

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 March 31, 2024

Or

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

For the transition period from _____ to _____

Qualigen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

<hr/> Delaware <hr/> (State or other jurisdiction of incorporation)	<hr/> 001-37428 <hr/> (Commission File Number)	<hr/> 26-3474527 <hr/> (I.R.S. Employer Identification No.)
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5857 Owens Avenue, Suite 300, Carlsbad, California 92008
(Address of principal executive offices) (Zip Code)

(760) 452-8111
(Registrant's telephone number, including area code)

n/a
(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

<hr/> Title of each class Common Stock, par value \$0.001 per share	<hr/> Trading Symbol QLGN	<hr/> Name of each exchange on which registered The Nasdaq Capital Market of The Nasdaq Stock Market LLC
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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.

<input type="checkbox"/> Large accelerated filer	<input type="checkbox"/> Accelerated filer
<input checked="" type="checkbox"/> Non-accelerated filer	<input checked="" type="checkbox"/> Smaller reporting company
	<input type="checkbox"/> 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

As of June 24, 2024, there were 9,613,899 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

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ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

QUALIGEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Uaudited)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash	\$ 93,217	\$ 401,803
Prepaid expenses and other current assets	909,994	764,964
Total current assets	<u>1,003,211</u>	<u>1,166,767</u>
Other assets	—	866,481
Total Assets	\$ 1,003,211	\$ 2,033,248
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	\$ 1,801,333	\$ 2,222,983
Accrued expenses and other current liabilities	819,015	560,006
Warrant liabilities	187,900	54,600
Convertible debt - related party	1,022,869	1,299,216
Derivative liabilities - related party	693,782	—
Total current liabilities	<u>4,524,899</u>	<u>4,136,805</u>
Commitments and Contingencies (Note 10)		
Stockholders' Deficit		
Qualigen Therapeutics, Inc. stockholders' equity (deficit):		
Common stock, \$0.001 par value; 225,000,000 shares authorized; 6,500,663 and 5,362,128 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively		
44,400	43,262	
Additional paid-in capital	115,269,047	114,655,565
Accumulated deficit	(118,835,135)	(116,802,384)
Total Stockholders' Deficit	<u>(3,521,688)</u>	<u>(2,103,557)</u>
Total Liabilities & Stockholders' Deficit	\$ 1,003,211	\$ 2,033,248

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

QUALIGEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS
(Uaudited)

	For the Three Months Ended March 31,	
	2024	2023
EXPENSES		
General and administrative	\$ 1,057,364	1,368,999
Research and development	364,385	1,281,817
Total expenses	<u>1,421,749</u>	<u>2,650,816</u>
LOSS FROM OPERATIONS	(1,421,749)	(2,650,816)
OTHER EXPENSE (INCOME), NET		
Loss (gain) on change in fair value of warrant liabilities	133,300	(1,038,673)
Gain on change in fair value of derivative liabilities	(164,497)	—
Interest expense, net	136,556	544,238
Loss on issuance of convertible debt	358,279	—
Loss on voluntary conversion of convertible debt into common stock	—	1,077,287
Loss on monthly redemptions of convertible debt into common stock	147,197	—
Other income, net	(1,619)	—
Total other expense (income), net	<u>609,216</u>	<u>582,852</u>
LOSS BEFORE PROVISION FOR INCOME TAXES	(2,030,965)	(3,233,668)

PROVISION FOR INCOME TAXES	(1,786)	(1,393)
NET LOSS FROM CONTINUING OPERATIONS	(2,032,751)	(3,235,061)
DISCONTINUED OPERATIONS		
Loss from discontinued operations, net of tax	—	(872,188)
LOSS FROM DISCONTINUED OPERATIONS	—	(872,188)
NET LOSS	(2,032,751)	(4,107,249)
Net loss attributable to non-controlling interest from discontinued operations	—	(261,028)
Net loss available to Qualigen Therapeutics, Inc.	\$ (2,032,751)	\$ (3,846,221)
Deemed dividend arising from warrant down-round provision	\$ (60,017)	\$ —
Net loss attributable to Qualigen Therapeutics, Inc.	\$ (2,092,768)	\$ (3,846,221)
Net loss per common share, basic and diluted - continuing operations	\$ (0.35)	\$ (0.65)
Net loss per common share, basic and diluted - discontinued operations	\$ —	\$ (0.12)
Weighted-average number of shares outstanding, basic and diluted	5,943,814	4,959,122
Other comprehensive loss, net of tax		
Net loss	\$ (2,032,751)	\$ (4,107,249)
Foreign currency translation adjustment from discontinued operations	—	119,723
Other comprehensive loss	(2,032,751)	(3,987,526)
Comprehensive loss attributable to noncontrolling interest from discontinued operations	—	(261,028)
Comprehensive loss attributable to Qualigen Therapeutics, Inc.	\$ (2,032,751)	\$ (3,726,498)

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

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QUALIGEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(Uaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at December 31, 2023	5,362,128	\$ 43,262	\$ 114,655,565	\$ (116,802,384)	\$ (2,103,557)
Monthly redemptions of convertible debt into common stock	1,138,535	1,138	545,094	—	546,232
Fair value of warrant modification for professional services	—	—	9,737	—	9,737
Stock-based compensation	—	—	58,651	—	58,651
Net loss	—	—	—	(2,032,751)	(2,032,751)
Balance at March 31, 2024	6,500,663	\$ 44,400	\$ 115,269,047	\$ (118,835,135)	\$ (3,521,688)

	Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Qualigen Therapeutics, Inc.		Noncontrolling Interest	Total Stockholders' Equity
						Stockholders' Equity	Noncontrolling Interest		
Balance at December 31, 2022	4,210,737	\$ 42,110	\$ 110,528,050	\$ 50,721	\$ (103,385,172)	\$ 7,235,709	\$ 1,530,881	\$ 8,766,590	
Voluntary conversion of convertible debt into common stock	841,726	842	1,111,740	—	—	1,112,582	—	—	1,112,582
Stock-based compensation	—	—	247,657	—	—	247,657	4,569	252,226	
Foreign currency translation adjustment	—	—	—	119,723	—	119,723	56,497	176,220	
Net loss	—	—	—	—	(3,846,221)	(3,846,221)	(261,028)	(4,107,249)	
Balance at March 31, 2023	5,052,463	\$ 42,952	\$ 111,887,447	\$ 170,444	\$ (107,231,393)	\$ 4,869,450	\$ 1,330,919	\$ 6,200,369	

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

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QUALIGEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Uaudited)

	For the Three Months Ended March 31,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (2,032,751)	\$ (4,107,249)
Loss from discontinued operations, net of tax	—	(872,188)
Loss from continuing operations	(2,032,751)	(3,235,061)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities:		
Stock-based compensation	58,651	252,226
Loss (gain) on change in fair value of warrant liabilities	133,300	(1,038,673)
Loss on voluntary conversion of convertible debt	—	1,077,287
Accretion of discount on convertible debt	103,653	533,336
Loss on monthly redemptions of convertible debt into common stock	147,197	—
Loss on issuance of convertible debt	358,279	—
Gain on change in fair value of derivative liabilities	(164,497)	—
Fair value of warrant modification for professional services	9,737	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	721,451	178,584
Accounts payable	(421,649)	(75,944)
Accrued expenses and other current liabilities	303,043	366,460
Net cash used in operating activities - continuing operations	(783,586)	(1,941,785)
Net cash used in operating activities - discontinued operations	—	(692,308)
Net cash used in operating activities	(783,586)	(2,634,093)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net cash used in investing activities - discontinued operations	—	(198,009)
Net cash used in investing activities	—	(198,009)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from the issuance of convertible notes payable	475,000	—
Net cash provided by financing activities - continuing operations	475,000	—
Net cash provided by financing activities - discontinued operations	—	—
Net cash provided by financing activities	475,000	—
Net change in cash and restricted cash	(308,586)	(2,832,102)
Effect of exchange rate changes on cash and restricted cash	—	160,320
Cash and restricted cash from continuing operations- beginning of period	401,803	3,165,985
Cash and restricted cash from discontinued operations - beginning of period	—	3,874,139
Less: cash and restricted cash from discontinued operations - end of period	—	(2,834,965)
Cash from continuing operations - end of period	\$ 93,217	\$ 1,533,377
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid during the year for:		
Interest	\$ —	\$ —
Taxes	\$ —	\$ —
NONCASH FINANCING AND INVESTING ACTIVITIES:		
Net transfers to equipment held for lease from inventory	\$ —	\$ 35,971
Monthly redemption of convertible debt into common stock	\$ 546,232	\$ —
Voluntary conversion of convertible debt into common stock	\$ —	\$ 1,112,582
Deemed dividend arising from warrant down-round provision	\$ 60,017	\$ —

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

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

NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND ESTIMATES

Organization

Ritter Pharmaceuticals, Inc. (the Company's predecessor) was formed as a Nevada limited liability company on March 29, 2004 under the name Ritter Natural Sciences, LLC. In September 2008, this company converted into a Delaware corporation under the name Ritter Pharmaceuticals, Inc. On May 22, 2020, upon completing a "reverse recapitalization" transaction with Qualigen, Inc., Ritter Pharmaceuticals, Inc. was renamed Qualigen Therapeutics, Inc. (the "Company"). Qualisys Diagnostics, Inc. was formed as a Minnesota corporation in 1996, reincorporated to become a Delaware corporation in 1999, and then changed its name to Qualigen, Inc. in 2000. Qualigen, Inc. was a wholly-owned subsidiary of the Company. On July 20, 2023, the Company sold all of the issued and outstanding shares of common stock of Qualigen, Inc. to Chembio Diagnostics, Inc. ("Chembio"), a wholly-owned subsidiary of Biosynex, S.A. ("Biosynex"). Following the consummation of this transaction, Qualigen, Inc. became a wholly-owned subsidiary of Chembio (see Note 5 – Discontinued Operations).

On May 26, 2022, the Company acquired 2,232,861 shares of Series A-1 Preferred Stock of NanoSynex, Ltd. ("NanoSynex") from Alpha Capital Anstalt ("Alpha"), a related party, in exchange for 350,000 reverse split adjusted shares of the Company's common stock and a prefunded warrant to purchase 331,464 reverse split adjusted shares of the Company's common stock at an exercise price of \$ 0.001 per share. These warrants were subsequently exercised on September 13, 2022. Concurrently with this transaction, the Company also entered into a Master Funding Agreement for the Operational and Technology Funding of NanoSynex Ltd., dated May 26, 2022, with NanoSynex (the "NanoSynex Funding Agreement"), to, among other things, provide for the further funding of NanoSynex, and purchased 381,786 shares of Series B preferred stock from NanoSynex for a total purchase price of

\$600,000. The transactions resulted in the Company acquiring a 52.8% interest in NanoSynex (the "NanoSynex Acquisition"). NanoSynex is a nanotechnology diagnostics company domiciled in Israel. On July 20, 2023, the Company entered into an Amendment and Settlement Agreement with NanoSynex (the "NanoSynex Amendment"), which amended the NanoSynex Funding Agreement, to, among other things, eliminate most of the Company obligation for the further funding of NanoSynex. Pursuant to the terms of the NanoSynex Amendment, the Company lost its controlling interest in NanoSynex (see Note 5 -Discontinued Operations).

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"), Regulation S-X and rules and regulations of the Securities and Exchange Commission ("SEC").

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its former wholly-owned and majority owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP. The Company views its operations and manages its business in one operating segment. In general, the functional currency of the Company and its subsidiaries is the U.S. dollar. For NanoSynex, the functional currency was the local currency, New Israeli Shekels (NIS). As such, assets and liabilities for NanoSynex were translated into U.S. dollars with the effects of foreign currency translation adjustments reflected as a component of accumulated other comprehensive loss within the Company's condensed consolidated statements of changes in stockholders' equity (deficit).

As of July 20, 2023, NanoSynex was deconsolidated from these financial statements as the transactions contemplated by the NanoSynex Amendment resulted in a loss of control of a subsidiary that constitutes a business under ASC 810. The retained investment in NanoSynex is accounted for prospectively as an equity method investment. See Note 5 – Discontinued Operations for further information.

Discontinued Operations

On July 20, 2023, the Company completed the sale of Qualigen, Inc. to Chembio Diagnostics, Inc. The sale of Qualigen Inc. constituted a significant disposition and as such, the Company concluded that the disposition of ownership in Qualigen, Inc. represented a strategic shift that had a major effect on its operations and financial results. Therefore, Qualigen, Inc. is classified as discontinued operations for all periods presented herein.

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On July 20, 2023, the Company entered into the NanoSynex Amendment, which amended the Master Funding Agreement for the Operational and Technology Funding of NanoSynex Ltd., dated May 26, 2022, by and between the Company and NanoSynex (the "NanoSynex Funding Agreement"), a former majority owned subsidiary of the Company, to, among other things, forfeit 281,000 Series B Preferred Shares of NanoSynex held by the Company, resulting in the deconsolidation of NanoSynex. The disposition represents a strategic shift that will have a material effect on the Company's operations and financial results. Accordingly, the business of NanoSynex is classified as discontinued operations for all periods presented herein.

See Note 5 - Discontinued Operations for further information.

Equity Method Investments

Following deconsolidation of NanoSynex on July 20, 2023, the Company accounts for its retained investment under the equity method of accounting as it retained the ability to exercise significant influence over the operating and financial policies of the investee. Under the equity method, the Company recognizes its proportionate share earnings or losses each reporting period with an adjustment to the carrying value of the investment. As of December 31, 2023, the carrying value of the retained investment was zero, and therefore the Company has suspended application of the equity method as the Company is not liable for the obligations of the investee nor otherwise committed to provide financial support. Future equity method earnings, if any, will not be recognized until the amount exceeds the unrecognized net losses in prior periods. See Note 5 – Discontinued Operations for further information.

Accounting Estimates

Management uses estimates and assumptions in preparing its condensed consolidated financial statements in accordance with U.S. GAAP. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. The most significant estimates relate to the estimated fair value of derivative financial instruments, warrant liabilities, and stock-based compensation. Actual results could vary from the estimates that were used.

Reverse Stock Split

On November 23, 2022, the Company effected a 1-for-10 reverse stock split of its outstanding shares of common stock (the "Reverse Stock Split"). The Reverse Stock Split reduced the Company's shares of outstanding common stock, stock options, and warrants to purchase shares of common stock. Fractional shares of common stock that would have otherwise resulted from the Reverse Stock Split were rounded down to the nearest whole share and cash in lieu of fractional shares was paid to stockholders. All share and per share data for all periods presented in the accompanying financial statements and the related disclosures have been adjusted retrospectively to reflect the Reverse Stock Split. The number of authorized shares of common stock and the par value per share remains unchanged.

Cash

The Company considers all highly liquid investments purchased with an initial maturity of 90 days or less and money market funds to be cash equivalents.

The Company maintains the majority of its cash in government money market mutual funds and in accounts at banking institutions in the U.S. that are of high quality. Cash held in these accounts often exceed the Federal Deposit Insurance Corporation (FDIC) insurance limits. If such banking institutions were to fail, the Company could lose all or a portion of amounts held in excess of such insurance limitations. In March 2023, Silicon Valley Bank and Signature Bank, and in May 2023, First Republic Bank, were closed due to liquidity concerns and taken over by the FDIC. While the Company did not have an account at any of these banks, in the event of failure of any of the financial institutions where the Company maintains its cash and cash equivalents, there can be no assurance that the Company would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect the Company's business and financial position.

Impairment of Long-Lived Assets

The Company assesses potential impairments to its long-lived assets when there is evidence that events or changes in circumstances indicate that assets may not be recoverable. An impairment loss would be recognized when the sum of the expected future undiscounted cash flows is less than the carrying amount of the assets. The amount of impairment loss, if any, will generally be measured as the difference between the net book value of the assets and their estimated fair values. During the three months ended March 31, 2024 and 2023, no such impairment losses have been recorded.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and managed its business as one segment operating primarily within the United States (and in Israel prior to the NanoSynex deconsolidation).

Research and Development

Except for acquired in process research and development (IPR&D), the Company expenses research and development costs as incurred including therapeutics license costs.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the condensed consolidated statement of operations.

Business Combinations

The Company accounts for business combinations using the acquisition method pursuant to Financial Accounting Standards Board's ("FASB") ASC Topic 805. This method requires, among other things, that results of operations of acquired companies are included in the Company's financial results beginning on the respective acquisition date, and that assets acquired and liabilities assumed are recognized at fair value as of the acquisition date. Intangible assets acquired in a business combination are recorded at fair value using a discounted cash flow model. The discounted cash flow model requires assumptions about the timing and amount of future net cash flows, the cost of capital and terminal values from the perspective of a market participant. Each of these factors can significantly affect the value of the intangible asset. Any excess of the fair value of consideration transferred (the "purchase price") over the fair values of the net assets acquired is recognized as goodwill. The fair value of assets acquired and liabilities assumed in certain cases may be subject to revision based on the final determination of fair value during a period of time not to exceed 12 months from the acquisition date. Legal costs, due diligence costs, business valuation costs and all other acquisition-related costs are expensed when incurred.

Goodwill

Goodwill represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets acquired, when accounted for using the purchase method of accounting. Goodwill has an indefinite useful life and is not amortized but is reviewed for impairment annually and whenever events or changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. In testing for impairment, the fair value of the reporting unit is compared to the carrying value. If the net assets assigned to the reporting unit exceed the fair value of the reporting unit, an impairment loss equal to the difference is recorded.

Derivative Financial Instruments and Warrant Liabilities

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates all of its financial instruments, including issued stock purchase warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the condensed consolidated statements of operations and comprehensive loss. Depending on the features of the derivative financial instrument, the Company uses either the Black-Scholes option-pricing model or a Monte-Carlo simulation to value the derivative instruments at inception and subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period (See Note 7-Warrant Liabilities and Note 8- Convertible Debt - Related Party).

Fair Value Measurements

The Company determines the fair value measurements of applicable assets and liabilities based on a three-tier fair value hierarchy established by accounting guidance and prioritizes the inputs used in measuring fair value. The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

- Level 1 - Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date;

- Level 2 - Inputs other than quoted prices that are observable for the assets or liability either directly or indirectly, including inputs in markets that are not considered to be active; and
- Level 3 - Inputs that are unobservable.

Fair Value of Financial Instruments

Cash, accounts receivable, prepaids, accounts payable, and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments.

Comprehensive Loss

Comprehensive loss consists of net income and foreign currency translation adjustments related to the discontinued operations of NanoSynex. Comprehensive gains (losses) have been reflected in the statements of operations and comprehensive loss and as a separate component in the statements of stockholders' equity (deficit) for all periods presented.

Stock-Based Compensation

Stock-based compensation cost for equity awards granted to employees and non-employees is measured at the grant date based on the calculated fair

value of the award using the Black-Scholes option-pricing model, and is recognized as an expense, under the straight-line method, over the requisite service period (generally the vesting period of the equity grant). If the Company determines that other methods are more reasonable, or other methods for calculating these assumptions are prescribed by regulators, the fair value calculated for the Company's stock options could change significantly. Higher volatility, lower risk-free interest rates, and longer expected lives would result in an increase to stock-based compensation expense to employees and non-employees determined at the date of grant.

Income Taxes

Deferred income taxes are recognized for temporary differences in the basis of assets and liabilities for financial statement and income tax reporting that arise due to net operating loss carry forwards, research and development credit carry forwards and from using different methods and periods to calculate depreciation and amortization, allowance for doubtful accounts, accrued vacation, research and development expenses, and state taxes. A provision has been made for income taxes due on taxable income and for the deferred taxes on the temporary differences.

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. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment. Realization of the deferred income tax asset is dependent on generating sufficient taxable income in future years.

In December 2023, the FASB issued Accounting Standards Update 2023-09, Improvements to Income Tax Disclosures, which requires more detailed income tax disclosures. The guidance requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is evaluating the disclosure requirements related to the new standard.

Foreign Currency Translation

The functional currency for the Company is the U.S. dollar. The functional currency for the discontinued operations of NanoSynex was the New Israeli Shekel (NIS). The financial statements of NanoSynex were translated into U.S. dollars using exchange rates in effect at each period end for assets and liabilities; using exchange rates in effect during the period for results of operations; and using historical exchange rates for certain equity accounts. The adjustment resulting from translating the financial statements of NanoSynex was reflected as a separate component of other comprehensive income (loss) (see Note 5 - Discontinued Operations).

Global Economic Conditions

Ongoing Wars in Ukraine and Israel

In February 2022, Russia invaded Ukraine. While the Company has no direct exposure in Russia and Ukraine, the Company continues to monitor any broader impact to the global economy, including with respect to inflation, supply chains and fuel prices. The full impact of the conflict on the Company's business and financial results remains uncertain and will depend on the severity and duration of the conflict and its impact on regional and global economic conditions.

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In October 2023, Hamas conducted terrorist attacks in Israel resulting in ongoing war. There continue to be hostilities between Israel and Hezbollah in Lebanon and Hamas in the Gaza Strip, both of which have resulted in rockets being fired into Israel, causing casualties and disruption of economic activities. In early 2023, there were a number of changes proposed to the political system in Israel by the current government which, if implemented as planned, could lead to large-scale protests and additional uncertainty, negatively impacting the operating environment in Israel. Popular uprisings in various countries in the Middle East over the last few years have also affected the political stability of those countries and have led to a decline in the regional security situation. Such instability may also lead to deterioration in the political and trade relationships that exist between Israel and these countries. Any armed conflicts, terrorist activities or political instability involving Israel or other countries in the region could adversely affect the Company's minority interest in NanoSynex, its results of operations, financial condition, cash flows and prospects (see Note 5 – Discontinued Operations).

Inflation and Global Economic Conditions

During the year ended 2022 and continuing into the current fiscal year, global commodity and labor markets experienced significant inflationary pressures attributable to government stimulus and recovery programs, government deficit spending and supply chain issues. The Company cannot provide assurance that it will be successful in fully offsetting increased costs resulting from inflationary pressure. In addition, the global economy suffers from slowing growth and rising interest rates, and some economists believe that there may be a global recession in the near future. If the global economy slows, the Company's business may be adversely affected.

Impact of COVID-19 Pandemic

The COVID-19 pandemic has had a dramatic impact on businesses globally and on the Company's business as well. During the height of the pandemic, sales of diagnostic products decreased significantly and the Company's net loss increased significantly, as clinics and small hospitals' demand for Qualigen, Inc.'s FastPack™ diagnostic test kits was reduced sharply, largely due to deferral of patients' non-emergency visits to physician offices. In July 2023 the Company sold Qualigen, Inc., its wholly-owned subsidiary, to Chembio (see Note 5 - Discontinued Operations).

Other accounting standard updates are either not applicable to the Company or are not expected to have a material impact on the Company's condensed consolidated financial statements.

NOTE 2 — LIQUIDITY

As of March 31, 2024, we had approximately \$ 0.1 million in cash and an accumulated deficit of \$ 118.8 million. For the three months ended March 31, 2024 and 2023, we used cash of \$0.8 million and \$2.6 million, respectively, in operations.

The Company's cash balances as of the date that these financial statements were issued, without additional financing, are expected to fund operations only into the third quarter of 2024. The Company expects to continue to have net losses and negative cash flow from operations, which will challenge its liquidity. These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period following the date that these financial statements were issued. There is no assurance that profitable operations will ever be achieved, or, if achieved, could be sustained on a continuing basis.

Historically, the Company's principal sources of cash have included proceeds from the issuance of common and preferred equity and proceeds from the issuance of debt. In December 2022 the Company raised \$3.0 million from the sale of an 8% Senior Convertible Debenture to Alpha and between February 2024 and April 2024 the Company raised \$1.5 million from the sale of an additional Convertible Debentures (see Note 8 - Convertible Debt - Related Party and Note 14 - Subsequent Events). There can be no assurance that further financing can be obtained on favorable terms, or at all. If the

Company is unable to obtain funding, the Company could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect the Company's business prospects.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The financial statements do not include any adjustments that would be necessary should the Company be unable to continue as a going concern, and therefore, be required to liquidate its assets and discharge its liabilities in other than the normal course of business and at amounts that may differ from those reflected in the accompanying financial statements.

NOTE 3 — PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following at March 31, 2024 and December 31, 2023:

	March 31, 2024	December 31, 2023
Prepaid insurance	\$ 388,348	\$ 566,011
Other prepaid expenses	71,646	25,053
Funds held in escrow	450,000	—
Prepaid research and development expenses	—	173,900
	<hr/> <u>\$ 909,994</u>	<hr/> <u>\$ 764,964</u>

NOTE 4 — OTHER NON-CURRENT ASSETS

Other non-current assets consisted of the following at December 31, 2023:

	December 31, 2023
Funds held in escrow	\$ 450,000
Long-term research and development deposits	416,481
	<hr/> <u>\$ 866,481</u>

NOTE 5 — DISCONTINUED OPERATIONS

The summary of gain (loss) from discontinued operations, net of tax, for the three months ended March 31, 2024 and 2023 are as follows:

	Three Months Ended March 31, 2024			Three Months Ended March 31, 2023		
	Qualigen, Inc.	NanoSynex	Total	Qualigen, Inc.	NanoSynex	Total
Loss from discontinued operations	\$ -	\$ -	\$ -	\$ (376,174)	\$ (496,014)	\$ (872,188)

Sale of Qualigen, Inc.

On July 20, 2023, the Company completed the sale of Qualigen, Inc., its formerly wholly-owned subsidiary, to Chembio Diagnostics, Inc. for net cash consideration of \$5.4 million, of which \$4.9 million was received during the year ended December 31, 2023, and \$ 450,000 was being held in escrow until January 20, 2025 to provide an available fund for payment of potential Company indemnification obligations. On June 4, 2024, the escrow account (reflected in prepaid expenses and other current assets on the Company's March 31, 2024 balance sheet), was settled early by mutual agreement of the Company and the buyer. (See Note 14 - Subsequent Events.)

There were no assets and liabilities remaining related to Qualigen, Inc. as of March 31, 2024 or December 31, 2023.

There was no activity related to Qualigen, Inc. during the three months ended March 31, 2024. The Company reclassified the following statement of operations items to discontinued operations for the three months ended March 31, 2023:

	For the Three Months March 31, 2023
REVENUES	
Net product sales	\$ 1,607,170
Total revenues	<hr/> <u>1,607,170</u>
EXPENSES	
Cost of product sales	1,264,828
General and administrative	345,433
Research and development	178,550
Sales and marketing	199,114
Goodwill and fixed asset impairment	—
Total expenses	<hr/> <u>1,987,925</u>
OTHER EXPENSE (INCOME), NET	
Other expense (income), net	(4,881)
Loss on fixed asset disposal	<hr/> <u>300</u>

Total other expense (income), net	<u>(4,581)</u>
LOSS FROM DISCONTINUED OPERATIONS OF QUALIGEN, INC.	<u>\$ (376,174)</u>

Amendment and Settlement Agreement with NanoSynex Ltd.

On July 20, 2023, the Company entered into and effectuated the NanoSynex Amendment, reducing its ownership from approximately 52.8% to approximately 49.97% of the voting equity of NanoSynex, and deconsolidation of the subsidiary. On November 22, 2023, the Company further agreed to eliminate the Company's obligations to lend additional funds to NanoSynex by surrendering shares of Series A-1 Preferred Stock of NanoSynex in an amount that reduced the Company's ownership in NanoSynex voting equity from approximately 49.97% to 39.90%.

On the date of deconsolidation, the Company recognized its retained investment at fair value, which during the preparation of these financial statements was determined to be de minimis based on various economic, industry, and other factors. As a result, the Company has discontinued recognition of its proportionate share of equity method losses following the date of initial recognition. Future equity method earnings, if any, will not be recognized until the amount exceeds the unrecognized net losses in prior periods.

There were no assets and liabilities recognized related to NanoSynex as of March 31, 2024 or December 31, 2023.

There was no activity related to NanoSynex during the three months ended March 31, 2024. The Company reclassified the following statement of operations items to discontinued operations for the three months ended March 31, 2023:

	For the Three Months March 31, 2023
EXPENSES	
Research and development	\$ 661,184
Total expenses	<u>661,184</u>
(BENEFIT) PROVISION FOR INCOME TAXES	<u>(165,170)</u>
LOSS FROM DISCONTINUED OPERATIONS OF NANOSYNEX, LTD.	<u>(496,014)</u>
Loss attributable to noncontrolling interest	<u>(261,028)</u>
NET LOSS ATTRIBUTABLE TO STOCKHOLDERS	<u>\$ (234,986)</u>

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NOTE 6 — ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following at March 31, 2024 and December 31, 2023:

	March 31, 2024	December 31, 2023
Board compensation	\$ 190,749	129,499
Interest (Convertible debt)	19,581	10,004
License fees	46,063	32,975
Payroll	206,805	1,215
Professional fees	163,935	121,775
Research and development	28,604	104,402
Vacation	159,491	151,286
Other	3,788	8,850
	<u>\$ 819,015</u>	<u>\$ 560,006</u>

NOTE 7 – WARRANT LIABILITIES

In 2004, the Company issued warrants to various investors and brokers for the purchase of Series C preferred stock in connection with a private placement (the "Series C Warrants"). The Series C Warrants were subsequently extended and, upon closing of the reverse recapitalization transaction with Ritter, exchanged for warrants to purchase common stock of the Company. The Series C Warrants were determined to be liability-classified pursuant to the guidance in ASC 480 and ASC 815-40, based on the inclusion of a leveraged ratchet provision for subsequent dilutive issuances. As of December 31, 2022 there were 1,349,570 Series C Warrants outstanding with an exercise price of \$1.32 per share.

On December 22, 2022, in conjunction with the issuance of the Debenture to Alpha (see Note 8 – Convertible Debt – Related Party), the Company issued to Alpha a warrant to purchase 2,500,000 shares of the Company's common stock (the "Alpha Warrant"). The exercise price of the Alpha Warrant was \$1.65 (equal to 125% of the conversion price of the Debenture on the closing date). The Alpha Warrant may be exercised by Alpha, in whole or in part, on or after June 22, 2023 and at any time before June 22, 2028, subject to certain terms and conditions described in the Alpha Warrant. The fair value of this Alpha Warrant was included in Warrant liabilities-related party on the Company's consolidated balance sheet as of December 31, 2022. On December 5, 2023, the Company entered into an Amendment No. 1 with regard to a Securities Purchase Agreement, with Alpha. This Amendment eliminated certain adjustment provisions of the Warrant. The Company determined the event resulted in equity classification for the Warrant and, accordingly, the Company remeasured the warrant liabilities to fair value, and reclassified to equity.

On November 24, 2023, 1,097,599 Series C Warrants expired, and on December 5, 2023 the remaining Series C Warrants were repriced from an exercise price of \$1.32 per share to an exercise price of \$0.73 per share, with 203,652 additional ratchet Series C Warrants issued, resulting in 455,623 of these Series C Warrants outstanding and exercisable as of December 31, 2023.

On February 27, 2024, these Series C Warrants were repriced again as a result of a down-round provision triggered by a Securities Purchase Agreement with Alpha for the purchase of the February 2024 Debenture, from an exercise price of \$0.73 per share to an exercise price of \$0.26 per share, with 823,633 additional ratchet Series C Warrants issued, resulting in 1,279,256 of these Series C Warrants outstanding and exercisable as of March 31, 2024, with a remaining term of 0.24 years.

The following table summarizes the activity in liability classified warrants for the three months ended March 31, 2024:

	Common Stock Warrants			
	Shares	Weighted-Average Exercise Price	Range of Exercise Price	Weighted-Average Remaining Life (Years)
Total outstanding – December 31, 2023	455,623	\$ 0.73	\$ 0.73	0.49
Exercised	—	—	—	—
Forfeited	—	—	—	—
Expired	—	—	—	—
Granted	823,633	\$ 0.26	\$ 0.26	—
Total outstanding – March 31, 2024	1,279,256	\$ 0.26	\$ 0.26	0.24
Exercisable	1,279,256	\$ 0.26	\$ 0.26	0.24

The following table summarizes the activity in liability classified warrants for the three months ended March 31, 2023:

	Common Stock Warrants			
	Shares	Weighted-Average Exercise Price	Range of Exercise Price	Weighted-Average Remaining Life (Years)
Total outstanding – December 31, 2022	3,849,571	\$ 1.53	\$ 1.32 - \$1.65	3.9
Exercised	—	—	—	—
Forfeited	—	—	—	—
Expired	—	—	—	—
Granted	—	—	—	—
Total outstanding – March 31, 2023	3,849,571	\$ 1.53	\$ 1.32 - \$1.65	3.66
Exercisable	1,349,571	\$ 1.32	\$ 1.32	0.76

The following table presents the Company's fair value hierarchy for its Common Stock Warrant liabilities measured at fair value on a recurring basis as of March 31, 2024:

Common Stock Warrant Liabilities	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	\$ —	\$ —	\$ 54,600	\$ 54,600
Balance as of December 31, 2023	\$ —	\$ —	\$ 54,600	\$ 54,600
Issuances	—	—	—	—
Exercises	—	—	—	—
Loss on change in fair value of warrant liabilities	—	—	133,300	133,300
Balance as of March 31, 2024	\$ —	\$ —	\$ 187,900	\$ 187,900

There were no transfers of financial assets or liabilities between category levels for the three months ended March 31, 2024.

The value of the warrant liabilities was based on a valuation received from an independent valuation firm. For volatility, the Company considers comparable public companies as a basis for its expected volatility to calculate the fair value of common stock warrants and transitions to its own volatility as the Company develops sufficient appropriate history as a public company. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected term of the common stock warrant. The Company uses an expected dividend yield of zero based on the fact that the Company has never paid cash dividends and does not expect to pay cash dividends in the foreseeable future. Any significant changes in the inputs may result in significantly higher or lower fair value measurements.

The following are the assumptions used in estimating the fair value of warrant liabilities as of March 31, 2024, and the weighted average and the range of assumptions used in estimating the fair value of warrant liabilities as of March 31, 2023:

	March 31, 2024		March 31, 2023
	Actual	Range	Weighted Average
Risk-free interest rate	5.32%	3.531% - 4.743%	3.93%
Expected volatility (peer group)	64.7%	70.3% - 132%	110.9%
Term of warrants (in years)	0.24	0.64 - 5.23	3.66
Expected dividend yield	0.00%	0.00%	0.00%

NOTE 8 — CONVERTIBLE DEBT - RELATED PARTY

2022 Convertible Debenture

On December 22, 2022, we issued to Alpha an 8% Senior Convertible Debenture in the aggregate principal amount of \$ 3,300,000 for a purchase price of \$3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022 (the "2022 Securities Purchase Agreement"). The 2022 Debenture has a maturity date of December 22, 2025 and is convertible, at any time, and from time to time, until the 2022 Debenture is no longer outstanding, at Alpha's option, into shares of our common stock (the "Conversion Shares"), at a price initially equal to \$1.32 per share, subject to adjustment as described in the 2022 Debenture and other terms and conditions described in the 2022 Debenture. On July 13, 2023, we obtained stockholder approval, for purposes of complying with Nasdaq Listing Rule 5635(d), for the issuance to Alpha of more than 20% of our issued and outstanding shares of common stock pursuant to the terms and conditions of (a) the 2022 Debenture, and (b) the common stock purchase warrant dated December 22, 2022 issued by us to Alpha. Between January 9 and 12, 2023, we issued 841,726 shares of common stock upon Alpha's partial conversion of the 2022 Debenture at \$1.32 per share for a total of \$ 1,111,078 principal. In October and December 2023, we issued 309,665 shares of common stock to Alpha in lieu of cash for monthly redemption payments on the 2022 Debenture at a weighted average price of \$0.71 per share. In January, February,

and March 2024, we issued 1,138,535 shares of common stock to Alpha in lieu of cash for monthly redemption payments on the 2022 Debenture at a weighted average price of \$0.33 per share. As of March 31, 2024, approximately 3,995,854 shares of common stock were issuable under the 2022 Debenture, based on the \$0.26 per share figure. The 2022 Debenture includes a beneficial ownership blocker of 9.99%, which may only be waived by Alpha upon 61 days' notice to us. Except in respect of an Exempt Issuance (as defined in the 2022 Securities Purchase Agreement), the 2022 Debenture contains a "ratchet" antidilution provision, with a \$0.26 floor.

Commencing June 1, 2023 (the "Initial Monthly Redemption Date") and continuing on the first day of each month thereafter until the earlier of (i) December 22, 2025 and (ii) the full redemption of the 2022 Debenture (each such date, a "Monthly Redemption Date"), we must redeem \$110,000 plus accrued but unpaid interest, liquidated damages and any amounts then owing under the 2022 Debenture (the "Monthly Redemption Amount"). The Monthly Redemption Amount must be paid in cash; *provided that* after the first two monthly redemptions, we may elect to pay all or a portion of a Monthly Redemption Amount in shares of our common stock, based on a conversion price equal to the lesser of (i) the then conversion price of the 2022 Debenture and (ii) 85% of the average of the VWAPs (as defined in the 2022 Debenture) for the five consecutive trading days ending on the trading day that is immediately before the applicable Monthly Redemption Date, subject to the Equity Conditions (as defined in the 2022 Debenture) having been satisfied or waived.

The 2022 Debenture accrues interest at the rate of 8% per annum, which did not begin accruing until December 1, 2023, and will be payable on a monthly or quarterly basis. Interest may be paid in cash or shares of our common stock or a combination thereof at our option; *provided that* interest may only be paid in shares if the Equity Conditions have been satisfied or waived.

In December 2022, pursuant to the terms of the 2022 Securities Purchase Agreement, we entered into a registration rights agreement with Alpha (the "Registration Rights Agreement"), pursuant to which we agreed to file one or more registration statements, as necessary, and to the extent permissible, to register under the Securities Act the resale of the remaining shares (underlying the 2022 Debenture and the 2022 Warrant) not otherwise registered under the Company's registration statement on Form S-3 (File No. 333-266430). The Registration Rights Agreement requires that the Company file, within 30 days after signing, a resale registration statement and use commercially reasonable efforts to cause the resale registration statement to be declared effective by the SEC on or before the 60th calendar day following the date of signing of the Registration Rights Agreement (or 120 days if such registration statement is subject to full review by the SEC). We filed a resale registration statement on Form S-3 pursuant to the requirements of the Registration Rights Agreement on December 2022 (File Number 333-269088), which registration statement was declared effective by the SEC on January 5, 2023. On September 1, 2023, we filed a Post-Effective Amendment No. 1 to Form S-3 on Form S-1 (File No. 333-269088), which Post-Effective Amendment was declared effective by the SEC on September 7, 2023. On May 1, 2024, we filed a Post-Effective Amendment No. 2 to Form S-1 on Form S-3 (File No. 333-269088), which Post-Effective Amendment was declared effective by the SEC on May 2, 2024.

The Company evaluated the 2022 Debenture and the 2022 Warrant and determined that the 2022 Warrant is a freestanding financial instrument. Initially, the 2022 Warrant is not considered indexed to the Company's own stock, because the settlement amount would not equal the difference between the fair value of a fixed number of the Company's equity shares and a fixed strike price and all of the adjustment features in Section 3(b) of the Alpha Warrant are not down round provisions, as defined in ASU 2017-11. Accordingly, the 2022 Warrant was classified as a liability and recognized at fair value, with subsequent changes in fair value recognized in earnings.

The proceeds from the 2022 Debenture were allocated to the initial fair value of the 2022 Warrant, with the residual balance allocated to the initial carrying value of the 2022 Debenture. The Company has not elected the fair value option for the 2022 Debenture. The 2022 Debenture was recognized as proceeds received after allocating the proceeds to the 2022 Warrant, and then allocating remaining proceeds to a suite of bifurcated embedded derivative features (conversion option, contingent acceleration upon an Event of Default, and contingent interest upon an Event of Default), with the resulting difference, if any, allocated to the loan host instrument. The suite of derivative features was measured and determined to have no fair value.

The original issue discount of \$0.3 million, the initial fair value of the 2022 Warrant of \$ 2.8 million, the initial fair value of the suite of bifurcated embedded derivative features of \$0, and the fees and costs paid to Alpha and other third parties of \$ 0.1 million comprised the debt discount upon issuance. The debt discount is amortized to interest expense over the expected term of the 2022 Debenture using the effective interest method, in accordance with ASC 835-30. The debt host instrument of the 2022 Debenture will subsequently be measured at amortized cost using the effective interest method to accrete interest over its term to bring the 2022 Debenture's initial carrying value to the principal balance at maturity.

On December 5, 2023, the Company and Alpha executed Amendment No. 1 with regard to Securities Purchase Agreement (the "SPA Amendment"), pursuant to which the Company and Alpha agreed to, among other things, reduce the Conversion Price of the 2022 Debenture from \$1.32 per share to \$0.73 per share and reduce the exercise price of the 2022 Warrant from \$ 1.65 per share to \$0.73 per share, in each case subject to certain adjustments. In addition, the SPA Amendment revised certain provisions of the 2022 Warrant to (i) limit the circumstances which would trigger a potential adjustment to the exercise price of the 2022 Warrant and (ii) clarify the treatment of the 2022 Warrant upon a Fundamental Transaction. The purpose of these revisions was to remove the terms that caused the 2022 Warrant to be liability-classified under U.S. GAAP. The Company performed an assessment and concluded that all remaining adjustment features in the revised language meet the FASB's definition of a down-round feature. In addition, the 2022 Warrant was determined to meet all of the additional requirements for equity classification. Accordingly, as of December 5, 2023, the Company remeasured the 2022 Warrant to its fair value immediately prior to the modification and recognized the change in fair value in earnings. The incremental fair value impact from the 2022 Warrant modification of \$0.09 million was included in the Company's evaluation of the 2022 Debenture modification under ASC 470, discussed further below. The Company then reclassified the 2022 Warrant liability to equity at its post-modification fair value of \$1.6 million.

In accordance with ASC 470-50, the Company determined that the modified terms of the 2022 Debenture were substantially different when compared to the original terms that existed prior to the SPA Amendment, and thus the event was required to be accounted for as a debt extinguishment. Accordingly, the Company derecognized the net carrying value of the original Debenture, and recorded the new debt instrument at its fair value of \$1.4 million, and recorded a \$0.6 million loss on debt extinguishment. The difference between the remaining 2022 Debenture principal and its fair value on December 5, 2023 was recorded as a debt discount and will be amortized to interest expense over the expected term of the Debenture using the effective interest method, in accordance with ASC 835-30.

During the three months ended March 31, 2024, the Company recognized an extinguishment loss of approximately \$ 147,000 upon debenture share redemptions, and recorded interest expense of approximately \$68,000 in other expenses in the condensed consolidated statements of operations related to the 2022 Debenture.

2024 Alpha Debenture

On February 27, 2024, upon our receipt of a cash purchase price payment of \$ 500,000 less expenses, we issued to Alpha an 8% Convertible Debenture (the "2024 Alpha Debenture") in the principal amount of \$550,000. The 2024 Alpha Debenture matures no later than December 31, 2024 and is convertible, at any time, and from time to time, at Alpha's option, into shares of common stock of the Company, at \$0.6111 per share, subject to adjustment as described in the 2024 Alpha Debenture. Except in respect of an Exempt Issuance, the 2024 Alpha Debenture contains a "ratchet" antidilution provision, with an \$0.1164 floor. The 2024 Alpha Debenture accrues interest on its outstanding principal balance at the rate of 8% per annum, payable at maturity. In connection with this issuance, we also issued to Alpha a 5-year common stock purchase warrant to purchase (at \$0.26 per share) 900,016 shares of our common stock. We also granted to Alpha an option, exercisable until July 1, 2024, to purchase from us additional 8% Convertible Debentures, of like tenor, with face amounts of up to an aggregate of \$1,100,000 (and with a proportional number of accompanying common stock

warrants of like tenor, up to a total of 1,800,032 additional warrants).

During the three months ending March 31, 2024 in connection with the 2024 Alpha Debenture, the Company recorded initial derivative liabilities with a fair value of \$858,279, and recorded interest expense of \$ 64,673 in other expenses in the condensed consolidated statements of operations related to the 2024 Alpha Debenture. The Securities Purchase Agreement related to the issuance of 2024 Alpha Debenture resulted in down-round provisions of various warrants being triggered which resulted in reductions of the exercise price of these warrants from \$0.73 per share to \$0.26 per share (see Note 7 - Warrant Liabilities and Note 12 - Stockholders Equity (Deficit)).

As of March 31, 2024, there were no unwaived events of default or violation of any covenants under the Company's financing obligations.

The following comprises the convertible debt-related party:

	March 31, 2024	December 31, 2023
2022 Senior convertible debenture	\$ 1,038,922	\$ 1,418,922
2022 Discount on convertible debenture	(76,571)	(119,706)
2024 Senior convertible debenture	550,000	—
2024 Discount on convertible debenture	(489,482)	—
Total convertible debt-related party	\$ 1,022,869	\$ 1,299,216

Derivative Liabilities

As of March 31, 2024, the fair value of derivative liabilities related to the 2024 Alpha Debenture was \$ 693,782.

NOTE 9 — EARNINGS (LOSS) PER SHARE

Basic loss per share ("EPS") is computed by dividing net loss by the weighted-average number of common shares outstanding. Diluted EPS is computed based on the sum of the weighted-average number of common shares and potentially dilutive common shares outstanding during the period. Potentially dilutive common shares consist of shares issuable from stock options and warrants.

The following potentially dilutive securities have been excluded from diluted net loss per share as of March 31, 2024 and 2023 because their effect would be anti-dilutive:

	As of March 31,	
	2024	2023
Shares of common stock subject to outstanding options	398,924	552,561
Shares of common stock subject to outstanding warrants	4,798,105	4,254,766
Shares of common stock subject to outstanding convertible debt	<u>4,895,869</u>	<u>1,658,274</u>
Total common stock equivalents	<u>10,092,898</u>	<u>6,465,601</u>

NOTE 10 — COMMITMENTS AND CONTINGENCIES

Litigation and Other Legal Proceedings

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of March 31, 2024, there were no pending or threatened lawsuits that could reasonably be expected to have a material effect on the results of the Company's operations.

NOTE 11 — RESEARCH AND LICENSE AGREEMENTS

UCL Business Limited

In January 2022, the Company entered into a License Agreement with UCL Business Limited to obtain an exclusive worldwide in-license of a genomic quadruplex (G4)-selective transcription inhibitor drug development program which had been developed at University College London, including lead and back-up compounds, preclinical data and a patent estate. (UCL Business Limited is the commercialization company for University College London.) The program's lead compound is now being developed at the Company under the name QN-302 as a candidate for treatment for pancreatic ductal adenocarcinoma, which represents the vast majority of pancreatic cancers. The License Agreement required a \$150,000 upfront payment, reimbursement of past patent prosecution expenses of approximately \$160,000, and (if and when applicable) tiered royalty payments in the low to mid-single digits, clinical/regulatory/sales milestone payments and a percentage of any non-royalty sublicensing consideration paid to the Company.

For the three months ended March 31, 2024 and 2023, there were license costs of approximately \$ 2,000 and \$5,000, respectively, related to this agreement which are included in research and development expenses in the condensed consolidated statements of operations.

QN-302 Phase 1 Study

In June 2023, the Company entered into a Master Clinical Research Services Agreement with Translational Drug Development, LLC ("TD2") whereby TD2 agreed to perform certain clinical research and development services for the Company including but not limited to trial management, site identification and selection, site monitoring/management, medical monitoring, project management, data collection, statistical programming or analysis, quality assurance auditing, scientific and medical communications, regulatory affairs consulting and submissions, strategic consulting, and/or other related services. From time to time, the Company shall enter into statements of work with TD2 for the performance of specific services under this Master Clinical Research Services Agreement.

In June 2023, the Company entered into a Master Laboratory Services Agreement with MLM Medical Labs, LLC ("MLM") whereby MLM agreed to perform certain clinical research and development services for the Company including but not limited to laboratory, supply, testing, validation, data management, and storage services. From time to time, the Company shall enter into work orders with MLM for the performance of specific services under this Master Laboratory Services Agreement.

In June 2023, the Company entered into a Master Services Agreement with Clinigen Clinical Supplies Management, Inc. ("Clinigen") whereby Clinigen agreed to provide certain pharmaceutical products and/or services. From time to time, the Company shall enter into statements of work with Clinigen for the performance of specific services under this Master Services Agreement.

In July 2023, pursuant to the above agreements, the Company entered into work orders and statements of work for clinical trial services for the conduct of the QN-302 Phase 1 study.

The University of Louisville Research Foundation

In March 2019, the Company entered into a sponsored research agreement and an option for a license agreement with University of Louisville Research Foundation, Inc. ("ULRF") for development of several small-molecule RAS interaction inhibitor drug candidates. Under the terms of this agreement, the Company agreed to reimburse ULRF for sponsored research expenses of initially up to \$693,000 for this program. This agreement was amended in February 2021, March 2022 and August 2023, with the current term of this agreement set to expire in December 2023 and the aggregate amount that the Company would reimburse ULRF for sponsored research expenses increased to approximately \$2.9 million. In July 2020, the Company entered into an exclusive license agreement with ULRF for RAS interaction inhibitor drug candidates. Under the agreement, the Company took over development, regulatory approval and commercialization of the candidates from ULRF and is responsible for maintenance of the related intellectual property portfolio. In return, ULRF received approximately \$112,000 for an upfront license fee and reimbursement of prior patent costs. In addition, the Company has agreed to pay ULRF (i) royalties, on patent-covered net sales associated with the commercialization, of 4% (on net sales up to a cumulative \$250,000,000) or 5% (on net sales above a cumulative \$250,000,000), until expiration of the licensed patent, and 2.5% (on net sales for any sales not covered by Licensed Patents), (ii) 30% to 50% of any non-royalty sublicensee income received (50% for sublicenses granted in the first two years of the ULRF license agreement, 40% for sublicenses granted in the third or fourth years of the ULRF license agreement, and 30% for sublicenses granted in the fifth year of the ULRF license agreement or thereafter), (iii) reimbursements for ongoing costs associated with the preparation, filing, prosecution and maintenance of licensed patents, incurred prior to July 2020, and (iv) payments ranging from \$50,000 to \$5,000,000 upon the achievement of certain regulatory and commercial milestones. Milestone payments for the first therapeutic indication would be \$ 50,000 for first dosing in a Phase 1 clinical trial, \$100,000 for first dosing in a Phase 2 clinical trial, \$ 150,000 for first dosing in a Phase 3 clinical trial, \$ 300,000 for regulatory marketing approval and \$5,000,000 upon achieving a cumulative \$500,000,000 of Licensed Product sales. The Company also must pay ULRF shortfall payments if the total amounts actually paid with respect to royalties and non-royalty sublicensee income for any year is less than the applicable annual minimum (ranging from \$20,000 to \$100,000) for such year.

Sponsored research expenses related to these RAS agreements for the three months ended March 31, 2024 and 2023 were zero and \$223,000, respectively, and are recorded in research and development expenses in the condensed consolidated statements of operations. License costs related to these agreements for the three months ended March 31, 2024 and 2023 were approximately \$25,000 and \$14,000, respectively, and are included in research and development expenses in the condensed consolidated statements of operations.

Between June 2018 and April 2022, the Company entered into license and sponsored research agreements with ULRF for QN-247, a novel aptamer-based compound that has shown promise as an anticancer drug. Under the agreements, the Company took over development, regulatory approval and commercialization of the compound from ULRF and is responsible for maintenance of the related intellectual property portfolio. In return, ULRF received a \$50,000 convertible promissory note in payment of an upfront license fee, which was subsequently converted into the Company's common stock, and the Company agreed to reimburse ULRF for sponsored research expenses of up to approximately \$805,000 and prior patent costs of up to \$200,000. In addition, the Company agreed to pay ULRF (i) royalties, on patent-covered net sales associated with the commercialization of anti-nucleolin agent-conjugated nanoparticles, of 4% (on net sales up to a cumulative \$250,000,000) or 5% (on net sales above a cumulative \$250,000,000), until expiration of the last to expire of the licensed patents, (ii) 30% to 50% of any non-royalty sublicensee income received (50% for sublicenses granted in the first two years of the ULRF license agreement, 40% for sublicenses granted in the third or fourth years of the ULRF license agreement, and 30% for sublicenses granted in the fifth year of the ULRF license agreement or thereafter), (iii) reimbursements for ongoing costs associated with the preparation, filing, prosecution and maintenance of licensed patents, incurred prior to June 2018, and (iv) payments ranging from \$100,000 to \$5,000,000 upon the achievement of certain regulatory and commercial milestones. Milestone payments for the first therapeutic indication would be \$ 100,000 for first dosing in a Phase 1 clinical trial, \$200,000 for first dosing in a Phase 2 clinical trial, \$ 350,000 for first dosing in a Phase 3 clinical trial, \$ 500,000 for regulatory marketing approval and \$5,000,000 upon achieving a cumulative \$500,000,000 of Licensed Product sales. The Company also agreed to pay another \$500,000 milestone payment for any additional regulatory marketing approval for each additional therapeutic (or diagnostic) indication. The Company must also pay ULRF shortfall payments if the total amounts actually paid with respect to royalties and non-royalty sublicensee income for any year is less than the applicable annual minimum (ranging from \$10,000 to \$50,000) for such year.

There were no sponsored research expenses related to these QN-247 agreements for the three months ended March 31, 2024 and 2023. License costs were approximately \$1,000 and \$21,000 related to these QN-247 agreements for the three months ended March 31, 2024 and 2023, respectively, and are included in research and development expenses in the condensed consolidated statements of operations.

NOTE 12 — STOCKHOLDERS' EQUITY (DEFICIT)

As of March 31, 2024 and December 31, 2023, the Company had two classes of capital stock: common stock and preferred stock.

Common Stock

Holders of common stock generally vote as a class with the holders of the preferred stock and are entitled to one vote for each share held. Subject to the rights of the holders of the preferred stock to receive preferential dividends, the holders of common stock are entitled to receive dividends when and if declared by the Board of Directors. Following payment of the liquidation preference of the preferred stock, any remaining assets will be distributed ratably among the holders of the common stock and, on an as-if-converted basis, the holders of any preferred stock upon liquidation, dissolution or winding up of the affairs of the Company. The holders of common stock have no preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions.

At March 31, 2024, the Company has reserved 10,449,689 shares of authorized but unissued common stock for possible future issuance as follows:

Exercise of issued and future grants of stock options	755,715
Conversion of convertible debt	4,895,869
Exercise of stock warrants	4,798,105
Total	<u>10,449,689</u>

Preferred Stock

At March 31, 2024 and December 31, 2023, there were no shares of preferred stock outstanding.

Stock Options and Warrants

Stock Options

The Company recognizes all compensatory share-based payments as compensation expense over the service period, which is generally the vesting period.

In April 2020, the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan"), which provides for the granting of incentive or non-statutory common stock options and other types of awards to qualified employees, officers, directors, consultants and other service providers. At both March 31, 2024 and December 31, 2023, there were 398,924 outstanding stock options under the 2020 Plan and on both such dates there were 356,791 shares reserved under the 2020 Plan for future grant.

The following represents a summary of the options granted under the 2020 Plan to employees and non-employee service providers that are outstanding at March 31, 2024, and changes during the three-month period then ended:

	Shares	Weighted-Average Exercise Price	Range of Exercise Price	Weighted-Average Remaining Life (Years)
Total outstanding – December 31, 2023	398,924	\$ 35.21	\$ 5.14 — \$51.30	7.06
Granted	—	—	—	—
Expired	—	—	—	—
Forfeited	—	—	—	—
Total outstanding – March 31, 2024	398,924	\$ 35.21	\$ 5.14 — \$51.30	6.81
Exercisable (vested)	321,751	\$ 41.89	\$ 5.14 — \$51.30	6.52
Non-Exercisable (non-vested)	77,173	\$ 7.33	\$ 5.14 — \$32.90	8.04

The following represents a summary of the options granted to employees and non-employee service providers that were outstanding at March 31, 2023, and changes during the three-month period then ended:

	Shares	Weighted-Average Exercise Price	Range of Exercise Price	Weighted-Average Remaining Life (Years)
Total outstanding – December 31, 2022	608,012	\$ 35.02	\$ 5.14 - \$51.30	8.09
Granted	—	—	—	—
Expired	—	—	—	—
Forfeited	(55,451)	33.05	\$ 5.14 — \$51.30	—
Total outstanding – March 31, 2023	552,561	\$ 35.22	\$ 5.14 — \$51.30	7.82
Exercisable (vested)	290,438	\$ 46.17	\$ 10.50 — \$51.30	7.35
Non-Exercisable (non-vested)	262,123	\$ 23.08	\$ 5.14 — \$51.30	8.40

There was approximately \$59,000 and \$252,000 of compensation cost related to outstanding stock options for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, there was approximately \$155,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. This cost is expected to be recognized over a weighted average period of 1.16 years.

The exercise price for an option issued under the 2020 Plan is determined by the Board of Directors, but will be (i) in the case of an incentive stock option (A) granted to an employee who, at the time of grant of such option, is a 10% stockholder, no less than 110% of the fair market value per share on the date of grant; or (B) granted to any other employee, no less than 100% of the fair market value per share on the date of grant; and (ii) in the case of a non-statutory stock option, no less than 100% of the fair market value per share on the date of grant. The options awarded under the 2020 Plan will vest as determined by the Board of Directors but will not exceed a 10-year period.

No stock options were granted or exercised during the three months ended March 31, 2024 and March 31, 2023.

Fair Value of Equity Awards

The Company utilizes the Black-Scholes option pricing model to value awards under its equity plans. Key valuation assumptions include:

- *Expected dividend yield.* The expected dividend is assumed to be zero, as the Company has never paid dividends and has no current plans to pay any dividends on the Company's common stock.
- *Expected stock-price volatility.* The Company's expected volatility is derived from the average historical volatilities of publicly traded companies within the Company's industry that the Company considers to be comparable to the Company's business over a period approximately equal to the expected term.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the expected term.

- *Expected term.* The expected term represents the period that the stock-based awards are expected to be outstanding. The Company's historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data. Therefore, the Company estimates the expected term by using the simplified method provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

The Company recorded stock-based compensation expense and classified it in the condensed consolidated statements of operations as follows:

	March 31, 2024	March 31, 2023
General and administrative	\$ 34,014	\$ 203,722
Research and development	24,637	48,504
Total	\$ 58,651	\$ 252,226

Equity Classified Compensatory Warrants

As part of the May 2020 reverse recapitalization transaction, the Company issued equity classified compensatory common stock warrants to an advisor and its designees. In addition, various service providers hold equity classified compensatory common stock warrants issued in 2017 and earlier (originally exercisable to purchase Series C convertible preferred stock, and now instead exercisable to purchase common stock). These are to be differentiated from the Series C Warrants described in Note 7- Warrant Liabilities.

On February 27, 2024, as a result of a down-round provision triggered by a Securities Purchase Agreement with Alpha for the purchase of the February 2024 Debenture, 67,620 warrants were repriced from \$0.73 per share exercise price to \$0.26 per share exercise price. The increase in fair value of \$9,737 for the modification of these warrants was charged to general and administrative expenses in the Company's condensed consolidated statements of operations and comprehensive loss.

No compensatory warrants were issued during the three months ended March 31, 2024 and March 31, 2023.

The following table summarizes the activity in the common stock equity classified compensatory warrants for the three months ended March 31, 2024:

	Common Stock			
	Shares	Weighted-Average Exercise Price	Range of Exercise Price	Weighted-Average Remaining Life (Years)
Total outstanding – December 31, 2023	119,046	\$ 10.69	\$ 0.73–\$25.40	1.25
Exercised	—			
Expired	(7,261)	\$ 20.66	\$ 20.26	
Forfeited	—			
Total outstanding – March 31, 2024	111,785	\$ 9.40	\$ 0.26–\$25.40	1.07
Exercisable	111,785	\$ 9.40	\$ 0.26–\$25.40	1.07
Non-Exercisable	—	—	—	—

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The following table summarizes the activity in the common stock equity classified compensatory warrants for the three months ended March 31, 2023:

	Common Stock			
	Shares	Weighted-Average Exercise Price	Range of Exercise Price	Weighted-Average Remaining Life (Years)
Total outstanding – December 31, 2022	179,046	\$ 9.12	\$ 1.32–\$25.40	1.73
Exercised	—			
Expired	—			
Forfeited	—			
Total outstanding – March 31, 2023	179,046	\$ 9.12	\$ 1.32–\$25.40	1.48
Exercisable	179,046	\$ 9.12	\$ 1.32–\$25.40	1.48
Non-Exercisable	—	—	—	—

There were \$9,737 in compensation costs related to outstanding warrants for the quarter ended March 31, 2024 and \$ 0 for the quarter ended March 31, 2023. As of March 31, 2024 and March 31, 2023, there was no unrecognized compensation cost related to nonvested warrants.

Noncompensatory Equity Classified Warrants

On May 22, 2020, as a commitment fee, the Company issued noncompensatory equity classified warrants to Alpha (a related party) for the purchase of common stock. 7,048 of these warrants remain outstanding and exercisable as of March 31, 2024 and may be exercised in whole or in part, at any time before May 22, 2025. On December 22, 2022, in conjunction with the issuance of a debenture to Alpha (see Note 8 – Convertible Debt – Related Party), the Company issued to Alpha a warrant to purchase 2,500,000 shares of the Company's common stock. The exercise price of this warrant was initially \$1.65, and may be exercised in whole or in part, on or after June 22, 2023 and at any time before June 22, 2028. On December 5, 2023, the Company entered into an Amendment No. 1 with regard to the related Securities Purchase Agreement, with Alpha. This Amendment reduced the Exercise Price of the December 22, 2022 warrant from \$1.65 per share to \$0.73 per share. The Amendment also revised certain provisions of the warrant which resulted in reclassification of the warrant from liabilities to equity.

On February 27, 2024 the Company entered into a new Securities Purchase Agreement with Alpha for the purchase of the February 2024 Debenture (see Note 8 – Convertible Debt – Related Party). This Securities Purchase Agreement resulted in the reduction of the exercise price of the December 22, 2022 warrant and the May 2020 warrant from \$0.73 per share to \$0.26 per share. The company recognized a deemed dividend of \$ 60,017, which represents the incremental fair value of the outstanding warrants as a result of the down-round provision. As the Company has an accumulated deficit, the deemed dividend was recorded as a reduction in additional paid-in capital, resulting in a net impact of zero to additional paid-in capital in the condensed consolidated statements of changes in stockholders' equity. In addition, on February 27, 2024, the Company issued to Alpha a warrant to purchase 900,016 shares of the Company's common stock at an exercise price of \$ 0.26 per share, which may be exercised in whole or in part, at any time before February 27, 2029.

No noncompensatory equity classified warrants were issued during the three months ended March 31, 2023.

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The following table summarizes the noncompensatory equity classified warrant activity for the three months ended March 31, 2024:

Common Stock			
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	Shares	Weighted-Average Exercise Price	Range of Exercise Price	Weighted-Average Remaining Life (Years)
Total outstanding – December 31, 2023	2,507,050	\$ 0.73	\$ 0.73	4.47
Granted	900,016	\$ 0.26	\$ 0.26	4.92
Exercised	—			
Expired	—			
Forfeited	(2)	\$ 0.26	\$ 0.26	—
Total outstanding – March 31, 2024	3,407,064	\$ 0.26	\$ 0.26	4.41
Exercisable	3,407,064	\$ 0.26	\$ 0.26	4.41
Non-Exercisable	—	—	—	—

The following table summarizes the noncompensatory equity classified warrant activity for the three months ended March 31, 2023:

	Common Stock			
	Shares	Weighted-Average Exercise Price	Range of Exercise Price	Weighted-Average Remaining Life (Years)
Total outstanding – December 31, 2022	547,003	\$ 19.76	1.32 - 20.00	0.33
Granted	—			
Exercised	—			
Expired	(320,853)	\$ 20.00	\$ 20.00	—
Forfeited	—			
Total outstanding – March 31, 2023	226,150	\$ 19.42	\$ 1.32 — \$20.00	—
Exercisable	226,150	\$ 19.42	\$ 1.32 — \$20.00	0.46
Non-Exercisable	—	\$ —	\$ —	—

NOTE 13 — RELATED PARTY TRANSACTIONS

Convertible Debt

On December 22, 2022, the Company issued to Alpha, an 8% Senior Convertible Debenture in the aggregate principal amount of \$ 3,300,000 for a purchase price of \$3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022. As of March 31, 2024 the Debenture had a remaining principal balance of \$1,038,922, and was convertible, at any time, and from time to time, at Alpha's option, into shares of common stock of the Company, at a price equal to \$0.26 per share, subject to adjustment as described in the Debenture and other terms and conditions described in the Debenture.

On February 27, 2024, the Company issued to Alpha, an 8% Convertible Debenture in the principal amount of \$ 550,000 for a purchase price of \$500,000 less expenses pursuant to the terms of a Securities Purchase Agreement dated February 26, 2024. As of March 31, 2024 the Debenture had a remaining principal balance of \$550,000, and was convertible, at any time, and from time to time, at Alpha's option, into shares of common stock of the Company, at a price equal to \$0.6111 per share, subject to adjustment as described in the Debenture and other terms and conditions described in the Debenture.

See Note 8 – Convertible Debt – Related Party for additional information concerning convertible debt – related party transactions.

Warrants

On May 22, 2020, as a commitment fee, the Company issued warrants to Alpha for the purchase of common stock. 7,048 of these warrants remain outstanding and exercisable as of March 31, 2024 and may be exercised in whole or in part, at any time before May 22, 2025.

On December 22, 2022, in conjunction with the issuance of a debenture to Alpha, the Company issued to Alpha a warrant to purchase 2,500,000 shares of the Company's common stock. As of March 31, 2024, the exercise price of this warrant was \$0.26. This warrant may be exercised by Alpha, in whole or in part, on or after June 22, 2023 and at any time before June 22, 2028, subject to certain terms and conditions described in the warrant.

On February 27, 2024, in conjunction with the issuance of a debenture to Alpha, the Company issued to Alpha a warrant to purchase 900,016 shares of the Company's common stock. As of March 31, 2024, the exercise price of the Alpha Warrant was \$0.26. The Alpha Warrant may be exercised by Alpha, in whole or in part, at any time before February 27, 2029, subject to certain terms and conditions described in the warrant.

The above warrants are included in equity on the Company's condensed consolidated balance sheets (see Note 12 – Stockholders' Equity (Deficit)).

NanoSynex

Pursuant to a Share Purchase Agreement dated April 29, 2022, the Company acquired 2,232,861 shares of NanoSynex Series A-1 Preferred Stock from Alpha in exchange for 350,000 reverse split adjusted shares of the Company's common stock and a prefunded warrant to purchase 331,464 reverse split adjusted shares of the Company's common stock at an exercise price of \$0.001 per share.

NOTE 14 — SUBSEQUENT EVENTS

Convertible Debenture and Common Stock Warrant

On February 27, 2024 we granted to Alpha an option, exercisable until July 1, 2024, to purchase from us additional 8% Convertible Debentures, of like tenor, with face amounts of up to an aggregate of \$1,100,000 with a proportional number of accompanying common stock warrants of like tenor, up to a total of 1,800,032 additional warrants. (See Note 8 – Convertible Debt – Related Party).

On April 11, 2024, Alpha assigned the option to Yi Hua Chen ("Chen") and Chen exercised the option in full on that date. On April 12, 2024, against Chen's Option exercise price of \$1,000,000 paid to us, we delivered to Chen an 8% Convertible Debenture in the principal amount of \$ 1,100,000, of like tenor as the 2024 Alpha Debenture except for the principal amount; and a common stock purchase warrant to purchase 1,800,032 shares of our common stock, exercisable until February 27, 2029, and otherwise of like tenor as the warrant issued to Alpha on February 27, 2024.

Co-Development Agreement

On April 11, 2024, we entered into a Co-Development Agreement with Marizyme, Inc. ("Marizyme"). Under the Co-Development Agreement, we agreed to pay Marizyme a Funding Payment of up to \$1,500,000 and an Exclusivity Fee of \$200,000. The Exclusivity Fee of \$200,000 and a Funding Payment of \$500,000 was paid to Marizyme on April 12, 2024. The Exclusivity Fee entitled us to an exclusivity period until May 31, 2024 for purposes of proposing and outlining a broader strategic relationship with Marizyme with regard to Marizyme's DuraGraft business. The Funding Payment is designed to provide financial support for commercialization of Marizyme's DuraGraft™ vascular conduit solution, which is indicated for adult patients undergoing coronary artery bypass grafting surgeries and is intended for the flushing and storage of the saphenous vein grafts used in coronary artery bypass grafting surgery. In return for the Funding Payment we will receive quarterly a 33% payment in the nature of royalties on any Net Sales (as defined with a meaning tantamount to gross profit on net sales) of DuraGraft, capped at double the amount of the Funding Payment cash provided. No such payments-in-the-nature-of-royalties would accrue until after DuraGraft has been launched in the United States and a cumulative total of \$500,000 of DuraGraft Net Sales have been made in the United States.

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Alpha Warrant Exercises

On May 16 and June 4, 2024, Alpha partially exercised an equity classified warrant for 288,462 shares at an exercise price of \$0.26 per share on each date for a total of 576,924 shares, which resulted in combined total cash proceeds to the company of \$ 150,000.

Possible Nasdaq Delisting

On May 23, 2024, the Company received written notice (the "Delist Notice") from The Nasdaq Stock Market ("Nasdaq") indicating the Company's continued non-compliance with Nasdaq's minimum bid price requirement, pursuant to Nasdaq Listing Rule 5550(b)(2).

On November 20, 2023, the Company had received a letter (the "Bid Price Deficiency Notice") from Nasdaq notifying the Company that, because the closing bid price for its common stock has been below \$1.00 per share for 30 consecutive business days, it no longer complies with the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of \$1.00 per share (the "Minimum Bid Price Requirement"), and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the Minimum Bid Price Requirement exists if the deficiency continues for a period of 30 consecutive business days.

Further, the Company had also received a letter from Nasdaq on November 21, 2023 notifying the Company that it did not comply with the \$ 2,500,000 minimum stockholders' equity requirement, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Equity Rule"). On January 12, 2024, Nasdaq granted the Company an extension of time until May 21, 2024, to regain compliance with the Equity Rule. The Company did not regain compliance with the Equity Rule by May 21, 2024 (and to date still has not regained compliance with the Equity Rule). As such, the Delist Notice states that this matter also serves as a separate and additional basis for delisting the Company's securities from The Nasdaq Stock Market.

On May 30, 2024, the Company requested a hearing before a Nasdaq Hearings Panel (the "Panel"), and the suspension of trading in the Company's securities on Nasdaq has been stayed pending the hearing date, which is currently scheduled for July 16, 2024.

The Company is working to evidence compliance with all applicable Nasdaq requirements for continued listing of the Company's common stock on the Nasdaq Capital Market and intends to present its plan to the Panel as part of the hearing process; however, there can be no assurance the Panel will grant any request for continued listing or that the Company will be able to regain compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

Sale of Qualigen, Inc. - Escrow Disbursement

On June 4, 2024, the \$450,000 escrow account from the sale of Qualigen, Inc. (reflected in prepaid expenses and other current assets on the Company's March 31, 2024 balance sheet) originally subject to release to the Company in January 2025, was settled early and liquidated by mutual agreement of the Company and the buyer (Chembio). In exchange for the early settlement, \$350,000 was paid to the Company, and \$ 100,000 was paid to Chembio. This settlement will result in a loss from discontinued operations in the second quarter of 2024.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our interim unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q (this "Quarterly Report") and the audited financial statements and notes thereto as of and for the twelve months ended December 31, 2023, which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on April 5, 2024. As used in this Quarterly Report, unless the context suggests otherwise, "we," "us," "our," or "Qualigen" refer to Qualigen Therapeutics, Inc. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions.

Cautionary Note Regarding Forward Looking Statements

This Quarterly Report contains forward-looking statements by the Company that involve risks and uncertainties and reflect the Company's judgment as of the date of this Report. These statements generally relate to future events or the Company's future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," or "continue" or the negative of these words or other similar terms or expressions that concern the Company's expectations, strategy, plans or intentions. Such forward-looking statements may relate to, among other things, potential future development, testing and launch of products and product candidates. Actual events or results may differ from our expectations due to a number of factors.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- our ability to procure sufficient working capital to continue and complete the development, testing and launch of our prospective drug products;
- our ability to successfully develop any drugs;
- our ability to progress our drug candidates through preclinical and clinical development;
- our ability to obtain the requisite regulatory approvals for our clinical trials and to begin and complete such trials according to any projected timeline;

- our ability to complete enrollment in our clinical trials as contemplated by any projected timeline;
- the likelihood that future clinical trial data will be favorable or that such trials will confirm any improvements over other products or lack negative impacts;
- our ability to successfully commercialize any drugs;
- the likelihood that patents will issue on our in-licensed patent applications;
- our ability to protect our intellectual property; and
- our ability to compete.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate, are consistent in some future periods with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in other future periods. Any forward-looking statement that we make in this Quarterly Report speaks only as of the date of this Quarterly Report, and we disclaim any intent or obligation to update these forward-looking statements beyond the date of this Quarterly Report, except as required by law. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Future filings with the Securities and Exchange Commission (the "SEC"), future press releases and future oral or written statements made by us or with our approval, which are not statements of historical fact, may also contain forward-looking statements. Because such statements include risks and uncertainties, many of which are beyond our control, actual results may differ materially from those expressed or implied by such forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

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Overview

We are an early-clinical-stage therapeutics company focused on developing treatments for adult and pediatric cancer. Our business now consists of one early-clinical-stage therapeutic program (QN-302) and one preclinical therapeutic program (Pan-RAS).

Our lead program, QN-302, is an investigational small molecule G-quadruplexes (G4)-selective transcription inhibitor with strong binding affinity to G4s prevalent in cancer cells (such as pancreatic cancer). Such binding could, by stabilizing the G4s against DNA "unwinding," help inhibit cancer cell proliferation. QN-302 is currently undergoing a Phase 1a clinical trial at START Midwest in Grand Rapids, Michigan, and HonorHealth in Scottsdale, Arizona.

Our Pan-RAS program, which is currently at the preclinical stage, consists of a family of RAS oncogene protein-protein interaction inhibitor small molecules believed to inhibit or block mutated RAS genes' proteins from binding to their effector proteins thereby leaving the proteins from the mutated RAS unable to cause further harm. In theory, such mechanism of action may be effective in the treatment of about one quarter of all cancers, including certain forms of pancreatic, colorectal, and lung cancers. The investigational compounds within our Pan-RAS portfolio are designed to suppress the interaction of endogenous RAS with c-RAF, upstream of the KRAS, HRAS and NRAS effector pathways.

We do not expect to be profitable before products from our therapeutics pipeline are commercialized. To experience losses while therapeutic products are still under development is of course typical for biotechnology companies.

In addition, under a Co-Development Agreement dated April 11, 2024 with Marizyme, Inc. ("Marizyme"), we are entitled to receive quarterly a 33% payment in the nature of royalties (capped at double the amount of Funding Payment cash we provide to Marizyme) on any Net Sales (as defined with a meaning tantamount to gross profit on net sales) of Marizyme's DuraGraft™ vascular conduit solution, which is indicated for adult patients undergoing coronary artery bypass grafting surgeries and is intended for the flushing and storage of the saphenous vein grafts used in coronary artery bypass grafting surgery. No such payments-in-the-nature-of-royalties would accrue until after DuraGraft has been launched in the United States and a cumulative total of \$500,000 of DuraGraft Net Sales have been made in the United States. To date we have provided \$500,000 of Funding Payments to Marizyme.

Recent Developments

Phase 1 Clinical Trial of QN-302

On August 1, 2023, we announced that the FDA has cleared our IND application for QN-302. Based on this clearance, we chose Translational Drug Development, LLC ("TD2") to serve as our contract research organization to conduct a Phase 1 clinical trial in patients with advanced or metastatic solid tumors. The Phase 1 trial (NCT06086522) is designed as a multicenter, open-label, dose escalation, safety, pharmacokinetic, and pharmacodynamic study with dose expansion to evaluate safety, tolerability, and antitumor activity of QN-302 in patients with advanced solid tumors that have not responded to or that have recurred following treatment with available therapies. On November 7, 2023, we announced that the first patient had been enrolled and dosed in the dose escalation (Phase 1a) portion of the study. The exact number of patients to be enrolled in the trial will depend on the observed safety profile, which will determine the number of patients per dose level, as well as the number of dose escalations required to meet the Maximum Tolerated Dose ("MTD"). Once the MTD has been established in dose escalation, dose expansion will begin.

Sale of Diagnostics Business

On July 20, 2023, we sold all of the issued and outstanding shares of common stock of Qualigen, Inc., a wholly-owned subsidiary and the legal entity operating our FastPack™ diagnostic business, to Chembio Diagnostics, Inc. ("Chembio"), a subsidiary of Biosynex, S.A. As consideration for the shares of Qualigen, Inc., we received cash payments of approximately \$4.9 million, which payment is subject to post-closing adjustments. An additional \$450,000 was delivered by Chembio to an escrow account to provide an available fund for payment of potential indemnification obligations. The escrow account was closed on June 4, 2024 by mutual agreement; \$350,000 was paid to us, and \$100,000 was paid to Chembio. Upon the consummation of the July 2023 transaction, Qualigen, Inc. became a wholly-owned subsidiary of Chembio.

Amendment and Settlement Agreement with NanoSynex Ltd.

On July 20, 2023, we entered into and effectuated the NanoSynex Amendment, by which we agreed to, among other things, forfeit 281,000

Series B Preferred Shares of NanoSynex held by us, resulting in our ownership in NanoSynex being reduced from approximately 52.8% to approximately 49.97% of the voting equity of NanoSynex. In addition, we agreed to cancel approximately \$3.0 million of promissory notes which NanoSynex had issued to us under the NanoSynex Funding Agreement, relieving NanoSynex of any repayment obligations to us with respect to such notes. The NanoSynex Amendment superseded any NanoSynex Funding Agreement obligations to provide funding to NanoSynex, except we agreed to provide future loans as follows: (i) \$560,000 on or before November 30, 2023, and (ii) \$670,000 on or before March 31, 2024. However, on November 22, 2023, in full settlement of any additional funding obligations to NanoSynex, we forfeited certain of our shares of Series A-1 Preferred Stock of NanoSynex in an amount that reduced our ownership in NanoSynex from approximately 49.97% to 39.90%. Accordingly, NanoSynex was deconsolidated from our financial statements as of July 20, 2023, and is reported as Discontinued Operations in this Quarterly Report. Our investment in NanoSynex will be accounted for in the future as an equity method investment.

Marizyme

On April 11, 2024, we entered into a Co-Development Agreement with Marizyme. Under the Co-Development Agreement, we agreed to pay Marizyme a Funding Payment of up to \$1,500,000 and an Exclusivity Fee of \$200,000. The Exclusivity Fee of \$200,000 and a Funding Payment of \$500,000 was paid to Marizyme on April 12, 2024. The Exclusivity Fee entitles us to an exclusivity period until May 31, 2024 for purposes of proposing and outlining a broader strategic relationship with Marizyme with regard to Marizyme's DuraGraft business. The Funding Payment is designed to provide financial support for commercialization of Marizyme's DuraGraft™ vascular conduit solution, which is indicated for adult patients undergoing coronary artery bypass grafting surgeries and is intended for the flushing and storage of the saphenous vein grafts used in coronary artery bypass grafting surgery. In return for the Funding Payment we will receive quarterly a 33% payment in the nature of royalties on any Net Sales (as defined with a meaning tantamount to gross profit on net sales) of DuraGraft, capped at double the amount of the Funding Payment cash provided. No such payments-in-the-nature-of-royalties would accrue until after DuraGraft has been launched in the United States and a cumulative total of \$500,000 of DuraGraft Net Sales have been made in the United States.

Warrant Liabilities

In 2004, Qualigen, Inc. issued Series C preferred stock warrants to investors and brokers in connection with a private placement. These warrants were subsequently extended and survived the May 2020 Ritter reverse recapitalization transaction and are now exercisable for Qualigen Therapeutics common stock. These warrants contain a provision that if we issue shares (except in certain defined scenarios) at a price below the warrants' exercise price, the exercise price will be re-set to such new price and the number of shares underlying the warrants will be increased in the same proportion as the exercise price decrease. For accounting purposes, such warrants give rise to warrant liabilities. Accounting principles generally accepted in the United States of America ("U.S. GAAP") require us to recognize the fair value of these warrants as warrant liabilities on our condensed consolidated balance sheets and to reflect period-to-period changes in the fair value of the warrant liabilities on our condensed consolidated statements of operations. The estimated fair value of these warrant liabilities was approximately \$0.2 million and \$0.1 million at March 31, 2024 and December 31, 2023, respectively. There were 1,279,256 of these warrants outstanding at March 31, 2024 and 455,623 of these warrants outstanding at December 31, 2023.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements historically have not separated our diagnostics-related activities from our therapeutics-related activities. All of our historically reported revenue was diagnostics-related. Before the third quarter of 2023, our reported expenses represented the total of our diagnostics-related and therapeutics-related expenses. In this Quarterly Report, all diagnostics-related revenues and expenses have been reclassified to discontinued operations (See Note 5 - Discontinued Operations in our condensed consolidated financial statements).

This discussion and analysis is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to impairment of goodwill and other intangible assets, fair value of warrant liabilities, and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our condensed consolidated financial statements, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations:

- Research and development
- Discontinued operations
- Derivative financial instruments and warrant liabilities
- Stock-based compensation
- Income taxes

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023:

	For the Three Months March 31,	
	2024	2023
EXPENSES		
General and administrative	\$ 1,057,364	1,368,999
Research and development	364,385	1,281,817
Total expenses	1,421,749	2,650,816
LOSS FROM OPERATIONS	(1,421,749)	(2,650,816)
OTHER EXPENSE (INCOME), NET		
Loss (gain) on change in fair value of warrant liabilities	133,300	(1,038,673)

Gain on change in fair value of derivative liabilities	(164,497)	—
Interest expense, net	136,556	544,238
Loss on issuance of convertible debt	358,279	—
Loss on voluntary conversion of convertible debt into common stock	—	1,077,287
Loss on monthly redemptions of convertible debt into common stock	147,197	—
Other income, net	(1,619)	—
Total other expense (income), net	<u>609,216</u>	<u>582,852</u>
LOSS BEFORE PROVISION FOR INCOME TAXES	(2,030,965)	(3,233,668)
PROVISION FOR INCOME TAXES	<u>(1,786)</u>	<u>(1,393)</u>
NET LOSS FROM CONTINUING OPERATIONS	(2,032,751)	(3,235,061)
DISCONTINUED OPERATIONS		
Loss from discontinued operations, net of tax	—	(872,188)
LOSS FROM DISCONTINUED OPERATIONS	<u>—</u>	<u>(872,188)</u>
NET LOSS	(2,032,751)	(4,107,249)
Net loss attributable to non-controlling interest from discontinued operations	—	(261,028)
Net loss available to Qualigen Therapeutics, Inc.	\$ (2,032,751)	\$ (3,846,221)
Deemed dividend arising from warrant down-round provision	\$ (60,017)	\$ —
Net loss attributable to Qualigen Therapeutics, Inc	<u>(2,092,768)</u>	<u>(3,846,221)</u>
Net loss per common share, basic and diluted - continuing operations	\$ (0.35)	\$ (0.65)
Net loss per common share, basic and diluted - discontinued operations	\$ —	\$ (0.12)
Weighted—average number of shares outstanding, basic and diluted	<u>5,943,814</u>	<u>4,959,122</u>
Other comprehensive loss, net of tax		
Net loss	\$ (2,032,751)	\$ (4,107,249)
Foreign currency translation adjustment from discontinued operations	—	119,723
Other comprehensive loss	(2,032,751)	(3,987,526)
Comprehensive loss attributable to noncontrolling interest from discontinued operations	—	(261,028)
Comprehensive loss attributable to Qualigen Therapeutics, Inc.	<u>\$ (2,032,751)</u>	<u>\$ (3,726,498)</u>

Expenses

General and Administrative Expenses

General and administrative expenses decreased from \$1.4 million for the three months ended March 31, 2023, to \$1.0 million for the three months ended March 31, 2024, primarily due to a decrease in stock-based compensation of approximately \$0.2 million, a decrease in professional fees of approximately \$0.1 million, and a decrease in license and insurance costs of approximately \$0.1 million.

Research and Development Costs

Research and development costs decreased from \$1.3 million for the three months ended March 31, 2023 to approximately \$0.4 million for the three months ended March 31, 2024. This decrease in research and development costs during the three months ended March 31, 2024 compared to the three months ended March 31, 2023 was primarily due to a decrease of \$0.6 million in preclinical and clinical research costs for QN-302, a \$0.2 million decrease in preclinical research costs for Pan-RAS, and a \$0.2 million decrease in payroll and related expenses.

Other Income (Expense), Net

Change in Fair Value of Warrant Liabilities

During the three months ended March 31, 2024 and 2023, we experienced a loss of approximately \$0.1 million and a gain of approximately \$1.0 million, respectively, on change in fair value of warrant liabilities, primarily due to a repricing of the exercise price of certain warrants from \$0.73 per share to \$0.26 per share during the current period, and changes in our stock price in the prior period. Typically, a decline in our stock price would result in a decline in the fair value of our warrant liabilities, generating a gain, while an increase in our stock price would result in an increase in the fair value of our warrant liabilities, generating a loss.

Gain on Change in Fair Value of Derivative Liabilities

During the three months ended March 31, 2024 we experienced a gain of approximately \$0.2 million on changes in fair value of derivative liabilities related to convertible debt.

Interest Expense (Income), Net

Interest expense, net during the three months ended March 31, 2024 decreased to approximately \$0.1 million, as compared to approximately \$0.5 million for the three months ended March 31, 2023, primarily due to reduced accretion of discount and lower outstanding principal balances on convertible debt.

Loss on Issuance of Convertible Debt

During the three months ended March 31, 2024 we incurred a \$0.3 million loss on issuance of convertible debt due to the fair value of the 2024 Alpha Debenture and derivative liabilities exceeding the cash proceeds.

Loss on Voluntary Conversion of Convertible Debt

During the three months ended March 31, 2024 there were no voluntary conversions of convertible debt.

During the three months ended March 31, 2023 we issued 841,726 shares of common stock upon Alpha Capital Anstalt's partial voluntary conversion of a debenture which we had issued to Alpha on December 22, 2022 (the "2022 Debenture") at \$1.32 per share for a total of \$1,111,078 principal converted. Upon conversion, we recognized a loss on voluntary conversion of convertible debt of approximately \$1.1 million.

Loss on Monthly Redemptions of Convertible Debt Into Common Stock

During the three months ended March 31, 2024, we issued 1,138,535 shares of common stock with a fair value of approximately \$545,000, in lieu of cash for monthly redemptions of \$380,000 principal and approximately \$19,000 accrued interest redeemed, pursuant to the terms of the 2022 Debenture at a weighted average share price of \$0.35. Upon redemption in shares, we recognized a loss on monthly redemptions of convertible debt into common stock of approximately \$147,000.

During the three months ended March 31, 2023, there were no monthly redemptions of convertible debt into common stock.

Other Income, Net

Other income for the three months ended March 31, 2024 was immaterial.

During the three months ended March 31, 2023 there was no other income, net.

Discontinued Operations

There was no loss from discontinued operations during the three months ended March 31, 2024, compared to a loss from discontinued operations of approximately \$872,000 during the three months ended March 31, 2023. The \$872,000 loss from discontinued operations during the three months ended March 31, 2023 consisted of approximately \$376,000 from our former Qualigen, Inc. subsidiary and approximately \$496,000 from NanoSynex.

There was no loss attributable to non-controlling interest from discontinued operations during the three months ended March 31, 2024, compared to a loss attributable to non-controlling interest from discontinued operations of approximately \$261,000 during the three months ended March 31, 2023.

Liquidity and Capital Resources

Our financial position is weak. As of March 31, 2024, we had approximately \$0.1 million in cash and net accounts payable of over \$1.8 million. We are in arrears on accounts payable to important partners. We have incurred recurring losses from operations and have an accumulated deficit of \$118.8 million at March 31, 2024. We expect to continue to incur losses subsequent to the condensed consolidated balance sheet date of March 31, 2024. For the three months ended March 31, 2024 and 2023, we used cash of \$0.8 million and \$2.6 million, respectively, in operations.

We currently expect our cash balances to fund operations only into the third quarter of 2024. We expect to continue to have net losses and negative cash flow from operations, which will challenge our liquidity. These factors raise substantial doubt regarding our ability to continue as a going concern for the one-year period following the date that the financial statements in this Quarterly Report were issued. There is no assurance that we will ever achieve profitable operations, or, if achieved, could be sustained on a continuing basis.

Historically, our principal sources of cash have, in addition to previous revenue from product sales and license revenues from the FastPack product of line of Qualigen, Inc. (which we divested in July 2023), included proceeds from the issuance of common and preferred equity and proceeds from the issuance of debt. There can be no assurance that further financing can be obtained on favorable terms, or at all. If we are unable to obtain funding, we could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, and we could be unable to continue operations.

In the first quarter of 2024 we raised \$500,000 (less expenses) by issuing to Alpha Capital Anstalt ("Alpha") an 8% Convertible Debenture (the "2024 Alpha Debenture") with a principal amount of \$550,000; in connection with this issuance, we also issued to Alpha a 5-year common stock purchase warrant to purchase (at \$0.26 per share) 900,016 shares of our common stock. We also granted to Alpha an option, exercisable until July 1, 2024, to purchase from us additional 8% Convertible Debentures, of like tenor, with face amounts of up to an aggregate of \$1,100,000 (and with a proportional number of accompanying common stock warrants of like tenor, up to a total of 1,800,032 additional warrants). In April 2024, Alpha assigned this option to Yi Hua Chen ("Chen") and Chen exercised the option in full; i.e., in exchange for \$1,000,000 (less expenses) we issued to Chen an 8% Convertible Debenture with a principal amount of \$1,100,000; in connection with this issuance, we also issued to Chen a 5-year common stock purchase warrant to purchase (at \$0.26 per share) 1,800,032 shares of our common stock. (See "2024 Alpha Debenture" below.)

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through third-party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, any future financing (depending on the terms and conditions) may be subject to the approval of Alpha and Chen under the terms of the Debentures and/or trigger certain adjustments to the Debentures or warrants held by Alpha and Chen.

Delisting of our common stock from Nasdaq would have a serious negative effect on any future financing efforts. As described in Note 14 in our condensed consolidated financial statements, a hearing before a Nasdaq Hearing Panel is currently scheduled for July 16, 2024; if the Panel does not grant our request for continued listing or if we are unable to regain compliance with the applicable Nasdaq listing criteria within any period of time that may be granted by the Panel, we expect the outcome would be that our common stock would be delisted from Nasdaq.

In June 2024, by way of a negotiated early release of escrow, we received \$350,000 from the \$450,000 escrow account established in connection with our July 2023 sale of Qualigen, Inc. The escrow account had originally been subject to release in January 2025. In exchange for the early release, the other \$100,000 of the \$450,000 escrow account was paid to Chembio Diagnostics, Inc., the buyer of Qualigen, Inc.

The accompanying financial statements have been prepared assuming that we will continue as a going concern. The financial statements do not include any adjustments that would be necessary should we be unable to continue as a going concern, and therefore, be required to liquidate its assets and discharge its liabilities in other than the normal course of business and at amounts that may differ from those reflected in the accompanying financial statements.

Our current liabilities at March 31, 2024 include \$1.8 million of accounts payable, \$1.0 million of convertible debt to a related party, \$0.8 million of accrued expenses and other current liabilities, \$0.2 million in warrant liabilities, and \$0.7 million in derivative liabilities.

Contractual Obligations and Commitments

We have no material contractual obligations that are not fully recorded on our condensed consolidated balance sheets or fully disclosed in the notes to the financial statements.

License and Sponsored Research Agreements

We have obligations under various license and sponsored research agreements to make future payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones (such as the start of a clinical trial, filing for product approval with the FDA or other regulatory agencies, product approval by the FDA or other regulatory agencies, product launch or product sales) or on the sublicense of our rights to another party. We have not included these commitments on our balance sheet because the achievement and timing of these events is not determinable. Certain milestones are in advance of receipt of revenue from the sale of products and, therefore, we may require additional debt or equity capital to make such payments.

We have multiple license and sponsored research agreements with ULRF. Under these agreements, we have taken over development, regulatory approval and commercialization of various drug compounds from ULRF and are responsible for maintenance of the related intellectual property portfolio. Under the terms of these agreements, we are required to make patent maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are \$5 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under these agreements, but we will be required to pay ULRF a percentage of any sublicense income.

On January 13, 2022, we entered into a License Agreement with UCL Business Limited to obtain an exclusive worldwide in-license of a genomic quadruplex (G4)-selective transcription inhibitor drug development program which had been developed at University College London, including lead and back-up compounds, preclinical data and a patent estate. (UCL Business Limited is the commercialization company for University College London.) We are further developing the program's lead compound under the name QN-302. The License Agreement requires (if and when applicable) tiered royalty payments in the low to mid-single digits, clinical/regulatory/sales milestone payments, and sharing of a percentage of any non-royalty sublicensing consideration paid to us. In November 2023, we became obligated to pay \$100,000 to UCL Business Limited upon the first patient dosing of QN-302, which was paid in January 2024.

2022 Convertible Debenture

On December 22, 2022, we issued to Alpha an 8% Senior Convertible Debenture in the aggregate principal amount of \$3,300,000 for a purchase price of \$3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022 (the "2022 Securities Purchase Agreement"). The 2022 Debenture has a maturity date of December 22, 2025 and is convertible, at any time, and from time to time, until the 2022 Debenture is no longer outstanding, at Alpha's option, into shares of our common stock (the "Conversion Shares"), at a price initially equal to \$1.32 per share, subject to adjustment as described in the 2022 Debenture and other terms and conditions described in the 2022 Debenture. On July 13, 2023, we obtained stockholder approval, for purposes of complying with Nasdaq Listing Rule 5635(d), for the issuance to Alpha of more than 20% of our issued and outstanding shares of common stock pursuant to the terms and conditions of (a) the 2022 Debenture, and (b) the common stock purchase warrant dated December 22, 2022 issued by us to Alpha. Between January 9 and 12, 2023, we issued 841,726 shares of common stock upon Alpha's partial conversion of the 2022 Debenture at \$1.32 per share for a total of \$1,111,078 principal. In October and December 2023, we issued 309,665 shares of common stock to Alpha in lieu of cash for monthly redemption payments on the 2022 Debenture at a weighted average price of \$0.71 per share. In January, February, and March 2024, we issued 1,138,535 shares of common stock to Alpha in lieu of cash for monthly redemption payments on the 2022 Debenture at a weighted average price of \$0.33 per share. As of March 31, 2024, approximately 3,995,854 shares of common stock were issuable under the 2022 Debenture, based on the \$0.26 per share figure. The 2022 Debenture includes a beneficial ownership blocker of 9.99%, which may only be waived by Alpha upon 61 days' notice to us. Except in respect of an Exempt Issuance (as defined in the 2022 Securities Purchase Agreement), the 2022 Debenture contains a "ratchet" antidilution provision, with a \$0.26 floor.

Commencing June 1, 2023 (the "Initial Monthly Redemption Date") and continuing on the first day of each month thereafter until the earlier of (i) December 22, 2025 and (ii) the full redemption of the 2022 Debenture (each such date, a "Monthly Redemption Date"), we must redeem \$110,000 plus accrued but unpaid interest, liquidated damages and any amounts then owing under the 2022 Debenture (the "Monthly Redemption Amount"). The Monthly Redemption Amount must be paid in cash; *provided that* after the first two monthly redemptions, we may elect to pay all or a portion of a Monthly Redemption Amount in shares of our common stock, based on a conversion price equal to the lesser of (i) the then conversion price of the 2022 Debenture and (ii) 85% of the average of the VWAPs (as defined in the 2022 Debenture) for the five consecutive trading days ending on the trading day that is immediately before the applicable Monthly Redemption Date, subject to the Equity Conditions (as defined in the 2022 Debenture) having been satisfied or waived.

During the three months ended March 31, 2024, we issued 1,138,535 shares of common stock with a fair value of approximately \$545,000, in lieu of cash for monthly redemptions of \$380,000 principal and approximately \$19,000 accrued interest redeemed, pursuant to the terms of the 2022 Debenture at a weighted average share price of \$0.35. Upon redemption in shares, we recognized a loss on monthly redemptions of convertible debt into common stock of approximately \$147,000.

Alpha has waived the Equity Conditions for certain Monthly Redemption Amounts, but Alpha is not required to continue such waivers. For the foreseeable future, we do not expect to be able to satisfy the Equity Conditions; as a result, where there is no waiver of the Equity Conditions we would not have the opportunity to make 2022 Debenture payments in the form of stock rather than in the form of cash, even for types of payments for which payment in the form of stock would have been allowed.

2024 Alpha Debenture

On February 27, 2024, upon our receipt of a cash purchase price payment of \$500,000 (less expenses), we issued to Alpha an 8% Convertible Debenture (the "2024 Alpha Debenture") in the principal amount of \$550,000. The 2024 Alpha Debenture matures no later than December 31, 2024 and is convertible, at any time, and from time to time, at Alpha's option, into shares of common stock of the Company, at \$0.6111 per share, subject to adjustment as described in the 2024 Alpha Debenture. Except in respect of an Exempt Issuance, the 2024 Alpha Debenture contains a "ratchet" antidilution provision, with an \$0.1164 floor. The 2024 Alpha Debenture accrues interest on its outstanding principal balance at the rate of 8% per annum,

payable at maturity. In connection with this issuance, we also issued to Alpha a 5-year common stock purchase warrant to purchase (at \$0.26 per share) 900,016 shares of our common stock. We also granted to Alpha an option, exercisable until July 1, 2024, to purchase from us additional 8% Convertible Debentures, of like tenor, with face amounts of up to an aggregate of \$1,100,000 (and with a proportional number of accompanying common stock warrants of like tenor, up to a total of 1,800,032 additional warrants).

During the three months ending March 31, 2024 in connection with the 2024 Alpha Debenture, the Company recorded initial derivative liabilities with a fair value of \$858,279, and recorded interest expense of \$64,673 in other expenses in the condensed consolidated statements of operations related to the 2024 Alpha Debenture. As of March 31, 2024, the fair value of derivative liabilities related to the 2024 Alpha Debenture was \$693,782.

On April 11, 2024, Alpha assigned this option to Yi Hua Chen, who exercised it in full on April 12, 2024.

NanoSynex Funding Agreement

As a condition to our acquisition of a majority voting equity interest in NanoSynex from Alpha and NanoSynex, we entered into a Master Agreement for the Operational and Technological Funding of NanoSynex (the "Funding Agreement"), on May 26, 2022, pursuant to which we agreed to fund NanoSynex up to an aggregate of approximately \$10.4 million, subject to NanoSynex's achievement of certain performance milestones specified in the Funding Agreement and the satisfaction of other terms and conditions described in the Funding Agreement.

On July 20, 2023, we entered into the NanoSynex Amendment, which amended the Funding Agreement, pursuant to which the Company agreed to, among other things, forfeit 281,000 Series B Preferred Shares of NanoSynex held by the Company, resulting in our ownership in NanoSynex being reduced from approximately 52.8% to approximately 49.97% of the voting equity of NanoSynex. In addition, we agreed to cancel approximately \$3.0 million of promissory notes which NanoSynex had issued to us under the NanoSynex Funding Agreement, relieving NanoSynex of any repayment obligations to us with respect to such notes. The surrender of shares reducing our interest in NanoSynex from approximately 52.8% to approximately 49.97% occurred on July 20, 2023. Accordingly, NanoSynex was deconsolidated from our financial statements as of July 20, 2023, and is reported as Discontinued Operations in this Quarterly Report.

The NanoSynex Amendment superseded any payment obligations contemplated by the original Funding Agreement and amended our obligations to provide funding to NanoSynex, except we agreed to provide future funding as follows: (i) \$560,000 on or before November 30, 2023, and (ii) \$670,000 on or before March 31, 2024, in each case issued in the form of a promissory note to the Company with a face value in the amount of such funding. However, on November 22, 2023, in full settlement of any additional funding obligations to NanoSynex, we forfeited certain of our shares of Series A-1 Preferred Stock of NanoSynex in an amount that reduced our ownership in NanoSynex from approximately 49.97% to 39.90%. Our investment in NanoSynex will be accounted as an equity method investment prospectively from the July 20, 2023 deconsolidation date.

Co-Development Agreement

On April 11, 2024, we entered into a Co-Development Agreement with Marizyme, Inc. ("Marizyme"). Under the Co-Development Agreement, we agreed to pay Marizyme a Funding Payment of up to \$1,500,000 and an Exclusivity Fee of \$200,000. The Exclusivity Fee of \$200,000 and a Funding Payment of \$500,000 was paid to Marizyme on April 12, 2024. The Exclusivity Fee entitles us to an exclusivity period until May 31, 2024 for purposes of proposing and outlining a broader strategic relationship with Marizyme with regard to Marizyme's DuraGraft business. The Funding Payment is designed to provide financial support for commercialization of Marizyme's DuraGraft™ vascular conduit solution, which is indicated for adult patients undergoing coronary artery bypass grafting surgeries and is intended for the flushing and storage of the saphenous vein grafts used in coronary artery bypass grafting surgery. In return for the Funding Payment we will receive quarterly a 33% payment in the nature of royalties on any Net Sales (as defined with a meaning tantamount to gross profit on net sales) of DuraGraft, capped at double the amount of the Funding Payment cash provided. No such payments-in-the-nature-of-royalties would accrue until after DuraGraft has been launched in the United States and a cumulative total of \$500,000 of DuraGraft Net Sales have been made in the United States.

Other Service Agreements

We enter into contracts in the normal course of business, including with clinical sites, contract research organizations, and other professional service providers for the conduct of clinical trials, contract manufacturers for the production of our product candidates, contract research service providers for preclinical research studies, professional consultants for expert advice and vendors for the sourcing of clinical and laboratory supplies and materials. These contracts generally provide for termination on notice, and therefore are cancelable contracts.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods set forth below:

	For the Three Months Ended March 31,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	\$ (783,586)	\$ (2,634,093)
Investing activities	—	(198,009)
Financing activities	475,000	—
Effect of exchange rate on cash	—	160,320
Net decrease in cash and restricted cash	\$ (308,586)	\$ (2,671,782)

Net Cash Used in Operating Activities

During the three months ended March 31, 2024, operating activities used \$0.8 million of cash, primarily resulting from a loss from continuing operations of \$2.0 million. Cash flows from operating activities for the three months ended March 31, 2024 were positively impacted by adjustments for \$0.4 million loss on issuance of convertible debt, \$0.1 million in stock-based compensation expense, a \$0.1 million increase in fair value of warrant liabilities, \$0.1 million in accretion of discount on convertible debt, \$0.1 million loss on monthly redemptions of convertible debt into common stock, a \$0.7 million decrease in prepaid expenses and other assets, and a \$0.3 million increase in accrued expenses and other current liabilities. Cash flows from operating activities for the three months ended March 31, 2024 were negatively impacted by a \$0.4 million decrease in accounts payable, and an adjustment for a \$0.2 million gain on change in fair value of derivative liabilities.

During the three months ended March 31, 2023, operating activities used \$2.6 million of cash, primarily resulting from a loss from continuing operations of \$3.2 million. Cash flows from operating activities for the three months ended March 31, 2023 were positively impacted by an adjustment for \$0.3 million in stock-based compensation expense, a \$1.1 million loss on voluntary conversion of convertible debt, accretion of discount of \$0.5 million on convertible debt, a \$0.2 million decrease in prepaid expenses and other assets, and a \$0.3 million increase in accrued expenses and other current liabilities. Cash flows from operating activities for the three months ended March 31, 2023 were negatively impacted by an adjustment for a \$1.0 million

decrease in fair value of warrant liabilities, cash used in discontinued operations of \$0.7 million, and a \$0.1 million decrease in accounts payable.

Net Cash Used in Investing Activities

During the three months ended March 31, 2024, net cash used in investing activities was \$0.

During the three months ended March 31, 2023, net cash used in investing activities was approximately \$0.2 million from discontinued operations, from the purchase of property and equipment.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2024, net cash provided by financing activities was \$0.5 million from the issuance of convertible debt.

During the three months ended March 31, 2023 net cash provided by financing activities was \$0.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2024, the end of the period covered by this Quarterly Report.

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Based on this evaluation, our principal executive officer and principal financial officer have concluded that, due to the material weakness described below, our disclosure controls and procedures as of March 31, 2024 were not effective to provide reasonable assurance that the information required to be disclosed by us in reports filed 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 SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. We believe that a disclosure controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the disclosure controls system are met, and no evaluation of disclosure controls can provide absolute assurance that all disclosure control issues, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. As of December 31, 2023, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework, or 2013 Framework. In connection with the audit of our financial statements as of and for the year ended December 31, 2023, we identified material weaknesses related to a lack of sufficient number of personnel within our accounting function to adequately segregate duties, and we have not designed and implemented effective Information Technology General Controls ("ITGC") related to access controls to financial accounting systems. We lack the resources to employ additional personnel to help mitigate these material weaknesses and we foresee that these material weaknesses will not be remediated until we receive additional funding to support our accounting department. We cannot assure you that these or other measures will fully remediate the material weakness in a timely manner.

There was no change in our internal control over financial reporting in the first quarter of 2024.

Notwithstanding the identified material weakness, our management believes that the condensed consolidated financial statements included in this Quarterly Report fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP. Nonetheless, we also believe that an internal control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the internal control system are met, and no evaluation of internal control can provide absolute assurance that all internal control issues and instances of fraud, if any, within a company are detected.

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PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently involved in any legal matters. From time to time, we could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters.

ITEM 1A. RISK FACTORS

The Company's business, reputation, results of operations and financial condition, as well as the price of its stock, can be affected by a number of factors, whether currently known or unknown, including those described in Part I, Item 1A of the Company's 2023 Annual Report under the heading "Risk Factors." When any one or more of these risks materialize, the Company's business, reputation, results of operations and financial condition, as well as the price of its stock, can be materially and adversely affected. There have been no material changes to the Company's risk factors since the 2023 Annual Report.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Unregistered Sales of Equity Securities

During the three months ended March 31, 2024, we issued to Alpha Capital Anstalt 1,138,535 shares of unregistered common stock in lieu of

cash for monthly redemptions of \$380,000 principal and \$19,036 accrued interest redeemed, pursuant to the terms of the 2022 Debenture at a weighted average share price of \$0.35.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

Exhibit No.	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1	<u>Contingent Value Rights Agreement, dated May 22, 2020, among the Company, John Beck in the capacity of CVR Holders' Representative and Andrew J. Ritter in his capacity as a consultant to the Company.</u>	8-K	001-37428	2.4	5/29/2020
3.1	<u>Amended and Restated Certificate of Incorporation</u>	8-K	001-37428	3.1	7/1/2015
3.2	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation</u>	8-K	001-37428	3.1	9/15/2017
3.3	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation</u>	8-K	001-37428	3.1	3/22/2018
3.4	<u>Certificate of Designation of Preferences, Rights and Limitations of Series Alpha Preferred Stock of the Company, filed with the Delaware Secretary of State on May 20, 2020</u>	8-K	001-37428	3.1	5/29/2020
3.5	<u>Certificate of Amendment to the Certificate of Incorporation of the Company, filed with the Delaware Secretary of State on May 22, 2020 [reverse stock split]</u>	8-K	001-37428	3.2	5/29/2020
3.6	<u>Certificate of Merger, filed with the Delaware Secretary of State on May 22, 2020</u>	8-K	001-37428	3.3	5/29/2020
3.7	<u>Certificate of Amendment to the Certificate of Incorporation of the Company, filed with the Delaware Secretary of State on May 22, 2020 [name change]</u>	8-K	001-37428	3.4	5/29/2020
3.8	<u>Amended and Restated Bylaws of the Company, through August 10, 2021</u>	8-K	001-37428	3.1	8/13/2021
3.9	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended</u>	8-K	001-37428	3.1	11/22/2022
4.1	<u>Warrant issued by the Company in favor of Alpha Capital Anstalt, dated May 22, 2020</u>	8-K	001-37428	10.13	5/29/2020
4.2	<u>Form of Warrant, issued by the Company in favor of GreenBlock Capital LLC and its designees, dated May 22, 2020 [post-Merger]</u>	8-K	001-37428	10.10	5/29/2020
4.3	<u>Common Stock Purchase Warrant in favor of Alpha Capital Anstalt, dated July 10, 2020</u>	8-K	001-37428	10.2	7/10/2020
4.4	<u>Common Stock Purchase Warrant in favor of Alpha Capital Anstalt, dated August 4, 2020</u>	8-K	001-37428	10.3	8/4/2020
4.5	<u>"Two-Year" Common Stock Purchase Warrant for 1,348,314 shares in favor of Alpha Capital Anstalt, dated December 18, 2020</u>	8-K	001-37428	10.3	12/18/2020
4.6	<u>"Deferred" Common Stock Purchase Warrant for 842,696 shares in favor of Alpha Capital Anstalt, dated December 18, 2020</u>	8-K	001-37428	10.4	12/18/2020

4.7	Form of liability classified Warrant to Purchase Common Stock	10-K	001-37428	4.13	3/31/2021
4.8	Form of "service provider" compensatory equity classified Warrant	10-K	001-37428	4.14	3/31/2021
4.9	Description of Common Stock	10-K/A	001-37428	4.9	7/7/2023
4.10	Amended and Restated Common Stock Purchase Warrant to GreenBlock Capital LLC, dated April 25, 2022	10-Q	001-37428	4.15	5/13/2022
4.11	Amended and Restated Common Stock Purchase Warrant to Christopher Nelson, dated April 25, 2022	10-Q	001-37428	4.16	5/13/2022
4.12	Common Stock Purchase Warrant for 2,500,000 shares in favor of Alpha Capital Anstalt, dated December 22, 2022	8-K	001-37428	4.1	12/22/2022
4.13	Common Stock Purchase Warrant for 900,016 shares in favor of Alpha Capital Anstalt, dated February 27, 2024	8-K	001-37428	10.3	2/27/2024
10.1	Securities Purchase Agreement, dated February 26, 2024, by and between Qualigen Therapeutics, Inc. and Alpha Capital Anstalt	8-K	001-37428	10.1	2/27/2024
10.2	8% Convertible Debenture Due December 31, 2024 in favor of Alpha Capital Anstalt	8-K	001-37428	10.2	2/27/2024
10.3	License and Sublicense Agreement dated February 15, 2024 between the Company and Pan-RAS Holdings, Inc.	8-K	001-37428	10.1	2/22/2024
10.4	Termination Agreement dated as of March 16, 2024 between the Company and Pan-RAS Holdings, Inc.	8-K	001-37428	10.1	3/28/2024
31.1*	Certificate of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certificate of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1*	Certificate of principal executive officer and principal financial officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
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)				

* Filed herewith.

** Furnished herewith.

+ Indicates management contract or compensatory plan or arrangement.

XBRL (Extensible Business Reporting Language) information is furnished and not filed herewith, is not a part of a registration statement or Prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

SIGNATURES

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

QUALIGEN THERAPEUTICS, INC.

July 2, 2024

By: /s/ Michael S. Poirier

Name: Michael S. Poirier

Title: Chief Executive Officer (Principal Executive Officer)

July 2, 2024

By: /s/ Christopher L. Lotz

Name: Christopher L. Lotz

Title: Vice President of Finance, Chief Financial Officer (Principal Financial Officer and Chief Accounting Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael S. Poirier, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Qualigen Therapeutics, Inc., a Delaware corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the condensed consolidated 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 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 is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such 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 condensed consolidated financial statements for external purposes 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.

July 2, 2024

By: /s/ Michael S. Poirier

Name: Michael S. Poirier

Title: Chief Executive Officer (Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Christopher L. Lotz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Qualigen Therapeutics, Inc., a Delaware corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the condensed consolidated 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 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 is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such 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 condensed consolidated financial statements for external purposes 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 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.

July 2, 2024

By: /s/ Christopher L. Lotz

Name: Christopher L. Lotz

Title: Vice President of Finance, Chief Financial Officer (Principal Financial Officer and Chief Accounting Officer)

**CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned, Michael S. Poirier, Chief Executive Officer of Qualigen Therapeutics, Inc., a Delaware corporation (the "Company"), and Christopher L. Lotz, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes- Oxley Act of 2002, that, to his knowledge (1) the quarterly report on Form 10-Q of the Company for the three months ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

July 2, 2024

By: /s/ Michael S. Poirier

Name: Michael S. Poirier

Title: Chief Executive Officer (Principal Executive Officer)

July 2, 2024

By: /s/ Christopher L. Lotz

Name: Christopher L. Lotz

Title: Vice President of Finance, Chief Financial Officer (Principal Financial Officer and Chief Accounting Officer)

These certifications accompanying and being "furnished" with this Report, shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.
