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 September 30, 2023

Or

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

For the transition period from _____ to _____

Qualigen Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-37428	26-3474527
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

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)

2042 Corte Del Nogal, Carlsbad, California 92011
(Former name or former address, if changed since last report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $.001 per share	QLGN	The Nasdaq Capital Market of The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of November 10, 2023, there were 5,181,058 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
(Unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets		
Cash	$ 2,073,849	$ 3,165,985
Prepaid expenses and other current assets	1,375,730	1,366,704
Current assets of discontinued operations	—	6,287,849
Total current assets	3,449,579	10,820,538
Property and equipment, net	—	26,242
Other assets	866,481	—
Non-current assets of discontinued operations	—	8,236,711
Total Assets	**$ 4,316,060**	**$ 19,083,491**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 1,571,831	$ 619,568
Accrued vacation	163,701	165,040
Accrued expenses and other current liabilities	1,144,188	699,519
Warrant liabilities	92,900	788,100
Warrant liabilities - related party	2,151,892	2,834,547
Convertible debt - related party	832,100	60,197
Current liabilities of discontinued operations	—	3,441,198
Total current liabilities	5,956,612	8,608,169
Non-current liabilities of discontinued operations	—	1,708,732
Total liabilities	5,956,612	10,316,901
Commitments and Contingencies (Note 10)		
Stockholders' equity (deficit)		
Qualigen Therapeutics, Inc. stockholders' equity (deficit):		
Common stock, $0.001 par value; 225,000,000 shares authorized; 5,052,463 and 4,210,737 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	42,952	42,110
Additional paid-in capital	112,668,631	110,528,050
Accumulated other comprehensive income	—	50,721
Accumulated deficit	(114,352,135)	(103,385,172)
Total Qualigen Therapeutics, Inc. stockholders' equity (deficit)	(1,640,552)	7,235,709
Noncontrolling interest	—	1,530,881
Total Stockholders' Equity (deficit)	(1,640,552)	8,766,590
Total Liabilities & Stockholders' Equity (Deficit)	**$ 4,316,060**	**$ 19,083,491**

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
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
EXPENSES				
General and administrative	$ 1,336,765	$ 2,539,389	$ 5,132,834	$ 7,705,823
Research and development	1,441,598	930,536	3,898,061	3,618,428
Total expenses	2,778,363	3,469,925	9,030,895	11,324,251
LOSS FROM OPERATIONS	(2,778,363)	(3,469,925)	(9,030,895)	(11,324,251)
OTHER EXPENSE (INCOME), NET				

(Gain) loss on change in fair value of warrant liabilities	101,112	(321,300)	(1,377,855)	(1,019,342)
Interest expense (income), net	367,257	(4,631)	1,288,908	(15,763)
Loss on voluntary conversion of convertible debt	—	—	1,077,287	—
Loss on fixed asset disposal	21,747	—	21,747	—
Other income, net	(33,454)	—	(33,534)	—
Total other expense (income), net	456,662	(325,931)	976,553	(1,035,105)
LOSS BEFORE (BENEFIT) PROVISION FOR INCOME TAXES	(3,235,025)	(3,143,994)	(10,007,448)	(10,289,146)
(BENEFIT) PROVISION FOR INCOME TAXES	—	—	—	6,173
NET LOSS FROM CONTINUING OPERATIONS	(3,235,025)	(3,143,994)	(10,007,448)	(10,295,319)
DISCONTINUED OPERATIONS				
Income (loss) from discontinued operations	159,507	(911,882)	(683,008)	(2,207,864)
Loss on disposal of discontinued operations	(619,545)	—	(619,545)	—
LOSS FROM DISCONTINUED OPERATIONS	(460,038)	(911,882)	(1,302,553)	(2,207,864)
NET LOSS	(3,695,063)	(4,055,876)	(11,310,001)	(12,503,183)
Net loss attributable to non-controlling interest from discontinued operations	(38,526)	(230,767)	(343,038)	(234,883)
Net loss attributable to Qualigen Therapeutics, Inc.	$ (3,656,537)	$ (3,825,109)	$ (10,966,963)	$ (12,268,300)
Net loss per common share, basic and diluted - continuing operations	$ (0.64)	$ (0.80)	$ (1.99)	$ (2.77)
Net loss per common share, basic and diluted - discontinued operations	$ (0.08)	$ (0.17)	$ (0.19)	$ (0.53)
Weighted—average number of shares outstanding, basic and diluted	5,052,463	3,944,406	5,021,691	3,715,462
Other comprehensive loss, net of tax				
Net loss	$ (3,695,063)	$ (4,055,876)	$ (11,310,001)	$ (12,503,183)
Foreign currency translation adjustment from discontinued operations	—	88,523	(50,721)	154,063
Other comprehensive loss	(3,695,063)	(3,967,353)	(11,360,722)	(12,349,120)
Comprehensive loss attributable to noncontrolling interest from discontinued operations	(38,526)	(230,767)	(343,038)	(234,883)
Comprehensive loss attributable to Qualigen Therapeutics, Inc.	$ (3,656,537)	$ (3,736,586)	$ (11,017,684)	$ (12,114,237)

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

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Qualigen Therapeutics, Inc. Stockholders' Equity	Noncontrolling	Total Stockholders' Equity
	Shares	Amount	Capital	Income	Deficit	(Deficit)	Interest	(Deficit)
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
Stock-based compensation	—	—	667,383	—	—	667,383	4,728	672,111
Foreign currency translation adjustment	—	—	—	(38,553)	—	(38,553)	(18,194)	(56,747)
Net loss	—	—	—	—	(3,464,205)	(3,464,205)	(43,484)	(3,507,689)
Balance at June 30, 2023	5,052,463	$ 42,952	$112,554,830	$ 131,891	$(110,695,598)	$ 2,034,075	$ 1,273,969	$ 3,308,044

Stock-based compensation	—	—	113,801	—	—	113,801	—	113,801
Net loss	—	—	—	—	(3,656,537)	(3,656,537)	(38,526)	(3,695,063)
Deconsolidation of discontinued operations	—	—	—	(131,891)	—	(131,891)	(1,235,443)	(1,367,334)
Balance at September 30, 2023	5,052,463	$ 42,952	$112,668,631	$ —	$(114,352,135)	$ (1,640,552)	$ —	$ (1,640,552)

	Common Stock		Additional Paid-In	Other Comprehensive	Accumulated	Therapeutics, Inc. Stockholders'	Noncontrolling	Total Stockholders'
	Shares	Amount $	Capital	Income	Deficit	Equity	Interest	Equity
Balance at December 31, 2021	3,529,018	$ 35,290	$101,274,073	$ —	$ (84,744,629)	$ 16,564,734	$ —	$ 16,564,734
Stock issued upon exercise of warrants	536	5	4,711	—	—	4,716	—	4,716
Stock-based compensation	—	—	1,267,166	—	—	1,267,166	—	1,267,166
Net Loss	—	—	—	—	(4,319,787)	(4,319,787)	—	(4,319,787)
Balance at March 31, 2022	3,529,554	$ 35,295	$102,545,950	$ —	$ (89,064,416)	$ 13,516,829	$ —	$ 13,516,829
Common stock issued for business acquisition	350,000	3,500	1,841,000	—	—	1,844,500	—	1,844,500
Prefunded warrants issued for business acquisition	—	—	1,746,816	—	—	1,746,816	—	1,746,816
Foreign currency translation adjustment	—	—	—	65,540	—	65,540	—	65,540
Estimated fair value of noncontrolling interest related to business acquisition	—	—	—	—	—	—	4,000,000	4,000,000
Fair value of warrant modification for business acquisition	—	—	696	—	—	696	—	696
Stock-based compensation	—	—	1,423,282	—	—	1,423,282	—	1,423,282
Net loss	—	—	—	—	(4,123,404)	(4,123,404)	(4,116)	(4,127,520)
Balance at June 30, 2022	3,879,554	$ 38,795	$107,557,744	$ 65,540	$ (93,187,820)	$ 14,474,259	$ 3,995,884	$ 18,470,143
Stock issued upon exercise of warrants	331,464	3,315	—	—	—	3,315	—	3,315
Foreign currency translation adjustment	—	—	—	88,523	—	88,523	—	88,523
Stock-based compensation	—	—	1,409,504	—	—	1,409,504	—	1,409,504
Net loss	—	—	—	—	(3,825,109)	(3,825,109)	(230,767)	(4,055,876)
Balance at September 30, 2022	4,211,018	$ 42,110	$108,967,248	$ 154,063	$ (97,012,929)	$ 12,150,492	$ 3,765,117	$ 15,915,609

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

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

	For the Nine Months Ended September 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (11,310,001)	$(12,503,183)
Loss from discontinued operations, net of tax	(1,302,553)	(2,207,864)
Loss from continuing operations	(10,007,448)	(10,295,319)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	—	9,122
Stock-based compensation	1,028,841	4,099,952
Change in fair value of warrant liabilities	(1,377,855)	(1,019,342)

Loss on voluntary conversion of convertible debt	1,077,287	—
Accretion of discount on convertible debt	1,247,198	—
Loss on disposal of fixed assets	21,747	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(640,105)	(378,498)
Accounts payable	952,269	(291,166)
Accrued expenses and other current liabilities	443,330	(728,233)
Net cash used in operating activities - continuing operations	(7,254,736)	(8,603,484)
Net cash provided by (used in) operating activities - discontinued operations	2,622,059	(2,406,331)
Net cash used in operating activities	(4,632,677)	(11,009,815)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net cash provided by investing activities - discontinued operations	3,980,541	60,612
Net cash provided by investing activities	3,980,541	60,612
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from warrant exercises	—	7,173
Payments on convertible notes payable	(440,000)	—
Net cash (used in)/provided by financing activities- continuing operations	(440,000)	7,173
Net cash used in financing activities - discontinued operations	—	—
Net cash (used in)/provided by financing activities	(440,000)	7,173
Net change in cash and restricted cash	(1,092,136)	(10,942,030)
Effect of exchange rate changes on cash and restricted cash	—	27,523
Cash and restricted cash - beginning of period	3,165,985	17,538,272
Cash and restricted cash - end of period	$ 2,073,849	$ 6,623,765
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid during the year for:		
Interest	$ —	$ —
Taxes	$ 4,900	$ 3,501
NONCASH FINANCING AND INVESTING ACTIVITIES:		
Net transfers to equipment held for lease from inventory	$ 83,271	$ —
Fair value of warrant liabilities on date of exercise	$ —	$ 858
Voluntary conversion of convertible debt into common stock	$ 1,112,582	$ —

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. (our 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. ("Qualigen" or 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, we 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 Capital"), 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 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 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"), to, among other things, provide for the further funding of NanoSynex, as contemplated by the NanoSynex Funding Agreement. 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 income within the Company's consolidated statements of changes in stockholders' equity.

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.

On July 20, 2023, the Company entered into an Amendment and Settlement Agreement with NanoSynex Ltd. ("NanoSynex") (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, provide for the further funding 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 September 30, 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 in-process research and development, goodwill, 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 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 more recently in May 2023, First Republic Bank, were closed due to liquidity concerns and taken over by the Federal Deposit Insurance Corporation (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 our 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 and nine months ended September 30, 2023 and 2022, 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.

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 other comprehensive income (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 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.

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).

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.

In October 2023, Hamas conducted several terrorist attacks in Israel resulting in ongoing war across the country. In addition, there continue to be hostilities between Israel and Hezbollah in Lebanon and Hamas in the Gaza Strip, both of which 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 our 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 ongoing economic recovery and supply chain issues. The Company is subject to inflationary pressures with respect to raw materials, labor and transportation. Accordingly, the Company continues to take actions with its suppliers to mitigate the impact of these inflationary pressures in the future. Actions to mitigate inflationary pressures with suppliers include negotiation of cost-reductions and identification of more cost competitive suppliers. While these actions are designed to offset the impact of inflationary pressures, 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, our business would 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, clinics and small hospitals' demand for Qualigen, Inc.'s FastPack™ diagnostic test kits reduced sharply, largely due to deferral of patients' non-emergency visits to physician offices. In July 2023 we sold Qualigen, Inc., our 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 September 30, 2023, we had approximately $ 2.1 million in cash and an accumulated deficit of $ 114.4 million. For the nine months ended September 30, 2023 and 2022, we used cash of $4.6 million and $11.0 million, respectively, in operations.

On July 20, 2023, the Company entered into a stock purchase agreement (the "Purchase Agreement") with Chembio Diagnostics, Inc. ("Chembio"), Biosynex, S.A. ("Biosynex") and Qualigen, Inc., a wholly-owned subsidiary of the Company. Pursuant to the Purchase Agreement, the Company agreed to sell to Chembio all of the issued and outstanding shares of common stock (collectively, the "Shares") of Qualigen, Inc., which was the legal entity operating the Company's FastPack™ diagnostics business (the "Transaction"). The Transaction closed on July 20, 2023. Following the consummation of the Transaction, Qualigen, Inc. became a wholly-owned subsidiary of Chembio.

The aggregate net purchase price paid to the Company for the Shares was $ 5.2 million in cash, based on a base purchase price of $ 5.8 million, subject to certain post-closing adjustments, upward or downward, as applicable, for: (i) cash held by Qualigen, Inc. as of the closing of the Transaction; (ii) net working capital of Qualigen, Inc. as of the closing of the Transaction, (iii) certain indebtedness of Qualigen, Inc. as of the closing of the Transaction, and (iv) certain Transaction expenses as of the closing of the Transaction. Of the $5.2 million in cash, $450,000 is being held in escrow to satisfy certain Company indemnification obligations (the "Indemnity Escrow"). Any amounts remaining in the Indemnity Escrow that have not been offset or reserved for claims will be released to the Company within five business days following the date that is 18 months after the closing. A post-closing adjustment resulting in a receivable from the Transaction of approximately $235,000 is reflected in prepaid expenses and other current assets on the Company's condensed consolidated balance sheet as of September 30, 2023.

The Company's cash balances as of the date that these financial statements were issued along with the proceeds from the above sale to Chembio, without additional financing, are expected to fund operations into the first quarter of 2024. The Company expects to continue to have net losses and negative cash flow from operations, which over time 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. In order to fully execute its business plan, the Company will require significant additional financing for planned research and development activities, capital expenditures, clinical testing for its QN-302 clinical trials and preclinical development of RAS, as well as commercialization activities.

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 2021, the Company raised $8.8 million from the issuance of common stock to several institutional investors, and in December 2022 the Company raised $3.0 million from the sale of an 8% Senior Convertible Debenture (the "Debenture") to a Alpha Capital (see Note 8 - Convertible Debt - Related Party). 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, which could adversely affect our business prospects.

On July 20, 2023, the Company entered into an Amendment and Settlement Agreement with NanoSynex Ltd. ("NanoSynex") (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, provide for the further funding of NanoSynex. However, the Company intends to forfeit shares in lieu of additional funding (see Note 5 - Discontinued Operations).

To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interests of its 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 the Company raises additional funds through government or other third-party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company. Additional funding may not be available to the Company on acceptable terms, or at all. In addition, any future financing (depending on the terms and conditions) may be subject to the approval of Alpha Capital, the holder of the Debenture, or trigger certain adjustments to the Debenture and/or warrants held by Alpha Capital.

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 September 30, 2023 and December 31, 2022:

	September 30, 2023	December 31, 2022
Prepaid insurance	$ 740,770	$ 1,329,033
Other prepaid expenses	53,787	37,671
Receivable from sale of Qualigen, Inc.	235,402	—
Prepaid research and development expenses	345,771	—
	$ 1,375,730	$ 1,366,704

Prepaid expenses attributable to Qualigen, Inc. and NanoSynex were disposed of as discontinued operations (see Note 5 - Discontinued Operations).

NOTE 4 — OTHER NON-CURRENT ASSETS

Other non-current assets consisted of the following at September 30, 2023:

	September 30, 2023
Funds held in escrow	$ 450,000
Long-term research and development deposits	416,481
	$ 866,481

NOTE 5 — DISCONTINUED OPERATIONS

Sale of Qualigen Inc.

On July 20, 2023, the Company completed the sale of Qualigen, Inc. to Chembio Diagnostics, Inc. for cash consideration of $ 5.5 million, of which $4.7 million was received at closing and $450,000 is being held in escrow to satisfy certain Company indemnification obligations. An additional $ 235,402 post-closing working capital adjustment is presented in Other Current Assets on the condensed consolidated balance sheet. The Company received the post-closing working capital adjustment payment on November 2, 2023.

The assets and liabilities classified in discontinued operations for Qualigen, Inc. as of December 31, 2022 are as follows :

	December 31, 2022
Cash	$ 2,246,482
Accounts receivable, net	512,088
Inventory, net	1,586,297
Prepaid expenses and other current assets	104,132
Total current assets of discontinued operations	4,448,999
Right-of-use assets	1,422,538
Property and equipment, net	289,696
Intangible assets, net	145,702
Other assets	18,334
Total non-current assets of discontinued operations	1,876,270
Total assets of discontinued operations of Qualigen, Inc.	**$ 6,325,269**
Accounts payable	$ 236,470
Accrued vacation	187,906
Accrued expenses and other current liabilities	518,766
Deferred revenue, current portion	116,161
Operating lease liability, current portion	240,645
Total current liabilities of discontinued operations	1,299,948
Operating lease liability, net of current portion	1,301,919
Deferred revenue, net of current portion	49,056
Total non-current liabilities of discontinued operations	1,350,975
Total liabilities of discontinued operations of Qualigen, Inc.	**$ 2,650,923**

The Company reclassified the following operations to discontinued operations for the three and nine months ended September 30, 2023 and 2022, respectively:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
REVENUES				

Net product sales	$ 426,920	$ 1,441,065	$ 3,661,121	$ 3,593,628
Total revenues	426,920	1,441,065	3,661,121	3,593,628
EXPENSES				
Cost of product sales	269,747	1,278,029	2,551,114	3,206,553
General and administrative	26,346	78,632	610,559	471,804
Research and development	2,612	268,127	206,819	942,484
Sales and marketing	37,288	239,865	405,626	683,291
Total expenses	335,993	1,864,653	3,774,118	5,304,132
OTHER EXPENSE (INCOME), NET				
Loss on disposal of equipment held for lease	—	—	63,302	—
Other expense (income), net	149	(1,139)	(4,898)	(795)
Loss on fixed asset disposal	—	—	300	—
Total other expense (income), net	149	(1,139)	58,704	(795)
INCOME (LOSS) FROM DISCONTINUED OPERATIONS BEFORE DISPOSAL	90,778	(422,449)	(171,701)	(1,709,709)
Gain on sale of Qualigen, Inc.	3,859,465	—	3,859,465	—
INCOME (LOSS) FROM DISCONTINUED OPERATIONS OF QUALIGEN, INC.	$ 3,950,243	$ (422,449)	$ 3,687,764	$ (1,709,709)

In connection with this transaction, the Company recorded a gain on the sale of Qualigen, Inc. in its condensed consolidated financial statements for the three and nine months ended September 30, 2023:

	Gain on sale of Qualigen, Inc.
Fair value of consideration received	$ 5,489,337
Working capital adjustment	235,402
Total Assets of discontinued operations	(4,225,562)
Total Liabilities of discontinued operations	3,005,407
Transaction expenses	(645,119)
Gain on sale of Qualigen, Inc.	$ 3,859,465

Amendment and Settlement Agreement with NanoSynex Ltd.

On July 20, 2023, the Company entered into the NanoSynex Amendment, which amended the NanoSynex Funding Agreement with NanoSynex (the "NanoSynex 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 the Company's ownership in NanoSynex being reduced from approximately 52.8% to approximately 49.7% of the voting equity of NanoSynex. In addition, the Company agreed to cancel approximately $3.0 million of promissory notes issued to the Company under the NanoSynex Funding Agreement, relieving NanoSynex of any repayment obligations to the Company with respect to such notes. The surrender of shares reducing the Company's interest in NanoSynex from approximately 52.8% to approximately 49.97% occurred on July 20, 2023.

The NanoSynex Amendment supersedes any payment obligations contemplated by the original NanoSynex Funding Agreement and amended the Company's obligations to provide funding to NanoSynex, except that Company 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, in lieu of fulfilling such obligations, the Company may, and intends to, instead forfeit shares of Series A-1 Preferred Stock of NanoSynex in a number that will be equal to a fraction, the numerator of which is the amount of the default (*i.e.*, the amount that the Company should have, but failed, to advance to NanoSynex pursuant to the terms of the NanoSynex Amendment), and the denominator of which shall be the price per share that the Company originally paid in consideration for its Preferred A-1 shares of NanoSynex to the previous holder thereof, being $1.5716 per share.

The surrender of Series B Preferred Shares of NanoSynex was accounted for as a loss of control of a subsidiary that constitutes a business under ASC 810. As a result, on July 20, 2023, the Company deconsolidated NanoSynex's related assets, liabilities, accumulated other comprehensive income, and the noncontrolling interest. Subsequently, the retained investment in NanoSynex is accounted for as an equity method investment. 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.

Based upon the magnitude of the disposition and because the Company is exiting certain research and development operations, 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.

The assets and liabilities classified in discontinued operations for NanoSynex as of December 31, 2022 are as follows:

	December 31, 2022
Cash	$ 1,621,967
Accounts receivable, net	26,499
Prepaid expenses and other current assets	190,384
Total current assets of discontinued operations	1,838,850
Restricted cash	5,690

Property and equipment, net	29,149
Intangible assets, net	5,700,000
Goodwill	625,602
Total non-current assets of discontinued operations	6,360,441
Total assets of discontinued operations of NanoSynex	$ 8,199,291
Accounts payable	$ 1,273
Accrued vacation	115,002
Accrued expenses and other current liabilities	293,571
R&D grant liability	780,682
Short term debt-related party	950,722
Total current liabilities of discontinued operations	2,141,250
Deferred tax liability	357,757
Total non-current liabilities of discontinued operations	357,757
Total liabilities of discontinued operations of NanoSynex	$ 2,499,007

The Company reclassified the following operations to discontinued operations for the three and nine months ended September 30, 2023 and 2022, respectively:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
EXPENSES				
Research and development	$ 81,640	$ 489,433	$ 869,064	$ 498,155
Total expenses	81,640	489,433	869,064	498,155
Loss on disposal of discontinued operations	4,479,010	—	4,479,010	—
(BENEFIT) PROVISION FOR INCOME TAXES	(150,369)	—	(357,757)	—
LOSS FROM DISCONTINUED OPERATIONS	(4,410,281)	(489,433)	(4,990,317)	(498,155)
Loss attributable to noncontrolling interest	(1,276,969)	(230,767)	(1,578,481)	(234,883)
NET LOSS ATTRIBUTABLE TO STOCKHOLDERS	$ (3,133,312)	$ (258,666)	$ (3,411,836)	$ (263,272)

In connection with this transaction, the Company recorded a loss on deconsolidation of NanoSynex in its condensed consolidated financial statements for the three and nine months ended September 30, 2023:

	Loss on deconsolidation of NanoSynex
Fair value of NanoSynex interest retained	$ —
Net assets deconsolidated	(2,768,403)
Non-controlling interest share	1,235,443
Accumulated OCI attributable to NanoSynex	131,891
Forgiveness of debt	(3,077,941)
Loss from deconsolidation of NanoSynex	**$ (4,479,010)**

NOTE 6 — ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following at September 30, 2023 and December 31, 2022:

	September 30, 2023	December 31, 2022
Board compensation	$ 40,833	70,000
Interest (Convertible debt - related party)	68,322	2,829
License fees	167,200	150,130
Payroll	35,939	1,247
Professional fees	506,080	136,203
Research and development	278,024	329,412
Other	47,790	9,698
	$ 1,144,188	$ 699,519

Other accrued liabilities attributable to Qualigen Inc, and NanoSynex were disposed of as discontinued operations (see Note 5 - Discontinued Operations).

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, at $7.195 per share, subject to adjustment. As of September 30, 2023, the Series C Warrants had remaining terms ranging from 0.14 to 0.74 years. 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. On April 25, 2022, the Series C warrants were repriced from $7.195 to $6.00 with 49,318 additional ratchet Warrants issued. On May 26, 2022, the Series C warrants were repriced from $6.00 to $5.136 with 49,952 additional ratchet Warrants issued. As a result of these repricings, 247,625 warrants were forfeited and 346,896 warrants were reissued. On December 22, 2022, the Series C warrants were repriced again from $ 5.136 to $1.32 with 1,002,717 additional ratchet Warrants issued.

Additionally, on December 22, 2022, in conjunction with the issuance of the Debenture to Alpha Capital (see Note 8 – Convertible Debt – Related Party),

the Company issued to Alpha Capital a warrant to purchase 2,500,000 shares of the Company's common stock (the "Alpha Warrant"). The exercise price of the Alpha Warrant is $1.65 (equal to 125% of the conversion price of the Debenture on the closing date). The Alpha Warrant may be exercised by Alpha Capital, in whole or in part, at any time before June 22, 2028, subject to certain terms and conditions described in the Alpha Warrant. The fair value of this warrant is included in Warrant liabilities-related party on the company's condensed consolidated balance sheet.

The following table summarizes the activity in liability classified warrants for the nine months ended September 30, 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 – September 30, 2023	3,849,571	$ 1.53	$ 1.32 - $1.65	3.16
Exercisable	3,849,571	$ 1.53	$ 1.32 - $1.65	3.16

The following table summarizes the activity in liability classified warrants for the nine months ended September 30, 2022:

	Common Stock Warrants			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding –December 31, 2021	248,161	$ 7.20		2.00
Exercised	(536)	7.20		
Forfeited	(247,625)	7.20		
Expired	—	—		
Granted	346,896	5.10		
Total outstanding – September 30, 2022	346,896	$ 5.10		
Exercisable	346,896	$ 5.10	$ 5.10	1.26

The following table presents the Company's fair value hierarchy for its liabilities measured at fair value on a recurring basis as of September 30, 2023:

Common Stock Warrant liabilities	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Balance as of December 31, 2022	$ —	$ —	$ 3,622,647	$ 3,622,647
Exercises	—	—	—	—
Gain on change in fair value of warrant liabilities	—	—	(1,377,855)	(1,377,855)
Balance as of September 30, 2023	$ —	$ —	$ 2,244,792	$ 2,244,792

There were no transfers of financial assets or liabilities between category levels for the three and nine months ended September 30, 2023.

The value of the warrant liabilities was based on a valuation received from an independent valuation firm determined using a Monte-Carlo simulation. 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 weighted average and the range of assumptions used in estimating the fair value of warrant liabilities (weighted average calculated based on the number of outstanding warrants on each issuance) as of September 30, 2023 and 2022:

	September 30, 2023		September 30, 2022	
	Range	Weighted Average	Range	Weighted Average
Risk-free interest rate	4.523% — 5.401%	4.83%	3.99% — 4.09%	4.01%
Expected volatility (peer group)	57.9% — 134.5%	108.41%	91% — 93%	92.0%
Term of warrants (in years)	.14 — 4.73	3.16	1.14 — 1.74	1.26
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

NOTE 8 — CONVERTIBLE DEBT - RELATED PARTY

On December 22, 2022, the Company issued to Alpha Capital 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 Debenture has a maturity date of December 22, 2025 and is convertible, at any time, and from time to time, until the Debenture is no longer outstanding, at Alpha Capital's option, into shares of common stock of the Company (the "Conversion Shares"), at a price equal to $1.32 per share, subject to adjustment as described in the Debenture (the "Conversion Price") and other terms and conditions described in the Debenture, including the necessary stockholder approvals, which the Company obtained at its 2023 annual meeting of stockholders on July 13, 2023. Additionally, on December 22, 2022, the Company issued to Alpha Capital a liability classified warrant (the "Alpha Warrant") to purchase 2,500,000 shares of the Company's common stock (see Note 7 - Warrant

Liabilities). The exercise price of the Alpha Warrant is $1.65 (equal to 125% of the Conversion Price of the Debenture on the closing date). The Alpha Warrant may be exercised by Alpha Capital, in whole or in part, at any time before June 22, 2028, subject to certain terms and conditions described in the Alpha Warrant, including the necessary stockholder approvals, which the Company obtained at its 2023 annual meeting of stockholders on July 13, 2023.

The proceeds from the transaction were used to advance the Company's QN-302 Investigative New Drug candidate towards clinical trials and other working capital purposes.

Commencing June 1, 2023 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 Debenture (each such date, a "Monthly Redemption Date"), the Company must redeem $110,000 plus accrued but unpaid interest, liquidated damages and any amounts then owing under the Debenture (the "Monthly Redemption Amount"). The Monthly Redemption Amount must be paid in cash; provided that after the first two monthly redemptions, the Company may elect to pay all or a portion of a Monthly Redemption Amount in shares of common stock of the Company, based on a Conversion Price equal to the lesser of (i) the then Conversion Price of the Debenture and (ii) 85% of the average of the VWAPs (as defined in the Debenture) for the five consecutive trading days ending on the trading day that is immediately prior to the applicable Monthly Redemption Date. The Company may also redeem some or all of the then outstanding principal amount of the Debenture at any time for cash in an amount equal to 105% of the then outstanding principal amount of the Debenture being redeemed plus accrued but unpaid interest, liquidated damages and any amounts then owing under the Debenture. The Company's election to pay monthly redemptions in Conversion Shares or to effect an optional redemption is subject to the satisfaction of the Equity Conditions (as defined in the Debenture), including the necessary stockholder approvals, which the Company obtained at its 2023 annual meeting of stockholders on July 13, 2023.

The Debenture accrues interest at the rate of 8% per annum, which does not begin accruing until December 1, 2023, and will be payable on a quarterly basis. Interest may be paid in cash or shares of common stock of the Company or a combination thereof at the option of the Company; provided that interest may only be paid in shares if the Equity Conditions have been satisfied, including the necessary stockholder approvals, which the Company obtained at its 2023 annual meeting of stockholders on July 13, 2023.

Both the Debenture and the Alpha Warrant provide for adjustments to the Conversion Price and exercise price, respectively, in connection with stock dividends and splits, subsequent equity sales and rights offerings, pro rata distributions, and certain fundamental transactions. Both the Debenture and the Alpha Warrant include a beneficial ownership blocker of 9.99%, which may only be waived by Alpha Capital upon 61 days' notice to the Company.

The Company filed a resale registration statement on Form S-3 (File Number 333-269088) on December 30, 2022 registering the resale by Alpha Capital of up to 5,157,087 shares of common stock of the Company which could be issued to Alpha Capital pursuant to the Debenture and the Alpha Warrant, which registration statement was declared effective by the SEC on January 5, 2023 (the "Original Registration Statement"). The Company later became ineligible to use the Original Registration Statement as a result of its failure to timely file its annual report on Form 10-K for the fiscal year ended December 31, 2022. Therefore, the Company filed a Post-Effective Amendment No. 1 to Form S-3 on Form S-1 (No. 333-269088)(the "Post-Effective Amendment No. 1") on September 1, 2023 in order to maintain the registration of the resale by Alpha Capital of up to 3,958,537 shares of common stock of the Company issuable under the Debenture and the Alpha Warrant., which Post-Effective Amendment No. 1 was declared effective by the SEC on September 7, 2023. On September 29, 2023, we filed the final resale prospectus on Form 424(b)(3).

The Company evaluated the Debenture and the Alpha Warrant and determined that the Alpha Warrant is a freestanding financial instrument. The Alpha 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 Alpha Warrant is classified as a liability and recognized at fair value, with subsequent changes in fair value recognized in earnings.

The proceeds from the Debenture were allocated to the initial fair value of the Alpha Warrant, with the residual balance allocated to the initial carrying value of the Debenture. The Company has not elected the fair value option for the Debenture. The Debenture was recognized as proceeds received after allocating the proceeds to the Alpha 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 Alpha 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 Capital 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 Debenture using the effective interest method, in accordance with ASC 835-30. The debt host instrument of the Debenture will subsequently be measured at amortized cost using the effective interest method to accrete interest over its term to bring the Debenture's initial carrying value to the principal balance at maturity.

Between January 9 and 12, 2023, the Company issued 841,726 shares of common stock upon Alpha Capital's partial conversion of the Debenture at $1.32 per share for a total of $ 1,111,078 principal. Upon conversion, the Company recognized a loss on conversion of convertible debt of approximately $1.1 million, recorded to other expenses in the condensed consolidated statements of operations.

On September 22, 2023, the Company entered into a consent and waiver (the "Waiver") with Alpha Capital. Pursuant to the Waiver, Alpha Capital consented to the Company's election to pay all of the Monthly Redemption Amount for October 2023 in Conversion Shares (the "October Payment") and waived the requirement of satisfaction of the Equity Conditions in relation to the October Payment only. On October 3, 2023 the Company issued 128,595 shares of common stock to Alpha Capital in satisfaction of the October Payment.

During the three and nine months ended September 30, 2023, the Company recorded interest of approximately $ 368,000 and $1.3 million, respectively (of which approximately $350,000 and $1.2 million was attributable to discount amortization, respectively) in other expenses in the condensed consolidated statements of operations. As of September 30, 2023, the fair value of the Alpha Warrant was approximately $ 2.2 million, and the fair value of the suite of bifurcated embedded derivative features was $0.

Convertible debt-related party is comprised of the following as of September 30, 2023 and December 31, 2022:

	September 30, 2023	December 31, 2022
Senior secured convertible debenture	$ 1,748,922	$ 3,300,000
Discount on convertible debenture	(916,822)	(3,239,803)
Total convertible debt-related party	$ 832,100	$ 60,197

As of September 30, 2023, there were no events of default or violation of any covenants under our financing obligations, except for the Equity Conditions in relation to the Company's ability to elect to pay all of the Monthly Redemption Amount for October 2023 in Conversion Shares as described above.

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 September 30, 2023 and 2022 because their effect would be anti-dilutive:

	As of September 30,	
	2023	2022
Shares of common stock subject to outstanding options	416,215	607,175
Shares of common stock subject to outstanding warrants	4,059,934	1,080,873
Total common stock equivalents	4,476,149	1,688,048

NOTE 10 — COMMITMENTS AND CONTINGENCIES

NanoSynex Funding Commitment

On July 20, 2023, the Company entered into an Amendment and Settlement Agreement with NanoSynex Ltd. ("NanoSynex") (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 majority owned subsidiary of the Company, to, among other things, provide for the further funding of NanoSynex. However, the Company intends to forfeit shares in lieu of additional funding (see Note 5 - Discontinued Operations).

Litigation and Other Legal Proceedings

On November 9, 2021, the Company was named as a defendant in an action brought by Mediant Communications Inc. ("Mediant") in the U.S. District Court for the Southern District of New York. The complaint alleged that Qualigen entered into an implied contract with Mediant, whereby Qualigen retained Mediant to distribute proxy materials and subsequently conduct shareholder vote tabulations. The Company filed a Motion to Dismiss with the District Court and on March 14, 2022 a hearing was held during which the presiding judge ruled in favor of the Motion to Dismiss. The Company and Mediant settled the litigation on April 5, 2022 in the amount of $96,558, at which time the amount was paid.

NOTE 11 — RESEARCH AND LICENSE AGREEMENTS

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 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 agreements for the three months ended September 30, 2023 and 2022 were approximately $ 101,000 and $196,000, respectively, and for the nine months ended September 30, 2023 and 2022 were approximately $ 657,000 and $601,000, respectively, and are recorded in research and development expenses in the condensed consolidated statements of operations and other comprehensive loss. License costs related to these agreements for the three months ended September 30, 2023 and 2022 were approximately $18,000 and $27,000, respectively, and for the nine months ended September 30, 2023 and 2022 were approximately $47,000 and $44,000, respectively, and are included in research and development expenses in the condensed consolidated statements of operations and other comprehensive loss.

Between June 2018 and April 2022, the Company entered into license and sponsored research agreements with the University of Louisville Research Foundation ("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.

The sponsored research agreement for QN-247 expired in August 2022 and there were no sponsored research expenses for the three months ended September 30, 2023 and 2022. For the nine months ended September 30, 2023 and 2022 were $0 and approximately $164,000 in sponsored research

expenses related to these agreements, respectively, and these amounts are recorded in research and development expenses in the condensed consolidated statements of operations and other comprehensive loss. License costs were $0 and approximately $5,000 related to these agreements for the three months ended September 30, 2023 and 2022, respectively, and approximately $22,000 and $74,000 related to these agreements for the nine months ended September 30, 2023 and 2022, respectively, and are included in research and development expenses in the condensed consolidated statements of operations and other comprehensive loss.

In June 2020, the Company entered into an exclusive license agreement with ULRF for its intellectual property in the use of QN-165 as a treatment for COVID-19. Under the agreement, the Company took over development, regulatory approval and commercialization of the compound (for such use) from ULRF and is responsible for maintenance of the related intellectual property portfolio. In return, ULRF received approximately $24,000 for an upfront license fee and reimbursement of prior patent costs. In addition, the Company was required to enter into a separate sponsored research agreement with ULRF (for QN-165 as a treatment for COVID-19) for at least $250,000. In November 2020, the Company executed a sponsored research agreement with ULRF (for QN-165 as a treatment for COVID-19) supporting up to approximately $430,000 in research which satisfied this requirement. This sponsored research agreement expired in November 2021 and the exclusive license agreement was terminated on October 31, 2022.

There were no sponsored research expenses or license costs related to these agreements for the three months ended September 30, 2023 and 2022, or for the nine months ended September 30, 2023 and 2022.

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 Qualigen under the name QN-302 as a candidate for treatment for pancreatic ductal adenocarcinoma (PDAC), which represents the vast majority of pancreatic cancers. The License Agreement required a $150,000 upfront payment, reimbursement of past patent prosecution expenses (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 Qualigen.

For the three months ended September 30, 2023 and 2022, there were license costs of $ 12,000 and $0, respectively and for the nine months ended September 30, 2023 and 2022, there were license costs of approximately $28,000 and $310,000, respectively, related to this agreement which are included in research and development expenses in the condensed consolidated statements of operations and other comprehensive loss.

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, side 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 project timeline started in July 2023 and is expected to continue until approximately July 2026. The total amount to be paid under these work orders and statements of work is currently expected to be approximately $7.6 million over the term of the QN-302 Phase 1 study, subject to available funding.

NOTE 12 — STOCKHOLDERS' EQUITY (DEFICIT)

As of September 30, 2023 and December 31, 2022, the Company had two classes of authorized 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.

On December 22, 2022, the Company issued to Alpha Capital 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 Debenture has a maturity date of December 22, 2025 and is convertible, at any time, and from time to time, until the Debenture is no longer outstanding, at Alpha Capital's option, into shares of common stock of the Company, at a price equal to $1.32 per share, subject to adjustment and other terms and conditions described in the Debenture (see Note 8 - Convertible Debt - Related Party). As part of this transaction, the Company issued to Alpha Capital a warrant to purchase 2,500,000 shares of the Company's common stock (see Note 7 - Warrant Liabilities). Between January 9 and 12, 2023, Alpha Capital voluntarily converted $1,111,078 of its outstanding the Debenture principal into 841,726 shares of common stock at a conversion price of $ 1.32 per share.

At September 30, 2023, the Company reserved 4,476,149 shares of authorized but unissued common stock for possible future issuance. At September 30, 2023, shares were reserved in connection with the following:

Exercise of issued and future grants of stock options	416,215
Exercise of stock warrants	4,059,934
Total	4,476,149

Preferred Stock

At September 30, 2023 and December 31, 2022, 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 September 30, 2023 and December 31, 2022, there were 416,215 and 608,012 outstanding stock options, respectively, under the 2020 Plan and on such dates there were 339,487 and 147,690 shares reserved under the 2020 Plan, respectively, for future grant.

The following represents a summary of the options granted (under the 2020 Plan and otherwise) to employees and non-employee service providers that are outstanding at September 30, 2023, and changes during the nine-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	(191,797)	34.02	5.14 - 51.30	—
Total outstanding – September 30, 2023	416,215	$ 35.50	$ 5.14 — $51.30	7.31
Exercisable (vested)	330,544	$ 42.38	$ 5.14 — $51.30	7.01
Non-Exercisable (non-vested)	85,671	$ 8.97	$ 5.14 - $35.20	8.52

There was approximately $1.0 and $4.0 million of compensation cost related to outstanding stock options for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, there was approximately $0.4 million 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 1.31 years.

	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2021	484,186	$ 60.70	$ 12.40 — $14,657.50	8.52
Granted	132,975	5.10	5.10 - 10.50	9.77
Expired	(9,386)	935.90	57.50 - 14,657.50	—
Forfeited	(600)	35.50	12.40 - 49.70	—
Total outstanding – September 30, 2022	607,175	$ 35.10	$ 10.50 — $51.30	8.33
Exercisable (vested)	266,016	$ 48.40	$ 12.40 — $51.30	7.76
Non-Exercisable (non-vested)	341,159	$ 36.80	$ 10.50 — $51.30	8.82

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 ten-year period.

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 material factors incorporated in the Black-Scholes model in estimating the fair value of the options granted for the periods presented were as follows:

	For the Nine Months Ended September 30,	
	2023	2022
Expected dividend yield	0.00%	0.00%
Expected stock-price volatility	—	103

Risk-free interest rate	—	1.58% — 3.03%
Expected average term of options (in years)	—	6.00
Stock price	$ —	$ 0.52

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

	For the Nine Months Ended September 30,	
	2023	2022
General and administrative	$ 881,365	$ 3,522,108
Research and development	140,674	577,844
Total	$ 1,022,039	$ 4,099,952

Equity Classified Compensatory Warrants

In connection with the $4.0 million equity capital raise as part of the May 2020 reverse recapitalization transaction, the Company issued common stock warrants to an advisor and its designees for the purchase of 81,143 reverse split adjusted shares of the Company's common stock at a reverse split adjusted exercise price of $11.10 per share. The issuance cost of these warrants was charged to additional paid-in capital, and did not result in expense in the Company's condensed consolidated statements of operations and comprehensive loss.

In addition, various service providers hold equity classified compensatory warrants issued in 2017 and earlier for the purchase of 66,802 reverse split adjusted shares of Company common stock (originally exercisable to purchase Series C convertible preferred stock) at a weighted average exercise price of $23.40 per share. These are to be differentiated from the Series C Warrants described in Note 7 - Warrant Liabilities.

During the year ended December 31, 2021, the Company issued equity classified compensatory warrants to a service provider for the purchase of 60,000 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $13.20 per share. The fair value issuance cost of approximately $0.3 million using the Black-Scholes options pricing model for these warrants was charged to general and administrative expenses in the Company's condensed consolidated statements of operations and comprehensive loss. On April 25, 2022, 60,000 warrants were repriced from $13.20 to a reverse split adjusted exercise price of $6.00 and extended from June 3, 2023 to September 14, 2023, when they expired . The increase in fair value of $67,370 using a Monte Carlo pricing model 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. On April 25, 2022 and May 26, 2022 an additional 67,619 reverse split adjusted warrants were repriced from a reverse split adjusted exercise price of $11.10 to $5.136. The increase in fair value of $31,010 using a Monte Carlo pricing model for the modification of these warrants was charged to additional paid-in capital and did not result in expense on the Company's condensed consolidated statements of operations and comprehensive loss. On December 22, 2022, 67,620 warrants were repriced from a reverse split adjusted exercise price of $5.136 to $1.32. The increase in fair value of $8,548 using a Monte Carlo pricing model for the modification of these warrants was charged to additional paid-in capital and did not result in expense on the Company's condensed consolidated statements of operations and comprehensive loss.

No compensatory warrants were issued during the nine months ended September 30, 2023.

The following table summarizes the activity in the common stock equity classified compensatory warrants for the nine months ended September 30, 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
Granted to advisor and its designees	—	—		
Exercised	—	—		
Expired	(60,000)	6.00	6.00	
Forfeited	—	—		
Total outstanding – September 30, 2023	119,046	$ 10.69	$ 1.32 — $25.40	1.50
Exercisable	119,046	$ 10.69	$ 1.32 — $25.40	1.50
Non-Exercisable	—	$ —	$ —	—

The following table summarizes the activity in the common stock equity classified compensatory warrants for the nine months ended September 30, 2022:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2021	179,065	$ 15.20	$ 11.10 — $25.40	2.64
Granted to advisor and its designees	—	—		
Exercised	—	—		
Expired	—	—		
Forfeited	—	—		
Total outstanding – September 30, 2022	179,065	$ 10.60	$ 5.14 — $25.40	1.98
Exercisable	179,065	$ 10.60	$ 5.14 — $25.40	1.98
Non-Exercisable	—	$ —	$ —	—

There were no compensation costs related to outstanding equity classified compensatory warrants for the nine months ended September 30, 2023 and

$67,370 for the nine months ended September 30, 2022.

Noncompensatory Equity Classified Warrants

In May 2020, as a commitment fee, the Company issued noncompensatory equity classified warrants to Alpha Capital (a related party) for the purchase of 27,048 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $ 11.10 per share (of which warrants for 20,000 shares were subsequently exercised in December 2020). In July 2020, the Company issued noncompensatory equity classified warrants to Alpha Capital for the purchase of 78,019 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $ 0.01 per share (which were subsequently exercised in July 2020), and 192,068 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $52.50 per share. In August 2020, the Company issued noncompensatory equity classified warrants to Alpha Capital for the purchase of 128,783 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $ 60.00 per share. In December 2020, the Company issued noncompensatory equity classified warrants to Alpha Capital for the purchase of 100,000 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $0.10 per share (which were exercised in February 2021) and 219,101 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $40.70 per share. In May 2022, the Company issued noncompensatory equity classified warrants to Alpha Capital for the purchase of 331,464 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $0.01 per share.

On November 29, 2021, with the exception of the warrants to purchase 27,048 reverse split adjusted shares of the Company's common stock at a reverse split adjusted exercise price of $11.10 per share, the exercise prices of all outstanding warrants to purchase a total of 539,951 reverse split adjusted shares of the Company's common stock were modified to a reverse split adjusted exercise price of $20.00 per share and each of their remaining terms extended by six months. The fair value of the modification cost of these warrant modifications of approximately $2.3 million was charged to additional paid-in capital and did not result in expense on the Company's condensed consolidated statements of operations and comprehensive loss. In May 2022, pre-funded warrants to purchase 331,464 reverse split adjusted shares of the Company's common stock at a reverse split adjusted exercise price of $0.01 per share with no expiration date were issued. These warrants were subsequently exercised during the period ended September 30, 2022.

In conjunction with the NanoSynex Acquisition, on April 25, 2022 the exercise price of 7,048 reverse split adjusted outstanding warrants with an exercise price of $11.10 per share was modified to a reverse split adjusted exercise price of $ 6.00. The increase in fair value of $ 2,533, using a Monte Carlo pricing model for the modification of these warrants, was charged to additional paid-in capital and did not result in expense on the Company's condensed consolidated statements of operations and comprehensive loss. On May 26, 2022, the reverse split adjusted exercise price of these warrants was modified again to $5.136, and the increase in fair value of $ 696, using a Monte Carlo pricing model for the modification of these warrants, was included in consideration transferred in the NanoSynex Acquisition. On December 22, 2022, the exercise price of these warrants was modified again to $ 1.32. The increase in fair value of $891, using a Monte Carlo pricing model for the modification of those warrants, was charged to additional paid-in capital and did not result in expense on the Company's condensed consolidated statements of operations and comprehensive loss.

No noncompensatory equity classified warrants were issued during the nine months ended September 30, 2023.

The following table summarizes the noncompensatory equity classified warrant activity for the nine months ended September 30, 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
Legacy Ritter warrants	—	—		
Granted	—	—		
Exercised	—	—		
Expired	(455,685)	20.00	20.00	
Forfeited	—	—		
Total outstanding – September 30, 2023	91,318	$ 18.56		
Exercisable	91,318	$ 18.56	$1.32 — $20.00	0.33
Non-Exercisable	—	$ —	$ —	—

The following table summarizes the noncompensatory equity classified warrant activity for the nine months ended September 30, 2022:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2021	554,914	$ 20.10		
Legacy Ritter warrants	—	—		
Granted	331,464	0.01	0.01	
Exercised	(331,464)	0.01	0.01	
Expired	—	—		
Forfeited	—	—		
Total outstanding – September 30, 2022	554,914	$ 20.10		
Exercisable	554,914	$ 20.10	$5.10 — $37.70	0.57
Non-Exercisable	—	$ —	$ —	—

NOTE 13 — RELATED PARTY TRANSACTIONS

Convertible Debt

See Note 8 – Convertible Debt – Related Party for additional information concerning convertible debt - related party transactions. On December 22, 2022, the Company issued to Alpha Capital, 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 Debenture is convertible, at any time, and from time to time, at Alpha Capital's option, into shares of common stock of the Company, at a price equal to $1.32 per share, subject to adjustment as described in the Debenture and other terms and conditions described in the Debenture.

Warrant Liabilities

Additionally, on December 22, 2022, in conjunction with the issuance of the Debenture to Alpha Capital, the Company issued to Alpha Capital a warrant to purchase 2,500,000 shares of the Company's common stock (the "Alpha Warrant"). The exercise price of the Alpha Warrant is $ 1.65 (equal to 125% of the conversion price of the Debenture on the closing date). The Alpha Warrant may be exercised by Alpha Capital, in whole or in part, at any time before June 22, 2028, subject to certain terms and conditions described in the Alpha Warrant. The fair value of this warrant is included in Warrant liabilities-related party on the Company's condensed consolidated balance sheets (see Note 7 - Warrant Liabilities).

NOTE 14 — SUBSEQUENT EVENTS

In October 2023, Hamas conducted several terrorist attacks in Israel resulting in ongoing war across the country. In addition, there continue to be hostilities between Israel and Hezbollah in Lebanon and Hamas in the Gaza Strip, both of which 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 our minority interest in NanoSynex, its results of operations, financial condition, cash flows and prospects (see Note 5 - Discontinued Operations).

On October 3, 2023 the Company issued 128,595 shares of common stock to Alpha Capital in satisfaction of the October Payment pursuant to the Debenture (see Note 8 - Convertible Debt - Related Party).

On November 7, 2023 the Company announced that first patient dosing occurred for its QN-302 Phase 1a clinical trial which triggered a $ 100,000 milestone payment obligation of the Company under the exclusive license agreement with UCL Business Limited (see Note 11 - Research and License Agreements).

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, 2022, which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on May 2, 2023, as amended by Amendment No. 1 filed with the SEC on July 7, 2023 (the "2022 Annual Report.) 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.

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

- there can be no assurance that we will successfully develop any drugs or therapeutic devices;
- there can be no assurance that preclinical or clinical development of our candidate drugs or therapeutic devices will be successful;
- there can be no assurance that clinical trials will be approved to begin by or will actually begin by or will proceed as contemplated by any projected timeline;
- there can be no assurance that clinical trials will complete enrollment as contemplated by any projected timeline;
- there can be no assurance that future clinical trial data will be favorable or that such trials will confirm any improvements over other products or lack negative impacts;
- there can be no assurance that any of our candidate drugs or therapeutic devices will receive the required regulatory approvals or that they will be commercially successful;
- there can be no assurance that we will be able to procure or earn sufficient working capital to complete the development, testing and launch of our prospective candidate drugs therapeutic products;
- there can be no assurance that patents will issue on our owned and in-licensed patent applications; and
- there can be no assurance that such patents, if any, and our current owned and in-licensed patents would prevent competition.

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. 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.

Future filings with 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.

Overview

We are a clinical stage therapeutics company focused on developing treatments for adult and pediatric cancers of high unmet medical need with potential for Orphan Drug designation.

Our cancer therapeutics pipeline includes QN-302, our Pan-RAS Inhibitor platform (formerly RAS-F) and QN-247.

Our lead oncology therapeutics program, QN-302, is a high potency small molecule selective transcription inhibitor with strong binding affinity to G-Quadruplexes (G4s) prevalent in cancer cells. By binding to, and stabilizing G4s against "unwinding," QN-302 could potentially help inhibit cancer cell proliferation and induce cancer cell death. QN-302 has received Investigational New Drug (IND) clearance from the U.S. Food and Drug Administration (FDA) to proceed with its Phase 1 clinical trial. Earlier this year, QN-302 also received Orphan Drug Designation (ODD) from FDA for the indication of pancreatic cancer.

Our Pan-RAS portfolio consists of a family of Pan-RAS inhibitor small molecules believed to inhibit or block mutated RAS genes' proteins from binding to their effector proteins. Preventing this binding could potentially stop tumor growth, especially in RAS-driven tumors such as pancreatic, colorectal and lung cancers.

Our investigational oligonucleotide-based drug candidate QN-247 binds nucleolin, a key multi-functional regulatory phosphoprotein that is overexpressed in cancer cells. Such binding could potentially inhibit the cancer cells' proliferation in nucleolin-expressing malignancies. We have de-prioritized deploying our internal resources to our QN-247 program and are seeking a partner to further its development.

On November 23, 2022, we effected a 1-for-10, reverse stock split of our outstanding shares of common stock (the "Reverse Stock Split"). The Reverse Stock Split reduced our shares of outstanding common stock, stock options, and warrants to purchase shares of our 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 this Quarterly Report on Form 10-Q 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.

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.

Recent Developments

FDA IND Clearance to Initiate 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 TD2 to serve as our contract research organization ("CRO") to conduct a Phase 1 clinical trial in patients with advanced or metastatic solid tumors. The Phase 1 trial (NCT06086522) is 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. Subject to available funding, we anticipate that Phase 1a of the trial can be completed by the end of 2024, funded in part by proceeds received by the divestiture of the Company's diagnostics business in July 2023 as described immediately below. 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 a cash payment of approximately $4.7 million, which payment is subject to post-closing adjustments. An additional $450,000 was delivered by Chembio to an escrow account to satisfy our indemnification obligations. Any amounts remaining in the escrow account that have not been offset or reserved for claims will be released to us within five business days following the date that is 18 months after the closing of the transaction. A post-closing adjustment resulting in a receivable from the Transaction of approximately $235,000 is reflected in prepaid expenses and other current assets on the Company's condensed consolidated balance sheet as of September 30, 2023. Following the consummation of the transaction, Qualigen, Inc. became a wholly-owned subsidiary of Chembio.

Amendment and Settlement Agreement with NanoSynex Ltd.

On July 20, 2023, the Company entered into the NanoSynex Amendment, which amended the NanoSynex Funding Agreement with NanoSynex (the "NanoSynex 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 the Company's ownership in NanoSynex being reduced from approximately 52.8% to approximately 49.7% of the voting equity of NanoSynex. In addition, the Company agreed to cancel approximately $3.0 million of promissory notes issued to the Company under the NanoSynex Funding Agreement, relieving NanoSynex of any repayment obligations to the Company with respect to such notes. The surrender of shares reducing the Company's interest in NanoSynex from approximately 52.8% to approximately 49.97% occurred on July 20, 2023.

The NanoSynex Amendment supersedes any payment obligations contemplated by the original NanoSynex Funding Agreement and amended the Company's obligations to provide funding to NanoSynex, except that Company 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, in lieu of fulfilling such obligations, the Company may, and intends to, instead forfeit shares of Series A-1 Preferred Stock of NanoSynex in a number that will be equal to a fraction, the numerator of which is the amount of the default (*i.e.*, the amount that the

Company should have, but failed, to advance to NanoSynex pursuant to the terms of the NanoSynex Amendment), and the denominator of which shall be the price per share that the Company originally paid in consideration for its Preferred A-1 shares of NanoSynex to the previous holder thereof, being $1.5716 per share.

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. Prior to the current quarter, our reported expenses represented the total of our diagnostics-related and therapeutics-related expenses. Beginning in the current quarter, all diagnostics-related revenues and expenses have been reclassified to discontinued operations (See Note 5 - Discontinued Operations).

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 - Organization And Summary Of Significant Accounting Policies And Estimates to our condensed consolidated financial statements appearing in "Item 1. Condensed Consolidated Financial Statements (Unaudited)," 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:

- Convertible debt
- Research and development
- Discontinued operations
- Impairment of long-lived assets
- Business combination
- Derivative financial instruments and warrant liabilities
- Stock-based compensation
- Income taxes

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. The operation of the "double-ratchet" provisions in these warrants in connection with the NanoSynex Acquisition and the convertible debenture financing transaction in December 2022 now allow the holders to exercise for a significantly higher number of shares than before. 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 $0.1 million and $0.8 million at September 30, 2023 and December 31, 2022, respectively. There were 1,349,571 of these warrants outstanding at September 30, 2023 and December 31, 2022.

On December 22, 2022, as part of the convertible debenture financing, the Company issued to Alpha Capital a common stock warrant for 2,500,000 shares of common stock of the Company (the "Alpha Warrant"). The exercise price of the Alpha Warrant is $1.65. The Alpha Warrant may be exercised by Alpha Capital, in whole or in part, at any time before June 22, 2028. U.S. GAAP requires us to recognize the fair value of this warrant as a warrant liability on our condensed consolidated balance sheets and to reflect period-to-period changes in the fair value of the warrant liability on our condensed consolidated statements of operations. The estimated fair value of this warrant liability was approximately $2.2 million and $2.8 million at September 30, 2023 and December 31, 2022, respectively.

Because the fair value of the above liability classified warrants will be determined each quarter on a "mark-to-market" basis, it could result in significant variability in our future quarterly and annual consolidated statement of operations and consolidated balance sheets based on changes in our public market common stock price. Pursuant to U.S. GAAP, a quarter-to-quarter increase in our stock price would result in an increase (possibly quite large) in the fair value of the warrant liabilities and a quarter-to-quarter decrease in our stock price would result in a decrease (possibly quite large) in the fair value of the warrant liabilities.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

	For the Three Months Ended September 30,	
	2023	**2022**
EXPENSES		
General and administrative	$ 1,336,765	$ 2,539,389
Research and development	1,441,598	930,536
Total expenses	2,778,363	3,469,925
LOSS FROM OPERATIONS	(2,778,363)	(3,469,925)
OTHER EXPENSE (INCOME), NET		

Loss (gain) on change in fair value of warrant liabilities	101,112	(321,300)
Interest (income) expense, net	367,257	(4,631)
Loss on fixed asset disposal	21,747	—
Other income (expense), net	(33,454)	—
Total other expense (income), net	456,662	(325,931)
LOSS BEFORE (BENEFIT) PROVISION FOR INCOME TAXES	(3,235,025)	(3,143,994)
(BENEFIT) PROVISION FOR INCOME TAXES	—	—
NET LOSS FROM CONTINUING OPERATIONS	(3,235,025)	(3,143,994)
DISCONTINUED OPERATIONS		
Income (loss) from discontinued operations before income taxes	159,507	(911,882)
Loss on disposal of discontinued operations	(619,545)	—
LOSS FROM DISCONTINUED OPERATIONS	(460,038)	(911,882)
NET LOSS	(3,695,063)	(4,055,876)
Net loss attributable to non-controlling interest from discontinued operations	(38,526)	(230,767)
Net loss attributable to Qualigen Therapeutics, Inc.	$ (3,656,537)	$ (3,825,109)
Net loss per common share, basic and diluted - continuing operations	$ (0.64)	$ (0.80)
Net loss per common share, basic and diluted - discontinued operations	$ (0.08)	$ (0.17)
Weighted—average number of shares outstanding, basic and diluted	5,052,463	3,944,406
Other comprehensive loss, net of tax		
Net loss	$ (3,695,063)	$ (4,055,876)
Foreign currency translation adjustment from discontinued operations	—	88,523
Other comprehensive loss	(3,695,063)	(3,967,353)
Comprehensive loss attributable to noncontrolling interest from discontinued operations	(38,526)	(230,767)
Comprehensive loss attributable to Qualigen Therapeutics, Inc.	$ (3,656,537)	$ (3,736,586)

Expenses

General and Administrative Expenses

General and administrative expenses decreased by 47% from $2.5 million, during the three months ended September 30, 2022, to $1.3 million during the three months ended September 30, 2023, primarily due to a decrease in stock-based compensation of approximately $1.1 million, as well as a decrease in professional fees of approximately $0.1 million. The decrease in stock-based compensation was due to the January 2023 reduction in force as well as certain option grants from prior years becoming fully vested.

Research and Development Costs

Research and development costs increased from $0.9 million for the three months ended September 30, 2022 to approximately $1.4 million for the three months ended September 30, 2023. This increase in research and development costs during the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was primarily due to a $0.5 million increase in preclinical research costs for QN-302.

Other Income (Expense), Net

Change in Fair Value of Warrant Liabilities

During the three months ended September 30, 2023 and 2022, we experienced a loss of approximately $0.1 million and a gain of approximately $0.3 million, respectively, on change in fair value of warrant liabilities, primarily due to changes in our stock price and reduction in the remaining terms of the warrants. 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.

Because the fair value of warrant liabilities will be determined each quarter on a “mark-to-market” basis, this item is likely to continue to result in significant variability in our future quarterly and annual consolidated statements of operations based on unpredictable changes in our public market common stock price and the number of warrants outstanding at the end of each quarter.

Interest Expense (Income), Net

Interest expense, net during the three months ended September 30, 2023 was approximately $367,000 due to accrued interest on the convertible debt, compared to interest income, net of approximately $5,000 during the three months ended September 30, 2022.

Loss On Fixed Asset Disposal

Loss on fixed asset disposal during the three months ended September 30, 2023 was approximately $22,000 due to a write off of equipment, compared to $0 during the three months ended September 30, 2022.

Other Income, Net

Other income was $33,000 during the three months ended September 30, 2023 compared to $0 during the three months ended September 30, 2022 due to dividend income on cash invested in money market funds during the current period.

Discontinued Operations

Income from discontinued operations during the three months ended September 30, 2023 was approximately $160,000 compared to loss from

discontinued operations of approximately $912,000 during the three months ended September 30, 2022. Of the $160,000 income from discontinued operations during the three months ended September 30, 2023, approximately $91,000 was due to net income from our former Qualigen, Inc. subsidiary, and $69,000 in income from NanoSynex, inclusive of a $150,000 benefit in provision for income taxes. The $912,000 loss from discontinued operations during the three months ended September 30, 2022 consisted of approximately $422,000 from our former Qualigen, Inc. subsidiary and approximately $489,000 from NanoSynex.

In addition, the Company recorded a loss of approximately $0.6 million on disposal of discontinued operations during the three months ended September 30, 2023, and $0 during the three months ended September 30, 2022. The loss during the three months ended September 30, 2023 consisted of approximately $4.5 million from deconsolidation of NanoSynex, offset by a gain of approximately $3.9 million from the sale of the Company's former Qualigen, Inc. subsidiary.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	For the Nine Months Ended September 30,	
	2023	**2022**
EXPENSES		
General and administrative	$ 5,132,834	$ 7,705,823
Research and development	3,898,061	3,618,428
Total expenses	9,030,895	11,324,251
LOSS FROM OPERATIONS	(9,030,895)	(11,324,251)
OTHER EXPENSE (INCOME), NET		
(Gain) loss on change in fair value of warrant liabilities	(1,377,855)	(1,019,342)
Interest expense (income), net	1,288,908	(15,763)
Loss on voluntary conversion of convertible debt	1,077,287	—
Loss on fixed asset disposal	21,747	—
Other income, net	(33,534)	—
Total other expense (income), net	976,553	(1,035,105)
LOSS BEFORE (BENEFIT) PROVISION FOR INCOME TAXES	(10,007,448)	(10,289,146)
(BENEFIT) PROVISION FOR INCOME TAXES	—	6,173
NET LOSS FROM CONTINUING OPERATIONS	(10,007,448)	(10,295,319)
DISCONTINUED OPERATIONS		
Loss from discontinued operations before income taxes	(683,008)	(2,207,864)
Loss on disposal of discontinued operations	(619,545)	—
LOSS FROM DISCONTINUED OPERATIONS	(1,302,553)	(2,207,864)
NET LOSS	(11,310,001)	(12,503,183)
Net loss attributable to non-controlling interest from discontinued operations	(343,038)	(234,883)
Net loss attributable to Qualigen Therapeutics, Inc.	$ (10,966,963)	$ (12,268,300)
Net loss per common share, basic and diluted - continuing operations	$ (1.99)	$ (2.77)
Net loss per common share, basic and diluted - discontinued operations	$ (0.19)	$ (0.53)
Weighted—average number of shares outstanding, basic and diluted	5,021,691	3,715,462
Other comprehensive loss, net of tax		
Net loss	$ (11,310,001)	$ (12,503,183)
Foreign currency translation adjustment from discontinued operations	(50,721)	154,063
Other comprehensive loss	(11,360,722)	(12,349,120)
Comprehensive loss attributable to noncontrolling interest from discontinued operations	(343,038)	(234,883)
Comprehensive loss attributable to Qualigen Therapeutics, Inc.	$ (11,017,684)	$ (12,114,237)

Expenses

General and Administrative Expenses

General and administrative expenses decreased 33% from $7.7 million, during the nine months ended September 30, 2022 to approximately $5.1 million during the nine months ended September 30, 2023, This $2.6 million decrease was primarily due to a $2.6 million decrease in stock-based compensation expense due to the January 2023 reduction in force as well as certain option grants from prior years becoming fully vested.

Research and Development Costs

Research and development costs increased from $3.6 million for the nine months ended September 30, 2022 to $3.9 million for the nine months ended September 30, 2023. The $0.3 million increase in therapeutics research and development costs during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to an increase of $1.5 million in preclinical research costs for QN-302, offset by a $0.9 million decrease in QN-247 preclinical research costs, a $0.1 million decrease in RAS preclinical research costs, a $0.1 million decrease in QN-165 preclinical research costs, and a $0.1 million decrease in payroll expenses.

Other Income (Expense), Net

Change in Fair Value of Warrant Liabilities

During the nine months ended September 30, 2023 and 2022, we experienced gains of $1.4 million and $1.0 million, respectively, on change in fair value of warrant liabilities, primarily due to declines in our stock price, and reductions in the remaining terms of the warrants during both periods. 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.

Because the fair value of warrant liabilities will be determined each quarter on a "mark-to-market" basis, this item is likely to continue to result in significant variability in our future quarterly and annual statements of operations based on unpredictable changes in our public market common stock price and the number of liability classified warrants outstanding at the end of each quarter.

Interest Expense (Income), Net

Interest expense, net during the nine months ended September 30, 2023 was approximately $1.3 million due to accrued interest on the convertible debt, compared to interest income, net of approximately $16,000 during the nine months ended September 30, 2022.

Loss on Voluntary Conversion of Convertible Debt

During the nine months ended September 30, 2023, we recognized a $1.1 million loss due to a voluntary conversion by Alpha Capital of approximately $1.1 million of convertible debt into 841,726 shares of common stock (see Note 8 - Convertible Debt - Related Party to our condensed consolidated financial statements). We did not have any outstanding convertible debt for the nine months ended September 30, 2022.

Loss on Fixed Asset Disposal

Loss on fixed asset disposal during the nine months ended September 30, 2023 was approximately $22,000 due to a write off of equipment, compared to $0 during the nine months ended September 30, 2022.

Other Income, Net

Other income was $33,000 during the nine months ended September 30, 2023, compared to $0 during the nine months ended September 30, 2022, due to dividend income on cash invested in money market funds during the current period.

Discontinued Operations

Loss from discontinued operations for the nine months ended September 30, 2023 was approximately $0.7 million compared to loss from discontinued operations of approximately $2.2 million during the nine months ended September 30 2022. The $0.7 million loss from discontinued operations during the nine months ended September 30, 2023 consisted of approximately $0.2 million from our former Qualigen, Inc. subsidiary and approximately $0.5 million from NanoSynex. The $2.2 million loss from discontinued operations during the nine months ended September 30, 2022 consisted of approximately $1.7 million from our former Qualigen, Inc. subsidiary and approximately $0.5 million from NanoSynex.

In addition, the Company recorded a loss of approximately $0.6 million on disposal of discontinued operations during the nine months ended September 30, 2023, and $0 during the nine months ended September 30, 2022. This loss consisted of approximately $4.5 million from deconsolidation of NanoSynex, offset by a gain of approximately $3.9 million from the sale of our former Qualigen, Inc. subsidiary.

Liquidity and Capital Resources

As of September 30, 2023, we had approximately $2.1 million in cash and an accumulated deficit of $114.4 million. For the nine months ended September 30, 2023 and 2022, we used cash of approximately $4.6 million and $11.0 million, respectively, in operations.

On July 20, 2023, we entered into the NanoSynex Amendment with NanoSynex, which amended the NanoSynex Funding Agreement. See "Contractual Obligations and Commitments" below.

On July 25, 2023, we received a cash payment of approximately $4.7 million from Chembio for all of the outstanding shares of common stock of Qualigen, Inc., which payment is subject to post-closing adjustments, upward or downward, as applicable, for: (i) cash held by the Subsidiary as of the closing of the Transaction; (ii) net working capital of the Subsidiary as of the closing of the Transaction, (iii) certain indebtedness of the Subsidiary as of the closing of the Transaction, and (iv) certain Transaction expenses as of the closing of the Transaction. At September 30, 2023 an additional $235,000 relating to a post-closing true-up adjustment is reflected in other current assets on the Company's condensed consolidated balance sheet, and an additional $450,000 reflected in other assets on the Company's condensed consolidated balance sheet is being held in an escrow account to satisfy certain indemnification obligations. Any amounts remaining in the Indemnity Escrow that have not been offset or reserved for claims will be released to us within five business days following the date that is 18 months after the closing of the Transaction.

The Company's cash balances as of the date that the accompanying financial statements were issued along with the proceeds from the above sale of Qualigen, Inc. to Chembio, without additional financing, are expected to fund operations into the first quarter of 2024. The Company expects to continue to have net losses and negative cash flow from operations, which over time 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. In order to fully execute our business plan, we will require significant additional funding for planned research and development activities, capital expenditures, clinical testing for our QN-302 clinical trials, preclinical development of RAS and QN-247, as well as commercialization activities.

Historically, our 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 we raised $3.0 million from the sale of a convertible debt instrument (see Note 8 - Convertible Debt - Related Party to our condensed consolidated financial statements). There can be no assurance that further financing will 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, which could adversely affect our business prospects.

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 our assets and discharge our liabilities in other than the normal course of business and at amounts that may differ from those reflected in the accompanying financial statements.

Our condensed consolidated balance sheet at September 30, 2023 includes $2.2 million of warrant liabilities. We do not consider the warrant liabilities to constrain our liquidity, as a practical matter. Our current liabilities at September 30, 2023 include $1.6 million of accounts payable, $1.1 million of accrued expenses and other current liabilities, $0.2 million of accrued vacation, $0.8 million convertible debt to a related party.

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 condensed consolidated 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. For example, we agreed to reimburse ULRF for sponsored research expenses of up to $2.9 million and prior patent costs of up to $112,000 for RAS. As of September 30, 2023, there was approximately $181,000 remaining due to ULRF under this sponsored research agreement for RAS. We also agreed to reimburse ULRF for sponsored research expenses of up to $830,000 and prior patent costs of up to $200,000 for QN-247. As of September 30, 2023, there were no remaining un-expensed amounts due to ULRF under this sponsored research agreement for QN-247 and the agreement was terminated effective August 31, 2022. 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, and we will be required to pay 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.) The program's lead compound is being developed by us under the name QN-302 as a candidate for treatment of pancreatic ductal adenocarcinoma (PDAC), which represents the vast majority of pancreatic cancers. The Agreement requires (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. On November 7, 2023 the Company announced that first patient dosing occurred for the Company's QN-302 clinical trial which triggered a $100,000 milestone payment obligation under this exclusive license agreement.

Alpha Convertible Debt

On December 22, 2022, we issued an 8% Senior Convertible Debenture in the aggregate principal amount of $3,300,000 (the "Debenture") to Alpha Capital for a purchase price of $3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022. The Debenture has a maturity date of December 22, 2025 and is convertible, at any time, and from time to time, until the Debenture is no longer outstanding, at Alpha Capital's option, into shares of our common stock, at a price equal to $1.32 per share, subject to adjustment and other terms and conditions described in the Debenture, including the Company's receipt of the necessary stockholder approvals, which were obtained at our 2023 annual meeting of stockholders on July 13, 2023.

In January 2023 Alpha Capital converted $1,111,078 of the Debenture principal into 841,726 shares of common stock at a conversion price of $1.32 per share.

Commencing June 1, 2023 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 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 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 common stock, based on a conversion price equal to the lesser of (i) the then applicable conversion price of the Debenture and (ii) 85% of the average of the VWAPs (as defined in the Debenture) for the five consecutive trading days ending on the trading day that is immediately prior to the applicable Monthly Redemption Date. We may also redeem some or all of the then outstanding principal amount of the Debenture at any time for cash in an amount equal to 105% of the then outstanding principal amount of the Debenture being redeemed plus accrued but unpaid interest, liquidated damages and any amounts then owing under the Debenture. Our election to pay monthly redemptions in shares of common stock or to effect an optional redemption is subject to the satisfaction of the Equity Conditions (as defined in the Debenture), including our receipt of the necessary stockholder approvals, which we obtained at our 2023 annual meeting of stockholders on July 13, 2023.

The Debenture accrues interest at the rate of 8% per annum, which does not begin accruing until December 1, 2023, and will be payable on a quarterly basis. Interest may be paid in cash or shares of common stock of the Company or a combination thereof at the option of the Company; provided that interest may only be paid in shares if the Equity Conditions have been satisfied, including our receipt of the necessary stockholder approvals, which we obtained at our 2023 annual meeting of stockholders.

During the three and nine months ended September 30, 2023, we recognized an extinguishment loss on voluntary conversion of convertible debt of $0 and approximately $1.1 million, respectively, and recorded accrued interest of approximately $368,000 and $1.3 million, respectively (of which approximately $350,000 and $1.2 million was a reduction to the discount, respectively) in other expenses in the condensed consolidated statements of operations. During the three and nine months ended September 2023 we paid Monthly Redemption Amounts of $330,000 and $440,000, respectively in cash, and as of September 30, 2023 the remaining Debenture principal balance was approximately $1.7 million, the remaining discount was approximately $0.9 million, the fair value of the Alpha Warrant was approximately $2.2 million, and the fair value of the suite of bifurcated embedded derivative features was $0.

NanoSynex Funding Agreement

As a condition to the NanoSynex Acquisition, we entered into the NanoSynex Funding Agreement with NanoSynex, pursuant to which we agreed to fund NanoSynex up to an aggregate of approximately $10.4 million over a three-year period, subject to NanoSynex's achievement of certain performance milestones specified in the NanoSynex Funding Agreement and the satisfaction of other terms and conditions described in the NanoSynex Funding Agreement.

These funding commitments were to be made in the form of convertible promissory notes to be issued to us with a face value equal to the amount paid by us to NanoSynex upon satisfaction of the applicable performance milestone, bearing interest at the rate of 9% per annum on the principal balance from time to time outstanding under the particular promissory note, convertible at our option into additional shares of NanoSynex in order for us to maintain at least a 50.1% controlling ownership interest in NanoSynex, should NanoSynex issue additional shares. During the year ended December 31, 2022, a total of approximately $2.4 million was funded to NanoSynex, and for the nine months ended September 30, 2023 an additional $0.5 million was funded to NanoSynex under the NanoSynex Funding Agreement.

On July 20, 2023, the Company entered into the NanoSynex Amendment, which amended the NanoSynex Funding Agreement with NanoSynex (the "NanoSynex 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 the Company's ownership in NanoSynex being reduced from approximately 52.8% to approximately 49.7% of the voting equity of NanoSynex. In addition, the Company agreed to cancel approximately $3.0 million of promissory notes issued to the Company under the NanoSynex Funding Agreement, relieving NanoSynex of any repayment obligations to the Company with respect to such notes. The surrender of shares reducing the Company's interest in NanoSynex from approximately 52.8% to approximately 49.97% occurred on July 20, 2023.

The NanoSynex Amendment supersedes any payment obligations contemplated by the original NanoSynex Funding Agreement and amended the Company's obligations to provide funding to NanoSynex, except that Company 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, in lieu of fulfilling such obligations, the Company may, and intends to, instead forfeit shares of Series A-1 Preferred Stock of NanoSynex in a number that will be equal to a fraction, the numerator of which is the amount of the default (*i.e.*, the amount that the Company should have, but failed, to advance to NanoSynex pursuant to the terms of the NanoSynex Amendment), and the denominator of which shall be the price per share that the Company originally paid in consideration for its Preferred A-1 shares of NanoSynex to the previous holder thereof, being $1.5716 per share.

The NanoSynex Amendment supersedes any payments contemplated by the NanoSynex Funding Agreement, such that except as described in the NanoSynex Amendment, we will have no further payment obligations to NanoSynex under the NanoSynex Funding Agreement or otherwise (including by way of equity investment, loan financing or credit lines), and NanoSynex will have no further payment obligations to us for advances previously received under the NanoSynex Funding Agreement.

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 Nine Months Ended September 30,	
	2023	**2022**
Net cash (used in) provided by:		
Operating activities	$ (4,632,677)	$ (11,009,815)
Investing activities	3,980,541	60,612
Financing activities	(440,000)	7,173
Effect of exchange rate on cash	—	27,523
Net decrease in cash and restricted cash	**$ (1,092,136)**	**$ (10,914,507)**

Net Cash Used in Operating Activities

During the nine months ended September 30, 2023, operating activities used $4.6 million of cash, primarily resulting from a loss from continuing operations of $10.0 million. Cash flows from operating activities for the nine months ended September 30, 2023 were positively impacted by adjustments for a $1.1 million non cash loss on voluntary conversion of convertible debt, accretion of discount of $1.2 million on convertible debt, $1.0 million in stock-based compensation expense, a $1.0 million increase in accounts payable, a $0.4 million increase in accrued expenses and other current liabilities, and cash provided by discontinued operations of $2.6 million. Cash flows from operating activities for the nine months ended September 30, 2023 were negatively impacted by adjustments for a $1.4 million decrease in fair value of warrant liabilities and a $0.6 million increase in prepaid expenses and other assets.

During the nine months ended September 30, 2022, operating activities used $11.0 million of cash, primarily resulting from a loss from continuing operations of $10.3 million. Cash flows from operating activities for the nine months ended September 30, 2022 were positively impacted by an adjustment for $4.1 million in stock-based compensation expense, Cash flows from operating activities for the nine months ended September 30, 2022 were negatively impacted by cash used in discontinued operations of $2.4 million, a $1.0 million decrease in fair value of warrant liabilities, a $0.7 million decrease in accrued expenses and other current liabilities, a $0.3 million decrease in accounts payable, and a $0.4 million increase in prepaid expenses and other assets.

Net Cash Provided by (Used in) Investing Activities

During the nine months ended September 30, 2023, net cash provided by investing activities was approximately $4.0 million from discontinued operations, due to $4.7 million in proceeds received from the sale of Qualigen, Inc., offset by $0.5 million advanced to NanoSynex, and $0.2 million in purchases of property and equipment prior to deconsolidation.

During the nine months ended September 30, 2022, net cash provided by investing activities was approximately $0.1 million from discontinued operations, primarily due to $0.7 million in cash acquired in the NanoSynex transaction, offset by the $0.6 million purchase of NanoSynex stock.

Net Cash Provided by Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2023 was approximately $0.4 million, due to monthly redemption payments on convertible notes payable.

Net cash provided by financing activities for the nine months ended September 30, 2022 was approximately $7,000, due to net proceeds from the exercise of warrants.

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 September 30, 2023, the end of the period covered by this Quarterly Report.

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 September 30, 2023 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, 2022, 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. Based on this assessment, our management concluded that, as of December 31, 2022, our internal control over financial reporting was not effective because of a material weakness in our internal control over financial reporting related to the lack of accounting department resources and/or policies and procedures to ensure recording and disclosure of items in compliance with generally accepted accounting principles. We have taken and continue to take steps to remediate the material weakness, including implementing additional procedures and utilizing external consulting resources with experience and expertise in U.S. GAAP and public company accounting and reporting requirements to assist management with its accounting and reporting of complex and/or non-recurring transactions and related disclosures.

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.

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 2022 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 2022 Annual Report.

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

Unregistered Sales of Equity Securities

None

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	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.	8-K	001-37428	2.4	5/29/2020
2.2	Stock Purchase Agreement, dated July 20, 2023, by and between Qualigen Therapeutics, Inc., Chembio Diagnostics, Inc., Biosynex, S.A., and Qualigen, Inc.	8-K	001-37428	2.1	7/26/2023
3.1	Amended and Restated Certificate of Incorporation	8-K	001-37428	3.1	7/1/2015
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-37428	3.1	9/15/2017
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-37428	3.1	3/22/2018
3.4	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	8-K	001-37428	3.1	5/29/2020
3.5	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]	8-K	001-37428	3.2	5/29/2020
3.6	Certificate of Merger, filed with the Delaware Secretary of State on May 22, 2020	8-K	001-37428	3.3	5/29/2020
3.7	Certificate of Amendment to the Certificate of Incorporation of the Company, filed with the Delaware Secretary of State on May 22, 2020 [name change]	8-K	001-37428	3.4	5/29/2020
3.8	Amended and Restated Bylaws of the Company, through August 10, 2021	8-K	001-37428	3.1	8/13/2021
3.9	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended	8-K	001-37428	3.1	11/22/2022
4.1	Warrant, issued by the Company in favor of Alpha Capital Anstalt, dated May 22, 2020	8-K	001-37428	10.13	5/29/2020
4.2	Form of Warrant, issued by the Company in favor of GreenBlock Capital LLC and its designees, dated May 22, 2020 [post-Merger]	8-K	001-37428	10.10	5/29/2020
4.3	Common Stock Purchase Warrant in favor of Alpha Capital Anstalt, dated July 10, 2020	8-K	001-37428	10.2	7/10/2020

4.4	Common Stock Purchase Warrant in favor of Alpha Capital Anstalt, dated August 4, 2020	8-K	001-37428	10.3	8/4/2020
4.5	"Two-Year" Common Stock Purchase Warrant for 1,348,314 shares in favor of Alpha Capital Anstalt, dated December 18, 2020	8-K	001-37428	10.3	12/18/2020
4.6	"Deferred" Common Stock Purchase Warrant for 842,696 shares in favor of Alpha Capital Anstalt, dated December 18, 2020	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

10.1	Amendment and Settlement Agreement, dated July 20, 2023, by and between Qualigen Therapeutics, Inc. and NanoSynex Ltd.	8-K	001-37428	10.1	7/26/2023
10.2	Consent and Waiver dated September 22, 2023, between Qualigen Therapeutics, Inc. and Alpha Capital Anstalt.	8-K	001-37428	10.1	9/28/2023
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.

November 14, 2023

By: */s/ Michael S. Poirier*
Name: Michael S. Poirier
Title: Chief Executive Officer (Principal Executive Officer)

November 14, 2023

By: */s/ Christopher L. Lotz*
Name: Christopher L. Lotz
Title: Vice President of Finance, Chief Financial Officer (Principal Financial Officer and Chief Accounting Officer)

Exhibit 31.1

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.

November 14, 2023

By: */s/ Michael S. Poirier*
Name: Michael S. Poirier
Title: Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

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.

November 14, 2023

By: */s/ Christopher L. Lotz*
Name: Christopher L. Lotz
Title: Vice President of Finance, Chief Financial Officer (Principal Financial Officer and Chief Accounting Officer)

Exhibit 32.1

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 September 30, 2023, 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.

November 14, 2023

By: */s/ Michael S. Poirier*
Name: Michael S. Poirier
Title: Chief Executive Officer (Principal Executive Officer)

November 14, 2023

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.