2022, following the inquiry the Company paid a total of $1,787,417 in repayment of the Second Draw PPP Loan principal and related interest and fees. The servicing bank waived the processing fees of approximately $63,000 related to the transaction, which the Company recognized as a gain for the same amount which was included in the other income (expense) portion of the condensed consolidated statements of operations. The Company is awaiting confirmation from the Civil Division's whether any additional action is required to conclude the investigation into the Second Draw PPP Loan.

Nasdaq Compliance

On December 31, 2021, we received a notice 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. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), we were provided an initial compliance period of 180 calendar days, or until June 29, 2022, to regain compliance. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. The notice letter also disclosed that if we do not regain compliance within the initial compliance period, we may be eligible for an additional 180-day compliance period. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of a plan to cure the deficiency during the second compliance period, including by effecting a reverse stock split if necessary. We did not regain compliance with the Rule by June 29, 2022. We requested additional time to regain compliance and provided notice to Nasdaq of our intention to cure the deficiency during the second compliance period, including by effecting a reverse stock split if necessary. On June 30, 2022, Nasdaq notified us that we were granted an additional 180-day compliance period, or until December 27, 2022, to regain compliance with the Rule. The letter also indicated that if at any time before December 27, 2022, the bid price of the Company's Common Stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, the Company will regain compliance with the Rule. If the Company does not meet the minimum bid requirement at some time during the additional 180-day grace period, Nasdaq will provide written notification to the Company that its shares will be subject to delisting. At such time, the Company may appeal the delisting determination to a Nasdaq Hearings Panel. The Company would remain listed pending the Panel's decision. There can be no assurance that if the Company does appeal a subsequent delisting determination, that such appeal would be successful. The letter and notification from Nasdaq had no immediate effect on the listing or trading of the Company's shares, which will continue to trade on the Nasdaq Capital Market under

the symbol “ADMP.” There are no assurances that we will be able to regain compliance with the minimum bid price requirements or will otherwise be in compliance with other Nasdaq listing rules.

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.

In March 2022, plaintiff filed a motion for a temporary restraining order and for expedited proceedings, seeking an order enjoining the Company and its directors from (a) changing the number of members of the Company's board of directors, (b) adding members to the Company's board of directors, and/or (c) replacing any resigning members of the Company's board of directors. The Company filed a response to the plaintiff's motion. The Court held a hearing on March 28, 2022, and denied the plaintiff's motion in full. On April 4, 2022, plaintiff filed a motion to amend the plaintiff's complaint. The proposed amended Complaint adds additional allegations relating to the manner in which the defendants established and disclosed the date of the Company's 2021 annual meeting of stockholders and to statements the defendants made about the plaintiff to the Company's stockholders. On April 28, 2022, the Court granted the motion, noting that as a general rule, leave to amend is freely given. On April 25, 2022, plaintiff filed a motion for a preliminary injunction seeking to enjoin the Company from holding its 2022 annual meeting of stockholders until the plaintiff's Complaint is resolved. The Company opposed the motion, and on April 28, 2022, the Court denied the plaintiff's motion. On May 23, 2022, the Company filed a motion for summary judgment on Count VI and a motion to dismiss Counts VII, VIII, and IX of plaintiff's amended Complaint. Those motions are pending before the Court, and the case continues to proceed. The Company believes the claims in plaintiff's Complaint are without merit, and intends to vigorously dispute them. The Company has not recorded a contingent liability related to this matter.

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.

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

The Company accounts for stock-based compensation transactions in which the Company receives employee services in exchange for restricted stock units (“RSUs”) or options to purchase common stock and the Company recognizes stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period. Stock-based compensation cost for RSUs is measured based on the closing fair market value of the Company’s common stock on the date of grant. Stock-based compensation cost for stock options is estimated at the grant date based on each option’s fair-value as calculated by the Black-Scholes option-pricing model. The Company accounts for forfeitures as they occur and will reduce compensation cost at the time of forfeiture. Cash-settled Stock Appreciation Rights ("SARs")provide for the cash payment of the excess of the fair market value of the Company’s common stock price on the date of exercise over the grant price. The fair value of the SARs is calculated during each reporting period and estimated using the Black-Scholes option pricing model. The SARs will vest over a period of three years and are accounted for as liability awards since they will be settled in cash. Cash-settled SARs have no effect on dilutive shares or shares outstanding as any appreciation of the Company’s common stock over the grant price is paid in cash and not in common stock. The Company accounts for forfeiture as they occur and reduces the compensation cost at the time of forfeiture.

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 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, 2022.

On January 1, 2022, pursuant to the 2020 Equity Incentive Plan the number of shares reserved for the issuance of stock awards increased by 7,479,713 shares.

In June 2022, the Company issued 250,000 shares of common stock to Dennis J. Carlo, former chief executive officer of the Company, pursuant to a separation agreement between the Company and Dr. Carlo. The separation agreement resulted to the modification of his RSU awards, accelerating the RSU vesting upon his separation. As a result of this Type III modification, the Company determined the cumulative compensation cost that should have been recognized at that date as if the fair value of the modified award had been recognized from the original grant date over his requisite service period, which resulted in the reversal of approximately $540,000 in expense.

Stock Options

The following table summarizes the outstanding stock option activity for the six months ended June 30, 2022:

Non-Plan Awards:

	Non - Plan Awards	Weighted Average Exercise Price	Weighted Average Remaining Contract Life
Total Outstanding Vested and Expected to Vest as of December 31, 2021	—	$ —	—
Granted	130,000	0.62	9.64
Options Canceled/Expired	—	—	—
Total Outstanding Vested and Expected to Vest as of June 30, 2022	130,000	0.62	9.64
Vested at June 30, 2022	35,833	0.62	9.64

2009 Equity Incentive Plan:

	2009 Equity Incentive Plan	Weighted Average Exercise Price	Weighted Average Remaining Contract Life
Total Outstanding Vested and Expected to Vest as of December 31, 2021	4,985,415	$ 4.21	4.05 years
Options Canceled/Expired	(254,273)	4.54	—
Total Outstanding Vested and Expected to Vest as of June 30, 2022	4,731,142	4.19	2.86 years
Vested at June 30, 2022	4,726,209	4.19	2.86 years

Continuing operations expense related to stock options for three months ended June 30, 2022 and 2021, was approximately $4,000 and $4,000, respectively.

Continuing operations expense related to stock options for the six months ended June 30, 2022 and 2021, was approximately $13,000 and $113,000, respectively.

Discontinued operations expense related to stock options for the three months ended June 30, 2022 and 2021 was approximately $0 and $1,000, respectively.

Discontinued operations expense related to stock options for the six months ended June 30, 2022 and 2021 was approximately $0 and $34,000, respectively.

As of June 30, 2022, the compensation expense related to stock options issued under the Company's 2009 Equity Incentive Plan has been fully recognized.

The aggregate intrinsic value (the difference between the Company's closing stock price on the last trading day of the year and the exercise price, multiplied by the number of in-the-money options) of 4,861,142 and 4,985,415 stock options outstanding at June 30, 2022 and December 31, 2021 was $0 and $0, respectively. The aggregate intrinsic value of 4,762,042 and 4,980,482 stock options exercisable at June 30, 2022, and December 31, 2021 was $0 and $0, respectively.

Restricted Stock Units

The following table summarizes the RSUs outstanding at June 30, 2022:

	Number of Shares/Unit	Weighted Average Grant Date Fair Value
Non-vested RSUs as of December 31, 2021	1,039,003	$ 4.16
RSUs vested during the period	(389,003)	3.35
RSUs forfeited during the period	—	—
Non-vested RSUs as of June 30, 2022	650,000	$ 4.64

For the three months ended June 30, 2022 and 2021, continuing operations expense related to RSUs was approximately $(464,000) and $794,000, respectively. The negative expense was due to the modification of certain outstanding RSUs during the three months ended June 30, 2022.

For the six months ended June 30, 2022 and 2021, continuing operations expense related to RSUs was approximately $(102,000) and $1,531,000, respectively. The negative expense was due to the modification of certain outstanding RSUs during the six months ended June 30, 2022.

For the three and six months ended June 30, 2022 and 2021, there was no RSU related expense within discontinued operations.

As of June 30, 2022, the unamortized compensation expense related to RSUs was approximately $478,000 and will be recorded as compensation expense over 1.41 years.

Warrants

The following table summarizes warrants outstanding at June 30, 2022 and at December 31, 2021:

	Warrant Shares	Exercise Price Per Share	Date Issued	Expiration Date
Old Adamis Warrants	58,824	$ 8.50	November 15, 2007	November 15, 2022
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	14,202,824			

* As of June 30, 2022 and December 31, 2021, the fair value of the warrant liability related to the 2020 Warrants was $70,728 and $ 99,655 respectively. See Note 8.

At June 30, 2022, the Company has reserved shares of common stock for issuance upon exercise of outstanding options, warrants including all of the warrants in the table above and restricted stock units, as follows:

Warrants	14,202,824
Restricted Stock Units	650,000
Non-Plan Awards	130,000
2009 Equity Incentive Plan	4,731,142
Total Shares Reserved	19,713,966

Note 12: Commitments and Contingencies

The Company has a production threshold commitment to a manufacturer of our SYMJEPI products pursuant to which 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 years ended June 30, 2022 and 2021 were $0 and $0, respectively.

For information concerning contingencies relating to legal proceedings, see Note 9 of the notes to the condensed consolidated financial statements.

Note 13: Subsequent Events

On July 5, 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with an institutional investor (the "Investor" or the "Purchaser"), pursuant to which the Company issued on July 5, 2022 (the "Closing Date"), in a private placement transaction (the "Offering" or the "Transaction"), an aggregate of 3,000 shares (the "Shares") of Series C Convertible Preferred Stock, par value $0.0001 per share (the "Series C Preferred"), together with warrants (the "Warrants") to purchase up to an aggregate of 750,000 shares (the "Warrant Shares") of common stock of the Company ("Common Stock") at an exercise price of $0.47 per share (subject to adjustment as provided in the Warrants), for an aggregate subscription amount equal to $300,000. The Warrant becomes exercisable commencing January 3, 2023, and has a term ending on January 5, 2028. The Purchase Agreement contains customary representations, warranties and agreements of the Company and the Purchaser, and customary indemnification rights and obligations of the parties. Pursuant to the Purchase Agreement, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of Delaware designating the rights, preferences and limitations of the Series C Preferred. The Certificate of Designation provides, among other things, that except as otherwise provided in the Certificate of Designation or as otherwise required by law, the Series C Preferred will have no voting rights (other than the right to vote as a class on certain matters as provided in the Certificate of Designation). However, pursuant to the Certificate of Designation, each share of Series C Preferred entitles the holder thereof (i) to vote on a proposal presented to the Company's stockholders for approval (the "Proposal") to approve a reverse stock split of the Company's outstanding Common Stock (the "Reverse Stock Split"), and any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Proposal, and (ii) to 1,000,000 votes per share of Series C Preferred on the Proposal and any such adjournment proposal. The Series C Preferred will, except as required by law, vote together with the Common Stock (and other issued and outstanding shares of preferred stock entitled to vote), as a single class; provided, however, that such shares of Series C Preferred shall, to the extent cast on the Proposal or any such adjournment proposal, be automatically and without further action of the holders thereof voted in the same proportion as the shares of Common Stock (excluding any shares of Common Stock that are not voted) and any other issued and outstanding shares of preferred stock of the Company entitled to vote (other than the Series C Preferred or shares of such other preferred stock, if any, not voted) are voted on the Proposal.

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 current or future expenses, commitments, obligations or liabilities; 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 will 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, 2021 (sometimes referred to as the "2021 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 2021 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 2021 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 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. In February 2022 we announced the enrollment and dosing of more than 100 subjects in the Phase 2/3 trial, and on March 14, 2022, we announced that the Data Safety Monitoring Board, or DSMB, overseeing the Phase 2/3 clinical trial met to evaluate the clinical and safety data from the first planned interim analysis and, following its evaluation, recommended that the study continue without modification. The DSMB is composed of subject matter experts and can unblind the data to determine the treatment effects of the subjects in the trial. On June 1, 2022, we announced that the DSMB had met again to evaluate interim clinical and safety data for the trial and based on an interim review of the data, determined that the study can continue as planned. Where applicable, we intend to create low cost therapeutic alternatives to existing treatments and 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, 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 was 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, provided 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. 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.

As previously reported in a Current Report on Form 8-K filed with the SEC on May 19, 2022, effective May 18, 2022, David J. Marguglio, previously Senior Vice President and Chief Business Officer, was appointed as the President and Chief Executive Officer of the Company, and pursuant to a separation agreement and release entered into between the company and Dennis J. Carlo, Ph.D., Dr. Carlo's separation from employment with the Company and all subsidiaries, status as President and Chief Executive Officer of the Company and resignation as a director of the Company and all subsidiaries was effective on such date.

To achieve our goals and support our overall strategy, we will need to raise additional funding in the future and make significant investments in, among other things, product development and working capital.

SYMJEPI (epinephrine) Injection Product

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 65 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.

On March 21, 2022, we announced a voluntary recall of four lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes to the consumer level. The four lots were recalled due to the potential clogging of the needle preventing the dispensing of epinephrine. The recall is being conducted with the knowledge of the FDA and USWM is handling the entire recall process for the company, with company oversight. As of the date of this Report, neither USWM nor we have received, or are aware of, any adverse events related to this recall.

SYMJEPI is manufactured and tested for us by Catalent Belgium S.A. For the manufacture of SYMJEPI, the company utilizes “Ready-to-Fill,” or RTF, syringes that consist of a pre-assembled glass syringe barrel with a staked-in stainless steel needle. During routine inspection of epinephrine pre-filled syringe batches, a small number of syringes with clogged needles were identified. An initial investigation suggested a syringe component issue as the likely cause of the observed needle clogging. Further investigation confirmed the steel used in one specific stainless steel needle batch as the root cause for the clogged syringes observed. The company and the manufacturer have developed corrective and preventive actions. New RTF syringes, which have been manufactured using a different batch of steel for their needles, are being sourced. Once Catalent has received the new syringes and begun to resume the manufacture process for SYMJEPI, the company expects to have additional information concerning the timing of resupplying USWM with product to enable a relaunch of SYMJEPI, although there can be no assurance concerning the timing of resumption of manufacturing or resupplying USWM with product to enable a relaunch of SYMJEPI. The company is committed to returning SYMJEPI to the market after all stakeholders are satisfied that these corrective actions should prevent a repeat of the observed failure in future batches.

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. Following the receipt of two Complete Response Letters, or CRLs, from the FDA regarding our NDA for ZIMHI and our resubmissions of the NDA, on October 18, 2021, we announced that the FDA had approved ZIMHI for the treatment of opioid overdose. On March 31, 2022, our commercial partner USWM and the company issued a press release announcing the commercial launch of ZIMHI. USWM has indicated to the company that initial feedback from the field has been positive. A recently launched website enables institutional customers to order and receive product directly. USWM has indicated to the company that progress has continued in adding ZIMHI to formularies for payors and PBMs, and that in many states ZIMHI has been added to the standing orders, which permits pharmacies to dispense ZIMHI without a prescription.

Tempol (APC400)

On June 12, 2020, we entered into a license agreement with a third party entity, 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.

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.

Preclinical studies of Tempol have shown it to have antiviral, anti-inflammatory, and antioxidant activity. The company believes this unique mechanism of action, combined with a relatively benign safety profile shown in prior preclinical studies, could provide physicians with a tool to intervene to slow or stop progression of COVID-19 or inflammation at multiple phases of the disease. If proven, this could provide Tempol with an advantage over oral antiviral drugs the FDA has cleared for the treatment of COVID-19.

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 decreases cytokines from stimulated cells from COVID-19 patients. In March 2021, we announced that in studies conducted at Galveston National Laboratory, or GNL, 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, and on March 22, 2022, we announced that in studies conducted at the GNL, hamsters challenged with high levels of the Omicron variant of the SAR-CoV-2 virus, resulted in significant decrease of inflammation in the lungs of animals treated with Tempol compared to controls.

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 and proposed clinical trial of Tempol for the treatment of COVID-19. 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, or DSMB, 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 initially experienced enrollment challenges primarily as a result of the decrease in COVID-19 infections and increased immunizations in the United States. We took certain responsive steps including opening new sites across the U.S. and modifying the protocol to include vaccinated subjects.

In February 2022 we announced the enrollment and dosing of more than 100 subjects in the Phase 2/3 trial. On March 14, 2022, we announced that the DSMB overseeing the Phase 2/3 clinical trial met to evaluate the clinical and safety data from the first planned interim analysis and, following its evaluation, recommended that the study continue without modification. On June 1, 2022, we announced that the DSMB had met again to evaluate interim clinical and safety data for the trial and based on an interim review of the data, determined that the study can continue as planned.

On July, 29, 2022, we announced that we had enrolled more than 200 patients in the trial. We believe that we have nearly completed patient enrollment needed for the next DSMB meeting for our Phase 2/3 clinical trial. The DSMB is scheduled to meet near the end of September 2022 to review unblinded interim data including safety and efficacy. The DSMB is comprised of infectious disease experts who independently review the unblinded trial data and make recommendations. The company will not have access to unblinded trial data until the trial has concluded and the final study data is compiled and reviewed. At the September meeting, the DSMB plans to evaluate the primary efficacy endpoint, the sustained resolution of COVID-19 symptoms, as well as safety in individuals who are at high risk for disease progression. If the DSMB recommendations indicate that the analysis of the clinical and safety data from the trial demonstrates significant efficacy, the DSMB might recommend stopping the trial in light of the demonstrated efficacy in even a relatively small dataset, and the company likely would submit a clinical study report to the FDA and request a meeting to discuss the findings and next regulatory steps, as well as requirements for applying for Emergency Use Authorization. If positive trends are observed in favor of the Tempol treatment group but significant efficacy is not demonstrated, the DSMB may recommend that we continue the study and enroll additional subjects. If no efficacy is demonstrated, then the company would likely stop the trial. In addition, the company is exploring other potential indications for Tempol and seeking both government and non-government funding to further development.

US Compounding, Inc.

On July 30, 2021, the company and its wholly-owned USC subsidiary entered into an Asset Purchase Agreement, or the USC Agreement, effective as of July 30, 2021, or 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, or 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 referred to as 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, or 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, or 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, or 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 at December 31, 2021 and paid in January 2022 a $700,000 liability for a transaction fee payable to a financial advisor.

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, in August 2021 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. 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. 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. The company has sold and disposed of certain customer information and other assets related to USC's veterinary compounded pharmaceuticals business, and will continue the process of selling or otherwise disposing of the remaining assets relating to USC's business.

In connection with the winding down of the USC business, we incurred significant expenses and made a number of payments. The substantial majority of cash payments related to personnel-related restructuring charges, including without limitation 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 pursuant to the USC Agreement, severance or other termination benefits or payments in connection with workforce reduction and termination of employment, and payments pursuant to retention agreements or incentive agreements with certain employees, were made during the third and fourth quarters of 2021 and were approximately $1.6 million. In addition, as part of the winding down of USC's business, we have incurred other costs. We also expect to incur commissions and other costs associated with the sale or other disposition of certain USC tangible assets such as building, property and certain equipment.

As a result of the transactions contemplated by the USC Agreement and the restructuring activities described above, the company's financial results for the third and fourth quarters of 2021 include approximately $8.6 million for the impairment charges of inventory, fixed assets, intangibles, goodwill and right of use assets. The impairment charges that the company incurred and 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.

Going Concern and Management Plan

The financial statements included elsewhere herein for the three and six months ended June 30, 2022, 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. We have incurred substantial recurring losses from continuing operations, have used, rather than provided, cash in our continuing operations, and are dependent on additional financing to fund operations. We incurred a net loss of approximately $18.8 million and $24.7 million for the six months ended June 30, 2022 and 2021. As of June 30, 2022, we had cash and cash equivalents of approximately $8.9 million, an accumulated deficit of approximately $296.8 million and liabilities of approximately $10.7 million. 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.

Our management intends to attempt to secure additional required funding through equity or debt financing if available, sales or out-licensing of product candidates or intellectual property assets, revenues relating to supply and sale of SYMJEPI and ZIMHI products and share of net profits received relating to sales in the U.S. of our SYMJEPI and ZIMHI 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. As of the date of this Report, we have a limited number of authorized shares available for issuance in funding transactions. 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.

Funding that we may receive during fiscal 2022 is expected to be used to satisfy existing and future obligations and liabilities and working capital needs, to support commercialization of our products and conduct the clinical and regulatory work to develop our product candidates, to begin building working capital reserves and to help fund a number of matters, which may include, without limitation, some or all of the following:

- support commercialization of our SYMJEPI and ZIMHI (naloxone) products;
- continue development of our product candidates;
- pursue the development of other product candidates or technologies that we may develop or acquire;
- fund clinical trials of Tempol;
- expand research and development activities;
- access manufacturing, commercialization and sales capabilities;
- implement additional internal systems and infrastructure;
- satisfy our current and future obligations and liabilities
- maintain, defend or expand the scope of our intellectual property portfolio;
- acquire products, technologies or intellectual property or companies; and
- hire management, sales, research, development and clinical personnel.

Results of Operations

Our consolidated results of operations are presented for the three months and six months ended June 30, 2022 and 2021. Certain financial results (revenues and expenses) relating to the business formerly conducted by USC are reflected in Note 2, Discontinued Operations and Assets Held for Sale, of the notes to the consolidated financial statements appearing elsewhere in this Report. Unless otherwise noted, the discussion below, and the revenue and expense amounts discussed below, are based on and relate to the continuing operations of the company, which we sometimes refer to as our drug development and commercialization business.

Three Months Ended June 30, 2022 and 2021

Revenues. Revenues were approximately $40,000 and $1,275,000 for the three months ended June 30, 2022 and 2021, respectively. Revenues for the three months ended June 30, 2022, consisted primarily of revenues from the amortization of deferred revenue relating to a milestone payment received from USWM in connection with entering into the USWM Agreement. The decrease was primarily attributable to a decrease in revenues relating to sales of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg. No revenues relating to SYMJEPI were reported for the second quarter of 2022, due to its manufacturing hold and the voluntary product recall announced in March 2022. As disclosed elsewhere in this Report, including above under the heading “General - SYMJEPI (epinephrine) Injection Product,” the manufacturing of SYMJEPI is currently on hold. The company and the manufacturer have developed corrective and preventive actions. New RTF syringes, which have been manufactured using a different batch of steel for their needles, are being sourced. Once Catalent has received the new syringes and begun to resume the manufacture process for SYMJEPI and all stakeholders are satisfied that these corrective actions should prevent similar issues in future batches, the company expects to have additional information concerning the timing of resupplying USWM with product to enable a relaunch of SYMJEPI, although there can be no assurance concerning the timing of resumption of manufacturing or resupplying USWM with product to enable a relaunch of SYMJEPI. There were no product revenues for ZIMHI during three months ended June 30, 2022 because the product was only recently launched and the product that was delivered to USWM in late March 2022 was intended to be used for the product launch. No additional ZIMHI product was delivered to USWM during the three months ended June 30, 2022.

Cost of Goods Sold. 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. Consolidated cost of goods sold was approximately $689,000 and $1,796,000 for the three months ended June 30, 2022 and 2021, respectively. The gross loss for the three months ended June 30, 2022 was approximately $649,000 compared to approximately $521,000 for the three months ended June 30, 2021. Cost of goods sold for the second quarter of 2022 compared to the comparable period of 2021 decreased primarily due to the decrease in direct material costs of approximately $1,085,000 largely resulting from decreased sales of SYMJEPI.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses consist primarily of consulting and employee compensation, professional fees which include legal, accounting and audit fees, and depreciation and amortization expenses. SG&A expenses for the three months ended June 30, 2022 and 2021 were approximately $4,206,000 and $4,934,000, respectively. The decrease in SG&A expenses was primarily due to a decrease in legal expenses of approximately $491,000 mainly attributable to an ongoing legal proceeding and a decrease in compensation expenses of approximately $319,000, offset primarily by an increase in insurance expenses. The decrease in compensation expenses during the three months ended June 30, 2022 compared to the same period in 2021 was due to a lower stock based compensation expense resulting primarily from the modification of certain outstanding equity awards in connection with accelerated vesting pursuant to a separation agreement and a reduction in bonus expense, offset mainly by employment separation payments made during the second quarter of 2022.

Research and Development Expenses. Our research and development, or R&D, costs are expensed as incurred. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as an asset and are expensed when the research and development activities are performed. R&D expenses were approximately $3,321,000 and $2,197,000 for the three months ended June 30, 2022 and 2021, respectively. The increase was primarily attributable to an increase in costs related to our ongoing clinical trial of our Tempol product candidate of approximately $1,735,000 (primarily CRO expenses), offset primarily by a decrease in development spending for SYMJEPI, ZIMHI and other projects of approximately $576,000.

Other Income (Expense). Other Income (Expense) 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, 2022 and 2021 was approximately ($160,000) and ($45,000), respectively. The increase in other expenses during the three-month period ended June 30, 2022, compared to the same period in 2021, was primarily attributable to the change in estimate of variable consideration of approximately $758,000 related to the sale of certain assets to Fagron, which reflects a reduction in the estimated consideration receivable from the Purchaser pursuant to the terms of the USC Agreement. This loss was offset primarily by an increase in other income of approximately $500,000 from insurance proceeds and a gain on the change in fair value of warrants of approximately $63,000 and a gain on the repayment of the Second Draw of the PPP loan due to the lending bank waiving certain processing fees of approximately $63,000.

Loss from Discontinued Operations. The company recorded a net loss from discontinued operations, after taxes, of approximately $62,000 and $1,617,000 for the three months ended June 30, 2022 and 2021, respectively. The decrease in loss from discontinued operations during the three months ended June 30, 2022, compared to the three months ended June 30, 2021, was primarily due to the absence of any revenues or costs of goods sold and significantly reduced SG&A expenses due to the cessation of USC's operating activities. The loss from discontinued operations for the three months ended June 30, 2021, primarily reflected revenues of approximately $2.7 million relating to sales of USC products, cost of goods sold of approximately $2.1 million and SG&A expenses of approximately $2.2 million, relating to the operations of USC's compounding pharmacy business.

Six Months Ended June 30, 2022 and 2021

Revenues. Revenues were approximately $1,194,000 and $2,608,000 for the six months ended June 30, 2022 and 2021, respectively. The decrease was primarily attributable to a decrease in revenues relating to sales of SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg of approximately $2,558,000, offset by an increase of sales of ZIMHI of approximately $1,144,000. No revenues relating to SYMJEPI were reported for the second quarter of 2022, due to the manufacturing hold and the voluntary product recall announced in March 2022. As disclosed elsewhere in this Report, including above under the heading “General - SYMJEPI (epinephrine) Injection Product,” the manufacturing of SYMJEPI is currently on hold. The company and the manufacturer have developed corrective and preventive actions. New RTF syringes, which have been manufactured using a different batch of steel for their needles, are being sourced. Once Catalent has received the new syringes and begun to resume the manufacture process for SYMJEPI and all stakeholders are satisfied that these corrective actions should prevent similar issues in future batches, the company expects to have additional information concerning the timing of resupplying USWM with product to enable a relaunch of SYMJEPI, although there can be no assurance concerning the timing of resumption of manufacturing or resupplying USWM with product to enable a relaunch of SYMJEPI.

Cost of Goods Sold. 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. Cost of goods sold was approximately $2,153,000 and $3,641,000 for the six-months ended June 30, 2022 and 2021, respectively. The gross loss for the six-months ended June 30, 2022 was approximately $958,000 compared to approximately $1,033,000 for the six-months ended June 30, 2021. Cost of goods sold for the six months ended June 30, 2022 compared to the comparable period of 2021 decreased by approximately $1,489,000, primarily due to a decrease in direct materials costs of approximately $2,302,000 largely resulting from decreased sales of SYMJEPI and a decrease in obsolescence and defective inventory costs of approximately $314,000, offset by an increase in direct material costs for the sales of ZIMHI of approximately $1,152,000.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses consist primarily of consulting and employee compensation, professional fees which include legal, accounting and audit fees, and depreciation and amortization. SG&A expenses for the six months ended June 30, 2022 and 2021 were approximately $7,589,000 and $8,453,000 respectively. The decrease in SG&A expenses was primarily attributable to a decrease in compensation expenses of approximately $769,000 and a decrease in legal expenses of approximately $640,000 mainly attributable to an ongoing legal proceeding, offset by an increase in consulting and outside services of approximately $320,000 for accounting and investor relations services, an increase in insurance costs of approximately $115,000 and an increase in recruitment fees of approximately $104,000. The decrease in compensation expenses during the six months ended June 30,2022 compared to the same period in 2021 was due to a lower stock based compensation expense resulting primarily from the modification of certain outstanding equity awards in connection with accelerated vesting pursuant to a separation agreement and a reduction in bonus expense, offset mainly by employment separation payments made during the first half of 2022.

Research and Development Expenses. Our research and development, or R&D, costs are expensed as incurred. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as an asset and are expensed when the research and development activities are performed. R&D expenses were approximately $7,542,000 and $4,446,000 for the six months ended June 30, 2022 and 2021, respectively. The increase was primarily attributable to an increase in development spending on our product candidate Tempol of approximately $3,864,000 (primarily CRO costs as the clinical trial progresses), offset by a decrease in development spending for SYMJEPI, ZIHMI and other projects of approximately $474,000 and a decrease in compensation expenses for research and development employees by approximately $294,000 primarily related to stock based compensation.

Other Income (Expense). Other Income (Expense) consists primarily of interest income, interest expense, changes to the fair value of warrant liabilities, and other transactions. Other income (expense) for the six months ended June 30, 2022 and 2021 was approximately ($2,436,000) and ($7,687,000), respectively. The decrease in other expenses during the six months ended June 30, 2022, compared to the same period in 2021, was primarily attributable to a decrease in expense associated with the change in fair value of warrants of approximately $7,714,000 and an increase in other income of approximately $500,000 from insurance proceeds, offset by the contingent loss accrual associated with the Second Draw PPP Loan of approximately $1,787,000 and the change in estimate of variable consideration of approximately $1,198,000 related to the sale of certain assets to Fagron, pursuant to the USC Agreement.

Loss from Discontinued Operations. The company recorded a net loss from discontinued operations of approximately $227,000 and $3,074,000 for the six months ended June 30, 2022, and 2021, respectively. The decrease in loss from discontinued operations during the six months ended June 30, 2022, compared to the six months ended June 30, 2021, primarily resulted from the absence of any revenues or costs of good sold expenses and significantly reduced SG&A expenses due to the cessation of USC’s operating activities. The loss from discontinued operations for the six months ended June 30, 2021, primarily reflected revenues of approximately $5.5 million relating to sales of USC products, cost of goods sold of approximately $3.9 million and SG&A expenses of approximately $4.6 million, relating to the operations of USC's compounding pharmacy business.

Liquidity and Capital Resources

We have incurred net losses from our continuing and discontinued operations of approximately $18.8 million and $24.7 million for the six months ended June 30, 2022 and 2021, respectively. Since inception, and through June 30, 2022, we have an accumulated deficit of approximately $296.8 million. Since inception and through June 30, 2022, we have financed operations principally through public and private issuances of common stock, preferred stock and warrants and through debt financing.

We will need additional funding in the future to satisfy our existing and future obligations and liabilities and working capital needs, to support commercialization of our products and conduct clinical and regulatory work to develop our product candidates, to begin building working capital reserves, and for other purposes. We intend to seek to 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 and ZIMHI products, sales of assets, out-licensing transactions, and/or collaborative agreements with corporate partners.

As of June 30, 2022, we had cash, cash equivalents and restricted cash of approximately $8.9 million. Total assets were approximately $17.7 million and $38.3 million as of June 30, 2022 and December 31, 2021 respectively. Current assets exceeded current liabilities by approximately $5.6 million as of June 30, 2022.

Net cash used in operating activities for the six months ended June 30, 2022 and 2021, was approximately $16.9 million and $21.3 million, respectively. Net cash used in operating activities for both periods were due to operating losses and, with respect to the six months ended June 30, 2022, the payment of product recall liability in 2022 and an approximately $1.4 million separation payment made to Dr. Carlo in connection with his employment separation during the second quarter of 2022, as compared to the six months ended June 30, 2021.

Net cash provided by investing activities was approximately $2.5 million for six months ended June 30, 2022 and net cash used in investing activities was approximately $0.8 million for six months ended June 30, 2021. The net cash provided by investing activities for the six months ended June 30, 2022, was primarily due to payments received from Fagron from the sale of USC assets, and net cash used in investing activities for the six months ended June 30, 2021, was primarily due to purchase of capital equipment.

Net cash provided by financing activities was $0 and approximately $56.0 million for the six months ended June 30, 2022 and 2021, respectively. Net cash provided by financing activities for the six months ended June 30, 2021, was primarily due to proceeds from the issuance of common stock in an underwritten public offering, exercise of investor warrants and proceeds from the Second Draw PPP Loan.

PPP Loans. As discussed in Note 7 to the financial statements included elsewhere herein, we applied for and obtained loan funding under the PPP pursuant to the PPP Loan and PPP Note in the principal amount of $3,191,700, 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 was also initially forgiven. However, as a result of the investigation by the Civil Division described elsewhere under the heading "Legal Proceedings" and in Note 9 to the consolidated financial statements included elsewhere herein, in June 2022, the company paid a total of $1,787,417 in repayment of the Second Draw PPP Loan principal and related interest and fees. 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 PPP loans 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, including that we were not eligible to apply for or receive the loan, we could be required to return or repay the full amount of the applicable loan and could be subject to additional fines or penalties, which could reduce our liquidity and adversely affect our business, financial condition and results of operations.

As noted above under the heading "Going Concern and Management Plan," through June 30, 2022, we have incurred substantial losses. We will be required to devote significant cash resources in order to continue development and commercialization of our product candidates and to support our other operations and activities. The availability of required additional funding cannot be assured. As of the date of this Report, we have a limited number of authorized shares available for issuance in funding transactions. In addition, an adverse outcome in legal or regulatory proceedings in which we are or in the future could be involved could adversely affect our liquidity and financial position. See Note 9 of the notes to our consolidated financial statements included elsewhere herein. If in the future we are not able to obtain additional required equity or debt funding, our cash resources could be depleted and we could be required to materially reduce or suspend operations. No assurance can be given as to the timing or ultimate success of obtaining future funding. 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. No assurance can be given as to the timing or ultimate success of obtaining any required future funding. In addition, as a result of the COVID-19 pandemic and actions taken to slow its spread, national or global developments, inflation or other economic considerations 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 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 the SEC and the Civil Division. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, Civil Division or other agencies, or determine what, if any, proceedings the USAO, SEC, Civil Division or other federal or state authorities may initiate, what, if any, remedies or remedial measures the USAO, SEC, the Civil Division, 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.

Material Cash Requirements

Based on our current and anticipated level of operations, we do not believe that our cash, cash equivalents and short-term investments, together with anticipated revenues from operations and amounts that we expect to receive as a result of our sales of assets relating to our former USC business, will be sufficient to meet our anticipated operating expenses, capital expenditures and obligations for at least 12 months from the date of this Report. As a result, before the end of 2022 or thereafter during such 12-month period, we will require additional capital to sustain operations, satisfy our obligations and liabilities, help fund the development and commercialization of our products and product candidates, conduct research, development and trials relating to our product candidates, and fund our ongoing operations, acquire product candidates or technologies, or for other purposes, and we intend to seek to raise additional capital during 2022 and/or thereafter. As of the date of this Report, we have a limited number of authorized shares available for issuance in funding transactions. Additional required capital may not be available on a timely basis, on favorable terms, or at all, and such funding, if raised, may not be sufficient to meet our obligations or enable us to continue to implement our long-term business strategy.

As of June 30, 2022, we had an operating lease for office space for our offices in San Diego, California, with a remaining term expiring in November 2023. Monthly rent through the remaining term of the lease is approximately $32,000 per month. We also have a lease agreement for space located in Conway, Arkansas, relating to the compounding pharmaceutical products business formerly conducted by our USC subsidiary, with a current term expiring December 31, 2023. As a result of the sale of assets pursuant to the USC Agreement and the winding down of USC's remaining business, the company will not need the leased property. Monthly rent for the remaining term of this lease is approximately $10,800 per month. See Note 6 of the notes to the consolidated financial statements included elsewhere herein for additional information about our lease obligations.

We have entered into arrangements with clinical sites and clinical research organizations, or CROs, for the conduct of our clinical trials. We make payments to these clinical sites and CROs based in part on the number of eligible patients enrolled, the length of their participation in the clinical trials and activities undertaken by the clinical sites and CROs. At this time, due to the variability associated with clinical site agreements, CRO agreements and manufacturing agreements, we are unable to estimate with certainty the future costs we will incur, including in connection with our ongoing Phase 2/3 clinical trial relating to Tempol, but such expenses may be material. In addition, we have entered into agreements and arrangements with third parties for the manufacture and supply of clinical and commercial materials and drug products, including for our SYMJEPI and ZIMHI products and our current clinical trial for our Tempol product candidate. In some of our agreements with manufacturers, we have a production threshold commitment where we would be required to pay for maintenance fees if we do not meet certain periodic purchase order minimums. Maintenance fees for the three months and six months ended June 30,2022 were $0. Under certain of these agreements, we may be subject to penalties in the event that we prematurely terminate these agreements. We intend to use our current financial resources to fund our obligations under these commitments.

As disclosed elsewhere in this Report, on March 21, 2022, we announced a voluntary recall of four lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes to the consumer level, due to the potential clogging of the needle preventing the dispensing of epinephrine. USWM is handling the entire recall process for the company, with company oversight. SYMJEPI is manufactured and tested for us by Catalent Belgium S.A. The ultimate costs of the recall and the allocation of costs of the recall, including the costs to us resulting from the recall, are unknown as of the date of this Report; however, the recall could cause the company to suffer reputational harm, depending on the resolution of matters relating to the recall could result in the company incurring financial costs and expenses which could be material, could adversely affect the supply of SYMJEPI products until manufacturing is resumed, and depending on the resolution of matters relating to the recall could have a material adverse effect on our 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 included in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 31, 2022, have not materially changed.

Recent Accounting Pronouncements

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

ITEM 3. Quantitative and Qualitative Disclosure of Market Risk

Not required.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

As required by the SEC Rule 13a-15(b), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2022.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that occurred during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Disclosure Controls and Internal Control over Financial Reporting

Because of their inherent limitations, our disclosure controls and procedures and our internal control over financial reporting may not prevent material errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The effectiveness of our disclosure controls and procedures and our internal control over financial reporting is subject to risks, including that the controls may become inadequate because of changes in conditions or that the degree of compliance with our policies or procedures may deteriorate.

PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

We may from time to time become party to actions, claims, suits, investigations or proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, breach of contract claims, labor and employment claims and other matters. We may also become party to litigation in federal and state courts relating to opioid drugs. Any litigation could divert management time and attention from Adamis, could involve significant amounts of legal fees and other fees and expenses, or could result in an adverse outcome having a material adverse effect on our financial condition, cash flows or results of operations. 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.

Investigations

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. 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, has wound down USC's business, and the employment of substantially all USC employees has ended. As a result, the company is no longer 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 and the USAO 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. 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 as needed. Additionally, on March 16, 2022, the company was informed that the Civil Division of the USAO ("Civil Division") was investigating the company's Second Draw PPP Loan application and the company's eligibility for the Second Draw PPP Loan. The Audit Committee of the Board engaged outside counsel to conduct an internal inquiry into the matter. The company intends to continue cooperating with the USAO, SEC, and Civil Division. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, Civil Division, or other agencies; what, if any, proceedings the USAO, SEC, Civil Division, or other federal or state authorities may initiate; what, if any, remedies or remedial measures the USAO, SEC, Civil Division 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, Civil Division, or other authorities, which may require further investigation. There can be no assurance that any discussions with the USAO, SEC or Civil Division 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.

As a result of the investigation by the Civil Division, the company's financial statements for the first quarter of 2022 included a $1,850,000 contingent loss liability relating to the possible repayment of the full amount of the Second Draw PPP Loan as well as accrued interest and processing fees of the lending bank. In June 2022, following the inquiry, the company paid a total of $1,787,417 in repayment of the Second Draw PPP Loan principal and such related interest and fees.

Nasdaq Compliance

On December 31, 2021, we received a notice 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. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), we were provided an initial compliance period of 180 calendar days, or until June 29, 2022, to regain compliance. To regain compliance, the closing bid price of our Common Stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. The notice letter also disclosed that if we do not regain compliance within the initial compliance period, we may be eligible for an additional 180-day compliance period. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of a plan to cure the deficiency during the second compliance period, including by effecting a reverse stock split if necessary. We did not regain compliance with the Rule by June 29, 2022. We requested additional time to regain compliance and provided notice to Nasdaq of our intention to cure the deficiency during the second compliance period, including by effecting a reverse stock split if necessary. On June 30, 2022, Nasdaq notified us that we were granted an additional 180-day compliance period or until December 27, 2022, to regain compliance with the Rule. The notice also indicated that if at any time before December 27, 2022, the bid price of the Common Stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, the Company will regain compliance with the Rule. If the Company does not meet the minimum bid requirement at some time during the additional 180-day grace period, Nasdaq will provide written notification to the Company that its shares will be subject to delisting. At such time, the Company may appeal the delisting determination to a Nasdaq Hearings Panel. The Company would remain listed pending the Panel's decision. There can be no assurance that if the Company does appeal a subsequent delisting determination, that such appeal would be successful. The letter and notification from Nasdaq had no immediate effect on the listing or trading of the Company's shares, which will continue to trade on the Nasdaq Capital Market under the symbol "ADMP." There are no assurances that we will be able to regain compliance with the minimum bid price requirements or will otherwise be in compliance with other Nasdaq listing rules.

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.

In March 2022, plaintiff filed a motion for a temporary restraining order and for expedited proceedings, seeking an order enjoining the Company and its directors from (a) changing the number of members of the Company's board of directors, (b) adding members to the Company's board of directors, and/or (c) replacing any resigning members of the Company's board of directors. The Company filed a response to the plaintiff's motion. The Court held a hearing on March 28, 2022 and denied the plaintiff's motion in full. On April 4, 2022, plaintiff filed a motion to amend the plaintiff's complaint. The proposed amended Complaint adds additional allegations relating to the manner in which the defendants established and disclosed the date of the Company's 2021 annual meeting of stockholders and to statements the defendants made about the plaintiff to the Company's stockholders. On April 28, 2022, the Court granted the motion, noting that as a general rule, leave to amend is freely given. On April 25, 2022, plaintiff filed a motion for a preliminary injunction seeking to enjoin the Company from holding its 2022 annual meeting of stockholders until the plaintiff's Complaint is resolved. The Company opposed the motion, and on April 28, 2022, the Court denied the plaintiff's motion. On May 23, 2022, the Company filed a motion for summary judgment on Count VI and a motion to dismiss Counts VII, VIII, and IX of plaintiff's amended Complaint. Those motions are pending before the Court, and the case continues to proceed. 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, 2021. 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.

Risk Factors Summary

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 2022, 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 will require additional funding in the future 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, and as of the date of this Report, we have a limited number of authorized shares available for issuance in any such funding transactions. We 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 reduce or cease operations.
- We may never commercialize additional product candidates that are subject to regulatory approval or earn a profit.
- Our development plans concerning our products and product candidates are affected by many factors, the outcome of which is 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 cannot assure you that any 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. There are no assurances concerning the outcome of any future meetings of the DSMB to evaluate interim data for our ongoing clinical trial regarding our Tempol product candidate or concerning the results of trial, and an adverse outcome regarding the results of the trial could have a material adverse effect on our business, financial conditions and results of operations.

- We are subject to the risk of lawsuits or other legal proceedings.
- We are subject to substantial government regulation and are impacted by state and federal statutes and regulations, 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 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.
- We borrowed funds pursuant to the Paycheck Protection Program ("PPP"). Even though our loans were initially forgiven pursuant to the program, we remain subject to review and audit in connection with such loans. In connection with an investigation by the Civil Division, in June 2022 we paid a total of $1,787,417 in repayment of our Second Draw PPP Loan principal and related interest and fees. We could be required to return or repay the full amount of our first PPP Loan and could be subject to fines or penalties, which could be material
- The COVID-19 pandemic has adversely affected and may continue to adversely affect our business, results of operations and financial condition.
- If there are injuries or deaths associated with use of our products, or if there is a product recall affecting one or more of our products, we may be exposed to significant liabilities. We have announced a voluntary recall of four lots of our SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringe products. As of the date of this Report, neither we nor our commercialization partner have received, or is aware of, any adverse events related to this recall. However, in the event of adverse events or deaths associated with our products, we could become subject to product and professional liability lawsuits or other claims or proceedings. In addition, the recall could adversely affect our business, results of operations, financial condition and liquidity.
- 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. The remaining operations and business of USC have been wound down, and remaining assets relating to USC's business have been or will be sold or otherwise disposed of. 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. Nevertheless, USC and we could become involved in proceedings with the FDA or other federal or state regulatory authorities alleging non-compliance with applicable federal or state regulatory legal requirements, or in other legal proceedings relating to the winding down of USC's business, which could adversely affect our 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 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, or 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, or 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, or the 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. Additionally, on March 16, 2022, the company was informed that the Civil Division of the USAO ("Civil Division") was investigating the company's Second Draw PPP Loan application and the company's eligibility for the Second Draw PPP Loan. The company intends to continue cooperating with the USAO, SEC, and Civil Division. At this time, the company is unable to determine what, if any, additional actions the USAO, SEC, Civil Division or other federal or state authorities may take, what, if any, remedies or remedial measures the USAO, SEC, Civil Division 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, Civil Division 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.
- 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 adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner and could 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.

- 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.

Risks Related to Our Financial Condition

* ***There is substantial doubt about our ability to continue as a going concern.***

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, 2021, included in our Annual Report on Form 10-K for the year ended December 31, 2021, and the consolidated financial statements included in this Report, we have sustained substantial recurring losses from operations. In addition, we have used, rather than provided, cash in our continuing operations. 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 If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

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

We incurred significant net losses for the six months ended June 30, 2022, and for the years ended December 31, 2021 and December 31, 2020. As of June 30, 2022, we had cash, cash equivalents and restricted cash of approximately $8.9 million. The development of our business will require additional capital. Based on our current and anticipated level of operations, we do not believe that our cash, cash equivalents and short-term investments, together with anticipated revenues from operations and amounts that we expect to receive as a result of our sales of assets relating to our former USC business, will be sufficient to meet our anticipated operating expenses, capital expenditures and obligations for at least 12 months from the date of this Report. As a result, before the end of 2022 or thereafter during such 12-month period, we will require additional capital to sustain operations, satisfy our obligations and liabilities, help fund the development and commercialization of our products and product candidates, conduct research, development and trials relating to our product candidates, and fund our ongoing operations, acquire product candidates or technologies, or for other purposes, and we intend to seek to raise additional capital during 2022 and/or thereafter. There are no assurances that required funding will be available at all or will be available in sufficient amounts or on reasonable terms. In addition to product revenues, we have historically relied upon sales of our equity or debt securities to fund our operations. As of the date of this Report, we have a limited number of authorized shares available for issuance in any such funding transactions. 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 to obtain any required funding. Delays in obtaining, or the inability to obtain, required funding from debt or equity financings, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions or sources, 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, and could adversely affect our ability to continue operations. In addition, our sale of assets pursuant to the USC Agreement relating to the human compounding pharmaceuticals business of our USC subsidiary, together with our previously announced 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 required financing 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 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, or if we determine in the future that other financial restatements are required, 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, any restatement or 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 six months ended June 30, 2022 and for the years ended December 31, 2021 and December 31, 2020, as 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 may incur expenses for product marketing and brand awareness and conduct significant research, development, testing and regulatory compliance activities that, together with general and administrative expenses, could result in substantial operating losses for the foreseeable future. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

**** We have received grand jury subpoenas issued in connection with a criminal investigation and are subject to other investigations.***

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. 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 as needed. Additionally, on March 16, 2022, we were informed that the Civil Division of the USAO ("Civil Division") is investigating the company's Second Draw PPP Loan application disclosed in previous reports. The Audit Committee of the Board engaged outside counsel to conduct an internal inquiry into the matter. In June 2022, following the inquiry the company paid a total of $1,787,417 in repayment of the Second Draw PPP Loan principal and such related interest and fees. The company intends to continue cooperating with the USAO, SEC, and Civil Division. At this time, the company is unable to predict the duration, scope, or outcome of the investigations by the USAO, SEC, Civil Division, or other agencies; what, if any, proceedings the USAO, SEC, Civil Division, or other federal or state authorities may initiate; what, if any, remedies or remedial measures the USAO, SEC, Civil Division 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, Civil Division, or other authorities, which may require further investigation. There can be no assurance that any discussions with the USAO, SEC or Civil Division 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 could have a material adverse effect on the company's business, financial condition and results of operations.

**** Our PPP loans may be audited or reviewed by federal or state regulatory authorities. We repaid our PPP Loan.***

We applied for and obtained loan funding 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 was initially forgiven. However, in connection with an investigation by the Civil Division, in June 2022 we paid a total of $1,787,417 in repayment of our Second Draw PPP Loan principal and related interest and fees. 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 additional fines or 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.

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

The development of new pharmaceutical products is a highly risky undertaking. Our potential products may require significant additional research and development before any commercial introduction. 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 outcome and results 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. 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.

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 has continued, has spread throughout most of the world including the United States. The outbreak 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 in 2020 and 2021, 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. 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, at various times, quarantines, shelter-in-place or work-from-home orders or policies, travel restrictions, social distancing and business shutdowns. The effects of such measures could 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, our operations could be adversely affected by outbreaks of COVID-19 among our employees. 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 have relied on and 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.

**** If there are injuries or deaths associated with use of our products, or if there is a product recall affecting one or more of our products, we may be exposed to significant liabilities.***

The production, manufacturing, labeling of pharmaceutical products and compounded pharmaceutical preparations is inherently risky. We could be adversely affected if any of our products, or the formulations or other products previously sold by USC, 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 our products or one of the compounded formulations previously sold by USC, 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 such products. On March 21, 2022, we announced a voluntary recall of four lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes, due to the potential clogging of the needle preventing the dispensing of epinephrine. As of the date of this Report, the manufacturing of SYMJEPI is currently on hold. There can be no assurance concerning the timing of resumption of manufacturing or resupplying USWM with product to enable a relaunch of SYMJEPI. 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 our products, or one of the formulations or compounds previously sold by USC, 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 or claims relating to the product recall or associated expenses, including third parties that have purchased our SYMJEPI products or that may purchase our ZIMHI product, or to which we have sold certain assets of USC, including claims pursuant to our agreements with third parties. Any of the foregoing matters could result in a material adverse effect on our business, results of operations, financial condition and liquidity. Our consolidated financial statements for the year ended December 31, 2021, included in our 2021 Form 10-K, and our consolidated financial statements for the three months ended March 31, 2022, included in our Quarterly Report on Form 10-Q for the three months ended March 31, 2022, included and reflected a reserve of approximately $2.0 million associated with the SYMJEPI recall. The recall may have an adverse effect on the amount or the timing of our revenues, and on our financial results and liquidity, for fiscal quarters in 2022 or thereafter. In addition, current or future insurance coverage may prove insufficient to cover any liability claims brought against USC or us with respect to the SYMJEPI recall, products previously sold by USC, or other matters. As of June 30, 2022, the remaining balance of the reserve relating to the SYMJEPI recall was approximately $601,000, after payments made to USWM for the identified recalled products.

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. For example, there are no assurances concerning the outcome of any future meetings of the DSMB to evaluate interim data for our ongoing clinical trial regarding our Tempol product candidate or concerning the results of trial, and an adverse outcome regarding the results of the trial could have a material adverse effect on our business, financial conditions and results of operations. We cannot assure you that any testing or clinical trials 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.

Except for our facilities at USC that were previously utilized to prepare compounded formulations, we do not own or operate manufacturing facilities for clinical or commercial production of pharmaceutical products and product candidates, we do not have any experience in drug formulation or manufacturing, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. Accordingly, we expect to depend on third-party contract manufacturers for the foreseeable future. Any performance failure on the part of our contract manufacturers could delay clinical development, regulatory approval or commercialization of our current or future product candidates, or result in product recalls or shortages or manufacturing halts or delays, 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 and our ZIMHI (naloxone) Injection product, 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 FDA sends the Section 505(b)(2) NDA applicant notice that 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 the development of any bioequivalence or other data 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 the specific patient;
- cost-effective;
- supported by peer-reviewed publications; or
- 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. The impact of these changes 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 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, before the winding down of its business as described elsewhere in this Report, 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 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 our reputation, customer relationships or otherwise have a material adverse effect on our business, financial condition and results of operations.

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 product 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 competes 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 or license patent rights, 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. 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.

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, 2021, we had federal and state net operating loss carryforwards, or NOLs, and credit carryforwards which, subject to certain limitations, we may use to reduce future taxable income or offset income taxes due. Insufficient future taxable income will adversely affect our ability to utilize these NOLs and credit carryforwards. Pursuant to Internal Revenue Code Section 382, the annual use of the NOLs and research and development tax credits could be limited by any greater than 50% ownership change during any three-year testing period. As noted in Note 20 of the notes to the audited consolidated financial statements of the company appearing in the 2021 Form 10-K, our existing NOLs are subject to limitations arising from previous ownership changes, and if we undergo additional ownership changes, our ability to use our NOLs could be further limited by Section 382 of the Code. As a result of these limitations, we may be materially limited in our ability to utilize our NOLs and credit carryforward.

Risks Related to Our Former Compounding Pharmacy Business

We have sold a substantial portion of the assets of USC and are 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 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 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. The remaining operations and business of USC have been or will be wound down and terminated, and remaining assets relating to USC's business have been sold or will be sold or otherwise transferred or disposed of. Effective October 31, 2021, USC surrendered its Arkansas retail pharmacy permit and wholesaler/outsourcer permit and is no longer engaged in the human or veterinary compounding pharmaceutical business. The USC Agreement provides for payment of consideration over time based on future sales of products by the Purchaser. 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 USC Agreement or other agreements or activities relating to the sale or disposition of USC's assets. There is no assurance regarding the amount of 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 USC 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, the termination of agreements relating to the USC business, 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 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.

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 2020 to June 30, 2022, the market price of our common stock has fluctuated between $0.27 and $2.34. 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;
- effects of public health crises, pandemics and epidemics, such as the COVID-19 outbreak; or
- other potentially negative financial announcements, such as a review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC.

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

Trading of our common stock is limited.

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

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.

On December 31, 2021, the Nasdaq Listing Qualifications Department of The NASDAQ Capital Market ("Nasdaq") notified 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. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), we were provided an initial compliance period of 180 calendar days, or until June 29, 2022, to regain compliance. The notice stated that if at any time before June 29, 2022, the closing bid price of our common stock met or exceeded $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the minimum bid price requirement, and the matter would be resolved. We did not regain compliance with the Rule by June 29, 2022. However, we requested additional time to regain compliance and provided notice to Nasdaq of our intention to cure the deficiency during the second compliance period, including by effecting a reverse stock split if necessary. One June 30, 2022 we received a letter from Nasdaq notifying us that we had been granted an additional 180-day compliance period or until December 27, 2022, to regain compliance with the Rule. If the Company does not meet the minimum bid requirement for at least 10 consecutive business days at some time during the additional 180-day grace period, Nasdaq will provide written notification to the Company that its shares will be subject to delisting. At such time, the Company may appeal the delisting determination to a Nasdaq Hearings Panel. The Company would remain listed pending the Panel's decision. There can be no assurance that if the Company does appeal a subsequent delisting determination, that such appeal would be successful. The letter and notification from Nasdaq had no immediate effect on the listing or trading of the Company's shares, which will continue to trade on the Nasdaq Capital Market under the symbol "ADMP." We intend to monitor the closing bid price for our common stock and will consider available strategies in an effort to satisfy the minimum bid price requirement. However, there are no assurances that we will be able to regain compliance with the minimum bid price requirements or will otherwise be in compliance with other Nasdaq listing rules.

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 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 June 30, 2022, we had 149,983,265 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, 2022, we had reserved for issuance 4,861,142 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 $4.09 per share, we had outstanding restricted stock units covering 650,000 shares of common stock, and we had outstanding warrants to purchase 14,202,824 shares of common stock at a weighted-average exercise price of $1.17 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, 2022, 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, 2022, 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.

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

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

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

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, identify or discover material weaknesses in our internal control over financial reporting or fail to effectively remediate any identified material weaknesses, 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 our Quarterly Reports on Form 10-Q for the first three quarters of 2021, we identified material weaknesses 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. We believe that the identified weakness was remediated as of December 31, 2021. Nevertheless, any failure to effectively remediate an 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, as occurred with respect to our Quarterly Reports on Form 10-Q for the first three quarters of 2021, results in loss of eligibility to utilize short form registration statements on Form S-3 and prospectuses outstanding under previous registration statements not being current or available, which may impair our ability to obtain required capital in a timely manner or issue shares for other purposes, and may 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 take responsive actions to address identified material weaknesses in our internal control over financial reporting. However, we can give no assurance that such measures will remediate any material weakness that are 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. 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. We currently do not have key person life insurance policies covering any of our executive officers or key employees. The employment of Dennis J. Carlo, Ph.D., our former president and chief executive officer, was terminated in May 2022. 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. Any significant growth in the future could impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. Our future financial performance and our ability to compete effectively may 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

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

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

3.1	Certificate of Designation of Preferences, Rights, and Limitations of Series C Convertible Preferred Stock. (1)
3.2	Amended and Restated Bylaws. (2)
4.1	Common Stock Purchase Warrant dated July 5, 2022. (1)
10.1	Securities Purchase Agreement dated July 5, 2022, between the Company and the parties thereto. (1)
10.2	Registration Rights Agreement dated July 5, 2022, between the Company and the parties thereto. (1)
10.3	Executive Employment Agreement between the Company and David C. Benedicto dated as of June 22, 2022. (3)
10.4	Separation Agreement and Release dated as of May 18, 2022, between the Company and Dennis J. Carlo. (4)
10.5	Executive Employment Agreement between the Company and David J. Marguglio dated as of May 18, 2022. (4)
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 July 6, 2022.
(2) Incorporated by reference to exhibits filed with the Report on Form 8-K filed by the Company on June 17, 2022.
(3) Incorporated by reference to exhibits filed with the Report on Form 8-K filed by the Company on June 24, 2022.
(4) Incorporated by reference to exhibits filed with the Report on Form 8-K filed by the Company on May 19, 2022.

SIGNATURES

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

ADAMIS PHARMACEUTICALS, INC.

Date: August 10, 2022

By: /s/ David J. Marguglio
David Marguglio
Chief Executive Officer

Date: August 10, 2022

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

Exhibit 31.1

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

I, David J. Marguglio, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Adamis Pharmaceuticals Corporation;

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

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

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

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

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

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

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

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

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

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

Date: August 10, 2022

By: /s/ David J. Marguglio
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: August 10, 2022

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, David J. Marguglio, 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, 2022 (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 J. Marguglio
David J. Marguglio
Chief Executive Officer

Date: August 10, 2022

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, 2022 (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

Date: August 10, 2022

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.