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, 2023

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 16, 2023, was 9,359,133.

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, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents (including $135,287 and $0 associated with variable interest entity at June 30, 2023 and December 31, 2022, respectively)	$ 640,254	$ 1,081,364
Restricted Cash	30,090	30,068
Accounts Receivable, net	—	1,054,058
Receivable from Fagron	18,971	30,951
Inventories	664,358	1,238,778
Prepaid Expenses and Other Current Assets	658,119	1,884,015
Current Assets of Discontinued Operations	1,438,906	3,952,916
Total Current Assets	3,450,698	9,272,150
LONG TERM ASSETS		
Fixed Assets, net	1,142,869	1,288,894
Right-of-Use Assets	145,909	317,622
Other Non-Current Assets	9,674	52,174
Total Assets	$ 4,749,150	$ 10,930,840
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts Payable	$ 11,365,931	$ 7,937,493
Deferred Revenue, current portion (including $147,118 and $0 associated with variable interest entity at June 30, 2023 and December 31, 2022, respectively)	174,897	27,779
Accrued Other Expenses	2,200,716	1,510,053
Product Recall Liability	175,190	305,806
Lease Liabilities, Current Portion	157,246	342,562
Current Liabilities of Discontinued Operations	933,246	1,272,173
Total Current Liabilities	15,007,226	11,395,866
LONG TERM LIABILITIES		
Deferred Revenue, net of current portion	164,357	178,247
Warrant Liabilities, at fair value	1,072,893	7,492
Total Liabilities	16,244,476	11,581,605
COMMITMENTS AND CONTINGENCIES (Note 13)		
MEZZANINE EQUITY		
Convertible Preferred Stock - Par Value $0.0001; 10,000,000 Shares Authorized; Series C Preferred Stock 3,000 Shares Authorized, liquidation preference $110 per share; 3,000 Issued and Outstanding at June 30, 2023 and December 31, 2022, respectively	330,000	157,303
STOCKHOLDERS' DEFICIT		
Convertible Preferred Stock - Par Value $0.0001; 10,000,000 Shares Authorized; Series E Preferred Stock 1,941.2 Shares Authorized, Issued and Outstanding at June 30, 2023 and no Shares Authorized, Issued and Outstanding at December 31, 2022	—	—
Common Stock - Par Value $0.0001; 200,000,000 Shares Authorized; 2,797,865 and 2,150,051 Issued, 2,790,395 and 2,142,581 Outstanding at June 30, 2023 and December 31, 2022, respectively (1)	15,831	15,051
Additional Paid-in Capital	310,245,208	303,746,217
Accumulated Deficit	(322,081,115)	(304,564,086)
Treasury Stock - 7,470 Shares, at cost (1)	(5,250)	(5,250)
Total Stockholders' Deficit	(11,825,326)	(808,068)
Total Liabilities, Mezzanine Equity and Stockholders' Deficit	$ 4,749,150	$ 10,930,840

(1) See Note 1, *Reverse Stock Split*

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
REVENUE, net	$ 6,945	39,847	$ 1,459,945	$ 1,194,361
COST OF GOODS SOLD	361,394	689,178	2,149,461	2,152,760
Gross Loss	(354,449)	(649,331)	(689,516)	(958,399)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	4,033,083	4,205,934	8,815,168	7,588,630
RESEARCH AND DEVELOPMENT	376,957	3,320,654	1,687,486	7,542,179
ACQUIRED IN-PROCESS RESEARCH & DEVELOPMENT (IPR&D)	6,539,675	—	6,539,675	—
Loss from Operations	(11,304,164)	(8,175,919)	(17,731,845)	(16,089,208)
OTHER INCOME (EXPENSE)				
Interest Income	703	16,174	713	20,322
Interest Expense	(46,312)	—	(106,344)	—
Other Income/(Expense)	463,018	(257,832)	410,017	(697,832)
Gain/(Loss) on PPP2 loan	—	62,583	—	(1,787,417)
Excess of March 2023 Warrant Fair Value over Offering Proceeds	—	—	(2,476,109)	—
Change in Fair Value of Warrants	3,883,364	19,540	3,885,569	28,927
Total Other Income (Expense), net	4,300,773	(159,535)	1,713,846	(2,436,000)
Net Loss from Continuing Operations	(7,003,391)	(8,335,454)	(16,017,999)	(18,525,208)
DISCONTINUED OPERATIONS				
Net Loss from Discontinued Operations before Income Taxes	(1,570,731)	(61,767)	(1,499,030)	(226,628)
Income Taxes - Discontinued Operations	—	—	—	—
Net Loss from Discontinued Operations	(1,570,731)	(61,767)	(1,499,030)	(226,628)
Net Loss Applicable to Common Stock	$ (8,574,122)	$ (8,397,221)	$ (17,517,029)	$ (18,751,836)
Basic and Diluted Loss Per Share:				
Continuing Operations (1) Note 1	$ (2.79)	$ (3.89)	$ (6.81)	$ (8.66)
Discontinued Operations (1)	$ (0.61)	$ (0.03)	$ (0.63)	$ (0.11)
Basic and Diluted Loss Per share (1) Note 1	$ (3.40)	$ (3.92)	$ (7.44)	$ (8.77)
Basic and Diluted Weighted Average Shares Outstanding (1)	2,569,400	2,140,224	2,378,006	2,138,816

(1) See Note 1, *Reverse Stock Split*

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

ADAMIS PHARMACEUTICALS CORPORATION AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT

For the Three Months Ended June 30, 2023	(Mezzanine Equity) Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Additional Paid-In	Treasury Stock		Accumulated	Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares[1]	Amount	Capital	Shares[1]	Amount	Deficit	Total
Balance March 31, 2023	3,000	$157,303	—	—	2,385,765	$15,051	$ 303,815,511	7,470	$ (5,250)	$ (313,506,993)	$ (9,681,681)
Accretion of Series C Preferred Stock	—	172,697	—	—	—	—	(172,697)	—	—	—	(172,697)
Issuance of Series E Preferred Stock pursuant to DMK Merger	—	—	1,941.2	—	—	—	4,853,000	—	—	—	4,853,000
Issuance of Common Stock upon Exercise of Prefunded Warrants	—	—	—	—	107,142	750	524,379	—	—	—	525,129
Issuance of Common Stock upon Vesting of Restricted Stock Units (RSUs)	—	—	—	—	2,143	—	—	—	—	—	—
Issuance of Common Stock pursuant to DMK Merger	—	—	—	—	302,815	30	757,008	—	—	—	757,038
Assumption of DMK options pursuant to DMK Merger	—	—	—	—	—	—	415,809	—	—	—	415,809
Stock Based Compensation	—	—	—	—	—	—	52,198	—	—	—	52,198
Net Loss	—	—	—	—	—	—	—	—	—	(8,574,122)	(8,574,122)
Balance June 30, 2023	3,000	$330,000	1,941.2	—	2,797,865	$ 15,831	$ 310,245,208	7,470	$ (5,250)	$(322,081,115)	$ (11,825,326)
For the Six Months Ended June 30, 2023											
Balance December 31, 2022	3,000	$ 157,303	—	—	2,150,051	$ 15,051	$ 303,746,217	7,470	$ (5,250)	$ (304,564,086)	$ (808,068)
Accretion of Series C Preferred Stock	—	172,697	—	—	—	—	(172,697)	—	—	—	(172,697)
Issuance of Common Stock pursuant to the March 2023 Offering	—	—	—	—	235,714	—	—	—	—	—	—
Issuance of Series E Preferred Stock pursuant to DMK Merger	—	—	1,941.2	—	—	—	4,853,000	—	—	—	4,853,000
Issuance of Common Stock upon Exercise of Prefunded Warrants	—	—	—	—	107,142	750	524,379	—	—	—	525,129
Issuance of Common Stock upon Vesting of Restricted Stock Units (RSUs)	—	—	—	—	2,143	—	—	—	—	—	—
Issuance of Common Stock pursuant to DMK Merger	—	—	—	—	302,815	30	757,008	—	—	—	757,038
Assumption of DMK options pursuant to DMK Merger	—	—	—	—	—	—	415,809	—	—	—	415,809
Stock Based Compensation	—	—	—	—	—	—	121,492	—	—	—	121,492
Net Loss	—	—	—	—	—	—	—	—	—	(17,517,029)	(17,517,029)
Balance June 30, 2023	3,000	$ 330,000	1,941.2	—	2,797,865	$ 15,831	$ 310,245,208	7,470	$ (5,250)	$ (322,081,115)	(11,825,326)

(1) See Note 1, *Reverse Stock Split*

For Three Months Ended June 30, 2022	(Mezzanine Equity) Convertible Preferred Stock		Preferred Stock		Common Stock		Additional Paid-In	Treasury Stock		Accumulated	Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares (1)	Amount	Capital	Shares (1)	Amount	Deficit	Total
Balance March 31, 2022	—	$ —	—	$ —	2,146,480	$ 15,026	$304,330,933	7,470	$ (5,250)	$(288,440,428)	$ 15,900,281
Issuance of Common Stock upon Vesting of Restricted Stock Units (RSUs)	—	—			3,571	25	(25)				—
Stock Based Compensation	—	—	—	—	—	—	(460,917)	—	—	—	(460,917)
Net Loss	—	—	—	—	—	—	—	—	—	(8,397,221)	(8,397,221)
Balance June 30, 2022	—	$ —	—	$ —	2,150,051	$ 15,051	$303,869,991	7,470	$(5,250)	$(296,837,649)	$ 7,042,143
For the Six Months Ended June 30, 2022											
Balance December 31, 2021	—	$—	—	$ —	2,144,494	$ 15,012	$ 303,958,829	7,470	$ (5,250)	$ (278,085,813)	$ 25,882,778
Issuance of Common Stock upon Vesting of Restricted Stock Units (RSUs)	—	—	—	—	5,557	39	(39)	—	—	—	—
Stock Based Compensation	—	—	—	—	—	—	(88,799)	—	—	—	(88,799)
Net Loss	—	—	—	—	—	—	—	—	—	(18,751,836)	(18,751,836)
Balance June 30, 2022	—	$ —	—	$ —	2,150,051	$ 15,051	$ 303,869,991	7,470	$ (5,250)	$ (296,837,649)	$ 7,042,143

(1) See Note 1, *Reverse Stock Split*

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

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

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (17,517,029)	$ (18,751,836)
Less: Loss from Discontinued Operations	1,499,030	226,628
Adjustments to Reconcile Net Loss to Net		
Cash Used in Operating Activities:		
Acquired IPR&D	6,539,675	—
Stock Based Compensation	121,492	(88,799)
Receivable from Fagron	—	1,197,832
Provision for Excess and Obsolete Inventory	—	(29,003)
Excess of March 2023 Warrant Fair Value over Offering Proceeds	2,476,109	—
Change in Fair Value of Warrant Liability	(3,885,569)	(28,927)
Cash Payments in Excess of Lease Expense	(13,604)	(8,054)
Depreciation Expense	196,819	712,510
Change in Operating Assets and Liabilities:		
Accounts Receivable	1,054,058	815,565
Inventories	574,420	7,412
Prepaid Expenses and Other Current & Non-Current Assets	1,180,897	574,670
Accounts Payable (including $9,352 and $0 associated with variable interest entity for the six months ended June 30, 2023 and 2022, respectively)	2,972,657	532,465
Product Recall Liability	(130,616)	(1,398,520)
Deferred Revenue (including $147,118 and $0 associated with variable interest entity for the six months ended June 30, 2023 and 22, respectively)	(13,889)	(50,000)
Accrued Other Expenses (including $1,698 and $0 associated with variable interest entity for the six months ended June 30, 2023 and 22, respectively)	985,425	(262,764)
Net Cash Used in Operating Activities of Continuing Operations	(3,960,125)	(16,550,821)
Net Cash Used in Operating Activities in Discontinued Operations	(155,947)	(329,564)
Net Cash Used in Operating Activities	(4,116,072)	(16,880,385)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of Equipment	—	(381,167)
Cash Acquired in DMK Acquisition	136,089	—
Proceeds from Receivable from Fagron	11,980	2,930,554
Net Cash Provided by Investing Activities of Continuing Operations	148,069	2,549,387
Net Cash Provided by Investing Activities of Discontinued Operations	832,000	—
Net Cash Provided by Investing Activities	980,069	2,549,387
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from March 2023 Offering related to Common Stock Warrant	2,099,862	—
Proceeds from March 2023 Offering related to Prefunded Warrant	899,388	—
March 2023 Offering Issuance Costs	(275,000)	—
Proceeds from Exercise of Prefunded Warrant	750	—
Net Cash Provided by Financing Activities of Continuing Operations	2,725,000	—
Net Cash Provided by Financing Activities of Discontinued Operations	—	—
Net Cash Provided by Financing Activities	2,725,000	—
Decrease in Cash and Cash Equivalents and Restricted Cash	(411,003)	(14,330,998)
Cash and Cash Equivalents and Restricted Cash:		
Beginning Balance	1,111,432	23,250,793
Decrease in Cash and Restricted Cash from Discontinued Operations	(30,085)	(13,825)
Ending Balance	$ 670,344	$ 8,905,970

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

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

	Six Months Ended June 30,	
	2023	**2022**
RECONCILIATION OF CASH & CASH EQUIVALENTS AND RESTRICTED CASH		
Cash & Cash Equivalents	$ 640,254	$ 8,875,925
Restricted Cash	30,090	30,045
Total Cash & Cash Equivalents and Restricted Cash	$ 670,344	$ 8,905,970
SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING ACTIVITIES		
Liabilities of DMK assumed from DMK Merger	$ 157,461	
Issuance of common stock for DMK Merger	$ (757,038)	
Issuance of Series E preferred stock for DMK Merger	$ (4,853,000)	
DMK options assumed and replaced by Adamis in connection with the DMK Merger	$ (415,809)	
SUPPLEMENTAL DISCLOSURES OF NONCASH FINANCING ACTIVITIES		
Accretion of Series C Preferred	$ 172,697	

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 ("Adamis" or 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, 2022 (the "2022 Form 10-K").

Reverse Stock Split

Effective May 22, 2023, the Company effected a 1-for-70 reverse stock split of its outstanding common stock (the "Reverse Stock Split"). Pursuant to the Reverse Stock Split, every 70 shares of issued and outstanding common stock were automatically combined into one share of common stock, without any change in the par value per share. The Company did not issue any fractional shares in the Reverse Stock Split. In lieu of such fractional shares, any stockholder of record who would otherwise be entitled to a fractional share of common stock as a result of the Reverse Stock Split (after taking into account all fractional shares of common stock otherwise issuable to such stockholder) was entitled to receive a cash payment (without interest) equal to the fair market value of the fraction to which such holder would otherwise be entitled multiplied by the fair market value of the common stock as determined by the Board of Directors. The number of authorized shares of common stock under the Company's restated certificate of incorporation remained unchanged at 200,000,000 shares. Unless otherwise indicated, share numbers, per share data and earnings per share data throughout this Report have been recast to reflect the Reverse Stock Split.

DMK Merger

On February 24, 2023, the Company entered into an Agreement and Plan of Reorganization (the "Merger Agreement") with DMK Pharmaceuticals Corporation ("DMK"), a privately-held New Jersey corporation focused on the development and commercialization of potential products for the treatment of a variety of neuro-based disorders, and Aardvark Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Adamis ("Merger Sub"). The Merger Agreement provided for the merger (the "Merger") of DMK with and into Merger Sub, with Merger Sub surviving as a wholly-owned subsidiary of Adamis.

On May 25, 2023, following a special meeting of stockholders of the Company, the Merger was completed in accordance with the terms of the Merger Agreement. In connection with the Merger, the name of Merger Sub as the surviving corporation was changed to DMK Pharmaceuticals Corporation.

As a result of the consummation of the Merger, and after giving effect to the Reverse Stock Split, effective at the effective time of the Merger (the "Effective Time"), the shares of DMK common stock then outstanding were canceled and automatically converted into and became the right to receive a total of 302,815 shares of Adamis common stock and, with respect to certain former DMK stockholders, 1,941.2 shares of Series E Convertible Preferred Stock ("Series E Preferred") of the Company. The Series E Preferred is convertible into shares of Adamis common stock at a conversion rate of 1,000 common shares for 1 Series E Preferred share (subject to beneficial ownership limitations of 9.99%). Based on the limited exception under ASC 480-10-S99-3A(3)(f) for equity instruments that are subject to a deemed liquidation provision if all of the holders of equally and more subordinated equity instruments of the entity would always be entitled to also receive the same form of consideration (for example, cash or shares) upon the occurrence of the event that gives rise to the redemption (that is, all subordinate classes would also be entitled to redeem), the Company determined that the Series E Preferred should be classified as permanent equity. Additionally, based on the accounting guidance per ASC 260-10-45-40 as the Series E Preferred receive no preferred dividends, there is no adjustment to the numerator for the calculation of diluted EPS and under the guidance of ASC 260-10-45-4, and the Series E Preferred common stock equivalents are not included in the calculation of diluted EPS as this would be anti-dilutive (since the Company generates net losses).

Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that conditions of the grant have been met. Cash received from grants in advance of incurring qualifying costs is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred Revenue and a corresponding grants receivable are recorded when qualifying costs are incurred before the grants are received.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Adamis and its wholly-owned and controlled subsidiaries, DMK (a variable interest entity wherein the Company is the primary beneficiary) and US Compounding, Inc (a discontinued operation). All intercompany accounts and transactions have been eliminated.

Variable Interest Entity

The purpose of DMK is to expand the Company's potential product pipeline. The Company intends to focus on developing therapies with novel mechanisms of action to treat conditions, including substance abuse disorders.

The Company has 100% ownership of DMK. In the event DMK requires additional funding to support its operations, the Company would provide such financial support; and any benefits from the development of any of the potential product candidates would be realized by the Company. Additionally, as with any product development program there are risks that could materially impact the Company's financial condition negatively. Conversely, positive outcomes during product development and/or achieving regulatory approval on a product or drug could materially impact the Company's financial condition positively. See Note 2, DMK Merger for additional information regarding the VIE.

Assets recognized as a result of consolidating DMK do not represent additional assets that could be used to satisfy claims against the Company's general assets. Cash specifically must be utilized based on the specific terms of the respective grant in which the monies were received; and any unspent grant funds would be required to be returned at the end of the respective grant term. Conversely, liabilities recognized as a result of consolidating DMK do not represent additional claims of the Company's general assets; they represent claims against the specific assets of DMK.

Going Concern

The Company's cash and cash equivalents were $640,254 and $1,081,364 at June 30, 2023 and December 31, 2022, respectively.

The condensed consolidated financial statements were prepared under the assumption that the Company will continue 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 incurred substantial recurring losses from continuing operations, negative cash flows from operations, and is dependent on additional financing to fund operations. The Company incurred a net loss of approximately $8.6 million and $17.5 million for the three months and six months ended June 30, 2023, respectively. As of June 30, 2023, the Company had an accumulated deficit of approximately $322.1 million. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The 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 the Company be unable to continue in existence. On July 25, 2023, the Company closed a transaction involving the sale of a building and real property located in Conway, Arkansas, formerly utilized by our discontinued USC compounding pharmacy business, as well as certain related personal property equipment and assets and intellectual property, to an unaffiliated third-party purchaser, for total aggregate net proceeds of approximately $1.8 million. In addition, on August 4, 2023, the Company completed an offering of 4,800,000 shares of its common stock, 1,130,000 prefunded warrants and common stock purchase warrants to purchase up to 5,930,000 shares of its common stock and received net proceeds of approximately $7.0 million. The Company, however, has a substantial accounts payable balance at June 30, 2023 and will need additional funding to satisfy these obligations and future obligations and liabilities, sustain operations, and otherwise support the Company's operations and business activities and working capital needs. Management's plans include attempting to secure additional required funding through equity or debt financing if available, seeking to enter into a partnership or other strategic agreement regarding, or sales or out-licensing of, our commercial products, product candidates or intellectual property assets or other 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. There can be no assurance that we will be able to obtain required funding in the future. If the Company does not obtain required funding, the Company's cash resources will be depleted in the near term and the Company would be required to materially reduce or suspend operations, which would likely have a material adverse effect on the Company's business, stock price and our relationships with third parties with whom the Company have business relationships. If the Company does not have sufficient funds to continue operations, the Company could be required to seek bankruptcy protection, dissolution or liquidation, or other alternatives that could result in the Company's stockholders losing some or all of their investment in us. The Company has implemented expense reduction measures including, without limitation, employee headcount reductions and the reduction or discontinuation of certain product development programs. 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 the Company business, including the ability to raise capital when needed on acceptable terms, if at all. Additionally, the Company is not in compliance with certain listing standards of the Nasdaq National Market and there can be no assurance that the Company will be successful in curing the deficiencies and regaining compliance by the applicable cure dates. (See Note 10 for additional information).

Basic and Diluted Loss per Share

Under ASC 260, the Company is required to apply the two-class method to compute earnings per share or, EPS. Under the two-class method both basic and diluted EPS are calculated for each class of common stock and participating security considering both dividends declared (or accumulated) and participation rights in undistributed earnings. The two-class method results in an allocation of all undistributed earnings as if all those earnings were distributed. Considering the Company has generated losses in each reporting period since its inception through June 30, 2023, the Company also considered the guidance related to the allocation of the undistributed losses under the two-class method. The contractual rights and obligations of the preferred stock shares and the warrants were evaluated to determine if they have an obligation to share in the losses of the Company. As there is no obligation for the preferred stock shareholders or the holders of the warrants to fund the losses of the Company nor is the contractual principal or redemption amount of the preferred stock shares or the warrants reduced as a result of losses incurred by the Company, under the two-class method, the undistributed losses will be allocated entirely to the common stock securities.

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. Adjustments to the loss attributable to holders of common stock include accretion or decretion of equity and the Company has elected to treat the entire adjustment to the security's carrying amount as being akin to a dividend. During the three-months ended June 30, 2023, the Series C Preferred was accreted $172,697 to its full redemption value of $330,000. The numerator in calculating the loss attributable to the holders of common stock was adjusted as follows:

	Three Months Ended June 30, 2023	Six Months Ended June 30, 2023
Net loss	(8,574,122)	(17,517,029)
Accretion on Series C Preferred	(172,697)	(172,697)
Adjusted Net Loss	(8,746,819)	(17,689,726)

With regard to the Series E Preferred, as it receives no preferred dividends, there is no adjustment to the numerator for the calculation of diluted EPS and the Series E common stock equivalents are not included in the calculation of diluted EPS as this would be anti-dilutive (since the Company generates net losses). The diluted loss per share calculation is based on the if-converted method for convertible preferred shares and gives effect to dilutive if-converted shares and the treasury stock method and gives effect to dilutive options, warrants and other potentially dilutive common stock. The preferred stock, however, is not considered potentially dilutive due to the contingency on the conversion feature not being tied to stock price or price of the convertible instrument. The warrants are assumed to be settled in shares, and at each reporting period the Company will evaluate the combined effect of the adjustment to the numerator (assumed beginning of the period exercise) and inclusion of the warrants in the denominator, with the warrants included for the purposes of diluted EPS calculation if such effect is dilutive. The warrants were determined to be anti-dilutive. The common stock equivalents were anti-dilutive and were excluded from the calculation of weighted average shares outstanding.

Potentially dilutive securities, which are not included in diluted weighted average shares outstanding for the period ended June 30, 2023 and 2022, consist of the following:

	June 30, 2023	June 30, 2022
Outstanding Warrants	899,323	202,895
Outstanding Options	34,315	69,445
DMK Options assumed by Adamis	231,490	—
Outstanding Restricted Stock Units	7,143	9,286

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, noncurrent 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.

Assets classified as held for sale that are not sold after the initial one-year period are assessed to determine if they meet the exception to the one-year requirement to continue being classified as held for sale. The primary asset that is held for sale is the US Compounding, Inc. (USC) property, the sale of which closed in July 2023 - see Subsequent Events for further details.

Note 2: DMK Merger

On May 25, 2023, the Company completed the merger transaction with DMK. The Company determined that the acquired group, DMK, is a variable interest entity, or VIE, as DMK's total equity at risk is not sufficient to permit DMK to finance its activities without additional subordinated financial support. Additionally, DMK did not constitute a business because substantially all of the fair value of the gross assets acquired were concentrated in a single identifiable asset (DP-125). In accordance with FASB Accounting Standards Codification ("ASC") Topic 805 "Business Combinations", the consolidation of DMK (the VIE) is considered an asset acquisition. Additionally, the Company determined that the Company (Adamis) is the primary beneficiary (because Adamis holds 100% equity ownership in DMK, will receive the returns from DMK operations and is also obligated to absorb 100% of any losses) and is the legal acquirer (because Adamis obtains control of DMK). Based on applicable accounting guidance, the Company was required to record DMK's assets and liabilities at fair value. At acquisition date, based on the provisions provided by ASC Topic 730 "Research and Development", the Company elected to expense the purchase consideration allocated to the early-stage acquired in-process research and development (acquired IPR&D) because there is no alternative future use related to the acquired IPR&D, and, as such, no further impairment assessments would be necessary for these assets. The Company incurred approximately $1.4 million of transaction costs were recorded within selling, general and administrative expenses on the condensed consolidated statement of operations.

The fair value of the acquired IPR&D was determined based upon the income approach using a multi period excess earnings model which included a forecast of the expected cash flows of DPI-125. The discount rate associated with this forecast was 27%.

The purchase price, or total consideration transferred, to acquire DMK in the Merger was comprised of the following:

Fair Value of Adamis Common Stock issued to DMK shareholders	$	757,038
Fair Value of Adamis Series E Preferred issued to DMK shareholders		4,853,000
Fair Value of DMK options assumed and replaced by Adamis		415,809
DMK incurred Merger-related costs paid for by Adamis		492,456
Total Consideration Transferred	$	6,518,303

The fair value of the 302,815 shares of common stock issued in connection with the Merger is based on the closing price of the Company's common stock on the date of acquisition multiplied by the number of common shares issued.

The fair value of the 1,941.2 shares of Series E Preferred issued in connection with the Merger is based on inputs that are observable or can be corroborated by observable market data (the Company's closing stock price), and, as such, qualify as Level 2 measurement. The fair value of the Series E Preferred is based on the closing price of the Company's common stock on the date of acquisition multiplied by the number of common shares the Series E Preferred is convertible into (1,941,200). The same fair value basis as the Company's common stock was utilized for the Series E Preferred because the Series E Preferred have no preferences over common stock and the issuance of the Series E Preferred stock was merely a mechanism to consummate the Merger transaction.

Pursuant to the Merger agreement, at the effective time, the outstanding DMK stock options to purchase shares of DMK common stock were assumed by the Company and became options to purchase a total of 231,490 shares of Adamis common stock, with proportionate adjustments to the exercise prices per share of such options based on the exchange ratio determined pursuant to the Merger Agreement. The assumed options continue to be governed by the terms of the DMK 2016 Stock Plan, which was assumed by the Company in connection with the closing of the Merger. The assumed options were fully vested and the fair value of the replacement awards was treated as additional purchase price consideration paid by the Company.

The fair value of the replacement awards is based primarily on inputs that are observable or can be corroborated by observable market data (such as the Company's closing stock price and the published treasury par yield curves from the US Department of the Treasury). The estimated fair value of the replacement options of $415,809 was calculated using the Black Scholes Option Pricing Model. Key inputs at the date of closing, include expected volatility of 119.5% based on a 50/50 weighting of calculated volatility of the Company stock of approximately 107% (based on calculated volatility) and DMK's implied volatility of 132%, the Company's stock price on the date of closing of $2.50, expected dividend yield of 0.0%, expected term ranging from 2.37 years to 4.37 years and average risk-free interest rate (based on the published treasury par yield curves from the US Department of Treasury) of approximately 4.06%.

The allocation of the total purchase price is estimated as follows:

Assets Acquired:		
Cash	$	136,089
Total assets acquired		136,089
Liabilities Assumed:		
Accounts Payable		30
Due to Related Party		1,698
Accrued Expenses		8,615
Deferred Grant Revenue		147,118
Total liabilities assumed		157,461
Net Liabilities acquired		(21,372)
Acquired IPR&D		6,539,675
Total Purchase Price	$	6,518,303

Note 3: Discontinued Operations and Assets Held for Sale

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.

In August 2021, the Company entered into a purchase agreement with Fagron Compounding Services, LLC ("Fagron") to sell to Fagron certain assets of USC, related to its 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. Fagron made monthly payments to the Company based on formulas related to the amounts actually collected by Fagron or its affiliates for sales of products or services made through July 30, 2022. As of June 30, 2023, the total amount received in connection with this purchase agreement was approximately $5.5 million. At June 30, 2023, the remaining receivable from Fagron was approximately $19,000.

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:

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

	June 30, 2023	December 31, 2022
Cash and Cash Equivalents	$ —	$ 30,085
Fixed Assets, held for sale	5,747,590	6,719,252
Other assets	5,407	5,407
Loss recognized on classification as held for sale	(4,314,091)	(2,801,828)
Total assets of the disposal group classified as held for sale in the statement of financial position	$ 1,438,906	$ 3,952,916
Carrying amounts of major classes of liabilities included as part of discontinued operations		
Accounts Payable	$ 665,753	$ 649,633
Accrued Other Expenses	67,459	75,602
Lease Liabilities	200,034	243,008
Contingent Loss Liability	—	50,000
Other Current Liabilities	—	208,000
Deferred Tax Liability	—	45,930
Total liabilities of the disposal group classified as held for sale in the statement of financial position	$ 933,246	$ 1,272,173

As of June 30, 2023, fixed assets held for sale are comprised of USC's land and building, which the Company had received an offer to purchase the land and building for $1,525,000. During the three-months ended June 30, 2023, an impairment charge of $1.5 million (inclusive of broker commissions) was recorded in the statement of operations, under discontinued operations, to bring the carrying value of the USC property down to its net sales price. On July 25, 2023, the sale of the USC property closed and the Company received net proceeds of approximately $1,419,000. Additionally, the Company received an offer to purchase previously impaired USC equipment with a carrying value of $0 at a purchase price of $475,000. On July 25, 2023, net proceeds of approximately $349,000 were received related to the sale of USC equipment.

In January 2023, the Company received approximately $832,000 relating to the completion of the sale of certain fixed assets to a third party. This amount plus the $208,000 of earnest money received as a deposit in December 2022 (previously recorded as other current liability), resulted in the recognition of a gain of approximately $68,000 which was recorded as a gain on sale of fixed assets in discontinued operations as of March 31, 2023.

As of June 30, 2023, the outstanding liabilities related to the contract termination costs recorded in contingent loss liability of discontinued operations was $0 as the Company paid $50,000 in January 2023, pursuant to a settlement agreement. Additionally, the remaining deferred tax liability related to indefinite lived assets and state deferred tax liabilities was adjusted to $0.

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

Major line items constituting pretax loss of discontinued operations	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022
Selling, General and Administrative Expenses	$ (62,969)	$ (91,911)
Impairment Expense	(1,512,263)	—
Other Income	4,501	8,614
Gain from asset disposal	—	21,530
Loss from discontinued operations before income taxes	(1,570,731)	(61,767)
Income tax benefit	—	—
Loss from discontinued operations after income taxes	$ (1,570,731)	$ (61,767)

Major line items constituting pretax loss of discontinued operations	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Selling, General and Administrative Expenses	$ (62,924)	$ (264,383)
Impairment Expense	(1,512,263)	—
Other Income	7,818	8,625
Gain from asset disposal	68,339	29,130
Loss from discontinued operations before income taxes	(1,499,030)	(226,628)
Income tax benefit	—	—
Loss from discontinued operations after income taxes	$ (1,499,030)	$ (226,628)

Note 4: 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

The Company's commercial products include: ZIMHI® (naloxone HCL Injection, USP) 5 mg/0.5 mL, which was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of opioid overdose; SYMJEPI® (epinephrine) Injection 0.3mg, which was approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis, for patients weighing 66 pounds or more; and SYMJEPI (epinephrine) Injection 0.15mg, which was approved by the FDA for use in the treatment of anaphylaxis for patients weighing 33-65 pounds.

Exclusive Distribution and Commercialization Agreement for SYMJEPI™ and ZIMHI™ with US WorldMeds ("USWM")

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 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.

The Company has 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 multiple performance obligations in the contract which are the following: the manufacture and supply of SYMJEPI™ and ZIMHI™ products to USWM, the license to distribute and commercialize SYMJEPI™ and ZIMHI™ products in the United States and the clinical development of ZIMHI™.

The Company utilized significant judgement to develop estimates of the stand-alone selling price for each distinct performance obligation based upon the relative stand-alone selling price. The transaction price allocated to the clinical development of ZIMHI was immaterial.

Revenues from the manufacture and supply of SYMJEPI™ and ZIMHI™ are recognized at a point in time upon delivery to the carrier. The licenses to distribute and commercialize SYMJEPI™ and ZIMHI™ products in the United States is distinct from the other performance obligations identified in the arrangement and has stand-alone functionality; the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to benefit from the license.

Payments received under USWM Agreement may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements and net-profit sharing payments based on certain percentages of net profit generated from the sales of products over a given quarter. At the inception of arrangements that include milestone payments, the Company uses judgement to evaluate whether the milestones are probable of being achieved and estimates the amount to include in the transaction price utilizing the most likely amount method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within the Company or the licensee's control, such as regulatory approvals are not included in the transaction price until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of development milestones and any related constraint and adjusts the estimate of the overall transaction price, if necessary. The Company recognizes aggregate sales-based milestones, and net-profit sharing as royalties from product sales at the later of when the related sales occur or when the performance obligation to which the sales-based milestone or royalty has been allocated has been satisfied. The amounts receivable from USWM have 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.

Deferred Revenue (Grant Revenue)

With the acquisition of DMK, the Company's DMK subsidiary has three grants that remain in progress:

March 9, 2022 New Jersey Small Business Innovation Research ("SBIR") and Small Business Technology Transfer ("STRR") Support Program grant. This is a $25,000 grant, with approximately $2,100 in deferred revenue at June 30, 2023.

July 28, 2022 New Jersey Commission on Science, Innovation and Technology ("CSIT") grant. This is a $150,000 grant, with approximately $120,000 in deferred revenue at June 30, 2023.

February 28, 2023 CSIT grant. This is a $25,000 grant, with approximately $25,000 in deferred revenue at June 30, 2023.

For the three- and six- months period ended June 30, 2023, no previously deferred grant revenue was recognized in the Company's condensed consolidated statement of operations related to the DMK grants.

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 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, 2023 and December 31, 2022, a liability of approximately $0.2 million and $0.3 million, respectively, associated with the recall is reflected in the balance sheet. Approximately, $29,000 and $56,000 in product recall costs were recorded in selling, general and administrative costs during the three months and six months ended June 30, 2023, respectively. Total product recall costs from inception of the recall through June 30, 2023, were approximately $2.6 million. 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. In February 2023, the Company received notice from the FDA that the FDA considers the voluntary recall of our SYMJEPI products to be terminated. Such notice does not preclude the FDA from taking action in the future related to the recall, and the Company remains responsible for compliance with applicable laws relating to the product and the recall.

Note 5: Inventories

Inventories at June 30, 2023 and December 31, 2022 consisted of the following:

	June 30, 2023	December 31, 2022
Finished Goods	$ —	$ 267,554
Work-in-Process	—	261,720
Raw Materials	664,358	709,504
Inventories	$ 664,358	1,238,778

There was no reserve for obsolescence as of June 30, 2023 and December 31, 2022.

Note 6: Fixed Assets, net

Fixed assets, net at June 30, 2023 and December 31, 2022 are summarized in the table below:

Description	Useful Life (Years)	June 30, 2023	December 31, 2022
Machinery and Equipment	3 - 7	$ 5,156,377	$ 5,209,575
Less: Accumulated Depreciation		(4,013,508)	(4,665,067)
Construction In Progress - Equipment		—	744,386
Fixed Assets, net		$ 1,142,869	$ 1,288,894

Depreciation expense for the three months ended June 30, 2023 and 2022 was approximately $87,000 and $368,000, respectively; and for the six months ended June 30, 2023 and 2022, depreciation expense was approximately $197,000 and $713,000, respectively.

Note 7: Debt

Second Draw Paycheck Protection Program (PPP) Loan (Second Draw PPP Loan)

On March 15, 2021, the Company entered into a Note (the "PPP2 Note") in favor of Arvest Bank (the "Bank"), as lender, 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 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"), and the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act enacted in December 2020. The Company applied for forgiveness of the PPP2 Loan and 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 $1,765,495, the amount forgiven, as other income in the third quarter of 2021. 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. 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.

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 PPP loans 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

See Note 10 below for additional information concerning certain matters relating to the Second Draw PPP Loan.

Note 8: Fair Value Measurement

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 carrying value of the Company's cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to the short-term nature of these items based on Level 1 of the fair value hierarchy.

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, 2023			
	Total	Level 1	Level 2	Level 3
Liabilities				
2020 Warrant Liability	$ 34	$ —	$ 34	$ —
March 2023 Common Stock Warrants	1,072,859	—	1,072,859	—
Total common stock warrants liabilities	$ 1,072,893	$ —	$ 1,072,893	$ —

The fair value measurement of the warrants issued by the Company in February 2020 ("2020 Warrant Liability") and March 16, 2023 Common Stock Warrant ("March 2023 Common Stock Warrants") are based on inputs that are observable or can be corroborated by observable market data (such as the Company's daily closing stock price and the published treasury par yield curves from the US Department of the Treasury), and, as such, qualify as Level 2 measurement. The Company's estimated fair value of the warrant liabilities was calculated using the Black Scholes Option Pricing Model. Key inputs at June 30, 2023 include the expected volatility of the Company's stock ranging from approximately 70% - 110.32%, the Company's stock price at valuation date of $2.41, expected dividend yield of 0.0%, expected term ranging from 2.18 to 5.21 years (with the weighted average term at 5.19) and average risk-free interest rate ranging from 4.117% - 4.839% (with the weighted average risk-free rate as 4.122%).

	Fair Value Measurements at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Liabilities				
2020 Warrant Liability	$ 7,492	$ —	$ 7,492	$ —

The fair value measurement of the warrants issued by the Company in February 2020 are based on inputs that are observable or can be corroborated by observable market data (such as the Company's daily closing stock price and the published treasury par yield curves from the US Department of the Treasury), and, as such, qualify as Level 2 measurement. The Company's estimated fair value of the warrant liabilities was calculated using the Black Scholes Option Pricing Model. Key inputs at December 31, 2022 include the expected volatility of the Company's stock of approximately 70% (based on calculated volatility and management's judgement), the Company's stock price at valuation date of $l1.90, expected dividend yield of 0.0%, expected term of 2.68 years and average risk-free interest rate (based on the published treasury par yield curves from the US Department of Treasury) of approximately 4.362%.

The following table sets forth a summary of changes in the fair value of the Company's liability-classified warrants that are measured at fair value on a recurring basis:

	2020 Warrants		March 2023 Prefunded Warrants		March 2023 Common Stock Warrants		
	Number of Warrants[(1)]	Liability	Number of Warrants	Liability	Number of Warrants[(1)]	Liability	Total
Balance at December 31, 2022	5,000	$ 7,492	—	$ —	—	$ —	$ 7,492
March 2023 Offering	—	—	107,142	899,388	685,715	4,575,971	5,475,359
Change in Fair Value, three months-ended March 31, 2023	—	(4,900)	—	—	—	2,695	(2,205)
Balance at March 31, 2023	5,000	2,592	107,142	899,388	685,715	4,578,666	5,480,646
May 2023 Exercise	—	—	(107,142)	(524,389)	—	—	(524,389)
Change in Fair Value, three months-ended June 30, 2023	—	(2,558)	—	(374,999)	—	(3,505,807)	(3,883,364)
Balance at June 30, 2023	5,000	$ 34	—	$ —	685,715	$ 1,072,859	$ 1,072,893

(1) Recast to reflect the 1 for 70 reverse stock split

Note 9: Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets at June 30, 2023 and December 31, 2022:

	June 30, 2023	December 31, 2022
Employee Retention Credit	$ —	$ 875,307
Prepaid Insurance	67,697	323,143
Prepaid - Research and Development	345,894	588,354
Other Prepaid	139,075	78,590
Other Current Assets	48,360	18,621
	$ 601,026	$ 1,884,015

Employee Retention Credit

The Company applied for the Employee Retention Credit (ERC) which was available under the CARES Act. The ERC is a fully refundable tax credit for employers equal to 50 percent of qualified wages (including allocable qualified health plan expenses) that eligible employers paid their employees. The ERC applied to wages paid after March 12, 2020 and before January 1, 2021. The Company received the full amount from the original ERC from the Department of Treasury in January 2023. The Company amended its ERC application due to its repayment of the PPP loans (discussed in Note 7) and was subsequently awarded an additional refund approximately $463,000, which the Company received in full as of June 30, 2023, and was recorded in the condensed consolidated statement of operations as other income.

Note 10: Legal Matters

The Company may from time to time become party to actions, claims, suits, investigations or proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, breach of contract claims, labor and employment claims 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, 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. The Company has also received requests from the Securities and Exchange Commission ("SEC") that the Company voluntarily provide documents and information in connection with the SEC's investigation relating to certain matters including matters arising from the subject matter of the subpoenas from the USAO. The Company has produced 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 and the SEC, and has continued to engage in communications with the SEC and USAO regarding their investigations. We have received additional requests for production of documents from the SEC and the USAO, have responded to those requests, could receive additional requests from the USAO, SEC, or other authorities, and continue to engage in communications with the SEC and the USAO regarding their investigations. Additional issues or facts could arise or be determined, which may expand the scope, duration, or outcome of the investigation. We are unable to predict the duration, scope, or final outcome of the investigations by the USAO, SEC, or other agencies; what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate; what penalties, payments, by the Company, remedies or remedial measures the USAO, SEC, or other federal or state authorities may seek or may require in order to resolve the investigations; what, if any, impact the foregoing matters may have on the Company's business, financial condition, previously reported financial results, financial results included in this Report, or future financial results; or what proceedings the USAO, SEC, or other federal or state authorities may initiate if the foregoing matters are not resolved. However, in connection with resolution of these matters, we or our USC subsidiary may be found to have violated one or more laws arising from the subject matter of the subpoenas, and to resolve the matters and investigations with the USAO and the SEC we may be required to pay material amounts in penalties or other payments, and to agree to other remedies or remedial measures. Payment of material amounts in connection with resolution of the foregoing matters would reduce the amount of financial resources that we have available to support our product development programs and commercialization activities and would adversely impact our development programs. Depending in part on the amount and timing of any payments that we may be required to make or other remedial measures that may be implemented in connection with resolution of these matters, a resolution of these matters with the USAO or SEC could have a material and adverse impact on the company. The foregoing matters have diverted and will likely continue to divert management's attention, have caused the company to suffer reputational harm, have required and will continue to require the company to devote significant financial resources, could subject the company, one or more of its subsidiaries, or its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, could result in fines, penalties, payments, or financial remedies in amounts that would have a material adverse effect on our financial condition, or equitable remedies, and adversely affect the company's business, previously reported financial results, financial results included or incorporated by reference herein, or future financial results.

Nasdaq Compliance

On December 28, 2022, the Company was notified by the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") that, based upon the Company's non-compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) (the "Rule") as of December 27, 2022, the Company's common stock was subject to delisting unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company timely requested a hearing before the Panel, and a hearing was held on February 16, 2023. On February 21, 2023, the Staff notified the Company that the Panel had granted the Company's request for continued listing of the Company's common stock on the Nasdaq Stock Market and an extension until June 26, 2023 (the "Compliance Period") to regain compliance with the continued listing requirements for The Nasdaq Capital Market, including the minimum $1.00 bid price requirement of Nasdaq Listing Rule 5500(a)(2) (the "Rule"). We effected the Reverse Stock Split on May 22, 2023. On June 21, 2023, we received a communication from Nasdaq indicating that we demonstrated compliance with the requirements to remain listed on The Nasdaq Capital Market, as required by the Panel's February 21, 2023, decision, and that pursuant to Listing Rule 5815(d)(4)(B), we will be subject to a Mandatory Panel Monitor for a period of one year from the date of the communication. If, within that one-year monitoring period, the Staff finds us again out of compliance with the Rule, notwithstanding Rule 5810(c)(2) we will not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and Staff will not be permitted to grant additional time for the Company to regain compliance with respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Rule 5810(c)(3), and the Staff will instead issue a delist determination letter and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. At any such hearing, we will have the opportunity to respond/present to the Hearings Panel as provided by Listing Rule 5815(d)(4)(C). There can be no assurance that any such Panel or Hearing Panel would grant us additional time to regain compliance.

On April 12, 2023, we received a notice (the "Notice") from the Staff of Nasdaq, notifying us that for the last 30 consecutive business days, our minimum Market Value of Listed Securities ("MVLS") was below the minimum of $35 million required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "Market Value Standard"). The Notice is only a notification of deficiency, not of imminent delisting, and has no current effect on the listing or trading of our common stock on the Nasdaq Capital Market. Consequently, a deficiency exists with regard to the Nasdaq listing rules. In accordance with the listing rules, we will have 180 days, or until October 9, 2023, to either regain compliance with the Market Value Standard, or satisfy another listing criteria such as having a minimum shareholder equity of $2.5 million. To regain compliance with the Market Value Standard, the MVLS for our common stock must be at least $35 million for a minimum of 10 consecutive business days at any time during this 180-day period. If we regain compliance with an applicable listing standard, we anticipate that the Nasdaq Staff will provide us with written confirmation and will close the matter. If we do not regain compliance with the applicable listing standard by October 9, 2023, Nasdaq will provide notice that our securities are subject to delisting from the Nasdaq Capital Market. In the event of such notification, the Nasdaq rules permit us an opportunity to appeal Nasdaq's determination and request a hearing before a Hearing Panel. We intend to monitor both the MVLS and our shareholder equity between now and October 9, 2023, and may, if appropriate, evaluate available options to resolve the deficiency and regain compliance with the MVLS rule. However, there can be no assurance that we will be able to regain or maintain compliance with Nasdaq listing criteria in the future.

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. On April 4, 2022, the plaintiff filed a motion to amend the Complaint. The proposed amended Complaint added 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. Trial on the merits of the plaintiff's claims was held on March 16, 2023, and the case is under consideration by the Court. The Company believes the claims in the plaintiff's complaint are without merit and intends to vigorously dispute them. The Company has not recorded a contingent liability related to this matter.

On January 20 and March 27, 2023, the plaintiff filed motions for sanctions against the defendants, asserting among other things that the alleged conduct that the plaintiff argues supports his case on the merits is sanctionable. These motions are pending before the Court. The Company believes the claims in the plaintiff's motions are without merit and intends to vigorously dispute them.

Supplemental Proxy Disclosures

On April 11, 2023, a purported stockholder of Adamis filed a complaint against Adamis and each of its directors in the United States District Court for the Southern District of New York, captioned *Lapin vs. Adamis Pharmaceuticals Corporation*, Case No. 1:23-cv-03023 (the "Complaint"). The Complaint alleges that in connection with the special meeting of stockholders of the Company held to consider and vote upon certain matters relating to the DMK Merger transaction, the defendants violated Sections 14(a) and 20(a) of the Securities Exchange Act of 1934, as amended, by causing a materially incomplete and misleading Preliminary Proxy Statement to be filed with the SEC. Specifically, the Complaint alleges that the Preliminary Proxy Statement contains materially incomplete and misleading information concerning the sales process, financial projections prepared by Adamis management, as well as the financial analysis conducted by Raymond James & Associates, Inc., Adamis' financial advisor. The Complaint seeks, among other things, (i) injunctive relief preventing the consummation of the transactions contemplated by the Merger Agreement or the filing of a definitive proxy statement with the SEC or causing a definitive proxy statement to be disseminated to Adamis' stockholders unless and until the material information described in the Complaint is included in the definitive proxy statement or otherwise disseminated to Adamis' stockholders, and (ii) in the event that the Merger transaction is consummated without the alleged material omissions referenced in the Complaint being remedied, damages and costs and disbursements of the action including reasonable plaintiff's attorneys' and experts' fees and expenses. On July 6, 2023, the plaintiff filed a notice of voluntary dismissal, dismissing the claims in the complaint without prejudice, which was entered by the court on July 7, 2023.

In addition, the Company has received additional demand letters from counsel (the "Demand Letters"), each representing a purported stockholder of the Company, asserting that the Preliminary Proxy Statement and/or Proxy Statement was deficient and demanding that the alleged deficiencies be rectified. The Demand Letters allege, among other matters, that the Proxy Statements contain materially incomplete and misleading information concerning the sales process, financial projections prepared by the Company's management, and the financial analysis conducted by Raymond James & Associates, Inc. In addition, each purported shareholder has reserved his or her rights, including the right to alter or amend the demands at any time, and/or seek monetary damages following the consummation of the Merger.

The Company believed that the allegations in the Complaint and the Demand Letters are without merit and that the disclosures set forth in the Proxy Statement comply fully with applicable law. However, in order to moot the unmeritorious claims, avoid nuisance and possible expense and delay, and to provide additional information to our shareholders, the Company provided a voluntary supplement to the Proxy Statement with the supplemental disclosures filed with the SEC on May 5, 2023. Nothing in the Supplemental Disclosures shall be deemed an admission of the legal necessity or materiality under applicable laws of any of the disclosures set forth in the Supplemental Disclosures. To the contrary, the Company specifically denies all allegations that any additional disclosure was or is required. Nevertheless, resolution of these matters may involve payments by the Company to the parties submitting the Demand Letters or other claims.

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

Note 11: Equity Transactions

Common Stock Transactions:

DMK Merger:

Pursuant to the DMK Merger, 302,815 shares of Adamis common stock were issued on May 25, 2023, to former DMK shareholders. See Note 2 for further information on the DMK Merger.

March 2023 Offering:

On March 14, 2023, the Company entered into a Securities Purchase Agreement or, SPA, with an investor providing for the purchase and sale of (i) an aggregate of 235,714 shares (the "Shares") of common stock, at a price of $8.75 per Share, (ii) a warrant to purchase up to an aggregate of 685,714 shares of our common stock at an exercise price of $9.66 per share (the "Common Stock Warrant"), and (iii) a prefunded warrant at a price of $8.74 per share to purchase up to an aggregate of 107,143 shares of our Common Stock (the "Prefunded Warrant" and, collectively with the Common Stock Warrant, the "Warrants"), which represents the per share price for the Shares less the $0.0007 per share exercise price for the Prefunded Warrant, pursuant to a previously filed and effective registration statement in a registered direct offering (the "March 2023 Offering"). Gross proceeds from the March 2023 Offering were approximately $3.0 million, before deducting offering expenses of approximately $0.3 million.

The Prefunded Warrant is immediately exercisable and will expire five years from the date of issuance. The Common Stock Warrant is exercisable on or after the six month and one day anniversary of the date of issuance and will expire five years and six months from the date of issuance. If the Company fails to deliver any shares of Common Stock issuable upon exercise of the Warrants (the "Warrant Shares"), the Warrants (i) require us to make "buy-in" payments and (ii) subject us to certain degrees of liquidated damages for each $1,000 of Warrant Shares subject to such exercise. The exercise price and number of Warrant Shares issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Common Stock.

The Warrants holder (together with its affiliates) may not exercise a (i) Common Stock Warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, up to 9.99%) of the outstanding Common Stock immediately after exercise (the "Beneficial Ownership Limitation"), except that upon at least 61 days' prior written notice from the holder to us, the holder may increase the amount of the Beneficial Ownership Limitation up to 9.99%, as such ownership percentage is determined in accordance with the terms of the Common Stock Warrant, or (ii) Prefunded Warrant to the extent that the holder would own more than 9.99% of the outstanding Common Stock immediately after exercise. No fractional shares of Common Stock will be issued in connection with the exercise of a Warrant. In lieu of fractional shares, we will pay the holder the cash value of any fractional shares otherwise issuable. If at the time of exercise of a Warrant, there is no effective registration statement registering the shares of Common Stock underlying the Warrant, such Warrant may be exercised on a cashless basis pursuant to its terms. Additionally, at the request of the holder following a change of control or certain other fundamental transactions, the Company or the successor entity, as the case may be, shall purchase the Warrant from the holder for an amount in cash equal to the Black Scholes Value (as defined in the Warrant). Due to this cash redemption feature, the Company determined that the Warrants should be classified as liabilities.

As the Warrants are liability-classified, the Warrants will be measured initially and subsequently at fair value each reporting period, with the changes in fair value recorded in the income statement.

At the closing of the Offering on March 16, 2023, the Company determined the fair value of the Warrants (based on the Black Scholes Option Pricing Model) was in excess of the proceeds and, as such, a day-one loss was recognized in earnings.

The following table provides the initial allocation of the March 2023 offering proceeds between the common stock and the Warrants issued:

	Allocation as of March 16, 2023
235,714 Common Stock Issued	$ —
107,142 Prefunded Warrant Issued	$ 899,388
685,714 Common Stock Warrant Issued	$ 4,575,971
Day 1 Loss due to Excess Warrant Fair Value	$ 2,476,109
Gross Proceeds	$ 2,999,250
Issuance Costs*	$ 275,000

* As the warrants are liability-classified, the issuance costs were expensed to SG&A in the condensed consolidated statement of operations.

In May 2023, the Prefunded Warrants were exercised in full, which resulted in recording approximately $375,000 in the condensed consolidated statement of operations as other income for the change in fair value during the period up until the exercise date. See Footnote 8 for the fair value of the remaining warrants at June 30, 2023.

Preferred Stock Transactions:

Series C Transaction:

On July 5, 2022, the Company entered into a private placement transaction with Lincoln Park Capital Fund, LLC, (or, "Lincoln Park") pursuant to which the Company issued an aggregate of 3,000 shares of Series C Convertible Preferred Stock, par value $0.0001 per share (the "Series C Preferred"), together with warrants (the "July Warrants") to purchase up to an aggregate of 10,714 shares of common stock of the Company, at an exercise price of $32.90 per share (subject to adjustment as provided in the July Warrants). Gross proceeds were $300,000, excluding transaction costs, fees and expenses of $15,000. The July Warrants become exercisable commencing January 3, 2023 and have a term ending on January 5, 2028.

Subsequent to the issuance of the Series C Preferred, in connection with the Company's 2022 annual meeting of stockholders, in September 2022 the Company's stockholders voted on a reverse stock split proposal, and the proposal was not approved. Pursuant to the Series C Preferred transaction agreements, the Company paid $15,000 to Lincoln Park resulting from the failure of the reverse stock split proposal to be approved at the meeting. With the approval of the Reverse Stock Split in May 2023 at the Company's special meeting of stockholders, redemption of the Series C Preferred is probable at June 30, 2023; and, although as of June 30, 2023, neither the holder nor the Company have elected to redeem the Series C Preferred, the Company recorded accretion of approximately $173,000 in the condensed consolidated statement of operations to reflect the Series C Preferred at the 110% redemption value.

DMK Merger:

Pursuant to the DMK Merger, 1,941.2 shares of Series E Preferred were issued to former DMK shareholders. The Series E Preferred is convertible into shares of Adamis common stock at a conversion rate of 1,000 common shares for 1 Series E Preferred share, and conversion is subject to certain beneficial ownership limitations. No Series E Preferred shares have been converted as of June 30, 2023. For information regarding the fair value of the Series E Preferred, refer to Note 2, DMK Merger.

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

The Company accounts for transactions in which the Company receives services in exchange for restricted stock units ("RSUs") or options to purchase common stock as stock-based compensation cost based on estimated fair value. 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.

At the Company's 2020 annual meeting of stockholders, the stockholders approved the Company's 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards, and other forms of equity compensation (collectively "stock awards"). In addition, the 2020 Plan provides for the grant of cash awards. The initial aggregate number of shares of common stock that may be issued initially pursuant to stock awards under the 2020 Plan is 2,000,000 shares. The number of shares of common stock reserved for issuance automatically increases on January 1 of each calendar year during the term of the 2020 Plan, commencing January 1, 2021, by 5.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares of common stock determined by the Company's board of directors before the start of a calendar year for which an increase applies. One of the provisions of the 2020 Plan is that no award may be granted, issued or made under the 2020 Plan until such time as the fair market value of the common stock has been equal to or greater than $210.00 per share (which figure has been adjusted to reflect the Reverse Stock Split) (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. In December 2022, the Board determined and resolved, that the 2020 Plan share reserve shall not be increased effective January 1, 2023, and that there shall not be any increase in share reserve for the 2023 year by virtue of the annual share reserve increase. No awards had been made pursuant to the 2020 Plan as of June 30, 2023.

The Company had a 2009 Equity Incentive Plan (the "2009 Plan"). The 2009 Plan terminated effective February 2019 and no new awards may be made under the 2009 Plan.

Stock Options

The following table summarizes the outstanding stock option activity for the six months ended June 30, 2023:

Non-Plan Awards:

	Non - Plan Awards[1]	Weighted Average Exercise Price[1]	Weighted Average Remaining Contract Life
Total Outstanding, as of December 31, 2022	1,857	$ 43.40	9.13 years
Total Outstanding as of June 30, 2023	1,857	43.40	6.63 years
Vested and Expected to Vest at June 30, 2023	1,131	43.40	6.63 years

(1) Recast to reflect the 1 for 70 reverse stock split

Non-plan awards are granted pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules, as a material inducement to the willingness of such person to join the Company as a non-officer employee, effective upon the effective date of Board of Director-approved resolutions to grant nonqualified stock options to such person (an inducement grant). Inducement grants, although granted outside of the Company's 2020 Plan, are subject to the terms and conditions set forth in that plan. The terms of inducement grants are generally the same as terms would be under the 2020 Plan, wherein the exercise price of the options is equal to the fair value of the Company's common stock at date of grant, with vesting commencing on date of grant, and a vesting schedule consisting of one-sixth (1/6) of the options becoming exercisable six (6) months after vesting commences, and one thirty-sixth (1/36) of the options on becoming exercisable each subsequent monthly anniversary of the vesting commencement date, such that the option is exercisable in full after three years from the vesting commencement date of the option grant, subject to the option holder providing continuous service.

As of June 30, 2023, the unamortized compensation expense related to non-plan awards was approximately $0.

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 all options outstanding at June 30, 2023 and December 31, 2022, was $0.

2009 Equity Incentive Plan:

	2009 Equity Incentive Plan[1]	Weighted Average Exercise Price[1]	Weighted Average Remaining Contract Life*
Total Outstanding Vested and Expected to Vest as of December 31, 2022	61,525	$ 291.41	2.09 years
Options Canceled/Expired	(29,068)	280.26	—
Total Outstanding and Vested as of June 30, 2023	32,457	306.44	3.00 years

(1) Recast to reflect the 1 for 70 reverse stock split

* Maximum contractual term for options is 10 years.

As of June 30, 2023, the unamortized compensation expense related to 2009 Plan awards was approximately $0.

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 all options outstanding at June 30, 2023 and December 31, 2022 was $0.

DMK Options Assumed

Pursuant to the Merger Agreement with DMK, the Company assumed the outstanding options of DMK. Based on the conversion mechanism in the Merger Agreement, the Company assumed 231,490 options with an exercise price of $2.90. The assumed options were fully vested and will continue to be governed by the terms of the DMK 2016 Stock Plan, which was assumed by the Company in connection with the closing of the Merger. Additionally, the assumed options were converted into an equivalent option to acquire shares of Adamis common stock.

Restricted Stock Units

The following table summarizes the RSUs outstanding at June 30, 2023:

	Number of Shares/Unit[1]	Weighted Average Grant Date Fair Value[1]
Non-vested RSUs as of December 31, 2022	9,286	$ 325.13
RSUs vested during the period	(2,143)	592.20
RSUs forfeited during the period	—	—
Non-vested RSUs as of June 30, 2023	7,143	$ 245.00
RSUs expected to vest as of June 30, 2023	7,143	$ 245.00

(1) Recast to reflect the 1 for 70 reverse stock split

The RSU's have cliff vesting after seven years of continuous service or upon change of control from date of grant or upon death or disability.

As of June 30, 2023, the unamortized compensation expense related to RSUs was approximately $67,000 and will be recognized over 0.67 years.

Total Stock-Based Compensation:

The following summarizes stock-based compensation recognized as research and development costs or, R&D, and selling, general and administrative costs or, SG&A, for the three months ended June 30, 2023 and 2022:

	June 30, 2023	June 30, 2022
R&D	$ —	$ (768)
SG&A	52,198	(460,149)
Total Stock-based Compensation	$ 52,198	$ (460,917)

The following summarizes stock-based compensation recognized as R&D and SG&A for the six months ended June 30, 2023 and 2022:

	June 30, 2023	June 30, 2022
R&D	$ —	$ 119,092
SG&A	121,492	(207,891)
Total Stock-based Compensation	$ 121,492	$ (88,799)

Warrants

The following table summarizes warrants outstanding at June 30, 2023:

	Warrant Shares[1]	Exercise Price Per Share[1]	Date Issued	Expiration Date
Old Adamis Warrants	840	$ 595.00	November 15, 2007	November 15, 2023
2019 Warrants	197,055	$ 80.50	August 5, 2019	August 5, 2024
2020 Warrants*	5,000	$ 49.00	February 25, 2020	September 3, 2025
Series C Preferred Warrants	10,714	$ 32.90	July 5, 2022	January 5, 2028
Common Stock Warrants*	685,714	$ 9.66	March 16, 2023	September 16, 2028
Total Warrants	899,323			

(1) Recast to reflect the 1 for 70 reverse stock split
* See Note 8 for the fair value of warrants which are liability classified.

Shares Reserved

At June 30, 2023, 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 (1)	899,323
Restricted Stock Units (1)	7,143
Non-Plan Awards (1)	1,858
2009 Equity Incentive Plan (1)	32,457
DMK Options Assumed by Adamis	231,490
Total Shares Reserved	1,172,271

(1) Recast to reflect the 1 for 70 reverse stock split

Note 13: Commitments and Contingencies

Maintenance Fees

The Company has a production threshold commitment to a manufacturer of our SYMJEPI Products where the Company would be required to pay for maintenance fees if it does not meet certain periodic purchase order minimums. Any such maintenance fees would be prorated as a percentage of the required minimum production threshold. Maintenance fees for the three- and six- months ended June 30, 2023 and 2022 were approximately $269,000 and $0 and $538,000 and $0, respectively, and were recorded as cost of sales in the condensed consolidated statement of operations.

Firm Purchase Commitments

The Company also has firm purchase commitments to a manufacturer of our SYMJEPI products based on rolling forecasts where a portion of the forecast represents binding orders and the remaining portion non-binding. For the six-months ended June 30, 2023 and 2022, there were no purchases under firm purchase commitments.

Contingent Lease Loss Liability

The Company is party to a lease agreement pertaining to certain real property located in Conway, Arkansas. The Company granted access rights to said property to a third party (“Accessee”) for a specified time period. The specified time period has lapsed and the Accessee remains on the premises of the said property. The Accessee claims to have purchased the said property and to be the “New Landlord”. The New Landlord’s legal counsel has sent a demand letter to the Company for repair work that it has undertaken at the premises. The Company has not been provided any evidence that the New Landlord is in fact the valid successor landlord under the Company’s lease agreement pertaining to the property. The Company’s legal counsel has responded to the demand letter stating there is no evidence of the New Landlord as a valid successor under the lease agreement, that the New Landlord breached the lease agreement as the Company was not provided first right of refusal as contemplated by the lease agreement and that only $53,000 of the approximately $1.4 million in alleged repairs undertaken fall under the responsibility of the tenant. The Company has not made a formal offer to pay for any repairs. However, because the demand letter has been presented and the Company acknowledges some repairs undertaken would be a tenant responsibility, the Company has accrued the minimum amount of loss per the range of loss as of June 30, 2023. The $53,000 accrual is included in accrued expenses in the condensed consolidated balance sheet. As of June 30, 2023, no settlement has been reached.

Note 14: Subsequent Events

On July 19, 2023, the Company entered into a purchase and sale agreement (the “Building Agreement”) to sell the building and real property located in Conway, Arkansas, formerly utilized by the Company’s discontinued compounding pharmacy business, to an unaffiliated third party purchaser ("Purchaser"). The Company also entered into a related agreement (the "Equipment Agreement") to sell to the Purchaser certain personal property assets and equipment located at the building and real property as well as certain related intellectual property assets. The total aggregate consideration for the real property under the Building Agreement and other assets under the Equipment Agreement were approximately $2.0 million before estimated commissions, fees and closing costs. On July 25, 2023, the closing of the transactions contemplated by the Building Agreement and Equipment Agreement occurred. Net proceeds of approximately $1.8 million were received by the Company.

On July 27, 2023, the Company received notice from the FDA that SYMJEPI 0.3 mg/0.3 mL qualified for an exception to an assessment of program free and, as such, the Company received a grant of $393,933 against fiscal year 2023's Prescription Drug Program Fee.

On August 4, 2023, the Company completed an offering of 4,800,000 shares of our Common Stock and 1,130,000 pre-funded warrants to purchase shares of Common Stock, and common stock purchase warrants to purchase up to 5,930,000 shares of our Common Stock, and received net proceeds of approximately $7.0 million after placement agent’s commissions and estimated offering expenses.

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

The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements and accompanying notes of the Company appearing elsewhere in this Quarterly Report on Form 10-Q (this "Report") and the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2022 (the "2022 Form 10-K"). Our financial results for the three- and six- months ended June 30, 2023, are not necessarily indicative of results that may occur in future interim periods or for the full fiscal year.

Information Relating to Forward-Looking Statements

This Report, and the discussion of our financial condition and results of operations, contain and include 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, 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 2022 Form 10-K, including without limitation the "Risk Factors" section in this Report and in the 2022 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 2022 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

On May 25, 2023, Adamis Pharmaceuticals Corporation ("we," "us," "our," "Adamis" or the "company") completed a merger transaction, or the Merger, with DMK Pharmaceuticals Corporation ("DMK") pursuant to an Agreement and Plan of Merger and Reorganization dated as of February 24, 2023, or the Merger Agreement, by and among DMK, Aardvark Merger Sub, Inc., a wholly-owned subsidiary of Adamis, and Adamis. Prior to the Merger, DMK was a privately-held, clinical stage biotechnology company focused on the development and commercialization of potential products for a variety of central nervous disorders. Pursuant to the Merger, each share of common stock of DMK was converted into the right to receive a number of shares of Adamis common stock and, in the case of certain DMK stockholders, shares of our Series E Convertible Preferred Stock, or Series E Preferred. Upon the closing of the Merger, Ebrahim (Eboo) Versi, M.D., Ph.D., the co-founder and chief executive officer of DMK, became the chairman and chief executive officer of Adamis, and David J. Marguglio, formerly the President, Chief Executive Officer and a director, continued as President and was also appointed Chief Operating Officer. Additionally, Aardvark Merger Sub, Inc. changed its name to DMK Pharmaceuticals Corporation, or DMK.

We are a specialty biopharmaceutical company focused on developing and commercializing products in the substance use disorder space including treatment of opioid use disorder. Our two commercial products are designed to treat opioid overdose and anaphylactic shock. The first is ZIMHI® (naloxone HCL Injection, USP) 5 mg/0.5 mL, which was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of opioid overdose, and the second is SYMJEPI® (epinephrine) Injection 0.3mg, which was approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis, for patients weighing 66 pounds or more, and SYMJEPI (epinephrine) Injection 0.15mg, which was approved by the FDA for use in the treatment of anaphylaxis for patients weighing 33-65 pounds. The foundation of our development pipeline is a proprietary portfolio of approximately 750 proprietary small molecule neuropeptide analogues. Our lead clinical-stage product candidate is for the treatment opioid use disorder and acute and chronic pain. The library also has the potential to generate other compounds for treatment of various substance use disorders and compounds for life cycle management and backup molecules.

Our US Compounding Inc. subsidiary, or USC, which we acquired in April 2016, is a discontinued operation, was previously 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, and 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.

To achieve our goals and support our overall strategy, we will need to raise additional funding to sustain operations, satisfy our obligations and liabilities and enable further product development.

Products and Product Candidates

Opioid Overdose*; *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 and eventually, death. Common opioids include morphine, heroin, tramadol, oxycodone, hydrocodone and fentanyl. Since the COVID-19 pandemic, the opioid crisis has become significantly worse, and this increase has disproportionately affected adolescents. According to Bloomberg industry data, the U.S. naloxone market grew by about 15% in 2022 and according to the December 31, 2022 Form 10-K of Emergent BioSolutions, Inc. filed in March 2023, sales of Narcan®, the leading naloxone product for treatment of opioid overdoses, were approximately $374 million for 2022.

The Centers for Disease Control and Prevention, or CDC, estimates that between 1999 and 2020 more than 932,000 people have died of drug overdoses, with annual deaths increasing during the COVID-19 pandemic. More recent statistics published by the CDC reported that drug overdoses resulted in approximately 107,081 deaths in the United States during the 12-month period ending December 2022, which was an approximately 51% increase over the approximately 71,030 deaths for the 12-month period ending December 2019. Overdose deaths involving opioids (including both prescription and synthetic) accounted for 81,045 of the overdose deaths in 2022 and are now the leading cause of death for Americans under age 50. More powerful synthetic opioids, like fentanyl and its analogues, are responsible for approximately 90% of those opioid deaths. These statistics are even more stark for adolescents according to the CDC. Comparing July-December 2019 to July-December 2021, overdose deaths among youngsters aged 10 to 19 years increased by 109% and in that same time period, deaths involving illicitly manufactured fentanyl increased by 182% in the same age group. In June 2021, the National Institute on Drug Abuse; National Institutes of Health; U.S. Department of Health and Human Services, published the policy brief, “Naloxone for Opioid Overdose: Life-Saving Science,” which reported that statistical modeling suggests that high rates of naloxone distribution among laypersons and emergency personnel could avert approximately 21% of opioid deaths. The brief also stated that overdoses involving highly potent synthetic opioids such as fentanyl or large quantities of opioids may require multiple doses of naloxone, and if respiratory function does not improve, naloxone doses may be repeated every two to three minutes. With the increasing prevalence of illicit fentanyl on the streets, we believe the need for ZIMHI as a product that results in rapid increase in higher blood levels of naloxone is becoming ever more important.

On October 18, 2021, we announced that the FDA had approved ZIMHI (naloxone hydrocholoride 5mg) for the treatment of opioid overdose, and it was commercially launched in the U.S. on March 31, 2022.

The results of a study sponsored by the FDA was recently presented by Dr. David Strauss, M.D., Ph.D. Dr. Straus at a virtual public meeting of the Reagan–Udall Foundation addressing fatal overdoses. Dr. Straus is the Director of the Division of Applied Regulatory Science at the Center for Drug Evaluation and Research. The current standard of care is a single intranasal 4mg dose of naloxone, as contained in Narcan. Given the fentanyl crisis, the investigators tested this single dose against two and four doses to reverse a simulated fentanyl overdose. They showed that the most effective reversal was achieved by four administrations of 4mg intranasal naloxone given within 2.5 minutes. We believe that this data from the FDA sponsored study suggests that rapid delivery of naloxone is necessary to help counter a fentanyl overdose and that a single administration of ZIMHI, based on its pharmacokinetic profile, could be an effective agent to counter a fentanyl overdose.

On July 28, 2023, we issued a press release announcing that we had committed to fund an unrestricted research grant to the Leiden University Medical Center Anesthesia and Pain Research Unit. The funding will support the work of Albert Dahan, MD, PhD, an expert on opioid-induced respiratory depression (opioid overdose) and professor of anesthesiology at the University. Dr. Dahan has been working with the FDA to understand better methods of reversing fentanyl overdoses. The objective of the work will be to assess the efficacy of the Company’s ZIMHI product compared to 4mg of intranasal naloxone, and the respective number of doses required to reverse fentanyl-induced respiratory depression.

Anaphylaxis; SYMJEPI; Epinephrine Injection Pre-Filled Single Dose Syringe

The American Academy of Allergy Asthma and Immunology, or AAAAI, defines anaphylaxis as a serious life-threatening allergic reaction. The most common anaphylactic reactions are to foods, insect stings, medications and latex. According to information published by AAAAI reporting on findings from a 2009-2010 study, up to 8% of U.S. children under the age of 18 had a food allergy, and approximately 38% of those with a food allergy had a history of severe reactions. Anaphylaxis requires immediate medical treatment, with epinephrine as the first course of treatment to open airways and maintain blood pressure.

We estimate that sales of prescription epinephrine products were more than approximately $1.75 billion in 2022, based on assumptions and estimates using industry data. While we cannot provide any assurances concerning whether annual prescription sales will decline or grow, we believe that the epinephrine market has the potential to grow in the future, based in part on the prevalence of medical conditions, such as anaphylaxis, cardiovascular diseases, respiratory diseases (asthma), and the increased awareness about the treatment options for the management of these diseases. The market for prescription epinephrine products is competitive. Our SYMJEPI (epinephrine) Injection 0.15mg and 0.3mg products allow users to administer a pre-measured epinephrine dose quickly with a device that we believe, based on human factors studies, to be intuitive to use.

On June 15, 2017, the FDA approved our SYMJEPI (epinephrine) Injection 0.3mg product for the emergency treatment of allergic reactions (Type I) including anaphylaxis. SYMJEPI (epinephrine) Injection 0.3mg is intended to deliver a dose of epinephrine, which is used for emergency, immediate administration in acute anaphylactic reactions to insect stings or bites, allergic reaction to certain foods, drugs and other allergens, as well as idiopathic or exercise-induced anaphylaxis for patients weighing 66 pounds or more. On September 27, 2018, the FDA approved our lower dose SYMJEPI (epinephrine) Injection 0.15mg product, for the emergency treatment of allergic reactions (Type I) including anaphylaxis in patients weighing 33 to 66 pounds. Our SYMJEPI injection products were fully launched in July 2019 by our then-commercialization partner Sandoz Inc. Our SYMJEPI products are currently marketed and sold by USWM, LLC, or USWM or US WorldMeds, with which we entered into an exclusive distribution and commercialization agreement, or the USWM Agreement, in May 2020 for the United States commercial rights for the SYMJEPI products, as well as for our ZIMHI product.

SYMJEPI is manufactured and tested for us by Catalent Belgium S.A. During Catalent's routine testing, a small number of syringes with clogged needles were identified. 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) due to the potential clogging of the needle preventing the dispensing of epinephrine. The recall was conducted with the knowledge of the FDA, and USWM handled the recall process for the Company, with Company oversight. As of the date of this Report, neither USWM nor we have received, nor are aware of, any adverse events related to this recall and in February 2023, the Company received notice from the FDA that the agency considers the voluntary recall of our SYMJEPI products to be terminated. Such notice does not preclude the FDA from taking action in the future related to the recall, and we remain responsible for compliance with applicable laws relating to the product and the recall. Catalent's investigation determined the steel used in a specific stainless steel needle batch as the root cause for the clogged syringes observed. The Company worked with Catalent to develop corrective and preventive actions. However, despite the corrective actions and sourcing syringes which used a different batch of steel for the needles, Catalent's attempt to resume manufacturing of SYMJEPI at its Belgium facility has resulted in similar product defects. Therefore, as of the date of this Report, the Company remains unable to manufacture product. While we are committed to returning SYMJEPI to the market, we will not do so until we are satisfied that sufficient corrective actions have been implemented to avoid a repeat of the circumstances which led to the voluntary recall. We are evaluating a range of options to restore SYMJEPI production, including a critical assessment of Catalent.

Product Candidates

As a result of our Merger with DMK, we acquired a library of approximately 750 novel small molecule neuropeptide analogues and a number of product candidates and technologies in development for opioid use disorder and other neuro-based disorders. We intend to focus on developing therapies with novel mechanisms of action to treat these important conditions where patients are currently underserved, including substance abuse disorders. We intend to develop mono, bi- and tri-functional small molecules that simultaneously modulate critical networks in the nervous system with the goal of creating treatments that are efficacious, safe, and tolerable and could address several unmet or underserved medical needs by taking the novel approach to integrate with the body's own efforts to regain balance of disrupted physiology. By designing small molecule analogs of neuropeptides, one or multiple receptors can be targeted by a single molecule to support a transition back to a balanced neurophysiological state.

Our lead clinical stage product candidate, DPI-125, is being developed as a potential novel treatment for opioid use disorder, or OUD. We also plan to study this compound for the treatment of moderate to severe pain, where it could potentially offer a product with competitive advantages compared to currently marketed opioids (pain killers) and hence help prevent opioid addiction. Other product candidates include DPI-221, for treating bladder control problems, and DPI-289 for treating severe end stage Parkinson's disease. We generally intend to focus on the development programs that target substance use disorder described above and to seek to out-license product candidates targeting indications outside of this focus.

DPI-125

DPI-125 is a small molecule that is currently being developed for two potential uses. The first is for the rapid stabilization of OUD patients actively using prescription or street opioids, including deadly fentanyl and its analogues. The second potential use is as a potent, acute analgesic, with a potentially reduced risk of respiratory depression and addiction compared to currently marketed opioids.

We have completed a human Phase 1 dose escalation study with DPI-125, and the pharmacokinetic data showed that the drug was well tolerated in the human study, with no serious adverse events, deaths or dropouts. The next anticipated development step, assuming available funding and no unexpected developments, will be human proof of concept studies, which will attempt to confirm what has been demonstrated in preclinical studies in terms of reduced or absent respiratory depression and abuse liability. Following these proof-of-concept studies, we believe that the next development step, assuming available funding and no unexpected developments, will be to proceed into Phase 2 trials for the treatment of OUD and acute pain, where the focus of the trials will not only be on efficacy, but also safety and tolerability. We believe that the same characteristics and mechanism of action that may make DPI-125 a useful product in the fight against addiction could also make it a significant alternative to currently marketed opioids used for treating pain.

DPI-221

DPI-221 is a small molecule as what we believe is a unique alternative to surgery for benign prostatic hyperplasia, or BPH, by reestablishing bladder control. BPH is a common problem with approximately six million men seeking treatment annually, with an estimated market size of approximately $5.4 billion annually in the United States. BPH is a common, chronic disease caused by an enlarged prostate. DPI-221 may offer a novel approach to the treatment of BPH by acting on the central nervous system to suppress abnormal activity without interfering with normal bladder function. In preclinical studies, DPI-221 was effective at reestablishing neural control of the bladder, which returns the bladder to more normal function, allowing coordinated bladder contractions and efficient voiding.

A first-in-human Phase 1 oral dose escalation study, showed that the drug was safe and tolerable in the study. There were no serious adverse events, deaths or study dropouts. The pharmacokinetic, or PK, characteristics have allowed planning of a proof-of-concept study, which, assuming available funding and no unexpected developments, is anticipated to be a human urodynamic study to determine the efficacious dose that will inform dosing in a subsequent Phase 2 study. We believe that if successfully developed, this medication could prevent or reduce the need for BPH surgery.

DPI-289

DPI-289, also a small molecule, has been developed to treat patients suffering from severe Parkinson's disease, or PD. Many of these patients will have been treated with a current leading treatment product called levodopa, or L-DOPA. Unfortunately, after a few years of treatment, the duration of effect is markedly curtailed (reduced "on-time") and patients can exhibit severe abnormal movements called levodopa induced dyskinesia, or LID, which make it difficult or impossible to lead a normal life. Preclinical studies have demonstrated DPI-289's ability to treat parkinsonian disability in rodent and non-human primate models to dramatically increase on-time without causing dyskinesia. Our initial goal with respect to this product candidate is to target patients late in their disease who require deep brain stimulation (DBS-brain surgery) to prevent such surgeries and also treat those patients who are not eligible for DBS. Given this target population, we plan to seek orphan drug status from the FDA and international regulatory agencies. Initially, assuming available funding and no unexpected developments, we intend to develop the compound as monotherapy, but we anticipate that future studies will examine its utility in PD patients as combination therapy with L-DOPA to increase "on-time" without increasing the debilitating side effect of dyskinesia.

We anticipate that the next step for this program, assuming adequate funding and no unexpected developments, will be to carry out IND-enabling toxicology studies to allow the filing of an Investigational New Drug Application, or IND, for the first in-person studies. If orphan drug status is conferred by the FDA or other international regulatory bodies, the cost and duration of the clinical development program may be significantly reduced, allowing for approval in an accelerated time frame.

Other

In June 2020, we entered into a license agreement with a third-party entity to in-license rights under patents, patent applications and related know-how of licensor relating to Tempol, an investigational drug. In September 2021 we commenced patient dosing in a Phase 2/3 clinical trial to examine the safety and efficacy of Tempol in COVID-19 patients. The Data Safety Monitoring Board, or DSMB, overseeing the Phase 2/3 clinical trial met in March and June 2022 to evaluate interim clinical and safety data and, following its evaluation, recommended that the study continue as planned. On September 21, 2022, we announced that the DSMB's third interim analysis of the Phase 2/3 clinical trial, which was the first interim review where the DSMB evaluated the primary efficacy endpoint, determined that the trial did not achieve its primary endpoint and recommended that the study be halted early due to lack of efficacy. Based on the recommendation from the DSMB, we halted the trial and stopped all further development of Tempol in October 2022.

Going Concern and Management Plan

The financial statements included elsewhere herein for the three and six months ended June 30, 2023, were prepared under the assumption that we would continue our operations as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. However, as of June 30, 2023, we had cash and cash equivalents of approximately $0.6 million, an accumulated deficit of approximately $322.1 million, and liabilities of approximately $16.2 million. 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. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued. 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, seeking to enter into a partnership or other strategic agreement regarding, or sales or out-licensing of, our commercial products, product candidates or intellectual property assets or other assets including assets held for sale related to our former USC business, 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. There can be no assurance that we will be successful in obtaining required funding. If we do not obtain required funding, our cash resources will be depleted in the near term and we would 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. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection, dissolution or liquidation, or other alternatives that could result in our stockholders losing some or all of their investment in us. We have implemented expense reduction measures including, without limitation, employee headcount reductions and the reduction or discontinuation of certain product development programs.

Results of Operations

Our consolidated results of operations are presented for the three- and six- months ended June 30, 2023 and 2022. Certain financial results (revenues and expenses) relating to the business formerly conducted by USC are reflected in Note 3, Discontinued Operations and Assets Held for Sale, of the notes to the condensed 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 includes the operations of DMK from the date of acquisition.

Three Months Ended June 30, 2023 and 2022

Revenues. Revenues were approximately $7,000 and $40,000 for the three months ended June 30, 2023 and 2022, respectively. Revenues for the three months ended June 30, 2023 and 2022, decreased $33,000 and consisted primarily of a decrease in deferred revenue recognized in the period relating to a milestone payment received from USWM in connection with entering into the USWM Agreement. There were no product revenues for SYMJEPI or ZIMHI during the three months ended June 30, 2023 due to continued sourcing issues with the syringes for SYMJEPI, and due to the lack of orders for ZIMHI from USWM resulting from increased ZIMHI orders in the first quarter of 2023. As of the date of this Report, the Company remains unable to manufacture SYMJEPI. While we are committed to returning SYMJEPI to the market, we will not do so until we are satisfied that sufficient corrective actions have been implemented to avoid a repeat of the circumstances which led to the voluntary recall.

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, assembly line depreciation and other related expenses. Cost of goods sold was approximately $361,000 and $689,000 for the three months ended June 30, 2023 and 2022, respectively. The gross loss for the three months ended June 30, 2023 was approximately $354,000 compared to approximately $649,000 for the three months ended June 30, 2022. Cost of goods sold for the second quarter of 2023 compared to the comparable period of 2022 decreased approximately $328,000 primarily due to a decrease in assembly line depreciation of approximately $308,000, and a decrease in defective and obsolete inventory of approximately $266,000, offset by an increase in maintenance fees of approximately $269,000 due to the lack of product production.

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 fixed assets depreciation and amortization expenses. SG&A expenses for the three months ended June 30, 2023 and 2022 were approximately $4,033,000 and $4,206,000, respectively. The decrease in SG&A expenses of approximately $173,000 was primarily due to a decrease in legal and patent expenses of approximately $207,000, and a decrease in compensation expenses of approximately $627,000 as there were no employment separation payments made in the second quarter of 2023, offset primarily by an increase of approximately $372,000 related to outside services, an increase in consulting expenses of approximately $124,000, an increase in marketing and selling expenses of approximately $143,000, and an increase in miscellaneous expenses of approximately $77,000 (principally insurance and fixed assets depreciation).

Research and Development Expenses. Our research and development, or R&D, costs are expensed as incurred and include costs to conduct clinical trials, contract research costs, R&D consulting and R&D employee compensation and R&D supplies. 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 $377,000 and $3,321,000 for the three months ended June 30, 2023 and 2022, respectively. The decrease of approximately $2,944,000 was primarily attributable to a decrease in costs of approximately $2,249,000 related to the Tempol product candidate clinical trial that was halted in the third quarter of fiscal year 2022 (primarily remaining close-out expenses in fiscal year 2023) and a decrease of approximately $853,000 related to compensation expenses resulting primarily from the reduction in workforce that occurred in 2022, offset by an increase of approximately $234,000 in development spending related to ZIMHI.

Acquired In-Process Research & Development (IPR&D). We elected to expense the fair value of the Acquired IPR&D from the DMK Merger due to its early stage and it having no alternative use. Acquired IPR&D was approximately $6,540,000 and $0, for the three months ended June 30, 2023 and 2022, respectively. There was no asset acquisition completed in the prior year comparable period.

Other Income or Expense. Other Income or Expense consists primarily of interest income, interest expense, penalty fees, changes to the fair value of warrant liabilities, and other miscellaneous transactions. Other income was approximately $4,301,000, for the three months ended June 30, 2023, compared to other expense of approximately $160,000, for the three months ended June 30, 2022. The change of approximately $4,461,000 to other income was primarily due to the decrease in the fair value of warrants of approximately $3,883,000 resulting in a gain and an increase in other income of approximately $463,000 due to additional Employee Retention Credit received and recorded as gain (other income) in the second quarter of 2023, compared to approximately $500,000 of insurance proceeds received related to a legal matter, approximately $758,000 loss on Fagron variable consideration and approximately $63,000 contingent liability loss recorded in the second quarter of 2022.

Loss from Discontinued Operations. The Company recorded a net loss from discontinued operations, after taxes, of approximately $1,571,000 and $62,000 for the three months ended June 30, 2023 and 2022, respectively. The increase in loss from discontinued operations of approximately $1,509,000 during the three months ended June 30, 2023, compared to the three months ended June 30, 2022, was primarily due to the impairment charge taken on the USC land and building of approximately $1,512,000 during the second quarter of 2023 to reduce the carrying value of the property based on the net purchase price.

Six Months Ended June 30, 2023 and 2022

Revenues. Revenues were approximately $1,460,000 and $1,194,000 for the six months ended June 30, 2023 and 2022, respectively. The increase of approximately $266,000 was primarily attributable to an increase in revenues relating to sales of ZIMHI of approximately $300,000, offset by a decrease in deferred revenue recognition related to a milestone payment during the current period, compared to the same period in the prior year. There were no revenues relating to SYMJEPI during the first six months of 2023, due to the manufacturing hold and the voluntary product recall, which was lifted in February 2023, and to continued sourcing issues continue regarding the syringes for SYMJEPI. As of the date of this Report, the Company remains unable to manufacture SYMJEPI. While we are committed to returning SYMJEPI to the market, we will not do so until we are satisfied that sufficient corrective actions have been implemented to avoid a repeat of the circumstances which led to the voluntary recall.

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, assembly line depreciation and other related expenses. Cost of goods sold was approximately $2,149,000 and $2,153,000 for the six-months ended June 30, 2023 and 2022, respectively. The gross loss for the six-months ended June 30, 2023 was approximately $690,000 compared to approximately $958,000 for the six-months ended June 30, 2022. Cost of goods sold for the six months ended June 30, 2023, compared to the comparable period of 2022 decreased by approximately $4,000, primarily due to a decrease in assembly line depreciation of approximately $569,000 and a decrease in defective and obsolete inventory of approximately $226,000, offset by an increase of $266,000 in ZIMHI production costs compared to the same period in 2022 and an increase in maintenance fees of approximately $538,000 due to the lack of product production.

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 fixed assets depreciation and amortization. SG&A expenses for the six months ended June 30, 2023 and 2022 were approximately $8,815,000 and $7,589,000 respectively. The increase in SG&A expenses of approximately $1,226,000 was primarily attributable to the following increases of approximately $1,009,000 for outside services related to the merger, approximately $751,000 related to legal expenses, approximately $268,000 related to consulting, approximately $172,000 related to selling and marketing expenses, approximately $108,000 related to insurance and depreciation and $195,000 in miscellaneous expenses (principally accounting and finance related spending), offset by a decrease in compensation expense of approximately $1,234,000 as there were no employment separation costs incurred in the comparable period of 2023 and approximately $45,000 of patent, taxes and other miscellaneous expenses

Research and Development Expenses. Our research and development, or R&D, costs are expensed as incurred and include costs to conduct clinical trials, contract research costs, R&D consulting and R&D employee compensation and R&D supplies. 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 $1,687,000 and $7,542,000 for the six months ended June 30, 2023 and 2022, respectively. The decrease of approximately $5,855,000 was primarily attributable to a decrease in development spending on the Tempol product candidate in which the related clinical trial was halted in the third quarter of 2022 of approximately $3,935,000, a decrease in other development spending of approximately $406,000 on other product candidates and a decrease in compensation expenses for research and development employees of approximately $1,519,000 primarily due to the reduction in work force.

Acquired In-Process Research & Development (IPR&D). We elected to expense the fair value of the Acquired IPR&D from the DMK Merger due to its early stage and it having no alternative use. Acquired IPR&D was approximately $6,540,000 and $0, for the six months ended June 30, 2023 and 2022, respectively. There was no asset acquisition completed in the prior year comparable period.

Other Income or Expense. Other Income or Expense consists primarily of interest income, interest expense, changes to the fair value of warrant liabilities, and other transactions. Other income for the six months ended June 30, 2023 was approximately $1,714,000 and other expense was approximately $2,436,000 for the six months ended June 30, 2022. The increase in other income during the six months ended June 30, 2023, compared to the same period in 2022, was of approximately $4,150,000 was primarily attributable to due to the change in the fair value of warrants of approximately $3,886,000 resulting in a gain and an increase in other income of approximately $463,000 due to additional Employee Retention Credit received and recorded as gain (other income) in the second quarter of 2023, offset by approximately $2,476,000 in loss related to the excess of the fair value of the March 2023 warrants over the proceeds received from that transaction, by approximately $53,000 recorded as contingent loss liability related to the USC lease and approximately $137,000 in interest expense. Additionally, for the six months period in 2023, no loss on Fagron variable consideration of approximately $1,198,000 was recorded, no insurance proceeds related to a legal matter of approximately $500,000 was received and no contingent accrual loss related to the PPP2 loan was of approximately $1,787,000 was recorded, as was in the comparable period in 2022.

Loss from Discontinued Operations. The company recorded a net loss from discontinued operations of approximately $1,499,000 and $227,000 for the six months ended June 30, 2023, and 2022, respectively. The increase in loss from discontinued operations of approximately $1,272,000 during the six months ended June 30, 2023, compared to the six months ended June 30, 2022, primarily resulted from the impairment charge taken on the USC land and building of approximately $1,512,000 during the second quarter of 2023 to reduce the carrying value of the property to the anticipated sales price less commissions, offset by the gain on disposal of other assets held for sale in the current period of approximately $68,000 and the decrease of approximately $201,000 in SG&A expenses as the Company continues the winding down of USC's former business operations.

Liquidity and Capital Resources

We have incurred net losses from our continuing and discontinued operations of approximately $17.5 million and $18.8 million for the six months ended June 30, 2023 and 2022, respectively. Since inception, and through June 30, 2023, we have an accumulated deficit of approximately $322.1 million. Since inception and through June 30, 2023, we have financed operations principally through public and private issuances of common stock, preferred stock and warrants and through debt financing. On July 25, 2023, we closed a transaction involving the sale of a building and real property located in Conway, Arkansas, formerly utilized by our discontinued USC compounding pharmacy business, as well as certain related personal property equipment and assets and intellectual property, to an unaffiliated third-party purchaser ("Purchaser"), for total aggregate net proceeds of approximately $1.8 million. In addition, on August 4, 2023, we completed an offering of 4,800,000 shares of our common stock, 1,130,000 prefunded warrants and common stock purchase warrants to purchase up to 5,930,000 shares of our common stock and received net proceeds of approximately $7.0 million. However, 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.

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, 2023, we had cash and cash equivalents of approximately $0.6 million. Total assets were approximately $4.7 million and $10.9 million as of June 30, 2023 and December 31, 2022 respectively. Current liabilities exceeded current assets by approximately $11.6 million as of June 30, 2023.

Net cash used in operating activities for the six months ended June 30, 2023 and 2022, was approximately $4.1 million and $16.9 million, respectively. Net cash used in operating activities decreased approximately $12.8 million due primarily to the change in working capital of $6.7 million.

Net cash provided by investing activities for the six months ended June 30, 2023 and 2022, was approximately $1.0 million and $2.5 million, respectively. Net cash provided by investing activities decreased by approximately $1.5 million primarily due to the proceeds of approximately $0.8 million related to the sale of certain fixed assets in the first quarter of 2023, were less than the proceeds received from the sale of USC assets to Fagron in the first half of 2022.

Net cash provided by financing activities was $2.7 million and approximately $0 for the six months ended June 30, 2023 and 2022, respectively. Net cash provided by financing activities increased by approximately $2.7 million due to the gross proceeds of approximately $3.0 million from the March 2023 Offering, net of issuance costs of $0.3 million. No financing transaction occurred during the first half of 2022.

As noted above under the heading “Going Concern and Management Plan,” through June 30, 2023, we have incurred substantial losses. We will be required to devote significant cash resources to support our intended development programs and sustain operations and activities. The availability of any required additional funding cannot be assured. 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 10 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 suspend operations or seek bankruptcy protection. 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 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, 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. In addition, as disclosed elsewhere in this Report, on May 11, 2021, both the USAO and the SEC have initiated investigations of the company 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. We have received additional requests for production of documents from the SEC and the USAO and continue to engage in communications with the SEC and the USAO regarding their investigations. We or our USC subsidiary may be found to have violated one or more laws arising from the subject matter of the subpoenas. There can be no assurance that any resolution of these matters and investigations with the USAO or SEC will not have a material and adverse effect on the company. The foregoing matters could subject the company and its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, could result in fines, payments, or financial remedies in amounts that may be material to our financial condition, or equitable remedies, and materially 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 and cash equivalents together with anticipated revenues from operations and cash inflows from other sources 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. Even giving effect to our sale of the building and real property in Conway, Arkansas, for total aggregate estimated net proceeds of approximately $1.8 million and the estimated net proceeds of approximately $7.0 million from our equity offering completed in August 2023, we will require additional funding in the near term to satisfy our substantial accounts payable balance and sustain operations. We will seek to raise additional funds or seek funding from a variety of sources including proceeds from equity or debt financings if available, loans, revenues relating to sales of our SYMJEPI product (after relaunch) and our ZIMHI product, sales or out-licensing of intellectual property assets or other assets, products, product candidates or technologies. 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. In addition, obtaining additional funding or entering into other strategic transactions could result in significant dilution to our stockholders. If we do not receive required funding and are not able to engage in a merger, sale or other strategic transaction, we would likely be required to reduce or cease operations or seek dissolution and liquidation or bankruptcy protection. As of June 30, 2023, 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. With the sale of assets relating our former USC business and the winding down and discontinuance of that business, the company does not need the leased property. Monthly rent for the remaining term of this lease is approximately $14,000 per month. The company is exploring alternatives with respect to termination of the lease or sub-lease of the property. The company has recorded a contingent lease loss liability of $53,000 related to repairs undertaken at this property, which represents the minimum amount of repairs that the company could be held responsible for reimbursement to the landlord. See Note 13 of the notes to the consolidated financial statements included elsewhere herein for additional information about the contingent lease loss liability.

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, the close-out of the Phase 2/3 clinical trial relating to Tempol was substantially completed in December 2022, and we are in the process of completing the final reconciliation of costs related to the Tempol clinical trial. 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 halted 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 or we have firm purchase commitments we would be liable for. Maintenance fees for the three months ended June 30, 2023 and 2022 were approximately $536,000 and $0, respectively. There were no firm purchase commitments for the three or six months ended June 30, 2023 and 2022. 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 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 FDA has notified us that the FDA considers the voluntary recall terminated. Additionally, 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 additional financial costs and expenses which could be material, has adversely affected and could continue to 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 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.

Critical accounting estimates related to the DMK Merger are as follows:

We determined that the acquired group, DMK, is a variable interest entity, or VIE, as DMK's total equity at risk is not sufficient to permit DMK to finance its activities without additional subordinated financial support. Additionally, DMK did not constitute a business because substantially all of the fair value of the gross assets acquired were concentrated in a single identifiable asset (DP-125). In accordance with accounting guidance, the consolidation of DMK (the VIE) is considered an asset acquisition. Additionally, we determined that we were the primary beneficiary and legal acquirer. Based on applicable accounting guidance, we were required to record DMK's assets and liabilities at fair value. At acquisition date, we elected to expense the purchase consideration allocated to the early-stage acquired in-process research and development (acquired IPR&D) because there is no alternative future use related to the acquired IPR&D, and, as such, no further impairment assessments would be necessary for these assets. The Company incurred approximately $1.4 million of transaction costs were recorded within selling, general and administrative expenses on the condensed consolidated statement of operations.

The fair value of the acquired IPR&D was determined based upon the income approach using a multi period excess earnings model which included a forecast of the expected cash flows of DPI-125. The discount rate associated with this forecast was 27%.

The purchase price, or total consideration transferred, to acquire DMK in the Merger was comprised of the following:

Fair Value of Adamis Common Stock issued to DMK shareholders	$	757,038
Fair Value of Adamis Series E Preferred issued to DMK shareholders		4,853,000
Fair Value of DMK options assumed and replaced by Adamis		415,809
DMK incurred Merger-related costs paid for by Adamis		492,456
Total Consideration Transferred	$	6,518,303

The fair value of the 302,815 shares of common stock issued in connection with the Merger was based on the closing price of our common stock on the date of acquisition multiplied by the number of common shares issued.

The fair value of the 1,941.2 shares of Series E Preferred issued in connection with the Merger was based on the closing price of our commons stock on the date of acquisition multiplied by the number of common shares the Series E preferred stock is convertible into (1,941,200). The same fair value basis was utilized as our common stock for the Series E Preferred because the Series E Preferred have no preferences over common stock and the issuance of the Series E Preferred was merely a mechanism to consummate the Merger transaction.

Pursuant to the Merger agreement, at the effective time, the outstanding DMK stock options to purchase shares of DMK common stock were assumed by us and became options to purchase a total of 231,490 shares of Adamis common stock, with proportionate adjustments to the exercise prices per share of such options based on the exchange ratio determined pursuant to the Merger Agreement. The assumed options continue to be governed by the terms of the DMK 2016 Stock Plan, which was assumed by us in connection with the closing of the Merger. The assumed options were fully vested and the replacement awards was treated as additional purchase price consideration paid by us.

The fair value of the replacement awards is based primarily on inputs that are observable or can be corroborated by observable market data (such as our closing stock price and the published treasury par yield curves from the US Department of the Treasury). The estimated fair value of the replacement options of $415,809 was calculated using the Black Scholes Option Pricing Model. Key inputs at the date of closing, include expected volatility of 119.5% based on a 50/50 weighting of calculated volatility of our stock of approximately 107% (based on calculated volatility) and DMK's implied volatility of 132% (as per the financial statements DMK provided to us), our stock price on the date of closing of $2.50, expected dividend yield of 0.0%, expected term ranging from 2.3699 years to 4.3726 years and average risk-free interest rate (based on the published treasury par yield curves from the US Department of Treasury) of approximately 4.06%.

Recent Accounting Pronouncements

We periodically monitor and review all current accounting pronouncements and standards from the Financial Accounting Standards Board for applicability to our operations. We do not expect the adoption of accounting pronouncements recently issued during the second quarter of calendar year 2023 to have a significant impact on our results of operations, financial position or cash flow.

ITEM 3. Quantitative and Qualitative Disclosure of Market Risk

Not required.

ITEM 4. 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, 2023.

Limitations on the Effectiveness of Controls

Because of their inherent limitations, our disclosure controls and procedures and our internal control over financial reporting may not prevent material errors or fraud. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. 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. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

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, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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, 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. The Company has also received requests from the Securities and Exchange Commission ("SEC") that the Company voluntarily provide documents and information in connection with the SEC's investigation relating to certain matters including matters arising from the subject matter of the subpoenas from the USAO. The Company has produced 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 and the SEC, and has continued to engage in communications with the SEC and USAO regarding their investigations. We have received additional requests for production of documents from the SEC and the USAO, have responded to those requests, could receive additional requests from the USAO, SEC, or other authorities, and continue to engage in communications with the SEC and the USAO regarding their investigations. Additional issues or facts could arise or be determined, which may expand the scope, duration, or outcome of the investigation. We are unable to predict the duration, scope, or final outcome of the investigations by the USAO, SEC, or other agencies; what, if any, proceedings the USAO, SEC, or other federal or state authorities may initiate; what penalties, payments, by the Company, remedies or remedial measures the USAO, SEC, or other federal or state authorities may seek or may require in order to resolve the investigations; what, if any, impact the foregoing matters may have on the Company's business, financial condition, previously reported financial results, financial results included in this Report, or future financial results; or what proceedings the USAO, SEC, or other federal or state authorities may initiate if the foregoing matters are not resolved. However, in connection with resolution of these matters, we or our USC subsidiary may be found to have violated one or more laws arising from the subject matter of the subpoenas, and to resolve the matters and investigations with the USAO and the SEC we may be required to pay material amounts in penalties or other payments, and to agree to other remedies or remedial measures. Payment of material amounts in connection with resolution of the foregoing matters would reduce the amount of financial resources that we have available to support our product development programs and commercialization activities and would adversely impact our development programs. Depending in part on the amount and timing of any payments that we may be required to make or other remedial measures that may be implemented in connection with resolution of these matters, a resolution of these matters with the USAO or SEC could have a material and adverse impact on the company. The foregoing matters have diverted and will likely continue to divert management's attention, have caused the company to suffer reputational harm, have required and will continue to require the company to devote significant financial resources, could subject the company, one or more of its subsidiaries, or its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, could result in fines, penalties, payments, or financial remedies in amounts that would have a material adverse effect on our financial condition, or equitable remedies, and adversely affect the company's business, previously reported financial results, financial results included or incorporated by reference herein, or future financial results.

Nasdaq Compliance

On December 28, 2022, the Company was notified by the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") that, based upon the Company's non-compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) (the "Rule") as of December 27, 2022, the Company's common stock was subject to delisting unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company timely requested a hearing before the Panel, and a hearing was held on February 16, 2023. On February 21, 2023, the Staff notified the Company that the Panel had granted the Company's request for continued listing of the Company's common stock on the Nasdaq Stock Market and an extension until June 26, 2023 (the "Compliance Period") to regain compliance with the continued listing requirements for The Nasdaq Capital Market, including the minimum $ 1.00 bid price requirement of Nasdaq Listing Rule 5500(a)(2) (the "Rule"). We effected the Reverse Stock Split on May 22, 2023. On June 21, 2023, we received a communication from Nasdaq indicating that we demonstrated compliance with the requirements to remain listed on The Nasdaq Capital Market, as required by the Panel's February 21, 2023, decision, and that pursuant to Listing Rule 5815(d)(4)(B), we will be subject to a Mandatory Panel Monitor for a period of one year from the date of the communication. If, within that one-year monitoring period, the Staff finds us again out of compliance with the Rule, notwithstanding Rule 5810(c)(2) we will not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and Staff will not be permitted to grant additional time for the Company to regain compliance with respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Rule 5810(c)(3), and the Staff will instead issue a delist determination letter and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. At any such hearing, we will have the opportunity to respond/present to the Hearings Panel as provided by Listing Rule 5815(d)(4)(C). There can be no assurance that any such Panel or Hearing Panel would grant us additional time to regain compliance.

On April 12, 2023, we received a notice (the "Notice") from the Staff of Nasdaq, notifying us that for the last 30 consecutive business days, our minimum Market Value of Listed Securities ("MVLS") was below the minimum of $35 million required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "Market Value Standard"). The Notice is only a notification of deficiency, not of imminent delisting, and has no current effect on the listing or trading of our common stock on the Nasdaq Capital Market. Consequently, a deficiency exists with regard to the Nasdaq listing rules. In accordance with the listing rules, we will have 180 days, or until October 9, 2023, to either regain compliance with the Market Value Standard, or satisfy another listing criteria such as having a minimum shareholder equity of $2.5 million. To regain compliance with the Market Value Standard, the MVLS for our common stock must be at least $35 million for a minimum of 10 consecutive business days at any time during this 180-day period. If we regain compliance with an applicable listing standard, we anticipate that the Nasdaq Staff will provide us with written confirmation and will close the matter. If we do not regain compliance with the applicable listing standard by October 9, 2023, Nasdaq will provide notice that our securities are subject to delisting from the Nasdaq Capital Market. In the event of such notification, the Nasdaq rules permit us an opportunity to appeal Nasdaq's determination and request a hearing before a Hearing Panel. We intend to monitor both the MVLS and our shareholder equity between now and October 9, 2023, and may, if appropriate, evaluate available options to resolve the deficiency and regain compliance with the MVLS rule. However, there can be no assurance that we will be able to regain or maintain compliance with Nasdaq listing criteria in the future.

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. On April 4, 2022, the plaintiff filed a motion to amend the Complaint. The proposed amended Complaint added 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. Trial on the merits of the plaintiff's claims was held on March 16, 2023, and the case is under consideration by the Court. The Company believes the claims in the plaintiff's complaint are without merit and intends to vigorously dispute them.

On January 20 and March 27, 2023, the plaintiff filed motions for sanctions against the defendants, asserting among other things that the alleged conduct that the plaintiff argues supports his case on the merits is sanctionable. These motions are pending before the Court. The Company believes the claims in the plaintiff's motions are without merit and intends to vigorously dispute them.

Supplemental Proxy Disclosures

On April 11, 2023, a purported stockholder of Adamis filed a complaint against Adamis and each of its directors in the United States District Court for the Southern District of New York, captioned *Lapin vs. Adamis Pharmaceuticals Corporation*, Case No. 1:23-cv-03023 (the "Complaint"). The Complaint alleges that the defendants violated Sections 14(a) and 20(a) of the Securities Exchange Act of 1934, as amended, by causing a materially incomplete and misleading Preliminary Proxy Statement to be filed with the SEC. Specifically, the Complaint alleges that the Preliminary Proxy Statement contains materially incomplete and misleading information concerning the sales process, financial projections prepared by Adamis management, as well as the financial analysis conducted by Raymond James & Associates, Inc., Adamis' financial advisor. The Complaint seeks, among other things, (i) injunctive relief preventing the consummation of the transactions contemplated by the Merger Agreement or the filing of a definitive proxy statement with the SEC or causing a definitive proxy statement to be disseminated to Adamis' stockholders unless and until the material information described in the Complaint is included in the definitive proxy statement or otherwise disseminated to Adamis' stockholders, and (ii) in the event that the Merger transaction is consummated without the alleged material omissions referenced in the Complaint being remedied, damages and costs and disbursements of the action including reasonable plaintiff's attorneys' and experts' fees and expenses. On July 6, 2023, the plaintiff filed a notice of voluntary dismissal, dismissing the claims in the complaint without prejudice, which was entered by the court on July 7, 2023.

In addition, the Company has received additional demand letters from counsel (the "Demand Letters"), each representing a purported stockholder of the Company, asserting that the Preliminary Proxy Statement and/or Proxy Statement was deficient and demanding that the alleged deficiencies be rectified. The Demand Letters allege, among other matters, that the Proxy Statements contain materially incomplete and misleading information concerning the sales process, financial projections prepared by the Company's management, and the financial analysis conducted by Raymond James & Associates, Inc. In addition, each purported shareholder has reserved his or her rights, including the right to alter or amend the demands at any time, and/or seek monetary damages following the consummation of the Merger.

The Company believes that the allegations in the Complaint and the Demand Letters are without merit and that the disclosures set forth in the Proxy Statement comply fully with applicable law. However, in order to moot the unmeritorious claims, avoid nuisance and possible expense and delay, and to provide additional information to our shareholders, the Company provided a voluntary supplement to the Proxy Statement with the supplemental disclosures filed with the SEC on May 5, 2023. Nothing in the Supplemental Disclosures shall be deemed an admission of the legal necessity or materiality under applicable laws of any of the disclosures set forth in the Supplemental Disclosures. To the contrary, the Company specifically denies all allegations that any additional disclosure was or is required. Nevertheless, resolution of these matters may involve payments by the Company to the parties submitting the Demand Letters or other claims.

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, 2022. Our business, financial condition, results of operations and future prospects could be materially and adversely affected by these risks if any of them actually occurs. In these circumstances, the market price of our common stock would likely decline. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business.

Risks Related to Our Financial Condition

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

Our consolidated financial statements are prepared using the generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, as shown in our consolidated financial statements for the year ended December 31, 2022, included in our Annual Report on Form 10-K for the year ended December 31, 2022 and the condensed 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. As of June 30, 2023, we had cash and equivalents of approximately $0.6 million. The above conditions raise substantial doubt about our ability to continue as a going concern within one year after such date. 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 in the near term and thereafter. If we cannot continue as a viable entity, we might be required to reduce or cease operations or seek dissolution and liquidation or bankruptcy protection, and our stockholders would likely lose most or all of their investment in us.

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 attempt to 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.

**** 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, 2023. We expect that these losses will continue as we continue our research and development activities, support commercialization of our approved products, and continue to conduct our business. 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 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. 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 will require additional funding to continue as a going concern.***

Our continued operations and 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 have received or expect to receive as a result of our sales of assets relating to our former U.S. Compounding, Inc. business or from other sources, will be sufficient to meet our anticipated operating expenses, liabilities and obligations for at least 12 months from the date of this Report. We will require additional funds to sustain operations, satisfy our obligations and liabilities, fund our ongoing operations, or for other purposes. 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. 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 equity or debt funding. Delays in obtaining, or the inability to obtain, required funding from revenues relating to sales of our commercial products, debt or equity financings, sales of assets, sales or out-licenses of intellectual property assets, products, product candidates or technologies, or other transactions or sources, would materially and adversely affect our ability to satisfy our current and future liabilities and obligations, and would materially and adversely affect our ability to continue operations.

Our ability to obtain required debt or equity financing or funds from other transactions will be subject to a number of factors, including without limitation market conditions, our capitalization, our operating performance and investor sentiment. The terms of any such funding, or the terms of any strategic transaction that we might enter into, could result in significant dilution to our stockholders. If we are unable to raise additional funds when required or on acceptable terms, we may have to significantly restrict our operations or seek to 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 dissolution and liquidation, 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.

Any statements contained in this Report concerning future events or developments or our future activities, such as concerning research and development activities or regulatory matters, commercial introduction of any products that we may develop in the future, 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 satisfy our liability and obligations in a timely manner. There can be no assurance that this will be the case. Also, such statements assume that there are no significant unexpected developments or events that delay or prevent such activities from occurring. Failure to timely obtain any required additional funding, or unexpected developments or events, could delay the occurrence of such events or prevent the events described in any such statements from occurring which could adversely affect our business, financial condition and results of operations.

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

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. The company has also received requests from the SEC that the company voluntarily provide documents and information in connection with the SEC's investigation relating to certain matters including matters arising from the subject matter of the subpoenas from the USAO. The company has produced and will continue to produce and provide documents in response to the subpoenas and requests. The company intends to continue cooperating with the USAO and the SEC, and has continued to engage in communications with the SEC and USAO regarding their investigations. We could receive additional requests from the USAO, SEC, or other authorities, which may require further investigation, and additional issues or facts could arise or be determined, which could expand the scope, duration or outcome of the investigation. We are unable to predict the duration, scope, or final outcome of the investigations by the USAO, SEC, or other agencies or what proceedings the USAO, SEC, or other federal or state authorities may initiate if the foregoing matters are not resolved. However, in connection with resolution of these matters, we or our USC subsidiary may be found to have violated one or more laws arising from the subject matter of the subpoenas, and to resolve the matters and investigations with the USAO and the SEC we may be required to pay material amounts in penalties or other payments, and to agree to other remedies or remedial measures. Payment of material amounts in connection with resolution of the foregoing matters would reduce the amount of financial resources that we have available to support our product development programs and commercialization activities and would adversely impact our development programs. Depending in part on the amount and timing of any payments that we may be required to make or other remedial measures that may be implemented in connection with resolution of these matters, a resolution of these matters with the USAO or SEC could have a material and adverse impact on the company. The foregoing matters have diverted and will likely continue to divert management's attention, have caused the company to suffer reputational harm, have required and will continue to require the company to devote significant financial resources, could subject the company, one or more of its subsidiaries, or its officers and directors to civil or criminal proceedings, and depending on the resolution of the matters or any proceedings, could result in fines, penalties, payments, or financial remedies in amounts that would have a material adverse effect on our financial condition, or equitable remedies, and adversely affect the company's business, previously reported financial results, financial results included or incorporated by reference herein, or future financial results.

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. On April 4, 2022, the plaintiff filed a motion to amend the Complaint. The proposed amended Complaint added 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. The plaintiff has also filed various motions with the Court, which have been resolved. The Company has filed a motion for summary judgment with respect to one of the counts in the Complaint and a motion to dismiss certain other counts of the plaintiff's amended Complaint. On March 13, 2023, the Court denied the Company's motion for summary judgment. Trial on the merits of the plaintiff's claims was held on March 16, 2023, and the case is under consideration by the Court. The Company believes the claims in the plaintiff's complaint are without merit. However, an adverse outcome in the proceeding could have a material and adverse effect on the Company's business, financial condition and results of operations. On January 20 and March 27, 2023, the plaintiff filed motions for sanctions against the defendants, asserting among other things that the alleged conduct that the plaintiff argues supports his case on the merits is sanctionable. These motions are pending before the Court. The Company believes the claims in the plaintiff's motions are without merit and intends to vigorously dispute them.

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

We applied for and obtained loan funding under the PPP pursuant to an initial 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 or obtaining forgiveness of that loan. 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.

**** Certain of our securities issued in prior offerings include a right to receive the Black-Scholes value of the unexercised portion of those securities in the event of a fundamental transaction, which payment could be significant.***

Most of our outstanding warrants to purchase shares of common stock issued by us in prior offerings provide that, in the event of a "fundamental transaction" that is approved by our board of directors, including, among other things, a merger or consolidation of our company, sale of all or substantially all of our assets or a sale of a certain percentage of our common stock, the holders of such warrants have the option to require us to pay to such holders an amount of cash equal to the Black-Scholes value of the warrants. Such amount could be significantly more than the warrant holders would otherwise receive if they were to exercise their warrants and receive the same consideration as the other holders of common stock, which in turn could reduce the consideration that holders of common stock would be concurrently entitled to receive in such fundamental transaction. Any payments we may be required to make to such holders under these provisions could also reduce the amount of net proceeds available to us from this offering. Additionally, any future equity financing that we conduct may require us to issue securities that have a similar feature.

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. 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 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. Any potential product that we might determine to research or develop in the future may require significant additional research and development before any commercial introduction, and our development plans concerning any such product candidate will be affected by many factors, many of which are difficult to predict. Some of the factors that could affect development plans concerning any product candidates that we might determine to research or develop in the future 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 regulatory pathway for the product candidate; 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 pre-clinical or clinical trials; the FDA's review of NDAs that we may file concerning any such product candidate; 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 future research, development or clinical trial efforts, if any, will be successful or result in viable products or meet efficacy standards. 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. Delays or setbacks in development efforts that we might determine to undertake 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 COVID-19 pandemic, which the World Health Organization announced in January 2020 was a global health emergency, 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 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. 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 or other similar outbreaks on such parties. The extent to which the COVID-19 pandemic will continue to impact our business is difficult to predict and subject to change. 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 any future governmental measures implemented to control the spread of the COVID-19 virus or other health emergencies 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.

We intend to rely on third parties to conduct any clinical trials that we may conduct in the future. 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, trial results or regulatory approval.

Like many companies our size, we do not have the ability to conduct preclinical or clinical studies for product candidates that we may in the future determine to develop 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. In the past we have relied 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, and if we undertake clinical trials for any product candidate that we may in the future develop we similarly intend to rely on such third parties. We may also rely on academic institutions or clinical research organizations to conduct, supervise or monitor some or all aspects of any clinical trials that we might undertake in the future. 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 conduct or continue these activities, replacing a third party contractor may result in a delay of the affected trials.

**** 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, or a prolonged failure to supply, one or more of our products, we may be exposed to significant liabilities.***

The testing of human 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. 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. Under the terms of our commercial agreement with USWM, if after a prolonged period of time we are unable to resume the supply of SYMJEPI to USWM, USWM may elect to terminate the agreement and we may be required to make certain payments to USWM, which could be material. 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. 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.

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. If we conduct additional clinical trials and introduce products into the United States market, the risk of adverse events will increase 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 commercial products and our product candidates for which we will be seeking FDA approval.

We do not own or operate manufacturing facilities for clinical or commercial production of pharmaceutical products and product candidates, 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 COVID-19 pandemic or other health emergencies, or natural disasters including earthquakes, typhoons, floods and fires, could adversely affect our supply chain. These risks and uncertainties are compounded by public health emergencies as was the case with 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 to provide commercial products 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.

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 Complete Response Letters 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.

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 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 investigations, 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.

On August 16, 2022, President Biden signed the Inflation Reduction Act, or IRA, into law, which sets forth meaningful changes to drug product reimbursement by Medicare. Among other actions, the IRA permits HHS to engage in price-capped negotiation to set the price of certain drugs and biologics reimbursed under Medicare Part D. The IRA also establishes a rebate obligation for drug manufacturers that increase prices of Medicare Part D covered drugs at a rate greater than the rate of inflation. The inflation rebates may require us to pay rebates if we increase the cost of a covered Medicare Part D approved product faster than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum and 20% once the out-of-pocket maximum has been reached. Our cost-sharing responsibility for any approved product covered by Medicare Part D could be significantly greater under the newly designed Part D benefit structure compared to the pre-IRA benefit design. Additionally, manufacturers that fail to comply with certain provisions of the IRA may be subject to penalties, including civil monetary penalties. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbursement we can receive for our products, among other effects.

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 discontinuance of its business, 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.

Laws that may affect our ability to operate include, but are not limited to, the federal Anti-Kickback Statute, federal civil and criminal false claims laws, state anti-kickback and false claims laws, HIPAA, as amended by HITECH, and the federal Physician Payments Sunshine Act, created under the ACA and its implementing regulations. Violations of these laws can result in imprisonment, civil or criminal fines, fines and disciplinary actions relating to our state licensure, disgorgement, exclusion of products from reimbursement under U.S. federal or state healthcare programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. Moreover, 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. Certain companies have established technologies that may be competitive with our products and any future product candidates that we may determine to 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, 2022, 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 audited consolidated financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2022, 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 discontinued our former compounding pharmacy business conducted by USC and have sold a substantial portion of the assets relating to that former business. We may incur significant costs in connection with the transfer or disposal of the remaining assets related to that former business.

As previously disclosed in our reports with the SEC and as disclosed elsewhere in this Report, 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 wound down and terminated, and remaining assets relating to USC's business have been sold or will be 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.

Other matters may arise relating to the former 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 former business and operations of USC. The compounding pharmaceuticals business formerly conducted by USC is subject to federal, state and local laws, regulations and administrative practices. 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 include a prohibition on stockholder action by written consent, which means that all stockholder action must be taken at an annual or special meeting of stockholders. Moreover, our charter documents to not provide for cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates. 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 2022 to June 30, 2023, the market price of our common stock has fluctuated between $1.90 and $59.32, as adjusted by and giving effect to the Reverse Stock Split. 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. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

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 currently listed on the Nasdaq Capital Market. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements, the minimum closing bid price requirement, or applicable market capitalization or shareholder equity requirements, 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 28, 2022, we were notified by the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") that, based upon our non-compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) (the "Rule") as of December 27, 2022, our common stock was subject to delisting unless we timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). We timely requested a hearing before the Panel, and a hearing was held on February 16, 2023. On February 21, 2023, the Staff notified us that the Panel has granted our request for continued listing of our common stock on the Nasdaq Capital Market and an extension until June 26, 2023 (the "Compliance Period") to regain compliance with the continued listing requirements for The Nasdaq Capital Market, including the Rule. We effected the Reverse Stock Split on May 22, 2023. On June 21, 2023, we received a communication from Nasdaq indicating that we demonstrated compliance with the requirements to remain listed on The Nasdaq Capital Market, as required by the Panel's February 21, 2023, decision, and that pursuant to Listing Rule 5815(d)(4)(B), we will be subject to a Mandatory Panel Monitor for a period of one year from the date of the communication. If, within that one-year monitoring period, the Staff finds us again out of compliance with the Rule, notwithstanding Rule 5810(c)(2) we will not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and Staff will not be permitted to grant additional time for the Company to regain compliance with respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Rule 5810(c)(3), and the Staff will instead issue a delist determination letter and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. At any such hearing, we will have the opportunity to respond/present to the Hearings Panel as provided by Listing Rule 5815(d)(4)(C). There can be no assurance that any such Panel or Hearing Panel would grant us additional time to regain compliance.

On April 12, 2023, we received a notice (the "Notice") from the Staff of Nasdaq, notifying us that for the last 30 consecutive business days, our minimum Market Value of Listed Securities ("MVLS") was below the minimum of $35 million required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "Market Value Standard"). The Notice is only a notification of deficiency, not of imminent delisting, and has no current effect on the listing or trading of our common stock on the Nasdaq Capital Market. Consequently, a deficiency exists with regard to the Nasdaq listing rules. In accordance with the listing rules, we will have 180 days, or until October 9, 2023, to either regain compliance with the Market Value Standard, or satisfy another listing criteria such as having a minimum shareholder equity of $2.5 million. To regain compliance with the Market Value Standard, the MVLS for our common stock must be at least $35 million for a minimum of 10 consecutive business days at any time during this 180-day period. If we regain compliance with an applicable listing standard, we anticipate that the Nasdaq Staff will provide us with written confirmation and will close the matter. If we do not regain compliance with the applicable listing standard by October 9, 2023, Nasdaq will provide notice that our securities are subject to delisting from the Nasdaq Capital Market. In the event of such notification, the Nasdaq rules permit us an opportunity to appeal Nasdaq's determination and request a hearing before a Hearing Panel. We intend to monitor both the MVLS and our shareholder equity between now and October 9, 2023, and may, if appropriate, evaluate available options to resolve the deficiency and regain compliance with the MVLS rule. However, there can be no assurance that we will be able to regain or maintain compliance with Nasdaq listing criteria in the future.

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.

If our common stock was delisted from the NASDAQ Capital Market and began to trade on the OTCQB or other markets platform, such trading platforms are viewed by most investors as a less desirable, and less liquid, marketplace. As a result, an investor could find it more difficult to purchase, dispose of or obtain accurate quotations as to the value of our common stock. The OTCQB, the OTC Bulletin Board and Pink Sheets are viewed by most investors as a less desirable, and less liquid, marketplace.

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 of June 30, 2023, we had 2,790,395 shares of common stock 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, 2023, we had reserved for issuance 34,315 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 $292.20 per share, we had outstanding restricted stock units covering 7,143 shares of common stock, and we had outstanding warrants to purchase 899,323 shares of common stock at a weighted-average exercise price of $26.22 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, 2023, we had outstanding warrants, other than the warrants described in the next sentence, to purchase 840 shares of common stock, at a weighted average exercise price of $595.00 per share. As of June 30, 2023, 197,055 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants, at an exercise price of $80.50 per share, that we issued in connection with our underwritten public offering of common stock and warrants in August 2019; 5,000 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants, at an exercise price of $49.00 per share, that we issued in connection with our private placement of warrants in February 2020, and, 10,714 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants, at an exercise price of $32.90 per share, that we issued in connection with the issuance of Series C Preferred Stock in July 2022. In connection with the March 2023 Offering 685,714 shares of our common stock were issuable (subject to certain beneficial ownership limitations) upon exercise of warrants, at an exercise price of $9.66 per share.

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.

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, including Ebrahim Versi, our Chief Executive Officer. We currently do not have key person life insurance policies covering any of our executive officers or key employees. If key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly recruited. There is competition for qualified personnel in all functional areas, which makes it difficult to attract and retain the qualified personnel necessary for the operation of our business. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. If we are unable to attract new employees and retain existing key employees, the development and commercialization of our product candidates could be delayed or negatively impacted. In addition, any staffing interruptions resulting from geopolitical actions, including war and terrorism, adverse public health.

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

Information concerning our sales of unregistered securities during the quarter ended September 30, 2022, has previously been reported in reports on Form 8-K that we filed during that quarter.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

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

3.1	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock. (Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 8-K filed May 26, 2023)
3.2	Certificate of Amendment to Restated Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 8-K filed May 22, 2023)
4.1	Form of Common Stock Warrant. (Incorporated by reference to Exhibit 4.12 to the Registration Statement on Form S-1 (File No. 333-273233 on July 13, 2023)
4.2	Form of Pre-Funded Warrant. (Incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1 (File No. 333-273233 on July 13, 2023)
4.3	Form of Warrant Agency Agreement. (Incorporated by reference to Exhibit 4.14 to the Registration Statement on Form S-1 (File No. 333-273233 on July 13, 2023)
10.1	Securities Purchase Agreement. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 3, 2023)
10.2	Placement Agency Agreement. (Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed August 3, 2023)
10.3	Letter dated May 24, 2023, between the Company and David J. Marguglio. (Incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed May 26, 2023) *
10.4	Offer letter dated May 24, 2023, between the Company and Ebrahim Versi, M.D., Ph.D. (Incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K filed May 26, 2023) *
10.5	DMK 2016 Stock Plan. (Incorporated by reference to Exhibit 10.3 to the Company's Report on Form 8-K filed May 26, 2023) *
10.6	Purchase and Sale Agreement.+/**** (Incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed July 24, 2023)
10.7	Sales Agreement. + (Incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K filed July 24, 2023)
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
+	Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplemental copies of any of the omitted schedules and exhibits upon request by SEC.
*	Represents a compensatory plan or arrangement.
**	We have received confidentiality treatment for certain portions of this exhibit.
***	Certain marked information (indicated by "[***]" has been omitted as the registrant has determined it is both not material and is the type that the registrant customarily and actually treats as private or confidential.
****	Certain marked information has been omitted from this exhibit because it is both not material and would be competitively harmful if publicly disclosed.

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 CORPORATION

Date: August 18, 2023

By: /s/ Ebrahim Versi
Ebrahim Versi
Chief Executive Officer

Date: August 18, 2023

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

Exhibit 31.1

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

I, Ebrahim Versi, 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 18, 2023

By: /s/ Ebrahim Versi
Chief Executive Officer

Exhibit 31.2

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 18, 2023

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

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Ebrahim Versi, 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, 2023 (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/ Ebrahim Versi
Ebrahim Versi
Chief Executive Officer

Date: August 18, 2023

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 J. Marguglio, 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, 2023 (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 Financial Officer

Date: August 18, 2023

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.