

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended June 30, 2022

OR

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

For the transition period from _____ to _____

Commission file number 000-28443



(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

23-3011702
(IRS Employer
Identification No.)

8285 El Rio, Suite 190
Houston, TX 77054
(Address of Principal Executive Offices) (Zip Code)

(346) 396-4770
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

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

Large Accelerated Filer ☐
Non-accelerated Filer ☒

Accelerated Filer ☐
Smaller Reporting Company ☒
Emerging Growth Company ☐

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

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

APPLICABLE ONLY TO CORPORATE ISSUERS

As of August 5, 2022, the number of shares outstanding of the registrant's common stock, \$0.0001 par value, was 41,081,962.

NUO THERAPEUTICS, INC.

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PART I
FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

NUO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2022 (unaudited)	December 31, 2021 (audited)
ASSETS		
Current assets		
Cash and cash equivalents	\$ 3,444,828	\$ 1,414,569
Inventory	238,172	-
Prepaid expenses and other current assets	188,270	51,349
Total current assets	3,871,270	1,465,918
Property and equipment, net	50,179	-
Operating lease right of use assets	401,702	-
Total assets	\$ 4,323,151	\$ 1,465,918
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 391,740	\$ 526,557
Accrued liabilities	16,522	146,522
Current portion of operating lease liabilities	56,571	-
Total current liabilities	464,833	673,079
Non-current portion of operating lease liabilities	296,307	-
Total liabilities	761,140	673,079
Commitments and contingencies (Note 7)		
Stockholders' equity		
Common stock; \$0.0001 par value, 100,000,000 shares authorized, 41,081,962 and 37,124,205 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	4,109	3,713
Additional paid-in capital	28,450,401	24,382,195
Accumulated deficit	(24,892,499)	(23,593,069)
Total stockholders' equity	3,562,011	792,839
Total liabilities and stockholders' equity	\$ 4,323,151	\$ 1,465,918

See accompanying notes to unaudited condensed consolidated financial statements.

NUO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months ended June 30, 2022	Three Months ended June 30, 2021
Revenue		
Product sales	\$ -	\$ -
Total revenue	<u>-</u>	<u>-</u>
Costs of sales	<u>-</u>	<u>-</u>
Gross profit (loss)	<u>-</u>	<u>-</u>
Operating expenses		
Selling, general and administrative	923,726	6,546
Total operating expenses	<u>923,726</u>	<u>6,546</u>
Loss from operations	<u>(923,726)</u>	<u>(6,546)</u>
Other income (expense)		
Interest expense, net	(324)	-
Other income	-	-
Total other income	<u>(324)</u>	<u>-</u>
Net loss	<u><u>\$ (924,050)</u></u>	<u><u>\$ (6,546)</u></u>
Loss per common share		
Basic and diluted	\$ (0.02)	\$ (0.00)
Weighted average common shares outstanding		
Basic and diluted	39,779,055	30,258,744

See accompanying notes to unaudited condensed consolidated financial statements.

NUO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Six Months ended June 30, 2022	Six Months ended June 30, 2021
Revenue		
Product sales	\$ -	\$ -
Total revenue	-	-
Costs of sales	-	-
Gross profit (loss)	-	-
Operating expenses		
Selling, general and administrative	1,445,544	12,267
Total operating expenses	1,445,544	12,267
Loss from operations	(1,445,544)	(12,267)
Other income (expense)		
Interest expense, net	(324)	-
Other income	146,438	-
Total other income	146,114	-
Net loss	\$ (1,299,430)	\$ (12,267)
Loss per common share		
Basic and diluted	\$ (0.03)	\$ (0.00)
Weighted average common shares outstanding		
Basic and diluted	38,458,964	30,258,744

See accompanying notes to unaudited condensed consolidated financial statements.

NUO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

For the Three and Six Months Ended June 30, 2022 and 2021

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount (par \$0.0001)			
Balance, January 1, 2022	37,124,205	\$ 3,713	\$ 24,382,195	\$ (23,593,069)	\$ 792,839
Issuance of options to settle related party compensation liabilities	-	-	103,333	-	103,333
Stock compensation expense	-	-	6,430	-	6,430
Net loss	-	-	-	(375,380)	(375,380)
Balance, March 31, 2022	37,124,205	\$ 3,713	\$ 24,491,958	\$ (23,968,449)	\$ 527,222
Issuance of common shares	3,957,757	396	3,957,361	-	3,957,757
Stock compensation expense	-	-	1,082	-	1,082
Net loss	-	-	-	(924,050)	(924,050)
Balance, June 30, 2022	41,081,962	\$ 4,109	\$ 28,450,401	\$ (24,892,499)	\$ 3,562,011

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount (par \$0.0001)			
Balance, January 1, 2021	30,258,744	\$ 3,026	\$ 22,995,854	\$ (23,502,399)	\$ (503,519)
Net loss	-	-	-	(5,721)	(5,721)
Balance, March 31, 2021	30,258,744	\$ 3,026	\$ 22,995,854	\$ (23,508,120)	\$ (509,240)
Net loss	-	-	-	(6,546)	(6,546)
Balance, June 30, 2021	30,258,744	\$ 3,026	\$ 22,995,854	\$ (23,514,666)	\$ (515,786)

See accompanying notes to unaudited condensed consolidated financial statements.

NUO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Six Months Ended June 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (1,299,430)	\$ (12,267)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	7,512	-
Gain on settlement of accounts payable	(146,438)	-
Depreciation of property and equipment	1,356	-
Amortization of operating lease right of use assets	24,836	-
Changes in operating assets and liabilities:		
Inventory	(238,172)	-
Prepaid expenses and other current assets	(136,921)	(1,500)
Accounts payable	11,621	3,920
Accrued liabilities	(26,667)	-
Operating lease liabilities	(73,660)	-
Net cash used in operating activities	(1,875,963)	(9,847)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(51,535)	-
Net cash used in investing activities	(51,535)	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock	3,957,757	-
Net cash provided by financing activities	3,957,757	-
NET DECREASE IN CASH AND CASH EQUIVALENTS	2,030,259	(9,847)
Cash and cash equivalents, beginning of period	1,414,569	161,432
Cash and cash equivalents, end of period	<u>\$ 3,444,828</u>	<u>\$ 151,585</u>
SUPPLEMENTAL INFORMATION		
Cash paid during the period for:		
Interest expense	\$ 324	\$ -
Income taxes	\$ -	\$ -
NON-CASH INVESTING AND FINANCING TRANSACTIONS		
Issuance of options to settle accrued compensation liabilities	\$ 103,333	\$ -
ROU assets and lease liabilities established at inception of lease	\$ 426,538	\$ -

See accompanying notes to unaudited condensed consolidated financial statements.

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

Note 1 – Description of BusinessDescription of Business

Nuo Therapeutics, Inc. (“Nuo Therapeutics,” the “Company,” “we,” “us,” or “our”) is a Delaware corporation organized in 1998 under the name Informatix Holdings, Inc. In 1999, Autologous Wound Therapy, Inc., an Arkansas Corporation, merged with and into Informatix Holdings, Inc. and the name of the surviving corporation was changed to Autologous Wound Therapy, Inc. In 2000, Autologous Wound Therapy, Inc. changed its name to Cytomedix, Inc. (“Cytomedix”). In 2001, Cytomedix filed for bankruptcy under Chapter 11 of the United States Bankruptcy Code, after which Cytomedix was authorized to continue to conduct its business as a debtor and debtor-in-possession. Cytomedix emerged from bankruptcy in 2002 under a Plan of Reorganization. In September 2007, Cytomedix received 510(k) clearance for the Aurix System (“Aurix”), formerly known as the AutoloGel™ System, from the U. S. Food and Drug Administration (“FDA”). In April 2010, Cytomedix acquired the Angel Whole Blood Separation System (“Angel”) and the Angel Business, from Sorin Group USA, Inc. In February 2012, Cytomedix acquired Aldagen, Inc. (“Aldagen”), a privately held developmental cell-therapy company located in Durham, NC. In 2014, Cytomedix changed its name to Nuo Therapeutics, Inc. In 2016, Nuo filed for and emerged from bankruptcy under Chapter 11. Effective May 1, 2019, we furloughed our remaining employees and ceased standard operational activities as we awaited developments concerning our reconsideration request with the Centers for Medicare & Medicaid Services (“CMS”) regarding Medicare coverage for Aurix. Based on a favorable National Coverage Determination issued in April 2021, we initiated restart activities for the business beginning in October 2021 and the Aurix product was available for commercial sale beginning May 2022. Aldagen is a non-operational, wholly owned subsidiary of Nuo.

Impact of COVID-19 Pandemic on Financial Statements

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a “pandemic”, or a worldwide spread of a new disease. Many countries imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the pandemic. The unaudited consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company has not experienced any significant negative impact on its June 30, 2022 unaudited consolidated financial statements related to COVID-19.

Note 2 – Recapitalization

In anticipation of returning to operational status, the Company undertook several financing transactions during 2019 - 2021 to stabilize its financial condition, as follows:

2018 Convertible Notes

In September 2018, the Company issued two separate convertible notes (the “2018 Convertible Notes”) with detachable stock purchase warrants (the “Warrants”) to two separate investors (the “Investors”). Pursuant to separate securities purchase agreements, the Company issued and sold to the Investors 12% convertible promissory notes, each in the principal amount of \$175,000, for an aggregate purchase price of \$315,800 (reflecting a combined \$34,200 in original issue discount and transaction fees). Pursuant to the purchase agreements, the Company also issued to each Investor a warrant exercisable to purchase 233,333 shares of the Company’s common stock, for an aggregate of 466,666 shares of common stock, subject to adjustment.

The notes had an original maturity date nine months from the date of issuance (June 17, 2019). Under the original terms of the 2018 Convertible Notes, after six months from the date of issuance, the Investors could convert the notes, at any time, in whole or in part, into shares of the Company’s common stock, at a conversion price corresponding to a 40% discount to the average of the two lowest trading prices of the common stock during the 25 trading days prior to the conversion, subject to certain adjustments and price-protection provisions contained in the notes, including full-ratchet anti-dilution protection in the case of dilutive issuances of securities that did not meet the requirements of “exempt issuances” as defined in the notes.

Throughout the first three quarters of 2019, the Company entered into various amendments to the 2018 Convertible Notes. The amendments extended the date when the Company could prepay the notes and deferred the date upon which the Investors could initiate conversion of the notes into common shares of the Company pursuant to the notes' terms until September 17, 2019. The Company paid the Investors amendment fees totaling \$69,000 representing approximately 20% of the face value of the 2018 Convertible Notes and agreed to an increase in the principal balance of each note by \$30,000 to \$205,000. The maturity date of the Auctus note was also extended until July 31, 2019.

In December 2019, the Company further amended the 2018 Convertible Notes to provide for the settlement and extinguishment of all obligations under the 2018 Convertible Notes upon the (i) payment of an aggregate \$220,000 to the Investors and (ii) issuance of an aggregate 350,000 shares of common stock to the Investors on or before February 10, 2020. The Company paid \$220,000 to the Investors on December 10, 2019 and issued 350,000 shares of common stock on February 5, 2020 in full settlement of all obligations including accrued interest, and recognized a gain on debt extinguishment of approximately \$246,000 in 2020 upon issuance of the common shares.

2019 Senior Secured Notes

In November and December 2019, the Company entered into note purchase agreements with certain investors providing for the issuance of \$305,000 principal amount of 12% senior secured promissory notes (the "2019 Senior Secured Notes") and warrants to acquire 457,500 shares of the Company's common stock. The \$220,000 of the proceeds were used primarily to partially repay the Company's obligations under the 2018 Convertible Notes as discussed above.

On September 1, 2020, the Noteholders notified the Company of its default under the 2019 Senior Secured Notes and submitted a forbearance and recapitalization proposal to the Company. The 2019 Senior Secured Notes were settled in full in October 2020 (see 2020 Recapitalization below).

2020 Recapitalization

In October 2020 and in response to the declared default under the 2019 Senior Secured Notes, the Company entered into a Recapitalization Agreement (the "Recapitalization") with its existing Deerfield Investors ("Deerfield") and holders of its 2019 Senior Secured Notes ("Noteholders") pursuant to which:

- Deerfield exchanged its Series A Preferred Stock for 2.7 million shares of Common Stock – note that the Series A Preferred Stock did not originally contain a conversion option or redemption feature and was perpetual preferred stock.
- The Noteholders converted \$305,000 of principal and \$30,400 of accrued and unpaid interest of their Senior Secured Notes (*the Company was in default at the time of the conversion*) into 838,487 shares of Common Stock.
- The Noteholders agreed to purchase 487,500 shares of Common Stock for gross proceeds of \$195,000 in cash.
- The Noteholders received warrants to purchase 3,977,961 shares of Common Stock at \$0.40 per share.
- The Noteholders agreed to cancel the warrants originally issued with the 2019 Senior Secured Notes.

The settlement of the Series A Preferred Stock was accounted for at fair value. The Company recognized a deemed dividend (contribution) resulting from the gain on the cancellation of its equity classified preferred stock, calculated as the difference between the fair value of the consideration transferred and the carrying value of the preferred stock. In addition, Lawrence S. Atinsky, the Deerfield Investors' representative on the Company's board, resigned and the number of Company directors was reduced to four. Outstanding options to purchase common stock held by Mr. Atinsky as of the Effective Date were forfeited.

The settlement of the 2019 Senior Secured Notes resulted in the conversion of the \$305,000 principal balance of the Notes plus accrued interest of approximately \$30,400 into an aggregate 838,487 shares of common stock (the "Conversion Shares") of the Company at a conversion price of \$0.40 per share, plus the purchase by the Noteholders, for cash, of 487,500 shares of common stock (the "Purchase Shares") at \$0.40 per share, or \$195,000 in total. The settlement of the 2019 Senior Secured Notes was accounted for at fair value. The Company recognized a gain on extinguishment of the 2019 Senior Secured Notes of \$89,776 calculated as the excess of the carrying amount of the debt (including the accrued interest) over the fair value of the reacquisition price (consisting of the fair value of the common stock and warrants issued net of the fair value of the warrants forfeited and cash received).

As part of the Recapitalization, the Company granted to each of three (3) individuals an aggregate of (i) 962,500 shares of common stock (the "Compensation Shares") and (ii) fully vested warrants to purchase 2,887,500 shares of common stock of the Company (the "Compensation Warrants") in consideration of past performance and service provided to the Company. The fair value of the Compensatory Shares and Compensatory Warrants was \$333,628 which was recognized as stock-based compensation expense upon issuance.

2021 Warrant Modification

In December 2021, the Company entered into a Warrant Modification Agreement (the "Agreement") with the employee holders and Investor holders of 6,865,461 Warrants whereby the Warrants were modified to decrease the exercise price from \$0.40 to \$0.20 per share provided the holders exercised the Warrant prior to January 31, 2022 (the "Modification"). All Warrants were exercised as of December 30, 2021. The Modification was accounted for at fair value; as such, additional stock-based compensation expense of \$13,936 was recognized with respect to the employee warrants and a deemed dividend of \$795,592 was recognized for the Investor warrants.

See Notes 5 and 6 for further discussion.

Note 3 – Liquidity and Summary of Significant Accounting Principles

Liquidity

Since our inception, we have financed our operations by raising debt, issuing equity and equity-linked instruments, and executing licensing arrangements, and to a lesser extent by generating royalties and product revenues. In mid-2019, we ceased ongoing operational activities as we worked to reach a favorable outcome to Medicare reimbursement coverage for the Aurix System. In April 2021 CMS issued an NCD establishing national reimbursement coverage for Aurix when used in chronic non-healing wounds where a diabetes clinical diagnosis exists for the patient. During 2021, 2020 and 2019, the Company raised net cash proceeds of approximately \$1.9 million from the issuance of senior secured debt, common stock and from the exercise of stock purchase warrants. In conjunction with warrant exercises in December 2021, the Company initiated efforts to return to operational status as a commercial business. During the three months ended June 30, 2022, the Company raised proceeds of \$3,957,757 from the sale of common stock to certain accredited investors in two equity private placements which closed on April 29 and May 18, 2022.

We have incurred, and continue to incur, recurring losses and negative cash flows. As of June 30, 2022, we have an accumulated deficit of \$24.9 million and cash and cash equivalents on hand of approximately \$3.4 million.

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations, the ability to generate sufficient cash from operations, and potential other funding sources, including cash on hand, to meet our obligations as they become due.

Although the achievement of future profitable operations and the ability to generate sufficient cash from operations is uncertain at this time, as a result of the closing of the private placements for proceeds of \$3,957,757 on April 29, and May 18, 2022, we have reevaluated our liquidity and financial condition and determined that the Company's cash on hand as of June 30, 2022 supports that the Company can fund its obligations for at least one year from the date these condensed consolidated financial statements are available to be issued and mitigates the substantial doubt consideration.

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States of America ("U.S. GAAP"). In our opinion, the accompanying unaudited interim consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The consolidated balance sheet at December 31, 2021, has been derived from audited financial statements of the Company as of that date. The interim unaudited consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules and regulations prescribed by the SEC. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim consolidated financial statements are read in conjunction with the audited financial statements and notes previously included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

The consolidated financial statements include the accounts of the Company and its wholly owned, controlled, and inactive subsidiary Aldagen, Inc. ("Aldagen"). All significant inter-company accounts and transactions are eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to stock-based compensation, the fair value of common stock and equity-linked and derivative financial instruments, recoverability and depreciable lives of long-lived assets, deferred taxes and associated valuation allowance. Actual results could differ from those estimates.

Cash and Cash Equivalents

We consider all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. We maintain our cash and cash equivalents in the form of money market deposit accounts and qualifying money market funds and checking accounts with financial institutions that we believe are credit worthy.

Accounts Receivables, net

We expect to generate accounts receivables from the sale of our products. We will provide for an allowance against receivables for estimated losses that may result from a customer's inability or unwillingness to pay. The allowance for doubtful accounts is estimated primarily based upon historical write-off percentages, known problem accounts, and current economic conditions. Accounts are written off against the allowance for doubtful accounts when we determine that amounts are not collectable. Recoveries of previously written-off accounts are recorded when collected. We had no trade accounts receivable as of June 30, 2022 and 2021 due to no commercial sales activities during those periods.

Inventory

Our inventory is produced by third-party manufacturers and consists of raw materials and finished goods. Inventory cost is determined on a first-in, first-out basis and is stated at the lower of cost or net realizable value. We will maintain an inventory of kits, reagents, and other disposables having shelf-lives that generally range from 18 months to two years.

As of June 30, 2022, our inventory consisted of approximately \$94,000 of finished goods inventory and approximately \$144,000 of raw materials acquired to facilitate the manufacturing of finished goods at our contract manufacturer and our warehouse/distribution facility.

We will provide for an allowance against inventory for estimated losses that may result in excess and obsolete inventory (i.e., from the expiration of products). Our allowance for expired inventory will be estimated based upon the inventory's remaining shelf-life and our anticipated ability to sell such inventory, which is estimated using past experience and future forecasts, within its remaining shelf life. Expired products are segregated and used for demonstration purposes only; we will record the associated expense for this reserve to cost of sales in the consolidated statements of operations.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Assets are depreciated, using the straight-line method, over their estimated useful life ranging from one to six years. Maintenance and repairs are charged to operations as incurred. Our medical equipment was fully depreciated as of June 30, 2022, while depreciation on property and equipment acquired during the six months ended June 30, 2022 was initiated at the beginning of the second quarter 2022 in the month following the date the property was placed in service.

Leases

At the inception of a contract, the Company determines if the arrangement is, or contains, a lease. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term.

The Company has made certain accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combines lease and non-lease elements of its operating leases.

Revenue Recognition

The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers; (ii) identification of distinct performance obligations in the contract; (iii) determination of contract transaction price; (iv) allocation of contract transaction price to the performance obligations; and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation. The Company recognizes revenues upon the satisfaction of its performance obligations (upon transfer of control of promised goods or services to customers) in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services.

We provide for the sale of our products, including disposable processing sets and supplies to customers. Revenue from the sale of products is recognized upon shipment of products to the customers. We do not maintain a reserve for returned products, as in the past those returns have not been material and are not expected to be material in the future. Direct costs associated with product sales are recorded at the time that revenue is recognized.

As more fully described above, we had no revenues from initial commercialization activities in the three and six months ended June 30, 2022 and no revenues in the three and six months ended June 30, 2021 due to non-operational status.

Stock-Based Compensation

The fair value of employee stock options is measured at the date of grant. Expected volatilities are based on the equally weighted average historical volatility from five comparable public companies with an expected term consistent with ours. Expected years until exercise represents the period of time that options are expected to be outstanding using the "simplified method." The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company estimated that the dividend rate on its common stock will be zero. The assumptions for the six months ended June 30, 2022 and 2021 are summarized in the following table:

	2022		2021
Risk free rate	1.65%	- 2.94%	0.33%
Weighted average expected years until exercise	5	- 6	5
Expected stock volatility	100%		100%
Dividend yield	-		-

The Company elected to account for forfeitures of stock-based awards as they occur.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under the asset and liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. Tax rate changes are reflected in income during the period such changes are enacted. We measure our deferred tax assets and liabilities using the enacted tax rates that we believe will apply in the years in which the temporary differences are expected to be recovered or paid.

A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. All of our tax years remain subject to examination by the tax authorities.

The Company's policy for recording interest and penalties associated with audits is to record such items as a component of income before taxes. There were no such items in 2022 and 2021.

Basic and Diluted Earnings (Loss) per Share

In periods of net loss, basic loss per share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period. In periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all potential dilutive common shares is anti-dilutive.

For periods of net income, diluted earnings per share is computed using the more dilutive of the "treasury method" or "two class method." Dilutive earnings per share under the "treasury method" is calculated by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the dilutive impact of all potential dilutive common shares, consisting primarily of common shares underlying common stock options and stock purchase warrants using the treasury stock method, and convertible notes using the if-converted method. Because none of the Company's equity-linked financial instruments contain non-forfeitable rights to dividends, the "two class" method results in the same diluted earnings per share as the "treasury method."

All of the Company's outstanding stock options and warrants were considered anti-dilutive for the three and six months ended June 30, 2022 and 2021. The following table sets forth the potential dilutive securities excluded from the calculation of diluted loss per share for the periods presented.

	Six months ended June 30, 2022	Six months ended June 30, 2021
Shares underlying:		
Common stock options	3,311,667	1,355,001
Stock purchase warrants	233,333	7,098,794
	<u>3,545,000</u>	<u>8,453,795</u>

Recently Adopted Accounting Standards

In August 2020, the FASB issued new accounting guidance (ASU 2020-06) with respect to the accounting for convertible debt instruments and contracts in an entity's own equity. The guidance simplifies the accounting for convertible instruments by reducing the various accounting models that can require the instrument to be separated into a debt component and equity component or derivative component. Additionally, the guidance eliminated certain settlement conditions previously required to be able to classify a derivative in equity. The new guidance is effective on a modified or full retrospective basis for fiscal years beginning after December 15, 2023, including interim periods with those fiscal years. The Company is currently evaluating the impact on the consolidated financial statements.

We have evaluated all other issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on our results of operations, financial position, or cash flows.

Note 4 – Property and Equipment

Property and equipment, net consisted of the following:

	June 30, 2022	December 31, 2021
Medical equipment	\$ 387,665	\$ 387,665
Office/warehouse equipment	31,569	-
Warehouse/production equipment	19,966	-
	439,200	387,665
Less accumulated depreciation and amortization	(389,021)	(387,665)
Property and equipment, net	<u>\$ 50,179</u>	<u>\$ -</u>

Depreciation expense was \$1,356 for the three and six months ended June 30, 2022 and there was no depreciation expense for property and equipment for the three or six months ended June 30, 2021. None of the Company's long-lived assets were deemed to be impaired during the three and six months ended June 30, 2022 and 2021.

Note 5 – Stock Purchase Warrants

The following schedule reflects outstanding stock purchase warrants activities as of:

Description	June 30, 2022	June 30, 2021
2018 Convertible Notes warrants	233,333	233,333
2020 Replacement warrants	-	3,977,961
2020 Compensatory warrants	-	2,887,500
Total	<u>233,333</u>	<u>7,098,794</u>

The 2018 Convertible Notes warrants have a \$0.15 strike price, approximately 1.25 years of remaining contractual term, approximately \$140,000 of intrinsic value as of June 30, 2022 and are equity classified.

In connection with the Recapitalization and the conversion of the 2019 Senior Secured Notes, the Company issued to the noteholders stock purchase warrants to acquire 3,977,971 shares of the Company's common stock. The warrants had an exercise price of \$0.40, a term of five years, and were equity classified.

In connection with the Recapitalization and to compensate certain individuals for services performed in maintaining the Company's viability, the Company issued stock purchase warrants to acquire 2,887,500 shares of the Company's common stock. The warrants had an exercise price of \$0.40, a term of five years, and were equity classified.

In connection with the Modification, the Company induced the exercise of existing stock purchase warrants to acquire 6,865,461 shares of the Company's common stock by reducing the exercise price from \$0.40 to \$0.20 and requiring exercise by a certain date. All warrants were exercised by December 31, 2021 for gross proceeds of \$1,373,092.

Note 6 – Equity and Stock-Based Compensation

Under the Second Amended and Restated Certificate of Incorporation, the Company has the authority to issue a total of 101,000,000 shares of capital stock, consisting of 100,000,000 shares of common stock and 1,000,000 shares of preferred stock, par value \$0.0001 per share, which will have such rights, powers and preferences as the Board of Directors shall determine.

Equity Issuance

The Company sold 3,957,757 shares of common stock to certain accredited investors pursuant to Security Purchase Agreements in two private placements which closed on April 29 and May 18, 2022 for proceeds of \$3,957,757.

Stock-Based Compensation

In July 2016, the Board of Directors approved the Company's 2016 Omnibus Incentive Plan (the "2016 Omnibus Plan"), and on August 4, 2016, the Board amended such plan to include an evergreen provision, intended to increase the maximum number of shares issuable under the Omnibus Plan on the first day of each fiscal year (starting on January 1, 2017) by an amount equal to six percent (6%) of the shares reserved as of the last day of the preceding fiscal year, provided that the aggregate number of all such increases may not exceed 1,000,000 shares. As of November 21, 2016, holders of a majority of our capital stock executed a written consent adopting and approving the 2016 Omnibus Plan, as amended and restated, which provides for the Company to grant equity and cash incentive awards to officers, directors and employees of, and consultants to, the Company and its subsidiaries. Further, on March 4, 2022, the Board approved an amendment to the 2016 Omnibus Plan to increase the shares available under to Plan to 4,250,000 and remove the annual evergreen provision. Effective as of April 21, 2022, holders of a majority of our common stock outstanding executed a written consent approving the March 2022 amendment to the 2016 Omnibus Plan which became effective on June 6, 2022.

A summary of stock option activity under the 2016 Omnibus Plan during the six months ended June 30, 2022 is presented below:

Stock Options – 2016 Omnibus Plan	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at January 1, 2022	1,355,001	\$ 0.52	3.90
Granted	1,956,666	\$ 0.72	10.00
Exercised	-	\$ -	-
Forfeited or expired	-	\$ -	-
Outstanding at June 30, 2022	3,311,667	\$ 0.64	7.15
Exercisable at June 30, 2022	2,103,334	\$ 0.57	5.64

There were 1,956,666 stock options granted under the 2016 Omnibus Plan during the six months ended June, 2022 of which (i) 206,666 options were granted to settle prior accrued compensation liabilities with senior management and Board of Directors, (ii) 450,000 of immediately vested options were granted to management, the Board of Directors, and a third-party service provider, and (iii) 1,300,000 incentive stock options vesting over 3 years were granted to employees. The fair value of the stock options granted in settlement of accrued liabilities was approximately \$3,000. As the options issued were to related parties, the \$103,333 of settled liabilities was credited to additional paid-in-capital. The fair value of 450,000 of immediately vested options was \$6,430 and was recognized as stock-based compensation expense for the six months ended June 30, 2022. The fair value of 1,300,000 of incentive stock options vesting over three years was approximately \$15,300 with \$1,082 recognized as stock-based compensation expense for the six months ended June 30, 2022 for one-third of one option grant which vested upon the June 6, 2022 effective approval of the amendment to the 2016 Omnibus Plan discussed above. No stock options were exercised during the six months ended June 30, 2022. As of June 30, 2022, there was approximately \$14,200 of unrecognized compensation cost related to the 1,208,334 non-vested stock options granted during the six months ended June 30, 2022.

For the three and six months ended June 30, 2022, the Company recorded stock-based compensation expense of \$7,512 and \$6,430, respectively. There was no stock based compensation expense for the three and six months ended June 30, 2021.

Note 7 – Commitments and Contingencies

Lease Agreements

In January 2022, the Company entered into a commercial operating lease agreement for its office space in Florida, expiring on December 31, 2024. The lease requires the Company to pay for its insurance, taxes, and its share of common operating expenses. The lease resulted in an increase in its right of use assets and lease liabilities of \$89,312, using a discount rate of 10%. The lease was cancellable by the landlord at any time prior to December 31, 2022 based on certain capital raising contingencies which the Company met in April 2022.

In February 2022, the Company entered into an additional commercial operating lease for its primary office and warehouse/distribution space in Texas. The lease requires the Company to pay for its insurance, taxes, and its share of common operating expenses. This lease expires in March 2027. The space remained under buildout and Landlord control during the three months ended March 31, 2022 with the Company acquiring control of the lease space effective April 1, 2022; as a result, a right of use asset and lease liability was recognized of \$337,226 as of April 1, 2022 using a discount rate of 10%.

Operating lease ROU assets are included in right of use assets in the Company's condensed consolidated balance sheet as of June 30, 2022. Operating lease liabilities are classified as other current and non-current liabilities in the Company's condensed consolidated balance sheet.

Total lease costs were approximately \$39,000 and \$49,500 for the three and six months ended June 30, 2022, respectively, consisting solely of base rental and common area maintenance costs.

Future undiscounted cash flows under these leases are:

2022	\$	35,344
2023		109,381
2024		112,833
2025		80,273
2026		82,705
2027		21,284
Total		441,820
Discount factor		(88,942)
Lease liability		352,878
Current lease liability		(56,571)
Non-current lease liability	\$	296,307

Note 8 – Subsequent Events

The Company has evaluated subsequent events through the date the condensed consolidated financial statements were available to be issued. No material events requiring disclosure were identified.

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

The following discussion and analysis of the financial condition and results of operations of Nuo Therapeutics, Inc. ("Nuo Therapeutics," the "Company," "we," "us," or "our") should be read in conjunction with the financial statements and related notes appearing elsewhere in this Quarterly Report and our Annual Report on Form 10-K for the years ended December 31, 2019, 2020, and 2021 (the "Annual Report"), filed with the U.S. Securities and Exchange Commission.

Special Note Regarding Forward Looking Statements

Certain statements, other than purely historical information in this Quarterly Report (including this section) constitute "forward-looking statements". Forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance, or achievements, and may contain the words "anticipate," "believe," "estimate," "expect," "intend," "will," "will be," "will continue," "will likely result," "could," "may" and words of similar import. These statements reflect the Company's current view of future events and are subject to certain risks and uncertainties as noted in this Quarterly Report and in other reports filed by us with the Securities and Exchange Commission, including Forms 8-K, 10-Q, and 10-K. These risks and uncertainties include, among others, the following:

- our limited revenue base and sources of working capital;
- our limited operating experience;
- the dilutive impact of raising additional equity or debt;
- our ability to timely and accurately report our financial results and prevent fraud if we are unable to maintain effective disclosure and internal controls;
- acceptance of our product by the medical community and patients;
- our ability to obtain adequate reimbursement from third-party payors;
- our ability to contract with healthcare providers;
- our reliance on several single source suppliers and our ability to source raw materials at affordable costs;
- our ability to protect our intellectual property;
- our compliance with governmental regulations;
- our ability to successfully sell and market the Aurix System;
- our ability to attract and retain key personnel, including our Chief Executive and Financial Officer;
- our ability to successfully pursue strategic collaborations to help develop, support, or commercialize our current and future products; and
- whether an active trading market will develop.

Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results could differ materially from those anticipated in these forward-looking statements.

In addition to the risks identified under the heading "Risk Factors" in our Annual Report and the other filings referenced above, other sections of this report may include additional factors which could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for management to predict all such risk factors, nor can it assess the impact of all such risk factors on our business, or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

The Company undertakes no obligation and does not intend to update, revise or otherwise publicly release any revisions to its forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events.

Business Overview

We are a regenerative therapies company focused on developing and marketing products for chronic wound care primarily within the U.S. We commercialize innovative cell-based technologies that harness the regenerative capacity of the human body to trigger natural healing. The use of autologous (i.e., from self, the patient's own) biological therapies for tissue repair and regeneration is part of a clinical strategy designed to improve long-term recovery in inherently complex chronic conditions with significant unmet medical needs.

Our current commercial offering consists of a point of care technology for the safe and effective separation of autologous blood to produce a platelet-based therapy for the chronic wound care market. This offering is known as “Aurix” or the “Aurix System”. The FDA cleared the Aurix System for marketing in 2007 as a device under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (“FDCA”). Aurix is one of two platelet derived products cleared by the FDA for chronic wound care use and is indicated for most exuding wounds. The advanced wound care market, within which Aurix competes, is composed of advanced wound care dressings, wound care devices, and wound care biologics, and is estimated to be an approximate \$10.8 billion global market in 2021 with the North American market estimated at approximately \$4.15 billion in 2020. Estimates remain that 1-2% of population in the developed countries will suffer from a chronic wound at least once in their lifetime. According to the National Institute of Health, treatment of diabetic foot ulcers cost an estimated \$9-\$13 billion annually in the U.S. alone. An aging population and the still increasing prevalence of diabetes suggests a continued increase in the patient population at risk of developing chronic, non-healing wounds.

The Aurix System produces a platelet rich plasma (“PRP”) gel at the point of care using the patient’s own platelets and plasma sourced from a small draw of peripheral blood. Aurix comprises a natural, endogenous complement of protein and non-protein signal molecules that contribute to effective healing. During treatment, the patient’s platelets are activated and release hundreds of growth factor proteins and other signaling molecules that form a biologically active hemagel. Aurix delivers concentrations of the natural complement of cytokines, growth factors and chemokines that are known to regulate angiogenesis (i.e., the development of new blood vessels), cell growth, and the formation of new tissue. Once applied to the prepared wound bed, the biologically active Aurix hemagel can restore the balance in the wound environment to transform a non-healing wound to a wound that heals naturally.

In 2012, a Medicare National Coverage Determination (“NCD”) from CMS reversed a twenty-year old non-coverage decision for autologous blood derived products used in wound care. This NCD allowed for Medicare coverage under the Coverage with Evidence Development (“CED”) program. CED programs have been employed for a selected number variety of other therapies, including transcatheter aortic valve repair and cochlear implantation. Under the CED program, CMS provides reimbursement for items or services on the condition that they be furnished in approved clinical protocols or in the collection of additional clinical data. Under the CED program, a facility treating a patient with Aurix was reimbursed by Medicare when health outcomes data were collected to inform future coverage decisions. The intent of the CED program is to evaluate the outcomes of Aurix therapy for the broader Medicare population when it is used in a “real world” continuum of care.

In May 2019, we transmitted a letter memorandum to CMS’ Coverage and Analysis Group (“CAG”) in support of our complete formal request for reconsideration of the then existing national coverage determination based on clinical data collected and published under the CED program. The complete formal public request for reconsideration was made on May 8, 2019 in accordance with the applicable requirements.

On April 13, 2021, CMS issued a final coverage decision memo indicating that Medicare would nationally cover autologous PRP for the treatment of chronic non-healing diabetic wounds for a duration of 20 weeks under Section 1862(a)(1)(A) of the Social Security Act. This coverage applies when using devices whose FDA-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers. Coverage of autologous PRP beyond 20 weeks for diabetic foot ulcers and for the treatment of all other chronic, non-diabetic, non-healing wounds will be determined by local Medicare Administrative Contractors.

Although FDA cleared the Aurix System for marketing in 2007 under Section 510(k) of the FDCA, CMS only established economically viable reimbursement for the product beginning in 2016. For 2022, the Medicare national average reimbursement rate for the Aurix System is \$1,749 per treatment, which we believe provides appropriate payment to facilities for product usage. We will market the Aurix System at an approximate cost of \$800 per treatment to wound care providers.

On June 23, 2022, we entered into an Exclusive Sales Agent and Services Agreement (the “Agreement”) with Pacific Medical, Inc. (“PacMed”) pursuant to which PacMed was appointed an exclusive distributor for the Aurix System product within a defined territory. The Agreement also covers any future products sold by the Company but under commercial terms to be agreed between the parties. The PacMed territory covers the states of Washington, Oregon, Idaho, Montana, Wyoming, most of California, the northern half of Nevada, plus Alaska.. The term of the Agreement extends for five (5) years subject to standard termination provisions including the failure to meet agreed sales quotas. The compensation under the Agreement consists of a commission percentage on product sales plus an annual bonus opportunity of a further percentage of product sales provided annual sales quotas are exceeded by an agreed percentage increment.

Our Strategy

Our immediate commercial focus is establishing engagement with providers treating chronic non-healing wounds to demonstrate the clinical benefits we believe result from the use of Aurix in the treatment of complex wounds. Increasing physician awareness of the differentiating attributes of Aurix will be key to establishing a base of product revenues upon which to grow. We anticipate developing these relationships with clinical providers and treatment facilities primarily by establishing a variety of distributor arrangements throughout the United States. Our commercial team consists of five senior employees who are leveraging their current and historical relationships to establish distributor arrangements. As of June 30, 2022, we had established contractual relationships with more than 50 individual distributor representatives including a multi-state agreement with Pacific Medical, Inc. covering multiple large markets in the western United States. The number of distributor representatives is expected to increase in the months ahead.

Commercially available Aurix product was first available in late May 2022 for demonstration and evaluation purposes. Through a growing distributor network, Aurix is presently being evaluated by various hospital/facility Value Analysis Committees (VACs) as part of the process of approving its clinical use. Commercial revenues are expected to begin during the third quarter 2022 and exhibit increasing growth in subsequent quarters.

Over the period from the cessation of normal operational activities in May 2019 through the final NCD in April 2021 leading to the late 2021 decision to reinstate business activities, the Company was focused on engaging with CMS as appropriate, monitoring the developments concerning our reconsideration request, advancing our positions during various public comment periods and maintaining overall yet limited corporate viability in the event that a sufficiently favorable coverage and reimbursement setting developed for Aurix.

In addition, the Company took actions during this period to address its capital structure by eliminating both its debt and exchanging the Series A Preferred Stock issued at the time of the May 2016 recapitalization for common stock.

The Science Underlying Aurix/Platelet Rich Plasma

Normal Wound Healing

The science underlying wound healing is well-established. An immediate early event critical for wound healing is the influx of platelets to the wound site. Platelets bind to elements within damaged tissue such as collagen fragments and endogenous thrombin molecules and are activated to release a diversity of growth factors and other biomolecules from their alpha and dense granules (Reed 2000, Nieswandt, 2003). These biomolecules provide signals essential for biological responses regulating hemostasis and effective tissue regeneration.

Chronic Wounds

Dysregulation of numerous cellular and biological responses contribute to the chronic wound phenotype. Chronic wounds have reduced levels of growth factors and concomitant decreases in cellular proliferation (Mast 1996). There is increased cellular senescence (Telgenhoff 2005), and there generally is a lack of perfusion that can inhibit the delivery of nutrients and cells required for regeneration (Guo 2010). As the body attempts to stave off infection, elevated concentrations of free radicals accumulate in the chronic wound and further damage surrounding tissue (Moseley 2004, James 2003).

Aurix Therapy

Aurix has been cleared by FDA as safe and effective with an indication for chronic wounds such as leg ulcers, pressure ulcers, and diabetic ulcers and other exuding wounds such as mechanically or surgically debrided wounds. The Aurix therapeutic is formed by mixing a sample of a patient's platelets and plasma with pharmaceutical grade thrombin and ascorbic acid. The thrombin activates platelets while ascorbic acid drives the synthesis of high tensile strength collagen, clears damaging free radicals and controls gel consistency. The topical dermal application of Aurix gel bypasses the lack of local perfusion to provide immediate signals for new tissue formation and ultimately healing.

The Efficacy of Aurix Relates to Biological Activity Released by Platelets

Regenerative Capacity

More than 300 proteins are released by human platelets in response to thrombin activation (Coppinger 2004). Important examples include vascular endothelial cell growth factor ("VEGF"), platelet derived growth factor ("PDGF"), epidermal growth factor ("EGF"), fibroblast growth factor ("FGF") and transforming growth factor-beta ("TGF-B") (Eppley 2004, Everts 2006). These proteins are critical for organized wound healing, regulating responses such as vascularization, cell proliferation, cell differentiation, and deposition of new extracellular matrix (Goldman 2004). Platelets also release chemokines such as Interleukin-8 ("IL-8"), stromal cell derived factor-1 ("SDF-1"), and platelet factor-4 ("PF-4") (Chatterjee 2011, Gear 2003) that control the mobilization and migration of stem cells and fibroblasts (Werner 2003 and Gillitzer 2001), which contribute to tissue regeneration.

Anti-infective Activity

Populations of bioburden in chronic wounds vary over time and wounds invariably retain or become re-infected with some level of bacteria that is detrimental to healing (Howell-Jones 2005). In addition to regenerative capacity, platelets release anti-microbial peptides effective against a broad range of pathogens including Methicillin Resistant Staphylococcus Aureus ("MRSA") (Moojen 2007, Jia 2010, Tang 2002, Bielecki 2007).

Clinical Efficacy

Multiple efficacy and effectiveness studies have been published in peer reviewed journals documenting the impact of using Aurix to treat chronic wounds. Key data include:

- In the published study of the clinical data collected during the CED program for diabetic foot ulcers, Aurix demonstrated a significant time to heal advantage compared to wounds treated with usual and customary care (including any available advanced therapy). A higher percentage of healing was observed across all wound severities (Wagner Grade 1-4) and in a patient population with significant comorbidities. (Gude W, Hagan D, Abood F, Clausen P: Aurix Gel is an Effective Intervention for Chronic Diabetic Foot Ulcers: A Pragmatic Randomized Controlled Trial. *Advances in Skin and Wound Care*, 2019; 32(9): 416-426.)
- In a double blinded randomized controlled trial, 81% of the most common-sized diabetic foot ulcers healed with Aurix compared with 42% of control wounds. Mean time to healing was six weeks. (Driver V, Hanft J, Fylling, C et al.: A Prospective, Randomized, Controlled Trial of Autologous Platelet-Rich Plasma Gel for the Treatment of Diabetic Foot Ulcers. *Ostomy Wound Management*, 2006; 52(6): 68-87.)
- In 285 chronic wounds in 200 patients, 96.5% of the wounds had a positive response within an average of 2.2 weeks with an average of 2.8 Aurix treatments (de Leon J, Driver VR, Fylling CP, Carter MJ, Anderson C, Wilson J, et al.: The Clinical Relevance of Treating Chronic Wounds with an Enhanced Near-physiological Concentration of Platelet-Rich Plasma (PRP) Gel. *Advances in Skin and Wound Care*, 2011; 24(8), 357-368.)
- In a retrospective, longitudinal study of 40 Wagner grade II through IV diabetic foot ulcers, most with critical limb ischemia, wounds increased in size in the approximate 100 days prior to the initiation of comprehensive wound care treatment. Upon treatment with debridement, revascularization, antibiotics and off-loading, the wounds continued to increase in size over a subsequent 75-day period. Once they were then treated with Aurix, the wounds immediately changed healing trajectory and 83% of the wounds healed with an average of 6.1 Aurix treatments per wound (Sakata, J., Sasaki, S., Handa, K., et al. A Retrospective, Longitudinal Study to Evaluate Healing Lower Extremity Wounds in Patients with Diabetes Mellitus and Ischemia Using Standard Protocols of Care and Platelet-Rich Plasma Gel in a Japanese Wound Care Program. *Ostomy Wound Management*, 2012; 58(4):36-49.)

Results of Operations**Comparison of Three Months Ended June 30, 2022 and 2021**

The amounts presented in this comparison section are rounded to the nearest thousand.

Revenue and Gross Profit

There were no revenues in the three months ended June 30, 2022 and 2021 as the Company ceased ongoing operational activities effective May 1, 2019 and no longer treated subjects under the previous CED program while selling its remaining Aurix inventory over the balance of 2019. Re-initiation of commercial activity for the Aurix product began in May 2022 as saleable product inventory became available at the Texas warehouse/distribution facility.

Operating Expenses

Total operating expenses increased approximately \$917,000 to approximately \$924,000 comparing the three months ended June 30, 2022 to the three months ended June 30, 2021. The increase from the nominal expense level in the prior year was due to expenses associated with continued company restart activities first initiated in fall 2021 in preparation of renewed commercial sales activities in May 2022. Expenses for the three months ended June 30, 2022 were primarily composed of (i) approximately \$444,000 of compensation and benefits expense, (ii) approximately \$237,000 of professional fees including accounting and audit and legal fees associated with our efforts to return to current reporting status as a public company and (iii) approximately \$243,000 of various other operating expenses including sales infrastructure and marketing costs, insurance expense, operating lease costs, and travel related expenses.

Other Income (Expense)

Other expense for the three months ended June 30, 2022 represents nominal interest expense from the financing of insurance premiums.

Comparison of Six Months Ended June 30, 2022 and 2021

The amounts presented in this comparison section are rounded to the nearest thousand.

Revenue and Gross Profit

There were no revenues in the six months ended June 30, 2022 and 2021 as the Company ceased ongoing operational activities effective May 1, 2019 and no longer treated subjects under the previous CED program while selling its remaining Aurix inventory over the balance of 2019. Re-initiation of commercial activity for the Aurix product began in May 2022 as saleable product inventory became available at the Texas warehouse/distribution facility.

Operating Expenses

Total operating expenses increased approximately \$1,433,000 to approximately \$1,446,000 comparing the six months ended June 30, 2022 to the six months ended June 30, 2021. The increase from the nominal expense level in the prior year was due to expenses associated with continued company restart activities first initiated in fall 2021 in anticipation of renewed commercial sales activities that began in May 2022. Expenses for the six months ended June 30, 2022 were primarily composed of (i) approximately \$592,000 of compensation and benefits expense, (ii) approximately \$473,000 of professional fees including accounting and audit and legal fees associated with our efforts to return to current reporting status as a public company and (iii) approximately \$381,000 of various other operating expenses including sales infrastructure and marketing costs, insurance expense, operating lease costs, and travel related expenses.

Other Income (Expense)

Other income for the six months ended June 30, 2022 primarily represents the gain realized from the negotiated settlement of legacy accounts payable including the full release of any ongoing payment liability.

Liquidity and Capital Resources

Overview

As of June 30, 2022, we had cash and cash equivalents of approximately \$3.4 million, total current assets of approximately \$3.9 million and total current liabilities of approximately \$0.5 million. As an operational business, we have a history of losses and are not currently profitable. For the years ended December 31, 2021, 2020, and 2019, we incurred net losses of approximately \$0.1 million, \$0.1 million, and \$1.2 million, respectively. As of June 30, 2022, our accumulated deficit was approximately \$24.9 million and our stockholders' equity was approximately \$3.6 million.

We sold 3,957,757 shares of common stock to certain accredited investors pursuant to Security Purchase Agreements in two private placements which closed on April 29 and May 18, 2022 for proceeds of \$3,957,757.

Based on our current operating forecast, we believe that our existing cash and cash equivalents will be sufficient to fund our operations through at least the next 12 months.

Financing and Related Developments During the Years 2019 through 2021

Spring 2019 Cessation of Normal Operating Activities

In April 2019, the Company made the decision to cease normal operational activities and we furloughed the Company's remaining employees effective May 1, 2019. This decision was necessitated by the depletion of the Company's resources during the conduct of the CED studies being undertaken to pursue Medicare reimbursement coverage for the Aurix System. In the spring of 2019, we had collected clinical outcomes and analyzed the data from the subjects involved in the CED studies and were engaged in discussions with CMS concerning the adequacy of the results and a NCD reconsideration request.

On December 10, 2019, the Company entered into fifth and final amendments to the 2018 Convertible Notes pursuant to which the Company's obligations under such notes were to be extinguished in their entirety upon receipt by each Convertible Note Investor of (i) a cash payment of \$110,000 and (ii) 175,000 unrestricted shares of the Company's common stock no later than February 10, 2020. The Company made the required cash payments totaling \$220,000 on December 10, 2019 and issued the common shares as of February 5, 2020 in final settlement of the 2018 Convertible Notes.

Senior Secured Note Issuance

On November 15, 2019 and December 6, 2019, the Company entered into note purchase agreements with certain individual accredited investors (the "Senior Note Investors") for the issuance and sale to the Investors of 12% senior secured promissory notes (the "Senior Notes"), in the aggregate principal amount of \$305,000 with an overall \$500,000 cap under the note purchase agreements. Pursuant to the purchase agreements, the Company also issued to the Senior Note Investors warrants exercisable to purchase an aggregate 457,500 shares of the Company's common stock, subject to adjustment as referenced below.

In conjunction with the note issuance, the Company granted a first-priority security interest in all the assets of the Company but fundamentally consisting of the Aurix System asset including all regulatory files and approvals and relevant intellectual property. The purchase agreements contained certain representations, warranties and covenants by, among and for the benefit of the respective parties. The purchase agreements also provided for customary indemnification of the Senior Note Investors by the Company.

The notes had a maturity date of June 30, 2020 and accrued interest at a rate of 12% per year. The Company could prepay the Senior Notes, in whole or in part, at any time. The warrants were exercisable at any time, at an exercise price per share equal to \$0.40, subject to certain adjustments and price protection provisions (including full ratchet anti-dilution protection) contained in the warrants. The warrants had five-year terms.

The use of proceeds from the Notes beyond the initial \$50,000 and up to an estimated aggregate amount of \$270,000 was specifically dedicated to payment to the 2018 Convertible Note Investors, in a final amount to be agreed between the Company and the Convertible Note Investors such that the 2018 Convertible Notes were considered retired and no longer in effect.

Series A Preferred Stock Exchange Agreement

On October 5, 2020, the Company entered into a Recapitalization Agreement (the “Recap Agreement”) with Deerfield Private Design Fund II, L.P. (“DPDF”) and Deerfield PDI Financing II, L.P. (“DPF”) and, together with DPDF, the “Deerfield Investors”) and the Noteholders, whereby the shares of Series A preferred stock held by the Deerfield Investors were exchanged for 2,700,000 shares of common stock of the Company. The Senior Note Investors agreed to the conversion of the \$305,000 principal balance of the Notes plus accrued interest through September 30, 2020 of approximately \$30,400 into an aggregate 838,487 shares of common stock of the Company at a conversion price of \$0.40 per share, plus the purchase, for cash, of 487,500 shares of common stock at \$0.40 per share, or \$195,000 in total. As of October 5, 2020, all shares of Series A preferred stock and Senior Notes were cancelled in full.

Pursuant to the Recap Agreement, the Company also issued to the Senior Note Investors warrants to purchase an aggregate of 3,977,961 shares of the Company’s common stock, subject to adjustment as referenced below. The warrants were exercisable at any time, at an exercise price per share equal to \$0.40, subject to certain adjustments and price protection provisions contained in the warrants. The warrants had five-year terms. The warrants to purchase 457,500 shares of common stock issued to the Noteholders upon the original 2019 issuance of the Notes were canceled.

Warrant Modification Agreement and Early Warrant Exercise

Effective as of December 1, 2021, the Company entered into a Warrant Modification Agreement (the “WMA”) with the holders of an aggregate 6,865,461 Warrants whereby the Warrants were modified to adjust the warrant exercise price from \$0.40 per share to \$0.20 per share provided the Investor exercised the warrant prior to January 31, 2022. All Warrants not exercised prior to January 31, 2022 were to be forfeited and deemed expired or otherwise cancelled.

As of December 31, 2021, all Warrants had been exercised for total consideration of \$1,373,092 and the resulting issuance of 6,865,461 shares of common stock.

Cash Flows

Net cash provided by (used in) operating, investing, and financing activities for the periods presented were as follows:

	Six months ended June 30, 2022	Six months ended June 30, 2021
Cash flows used in operating activities	\$ (1,875,963)	\$ (9,847)
Cash flows used in investing activities	\$ (51,535)	\$ -
Cash flow provided by financing activities	\$ 3,957,757	\$ -

Operating Activities

Cash used in operating activities for the six months ended June 30, 2012 of approximately \$1,876,000 primarily reflects our net loss of approximately \$1.3 million adjusted by i) a non-cash gain of approximately \$146,000 from the negotiated settlement of legacy accounts payable obligations and ii) approximately \$464,000 net change in operating assets and liabilities.

Cash used in operating activities for the six months ended June 30, 2021 was approximately \$9,800 and primarily reflects our largely non-operational status as we awaited further developments concerning Medicare reimbursement coverage for the Aurix product.

Investing Activities

Cash flows used in investing activities for the six months ended June 30, 2022 reflects the acquisition of warehouse and office equipment primarily in the newly leased Texas distribution facility. We did not have any investing activities for the six months ended June 30, 2021.

Financing Activities

Cash flows from financing activities for the six months ended June 30, 2022 reflects proceeds raised from the sale of 3,957,757 shares of common stock in two private placements closed in April and May 2022. We did not have any financing activities for the six months ended June 30, 2021.

Inflation

The Company believes that the rates of inflation in recent years have not had a significant impact on its operations.

Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements.

Critical Accounting Policies

Our consolidated financial statements included in Part I, Item 1 of this Quarterly Report are prepared in conformity with U.S. GAAP, which require us to make estimates and assumptions regarding future events that affect the amounts reported in our financial statements and accompanying notes. We base these estimates on our experience and assumptions regarding future events we believe to be reasonable under the circumstances. Actual results could differ from those estimates and such differences may be material to the consolidated financial statements. We have described our most critical accounting policies in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes to our critical accounting policies or estimates since December 31, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of June 30, 2022. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were not effective due to the un-remediated material weakness disclosed in our Annual Report on Form 10-K. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

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

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

There are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition, or cash flows.

Item 1A. Risk Factors.

There have been no material changes from the risk factors as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of Nuo Therapeutics, Inc. (previously filed on May 10, 2016 as Exhibit 3.1 to the registrant's Registration Statement on Form 8-A and incorporated by reference herein).
3.2	Certificate of Designation of Series A Preferred Stock of Nuo Therapeutics, Inc. (previously filed on May 10, 2016 as Exhibit 3.3 to the registrant's Current Report on Form 8-K and incorporated by reference herein).
3.3	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of Nuo Therapeutics, Inc. (previously filed on September 5, 2018 as Exhibit 3.1 to the registrant's Current Report on Form 8-K and incorporated by reference herein).
3.4	Amended and Restated By-Laws of Nuo Therapeutics, Inc. (previously filed on May 10, 2016 as Exhibit 3.2 to the registrant's Registration Statement on Form 8-A and incorporated by reference herein).
10.1	Employment Agreement between David Jorden and Nuo Therapeutics, Inc. dated May 9, 2022 (previously filed on May 16, 2022 as Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022 and incorporated by reference herein).
10.2	Employment Agreement between Peter Clausen and Nuo Therapeutics, Inc. dated May 9, 2022 (previously filed on May 16, 2022 as Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022 and incorporated by reference herein).
10.3	Securities Purchase Agreement dated April 11, 2022 (previously filed on May 2, 2022 as Exhibit 10.1 to the registrant's Current Report on Form 8-K and incorporated by reference herein).
10.4	Securities Purchase Agreement dated May 13, 2022 (previously filed on May 16, 2022 as Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022 and incorporated by reference herein).
31	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Nuo Therapeutics, Inc. Form 10-Q for the quarter ended June 30, 2022, formatted in Inline Extensible Business Reporting Language (Inline XBRL): (i) Condensed Consolidated Balance Sheets at June 30, 2022 and December 31, 2021, (ii) Condensed Consolidated Statements of Operations for the three and six month periods ended June 30, 2022 and 2021, (iii) Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the six month periods ended June 30, 2022 and 2021, (iv) Consolidated Statements of Cash Flows for the six month periods ended June 30, 2022 and 2021 and (v) Notes to the Unaudited Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

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

NUO THERAPEUTICS, INC.

Date: August 8, 2022

By: /s/ David E. Jorden
David E. Jorden
Chief Executive and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

**Certification of Principal Executive and Principal Financial Officer Pursuant to Exchange Act Rule
13a-14(a)/15d-14(a) as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, David E. Jorden, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuo 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. I am 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. 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 8, 2022

David E. Jorden
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

A signed original of this written statement has been provided to Nuo Therapeutics, Inc. and will be retained by Nuo Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**Certification of Principal Executive and Principal Financial Officer Pursuant to
18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. §1350 and in connection with the Quarterly Report on Form 10-Q of Nuo Therapeutics, Inc. (the "Company") for the period ended June 30, 2022 (the "Report"), I, David E. Jorden, Chief Executive and Chief Financial Officer of the Company, hereby certify that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2022

David E. Jorden
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

/s/ David E. Jorden
David E. Jorden
Chief Executive and Chief Financial Officer
(Principal Executive and Principal Financial
Officer)

A signed original of this written statement has been provided to Nuo Therapeutics, Inc. and will be retained by Nuo Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.