

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2022

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT

For the transition period from N/A to N/A

Commission File Number: 000-54986

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

46-0524102

(I.R.S. Employer Identification No.)

235 Walnut Street, Suite 6

Framingham, MA

(Address of principal executive offices)

01702

(Zip Code)

(617) 431-2313

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
N/A	N/A	N/A

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 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, 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

Non-accelerated filer

Emerging growth company

Accelerated filer

Smaller reporting 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

As of August 11, 2022, 249,936,370 shares of the registrant's common stock were outstanding.

ARCH THERAPEUTICS, INC.
Quarterly Report on Form 10-Q

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Arch Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets
As of June 30, 2022 (Unaudited) and September 30, 2021

	June 30, 2022	September 30, 2021
ASSETS		
Current assets:		
Cash	\$ 54,997	\$ 2,266,639
Inventory	1,428,264	1,093,765
Prepaid expense and other current assets	83,487	307,341
Total current assets	<u>1,566,748</u>	<u>3,667,745</u>
Long-term assets:		
Property and equipment, net	2,843	5,240
Other assets	3,500	3,500
Total long-term assets	<u>6,343</u>	<u>8,740</u>
Total assets	<u>\$ 1,573,091</u>	<u>\$ 3,676,485</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,696,213	\$ 408,083
Accrued expense and other liabilities	223,094	319,464
Current portion of derivative liability	-	1,000,000
Total current liabilities	<u>1,919,307</u>	<u>1,727,547</u>
Long-term liabilities:		
Series 1 convertible notes	550,000	550,000
Series 2 convertible notes	1,050,000	1,050,000
Advances from investors	575,000	-
Accrued interest	286,808	167,137
Derivative liability, net of current portion	1,207,475	1,207,475
Total long-term liabilities	<u>3,669,283</u>	<u>2,974,612</u>
Total liabilities	<u>5,588,590</u>	<u>4,702,159</u>
Commitments and contingencies		
Stockholders' deficit:		
Common stock, \$0.001 par value, 800,000,000 shares authorized; 237,169,770 shares issued as of June 30, 2022 and September 30, 2021, respectively, and 236,994,770 and 236,719,770 shares outstanding as of June 30, 2022 and September 30, 2021, respectively	236,995	236,720
Additional paid-in capital	48,931,720	48,534,525
Accumulated deficit	(53,184,214)	(49,796,919)
Total stockholders' deficit	<u>(4,015,499)</u>	<u>(1,025,674)</u>
Total liabilities and stockholders' deficit	<u>\$ 1,573,091</u>	<u>\$ 3,676,485</u>

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations (Unaudited)
For the Three and Nine Months Ended June 30, 2022 and 2021

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Nine Months Ended June 30, 2022	Nine Months Ended June 30, 2021
Revenue	\$ 6,261	\$ —	\$ 14,086	\$ 10,000
Operating expense:				
Cost of revenues	17,140	—	51,363	10,102
Selling, general and administrative expense	836,215	1,370,395	3,308,227	3,600,419
Research and development expense	159,846	297,553	922,120	1,051,755
Total costs and expenses	<u>1,013,200</u>	<u>1,667,948</u>	<u>4,281,710</u>	<u>4,662,276</u>
Loss from operations	<u>(1,006,940)</u>	<u>(1,667,948)</u>	<u>(4,267,624)</u>	<u>(4,652,276)</u>
Other income (expense):				
Interest expense	(39,890)	(40,186)	(119,671)	(110,202)
Gain on forgiveness of loan	—	178,229	—	178,229
Decrease to fair value of derivative liability	—	—	1,000,000	108,944
Total other income (expense)	<u>(39,890)</u>	<u>138,043</u>	<u>880,329</u>	<u>176,971</u>
Net loss	<u>\$ (1,046,830)</u>	<u>\$ (1,529,905)</u>	<u>\$ (3,387,295)</u>	<u>\$ (4,475,305)</u>
Loss per share - basic and diluted				
Net loss per common share - basic and diluted	\$ 0.00	\$ (0.01)	\$ (0.01)	\$ (0.02)
Weighted common shares - basic and diluted	236,947,517	236,719,770	236,853,195	214,289,567

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Deficit (Unaudited)
For the Three and Nine Months Ended June 30, 2022 and 2021

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Three Months Ended June 30, 2022					
Balance at March 31, 2022	236,919,770	\$ 236,920	\$ 48,841,040	\$ (52,137,384)	\$ (3,059,424)
Net loss	—	—	—	(1,046,830)	(1,046,830)
Vesting of Restricted Stock	75,000	75	(75)	—	—
Stock-based compensation expense	—	—	90,755	—	90,755
Balance at June 30, 2022	<u>236,994,770</u>	<u>\$ 236,995</u>	<u>\$ 48,931,720</u>	<u>\$ (53,184,214)</u>	<u>\$ (4,015,499)</u>

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Three Months Ended June 30, 2021					
Balance at March 31, 2021	236,719,770	\$ 236,720	\$ 48,316,799	\$ (46,501,837)	\$ 2,051,682
Net loss	—	—	—	(1,529,905)	(1,529,905)
Stock-based compensation expense	—	—	93,856	—	93,856
Balance at June 30, 2021	<u>236,719,770</u>	<u>\$ 236,720</u>	<u>\$ 48,410,655</u>	<u>\$ (48,031,742)</u>	<u>\$ 615,633</u>

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Nine Months Ended June 30, 2022					
Balance at September 30, 2021	236,719,770	\$ 236,720	\$ 48,534,525	\$ (49,796,919)	\$ (1,025,674)
Net loss	—	—	—	(3,387,295)	(3,387,295)
Vesting of Restricted Stock	275,000	275	(275)	—	—
Stock-based compensation expense	—	—	397,470	—	397,470
Balance at June 30, 2022	<u>236,994,770</u>	<u>\$ 236,995</u>	<u>\$ 48,931,720</u>	<u>\$ (53,184,214)</u>	<u>\$ (4,015,499)</u>

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Nine Months Ended June 30, 2021					
Balance at September 30, 2020	193,044,766	\$ 193,045	\$ 41,862,901	\$ (43,556,437)	\$ (1,500,491)
Net loss	—	—	—	(4,475,305)	(4,475,305)
Issuance of common stock and warrants, net of financing costs	43,125,004	43,125	6,176,108	—	6,219,233
Vesting of Restricted stock	550,000	550	(550)	—	—
Stock-based compensation expense	—	—	372,196	—	372,196
Balance at June 30, 2021	<u>236,719,770</u>	<u>\$ 236,720</u>	<u>\$ 48,410,655</u>	<u>\$ (48,031,742)</u>	<u>\$ 615,633</u>

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows (Unaudited)
For the Nine Months Ended June 30, 2022 and 2021

	Nine Months Ended June 30, 2022	Nine Months Ended June 30, 2021
Cash flows from operating activities:		
Net loss	\$ (3,387,295)	\$ (4,475,305)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	2,397	1,788
Stock-based compensation	397,470	372,196
Decrease to fair value of derivative liability	(1,000,000)	(108,944)
Inventory obsolescence charge	248,073	181,988
Gain on forgiveness of loan	—	(178,229)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Inventory	(582,572)	(42,215)
Prepaid expenses and other current assets	223,854	(163,135)
Increase (decrease) in:		
Accounts payable	1,288,130	(64,853)
Accrued interest	119,671	110,956
Accrued expenses and other liabilities	(96,370)	(80,324)
Net cash used in operating activities	<u>(2,786,642)</u>	<u>(4,446,077)</u>
Cash flows from investing activities:		
Purchases of property and equipment	—	(3,275)
Net cash used in investing activities	<u>—</u>	<u>(3,275)</u>
Cash flows from financing activities:		
Proceeds received from advances from investors	575,000	—
Proceeds received from series 2 convertible notes	—	1,050,000
Proceeds from issuance common stock and warrants, net of financing costs	—	6,219,233
Net cash provided by financing activities	<u>575,000</u>	<u>7,269,233</u>
Net increase (decrease) in cash	(2,211,642)	2,819,881
Cash, beginning of period	<u>2,266,639</u>	<u>959,309</u>
Cash, end of period	<u>\$ 54,977</u>	<u>\$ 3,779,190</u>
Non-cash financing activities:		
Issuance of restricted stock for services	<u>\$ 29,831</u>	<u>\$ 103,750</u>

The accompanying notes are an integral part of these consolidated financial statements.

ARCH THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. BASIS OF PRESENTATION AND DESCRIPTION OF BUSINESS

Organization and Description of Business

Arch Therapeutics, Inc. (together with its subsidiary, the “*Company*” or “*Arch*”) was incorporated under the laws of the State of Nevada on September 16, 2009, under the name “Almah, Inc.”. Effective June 26, 2013, the Company completed a merger (the “*Merger*”) with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation (“*ABS*”), and Arch Acquisition Corporation (“*Merger Sub*”), the Company’s wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. The Company’s principal offices are located in Framingham, Massachusetts.

ABS was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006, as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5® Advanced Wound System, and has devoted substantially all of the Company’s operational effort to the research, development and regulatory programs necessary to turn the Company’s core technology into commercial products. To date, the Company has principally raised capital through the issuance of convertible debt, and the issuance of units consisting of its common stock, \$0.001 par value per share (“*Common Stock*”), and warrants to purchase Common Stock (“*warrants*”).

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential products. However, there can be no assurance that the Company will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying unaudited interim consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“*US GAAP*”). The interim consolidated financial statements included herein are unaudited; however, they contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the Company’s results of operations and financial position for the interim periods.

Although the Company believes that the disclosures in these unaudited interim consolidated financial statements are adequate to make the information presented not misleading, certain information normally included in the footnotes prepared in accordance with US GAAP has been omitted as permitted by the rules and regulations of the Securities and Exchange Commission (“*SEC*”). These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended September 30, 2021, filed with the SEC on December 17, 2021 (the “*Annual Report*”).

For a complete summary of the Company’s significant accounting policies, please refer to Note 2 included in Item 8 of the Company’s Annual Report. There have been no material changes to the Company’s significant accounting policies during the nine months ended June 30, 2022.

Basis of Presentation

The consolidated financial statements include the accounts of Arch Therapeutics, Inc. and its wholly owned subsidiary, Arch Biosurgery, Inc., a biotechnology company. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expense during the reporting periods. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents as of June 30, 2022 and September 30, 2021.

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories comprises expenditures incurred in acquiring the inventories, the cost of conversion and other costs incurred in bringing them to their existing location and condition. The cost of raw materials, goods-in-process and finished goods are determined on a First in First out (FiFo) basis. When determining net realizable value, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash. The Company maintains its cash in bank deposits accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of the related asset. Upon sale or retirement, the cost and accumulated depreciation are eliminated from their respective accounts, and the resulting gain or loss is included in income or loss for the period. Repair and maintenance expenditures are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 360, *Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the three and nine months ended June 30, 2022 and 2021 there has not been any impairment of long-lived assets.

Leases

The Company determines if an arrangement is a lease at its inception. Operating lease right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company’s lease does not provide an implicit interest rate, the Company used an incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Income Taxes

In accordance with FASB ASC Topic 740, *Income Taxes*, the Company recognizes deferred tax assets and liabilities for the expected future tax consequences or events that have been included in the Company’s consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is more likely than not that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable.

Revenue

In accordance with FASB ASC Topic 606, *Revenue Recognition*, the Company recognizes revenue through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The Company's source of revenue is product sales. Contracts with customers contain a single performance obligation and the Company recognizes revenue from product sales when the Company has satisfied our performance obligation by transferring control of the product to the customers. Control of the product transfers to the customer upon shipment from the Company's third-party warehouse.

Cost of Revenue

Cost of revenue includes product costs, warehousing, overhead allocation and royalty expense.

Research and Development

The Company expenses internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred.

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the guidance of FASB ASC Topic 718, *Compensation-Stock Compensation* ("ASC 718"), which requires all share-based payments be recognized in the consolidated financial statements based on their fair values. In accordance with ASC 718, the Company has elected to use the Black-Scholes Option Pricing Model (the "*Black-Scholes Model*") to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the Common Stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life for awards uses the simplified method for all "plain vanilla" options, as defined in ASC 718-10-S99, and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the Company's awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

The Company measures both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, including those that are recognized or disclosed in the consolidated financial statements at fair value on a recurring basis. The standard created a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company's own views about the assumptions market participants would use in pricing the asset or liability.

At June 30, 2022 and September 30, 2021, the carrying amounts of cash, accounts payables and accrued expense and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Convertible Notes (See Note 10) approximate fair value because borrowing rates and term are similar to comparable market participants.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with FASB ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Going Concern Basis of Accounting

As reflected in the consolidated financial statements, the Company has an accumulated deficit, has suffered significant net losses and negative cash flows from operations, only recently commenced generating limited operating revenues, and has limited working capital. The continuation of the Company's business as a going concern is dependent upon raising additional capital, the ability to successfully market and sell its product(s) and eventually attaining and maintaining profitable operations. As of the date of issuance of the accompanying consolidated financial statements, the Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations, and therefore there is substantial doubt about the Company's ability to continue as a going concern. The Company expects to incur substantial expenses into the foreseeable future for the research, development and commercialization of its current and potential other products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. Finally, some of the Company's product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients ("APIs") for our AC5® product line), are manufactured from facilities in areas impacted by the outbreak of the coronavirus, which could result in shortages due to ongoing efforts to address the outbreak. Historically, the Company has principally funded operations through the issuance of convertible debt, and the issuance of units consisting of Common Stock and warrants. Provisions in the Securities Purchase Agreements that the Company entered into on June 28, 2018 ("2018 SPA") restrict the Company's ability to effect or enter into an agreement to effect any issuance by the Company or its subsidiary of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2018 SPA) including, but not limited to, an equity line of credit or "At-the-Market" financing facility until the institutional investors in the 2018 SPA collectively own less than 20% of the Series G Warrants (See Note 6) purchased by them pursuant to the 2018 SPA.

The continued spread of coronavirus and geopolitical conflicts, including the recent war in Ukraine, as well as uncertain market conditions, may also limit the Company's ability to access capital. If the Company is unable to obtain adequate capital, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned activities. These conditions, in the aggregate, raise substantial doubt as to the Company's ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

3. PROPERTY AND EQUIPMENT

At June 30, 2022 and September 30, 2021, property and equipment consisted of:

	Estimated Useful Life (years)	June 30, 2022	September 30, 2021
Computer equipment	3	\$ 9,357	\$ 9,357
Furniture and fixtures	5	8,983	8,983
Leasehold improvements	Life of Lease	14,416	14,416
Lab equipment	5	1,000	1,000
		33,756	33,756
Less – accumulated depreciation		30,913	28,516
Property and equipment, net		<u>\$ 2,843</u>	<u>\$ 5,240</u>

For the three months ended June 30, 2022 and 2021, depreciation expense recorded was \$799, respectively. For the nine months ended June 30, 2022 and 2021, depreciation expense was \$2,397 and \$1,788, respectively.

4. INVENTORIES

Inventories consist of the following:

	June 30, 2022	September 30, 2021
Finished goods	\$ —	\$ 249,571
Goods-in-process	1,428,264	844,194
Total	<u>\$ 1,428,264</u>	<u>\$ 1,093,765</u>

The Company capitalizes inventory that has been produced for commercial sale and has been determined to have a probable future economic benefit. The determination of whether or not the inventory has a future economic benefit requires estimates by management. To the extent that inventory is expected to expire prior to being sold or used for research and development or used for samples, the Company will write down the value of inventory.

5. STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the “2013 Plan”). Under the 2013 Plan, during the fiscal year ended September 30, 2021, a maximum number of 31,114,256 shares of the Company’s authorized and available Common Stock could be issued in the form of options to purchase common stock (“options”), stock appreciation rights, sales or bonuses of restricted Common Stock (“Restricted Stock”), restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of the Company’s Common Stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 3,000,000 shares, (B) four percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company’s Board of Directors (the “Board”). The exercise price of each option shall be the fair value as determined in good faith by the Board at the time each option is granted. On October 1, 2021, the aggregate number of authorized shares under the 2013 Plan was further increased by 3,000,000 shares to a total of 34,114,256 shares.

The exercise price of each option is equal to the closing price of a share of the Company’s Common Stock on the date of grant.

Share-Based Awards

During the nine months ended June 30, 2022, the Company awarded 475,000 options to employees and directors and 200,000 options to consultants to purchase shares of Common Stock under the 2013 Plan.

Share-based compensation expense for awards granted during the nine months ended June 30, 2022 was based on the grant date fair value estimated using the Black-Scholes Model.

Common Stock Options

Stock compensation activity under the 2013 Plan for the nine months ended June 30, 2022 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2021	24,899,014	\$ 0.29	1.83	\$ 140,151
Awarded	675,000	0.06	—	—
Forfeited/Cancelled	(3,083,818)	0.33	—	—
Outstanding at June 30, 2022	22,490,196	0.28	1.47	—
Vested at June 30, 2022	19,135,976	0.31	1.70	—
Vested and expected to vest at June 30, 2022	22,490,196	0.28	1.47	—

As of June 30, 2022, 5,508,158 shares are available for future grants under the 2013 Plan.

Share-based compensation expense recorded in the Company’s Consolidated Statements of Operations for the three months ended June 30, 2022 and 2021 resulting from options awarded to the Company’s employees, directors and consultants was approximately \$81,000 and \$94,000, respectively. Of this amount, during the three months ended June 30, 2022 and 2021, \$29,000 and \$35,000, respectively, were recorded as research and development expense, and \$52,000 and \$59,000, respectively were recorded as general and administrative expense in the Company’s Consolidated Statements of Operations.

Share-based compensation expense recorded in the Company’s Consolidated Statements of Operations for the nine months ended June 30, 2022 and 2021 resulting from options awarded to the Company’s employees, directors and consultants was approximately \$367,000 and \$269,000, respectively. Of this amount during the nine months ended June 30, 2022 and 2021, \$123,000 and \$89,000, respectively, were recorded as research and development expense, and \$245,000 and \$180,000, respectively, were recorded as general and administrative expense in the Company’s Consolidated Statements of Operations.

During the nine months ended June 30, 2022 and 2021, no options awarded were exercised.

As of June 30, 2022, there is approximately \$230,633 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan. That cost is expected to be recognized over a weighted average period of 1.79 years.

Restricted Stock

Restricted Stock activity under the 2013 Plan for the nine months ended June 30, 2022 and 2021, in shares, follows:

	Nine Months Ended	
	June 30, 2022	June 30, 2021
Non Vested at September 30, 2021 and 2020	450,000	—
Awarded	—	550,000
Vested	(275,000)	(550,000)
Forfeited	—	—
Non Vested at June 30, 2022 and 2021	<u>175,000</u>	<u>—</u>

The weighted average Restricted Stock award date fair value information for the nine months ended June 30, 2022 and 2021 follows:

	Nine Months Ended	
	June 30, 2022	June 30, 2021
Non Vested at September 30, 2021 and 2020	\$ 0.10	\$ —
Awarded	—	0.19
Vested	(0.10)	(0.19)
Forfeited	—	—
Non Vested at June 30, 2022 and 2021	<u>\$ 0.10</u>	<u>\$ —</u>

For the three months ended June 30, 2022 and 2021, compensation expense recorded for the Restricted Stock awards was approximately \$10,000 and \$0, respectively. For the nine months ended June 30, 2022 and 2021, compensation expense recorded for the Restricted Stock awards was approximately \$30,000 and \$104,000, respectively.

6. REGISTERED DIRECT OFFERINGS THAT CREATED DERIVATIVE LIABILITIES

On September 30, 2016, the Company filed a registration statement with the SEC utilizing a “shelf” registration process, which was subsequently declared effective by the SEC on October 20, 2016 (such registration statement, the “*Shelf Registration Statement*”). Under the Shelf Registration Statement, the Company may offer and sell any combination of its Common Stock, warrants, debt securities, subscription rights, and/or units comprised of the foregoing to raise up to \$50,000,000 in gross proceeds.

On February 20, 2017, the Company entered into a Securities Purchase Agreement (the “*2017 SPA*”) with six accredited investors (collectively, the “*2017 Investors*”) providing for the issuance and sale by the Company to the 2017 Investors of an aggregate of 10,166,664 units at a purchase price of \$0.60 per unit in a registered offering (the “*2017 Financing*”). The securities comprising the units sold in the 2017 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant equal to 55% of the shares of Common Stock at an exercise price of \$0.75 per share (“*Series F Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series F Warrant subject to certain restrictions on exercise (the “*2017 Warrants*”) and the shares issuable upon exercise of the 2017 Warrants (the “*2017 Warrant Shares*”).

On June 28, 2018, the Company entered into a Securities Purchase Agreement (“*2018 SPA*”) with eight accredited investors (collectively, the “*2018 Investors*”) providing for the issuance and sale by the Company to the 2018 Investors of an aggregate of 9,070,000 units at a purchase price of \$0.50 per unit in a registered offering (“*2018 Financing*”). The securities comprising the units sold in the 2018 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase up to a number of shares of the Company’s Common Stock equal to 75% of the shares of Common Stock at an exercise price of \$0.70 per share (“*Series G Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series G Warrant subject to certain restrictions on exercise (the “*2018 Warrants*”) and the shares issuable upon exercise of the 2018 Warrants (the “*2018 Warrant Shares*”).

On May 12, 2019, the Company entered into a Securities Purchase Agreement (“2019 SPA”) with five accredited investors (collectively, the “2019 Investors”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 8,615,384 units at a purchase price of \$0.325 per unit in a registered offering (“2019 Financing”). The securities comprising the units sold in the 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$0.40 per share (“Series H Warrant”) at any time prior to the fifth anniversary of the issuance date of the Series H Warrant subject to certain restrictions on exercise (the “2019 Warrants”) and the shares issuable upon exercise of the 2019 Warrants (the “2019 Warrant Shares”).

During the three and nine months ended June 30, 2022 and 2021, no Series F, Series G and Series H Warrants were exercised. As of June 30, 2022, up to 6,802,500 shares may be acquired upon the exercise of the Series G Warrants. As of June 30, 2022, up to 8,615,384 shares may be acquired upon the exercise of Series H Warrants. During the three and nine months ended June 30, 2022, all 5,591,664 remaining Series F Warrants expired.

7. DERIVATIVE LIABILITIES

The Company accounted for the Series F Warrants, the Series G Warrants and the Series H Warrants in accordance with ASC 815-10. Since the Company may be required to purchase its Series F Warrants, Series G Warrants and Series H Warrants for an amount of cash equal to \$0.18, \$0.11 and \$0.0533, respectively, for each share of Common Stock (“Minimum”) and the underlying Series F, Series G and Series H Warrants are not classified within stockholders’ deficit, they are recorded as liabilities at the greater of the Minimum or fair value. They are marked to market each reporting period through the Consolidated Statement of Operations.

On the respective closing dates, the derivative liabilities related to the Series F Warrants, Series G Warrants and Series H Warrants were recorded at an aggregate fair value of \$1,628,113. Given that the fair value of the derivative liabilities was less than the net proceeds, the remaining proceeds were allocated to Common Stock and additional-paid-in-capital. During the three months ended June 30, 2022 and 2021, \$0 and \$0 was recorded to decrease the fair value of derivative liability, respectively. During the nine months ended June 30, 2022 and 2021, \$0 and \$108,944 was recorded to decrease the fair value of derivative liability, respectively.

Fair Value Measurements Using Significant Unobservable Inputs - Nine Months Ended June 30, 2022

(Level 3)

	Series F	Series G	Series H
Beginning balance at September 30, 2021	\$ 1,000,000	\$ 748,275	\$ 459,200
Issuances	—	—	—
Adjustments to estimated fair value	(1,000,000)	—	—
Ending balance at June 30, 2022	<u>\$ —</u>	<u>\$ 748,275</u>	<u>\$ 459,200</u>

Fair Value Measurements Using Significant Unobservable Inputs – Year Ended September 30, 2021

(Level 3)

	Series F	Series G	Series H
Beginning balance at September 30, 2020	\$ 1,000,000	\$ 748,275	\$ 568,144
Issuances	—	—	—
Adjustments to estimated fair value	—	—	(108,944)
Ending balance at September 30, 2021	<u>\$ 1,000,000</u>	<u>\$ 748,275</u>	<u>\$ 459,200</u>

The derivative liabilities were valued as of June 30, 2022 using the Black Scholes Model with the following assumptions:

	Series G	Series H
Closing price per share of Common Stock	\$ 0.046	\$ 0.046
Exercise price per share	\$ 0.70	\$ 0.40
Expected volatility	106.18%	95.85%
Risk-free interest rate	2.80%	2.92%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.94	1.83

The derivative liabilities were valued as of September 30, 2021 using the Black Scholes Model with the following assumptions:

	Series F		Series G		Series H	
Closing price per share of Common Stock	\$	0.12	\$	0.12	\$	0.12
Exercise price per share	\$	0.75	\$	0.70	\$	0.40
Expected volatility		90.28%		87.40%		86.59%
Risk-free interest rate		0.04%		0.19%		0.41%
Dividend yield		—		—		—
Remaining expected term of underlying securities (years)		0.34		1.70		2.58

8. OCTOBER 2019 REGISTERED DIRECT OFFERING

On October 16, 2019, the Company entered into a Securities Purchase Agreement (the “*October 2019 SPA*”) with seven accredited investors (collectively, the “*October 2019 Investors*”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 14,285,714 units at a purchase price of \$0.175 per unit in a registered offering (“*October 2019 Financing*”). The securities comprising the units sold in the October 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$0.22 per share (“*Series I Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series I Warrant subject to certain restrictions on exercise and the shares issuable upon exercise of the Series I Warrants (collectively, the “*October 2019 Warrant Shares*”). As of October 18, 2019, the Company recorded the 14,285,714 shares as Common Stock. Pursuant to the Engagement Agreement (as defined below), the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 1,071,429 shares (the “*Placement Agent Warrants*”). The Placement Agent Warrants have substantially the same terms as the Series I Warrants, except that the exercise price of the Placement Agent Warrants is \$0.21875 per share and the term of the Placement Agent Warrants is five years.

The gross proceeds to the Company from the October 2019 Financing, which were received as of October 18, 2019, were approximately \$2.5 million before deducting financing costs of approximately \$333,000 which includes approximately \$158,000 of placement fees. The number of shares of the Company’s Common Stock into which each of the Series I Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series I Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

The Company engaged H.C. Wainwright as its exclusive institutional investor placement agent (the “*Placement Agent*”) in connection with the October 2019 SPA pursuant to an engagement agreement dated as of October 10, 2019 (the “*2019 Engagement Agreement*”). In consideration for the services provided by it, it was entitled to receive cash fees ranging from 6.0% to 8.2% of the gross proceeds received by the Company, as well as reimbursement for all reasonable expenses incurred by it in connection with its engagement. The Company received gross proceeds of approximately \$2.5 million in the aggregate, resulting in a fee of approximately \$158,000.

During the nine months ended June 30, 2022 and 2021, no Series I Warrants or Placement Agent Warrants were exercised. As of June 30, 2022, up to 14,285,714 and 1,071,429 shares may be acquired upon the exercise of the Series I Warrants and Placement Agent Warrants, respectively.

Common Stock

On October 18, 2019, the Closing Date of the October 2019 Financing, the Company issued 14,285,714 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series I Warrants and the Placement Agent Warrants relating to the aforementioned October 2019 Financing in accordance with ASC 815-40. Because the Series I Warrants and the Placement Agent Warrants are indexed to the Company’s Common Stock, they are classified within stockholders’ deficit in the accompanying consolidated financial statements.

9. 2021 REGISTERED DIRECT OFFERING

On February 11, 2021, the Company entered into a Securities Purchase Agreement (the “2021 SPA”) with certain institutional and accredited investors (collectively, “2021 Investors”) providing for the issuance and sale by the Company to the 2021 Investors of an aggregate of 43,125,004 shares (the “Shares”) of the Company’s Common Stock, and warrants (the “Series K Warrants”) to purchase an aggregate of 32,343,754 shares (the “Warrant Shares”) of Common Stock, at a combined offering price of \$0.16 per share (the “2021 Financing”). The Series K Warrants have an exercise price of \$0.17 per share and are exercisable for a period of 5.5 years. The aggregate gross proceeds for the sale of the Shares and Series K Warrants were approximately \$6.9 million, before deducting the Placement Agent’s fees and expenses and other offering expenses payable by the Company, of approximately \$700,000. Pursuant to an engagement agreement dated as of February 8, 2021 (the “2021 Engagement Agreement”), by and between the Company and the Placement Agent, the Company agreed to pay the Placement Agent cash fees equal to (i) 7.5% of the gross proceeds received by the Company from certain investors in the 2021 Financing, and (ii) 6.0% of the gross proceeds received by the Company from certain investors that had pre-existing relationships with the Company. In addition, the Placement Agent received a one-time non-accountable expense fee of \$10,000, up to \$50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and \$10,000 for clearing expenses. Pursuant to the 2021 Engagement Agreement, the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 7.5% of the aggregate number of Shares sold to the 2021 Investors, or warrants to purchase up to 3,234,375 shares (the “Placement Agent 2 Warrants”) of the Company’s Common Stock. The Placement Agent 2 Warrants have substantially the same terms as the Series K Warrants, except that the exercise price of the Placement Agent 2 Warrants is \$0.20 per share. The 2021 Engagement Agreement contained indemnity and other customary provisions for transactions of this nature.

The 2021 SPA contained certain restrictions on the Company’s ability to conduct subsequent sales of the Company’s equity securities. In particular, we were prohibited from entering into or effecting a Variable Rate Transaction (as defined in the 2021 SPA) until February 11, 2022; *provided, however*, the Company may enter into and effect an at-the-market offering facility with the Placement Agent.

The number of shares of the Company’s Common Stock into which each of the Series K Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series K Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

During the nine months ended June 30, 2022, no Series K Warrants or Placement Agent 2 Warrants were exercised. As of June 30, 2022, up to 32,343,754 and 3,234,375 shares may be acquired upon the exercise of the Series K Warrants and Placement Agent Warrants, respectively.

Common Stock

On February 17, 2021, the Closing Date of the 2021 Financing, the Company issued 43,125,004 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series K Warrants and the Placement Agent 2 Warrants relating to the aforementioned February 2021 Registered Direct Offering in accordance with ASC 815-40, *Derivatives and Hedging*. Because the Series K Warrants and the Placement Agent 2 Warrants are indexed to the Company’s stock, they are classified within stockholders’ deficit in the accompanying consolidated financial statements.

10. SERIES 1 AND SERIES 2 CONVERTIBLE NOTES

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“Series 1 Notes”) and Series 2 Convertible Notes (“Series 2 Notes”, and collectively with the Series 1 Notes, the “Convertible Notes”) in the aggregate principal amount of \$550,000 and \$1,050,000, respectively. The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. The Convertible Notes provide, among other things, for (i) a term of approximately three years; (ii) the Company’s ability to prepay the Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms of the Convertible Notes) into shares of the Company’s Common Stock, at a per share price of \$0.27 and \$0.25 (the “Conversion Price”) for the Series 1 Notes and Series 2 Notes, respectively; (iv) the ability of the holders of the Convertible Note (a “Holder”) to convert the principal of the Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price; (v) the Company’s ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the respective Conversion Price; (vi) the Company’s ability to convert the principal of the Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price in the event the volume weighted average price (“VWAP”) of the Common Stock equals or exceeds \$0.32 per share for at least fifteen consecutive Trading Days; (vii) the Company’s ability to convert all outstanding Note Obligations into shares of Common Stock at the respective Conversion Price (an “In-Kind Note Repayment”) in lieu of repaying the Note Obligations outstanding on the Maturity Date, *provided, however*, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. During the quarter ended March 31, 2022, all holders of the Convertible Notes executed subordination agreements in anticipation of the potential issuance of additional promissory notes convertible into Common Stock. As consideration for agreeing to subordinate the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent.

On June 3, 2020, the Company entered into an agreement (the “*Agreement*”) with the holders of a majority (the “*Majority Holders*”) of the outstanding warrants classified as “*Series D Warrants*”, resulting in approximately \$850,000 of proceeds as a result of the full exercise of all Series D Warrants. Under the terms of the Agreement, in exchange for fully exercising their remaining Series D Warrants for 4,727,273 shares of Common Stock on June 4, 2020, the Majority Holders were issued warrants to purchase 3,545,454 shares of Common Stock at an exercise price of \$0.25 over a 1-year term (“*Series J Warrants*”). On November 6, 2020, as consideration for an investment in the Convertible Notes, the Company entered into an amendment to the Series J Warrants with a holder of a Series J Warrant exercisable for up to 3,375,000 shares of Common Stock, to extend the term of the Series J Warrant from one year to thirty months.

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the “*Keyes Sulat Agreement*”) with the Keyes Sulat Revocable Trust (the “*Trust*”), also a holder of outstanding Series D Warrants, resulting in approximately \$82,000 of proceeds as a result of the full exercise of the Trust’s Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust’s remaining Series D Warrants for 454,546 shares of Common Stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 340,910 shares of Common Stock at an exercise price of \$0.25 over a one-year term. James R. Sulat, a former member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat’s immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction.

During the three months ended June 30, 2022 and 2021, the Company recorded interest expense on the Convertible Notes of approximately \$40,000. During the nine months ended June 30, 2022 and 2021, the Company recorded interest expense on the Convertible Notes of approximately \$120,000 and \$110,000, respectively.

11. ADVANCES FROM INVESTORS

As of June 30, 2022, the Company raised \$575,000 in the form of shareholder advances towards its planned upcoming financing of Senior Secured Convertible Promissory Notes. See subsequent events note (Note 14), for further details for this financing.

Terrence Norchi, the Company’s President and Chief Executive Officer, Michael Abrams, the Company’s Chief Financial Officer, and Laurence Hicks, a member of the Company’s board of directors, through Drake Partners LLC, participated in the Convertible Notes Offering for an aggregate of \$80,000.

12. PAYROLL PROTECTION PROGRAM LOAN

On April 25, 2020, the Company executed a promissory note (the “*PPP Note*”) evidencing an unsecured loan in the amount of \$176,300 under the Paycheck Protection Program (the “*PPP Loan*”). The Paycheck Protection Program (or “*PPP*”) was established under the Coronavirus Aid, Relief, and Economic Security Act (the “*CARES Act*”) and is administered by the U.S. Small Business Administration (“*SBA*”). The Loan has been made through First Republic Bank (the “*Lender*”).

The PPP Loan had a two-year term and bears interest at a rate of 1.00% per annum. Monthly principal and interest payments were deferred until the SBA decided on the Company’s loan forgiveness application. If the PPP Loan was not forgiven, the Company would be required to make monthly payments of principal and interest of approximately \$20,000 to the Lender.

The PPP Note contained customary events of default relating to, among other things, payment defaults, providing materially false and misleading representations to the SBA or Lender, or breaching the terms of the PPP Loan documents. The occurrence of an event of default would have resulted in the immediate repayment of all amounts outstanding, collection of all amounts owing from the Company, or filing suit and obtaining judgment.

Under the terms of the CARES Act, PPP Loan recipients can apply for and be granted forgiveness for all or a portion of the loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. During November 2020, the Company applied for forgiveness of the PPP Loan. On May 28, 2021, the Company received notice that the SBA completed its review of the Company’s application for forgiveness of the PPP Loan, and all principal and interest was forgiven.

The SBA reserves the right to audit any PPP loan, regardless of size. These audits may occur after forgiveness has been granted. In accordance with the CARES Act all borrowers are required to maintain the PPP loan documentation for six years after the PPP loan was forgiven or repaid in full and to provide that documentation to the SBA upon request.

13. RISKS AND UNCERTAINTIES – COVID-19 AND GEOPOLITICAL CONFLICTS

The Company sources its materials and services for its products and product candidates from facilities in areas impacted or which may be impacted by the outbreak of the coronavirus or geopolitical conflicts. The Company's ability to obtain future inventory may be impacted, therefore potentially affecting the Company's future revenue stream. In addition, the Company has historically and principally funded its operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of Common Stock and warrants which may also be impacted by economic conditions beyond the Company's control as well as uncertainties resulting from geopolitical conflicts, including the recent war in Ukraine. The extent to which the coronavirus and recent events in Ukraine will impact the global economy and the Company is uncertain and cannot be reasonably measured.

14. SUBSEQUENT EVENTS

The Company evaluated all events or transactions through August 11, 2022, the date which these unaudited interim consolidated financial statements were issued. There were no material subsequent events, other than provided below:

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement (the "SPA") with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of (i) Senior Secured Convertible Promissory Notes (each a "2022 Note" and collectively, the "2022 Notes") in the aggregate principal amount of \$4.23 million, which includes an aggregate \$0.71 million original issue discount in respect of the 2022 Notes; (ii) Warrants (the "2022 Warrants"), to purchase an aggregate of 85,110,664 shares (the "Warrant Shares") of Common Stock; and (iii) 12,766,600 shares of Common Stock (the "Inducement Shares") equal to 15% of the principal amount of the 2022 Notes divided by the closing price of the Common Stock immediately prior to the Closing Date (as defined below). The 2022 Notes, 2022 Warrants and Inducement Shares were issued as part of a convertible note offering authorized by the Company's board of directors (the "Convertible Notes Offering"). The aggregate gross proceeds for the sale of the 2022 Notes, 2022 Warrants and Inducement Shares was approximately \$3.5 million, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. Included in the gross proceeds of approximately \$3.5 million is approximately \$0.6 million received as advances from investors (see Note 11). The closing of the sales of these securities under the SPA occurred on July 6, 2022 (the "Closing Date").

The Company retained a placement agent in connection with the private placement of \$2.4 million of the 2022 Notes to the institutional investors.

In addition, as a part of the Convertible Notes Offering, certain holders (the "Series Holders") of the Company's 10% Series 1 Convertible Notes and 10% Series 2 Convertible Notes (the "Series Notes") have agreed to exchange their Series Notes for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the "Exchanged Notes"). In connection with the issuance of the Exchanged Notes, the Series Holders entered into a subordination agreement on the Closing Date to subordinate their rights in respect of the Exchange Notes to the rights of the Investors in respect of the 2022 Notes.

Further, in connection with the 2022 Private Placement Financing, we are required to complete an Uplist Transaction by February 15, 2023 under the terms of the 2022 Notes. If we are unable to complete an Uplist Transaction, then the 2022 Notes will become immediately due and payable and we will be obligated to pay to each 2022 Note holder an amount equal to 125%, multiplied by the sum of the outstanding principal amount of the 2022 Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2022 Notes to the date of payment, plus any default interest and any other amounts owed to the holder, payable in cash or shares of Common Stock.

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

References in this Quarterly Report on Form 10-Q (this "Quarterly Report", or this "Report") to "Arch Biosurgery, Inc." "Company", "we", "us", "our", "Arch" or similar references mean Arch Therapeutics, Inc. and its consolidated subsidiary, Arch Biosurgery, Inc. References to the "SEC" refer to the U.S. Securities and Exchange Commission.

Forward Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated condensed financial statements and the related notes included elsewhere in this Report. Our consolidated condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," or similar language. All forward-looking statements included in this Report are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under the heading "Risk Factors" included Part I, Item 1A of our Annual Report on Form 10-K for the year ended September 30, 2021 (the "Annual Report"), as well as in Item II, Part 1A of this Report. Readers are cautioned not to place undue reliance on these forward-looking statements.

Corporate Overview

Arch Therapeutics, Inc., (together with its subsidiary, the "Company" or "Arch") was incorporated under the laws of the State of Nevada on September 16, 2009, under the name "Almah, Inc." Effective June 26, 2013, the Company completed a merger (the "Merger") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("ABS"), and Arch Acquisition Corporation ("Merger Sub"), the Company's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. Our principal offices are located in Framingham, Massachusetts.

ABS was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006, as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5® Advanced Wound System, and has devoted substantially all of our operational effort to the research, development and regulatory programs necessary to turn our core technology into commercial products. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of the Company's common stock, \$0.001 par value per share ("Common Stock"), and warrants to purchase Common Stock ("warrants").

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential products. However, there can be no assurance that the Company will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

Business Overview

We are a biotechnology company marketing and developing a number of products based on our innovative AC5® self-assembling technology platform. We believe these products can be important advances in the field of stasis and barrier applications, which includes stopping bleeding ("hemostasis"), controlling leaking ("sealant") and managing wounds created during surgery, trauma or interventional care or from disease. We have only recently commenced commercial sales of our first product, AC5® Advanced Wound System, and have devoted substantially all of our operational effort to the research, development and regulatory programs necessary to turn our core technology into commercial products. Our goal is to make care faster and safer for patients with products for use in external wounds, which we refer to as Dermal Sciences applications, and products for use inside the body, which we refer to as Biosurgery applications.

Core Technology

Our flagship products and product candidates are derived from our AC5® self-assembling peptide (“SAP”) technology platform and are sometimes referred to as AC5® or the “AC5® Devices.” These include AC5® Advanced Wound System and AC5 Topical Hemostat, which have received marketing authorization as medical devices in the United States and Europe, respectively, and which are intended for skin applications, such as management of complicated chronic wounds or acute surgical wounds. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-GTM for gastrointestinal endoscopic procedures and AC5-V® and AC5® Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

Products based on the AC5® platform contain a biocompatible peptide that is synthesized from proteogenic, naturally occurring L-amino acids. Unlike products that contain traditional peptide sequences, when applied to a wound, AC5®-based products intercalate into the interstices of the connective tissue and self-assemble into a protective physical-mechanical nanoscale structure that can provide a barrier to leaking substances, such as blood, while also acting as a biodegradable scaffold that enables healing. Self-assembly is a central component of the mechanism of action of our technology. Individual AC5® peptide units readily build themselves, or self-assemble, into an ordered network of nanofibrils when in aqueous solution by the following process:

- Peptide strands line up with neighboring peptide strands, interacting via hydrogen bonds (non-covalent bonds) to form a ribbon-like structure called a beta sheet.
- This process continues such that hundreds of strands organize with charged and polar side chains oriented on one face and non-polar side chains oriented on the opposite face of the beta sheets.
- Interactions of the resulting structure with water molecules and ions results in formation nanofibrils, which extend in length and can join together to form larger nanofibers.
- This network of AC5® peptide nanofibers form the physical-mechanical barrier that is responsible for sealant, hemostatic and other properties, regardless of the presence of antithrombotic agents, and which subsequently becomes the scaffold that supports the repair and regeneration of damaged tissue.

Based on the intended application, we believe that the underlying AC5® SAP technology can impart important features and benefits to our products that may include, for instance, stopping bleeding (hemostasis), mitigating contamination, modulating inflammation, donating moisture, and enabling an appropriate wound microenvironment conducive to healing. For instance, AC5® Advanced Wound System, which is indicated for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds, is shipped and stored at room temperature, is applied directly as a liquid, can conform to irregular wound geometry, and does not possess sticky or glue-like handling characteristics. We believe these properties enhance its utility in several settings and contribute to its user-friendly profile.

We believe that our technology lends itself to a range of potential applications in which there is a wound inside or on the body, and in which there is need for a hemostatic agent or sealant. For instance, the results of certain preclinical and clinical investigations that either we have conducted, or others have conducted on our behalf, have shown quick and effective hemostasis with the use of AC5® SAP technology, and that time to hemostasis (“TTH”) is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called “*blood thinners*.” Furthermore, the transparency and physical properties of certain AC5® Devices may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as surgery starts, a concept that we call Crystal Clear Surgery™. An example of a product that contains related features and benefits is AC5® Topical Hemostat, which is indicated for use as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound.

Operations

Much of our operational efforts to date, which we often perform in collaboration with partners, have included selecting compositions and formulations for our initial products; conducting preclinical studies, including safety and other tests; conducting a human trial for safety and performance of AC5®; developing and conducting a human safety study to assess for irritation and sensitization potential; securing marketing authorization for our first product in the United States and in Europe; developing, optimizing, and validating manufacturing methods and formulations, which are particularly important components of self-assembling peptide development; developing methods for manufacturing scale-up, reproducibility, and validation; engaging with regulatory authorities to seek early regulatory guidance as well as marketing authorization for our products; sourcing and evaluating commercial partnering opportunities in the United States and abroad; and developing and protecting the intellectual property rights underlying our technology platform.

Our long-term business plan includes the following goals:

- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop academic, scientific and institutional relationships to collaborate on product research and development;
- expanding and maintaining protection of our intellectual property portfolio; and
- developing additional product candidates in Dermal Sciences, Biosurgery, and other areas.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- seek additional funding as required to support the milestones described previously and our operations generally;
- work with our manufacturing partners to scale up production of product compliant with current good manufacturing practices (“cGMP”), which activities will be ongoing and tied to our development and commercialization needs;
- further clinical development of our product platform;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek regulatory input to guide activities related to expanded and new product marketing authorizations;
- continue to expand and enhance our financial and operational reporting and controls;
- pursue commercial partnerships; and
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio.

In addition to capital required for operating expenses, depending upon additional input from EU and US regulatory authorities, as well as the potential for additional regulatory filings and approvals during the next two years, additional capital will be required.

We have no commitments for any future capital. As indicated above, we will require significant additional financing to fund our planned operations, including further research and development relating to AC5®, seeking regulatory approval of that or any other product we may choose to develop, commercializing any product for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or business, and maintaining our intellectual property rights, pursuing new technologies and for financing the investor relations and incremental administrative costs associated with being a public corporation. We do not presently have, nor do we expect in the near future to have, sufficient revenue to fund our business from operations, and we will need to obtain substantially all of our necessary funding from external sources for the foreseeable future. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investment.

Since inception, we have funded our operations primarily through debt borrowings, the issuance of convertible debt and the issuance of units consisting of Common Stock and warrants, and we may continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders' ownership will be diluted. The terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors. Further, newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt. Further, obtaining any loan, assuming a loan on acceptable terms would be available when needed, would increase our liabilities and future cash commitments. We may also seek funding from additional collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment-banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs.

Merger with ABS and Related Activities

On June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. In contemplation of the Merger, effective May 24, 2013, the Company increased its authorized Common Stock from 75,000,000 shares to 300,000,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. Also, in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its Common Stock trades on the OTC Bulletin Board from "AACH" to "ARTH".

Recent Developments

On December 13, 2021 the Company announced that in partnership with Lovell Government Services, Arch's AC5® Advanced Wound System ("AC5®") has been added to the Federal Supply Schedule ("FSS") and General Services Administration ("GSA") contracts, and is approved for purchase by all federal government agencies, including the Department of Veterans Affairs ("VA"), Indian Health Services ("IHS"), and Department of Defense ("DOD") Medical Treatment Facilities effective December 15, 2021.

On March 14, 2022, the Company announced it had entered into a distribution agreement with Centurion Therapeutics Inc. ("Centurion"), an exclusive strategic partner to the world's largest tissue bank, to expand sales opportunities for AC5® Advanced Wound System. Centurion distributes a comprehensive portfolio of aseptically processed human tissues to support surgeons in a broad array of specialties through over a hundred contracted wound care distributors nationwide. AC5® Advanced Wound System will be added to their advanced wound care product line as part of this distribution agreement.

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement (the "SPA") with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of (i) Senior Secured Convertible Promissory Notes (each a "2022 Note" and collectively, the "2022 Notes") in the aggregate principal amount of \$4.23 million, which includes an aggregate \$0.71 million original issue discount in respect of the 2022 Notes; (ii) Warrants (the "2022 Warrants"), to purchase an aggregate of 85,110,664 shares (the "Warrant Shares") of Common Stock; and (iii) 12,766,600 shares of Common Stock (the "Inducement Shares") equal to 15% of the principal amount of the 2022 Notes divided by the closing price of the Common Stock immediately prior to the Closing Date (as defined below). The 2022 Notes, 2022 Warrants and Inducement Shares were issued as part of a convertible note offering authorized by the Company's board of directors (the "Convertible Notes Offering"). The aggregate gross proceeds for the sale of the 2022 Notes, 2022 Warrants and Inducement Shares was approximately \$3.5 million, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The closing of the sales of these securities under the SPA occurred on July 6, 2022 (the "Closing Date").

Results of Operations

The following discussion of our results of operations should be read together with the unaudited interim consolidated financial statements included in this Report. The period-to-period comparisons of our interim results of operations that follow are not necessarily indicative of future results.

Three Months Ended June 30, 2022 Compared to Three Months Ended June 30, 2021

	June 30, 2022 (\$)	June 30, 2021 (\$)	Increase (Decrease) (\$)
Revenue	6,261	—	6,261
Operating Expense:			
Cost of revenues	17,140	—	17,140
Selling, general and administrative	836,215	1,370,395	(534,180)
Research and development	159,846	297,553	(137,707)
Loss from Operations	(1,006,940)	(1,667,948)	(661,008)
Other Income (Expense)	(39,890)	138,043	(177,933)
Net loss	(1,046,830)	(1,529,905)	483,075

Revenue

Revenue for the three months ended June 30, 2022 was \$6,261, an increase of \$6,261 compared to no revenue for the three months ended June 30, 2021. Revenue for the three months ended June 30, 2022 was the result of a single transaction into a VA hospital through our distribution partner, LGS.

Cost of Revenue

Cost of revenue during the three months ended June 30, 2022 was \$17,140, an increase of \$17,140 compared to no cost of revenue for the three months ended June 30, 2021. Cost of revenue includes product costs, third party warehousing, overhead allocation, royalty and shipping costs.

Selling, General and Administrative Expense

Selling, general and administrative expense during the three months ended June 30, 2022 was \$836,215, a decrease of \$534,180 compared to \$1,370,395 for the three months ended June 30, 2021. The decrease in selling, general and administrative expense for the three months ended June 30, 2022 is primarily attributable to a decrease in legal and consulting costs and compensation costs attributed to a reduction in headcount.

Research and Development Expense

Research and development expense during the three months ended June 30, 2022 was \$159,846 a decrease of \$137,707 compared to \$297,553 for the three months ended June 30, 2021. The decrease in research and development expense is primarily attributable to a decrease in compensation costs attributed to a reduction in headcount.

Other Income (Expense)

Other expense during the three months ended June 30, 2022 was \$39,890, a decrease of \$177,933 compared to total other income of \$138,043 for the three months ended June 30, 2021. The decrease in other income is attributed to a gain on forgiveness of loan of approximately \$178,000 recorded in the three months ended June 30, 2021.

Nine Months Ended June 30, 2022 Compared to Nine Months Ended June 30, 2021

	June 30, 2022	June 30, 2021	Increase (Decrease)
	(\$)	(\$)	(\$)
Revenue	14,086	10,000	4,086
Operating Expenses			
Cost of revenues	51,363	10,102	41,261
Selling, general and administrative	3,308,227	3,600,419	(292,192)
Research and development	922,120	1,051,755	(129,635)
Loss from Operations	<u>(4,291,710)</u>	<u>(4,652,276)</u>	<u>(380,566)</u>
Other Income (Expense)	<u>880,329</u>	<u>176,971</u>	<u>703,358</u>
Net Loss	<u><u>(3,387,295)</u></u>	<u><u>(4,475,305)</u></u>	<u><u>1,088,010</u></u>

Revenue

Revenue for the nine months ended June 30, 2022 was \$14,086, an increase of \$4,086 compared to \$10,000 for the nine months ended June 30, 2021. Revenue for the nine months ended June 30, 2022 was the result of two transactions into a VA hospital through our distribution partner, LGS. Revenue for the nine months ended June 30, 2021 was the result of a single transaction with an established key opinion leader that has provided services for compensation in the past and expected to continue to provide services for compensation in the future.

Cost of Revenues

Cost of revenue during the nine months ended June 30, 2022 was \$51,363, an increase of \$41,261 compared to \$10,102 for the nine months ended June 30, 2021. Cost of revenue includes product costs, third party warehousing, overhead allocation, royalty and shipping costs.

Selling, General and Administrative Expense

Selling, general and administrative expense during the nine months ended June 30, 2022 was \$3,308,227, a decrease of \$292,192 compared to \$3,600,419 for the nine months ended June 30, 2021. The decrease in selling, general and administrative expense for the nine months ended June 30, 2022 is primarily attributable to decrease in legal and consulting costs partially offset by an increase in compensation costs attributed to an increase in headcount.

Research and Development Expense

Research and development expense during the nine months ended June 30, 2022 was \$922,120, a decrease of \$129,635 compared to \$1,051,755 for the nine months ended June 30, 2021. The decrease in research and development expense is primarily attributable to a decrease in compensation costs, partially offset by an inventory obsolescence charge of \$250,000 for shelf-life, research and development and product samples.

Other Income (Expense)

Other income during the nine months ended June 30, 2022 was \$880,329, an increase of \$703,358 compared to other income of \$176,971 for the nine months ended June 30, 2021. The increase in other income is attributable to a change in fair market value of the derivative liabilities, partially offset by the gain on the forgiveness of loan recorded in the nine months ended June 30, 2021.

Liquidity and Capital Resources

We have only recently completed the first sale of our first product, AC5® Advanced Wound System. We devote a significant amount of our efforts on fundraising as well as planning and conducting product research and development and activities in connection with obtaining regulatory marketing authorization. We have principally raised capital through borrowings and the issuance of convertible debt and units consisting of Common Stock and warrants to fund our operations.

Working Capital

At June 30, 2022, we had total current assets of \$1,566,748 (including cash of \$54,977) and negative working capital of \$352,559. Our working capital as of June 30, 2022 and September 30, 2021 are summarized as follows:

	June 30, 2022	September 30, 2021
Total Current Assets	\$ 1,566,748	\$ 3,667,745
Total Current Liabilities	1,919,307	1,727,547
Working Capital	<u>\$ (352,559)</u>	<u>\$ 1,940,198</u>

Total current assets as of June 30, 2022 were \$1,455,748, a decrease of \$2,100,997 compared to \$3,667,745 as of September 30, 2021. The decrease in current assets is primarily attributable to selling, general and administrative expense and research and development expense incurred in connection with activities to develop our primary product candidate. Our total current assets as of June 30, 2022 and September 30, 2021 were comprised primarily of cash, inventory and prepaid expense.

Total current liabilities as of June 30, 2022 were \$1,919,307, an increase of \$191,760 compared to \$1,727,547 as of September 30, 2021. The increase is primarily due to an increase in accounts payable, partially offset by a decrease in the fair value of the derivative liability. Our total current liabilities as of June 30, 2022 were comprised of accounts payable and accrued expense and other liabilities. Current liabilities as of September 30, 2021 were comprised of accounts payable, accrued expense and other liabilities, and the current portion of derivative liabilities.

Cash Flow for the Nine Months Ended June 30, 2022 Compared to the Three Months Ended June 30, 2021

	June 30, 2022	June 30, 2021
Cash Used in Operating Activities	\$ (2,786,642)	\$ (4,446,077)
Cash Used in Investing Activities	—	(3,275)
Cash Provided by Financing Activities	575,000	7,269,233
Net Increase (decrease) in Cash	<u>\$ (2,211,642)</u>	<u>\$ 2,819,881</u>

Cash Used in Operating Activities

Cash used in operating activities decreased by \$1,659,435 to \$2,786,642 during the nine months ended June 30, 2022, compared to \$4,446,077 during the nine months ended June 30, 2021. The decrease in cash used in operating activities is primarily attributable to an increase in accounts payable.

Cash Used in Investing Activities

Cash used in investing activities decreased by \$3,275 to \$0 during the nine months ended June 30, 2022, compared to \$3,275 during the nine months ended June 30, 2021. For the nine months ended June 30, 2021, cash used in investing activities is attributed to computer hardware purchases.

Cash Provided by Financing Activities

Cash provided by financing activities decreased by \$6,694,233 to \$575,000 during the nine months ended June 30, 2022, compared to \$7,269,233 during the nine months ended June 30, 2021. For the nine months ended June 30, 2022, the cash provided by financing activities resulted from net proceeds of \$575,000 raised from the advances from investors. For the nine months ended June 30, 2021, the cash provided by financing activities resulted from net proceeds of \$6,219,233 raised from issuance of Common Stock and warrants in the 2021 Financing and \$1,050,000 from the issuance of Series 2 Notes.

Cash Requirements

We anticipate that our operating and other expense will increase significantly as we continue to implement our business plan and pursue our operational goals. As of August 11, 2022, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2023. Depending upon additional input from EU and US regulatory authorities, however, we do not expect to generate sufficient revenues from operations before we need to raise additional capital. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, including without limitation those set forth under the heading “RISK FACTORS” described in our Annual Report, in which case our current funds may not be sufficient to operate our business for the period we expect.

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5® Advanced Wound System. That revenue will not be sufficient to fund our business operations and we will need to obtain additional funding from external sources for the foreseeable future. We do not have any commitments for future capital. Significant additional financing will be required to fund our planned operations in the near term and in future periods, including research and development activities relating to our principal product candidate, seeking regulatory approval of that or any other product candidate we may choose to develop, commercializing any product candidate for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or businesses, and maintaining our intellectual property rights and pursuing rights to new technologies. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. We are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the 2018 SPA (see Note 6) restricting our ability to effect or enter into an agreement to effect any issuance by the Company or any of its subsidiaries of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2018 SPA) including, but not limited to, an equity line of credit or “At-the-Market” financing facility until the three lead investors in the 2018 Financing collectively own less than 20% of the Series G Warrants purchased by them pursuant to the 2018 SPA. These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of debt or through equity issuances. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investments.

As previously noted, since inception we have funded our operations primarily through equity and debt financings and we expect to continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders’ ownership will be diluted. Additionally, the terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors, and in particular may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt. Further, obtaining any loan, assuming a loan would be available when needed on acceptable terms, would increase our liabilities and future cash commitments. We may also seek funding from collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs.

Going Concern

We have commenced commercial sales of our first product, AC5® Advanced Wound System. From inception, we have had recurring losses from operations. While the Company anticipates that it will have cash on hand into the second quarter of fiscal 2023, the continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of June 30, 2022, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements included in this Report do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

Pursuant to certain disclosure guidance issued by the SEC, the SEC defines "critical accounting policies" as those that require the application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our critical accounting policies that we anticipate will require the application of our most difficult, subjective or complex judgments are as follows:

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with the Financial Accounting Standards Board Accounting Standards Code Topic 815, *Derivatives and Hedging*. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories comprises expenditures incurred in acquiring the inventories, the cost of conversion and other costs incurred in bringing them to their existing location and condition. The cost of raw materials, work-in-progress and finished goods and other products are determined on a First in First out (FIFO) basis. When determining net realizable value, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors in evaluating net realizable value.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer (who is our Principal Executive Officer) and our Chief Financial Officer (who is our Principal Financial Officer and Principal Accounting Officer), of the effectiveness of the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)) as of June 30, 2022, pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures are effective as of June 30, 2022, in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the quarter ended June 30, 2022, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II – OTHER INFORMATION**Item 1. Legal Proceedings**

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. The impact and outcome of litigation, if any, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are not currently a party to any proceedings the adverse outcome of which, individually or in the aggregate, would have a material adverse effect on our financial position or results of operations.

Item 1A. Risk Factors

In addition to the other information set forth in this Report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended September 30, 2021, as filed with the SEC on December 17, 2021 (our “*Annual Report*”), which could materially affect our business, financial condition or future results. The risks described in our Annual Report may not be the only risks facing the Company. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company’s business, financial condition and/or operating results.

There were no material changes to the risk factors previously disclosed in our Annual Report.

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

Not applicable

Item 6. Exhibits

Exhibit No.	Exhibit Title
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Terrence W. Norchi, President and Chief Executive Officer, and Michael S. Abrams, Chief Financial Officer and Treasurer
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13A-14(A) OR 15D-14(A) UNDER THE SECURITIES AND EXCHANGE ACT OF 1934**

I, Terrence W. Norchi, certify that:

1. I have reviewed this Form 10-Q of Arch Therapeutics, Inc.;

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 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 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 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 information; 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 11, 2022

/s/ TERRENCE W. NORCHI, MD

Name: *Terrence W. Norchi, MD*

Title: *President and Chief Executive Officer
(Principal Executive Officer)*

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13A-14(A) OR 15D-14(A) UNDER THE SECURITIES AND EXCHANGE ACT OF 1934**

I, Michael S. Abrams, certify that:

1. I have reviewed this Form 10-Q of Arch Therapeutics, Inc.;

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 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 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 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 information; 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.

Dated: August 11, 2022

/s/ MICHAEL S. ABRAMS

Name: Michael S. Abrams

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION REQUIRED BY
SECTION 1350 OF TITLE 18 OF THE UNITED STATES CODE**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Arch Therapeutics, Inc. (the “Company”) certify that the quarterly report of the Company on Form 10-Q for the fiscal quarter ended June 30, 2022 fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 11, 2022

/s/ TERRENCE W. NORCHI, MD

Name: Terrence W. Norchi, MD
Title: *President and Chief Executive Officer*
(Principal Executive Officer)

Dated: August 11, 2022

/s/ MICHAEL S. ABRAMS

Name: Michael S. Abrams
Title: *Chief Financial Officer*
(Principal Financial and Accounting Officer)

This certification accompanies this Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.