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

FORM 10-K

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

For the fiscal year ended December 31 , 2023

or

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

Commission File Number 001-37428

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

Delaware	**26-3474527**
(State or other jurisdiction of incorporation or organization)	**(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

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

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.001 per share	**QLGN**	**The Nasdaq Capital Market**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 emerging growth company. See 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2023, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $ 4,570,535 based on the closing price for the common stock of $0.91 on that date. Shares of common stock held by the registrant's executive officers and directors have been excluded from this calculation, as such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 25, 2024, there were 6,307,371 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements by Qualigen Therapeutics, Inc. that involve risks and uncertainties and reflect our judgment as of the date of this Report. These statements generally relate to future events or our 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 our expectations, strategy, plans or intentions. Such forward-looking statements may relate to, among other things, potential future development, testing and launch of products and product candidates. Actual events or results may differ from our expectations due to a number of factors.

These forward-looking statements include, but are not limited to, statements about:

- our ability to procure sufficient working capital to continue and complete the development, testing and launch of our prospective drug products;
- our ability to successfully develop any drugs;
- our ability to progress our drug candidates through preclinical and clinical development;
- our ability to obtain the requisite regulatory approvals for our clinical trials and to begin and complete such trials according to any projected timeline;
- our ability to complete enrollment in our clinical trials as contemplated by any projected timeline;
- the likelihood that future clinical trial data will be favorable or that such trials will confirm any improvements over other products or lack negative impacts;
- our ability to successfully commercialize any drugs;
- the likelihood that patents will issue on our in-licensed patent applications;
- our ability to protect our intellectual property; and
- our ability to compete.

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

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

PART I

As used in this Annual Report, unless the context suggests otherwise, "we," "us," "our,"or "the Company" refer to Qualigen Therapeutics, Inc.

Item 1. Business

Overview

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

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

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

On May 22, 2020, we completed a "reverse recapitalization" transaction with Qualigen, Inc. (not to be confused with the Company); pursuant to which our merger subsidiary merged with and into Qualigen, Inc. with Qualigen, Inc. surviving as a wholly owned subsidiary of the Company. The Company, which had previously been known as Ritter Pharmaceuticals, Inc., was renamed Qualigen Therapeutics, Inc., and the former stockholders of Qualigen, Inc. acquired, via the recapitalization, a substantial majority of the shares of the Company. Ritter/Qualigen Therapeutics common stock, which was previously traded on the Nasdaq Capital Market under the ticker symbol "RTTR," commenced trading on Nasdaq, on a post-reverse-stock-split adjusted basis, under the ticker symbol "QLGN" on May 26, 2020. We are no longer pursuing the gastrointestinal disease treatment business on which Ritter Pharmaceuticals, Inc. had focused before the reverse recapitalization transaction. On July 20, 2023, we sold our Qualigen, Inc. subsidiary, which contained our former FastPack® diagnostics business to Chembio Diagnostics, Inc., an American subsidiary of French diagnostics provider Biosynex, S.A. Accordingly, our former FastPack® diagnostics business is reported as Discontinued Operations in this Annual Report.

The aggregate net purchase price for Qualigen, Inc. was $5.4 million in cash, of which $450,000 is being held in escrow to satisfy certain Company indemnification obligations. Any amounts remaining in the escrow that have not been offset or reserved for claims will be released to us within five business days following January 20, 2025.

We own a minority interest in NanoSynex, Ltd. ("NanoSynex"), a privately-held microbiologics diagnostic company domiciled in Israel. NanoSynex's technology is for Antimicrobial Susceptibility Testing that aims to enable better targeting of antibiotics for their most suitable uses to ultimately result in faster and more efficacious treatment, hence reducing hospitals' mortality and morbidity rates. On May 26, 2022, we acquired a 52.8% interest in NanoSynex from our related party Alpha Capital Anstalt ("Alpha") and NanoSynex, and entered into a Master Agreement for the Operational and Technological Funding of NanoSynex with NanoSynex (the "NanoSynex Funding Agreement"). On July 20, 2023, we entered into an Amendment and Settlement Agreement with NanoSynex (the "NanoSynex Amendment"), pursuant to which we agreed to, in exchange for eliminating all future Funding Agreement obligations for us to invest further cash in NanoSynex (except for obligations to lend NanoSynex $560,000 on or before November 30, 2023, and $670,000 on or before March 31, 2024), surrender 281,000 Series B Preferred Shares of NanoSynex held by us, resulting in our ownership in NanoSynex being reduced from approximately 52.8% to approximately 49.97% of the voting equity of NanoSynex; in addition, we agreed to surrender approximately $3.0 million of promissory notes which NanoSynex had issued to us under the Funding Agreement. On November 22, 2023 we further agreed to eliminate our obligations to lend NanoSynex $560,000 on or before November 30, 2023, and $670,000 on or before March 31, 2024, by instead surrendering shares of Series A-1 Preferred Stock of NanoSynex in an amount that reduced our ownership in NanoSynex voting equity from approximately 49.97% to 39.90%. NanoSynex was deconsolidated from our financial statements as of July 20, 2023, and is reported as Discontinued Operations in this Annual Report. Our investment in NanoSynex will be accounted for in the future as an equity method investment.

Product Pipeline

QN-302

We exclusively in-licensed the global rights to the G-Quadruplex ("G4") selective transcription inhibitor platform from University College London ("UCL") in January 2022. The licensed technology comprises lead compound QN-302 (formerly known as SOP1812) and back-up compounds that target regulatory regions of cancer genes that down-regulate gene expression in multiple cancer pathways. Developed by Dr. Stephen Neidle and his group at UCL, the G4 binding concept is derived from nucleic acid research conducted over more than over 30 years, including research on G4s, which are higher order DNA and RNA structures formed by sequences containing guanine-rich repeats. G4s are overrepresented in telomeres (a region of repetitive DNA

sequences at the end of a chromosome) as well as promoter sequences and untranslated regions of many oncogenes. Their prevalence is therefore significantly greater in cancer cells compared to normal human cells.

G4-selective small molecules such as QN-302 and backup compounds target the regulatory regions of cancer genes, which have a high prevalence of enriched G4s. Stable G4-QN-302 complexes can be impediments to replication, transcription or translation of those cancer genes containing G4s, and the drugs' binding to G4s are believed to stabilize the G4s against possible "unwinding." G4 binders like QN-302 could be efficacious in a variety of cancer types with a high prevalence of G4s.

We believe that QN-302 has the potential to demonstrate superior efficacy and activity against pancreatic ductal adenocarcinoma ("PDAC"), which represents 98% of pancreatic cancers. Pancreatic cancer is the tenth most common cancer in men and the seventh most common in women, but it is the fourth leading cause of cancer deaths in men and the third leading cause in women; it accounts for about 3% of all cancers in the United States but is responsible for about 8% of all cancer-related deaths. It has one of the lowest rates of survival of all cancer types.

In-vitro and *in-vivo* studies have shown that G4 stabilization by QN-302 resulted in inhibition of target gene expression and cessation of cell growth in various cancers, including PDAC. In *in-vitro* studies, QN-302 was potent in inhibiting the growth of several PDAC cell lines at low nanomolar concentrations. Similarly, in *in-vivo* studies, QN-302 showed a longer survival duration in a KPC genetic mouse model for pancreatic cancer than gemcitabine (the current standard of care for PDAC) has historically shown. Additional preclinical *in-vivo* studies suggest activity in gemcitabine-resistant PDAC. Data further demonstrated that QN-302 had significant anti-tumor activity in three patient-derived PDAC xenograft models. Early safety indicators in pancreatic cancer mouse *in-vivo* models suggest no significant adverse toxic effects at proposed therapeutic doses.

On January 9, 2023, the U.S. Food and Drug Administration ("FDA") granted Orphan Drug Designation ("ODD") to QN-302 for the indication of pancreatic cancer. ODD provides advantages to pharmaceutical companies that are developing investigational drugs or biological products that show promise in treating rare diseases or conditions that affect fewer than 200,000 people in the United States, including seven-year marketing exclusivity and eligibility to receive regulatory support and guidance from the FDA in the design of an overall drug development plan.

There are also economic advantages to receiving ODD, including a 25% federal tax credit for expenses incurred in conducting clinical research on the orphan designated product within the United States. Tax credits may be applied to the prior year or applied to up to 20 years of future taxes. ODD recipients may also have their Prescription Drug User Fee Act (PDUFA) application fees waived, a potential savings of around $3.2 million (as of fiscal year 2023) for applications requiring covered clinical data, and may qualify to compete for research grants from the Office of Orphan Products Development that support clinical studies.

On August 1, 2023 we announced that the FDA had cleared our investigational new drug ("IND") application for QN-302, and on November 1, 2023 the first patient in our Phase 1a clinical trial for QN-302 was dosed at START Midwest in Grand Rapids, Michigan.

We will require additional cash resources to be able to continue and complete this Phase 1a clinical trial.

Pan-RAS (formerly referred to as RAS or RAS-F)

In July 2020 we entered into an exclusive worldwide in-license agreement with the University of Louisville's Research Foundation ("UofL" or "ULRF") for the intellectual property covering the "RAS" family of pan-RAS inhibitor small molecule drug candidates, which are believed to work by blocking RAS mutations directly, thereby inhibiting tumor formation (especially in pancreatic, colorectal and lung cancers). Pursuant to the license agreement, we will seek to identify and develop a lead drug candidate from the compound family and, upon commercialization, will pay UofL royalties in the low-to-mid-single-digit percentages on net sales of Pan-RAS inhibitor licensed products. The license agreement with UofL for Pan-RAS was amended in March 2021 and June 2023.

RAS is the most common oncogene in human cancer. Activating mutations in one of the three human RAS gene isoforms (KRAS, HRAS or NRAS) are present in about one-fourth to one-third of all cancers. For example, mutant KRAS is found in 98% of pancreatic ductal adenocarcinomas, 52% of colon cancers, and 32% of lung adenocarcinomas. For these three cancer types, cancers with mutant KRAS are diagnosed in more than 170,000 people each year in the United States and cause more than 120,000 deaths. Drugs that target signaling downstream of RAS are available; however, such drugs have shown disappointing clinical durability because RAS is a "hub" that activates multiple effectors, so drugs that block a single pathway downstream may not account for the many other activated pathways.

We also had a sponsored research agreement with UofL for Pan-RAS research; that agreement expired in December 2023.

We currently do not have the resources to advance our Pan-RAS program, and so we are seeking to out-license it.

On February 15, 2024, we entered into a License and Sublicense Agreement with Pan-RAS Holdings, Inc., a New York corporation ("Pan-RAS Holdings"), which contemplated an exclusive out-license of our Pan-RAS drug development program, including our rights under the ULRF license agreement, Pan-RAS Holdings.

Although the License and Sublicense Agreement called for a closing by March 16, 2024, the License and Sublicense Agreement was in essence structured as a 30-day option in favor of Pan-RAS Holdings.

At the contemplated closing, Pan-RAS Holdings would have paid us an upfront fee of $1,000,000 in cash. In addition, Pan-RAS Holdings would have become responsible to pay on our behalf our in-license royalty obligations to ULRF, as and when required.

Finally, if the contemplated closing had occurred, Pan-RAS Holdings would have required to pay to us for our own account, on a semiannual basis, royalties equal to 1.0% of net sales of any RAS products.

We would have owed certain amounts to ULRF under our in-license agreement from them, if, as and when we received any Non-Royalty Sublicensing Income from Pan-RAS Holdings.

Pan-RAS Holdings did not effectuate the closing by March 16, 2024, and we and they voluntarily terminated the License and Sublicense Agreement effective as of March 16, 2024.

Previous Programs

We have discontinued all of our efforts the following programs, and we do not plan to resume them:

1. ***QN-247(formerly referred to as ALAN or AS1411-GNP)*** – an oligonucleotide aptamer-based, nucleolin-inhibiting anticancer drug candidate, consisting of QN-165 conjugated with gold nanoparticles.

2. ***QN-165 (formerly referred to as AS1411)*** – an oligonucleotide aptamer-based drug candidate for the potential broad-spectrum treatment of infectious diseases such as COVID-19.

3. ***Selective Target Antigen Removal System (STARS)*** – a therapeutic blood-filtering device product concept, which would be designed to remove circulating tumor cells, viruses, inflammation factors and immune checkpoints.

Research and Development

For research and development of our drug candidates, we have historically leveraged the scientific and technical resources and laboratory facilities of UofL and UCL, through technology licensing, sponsored research, and other consulting agreements. We have engaged contract research organizations ("CROs") and clinical sites for the Phase 1a clinical trial of QN-302. We intend to focus our internal research and development on oversight of these CROs. We currently have no internal research and development facilities.

Regulatory Matters

We have obtained FDA clearance/approval for our QN-302 Phase 1a clinical trial. We have not obtained FDA or other regulatory approval for any other drug candidate.

United States—FDA Drug Approval Process

The research, development, testing, and manufacture of product candidates are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Food, Drug and Cosmetics Act and its implementing regulations.

The steps required to be completed before a drug may be marketed in the United States include, among others:

- preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin and for which progress reports must be submitted annually to the FDA;
- approval by an independent institutional review board ("IRB") or Ethics Committee ("EC") at each clinical trial site before each trial may be initiated;
- adequate and well-controlled human clinical trials, conducted in accordance with applicable IND regulations, Good Clinical Practices ("GCP"), and other clinical trial related regulations, to establish the safety and efficacy of the drug for each proposed indication to the FDA's satisfaction;
- submission to the FDA of a New Drug Application ("NDA") and payment of user fees for FDA review of the NDA (unless a fee waiver applies);
- satisfactory completion of an FDA pre-approval inspection of one or more clinical trial site(s) at which the drug was studied in a clinical trial(s) and/or of us as a clinical trial sponsor to assess compliance with GCP regulations;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current GMPs regulations;
- agreement with the FDA on the final labeling for the product and the design and implementation of any required Risk Evaluation and Mitigation Strategy; and
- FDA review and approval of the NDA, including satisfactory completion of an FDA advisory committee review, if applicable, based on a determination that the drug is safe and effective for the proposed indication(s).

Preclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application, which must become effective before human clinical trials may begin. An IND application will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND application, and places the clinical trial(s) on a clinical hold. In such a case, the IND application sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be certain that submission of an IND application will result in the FDA allowing clinical trials to begin.

Clinical trials necessary for product approval are typically conducted in three sequential phases, but the phases may overlap or be combined. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an IRB for each institution where the trials will be conducted, and each IRB must monitor the study until completion. Study subjects must provide informed consent and sign an informed consent form before participating in a clinical trial. Clinical testing also must satisfy the extensive GCP regulations for, among other things, informed consent and privacy of individually identifiable information.

- Phase 1—Phase 1 clinical trials involve initial introduction of the study drug in a limited population of healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the study drug in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2—Phase 2 clinical trials typically involve administration of the study drug to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—Phase 3 clinical trials typically involve administration of the study drug to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the study drug and to provide an adequate basis for product approval. Generally, adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after receiving initial marketing approval. These trials are

used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or, in certain circumstances, post-approval.

The FDA has various programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, which are intended to expedite or simplify the process for the development, and the FDA's review of drugs (*e.g.,* approving an NDA on the basis of surrogate endpoints subject to post-approval trials). Generally, drugs that may be eligible for one or more of these programs are those intended to treat serious or life-threatening diseases or conditions, those with the potential to address unmet medical needs for those disease or conditions, and/or those that provide a meaningful benefit over existing treatments. For example, a sponsor may be granted FDA designation of a drug candidate as a "breakthrough therapy" if the drug candidate is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is designated as breakthrough therapy, the FDA will take actions to help expedite the development and review of such drug. Moreover, if a sponsor submits an NDA for a product intended to treat certain rare pediatric or tropical diseases or for use as a medical countermeasure for a material threat, and that meets other eligibility criteria, upon approval such sponsor may be granted a priority review voucher that can be used for a subsequent NDA. From time to time, we anticipate applying for such programs where we believe we meet the applicable FDA criteria. A company cannot be sure that any of its drugs will qualify for any of these programs, or even if a drug does qualify, that the review time will be reduced.

The results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more proposed indications. The testing and approval process requires substantial time, effort and financial resources. Unless the applicant qualifies for an exemption, the filing of an NDA typically must be accompanied by a substantial "user fee" payment to the FDA. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product in the proposed patient population to the satisfaction of the FDA. After an NDA is accepted for filing, the FDA substantively reviews the application and may deem it to be inadequate, and companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved, but is not bound by the recommendations of the advisory committee.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured and determine whether the manufacturing and production and testing facilities are in compliance with cGMP regulations. The FDA also may audit the clinical trial sponsor and one or more sites at which clinical trials have been conducted to determine compliance with GCPs and data integrity. If the NDA and the manufacturing facilities are deemed acceptable by the FDA, it may issue an approval letter, and, if not, the Agency may issue a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication(s). A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also require, as a condition of NDA approval, post-marketing testing and surveillance to monitor the drug's safety or efficacy or impose other conditions, or a Risk Evaluation and Mitigation Strategy that may include both special labeling and controls, known as Elements to Assure Safe Use, on the distribution, prescribing, dispensing and use of a drug product. Once issued, the FDA may withdraw product approval if, among other things, ongoing regulatory requirements are not met, certain defects exist in the NDA, or safety or efficacy problems occur after the product reaches the market.

Intellectual Property

Information regarding our (in-licensed) issued patents and pending patent applications, as of December 31, 2023, is as follows (excluding patents and pending patent applications which pertain to programs which we have discontinued). As of that date we did not have any directly-owned issued patents and pending patent applications.

Subject Matter	Issued	Pending	Geographic Scope	Patent Term
In-Licensed Patents				
University College London (UCL)				
QN-302	3	10	U.S., Europe, Australia, Canada, China, Hong Kong, India, Japan, Korea, Russia	2030-2040
University of Louisville (ULRF)				
Pan-RAS	0	12	U.S., Europe, Australia, Canada, China, Hong Kong, India, Israel, Japan, Korea, Mexico, Russia, South Africa	2039*
TOTAL	**3**	**22**		

**Anticipated patent term*

Human Capital Management

As of March 25, 2024, we had 4 employees, all of whom were full-time. None of our employees is represented by a labor union or covered by a collective bargaining agreement.

Diversity & Inclusion. With respect to our employees overall, fifty percent (50%) are women and 0% are people of color.

Additional Information

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 the "reverse recapitalization" transaction with Qualigen, Inc., Ritter Pharmaceuticals, Inc. was renamed Qualigen Therapeutics, Inc. and Qualigen, Inc. became a wholly-owned subsidiary of the Company. On July 20, 2023 we sold Qualigen Inc. to ChemBio Diagnostics, Inc., an American subsidiary of French diagnostics provider Biosynex S.A.

Our website address is *www.qlgntx.com*. We post links to our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, information statements, beneficial ownership reports and any amendments to those reports or statements filed or furnished pursuant to Sections 13(a), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All such filings are available through our website free of charge. However, the information contained on or accessed through our website does not constitute part of this Annual Report, and references to our website address in this Annual Report are inactive textual references only. All such reports are also available free of charge via EDGAR through the SEC website at *www.sec.gov*.

Item 1A. Risk Factors

An investment in our common stock involves risks. You should carefully consider the risks described below, together with all of the other information included in this Annual Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below, which are the risks we judge (rightly or wrongly) to be the most significant to investors, are not the only ones we face. Additional risks that we currently do not judge to be among the "most significant" may also impair our business, financial condition, operating results and prospects.

Certain statements below are forward-looking statements. For additional information, see the section of this Annual Report under the caption "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to Our Business Generally

Our business strategy is high-risk

We are focusing our resources and efforts on development of drug product candidates, which requires extensive cash needs for research and development activities. This is a high-risk strategy because there is no assurance that that our cash resources will be adequate to develop our product candidates, that our product candidates will ever be proven to be safe and effective or that any products will ever become commercially viable. This makes our stock an unsuitable investment for many investors.

We do not currently have enough working capital to execute our strategic plan .

We have suffered recurring losses from operations, and we are now essentially a non-revenue company. We will need capital to maintain our operations and to support our intended development of our therapeutics business. Future financings will be necessary in order for us to survive as a going concern and to properly execute our strategic plan. However, there can be no assurance that such future financings will be available to us (or, if they are, that they can be consummated on desirable terms).

We may, in the short and long-term, seek to raise capital through the issuance of equity securities or through other financing sources. To the extent that we seek to raise additional funds by issuing equity or equity-linked securities, our stockholders may (as has already occurred several times) experience significant dilution. Any debt financing, if available, may include financial and other covenants that could restrict our use of the proceeds from such financing or impose other business and financial restrictions on us. In addition, we may consider alternative approaches such as licensing, joint venture, or partnership arrangements to provide short term or long term capital. Additional funding may not be available to us 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, a related party and the holder of our 8% Senior Convertible Debenture and of our 8% Convertible Debenture (together, the "Debentures"), and/or trigger certain adjustments to the conversion prices of the Debentures or to the exercise prices of warrants held by Alpha and/or by other persons. See Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" for additional details regarding the Debentures.

Servicing our debt will require a significant amount of cash, and we do not expect to have sufficient cash flow from our business to pay this debt.

Our ability to make payments to Alpha of principal or interest on the Debentures or to make any potential prepayments for the Debentures, to the extent applicable, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our cash resources currently on hand, plus any anticipated near-term cash flow from operations or dispositions, would not be sufficient to service our indebtedness and/or to make necessary expenditures.

In December 2022, we entered into a Securities Purchase Agreement with Alpha and in exchange for $3,000,000 in cash (less $50,000 for expense reimbursement) issued to Alpha our 8% Senior Convertible Debenture with an original face amount of $3,300,000 due on December 22, 2025 (the "2022 Debenture"), plus 2,500,000 common stock warrants exercisable (from June 22, 2023 through June 22, 2028) at $1.65 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 2022 Debenture (each such date, a "Monthly Redemption Date"), we must redeem $110,000 plus accrued but unpaid interest, liquidated damages and any amounts then owing under the 2022 Debenture (the "Monthly Redemption Amount"). The Monthly Redemption Amount must be paid in cash; provided that after the first two monthly redemptions, we may (if the Equity Conditions, as defined in the 2022 Debenture, are then satisfied or have been waived) elect to pay all or a portion of a Monthly Redemption Amount in shares of our common stock, based on a conversion price equal to the lesser of (i) the then applicable conversion price of the 2022 Debenture and (ii) 85% of the average of the VWAPs (as defined in the 2022 Debenture) for the five consecutive trading days ending on the trading day that is immediately prior to the applicable Monthly Redemption Date.

The 2022 Debenture accrues interest at the rate of 8% per annum, which began accruing on December 1, 2023, and will be payable on a quarterly basis. Interest may be paid in cash or shares of common stock or a combination thereof at our option; provided that the Equity Conditions have been satisfied.

Alpha has waived the Equity Conditions for certain Monthly Redemption Amounts, but Alpha is not required to continue such waivers beyond May 2024. For the foreseeable future, we do not expect to be able to satisfy the Equity Conditions; as a result, where there is no waiver of the Equity Conditions we would not have the opportunity to make 2022 Debenture payments in the form of stock rather than in the form of cash, even for types of payments for which payment in the form of stock would have been allowed.

The 2022 Debenture is convertible into our common stock at any time at the holder's option; the conversion price was originally $1.32 but pursuant to a Securities Purchase Agreement amendment in December 2023 it was reduced to $0.73 and then in February 2024 it was adjusted downward to $0.26 per share by virtue of the operation of a "ratchet" antidilution provision. (The exercise price of the warrants issued with the 2022 Debenture was originally $1.65 but pursuant to a Securities Purchase Agreement amendment in December 2023 it was reduced to $0.73 and then in February 2024 it was adjusted downward to $0.26 per share by virtue of the operation of a "ratchet" antidilution provision.)

Other than the Monthly Redemption Amounts, the 2022 Debenture does not call for scheduled payments of principal before the scheduled maturity date.

Both the 2022 Debenture and the accompanying warrants provide for "ratchet" antidilution adjustments to their conversion price and exercise price.

Both the 2022 Debenture and the accompanying warrants include a beneficial ownership blocker of 9.99%, which may only be waived by Alpha upon 61 days' notice to the Company.

We granted Alpha resale registration rights for the common shares underlying the 2022 Debenture and the accompanying warrants.

The December 2023 amendment of the 2022 Debenture conversion price (and the accompanying warrants' exercise price) to be $0.73 per share resulted in the 2022 Debenture's then current $1,528,922 principal amount thereof becoming convertible into 2,094,414 shares of Company common stock (as opposed to the 1,158,274 shares into which such outstanding principal amount was convertible pre-adjustment). Also, the December 2023 amendment triggered a "ratchet" antidilution adjustment in the Company's outstanding "exploding" "Series C Warrants," resulting in such Series C Warrants becoming exercisable for 455,623 common shares (at an exercise price of $0.73 per share), as opposed to the 251,971 common shares into which such outstanding Series C Warrants would have been exercisable (at $1.32 per share) pre-adjustment. Finally, the $0.73 price triggered a "ratchet" antidilution adjustment in the exercise price of other outstanding Company common stock warrants, including 7,048 warrants held by Alpha and 67,620 warrants held by other persons, which were previously exercisable at $1.32 per share.

In February 2024, we entered into a Securities Purchase Agreement with Alpha and in exchange for $500,000 in cash (less $25,000 for expense reimbursement) issued to Alpha an 8% Convertible Debenture with a face amount of $550,000 due on December 31, 2024 (the "2024 Debenture"), plus 900,016 5-year common stock warrants exercisable at $0.26 per share. In addition, per this Securities Purchase Agreement Alpha obtained an option to purchase additional 8% Convertible Debentures, of like tenor, with face amounts of up to an aggregate of $1,100,000 (and with a proportional number of accompanying common stock warrants of like tenor, up to a total of 1,800,032 additional warrants), which would (if and when Alpha exercises such option) provide us up to an additional $1.0 million in cash proceeds (less expense reimbursement, and not including any possible cash proceeds from any future exercise of the additional warrants). This option is valid through July 1, 2024.

The 2024 Debenture has a maturity date of December 31, 2024 and is convertible, at any time, and from time to time, at Alpha's option, into shares of our common stock, at $0.6111 per share. The 2024 Debenture does not call for scheduled payments of principal or interest before the scheduled maturity date. Interest on the 2024 Debenture accrues on its outstanding principal balance at the rate of 8% per annum.

Both the 2024 Debenture and the accompanying warrants provide for "ratchet" antidilution adjustments to the Conversion Price and Exercise Price.

Both the 2024 Debenture and the accompanying warrants include a beneficial ownership blocker of 9.99%, which may only be waived by Alpha upon 61 days' notice to the Company.

We granted Alpha "piggyback" registration rights for the common shares underlying the 2024 Debenture and the accompanying warrants.

The $0.26 exercise price of the warrants issued with the 2024 Debenture triggered a "ratchet" antidilution adjustment in the 2022 Debenture, resulting in the then current $1,198,922 principal amount thereof becoming convertible into 4,611,238 shares of Company common stock (as opposed to the 1,642,359 shares into which such outstanding principal amount were convertible pre-adjustment). Also, the $0.26 exercise price of the warrants issued with the 2024 Debenture triggered a "ratchet" antidilution adjustment in the Company's outstanding "exploding" "Series C Warrants," resulting in such Series C Warrants becoming exercisable for 1,279,261 common shares (at an exercise price of $0.26 per share), as opposed to the 455,623 common shares into which such outstanding Series C Warrants would have been exercisable (at $0.73 per share) pre-adjustment. Finally, the $0.26 exercise price of the Warrant would trigger a "ratchet" antidilution adjustment in the exercise price of other outstanding Company common stock warrants, including 2,507,048 warrants held by Alpha and 67,620 warrants held by other persons, all of which were previously exercisable at $0.73 per share.

If we continue to lack cash resources sufficient to service our indebtedness, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or issuing additional equity, equity-linked or debt instruments on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. If we are unable to engage in any of these activities or engage in these activities on desirable terms, we may be unable to meet our debt obligations, which would materially and adversely impact our business, financial condition and operating results or even put us out of business.

Risks Related to Our Product Pipeline

Our product candidates are still in the early stages of development. Although we have begun Phase 1a clinical trials for QN-302, we might be unable to obtain further regulatory approval for QN-302 or any other drug candidate. We may never obtain marketing approval for any of our drug candidates.

We are still early in our Pan-RAS development efforts and have not yet sought approval for, or begun enrollment, in any clinical trials evaluating Pan-RAS. There can be no assurance that any of our drug product candidates will achieve success in their clinical trials or obtain regulatory approval.

Our ability to generate revenues from our drug product candidates will depend on the successful development and eventual commercialization of such drug candidates. The success of these products will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- acceptance of an IND application by the FDA or other clinical trial or similar applications from foreign regulatory authorities for our future clinical trials for our pipeline;
- timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;
- demonstration of safety, efficacy and acceptable risk-benefit profiles of our products to the satisfaction of the FDA and foreign regulatory agencies;
- receipt and related terms of marketing approvals from applicable regulatory authorities, including the completion of any required post-marketing studies or trials;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our products;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our drugs, if and when approved, by patients, the medical community and third-party payors;

- effectively competing with other therapies;
- obtaining and maintaining third-party payor coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of the products following approval.

Many of these factors are beyond our control, and it is possible that none of our drug candidates will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates. For example, our business could be harmed if results of the clinical trials of QN-302, Pan-RAS or any other drug candidates vary adversely from our expectations.

Drug development involves a lengthy and expensive process. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug product candidates.

Most drug candidates fail, and taking a drug candidate from concept through clinical trials and regulatory approval is not easy or guaranteed. We are unable to predict when or if our drug candidates, will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of these products, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of these products for humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial do not necessarily predict final results.

We may experience numerous unforeseen events that could delay or prevent our ability to obtain marketing approval or commercialize our drug candidates, including:

- we may not be able to obtain enough capital to begin clinical trials ort to complete any already-begun clinical trials, or to complete any necessary preclinical studies;
- regulators or IRBs or ECs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials for our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay clinical trials or abandon product development programs;
- the number of patients required for clinical trials for our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in our clinical trials;
- our third-party contractors may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend or terminate clinical trials for our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- our drug candidates may have undesirable or unexpected side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs/ECs to suspend or terminate the trials;
- the cost of clinical trials for our drug candidates may be greater than we anticipate; and
- the supply or quality of our drug candidates, or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of our clinical trials.

Our product development costs will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, the FDA may place a partial or full clinical hold on any of our clinical trials for a variety of reasons.

Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates.

Any delays in the commencement or completion, or termination or suspension, of our current clinical trial or our future clinical trials, if any, could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before we can initiate clinical trials of a drug candidate, we must submit the results of preclinical studies to the FDA along with other information as part of an IND application or similar regulatory filing, and the FDA (or corresponding foreign regulatory body) must approve the application.

Before obtaining marketing approval from the FDA for the sale of QN-302, Pan-RAS or any other future drug candidate, we must conduct extensive clinical studies to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. The FDA may require us to conduct additional preclinical studies for any drug candidate before it allows us to initiate clinical trials under any IND application, which may lead to additional delays and increase the costs of our preclinical development programs.

Any delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly increase our costs, slow down

our development and approval process and jeopardize our ability to commence product sales and generate revenues. We do not know whether our planned trials will begin on time or at all, or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- our ability to pay for the costs and expenses for the clinical trials;
- the FDA disagreeing as to the design or implementation of our clinical trials or with our recommended dose for any of our pipeline programs;
- obtaining FDA authorization to commence a trial or reaching a consensus with the FDA on trial design;
- obtaining approval from one or more IRBs/ECs;
- IRBs/ECs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- failing to manufacture or obtain sufficient quantities of drug candidate, or, if applicable, combination therapies for use in clinical trials;
- patients failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- patients choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- patients experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selecting or being required to use clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our drug candidates, or any of their components, including without limitation, our own facilities being ordered by the FDA to temporarily or permanently shut down due to violations of cGMP, regulations or other applicable requirements, or infections or cross-contaminations in the manufacturing process;
- lack of stability of our clinical trial material or any quality issues that arise with the clinical trial material;

- any changes to our manufacturing process that may be necessary or desired;
- Our, or our third-party contractors, not performing data collection or analysis in a timely or accurate manner or improperly disclosing data prematurely or otherwise in violation of a clinical trial protocol; or
- any third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs/ECs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the product under investigation, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs/ECs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays or difficulties enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to initiate or continue our ongoing or planned clinical trials for our products if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. In addition, some of our competitors may have ongoing clinical trials for products that would treat the same patients as QN-302 or Pan-RAS, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' products. In addition, introduction of new drugs or devices to the marketplace may have an effect on the number of patients available or timing of the availability of the patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

Adverse side effects or other safety risks associated with our drug product candidates could delay or preclude approval, cause us to suspend or discontinue any clinical trials or abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any.

Results of our current and planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our products could result in the delay, suspension or termination of clinical trials by us or the FDA for a number of reasons.

Moreover, if our products are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for our products, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many drug candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our drug candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our drug candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients.

The development and commercialization of pharmaceutical and device products are subject to extensive regulation, and we may not obtain regulatory approvals for any product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to drug product candidates such as ours are subject to extensive regulation.

We rely, and intend to continue to rely, on third parties to conduct our preclinical studies and clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval.

We are dependent on third parties to conduct our planned preclinical studies and clinical trials of our drug product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. We have relied heavily on UofL for preclinical studies related to Pan-RAS, and we expect to rely heavily on CROs and sponsored academic researchers for any further preclinical studies. As to any clinical trials, we expect to rely on CROs, sponsored academic researchers, clinical investigators and/or consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, including GCP, requirements, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities.

There is no guarantee that any such CROs, clinical trial investigators and/or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If one of our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our drug product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We contract with third parties for the manufacture of our product candidates for preclinical testing and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We rely, and expect to continue to rely, on third parties for the manufacture of our products for preclinical and any clinical testing, as well as for future commercial manufacture if any of our product candidates obtain regulatory approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We may be unable to establish any agreements with third-party manufacturers or to do so on favorable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third-party for regulatory, compliance and quality assurance;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of an FDA Form 483 notice or warning letter;
- the possible breach of the manufacturing agreement by the third-party; and
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

We do not have manufacturing agreements in place for any of our current drug candidates. We acquire many key materials on a purchase order basis. As a result, we do not have long-term committed arrangements with respect to our product candidates and other materials. If we obtain regulatory approval for any of our product candidates, we will need to establish an agreement for commercial manufacture with a third-party.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance for QN-302 or Pan-RAS.

We will need to seek and enter into out-licenses or collaborations with third parties for the development and commercialization of our products, resulting in a limitation of our upside potential.

We expect that we will need third-party out-licensees or collaborators for the development and commercialization of our products.

Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that such collaborators dedicate to the development or commercialization of our products. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Any out-license or collaboration will necessarily result in a sharing of economics with the out licensee or collaborator, which might otherwise have been captured by us directly.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our therapeutic product candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected.

Our commercial success depends significantly on our ability to protect our proprietary (and exclusively in-licensed) product candidates or technologies that we believe are important to our business, including pursuing, obtaining and maintaining patent protection in the United States and other countries intended to cover the composition of matter of our product candidates, the methods of use, related technologies, and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. If we do not adequately pursue, obtain, maintain, protect or enforce our intellectual property, third parties, including our competitors and/or collaborators, may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Moreover, depending on the terms of any license agreements to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain or defend the patents, covering technology licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and product candidates. Our licensors have not filed patent applications in every jurisdiction, and some filings are only pending in the United States.

Moreover, because the issuance of a patent, although presumptive, is not conclusive as to its inventorship, scope, validity or enforceability, our licensors' patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in the patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and technologies or limit the duration of the patent protection of our products and technologies. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Our licensors' pending and future patent applications may not result in patents being issued that protect our product candidates and technologies, in whole or in part, or that effectively prevent others from commercializing competitive products and technologies. Even if the patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors and other third parties may be able to circumvent our licensors' patents by developing similar or alternative products or technologies in a non-infringing manner. Our competitors and other third parties may also seek approval to market their own products and technologies similar to or otherwise competitive with our products and technologies. Alternatively, our competitors or other third parties may seek to market generic versions of any approved products by submitting abbreviated NDAs to the FDA during which process they may claim that patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our licensors' patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensors' patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have in-licensed valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The term of our in-licensed patents may be inadequate to protect our competitive position on our products.

Given the amount of time required for the development, testing and regulatory review of drug candidates, our in-licensed patents protecting such candidates might expire before or shortly after such candidates are commercialized. In such an event (and if we are unable to obtain patent term extension or the term of any such extension is less than we request), our competitors and other third parties may be able to obtain approval of competing products following patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Generic competition usually results in serious price erosion for the original drug brand.

Risks Related to Employee Matters, Potential Dilution, Stock Price Variability and Other Risks Related to Our Business

Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel.

We are highly dependent on Michael Poirier, our Chief Executive Officer and Chairman, and Christopher Lotz, our Vice President and Chief Financial Officer. In addition, the rest of our team has been sharply reduced due to rightsizing, voluntary departures and the disposition of our Qualigen, Inc. diagnostics-products subsidiary – we currently have only two other employees.

Our ability to compete depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, clinical, regulatory, manufacturing and management skills and experience. We may not be able to attract or retain qualified personnel in the future. Many of the companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors (as well as our own limited resources) may limit our ability to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our product candidates and to grow our business and operations as currently contemplated.

We will need to rebuild our development and regulatory teams.

Due to rightsizing, voluntary departures and the disposition of Qualigen, Inc. and our former FastPack®products business, we currently have only four employees. Although we outsource many drug development functions and may choose to continue to do so in the future, we expect that (resources allowing) to recruit and retain more employees in all areas, and particularly in the areas of clinical development, clinical operations, and regulatory affairs (and maybe, longer-term, in areas such as manufacturing, sales, marketing and distribution). We will also need to implement and improve our managerial, operational and financial systems, and obtain stage-appropriate facilities. We do not currently have the cash resources needed for any of the above.

We currently rely, and for the foreseeable future will continue to rely, in substantial part, on certain third-party contract research organizations and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials. We cannot assure that the services of such third-party contract research organizations and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services

provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated. We cannot assure that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

We may engage in strategic transactions that could impact liquidity, increase expenses and present significant distractions to management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, businesses or assets and out-licensing or in-licensing of products, drug candidates or technologies. Potential transactions that we may consider include a variety of different business arrangements, including spin-offs, in-licensing, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase near term or long-term expenditures and may pose significant integration challenges or disrupt management or business, which could adversely affect our operations and financial results. These transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of business and diversion of management's time and attention in order to develop acquired products, drug candidates or technologies;

- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations, systems and personnel of any acquired businesses with our operations, systems and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Our minority-interest investment in NanoSynex is illiquid and has many risks associated with it.

Our investment in NanoSynex has been reduced to a 39% equity interest and has a number of risks associated with it, including, among others, the following:

- a history of operating losses, with no assurance of future revenues or operating profits;
- uncertainty as to the availability to NanoSynex of the cash resources it needs to execute its plans;
- technological risk;
- our inability, now that we are no longer a majority shareholder of NanoSynex, to control or veto NanoSynex's decisions;
- risks associated with the development of medical devices and NanoSynex's ability to obtain the necessary regulatory approvals for the development and commercialization of its antimicrobial susceptibility test platform;
- very limited manufacturing, marketing, distribution and sales capabilities;
- competition from both public and private companies and academic collaborators, many of which have significantly greater experience and financial resources;
- acceptance by life sciences research and diagnostic communities is not assured;
- commercial development of its antimicrobial susceptibility test platform is not assured;
- an inability to manufacture, market or sell its proposed products if it is unsuccessful in entering into strategic alliances or joint ventures with third parties; and
- risks related to the political, economic and military conditions in Israel.

In addition, NanoSynex is a privately-held company and its shares are illiquid, which means that we could not readily obtain cash in exchange for some or all of our equity interest. We no longer hold any NanoSynex debt instruments.

Our reported financial condition may fluctuate significantly from quarter to quarter and year to year, which makes them difficult to predict or understand.

We expect our financial condition and results of operations to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not blindly rely upon the results of any quarterly or annual periods as indications of future financial status or operating performance. Other investors may, however, attach undue significance to reported results which are heavily influenced by such distortions and variability, which in turn could cause our stock price to rise or fall despite there being no corresponding change in our prospects or position as a practical matter.

We have a substantial amount of derivative securities outstanding.

As of December 31, 2023 there were 398,924 stock options outstanding under our equity incentive plans, 3,081,717 outstanding warrants, and 1,943,729 shares issuable upon voluntary conversion of principal amount of the 2022 Debenture issued to Alpha. (At December 31, 2023, such principal amount was $1,418,922) Due to antidilution adjustments occurring as a result of the 2024 Debenture transaction in February 2024, the outstanding principal balance of the 2022 Debenture (which at March 25, 2024 was $1,088,922) is now convertible upon voluntary conversions into 4,188,162 shares; and in addition the 2024 Debenture's principal amount is convertible upon voluntary conversions into 900,016 shares, and the warrants issued with the 2024 Debenture are exercisable for 900,016 shares.

The 2022 and 2024 Debentures issued to Alpha are convertible, at any time, and from time to time, at Alpha's option, into shares of our common stock, subject to the terms and conditions described in the Debentures. Currently the conversion price for such optional conversions is $0.26 per share for the 2022 Debenture and $0.6111 per share for the 2024 Debenture. Furthermore, subject to certain terms and conditions described in the 2022 Debenture, we may elect to pay all or a portion of the Monthly Redemption Amount and/or interest required by the 2022 Debenture in shares of our common stock.

The issuance of shares upon the exercise or conversion of outstanding stock options, warrants and the Debentures (or our election to pay amounts owed under the Debentures in shares of our common stock) could result in significant dilution to the holders of our existing outstanding common stock.

We rely significantly upon information technology, and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively and result in a material disruption of our product development programs.

We utilize information technology systems to transmit and store information, including sensitive personal information and proprietary or confidential information, and otherwise to support our business and process. In the future, our systems may prove inadequate to our business needs and necessary upgrades may not operate as designed, which could result in excessive costs or disruptions in portions of our business. In particular, any disruptions, delays or deficiencies from our enterprise resource planning systems could adversely affect our ability to, among other matters, process orders, procure supplies, manufacture and ship products, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We could also be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company. Outside parties may attempt to penetrate our systems or those of our partners or fraudulently induce our employees or employees of our partners to disclose sensitive information to gain access to our data. Like other companies, we may experience threats to our data and systems, including malicious codes and computer viruses, cyber-attacks or other system failures. Furthermore, a security breach could be facilitated by ineffective protection measures, employee errors or omissions, and malfeasance. Despite our efforts to protect against cyber-attacks and security breaches, hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend substantial additional resources to continue to protect against potential security breaches or to remediate problems caused by such attacks or any breach of our safeguards. Any system failure, accident or security breach that causes interruptions in our operations, for us or our partners, could result in a material disruption of our product development programs and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. For example, the loss of clinical trial data from completed clinical trials could result in delays in our regulatory approval efforts and we could incur significant increases in costs to recover or reproduce the data. The risk of cyber incidents could also be increased by cyberwarfare in connection with the ongoing war in Ukraine, including potential proliferation of malware from the conflict into systems unrelated to the conflict. To the extent that any disruption or security breach results in a loss of, or damage to, our data or applications, or inappropriate public disclosure of confidential or proprietary information, we may incur liabilities and the further development of our product candidates may be delayed.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We are located in southern California and are subject to risks posed by natural disasters, including wildfires, earthquakes and severe weather that may interfere with our operations. Extreme weather events and other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that damaged critical infrastructure, such as the facilities of our third-party clinical sites or contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Any disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event.

Any failure to develop or maintain effective internal controls over financial reporting or difficulties encountered in implementing or improving our internal controls over financial reporting could harm our operating results and prevent us from meeting our reporting obligations.

Effective internal controls, particularly those related to financial reporting, are necessary for us to produce reliable financial reports. If we cannot provide reliable financial reports, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly. In addition, investors relying upon this misinformation could make an uninformed investment decision, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities or to stockholder class action securities litigation.

As previously described in our annual report on Form 10-K for the year ended December 31, 2021, in connection with the audit of our financial statements as of and for the year ended December 31, 2021 (the "2021 audit"), our management identified 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 U.S. GAAP. This material weakness resulted in adjustments to our warrant valuations in connection with the 2021 audit. In response to the material weakness, we took a number of remediation steps to enhance our internal controls, 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.

In connection with the audit of our financial statements as of and for the year ended December 31, 2022 (the "2022 audit"), our management determined that the material weakness identified in connection with the 2021 audit had not been fully remediated and resulted in adjustments to the accounting treatment related to convertible debt, the business combination and goodwill impairment during the 2022 audit, which resulted in the late filing of the 2022 Annual Report.

In connection with the audit of our financial statements as of and for the year ended December 31, 2023, our management identified material weaknesses in our internal control over financial reporting related to limited accounting personnel and resources resulting in lack of segregation of duties, and to the fact that we have not designed and implemented effective Information Technology General Controls related to access controls to financing accounting systems.

We intend to continue to take steps to enhance our internal controls, including implementing additional internal procedures and utilizing well-established external consulting resources with experience and expertise in U.S. GAAP and public company accounting and reporting requirements.

If we are unable to remediate the material weaknesses and achieve and maintain effective internal control over financial reporting and effective disclosure controls, our business could be adversely affected.

Our right to use our "shelf" Form S-3 registration statement is sharply limited.

We filed a Form S-3 "shelf" registration statement with the SEC for the issuance of up to $150,000,000 of securities, and the SEC declared the registration statement effective on August 5, 2022. However, due to the "baby shelf" rules adopted by the SEC, the maximum amount of securities we can sell under this registration is now limited to one-third of our public float. Because our public float is very modest (e.g., $2.9 million at December 31, 2023), the maximum amount we could sell using this registration statement was under $1.0 million at that time. Therefore, the registration statement no longer constitutes an important tool for accessing the public markets to satisfy our needs for capital.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so.

On April 20, 2023, we received a notification letter from the Listing Qualifications Department of Nasdaq indicating that, as a result of our delay in filing the 2022 Annual Report, we were not in compliance with the timely filing requirements for continued listing under Nasdaq Listing Rule 5250(c)(1). The notification letter had no immediate effect on the listing or trading of our common stock on the Nasdaq Capital Market. On May 2, 2023, the Company filed the Form 10-K with the SEC and was subsequently notified by Nasdaq on May 4, 2023 that it had regained compliance with Nasdaq's listing rule 5250(c)(1) as a result thereof and that the matter was closed.

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

The Bid Price Deficiency Notice has no immediate effect on the listing of the Company's common stock on The Nasdaq Capital Market. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has been provided an initial compliance period of 180 calendar days, or until May 20, 2024 to regain compliance with the Minimum Bid Price Requirement. During the compliance period, the Company's shares of common stock will continue to be listed and traded on The Nasdaq Capital Market. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period.

In the event the Company is not in compliance with the Minimum Bid Price Requirement by May 20, 2024, the Company may be afforded a second 180 calendar day grace period.

The Company intends to actively monitor the bid price for its common stock between now and May 20, 2024 and will consider available options to regain compliance with the Minimum Bid Price Requirement.

On November 21, 2023, the Company also received a letter (the "Equity Deficiency Letter") from Nasdaq notifying the Company that, based on the Company's stockholders' deficit of ($1,640,552) as of September 30, 2023, as reported in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, it is no longer in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1), which requires listed companies to maintain stockholders' equity of at least $2.5 million (the "Minimum Stockholders' Equity Requirement"), or the alternative criteria of $35 million market value of listed securities or $500,000 in net income from continuing operations in the most recent fiscal year or two or the last three fiscal years—which alternatives, as noted in the Equity Deficiency Letter, the Company does not meet. The Company was given until January 5, 2024 to provide Nasdaq with a specific plan (the "Compliance Plan") to achieve and sustain compliance with the Minimum Stockholders' Equity Requirement or its alternatives. If the Company's Compliance Plan is accepted, Nasdaq may grant an extension of up to 180 calendar days from the date of the Equity Deficiency Letter for the Company to evidence compliance.

The Company submitted a Compliance Plan to Nasdaq on January 5, 2024 to regain compliance with the Nasdaq Listing Rules. The Compliance Plan was accepted by Nasdaq and the Company was granted an extension of up to 180 calendar days from the date of the Equity Deficiency Letter (i.e., until May 20, 2024) for the Company to evidence compliance. If the Company does not regain compliance within the requisite time period, or if the Company fails to satisfy another Nasdaq requirement for continued listing, Nasdaq could provide notice that the Company's securities will become subject to delisting, which delisting determination the Company has the right to appeal.

If we are unable to maintain compliance with Nasdaq's continued listing requirements, and in the event of a delisting, we would take action to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's other listing requirements.

Losing our Nasdaq other listing would seriously harm us, by undermining our ability to raise capital and decreasing our attractiveness to possible merger partners.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity

Our processes for assessing, identifying, and managing material risks from cybersecurity threats are not advanced. None of our personnel are trained specialists in cybersecurity; we rely on off-the-shelf" security software. We have not conducted employee training regarding cybersecurity or conducted internal tests or simulations. Nonetheless, we believe that, due to the nature and status of our business, our cybersecurity position is currently satisfactory for our situation. We do not believe that cybersecurity risks have materially affected (or are reasonably likely to materially affect) us.

We have only four employees and so disclosure of cybersecurity events to management would occur organically, or would in the first instance be observed by management.

For information of ours which resides on our CROs' computer systems, we rely on the CROs' own cybersecurity processes and systems.

Item 2. Properties.

None. The lease for our previous operating facilities at 2042 Corte Del Nogal, Carlsbad, California had been in the name of our subsidiary Qualigen, Inc. We sold Qualigen, Inc. in 2023 and the Company has no responsibility for the lease going forward. The Company had also utilized such facility (in addition to Qualigen, Inc.'s use), but now has removed from it. The Company is currently essentially "virtual."

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been listed and traded on the Nasdaq Capital Market under the symbol "QLGN" since May 26, 2020.

Holders

As of March 25, 2024, there were 287 registered holders of record of our common stock. This figure does not reflect the beneficial ownership of shares held in nominee name.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for information relating to our equity compensation plans.

Recent Sales of Unregistered Securities

No further disclosure is required in response to this Item.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with the consolidated financial statements and related notes that are included elsewhere in this Annual Report. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" or in other parts of this Annual Report. See "Cautionary Note Regarding Forward-Looking Statements" for additional information. Unless otherwise indicated, all information in this Annual Report on Form 10-K gives effect to a 1-for-10 reverse stock split of our common stock that became effective on November 23, 2022, and all references to shares of common stock outstanding and per share amounts give effect to the reverse stock split.

Overview

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

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

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

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 Annual Report on Form 10-K 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

Phase 1 Clinical Trial of QN-302

On August 1, 2023, we announced that the FDA has cleared our IND application for QN-302. Based on this clearance, we chose Translational Drug Development, LLC ("TD2") to serve as our contract research organization to conduct a Phase 1 clinical trial in patients with advanced or metastatic solid tumors. The Phase 1 trial (NCT06086522) is designed as a multicenter, open-label, dose escalation, safety, pharmacokinetic, and pharmacodynamic study with dose expansion to evaluate safety, tolerability, and antitumor activity of QN-302 in patients with advanced solid tumors that

have not responded to or that have recurred following treatment with available therapies. On November 7, 2023, we announced that the first patient had been enrolled and dosed in the dose escalation (Phase 1a) portion of the study. Subject to available funding (which is, however, not all currently in hand), we anticipate that Phase 1a of the trial can be completed by the end of 2024. The exact number of patients to be enrolled in the trial will depend on the observed safety profile, which will determine the number of patients per dose level, as well as the number of dose escalations required to meet the Maximum Tolerated Dose ("MTD"). Once the MTD has been established in dose escalation, dose expansion will begin.

Sale of Diagnostics Business

On July 20, 2023, we sold all of the issued and outstanding shares of common stock of Qualigen, Inc., a wholly-owned subsidiary and the legal entity operating our FastPack™ diagnostic business, to Chembio Diagnostics, Inc. ("Chembio"), a subsidiary of Biosynex, S.A. As consideration for the shares of Qualigen, Inc., we received cash payments of approximately $4.9 million, which payment is subject to post-closing adjustments. An additional $450,000 was delivered by Chembio to an escrow account to 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 January 20, 2025. 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, we entered into and effectuated the NanoSynex Amendment, by which we agreed to, among other things, forfeit 281,000 Series B Preferred Shares of NanoSynex held by us, resulting in our ownership in NanoSynex being reduced from approximately 52.8% to approximately 49.97% of the voting equity of NanoSynex. In addition, we agreed to cancel approximately $3.0 million of promissory notes which NanoSynex had issued to us under the NanoSynex Funding Agreement, relieving NanoSynex of any repayment obligations to us with respect to such notes. The NanoSynex Amendment superseded any NanoSynex Funding Agreement obligations to provide funding to NanoSynex, except we agreed to provide future loans as follows: (i) $560,000 on or before November 30, 2023, and (ii) $670,000 on or before March 31, 2024. However, on November 22, 2023, in full settlement of any additional funding obligations to NanoSynex, we forfeited certain of our shares of Series A-1 Preferred Stock of NanoSynex in an amount that reduced our ownership in NanoSynex from approximately 49.97% to 39.90%. Accordingly, NanoSynex was deconsolidated from our financial statements as of July 20, 2023, and is reported as Discontinued Operations in this Annual Report. Our investment in NanoSynex will be accounted for in the future as an equity method investment.

Critical Accounting Policies and Estimates

Our consolidated financial statements historically have not separated our diagnostics-related activities from our therapeutics-related activities. All of our historically reported revenue was diagnostics-related. Before the third quarter of 2023, our reported expenses represented the total of our diagnostics-related and therapeutics-related expenses. In this Annual Report, 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 consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these 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 consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to impairment of goodwill and other intangible assets, fair value of warrant liabilities, and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing in "Item 8. Financial Statements and Supplementary Data," we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations:

- Research and development
- Discontinued operations
- Impairment of long-lived assets
- Business combinations
- 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 the Company issues shares (except in certain defined scenarios) at a price below the warrants' exercise price, the exercise price will be re-set to such new price and the number of shares underlying the warrants will be increased in the same proportion as the exercise price decrease. For accounting purposes, such warrants give rise to warrant liabilities. Accounting principles generally accepted in the United States of America ("U.S. GAAP") require us to recognize the fair value of these warrants as warrant liabilities on our Consolidated Balance Sheets and to reflect period-to-period changes in the fair value of the warrant liabilities on our Consolidated Statements of Operations. The estimated fair value of these warrant liabilities was approximately $0.1 million and $3.6 million at December 31, 2023 and 2022, respectively. There were 455,623 of these warrants outstanding at December 31, 2023 and 1,349,571 of these warrants outstanding at December 31, 2022.

Because the fair value of the above liability classified warrants will be determined each quarter on a "mark-to-market" basis , significant variability in our future quarterly and annual Consolidated Statement of Operations and Consolidated Balance Sheets could occur 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 in the fair value of the warrant liabilities and a quarter-to-quarter decrease in our stock price would result in a decrease in the fair value of the warrant liabilities.

On December 22, 2022, as part of the 2022 Debenture financing, we issued to Alpha a common stock warrant (exercisable from June 22, 2023 through June 22, 2028) to purchase 2,500,000 shares of our common stock. The exercise price of the warrant was modified from $1.65 to $0.73 on December 5, 2023, and was further modified to $0.26 on February 27, 2024. The warrant may be exercised by Alpha, in whole or in part before June 22, 2028. The warrant was originally liability classified, but was modified on December 5, 2023 to allow for equity classification. The estimated fair value of this warrant upon reclassification from warrant liabilities to equity was approximately $1.6 million and the estimated fair value of this warrant which was

included in warrant liabilities-related party on December 31, 2022 was approximately $2.8 million.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

	For the Years Ended December 31,	
	2023	**2022**
EXPENSES		
General and administrative	$ 6,095,607	10,274,600
Research and development	5,209,250	4,486,120
Total expenses	11,304,857	14,760,720
LOSS FROM OPERATIONS	(11,304,857)	(14,760,720)
OTHER EXPENSE (INCOME), NET		
Gain on change in fair value of warrant liabilities	(2,035,469)	(907,203)
Interest expense, net	1,524,722	34,397
Loss on voluntary conversion of convertible debt	1,077,287	—
Loss on debt extinguishment	625,653	—
Loss on fixed asset disposal	21,747	—
Other income, net	(38,994)	
Total other expense (income), net	1,174,946	(872,806)
LOSS BEFORE (BENEFIT) PROVISION FOR INCOME TAXES	(12,479,803)	(13,887,914)
(BENEFIT) PROVISION FOR INCOME TAXES	(4,793)	6,548
NET LOSS FROM CONTINUING OPERATIONS	(12,475,010)	(13,894,462)
DISCONTINUED OPERATIONS		
Loss from discontinued operations, net of tax	(683,008)	(7,140,181)
Loss on disposal of discontinued operations, net of tax	(602,232)	—
LOSS FROM DISCONTINUED OPERATIONS	(1,285,240)	(7,140,181)
NET LOSS	(13,760,250)	(21,034,643)
Net loss attributable to non-controlling interest from discontinued operations	(343,038)	(2,394,100)
Net loss attributable to Qualigen Therapeutics, Inc.	$ (13,417,212)	$ (18,640,543)
Net loss per common share, basic and diluted - continuing operations	$ (2.46)	$ (3.62)
Net loss per common share, basic and diluted - discontinued operations	$ (0.19)	$ (1.24)
Weighted—average number of shares outstanding, basic and diluted	5,072,709	3,840,340
Other comprehensive loss, net of tax		
Net loss	$ (13,760,250)	$ (21,034,643)
Foreign currency translation adjustment from discontinued operations	119,473	50,721
Other comprehensive loss	(13,640,777)	(20,983,922)
Comprehensive loss attributable to noncontrolling interest from discontinued operations	(304,735)	(2,394,100)
Comprehensive loss attributable to Qualigen Therapeutics, Inc.	$ (13,336,042)	$ (18,589,822)

Expenses

General and Administrative Expenses

General and administrative expenses decreased from $10.3 million for the year ended December 31, 2022 to $6.1 million for the year ended December 31, 2023. This decrease was due to a $3.8 million decrease in stock-based compensation expense, a $0.4 million decrease in payroll related expenses, a $0.3 million decrease in insurance expenses, and a $0.2 million decrease in license fees, offset by an increase of $0.5 million in professional fees. (The foregoing comparison, and all other comparisons presented in this Item, exclude Qualigen, Inc. and NanoSynex, Ltd. results for both years.)

Research and Development Costs

Research and development expenses increased from $4.5 million for the year ended December 31, 2022 to approximately $5.2 million for year ended December 31, 2023. This increase in research and development expenses for the year ended December 31, 2023 compared to for the year ended December 31, 2022 was primarily due to a $2.1 million increase in pre-clinical and clinical research costs for QN-302, offset by a $1.0 million decrease in pre-clinical research costs for QN-247 a $0.3 million decrease in preclinical research costs for Pan-RAS, and a $0.1 million decrease in preclinical research costs for QN-165.

Other Expense (Income)

Change in Fair Value of Warrant Liabilities

During the year ended December 31, 2023 we experienced a $2.0 million gain in other income because of the change in fair value of the warrant liabilities arising from our liability classified warrants described above. The estimated fair value of these warrant liabilities decreased to $0.1 million as of

December 31, 2023 from $3.6 million as of December 31, 2022 due to a reduction in fair value of the warrant liabilities resulting from an associated decrease in the market price of our common stock, and the reclassification at fair value of a liability classified warrant to equity of $1.6 million. For the year ended December 31, 2022, the gain on change in fair value of warrant liabilities was $0.9 million due to an associated decrease in the market price of our common stock. 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.

The remaining liability classified warrants expire on June 26, 2024. Because the fair value of the warrant liabilities will be determined each quarter on a "mark-to-market" basis, this item is likely to, until then, continue to result in variability in our future quarterly 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 (Income) Expense, Net

There was $1.5 million in net interest expense during the year ended December 31, 2023 compared to net interest income of $34,000 during the year ended December 31, 2022. The increase was due to the interest on the 2022 Debenture.

Loss on Voluntary Conversion of Convertible Debt

During the year ended December 31, 2023 we issued 841,726 shares of common stock upon Alpha's partial voluntary conversion of the 2022 Debenture at $1.32 per share for a total of $1,111,078 principal converted. Upon conversion, we recognized a loss on voluntary conversion of convertible debt of approximately $1.1 million.

Loss on Debt Extinguishment

During the year ended December 31, 2023, we issued 309,665 shares of common stock in lieu of cash for the October and December 2023 monthly redemptions, for a total of $220,000 principal redeemed, pursuant to the terms of the 2022 Debenture at a weighted average share price of $0.71. Upon redemption in shares, we recognized a loss on partial debt extinguishment of $34,315. The modification of the 2022 Debenture during the year ended December 31, 2023 met the criteria to be accounted for as a debt extinguishment in the amount of $591,338. Accordingly, we recognized an additional loss on partial debt extinguishment of that amount.

Loss on Fixed Asset Disposal

During the year ended December 31, 2023, we incurred a $21,747 loss on fixed asset disposal due to disposal of research and development equipment previously used for QN-165.

Liquidity and Going Concern

Our financial position is weak. As of December 31, 2023, we had approximately $0.4 million in cash and net accounts payable of over $2.2 million. We are in arrears on accounts payable to important partners. We have incurred recurring losses from operations and have an accumulated deficit of $116.8 million at December 31, 2023. We expect to continue to incur losses subsequent to the consolidated balance sheet date of December 31, 2023. For the years ended December 31, 2023 and 2022, we used cash of $10.3 million and $13.2 million, respectively, in operations. We sold our Qualigen, Inc. FastPack® diagnostics products business in 2023.

On February 26, 2024, we entered into a Securities Purchase Agreement ("Agreement") with Alpha. The transactions contemplated by the Agreement closed on February 27, 2024, at which time we delivered to Alpha a new Debenture and warrant, as described in this paragraph, and Alpha paid the Company a cash purchase price of $500,000 (less expenses). Pursuant to the Agreement, we issued to Alpha an 8% Convertible Debenture (the "2024 Debenture") in the principal amount of $550,000. The 2024 Debenture has a maturity date of December 31, 2024 and is convertible, at any time, and from time to time, at Alpha's option, into shares of common stock of the Company, at $0.6111 per share, subject to adjustment as described in the 2024 Debenture. The 2024 Debenture accrues interest on its outstanding principal balance at the rate of 8% per annum, payable at maturity. Pursuant to the terms of the Agreement, we also issued to Alpha a 5-year common stock purchase warrant to purchase (at $0.26 per share) 900,016 shares of common stock of the Company. We also granted to Alpha an option, exercisable until July 1, 2024, to purchase from us additional 8% Convertible Debentures, of like tenor, with face amounts of up to an aggregate of $1,100,000 (and with a proportional number of accompanying common stock warrants of like tenor, up to a total of 1,800,032 additional warrants), which would (if and when Alpha exercises such option) provide us up to an additional $1.0 million in cash proceeds (less expense reimbursement, and not including any possible cash proceeds from any future exercise of the additional warrants).

We currently expect our cash balances to fund operations only into the second quarter of 2024. We expect to continue to have net losses and negative cash flow from operations, which will challenge our liquidity. These factors raise substantial doubt regarding our ability to continue as a going concern for the one-year period following the date that the financial statements in this Annual Report were issued.

There is no assurance that we will ever achieve profitable operations, or, if achieved, could be sustained on a continuing basis. In order to fully execute our business plan, we will require significant additional financing for planned research and development activities, capital expenditures, QN-302 clinical trials, and preclinical development of Pan-RAS, as well as commercialization activities.

Historically, our principal sources of cash have, in addition to revenue from FastPack product sales and license revenues (see Note 5 - Discontinued Operations), included proceeds from the issuance of common and preferred equity and proceeds from the issuance of debt. In December 2022 and February 2024 we raised approximately $3.0 million and $0.5 million, respectively from the sale of convertible debentures to Alpha. There can be no assurance that further financing can be obtained on favorable terms, or at all. If we are unable to obtain funding, we could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, and we could be unable to continue operations.

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

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.

Our current liabilities at December 31, 2023 include $2.2 million of accounts payable, $0.6 million of accrued expenses and other current liabilities, $0.1 million in warrant liabilities, and $1.3 million of convertible debt to a related party.

Contractual Obligations and Commitments

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

License and Sponsored Research Agreements

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

We have multiple license and sponsored research agreements with ULRF. Under these agreements, we have taken over development, regulatory approval and commercialization of various drug compounds from ULRF and are responsible for maintenance of the related intellectual property portfolio. We agreed to reimburse ULRF for sponsored research expenses of up to $2.7 million and prior patent costs of up to $112,000 for Pan-RAS. As of December 31, 2023, there were no remaining un-expensed amounts under this sponsored research agreement for Pan-RAS. Under the terms of these agreements, we are required to make patent maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $5 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under these agreements, but we will be required to pay ULRF a percentage of any sublicense income.

We previously had sponsored research agreements with ULRF for QN-247 and QN-165. As of December 31, 2023, there were no remaining un-expensed amounts under these sponsored research agreements and the agreements were terminated effective August 31, 2022, and November 30, 2021 respectively.

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

Alpha Convertible Debt

On December 22, 2022, pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022 (the "Alpha Purchase Agreement"), we issued to Alpha, in exchange for $3,000,000 in cash (less $50,000 for expense reimbursement), the 2022 Debenture with an original face amount of $3,300,000 due on December 22, 2025, plus 2,500,000 common stock warrants exercisable (from June 22, 2023 through June 22, 2028) at $1.65 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 2022 Debenture, we must redeem $110,000 plus accrued but unpaid interest, liquidated damages and any amounts then owing under the 2022 Debenture. The Monthly Redemption Amount must be paid in cash; provided that after the first two monthly redemptions, we may (if the Equity Conditions, as defined in the 2022 Debenture, are then satisfied or have been waived) elect to pay all or a portion of a Monthly Redemption Amount in shares of our common stock, based on a conversion price equal to the lesser of (i) the then applicable conversion price of the 2022 Debenture and (ii) 85% of the average of the VWAPs (as defined in the 2022 Debenture) for the five consecutive trading days ending on the trading day that is immediately prior to the applicable Monthly Redemption Date.

The 2022 Debenture accrues interest at the rate of 8% per annum, which began accruing on December 1, 2023, and will be payable on a quarterly basis. Interest may be paid in cash or shares of common stock or a combination thereof at our option; provided that the Equity Conditions have been satisfied.

Alpha has waived the Equity Conditions for certain Monthly Redemption Amounts, but Alpha is not required to continue such waivers beyond May 2024. For the foreseeable future, we do not expect to be able to satisfy the Equity Conditions; as a result, where there is no waiver of the Equity Conditions we would not have the opportunity to make 2022 Debenture payments in the form of stock rather than in the form of cash, even for types of payments for which payment in the form of stock would have been allowed.

The 2022 Debenture is convertible into our common stock at any time at the holder's option; the conversion price was originally $1.32 but pursuant to a Securities Purchase Agreement amendment it was reduced to $0.73 on December 5, 2023 and then on February 27, 2024 it was adjusted downward to $0.26 per share by virtue of the operation of a "ratchet" antidilution provision. (The exercise price of the warrants issued with the 2022 Debenture was originally $1.65 but pursuant to the Securities Purchase Agreement amendment it was reduced to $0.73 on December 5, 2023 and then on February 27, 2024 it was adjusted downward to $0.26 per share by virtue of the operation of a "ratchet" antidilution provision.)

Both the 2022 Debenture and the accompanying warrants provide for "ratchet" antidilution adjustments to their conversion price and exercise price.

Both the 2022 Debenture and the accompanying warrants include a beneficial ownership blocker of 9.99%, which may only be waived by Alpha upon 61 days' notice to the Company.

We granted Alpha resale registration rights for the common shares underlying the 2022 Debenture and the accompanying warrants.

On December 5, 2023, we entered into an Amendment No. 1 with regard to Securities Purchase Agreement, with Alpha, which, among other

things, revised certain provisions of the 2,500,000 warrants to clarify the intention that such 2,500,000 warrants would not be liability-classified for GAAP purposes.

During the year ended December 31, 2023, we recognized an extinguishment loss on voluntary conversion of convertible debt of approximately $1.1 million, an extinguishment loss of $0.6 million upon October and December 2023 share redemptions and the modification of the 2022 Debenture in December 2023, and recorded accrued interest of approximately $1.5 million, in other expenses in the consolidated statements of operations. During the year ended December 31, 2023 we paid Monthly Redemption Amounts of $550,000 in cash and $220,000 in common stock, and as of December 31, 2023 the remaining 2022 Debenture principal balance was approximately $1.4 million, the remaining discount was approximately $0.1 million, and the fair value of the suite of bifurcated embedded derivative features was $0.

Reference is also made to the 2024 Debenture, which was issued to Alpha after the end of the 2023 fiscal year and is described above.

NanoSynex Funding Agreement

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

During the year ended December 31, 2022, we funded a total of approximately $2.4 million and in February 2023 we funded an additional $0.5 million to NanoSynex under the Funding Agreement.

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

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

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 Twelve Months Ended December 31,	
	2023	**2022**
Net cash (used in) provided by:		
Operating activities	$ (10,304,263)	$ (13,247,541)
Investing activities	4,215,943	(183,763)
Financing activities	(550,000)	2,910,515
Effect of exchange rate on cash	—	22,639
Net decrease in cash and restricted cash	**$ (6,638,320)**	**$ (10,498,150)**

Net Cash Used in Operating Activities

During the year ended December 31, 2023, operating activities used $10.3 million of cash, primarily resulting from a loss from continuing operations of $12.5 million. Cash flows from operating activities for the year ended December 31, 2023 were positively impacted by adjustments for a $1.1 million non cash loss on voluntary conversion of convertible debt, a $0.6 million non cash loss on convertible debt extinguishment, accretion of discount of $1.5 million on convertible debt, a $1.6 million increase in accounts payable, and $1.1 million in non cash stock-based compensation expense. Cash flows from operating activities for the year ended December 31, 2023 were negatively impacted by adjustments for a $2.0 million decrease in fair value of warrant liabilities, a $0.3 million increase in prepaid expenses and other assets, a $0.2 million decrease in accrued expenses and other current liabilities, and cash used in discontinued operations of $1.2 million.

During the year ended December 31, 2022, operating activities used $13.2 million of cash, primarily resulting from a loss from continuing operations of $13.9 million. Cash flows from operating activities for the year ended December 31, 2022 were positively impacted by an adjustment for $4.8 million in non cash stock-based compensation expense. Cash flows from operating activities for the year ended December 31, 2022 were negatively impacted by cash used in discontinued operations of $2.6 million, a $0.9 million decrease in fair value of warrant liabilities, a $0.5 million decrease in accrued expenses and other current liabilities, and a $0.1 million increase in prepaid expenses.

Net Cash Provided By Investing Activities

During the year ended December 31, 2023, net cash provided by investing activities was approximately $4.2 million resulting from discontinued operations due to $4.9 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 year ended December 31, 2022, net cash used in investing activities was approximately $0.2 million, due to capital expenditures offset by cash acquired in the NanoSynex acquisition.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023, was approximately $0.6 million, due to monthly redemption payments which we made in the form of stock (rather than in the form of cash) on the 2022 Debenture.

Net cash provided by financing activities for the year ended December 31, 2022, was approximately $2.9 million, due to the issuance of convertible debt to Alpha.

Item 7A. 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 8. Consolidated Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Qualigen Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Qualigen Therapeutics, Inc. (the "Company") as of December 31, 2023 and December 31, 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and December 31, 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company's current liquidity position and projected cash needs raise substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Financial Instruments – Modification of Convertible Debt with Warrants

Critical Audit Matter Description

As described in Note 8 to the consolidated financial statements, during the year ended December 31, 2023, the Company modified the conversion price and strike price of its convertible debenture and common stock purchase warrants, respectively. Further, the Company modified certain terms of its stock warrant agreements that were originally classified as liabilities enabling them to be classified as equity.

We identified the accounting for the modification of this complex financial instrument as a critical audit matter. This includes both the evaluation of the various features as potential embedded derivatives and the determination of the respective fair value of the instruments and the embedded features, as well as the determination of the appropriate classification of warrants between equity and liabilities. The application of the accounting guidance applicable to issuing and modifying a complex financial instrument requires significant judgment.

Determination of appropriate classification of warrants requires management's judgments relating to the interpretations of relevant accounting guidance based on specific provisions of the warrant agreement. Accounting for the convertible notes and embedded conversion features requires management's judgments related to initial and subsequent recognition of the debt and related features, use of a valuation model, and key inputs used in the selected valuation model.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- Inspecting the agreements associated with the transactions and evaluating management's technical accounting analysis, including the application of the relevant accounting literature.

- Utilizing an auditor's specialist to assist in assessing management's analysis of the transaction, including (i) evaluating the contracts to identify relevant terms that affect the recognition of the financial instruments, (ii) assessing the appropriateness of conclusions reached by management, and (iii) reviewing the valuation model for derivatives, performing independent calculations, and examining the significant assumptions utilized in the valuation model.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2018.

San Diego, California
April 5, 2024

QUALIGEN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash	$ 401,803	$ 3,165,985
Prepaid expenses and other current assets	764,964	1,366,704
Current assets of discontinued operations	—	6,287,849
Total current assets	1,166,767	10,820,538
Property and equipment, net	—	26,242
Other assets	866,481	—
Non-current assets of discontinued operations	—	8,236,711
Total Assets	**$ 2,033,248**	**$ 19,083,491**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 2,222,983	$ 619,568
Accrued expenses and other current liabilities	560,006	864,559
Warrant liabilities	54,600	788,100
Warrant liabilities - related party	—	2,834,547
Convertible debt - related party	1,299,216	60,197
Current liabilities of discontinued operations	—	3,441,198
Total current liabilities	4,136,805	8,608,169
Non-current liabilities of discontinued operations	—	1,708,732
Total liabilities	4,136,805	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; 5,362,128 and 4,210,737 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	43,262	42,110
Additional paid-in capital	114,655,565	110,528,050
Accumulated other comprehensive income	—	50,721
Accumulated deficit	(116,802,384)	(103,385,172)
Total Qualigen Therapeutics, Inc. stockholders' equity (deficit)	(2,103,557)	7,235,709
Noncontrolling interest	—	1,530,881
Total Stockholders' Equity (deficit)	(2,103,557)	8,766,590
Total Liabilities & Stockholders' Equity (Deficit)	**$ 2,033,248**	**$ 19,083,491**

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

QUALIGEN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Years Ended December 31,	
	2023	**2022**
EXPENSES		
General and administrative	$ 6,095,607	10,274,600
Research and development	5,209,250	4,486,120
Total expenses	11,304,857	14,760,720
LOSS FROM OPERATIONS	(11,304,857)	(14,760,720)
OTHER EXPENSE (INCOME), NET		
Gain on change in fair value of warrant liabilities	(2,035,469)	(907,203)
Interest expense, net	1,524,722	34,397
Loss on voluntary conversion of convertible debt	1,077,287	—
Loss on debt extinguishment	625,653	—
Loss on fixed asset disposal	21,747	—
Other income, net	(38,994)	—
Total other expense (income), net	1,174,946	(872,806)
LOSS BEFORE (BENEFIT) PROVISION FOR INCOME TAXES	(12,479,803)	(13,887,914)
(BENEFIT) PROVISION FOR INCOME TAXES	(4,793)	6,548
NET LOSS FROM CONTINUING OPERATIONS	(12,475,010)	(13,894,462)
DISCONTINUED OPERATIONS		
Loss from discontinued operations, net of tax	(683,008)	(7,140,181)
Loss on disposal of discontinued operations, net of tax	(602,232)	—
LOSS FROM DISCONTINUED OPERATIONS	(1,285,240)	(7,140,181)
NET LOSS	(13,760,250)	(21,034,643)
Net loss attributable to non-controlling interest from discontinued operations	(343,038)	(2,394,100)
Net loss attributable to Qualigen Therapeutics, Inc.	$ (13,417,212)	$ (18,640,543)
Net loss per common share, basic and diluted - continuing operations	$ (2.46)	$ (3.62)
Net loss per common share, basic and diluted - discontinued operations	$ (0.19)	$ (1.24)
Weighted-average number of shares outstanding, basic and diluted	5,072,709	3,840,340
Other comprehensive loss, net of tax		
Net loss	$ (13,760,250)	$ (21,034,643)
Foreign currency translation adjustment from discontinued operations	119,473	50,721
Other comprehensive loss	(13,640,777)	(20,983,922)
Comprehensive loss attributable to noncontrolling interest from discontinued operations	(304,735)	(2,394,100)
Comprehensive loss attributable to Qualigen Therapeutics, Inc.	$ (13,336,042)	$ (18,589,822)

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

QUALIGEN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional	Accumulated Other Comprehensive		Total Qualigen Therapeutics, Inc. Stockholders'		Total Stockholders'
	Shares	**Amount**	**Paid-In Capital**	**Income (Deficit)**	**Accumulated Deficit**	**Equity (Deficit)**	**Noncontrolling Interest**	**Equity (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
Redemptions of convertible debt into common stock	309,665	310	254,006	—	—	254,316	—	254,316
Fair value of warrant modification for professional services	—	—	7,945	—	—	7,945	—	7,945

Fair value of warrant reclassified from liabilities to equity	—	—	1,626,694	—	—	1,626,694	—	1,626,694
Stock-based compensation	—	—	1,098,533	—	—	1,098,533	9,297	1,107,830
Foreign currency translation adjustment	—	—	28,597	81,170	—	109,767	38,303	148,070
Deconsolidation of discontinued operations	—	—	—	(131,891)	—	(131,891)	(1,235,443)	(1,367,334)
Net loss	—	—	—	—	(13,417,212)	(13,417,212)	(343,038)	(13,760,250)
Balance at December 31, 2023	5,362,128	$ 43,262	$114,655,565	$ —	$116,802,384)	$ (2,103,557)	$ —	$ (2,103,557)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Qualigen Therapeutics, Inc. Stockholders' Equity	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount						
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	332,000	3,320	4,711	—	—	8,031	—	8,031
Stock-based compensation	—	—	5,484,044	—	—	5,484,044	—	5,484,044
Common stock and prefunded warrants issued for business acquisition	350,000	3,500	3,740,417	—	—	3,743,917	3,882,225	7,626,142
Noncontrolling interest adjustments relating to Stock-based compensation and other	—	—	(42,756)	—	—	(42,756)	42,756	—
Foreign currency translation adjustment	—	—	—	50,721	—	50,721	—	50,721
Fair value of warrant modification for professional services	—	—	67,370	—	—	67,370	—	67,370
Fair value of warrant modification for business acquisition	—	—	696	—	—	696	—	696
Issuance of rounded shares as a result of the reverse stock split	(281)	—	(505)	—	—	(505)	—	(505)
Net loss	—	—	—	—	(18,640,543)	(18,640,543)	(2,394,100)	(21,034,643)
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

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

QUALIGEN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (13,760,250)	$ (21,034,643)
Loss from discontinued operations, net of tax	(1,285,240)	(7,140,181)
Loss from continuing operations	(12,475,010)	(13,894,462)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	4,495	12,165
Stock-based compensation	1,098,533	4,765,276

Change in fair value of warrant liabilities	(2,035,469)	(906,345)
Loss on voluntary conversion of convertible debt	1,077,287	—
Accretion of discount on convertible debt	1,469,640	—
Loss on debt extinguishment	625,653	—
Loss on disposal of fixed assets	21,747	—
Fair value of warrant modification for professional services	7,945	67,370
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(264,741)	(126,985)
Accounts payable	1,603,422	(43,440)
Accrued expenses and other current liabilities	(227,101)	(472,441)
Net cash used in operating activities - continuing operations	(9,093,599)	(10,598,862)
Net cash provided by (used in) operating activities - discontinued operations	(1,210,664)	(2,648,679)
Net cash used in operating activities	(10,304,263)	(13,247,541)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net cash provided by (used in) investing activities - discontinued operations	4,215,943	(183,763)
Net cash provided by (used in) investing activities	4,215,943	(183,763)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from warrant exercises	—	7,173
Proceeds from issuance of convertible debt	—	2,903,847
Payments on convertible notes payable	(550,000)	—
Fractional share payments related to the reverse stock split	—	(505)
Net cash (used in)/provided by financing activities - continuing operations	(550,000)	2,910,515
Net cash used in financing activities - discontinued operations	—	—
Net cash (used in) provided by financing activities	(550,000)	2,910,515
Net change in cash and restricted cash	(6,638,320)	(10,520,789)
Effect of exchange rate changes on cash and restricted cash	—	22,639
Cash and restricted cash from continuing operations - beginning of period	3,165,985	9,174,383
Cash and restricted cash from discontinued operations - beginning of period	3,874,138	8,363,890
Less: cash and restricted cash from discontinued operations - end of period	—	(3,874,138)
Cash from continuing operations - end of period	$ 401,803	$ 3,165,985
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid during the year for:		
Interest	$ —	$ —
Taxes	$ 5,571	$ 5,571
NONCASH FINANCING AND INVESTING ACTIVITIES:		
Net transfers to equipment held for lease from inventory	$ 83,281	$ —
Fair value of warrant liabilities on date of exercise	$ —	$ 858
Redemption of convertible debt into common stock	$ 254,316	$ —
Voluntary conversion of convertible debt into common stock	$ 1,112,582	$ —
Fair value of warrant modifications pursuant to Securities Purchase Agreement	$ —	$ 9,439
Fair value of warrant modifications for business acquisition	$ —	$ 33,543

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

QUALIGEN THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

Organization

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

On May 26, 2022, the Company acquired 2,232,861 shares of Series A-1 Preferred Stock of NanoSynex, Ltd. ("NanoSynex") from Alpha Capital Anstalt ("Alpha"), a related party, in exchange for 350,000 reverse split adjusted shares of the Company's common stock and a prefunded warrant to purchase 331,464 reverse split adjusted shares of the Company's common stock at an exercise price of $ 0.001 per share. These warrants were subsequently exercised on September 13, 2022. Concurrently with this transaction, the Company also entered into a Master Funding Agreement for the Operational and Technology Funding of NanoSynex Ltd., dated May 26, 2022, with NanoSynex (the "NanoSynex Funding Agreement"), to, among other things, provide for the further funding of NanoSynex, and purchased 381,786 shares of Series B preferred stock from NanoSynex for a total purchase price of $ 600,000 . The transactions resulted in the Company acquiring a 52.8 % interest in NanoSynex (the "NanoSynex Acquisition"). NanoSynex is a nanotechnology diagnostics company domiciled in Israel. On July 20, 2023, the Company entered into an Amendment and Settlement Agreement with NanoSynex (the "NanoSynex Amendment"), which amended the NanoSynex Funding Agreement, to, among other things, eliminate most of the Company obligation for the further funding of NanoSynex. Pursuant to the terms of the NanoSynex Amendment, the Company lost its controlling interest in NanoSynex (see Note 5 -Discontinued Operations).

Basis of Presentation

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

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

Discontinued Operations

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

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

See Note 5 - Discontinued Operations for further information.

Equity Method Investments

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

Accounting Estimates

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

Impairment of Long-Lived Assets

The Company assesses potential impairments to its long-lived assets when there is evidence that events or changes in circumstances indicate that assets may not be recoverable. An impairment loss would be recognized when the sum of the expected future undiscounted cash flows is less than the carrying amount of the assets. The amount of impairment loss, if any, will generally be measured as the difference between the net book value of the assets and their estimated fair values. During the years ended December 31, 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 consolidated statement of operations.

Business Combinations

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

Goodwill

Goodwill represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets acquired, when accounted for using the purchase method of accounting. Goodwill has an indefinite useful life and is not amortized but is reviewed for impairment annually and whenever events or changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. In testing for impairment, the fair value of the reporting unit is compared to the carrying value. If the net assets assigned to the reporting unit exceed the fair value of the reporting unit, an impairment loss equal to the difference is recorded. As a result of the annual goodwill impairment analysis, the Company recognized a $ 4,239,000 non-cash goodwill and fixed asset impairment charge in the valuation of its business acquisition of NanoSynex for the year ended December 30, 2022.

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 consolidated statements of operations and comprehensive loss. Depending on the features of the derivative financial instrument, the Company uses either the Black-Scholes option-pricing model or a Monte-Carlo simulation to value the derivative instruments at inception and subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period (See Note 7-Warrant Liabilities and Note 8- Convertible Debt - Related Party).

Fair Value Measurements

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

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

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

Fair Value of Financial Instruments

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

Comprehensive Loss

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

Stock-Based Compensation

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

and non-employees determined at the date of grant.

Income Taxes

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

Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment. Realization of the deferred income tax asset is dependent on generating sufficient taxable income in future years. For more information, refer to Note 14 - Income Taxes.

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

Foreign Currency Translation

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

Recent Accounting Pronouncements

The Company reviewed all other recently issued accounting pronouncements and concluded that they were either not applicable or not expected to have a significant impact to the financial statements.

Global Economic Conditions

Ongoing Wars in Ukraine and Israel

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

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

Inflation and Global Economic Conditions

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

Impact of COVID-19 Pandemic

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

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

NOTE 2 — LIQUIDITY AND GOING CONCERN

As of December 31, 2023, the Company had approximately $ 0.4 million in cash and an accumulated deficit of $ 116.8 million. For the years ended December 31, 2023 and 2022, the Company used cash of $ 10.3 million and $ 13.2 million, respectively, in operations.

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 only into the second quarter of 2024. The Company expects to continue to have net losses and negative cash flow from operations, which will challenge its liquidity. These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period following the date that these financial statements were issued.

There is no assurance that profitable operations will ever be achieved, or, if achieved, could be sustained on a continuing basis. 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 QN-302 and preclinical development of Pan-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 2022 the Company raised $ 3.0 million from the sale of an 8% Senior Convertible Debenture (the "Debenture") to Alpha (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 the Company is unable to obtain funding, the Company could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect the Company's business prospects.

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

NOTE 3 — PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following at December 31, 2023 and December 31, 2022:

	December 31, 2023	December 31, 2022
Prepaid insurance	$ 566,011	$ 1,329,034
Other prepaid expenses	25,053	37,670
Receivable from sale of Qualigen, Inc.	—	—
Prepaid research and development expenses	173,900	—
	$ 764,964	$ 1,366,704

Prepaid expenses attributable to Qualigen, Inc. and NanoSynex were deemed 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 December 31, 2023:

	December 31, 2023
Funds held in escrow	$ 450,000
Long-term research and development deposits	416,481
	$ 866,481

NOTE 5 — DISCONTINUED OPERATIONS

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

	Qualigen, Inc.	NanoSynex	Total
Current assets of discontinued operations	$ 4,448,999	$ 1,838,850	$ 6,287,849
Non-current assets of discontinued operations	1,876,270	6,360,441	8,236,711
Total assets of discontinued operations	$ 6,325,269	$ 8,199,291	$ 14,524,560
Current liabilities of discontinued operations	$ 1,299,948	$ 2,141,250	$ 3,441,198
Non-current liabilities of discontinued operations	1,350,975	357,757	1,708,732
Total liabilities of discontinued operations	$ 2,650,923	$ 2,499,007	$ 5,149,930

The summary of gain (loss) from discontinued operations, net of tax, as of December 31, 2023 and 2022 are as follows:

	Year ended December 31, 2023			Year ended December 31, 2022		
	Qualigen, Inc.	NanoSynex	Total	Qualigen, Inc.	NanoSynex	Total
(Loss) from discontinued operations	$ (171,701)	$ (511,307)	$ (683,008)	$ (2,142,763)	$ (4,997,418)	$ (7,140,181)
Gain (loss) on disposal of discontinued operations	3,876,778	(4,479,010)	(602,232)	—	—	—
Total gain (loss) from discontinued operations	$ 3,705,077	$ (4,990,317)	$ (1,285,240)	$ (2,142,763)	$ (4,997,418)	$ (7,140,181)

Sale of Qualigen, Inc.

On July 20, 2023, the Company completed the sale of Qualigen, Inc., its formerly wholly-owned subsidiary, to Chembio Diagnostics, Inc. for net cash consideration of $ 5.4 million, of which $ 4.9 million was received during the year ended December 31, 2023, and $ 450,000 is being held in escrow until January 20, 2025 to satisfy certain Company indemnification obligations.

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 statement of operations items to discontinued operations for the years ended December 31, 2023 and 2022, respectively:

	For the Years Ended December 31,	
	2023	2022
REVENUES		
Net product sales	$ 3,661,121	$ 4,983,556
Total revenues	3,661,121	4,983,556
EXPENSES		
Cost of product sales	2,551,114	4,302,755
General and administrative	610,559	561,047
Research and development	206,819	1,245,973
Sales and marketing	405,626	950,420
Goodwill and fixed asset impairment	—	75,000
Total expenses	3,774,118	7,135,195
OTHER EXPENSE (INCOME), NET		
Loss on disposal of equipment held for lease	63,302	—
Interest (income) expense, net	—	(7,751)
Other expense (income), net	(4,898)	(1,125)
Loss on fixed asset disposal	300	—
Total other expense (income), net	58,704	(8,876)
INCOME (LOSS) FROM DISCONTINUED OPERATIONS BEFORE DISPOSAL	(171,701)	(2,142,763)
Gain on sale of Qualigen, Inc., net of tax	3,876,778	—
INCOME (LOSS) FROM DISCONTINUED OPERATIONS OF QUALIGEN, INC.	$ 3,705,077	$ (2,142,763)

In connection with this transaction, the Company recorded a gain on the sale of Qualigen, Inc. in its consolidated financial statements for the years ended December 31, 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	(627,806)
Gain on sale of Qualigen, Inc.	$ 3,876,778

In the fourth quarter of 2023, the gain was adjusted upward by $ 17,000 upon final payment of transaction costs.

Amendment and Settlement Agreement with NanoSynex Ltd.

On July 20, 2023, the Company entered into and effectuated the NanoSynex Amendment, pursuant to which the Company agreed to, in exchange for eliminating all future NanoSynex Funding Agreement obligations for the Company to invest further cash in NanoSynex (except for obligations to lend NanoSynex $ 560,000 on or before November 30, 2023, and $ 670,000 on or before March 31, 2024), surrender 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

49.97 % of the voting equity of NanoSynex; in addition, the Company agreed to surrender approximately $ 3.0 million of promissory notes which NanoSynex had issued to the Company under the NanoSynex Funding Agreement. On November 22, 2023, the Company further agreed to eliminate the Company's obligations to lend NanoSynex $ 560,000 on or before November 30, 2023, and $ 670,000 on or before March 31, 2024, by instead surrendering shares of Series A-1 Preferred Stock of NanoSynex in an amount that reduced the Company's ownership in NanoSynex voting equity from approximately 49.97 % to 39.90 %.

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 statement of operations items to discontinued operations for the years ended December 31, 2023 and 2022, respectively:

	For the Years Ended December 31,	
	2023	2022
EXPENSES		
Research and development	$ 869,064	$ 1,105,040
Goodwill and fixed asset impairment	—	4,164,000
Total expenses	869,064	5,269,040
Loss on disposal of discontinued operations	4,479,010	—
(BENEFIT) PROVISION FOR INCOME TAXES	(357,757)	(271,622)
LOSS FROM DISCONTINUED OPERATIONS	(4,990,317)	(4,997,418)
Loss attributable to noncontrolling interest	(343,038)	(2,394,100)
NET LOSS ATTRIBUTABLE TO STOCKHOLDERS	$ (4,647,279)	$ (2,603,318)

In connection with this transaction, the Company recorded a loss on deconsolidation of NanoSynex in its consolidated financial statements for the years ended December 31, 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 other comprehensive income 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 December 31, 2023 and December 31, 2022:

	December 31, 2023	December 31, 2022
Board compensation	$ 129,499	70,000
Interest (Convertible debt)	10,004	2,829
License fees	32,975	150,130
Payroll	1,215	1,247
Professional fees	121,775	136,203
Research and development	104,402	329,412
Vacation	151,286	165,040
Other	8,850	9,698
	$ 560,006	$ 864,559

Other accrued liabilities attributable to Qualigen Inc, and NanoSynex were deemed 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 December 31, 2023, the Series C Warrants had a remaining term of 0.49 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 per share exercise price to $ 6.00 per share exercise price with 49,318 additional ratchet Warrants issued. On May 26, 2022, the Series C warrants were repriced from $ 6.00 per share exercise price to $ 5.136 per share exercise price 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 per share exercise price to $ 1.32 per share exercise price with 1,002,717 additional ratchet Warrants issued.

Additionally, on December 22, 2022, in conjunction with the issuance of the Debenture to Alpha (see Note 8 – Convertible Debt – Related Party), the Company issued to Alpha a warrant to purchase 2,500,000 shares of the Company's common stock (the "Alpha Warrant"). The exercise price of the Alpha Warrant was $ 1.65 (equal to 125 % of the conversion price of the Debenture on the closing date). The Alpha Warrant may be exercised by Alpha, in whole or in part, at any time before June 22, 2028, subject to certain terms and conditions described in the Alpha Warrant. The fair value of this warrant was included in Warrant liabilities-related party on the Company's consolidated balance sheet as of December 31, 2022. On December 5, 2023, the Company entered into an Amendment No. 1 with regard to Securities Purchase Agreement, with Alpha. This Amendment amended two instruments which the Company issued under the Securities Purchase Agreement dated December 21, 2022: (a) the 8% Senior Convertible Debenture dated December 22, 2022 in favor of Alpha, and (b) the Common Stock Purchase Warrant dated December 22, 2022 in favor of Alpha. The Amendment reduced the conversion price of the Debenture from $ 1.32 per share to $ 0.73 per share (subject to possible future adjustment pursuant to the terms of the Debenture) and reduced the exercise price of the Warrant from $ 1.65 per share to $ 0.73 per share (subject to possible future adjustment pursuant to the terms of the Warrant). The Amendment also eliminated certain adjustment provisions of the Warrant. The Company determined the event resulted in equity classification for the Warrant and, accordingly, the Company remeasured the warrant liabilities to fair value, and reclassified.

As a result of the Alpha Warrant repricing, on December 5, 2023 the Series C Warrants were repriced again from $ 1.32 per share exercise price to $ 0.73 per share exercise price with 203,652 additional ratchet Series C Warrants issued, resulting in 455,623 of these Series C Warrants outstanding and exercisable as of December 31, 2023.

The following table summarizes the activity in liability classified warrants for the year ended December 31, 2023:

	Common Stock Warrants			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2022	3,849,571	$ 1.53	$ 1.32 - $ 1.65	3.9
Exercised	—	—	—	—
Forfeited	(2,751,976)	1.53	—	—
Expired	(1,097,595)	1.32	1.32	—
Granted	455,623	0.73	0.73	0.49
Total outstanding – December 31, 2023	455,623	$ 0.73	$ 0.73	0.49
Exercisable	455,623	$ 0.73	$ 0.73	0.49

The following table summarizes the activity in the Common Stock Warrants received in exchange for the Series C Warrants for the year ended December 31, 2022:

	Common Stock Warrants			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding –December 31, 2021	248,162	$ 7.20	$ 7.20	2.00
Exercised	(536)	7.20		
Forfeited	(247,625)	7.20		
Expired	—	—		
Granted	3,849,570	1.53		
Total outstanding – December 31, 2022	3,849,571	$ 1.53	$ 1.32 - 1.65	3.9
Exercisable	1,349,571	$ 1.32	$ 1.32	1.00

The following table presents the Company's fair value hierarchy for its Common Stock Warrant liabilities measured at fair value on a recurring basis as of December 31, 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	—	—	—	—
Fair value of warrant reclassified from liabilities to equity	—	—	(1,626,694)	(1,626,694)
Loss on debt extinguishment	—	—	94,116	94,116
Gain on change in fair value of warrant liabilities	—	—	(2,035,469)	(2,035,469)
Balance as of December 31, 2023	$ —	$ —	$ 54,600	$ 54,600

There were no transfers of financial assets or liabilities between category levels for the year ended December 31, 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 assumptions used in, and 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 December 31, 2023 and December 31, 2022:

	December 31, 2023	December 31, 2022	
	Actual	Range	Weighted Average
Risk-free interest rate	5.13%	3.906 % — 4.628 %	4.15%
Expected volatility (peer group)	68.9%	88 % — 103 %	98%
Term of warrants (in years)	0.49	.90 — 5.48	3.9
Expected dividend yield	0.00%	0.00 %	0.00%

NOTE 8 — CONVERTIBLE DEBT- RELATED PARTY

On December 22, 2022, the Company issued to Alpha an 8 % Senior Convertible Debenture in the aggregate principal amount of $ 3,300,000 for a purchase price of $ 3,000,000 (less expenses) pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022. The Debenture has a maturity date of December 22, 2025 and was initially convertible, at any time, and from time to time, until the Debenture is no longer outstanding, at Alpha'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. As a part of the same transaction, on December 22, 2022, the Company issued to Alpha 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 was initially $ 1.65 (equal to 125 % of the Conversion Price of the Debenture on the closing date) subject to adjustment as described in the Alpha Warrant. The Alpha Warrant may be exercised by Alpha, 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 (or waiver) 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 did not begin accruing until December 1, 2023. 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 (or waived).

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 upon 61 days' notice to the Company.

Pursuant to resale registration rights granted by the Company to Alpha in such Securities Purchase Agreement, the Company filed a resale registration statement on Form S-3 (File Number 333-269088) on December 30, 2022 registering the resale by Alpha of up to 5,157,087 shares of common stock of the Company which could be issued to Alpha 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 update the Original Registration Statement via incorporation by reference of its future SEC periodic and current reports 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 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.

The Company evaluated the Debenture and the Alpha Warrant and determined that the Alpha Warrant is a freestanding financial instrument. Initially, 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 was 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 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'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 consolidated statements of operations.

In October and December 2023, the Company issued 309,665 shares of common stock to Alpha in lieu of cash for monthly redemption payments on the Debenture at a weighted average price of $ 0.71 per share. Upon redemption for shares, the Company recognized a loss on partial debt extinguishment of $ 34,315 .

On September 22, 2023, the Company entered into a consent and waiver (the "Waiver") with Alpha. Pursuant to the Waiver, Alpha 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 and December Payment. On October 3, 2023 the Company issued 128,595 shares of common stock to Alpha in satisfaction of the October Payment. On December 8, 2023 the Company issued 181,070 shares of common stock to Alpha in satisfaction of the December Payment.

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

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

During the year ended December 31, 2023, the Company recognized a loss on voluntary conversion of convertible debt of approximately $ 1.1 million, recognized an extinguishment loss of $ 0.6 million upon October and December 2023 share redemptions and December 2023 modification of the Debenture, and recorded accrued interest of approximately $ 1.5 million, in other expenses in the consolidated statements of operations. During the year ended December 31, 2023 the Company paid Monthly Redemption Amounts of $ 550,000 in cash and $ 220,000 in common stock, and as of December 31, 2023 the remaining Debenture principal balance was approximately $ 1.4 million, the remaining discount was approximately $ 0.1 million, and the fair value of the suite of bifurcated embedded derivative features was $ 0 .

The senior convertible debt comprises the following:

	December 31, 2023	December 31, 2022
Senior convertible debenture	$ 1,418,922	$ 3,300,000
Discount on convertible debenture	(119,706)	(3,239,803)
Total convertible debt-related party	$ 1,299,216	$ 60,197

As of December 31, 2023, there were no unwaived events of default or violation of any covenants under the Company's financing obligations.

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 convertible debt, stock options and warrants.

The following potentially dilutive securities have been excluded from diluted net loss per share as of December 31, 2023 and 2022 because their effect would be anti-dilutive:

	For the Years Ended December 31,	
	2023	2022
Net loss used for basic earnings per share	$ (13,417,212)	$ (18,640,543)
Basic weighted-average common shares outstanding	5,072,709	3,840,340
Dilutive potential shares issuable from convertible debt, stock options and warrants	—	—
Diluted weighted-average common shares outstanding	5,072,709	3,840,340

NOTE 10 — COMMITMENTS AND CONTINGENCIES

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

UCL Business Limited

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

For the years ended December 31, 2023 and 2022 there were license costs of approximately $ 128,000 and $ 338,000 , respectively, related to this agreement which are included in research and development expenses in the 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 intends to 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 intends to 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 intends to 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.

University of Louisville Research Foundation

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

Sponsored research expenses related to these RAS agreements for the years ended December 31, 2023 and December 31, 2022 were approximately $ 743,000 and $ 758,000 , respectively, and are recorded in research and development expenses in the Consolidated Statements of Operations. License

costs related to these agreements for the years ended December 31, 2023 and December 31, 2022 were approximately $ 133,000 and $ 40,000 , respectively, and are included in research and development expenses in the Consolidated Statements of Operations.

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

The sponsored research agreement for QN-247 expired in August 2022. The sponsored research expenses related to these QN-247 agreements for the years ended December 31, 2023 and December 31, 2022 were $ 0 and approximately $ 164,000 , respectively, and these amounts are recorded in research and development expenses in the consolidated statements of operations and other comprehensive loss. License costs related to these agreements were approximately $ 23,000 and $ 94,000 for the years ended December 31, 2023 and December 31, 2022, respectively, and are included in research and development expenses in the 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 QN-165 agreements for the years ended December 31, 2023 and 2022.

NOTE 12 — STOCKHOLDERS' EQUITY

As of December 31, 2023, and 2022 the Company had two classes of capital stock: common stock and preferred stock.

Common Stock

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

At December 31, 2023, the Company has reserved 5,781,161 shares of authorized but unissued common stock for possible future issuance as follows:

Exercise of issued and future grants of stock options	755,715
Conversion of convertible debt	1,943,729
Exercise of stock warrants	3,081,717
Total	5,781,161

Preferred Stock

At December 31, 2023 and December 31, 2022, there were no shares of preferred stock outstanding.

Stock Options and Equity Classified Warrants

Stock Options

The Company recognizes all compensatory stock-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 grant of incentive or non-statutory common stock options, restricted stock, stock bonus awards, stock appreciation rights, restricted stock units and performance awards to qualified employees, officers, directors, consultants and other service providers. At December 31, 2023 and December 31, 2022 there were 398,924 and 608,012 outstanding stock options, respectively, under the 2020 Plan and there were 356,778 and 147,690 Plan shares available, respectively, for future grant.

The following represents a summary of the options granted to employees and non-employee service providers that were outstanding at December 31, 2023, and changes during the twelve months 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	(209,088)	34.71	5.14 - 51.30	—
Total outstanding – December 31, 2023	398,924	$ 35.21	$ 5.14 — $ 51.30	7.06
Exercisable (vested)	320,918	$ 41.97	$ 5.14 — $ 51.30	6.77
Non-Exercisable (non-vested)	78,006	$ 7.36	$ 5.14 - $ 32.90	8.36

The following represents a summary of the options granted (under the 2020 Plan and otherwise) to employees and non-employee service providers that were outstanding at December 31, 2022, and changes during the twelve months then ended:

	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	134,469	5.24	5.14 — 10.50	5.99
Expired	(9,379)	932.75	57.50 - 14,657.50	—
Forfeited	(1,264)	22.64	5.14 - 49.70	—
Total outstanding – December 31, 2022	608,012	$ 35.02	$ 5.14 — $ 51.30	8.09
Exercisable (vested)	288,704	$ 46.32	$ 12.40 — $ 51.30	7.59
Non-Exercisable (non-vested)	319,308	$ 24.80	$ 5.14 — $ 10.50	8.59

There was approximately $ 1.1 million and $ 5.4 million of compensation costs related to outstanding options for the year ended December 31, 2023 and December 31, 2022, respectively. This cost is expected to be recognized over a weighted average period of 1.09 years.

No stock options were granted or exercised during the year ended December 31, 2023 or 2022.

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

There were no options granted during the year ended December 31, 2023. The weighted average grant date fair value per share of the shares underlying options granted during the year ended December 31, 2022 was $ 3.96 .

Fair Value of Equity Awards

The Company utilizes the Black-Scholes option pricing model to value awards under the 2020 Plan, and for equity classified compensatory warrants. 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 Years Ended December 31,	
	2023	2022
Expected dividend yield	n/a	0.00 %
Expected stock-price volatility	n/a	103 %
Risk-free interest rate	n/a	1.58 % — 3.77 %
Expected average term of options (in years)	n/a	5.99
Stock price	n/a	5.14 - 10.50

The Company recorded stock-based compensation expense and classified it in the Consolidated Statements of Operations as follows:

	For the Years Ended December 31,	
	2023	2022
General and administrative	$ 939,228	$ 4,649,649
Research and development	159,305	834,395
Total	$ 1,098,533	$ 5,484,044

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 consolidated statements of operations and comprehensive loss.

In addition, various service providers hold equity classified compensatory warrants issued in 2017 and earlier (originally exercisable to purchase Series C convertible preferred stock, and now instead exercisable to purchase common stock) for the purchase of 66,802 reverse split adjusted shares of Company common 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.

On April 25, 2022, 60,000 warrants were repriced from $ 13.20 per share exercise price to a reverse split adjusted exercise price of $ 6.00 per share exercise price and extended from June 3, 2023 to September 14, 2023 . The increase in fair value of $ 67,370 for the modification of these warrants was charged to general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss. These warrants expired on September 14, 2023 . On April 25, 2022 and May 26, 2022 an additional 67,620 reverse split adjusted warrants were repriced from reverse split adjusted $ 11.10 per share exercise price to $ 5.136 per share exercise price. The increase in fair value of $ 31,010 for the modification of these warrants was charged to additional paid-in capital and did not result in expense on the Company's consolidated statements of operations and comprehensive loss. On December 22, 2022 67,620 warrants were repriced from $ 5.136 per share exercise price to $ 1.32 per share exercise price. The increase in fair value of $ 8,548 for the modification of these warrants was charged to additional paid-in capital and did not result in expense on the Company's consolidated statements of operations and comprehensive loss. On December 5, 2023, 67,620 warrants were repriced from $ 1.32 per share exercise price to $ 0.73 per share exercise price. The increase in fair value of $ 7,945 for the modification of these warrants was charged to general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss.

No new compensatory warrants were issued during the year ended December 31, 2023 or 2022.

The following table summarizes the equity classified compensatory warrant activity for the year ended December 31, 2023:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2022	179,046	$ 9.12	$ 1.32 — $ 25.40	1.73
Granted to advisor and its designees	—	—		
Exercised	—	—		
Expired	(60,000)	6.00	6.00	
Forfeited	—	—		
Total outstanding – December 31, 2023	119,046	$ 10.69	$ 0.73 — $ 25.40	1.25
Exercisable	119,046	$ 10.69	$ 0.73 — $ 25.40	1.25
Non-Exercisable	—	$ —	$ —	—

The following table summarizes the equity classified compensatory warrant activity for the year ended December 31, 2022:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2021	179,046	$ 15.20	$ 11.10 — $ 25.40	2.64
Granted to advisor and its designees	—	—		
Exercised	—	—		
Expired	—	—		
Forfeited	—	—		
Total outstanding – December 31, 2022	179,046	$ 9.12	$ 1.32 — $ 25.40	1.73
Exercisable	179,046	$ 9.12	$ 1.32 - $ 25.40	1.73
Non-Exercisable	—	$ —	$ —	—

There was $ 7,945 in compensation costs related to outstanding warrants for the year ended December 31, 2023 and $ 67,370 for the year ended December 31, 2022. As of December 31, 2023 and December 31, 2022, there was no unrecognized compensation cost related to nonvested warrants.

Noncompensatory Equity Classified Warrants

In May 2020, as a commitment fee, the Company issued noncompensatory equity classified warrants to Alpha (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 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 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 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 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 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 to Alpha. These warrants were subsequently exercised in 2022.

In conjunction with the NanoSynex Acquisition, on April 25, 2022 the exercise price of 7,048 reverse split adjusted outstanding warrants at $ 11.10 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 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 consolidated statements of operations and comprehensive loss.

On December 5, 2023, the Company entered into an Amendment No. 1 with regard to Securities Purchase Agreement, with Alpha. This Amendment amended two instruments which the Company issued under the Securities Purchase Agreement dated December 21, 2022: (a) the 8% Senior Convertible Debenture dated December 22, 2022 in favor of Alpha, and (b) the Common Stock Purchase Warrant dated December 22, 2022 in favor of Alpha. The Amendment reduced the Conversion Price of the Debenture from $ 1.32 per share to $ 0.73 per share (subject to possible future adjustment pursuant to the terms of the Debenture) and reduced the Exercise Price of the Alpha Warrant from $ 1.65 per share to $ 0.73 per share (subject to possible future adjustment pursuant to the terms of the Alpha Warrant). The Amendment revised certain provisions of the Warrant which resulted in reclassification of the Warrant from liabilities to equity. For more details see Note 7 - Warrant Liabilities.

The following table summarizes the noncompensatory equity classified warrant activity for the year ended December 31, 2023:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2022	547,003	$ 19.76	$ 1.32 - $ 20.00	0.33
Legacy Ritter warrants	—	—		
Reclassification of Alpha Warrant from warrant liabilities to equity	2,500,000	0.73	0.73	
Exercised	—	—		
Expired	(539,953)	20.00	20.00	
Forfeited	—	—		
Total outstanding – December 31, 2023	2,507,050	$ 0.73		
Exercisable	2,507,050	$ 0.73	0.73	4.47
Non-Exercisable	—	$ —	$ —	—

The following table summarizes the noncompensatory equity classified warrant activity for the year ended December 31, 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	11.10 — 37.78	1.32
Legacy Ritter warrants	—	—		
Granted	331,464	0.01	0.01	
Exercised	(331,464)	0.01	0.01	
Expired	(7,911)	37.78	37.78	
Forfeited	—	—	0	
Total outstanding – December 31, 2022	547,003	$ 19.76	1.32 - 20.00	0.33
Exercisable	547,003	$ 19.76	1.32 - 20.00	0.33
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, an 8 % Senior Convertible Debenture in the aggregate principal amount of $ 3,300,000 for a purchase price of $ 3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022. As of December 31, 2023 the Debenture had a remaining principal balance of $ 1,418,922 , and was convertible, at any time, and from time to time, at Alpha's option, into shares of common stock of the Company, at a price equal to $ 0.73 per share, subject to adjustment as described in the Debenture and other terms and conditions described in the Debenture.

Warrants

Additionally, on December 22, 2022, in conjunction with the issuance of the Debenture to Alpha, the Company issued to Alpha the Alpha Warrant to purchase 2,500,000 shares of the Company's common stock (the "Alpha Warrant"). As of December 31, 2023, the exercise price of the Alpha Warrant was $ 0.73 . The Alpha Warrant may be exercised by Alpha, in whole or in part, at any time before June 22, 2028, subject to certain terms and conditions described in the Alpha Warrant. The Alpha Warrant is included in equity on the Company's consolidated balance sheets (see Note 12 – Stockholders' Equity).

NanoSynex

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

NOTE 14 — INCOME TAXES

The following table presents domestic and foreign components of consolidated loss before income taxes from continuing operations for the periods presented:

	December 31, 2023	December 31, 2022
Domestic	$ (12,479,803)	$ (13,887,914)
Foreign	—	—
Loss before provision for income taxes	$ (12,479,803)	$ (13,887,914)

A reconciliation of the statutory income tax rates and the Company's effective tax rate is as follows:

	December 31, 2023	December 31, 2022
Statutory federal income tax rate	21.00%	21.00%
State taxes, net of federal tax benefit	1.76%	7.50%
Non-deductible expenses	- 0.64%	- 2.09%
NOL expiration	- 5.26%	- 19.88%
Tax credit	2.92%	3.71%
Goodwill impairment	0.00%	0.00%
Foreign rate differential	0.00%	0.00%
Change in fair value of warrant liability	3.35%	0.00%
Tax impact of convertible debenture	- 5.46%	1.37%
Tax impact of divestiture	- 229.26%	4.01%
True-up	- 10.65%	2.24%
Change in valuation allowance	222.28%	- 17.91%
Income taxes provision (benefit)	0.04%	- 0.05%

Income tax expense for the year ended December 31, 2023 and 2022 consisted of the following:

	For the Years Ended	
	December 31, 2023	December 31, 2022
Current		
U.S. Federal	$ (10,000)	$ —
U.S. State	5,000	7,000
Total current provision	(5,000)	7,000
Deferred Benefit		
U.S. Federal	23,128,000	(236,000)
U.S. State	4,697,000	(2,252,000)
Total deferred benefit	27,825,000	(2,488,000)
Change in valuation allowance	(27,825,000)	2,488,000
Total provision (benefit) for income taxes	$ (5,000)	$ 7,000

The components of deferred tax assets and liabilities are as follows:

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating loss	$ 8,644,000	$ 32,587,000
Research and development credits	4,970,000	7,857,000
Accrued expenses	68,000	1,020,000
Patent	—	—
Stock compensation	3,004,000	3,069,000
Research and development expenses	1,102,000	1,196,000
Fixed assets	—	280,000
Total deferred income tax assets	17,788,000	46,009,000
Deferred tax liabilities:		
Intangible assets	—	(13,000)
Right-of-use asset	—	(382,000)
Total deferred income tax liabilities	—	(395,000)
Net deferred income tax assets	17,788,000	45,614,000
Valuation allowance	(17,788,000)	(45,614,000)
Deferred tax asset, net of allowance	$ —	$ —

Based on the available objective evidence, including the Company's history of cumulative losses, management believes it is likely that the Company's U.S. federal and state net deferred tax assets will not be realizable. Accordingly, the Company provided for a full valuation allowance against its U.S. federal and state net deferred tax assets at December 31, 2023 and December 31, 2022.

Due to the full valuation allowance already in place on the Company's U.S. federal and state net deferred tax assets, the Company does not anticipate significant changes in the Company's effective tax rate. However, there is no valuation allowance recorded against the Company's foreign net operating loss deferred tax assets, as the Company's foreign IPR&D deferred tax liabilities and foreign net operating loss deferred tax assets are both indefinite-

lived and thus they may be netted to arrive at a net foreign deferred tax liability.

The Tax Cuts and Jobs Act resulted in significant changes to the treatment of research or experimental ("R&E") expenditures under Section 174. For tax years beginning after December 31, 2021, taxpayers are required to capitalize and amortize all R&E expenditures that are paid or incurred in connection with their trade or business which represent costs in the experimental or laboratory sense. Specifically, costs for U.S. based R&E activities must be amortized over five years and costs for foreign R&E activities must be amortized over 15 years; both using a midyear convention. The Company has incorporated the impact of this new tax legislation into its 2023 and 2022 consolidated financial statements, noting that the impact on the Company's consolidated financial statements was immaterial.

At December 31, 2023, the Company has U.S. federal and state net operating loss carryforwards of approximately $ 15,942,000 and $ 78,693,000 , respectively, which are available to offset future taxable income. U.S. federal and state net operating loss carryovers began to expire in 2020. As a result of the May 2020 reverse recapitalization, an ownership change has occurred. The Company has not completed an Internal Revenue Code Section 382 analysis. As a result, there could be substantial limitations on the Company's ability to utilize its pre-ownership change net operating loss and tax credit carryforwards. These substantial limitations may result in both a permanent loss of certain tax benefits related to net operating loss carryforwards and federal research and development credits, and an annual utilization limitation.

The Company also has research and development credit carryforwards for federal and state tax purposes of approximately $ 3,560,000 and $ 1,410,000 , respectively. The research and development credit carryforwards began to expire in 2020 for federal tax purposes and have an indefinite life for state tax purposes .

U.S. income tax has not been recognized on the excess of the amount for financial reporting over the tax basis of investments in foreign subsidiaries that is indefinitely reinvested outside the United States. This amount becomes taxable upon a repatriation of assets from the subsidiary or a sale or liquidation of the subsidiary. Determination of the amount of any unrecognized deferred income tax liability on this temporary difference is not practicable because of the complexities of the hypothetical calculation.

The Company files income tax returns in the U.S. federal jurisdiction and in various states. The Company's U.S. federal income tax returns remain subject to examination by the Internal Revenue Service. The Company's California income tax returns remain subject to examination by the California Franchise Tax Board. Due to net operating losses, research and development credits and other tax credit carryforwards that may be utilized in future years, all U.S. federal and state tax years are open to examination.

Generally accepted accounting principles clarify the accounting for uncertainty in income taxes recognized in the Company's financial statements and prescribe thresholds for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and also provide guidance on de-recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company adopted these provisions effective April 1, 2009.

The Company did no t have any unrecognized tax benefits as of December 31, 2023 and December 31, 2022 and does not expect this to change significantly over the next 12 months. In accordance with generally accepted accounting principles, the Company will recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of December 31, 2023, the Company has not accrued any interest or penalties related to uncertain tax positions.

NOTE 15 — SUBSEQUENT EVENTS

On February 26, 2024, the Company entered into a Securities Purchase Agreement ("Agreement") with Alpha. The transactions contemplated by the Agreement closed on February 27, 2024, at which time the Company delivered to Alpha the 2024 Debenture and the 2024 Warrant, as described below, and Alpha paid the Company a cash purchase price of $ 500,000 (less $ 25,000 for expense reimbursement). Pursuant to the Agreement, the Company issued to Alpha an 8% Convertible Debenture (the "2024 Debenture") in the principal amount of $ 550,000 . The Debenture has a maturity date of December 31, 2024 and is convertible, at any time, and from time to time, at Alpha's option, into shares of common stock of the Company, at $ 0.6111 per share, subject to adjustment as described in the 2024 Debenture (the "Conversion Price"). The Debenture accrues interest on its outstanding principal balance at the rate of 8 % per annum. The 2024 Debenture does not call for scheduled payments of principal or interest before the scheduled maturity date of December 31, 2024. Pursuant to the terms of the Agreement, the Company also issued to Alpha a 5-year common stock purchase warrant (the "2024 Warrant") to purchase (at $ 0.26 per share) 900,016 shares of common stock of the Company. Under the Agreement, Alpha also has an option, exercisable until July 1, 2024, to purchase from the Company up to an additional $ 1,100,000 in principal amount of 2024 Debentures of like tenor, together with up to an additional 1,800,032 2024 Warrants of like tenor, which would (if and when Alpha exercises such option) provide us up to an additional $ 1.0 million in cash proceeds (less expense reimbursement, and not including any possible cash proceeds from any future exercise of the additional 2024 Warrants). We granted Alpha "piggyback" registration rights for the common shares underlying the 2024 Debenture and the 2024 Warrant.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. 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 defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2023, the end of the year covered by this Annual Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2023, our disclosure controls and procedures were effective. 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.

Management's Report on 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 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 accounting principles generally accepted in the United States of America.

As of December 31, 2023, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on the continuing material weakness described below, our management concluded that as of December 31, 2023, our internal control over financial reporting was not effective.

Description of Material Weaknesses

In connection with the audit of our financial statements as of and for the year ended December 31, 2023, we identified material weaknesses related to a lack of sufficient number of personnel within our accounting function to adequately segregate duties, and we have not designed and implemented effective Information Technology General Controls ("ITGC") related to access controls to financial accounting systems.

We lack the resources to employ additional personnel to help mitigate these material weaknesses and we foresee that these material weaknesses will not be remediated until we receive additional funding to support our accounting department.

Remediation of Material Weakness

We cannot assure you that these or other measures will fully remediate the material weakness in a timely manner. Notwithstanding the identified material weakness, our management believes that the consolidated financial statements included in this 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.

Changes in Internal Control over Financial Reporting

Other than as described above, there were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the year ended December 31, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitation on Effectiveness of Controls

In designing and evaluating our controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. 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. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The Board of Directors

Our board of directors currently consists of six members, each of whose current term of office as a director expires at the 2024 annual meeting of stockholders. Biographical information with respect to our directors is provided below.

Our directors hold office for one year or until their respective successors have been duly elected or until their death, resignation or removal. Our amended and restated bylaws provide that the authorized number of directors comprising our board of directors will be fixed, from time to time, by a majority of the total number of directors.

There are no family relationships among any of our directors or executive officers. There is no arrangement or understanding between any director and any other person pursuant to which the director was selected.

Name	Position with the Company	Age	Director Since
Michael Poirier	Chairman and Chief Executive Officer	68	2020
Richard David	Director	64	2020
Sidney Emery, Jr.	Director	77	2020
Matthew Korenberg	Director	49	2020
Kurt Kruger	Director	68	2020
Ira Ritter	Director	75	2008

Michael S. Poirier. Mr. Poirier founded the Qualigen business in 1996 and is its Chairman and Chief Executive Officer. Before founding Qualigen, Mr. Poirier had relevant operating, marketing and sales positions with Ashirus Technologies, Inc., EnSys, Inc., Sanofi Pasteur and Abbott Laboratories, Inc. Before working at Abbott, Mr. Poirier served as an officer in the United States Navy, assigned to the US Atlantic Fleet. Mr. Poirier holds a B.A. from Providence College and attended the University of Zürich, Switzerland, School of Law.

Mr. Poirier's commitment to our strategic goals, his long experience leading our company and his deep knowledge of its technologies and business contributed to our board of directors' conclusion that he should serve as a director of our company.

Richard A. David, MD FACS. Dr. David serves as Chief Medical Officer for the Los Angeles Division of Genesis Healthcare Partners, the largest urology group in Southern California. He also serves as medical director for Genesis' Advanced Prostate Cancer Center of Excellence. In addition, Dr. David serves as Clinical Professor of Urology for the David Geffen School of Medicine at UCLA. Dr. David obtained his undergraduate education at Stanford University and his medical degree at Thomas Jefferson University in Philadelphia. He also holds a Master's degree in Medical Management

(MMM) from the Marshall School of Business at the University of Southern California. He trained in general surgery and completed his urology residency at UCLA Medical Center in Los Angeles. Dr. David is a fellow of the American College of Surgeons.

Dr. David's experience as an executive of a large healthcare organization, including his background as a medical doctor, contributed to our board of directors' conclusion that he should serve as a director of our company.

Sidney W. Emery, Jr. Mr. Emery is a seasoned executive in manufacturing, distribution and supply chain management. He served as Chairman and Chief Executive Officer of MTS Systems Corporation (Nasdaq-GS: MTSC), a leading global supplier of mechanical testing systems and high-performance industrial position sensors. Mr. Emery served on the Board of Directors of Allete, Inc. (NYSE: ALE), a Minnesota-based utilities and energy company, from 2006 to 2018. Mr. Emery chairs the University of St. Thomas College of Engineering Board of Governors. Mr. Emery holds a PhD in Industrial Engineering from Stanford University and a B.S. in Engineering from the US Naval Academy.

Mr. Emery's extensive board service with and executive leadership of major companies contributed to our board of directors' conclusion that he should serve as a director of our company.

Matthew E. Korenberg. Mr. Korenberg has served as President and Chief Operating Officer of Ligand Pharmaceuticals Incorporated (Nasdaq: LGND), a biopharmaceutical company focused on developing or acquiring technologies that help pharmaceutical companies discover and develop medicines, since November 2022, and before that as Executive Vice President, Finance and Chief Financial Officer of Ligand Pharmaceuticals Incorporated since August 2015. Before joining Ligand, commencing in September 2013, Mr. Korenberg was the founder, Chief Executive Officer and a director of NeuroCircuit Therapeutics, a company focused on developing drugs to treat genetic disorders of the brain with an initial focus on Down syndrome. Before founding NeuroCircuit Therapeutics, Mr. Korenberg was a Managing Director and member of the healthcare investment banking team at Goldman Sachs from July 1999 through August 2013. During his 14 year tenure at Goldman Sachs, Mr. Korenberg was focused on advising and financing companies in the biotechnology and pharmaceutical sectors and was based in New York, London and San Francisco. Before Goldman Sachs, Mr. Korenberg was a healthcare investment banker at Dillon, Read & Co. Inc. where he spent two years working with healthcare companies in the biotechnology and pharmaceutical sectors and industrial companies. Mr. Korenberg holds a B.B.A. in Finance and Accounting from the University of Michigan.

Mr. Korenberg's financial and accounting expertise, his experience as chief financial officer of a large public biopharmaceutical company and his investment banking background contributed to our board of directors' conclusion that he should serve as a director of our company.

Kurt H. Kruger. Mr. Kruger has enjoyed a 30-year career in medical technology. His deep involvement in the field has ranged from product design and development as a biomedical engineer to raising capital for, and following, publicly traded medical product companies as an equities research analyst. As a marketing manager at Guidant, now a part of Boston Scientific, he developed the launch plans for the first-ever implantable defibrillator. As a securities analyst he led Hambrecht & Quist's efforts in providing venture funds for, and then taking public, Ventritex, which was later acquired by St. Jude Medical/Abbott. After H&Q, Mr. Kruger worked as an analyst for Montgomery Securities and Bank of America. Across 20 years of research work, Mr. Kruger has overseen the IPOs of over 30 medical products companies. Later he headed up the Life Sciences banking effort for WR Hambrecht & Co. Mr. Kruger received a Sc.B. degree in Biomedical Engineering from Brown University; a Master's degree in Bioengineering from the University of Michigan; and a business degree (S.M.) from the Sloan School at the Massachusetts Institute of Technology (MIT). He also completed the premedical post-baccalaureate program at Columbia University.

Mr. Kruger's long experience in investment banking and securities analysis with a life sciences focus contributed to our board of directors' conclusion that he should serve as a director of our company.

Ira E. Ritter. Mr. Ritter served as Co-Founder, Chief Strategic Officer and Executive Chairman of the Company during its Ritter Pharmaceuticals, Inc. phase, from its inception in 2004 through the formation of the Ritter Pharmaceuticals, Inc. corporate entity in 2008 and served in those positions with Ritter Pharmaceuticals, Inc. from 2008 until the May 22, 2020 reverse recapitalization transaction (the "Reverse Recapitalization Transaction") in which Ritter Pharmaceuticals, Inc. changed its name to Qualigen Therapeutics, Inc. Mr. Ritter has extensive experience creating and building diverse business enterprises and since 1987 through Andela Corporation, of which he is the CEO, has provided corporate management, strategic planning and financial consulting for a wide range of market segments including; health product related national distribution and private label production, television and publishing. He assisted taking Ritter Pharmaceuticals, Inc. public on Nasdaq and Martin Lawrence Art Galleries public on the New York Stock Exchange. Since 2010, Mr. Ritter has also acted as a managing partner of Stonehenge Partners, LLC. Mr. Ritter has a long history of public service that includes appointments by three Governors to several State of California Commissions including eight years as Commissioner on the California Prison Industry Authority.

Mr. Ritter's experience as an entrepreneur and chairman of a publicly traded development-phase therapeutics company contributed to our board of directors' conclusion that he should serve as a director of our company. Mr. Ritter continued his service on our board of directors, by agreement in connection with the Reverse Recapitalization Transaction, as the designated legacy member from the pre-Reverse Recapitalization Transaction public-company board of directors.

Committees of the Board of Directors

Our board of directors has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each committee operates under a charter. Copies of each committee's charter are posted on the Investor Relations section of our website, which is located at *www.qlgntx.com*.

Audit Committee. The current members of our Audit Committee are Mr. Kruger (Chair), Mr. Emery, and Mr. Korenberg, each of whom was determined by our board of directors to be independent under Rule 10A-3 under the Exchange Act and the continued listing requirements of Nasdaq, and to satisfy the other continued listing requirements of Nasdaq for audit committee membership. The Company has identified Matthew Korenberg as an "audit committee financial expert" as such term is defined in Item 407(d)(5) of SEC Regulation S-K, and has determined that he has the requisite level of financial sophistication required by the continued listing requirements of Nasdaq; this identification does not constitute a determination that other members of the Audit Committee would not also be able to qualify as an "audit committee financial expert."

EXECUTIVE OFFICERS

The following table sets forth information about our current executive officers.

Name	Age	Position with the Company
Michael Poirier	68	Chairman and Chief Executive Officer
Christopher Lotz	59	Chief Financial Officer, Vice President of Finance

Officers serve at the discretion of the board of directors. There are no family relationships among any of our directors or executive officers. There is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected.

For the biography of Mr. Poirier, please see “Board of Directors” above.

Christopher L. Lotz | Chief Financial Officer, Vice President of Finance. Mr. Lotz joined Qualigen, Inc. as Director of Finance in 2002 and was promoted to his current role of Chief Financial Officer, Vice President of Finance in 2003. He became an officer of the Company at the time of the Reverse Recapitalization Transaction in 2020. Before joining Qualigen, Inc. Mr. Lotz spent the previous 15 years serving in financial leadership positions with Bexcom, an Asian-based software developer, California Furniture Collections, Inc., a custom furniture manufacturer, and Group Publishing, Inc., an educational media publisher. Mr. Lotz holds a B.S. in Business Administration from Colorado State University.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires the Company’s officers and directors, and persons who own more than 10% of our common stock, to file reports of securities ownership and changes in such ownership with the SEC. Officers, directors, and greater than 10% stockholders also are required by SEC rules to furnish the Company with copies of all Section 16(a) forms they file.

Based solely on the Company’s review of Forms 3, 4 and 5 filed by such persons and information provided by the Company’s directors and officers, the Company believes that during the year ended December 31, 2023, all Section 16(a) filing requirements applicable to such persons were met in a timely manner.

Item 11. Executive Compensation.

Summary Compensation Table (2023 and 2022)

The following table sets forth the compensation paid to or earned by our named executive officers for the periods presented.

Name and Principal Position	“Year”	Salary ($)	Bonus ($)	Option Awards[1] ($)	All Other Compensation[2] ($)	Total ($)
Michael Poirier, Chairman and Chief Executive Officer	2023	512,635	118,174	—	1,889	632,698
	2022	575,000	—	145,274	8,180	728,454
Tariq Arshad, Former Chief Medical Officer and Senior Vice President [3]	2023	356,615	101,231	—	5,326	463,172
	2022	400,000	—	39,512	138	439,650
Amy Broidrick, Former President, Chief Strategy and Operating Officer[4]	2023	194,017	—	—	371,454	565,470
	2022	450,000	—	50,359	7,642	508,001

(1) The amounts reported in this column reflect the aggregate grant date fair value of the option awards granted during 2022, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (“ASC 718”). Such grant date fair values do not take into account any estimated forfeitures related to service-based vesting conditions. Assumptions used in the calculation of these amounts are included in the notes to our consolidated financial statements included in this Annual Report. These amounts do not reflect the actual economic value that may be realized by the executive officers upon the exercise of the stock options or the sale of the common stock underlying such stock options. There were no option awards granted during 2023.
(2) The amounts reported in this column represent 401(k) matching contributions and life insurance premiums paid by us for Mr. Poirier and Dr. Arshad, and $1,316 in 401(k) matching contributions and life insurance premiums paid by us for Ms. Broidrick, and $370,138 in severance compensation for Ms. Broidrick.
(3) Dr. Arshad resigned from his role as Chief Medical Officer and Senior Vice President effective February 25, 2024.
(4) Ms. Broidrick resigned from her role as President, Chief Strategy and Operating Officer and as a Director effective June 16, 2023. The 2023 “Salary” for Ms. Broidrick includes amounts we paid through June 16, 2023. The 2023 “All Other Compensation” for Ms. Broidrick includes $370,138 of severance compensation.

Executive Employment Agreements

Employment Agreement with Michael Poirier

Mr. Poirier is party to an Executive Employment Agreement dated February 1, 2017, as amended January 9, 2018 (the “Poirier Employment Agreement”). The Poirier Employment Agreement had an initial three-year term and is now automatically renewed for successive one-year periods unless either party gives notice of nonrenewal at least 90 days before the end of such a one-year period.

Under the terms of the Poirier Employment Agreement, Mr. Poirier is entitled to an annual base salary of at least $315,000, is eligible to participate in the Company’s bonus plans, benefit programs and medical benefits, is eligible for certain event-based bonuses (including for “Liquidity Event” acquisition transactions), and is entitled to four weeks of vacation per year. If Mr. Poirier’s employment is terminated without Cause or he resigns for Good Reason (as such terms are defined in the Poirier Employment Agreement), and he provides a general release to the Company, he will be entitled to one year of salary continuation plus the cost of COBRA coverage continuation for such one year period. In May 2021, our board of directors and its compensation committee increased Mr. Poirier’s annual base salary to $575,000. On January 13, 2023, the Company’s board of directors, as part of certain cost-cutting measures, approved a temporary 20% reduction to the base salaries of all executive officers of the Company. Accordingly, on January 16, 2023, Mr. Poirier’s base salary was reduced to $460,000; it was subsequently restored in August 2023.

Employment Agreement with Christopher Lotz

Mr. Lotz is party to an Executive Employment Agreement dated February 1, 2017, as amended January 9, 2018 (the “Lotz Employment Agreement”). The Lotz Employment Agreement had an initial three-year term and is now automatically renewed for successive one-year periods unless either party gives notice of nonrenewal at least 90 days before the end of such a one-year period.

Under the terms of the Lotz Employment Agreement, Mr. Lotz is entitled to an annual base salary of at least $225,000, is eligible to participate in

the Company's bonus plans, benefit programs and medical benefits, is eligible for certain event-based bonuses (including for "Liquidity Event" acquisition transactions), and is entitled to four weeks of vacation per year. If Mr. Lotz's employment is terminated without Cause or he resigns for Good Reason (as such terms are defined in the Lotz Employment Agreement), and he provides a general release to the Company, he will be entitled to 180 days of salary continuation plus the cost of COBRA coverage continuation for such 180 day period. In May 2021, our board of directors and its compensation committee increased Mr. Lotz's annual base salary to $300,000. On January 13, 2023, the Company's board of directors, as part of certain cost-cutting measures, approved a temporary 20% reduction to the base salaries of all executive officers of the Company. Accordingly, on January 16, 2023, Mr. Lotz's base salary was reduced to $240,000; it was subsequently restored in August 2023.

Offer Letter with Tariq Arshad

Under the terms of his hire offer letter with the Company, dated May 17, 2021, Dr. Arshad was entitled to an annual base salary of at least $400,000. He received a cash signing bonus of $25,000 when he joined the Company, was eligible to receive annual cash bonuses equal to an amount up to 40% of his annualized base salary, and is entitled to four weeks of vacation per year. Under the terms of his hire offer letter, if Dr. Arshad's employment is terminated without Cause or he resigns for Good Reason, and he provides a general release to the Company, he will be entitled to 180 days of salary continuation plus the cost of COBRA coverage continuation for such 180 day period.

On February 25, 2024, Dr. Arshad resigned from his position as the Company's Chief Medical Officer and Senior Vice President. He did not assert that the resignation was for Good Reason and he did not provide a general release to the Company.

Employment Agreement with Amy Broidrick

Ms. Broidrick was party to an Executive Employment Agreement with Qualigen, Inc., a former wholly-owned subsidiary of the Company, dated December 10, 2021. On May 16, 2023, Ms. Broidrick resigned from all officer and director positions with the Company and its subsidiaries, which became effective June 16, 2023 (the "Separation Date"). Ms. Broidrick's departure was not related to any disagreement with the Company on any matter relating to the Company's operations, policies, or practices. In connection with her termination of employment, on June 20, 2023, Qualigen, Inc, entered into a separation agreement and general release with Ms. Broidrick, which became effective after a 7 day revocation period following Ms. Broidrick's signing of it, on June 24, 2023. Under the terms of the Separation Agreement, Qualigen, Inc. was obligated to provide Ms. Broidrick severance in the form of continued salary pay at the rate then in effect on the Separation Date ($360,000 per annum) for a period of 12 months following the Separation Date, subject to applicable withholding, and payment or reimbursement for the cost of COBRA continuation medical and dental insurance coverage for 12 months following the Separation Date, less any required taxes or withholdings. Upon the July 20, 2023 closing of our sale of Qualigen, Inc., Chembio (as the new parent company of Qualigen, Inc.) undertook the remaining severance liability to Ms. Broidrick.

Stock Incentive Plan

The material terms of our 2020 Stock Equity Incentive Plan (as amended, the "2020 Plan") are outlined below. This summary is qualified in its entirety by reference to the complete text of the 2020 Plan, which is incorporated herein by reference.

Authorized Shares. We have reserved an aggregate of 755,702 shares of our common stock for issuance under the 2020 Plan. The number of shares is subject to adjustment in the event of any recapitalization, stock split, reclassification, stock dividend or other change in our capitalization. In addition, the following shares of our common stock will be available for grant and issuance under the 2020 Plan:

- shares subject to stock options or stock appreciation rights ("SARs"), granted under the 2020 Plan that cease to be subject to the stock option or SAR for any reason other than exercise of the stock option or SAR;
- shares subject to awards granted under the 2020 Plan that are subsequently forfeited or repurchased by us at the original issue price;

- shares subject to awards granted under the 2020 Plan that otherwise terminate without shares being issued;
- shares surrendered, canceled, or exchanged for cash or a different award (or combination thereof); and
- shares subject to awards under the 2020 Plan that are used to pay the exercise price of an award or withheld to satisfy the tax withholding obligations related to any award.

Plan Administration. The 2020 Plan will be administered by our Compensation Committee or by our board of directors acting in place of our Compensation Committee. Our Compensation Committee will have the authority to construe and interpret the 2020 Plan, grant awards and make all other determinations necessary or advisable for the administration of the 2020 Plan.

Awards and Eligible Participants. The 2020 Plan authorizes the award of stock options, stock appreciation rights, restricted stock unit, performance awards and stock bonuses. The 2020 Plan provides for the grant of awards to our employees, directors, consultants and independent contractor service providers, subject to certain exceptions. No non-employee director may be granted awards under the 2020 Plan in any calendar year that, taken together with any cash fees paid by us to such non-employee director during such calendar year, exceed $5,000,000 (calculating the value of any award based on the grant date fair value determined in accordance with GAAP). No more than 98,000,000 shares of our common stock will be issued under the 2020 Plan pursuant to the exercise of incentive stock options.

Stock Options. The 2020 Plan permits us to grant incentive stock options and non-qualified stock options. The exercise price of stock options will be determined by our Compensation Committee, and may not be less than 100% of the fair market value of our common stock on the date of grant. Our Compensation Committee has the authority to reprice any outstanding stock option (by reducing the exercise price, or canceling the stock option in exchange for cash or another equity award) under the 2020 Plan without the approval of our stockholders. Stock options may vest based on the passage of time or the achievement of performance conditions in the discretion of our compensation committee. Our Compensation Committee may provide for stock options to be exercised only as they vest or to be immediately exercisable with any shares issued on exercise being subject to our right of repurchase that lapses as the shares vest. The maximum term of stock options granted under the 2020 Plan is 10 years.

Stock Appreciation Rights. SARs provide for a payment to the holder, in cash or shares of our common stock, based upon the difference between the fair market value of our common stock on the date of exercise and the stated exercise price on the date of grant, up to a maximum amount of cash or number of shares. SARs may vest based on the passage of time or the achievement of performance conditions in the discretion of our Compensation Committee. Our Compensation Committee has the authority to reprice any outstanding SAR (by reducing the exercise price, or canceling the SAR in exchange for cash or another equity award) under the 2020 Plan without the approval of our stockholders.

Restricted Stock Awards. A restricted stock award represents the issuance to the holder of shares of our common stock, subject to the forfeiture of those shares in the event of failure to achieve certain performance conditions or termination of employment. The purchase price, if any, for the shares will be determined by our Compensation Committee. Unless otherwise determined by the administrator at the time of award, vesting will cease on the date the holder no longer provides services to us and unvested shares will be forfeited to us or can be repurchased by us.

Restricted Stock Units. Restricted stock units ("RSUs") represent the right on the part of the holder to receive shares of our common stock at a specified date in the future, subject to forfeiture of that right in the event of failure to achieve certain performance conditions or termination of employment. If a RSU has not been forfeited, then, on the specified date, we will deliver to the holder of the RSU shares of our common stock, cash or a combination of cash and shares of our common stock, as previously determined by the Compensation Committee at the time of the award.

Performance Awards. Performance awards cover a number of shares of our common stock that may be settled upon achievement of performance conditions as provided in the 2020 Plan in cash or by issuance of the underlying common stock. These awards are subject to forfeiture before settlement in the event of failure to achieve certain performance conditions or termination of employment.

Stock Bonuses. Stock bonuses may be granted as additional compensation for past or future service or performance and, therefore, no payment will be required from a participant for any shares awarded under a stock bonus. Unless otherwise determined by our Compensation Committee at the time of award, vesting will cease on the date the holder no longer provides services to us and unvested shares will be forfeited to us.

Change-in-Control. If we are party to a merger or consolidation, sale of all or substantially all our assets or similar change-in-control transaction, outstanding awards, including any vesting provisions, may be assumed or substituted by the successor company. In the alternative, the successor company may issue, in place of outstanding shares held by a 2020 Plan participant, substantially similar shares or other property subject to repurchase obligations no less favorable to the participant. Outstanding awards that are not assumed, substituted or cashed out will accelerate in full and expire immediately before the transaction, and awards will be exercisable for a period of time determined by the administrator.

Amendment; Termination. The 2020 Plan will terminate 10 years from April 8, 2020, unless it is terminated earlier by our board of directors. Our board of directors may amend, suspend or terminate the 2020 Plan at any time, subject to compliance with applicable law.

Federal Income Tax Summary. The following is a brief summary of the principal federal income tax consequences to us and to an eligible person (who is a citizen or resident of the United States for U.S. federal income tax purposes) (a "Participant") of awards that may be granted under the 2020 Plan. The summary is not intended to be exhaustive and, among other things, does not describe state, local or foreign tax consequences. The federal income tax consequences of an eligible person's award under the 2020 Plan are complex, are subject to change and differ from person to person. Each person should consult with his or her own tax adviser as to his or her own particular situation.

This discussion is based on the Code, Treasury Regulations promulgated under the Code, Internal Revenue Service rulings, judicial decisions and administrative rulings as of the date of this proxy statement, all of which are subject to change or differing interpretations, including changes and interpretations with retroactive effect. No assurance can be given that the tax treatment described herein will remain unchanged at the time that awards under the 2020 Plan are made.

A Participant will not recognize income upon the grant of an option or at any time prior to the exercise of the option. At the time the participant exercises a non-qualified option, he or she will recognize compensation taxable as ordinary income in an amount equal to the excess of the fair market value of the common stock on the date the option is exercised over the price paid for the common stock, and we will then be entitled to a corresponding deduction.

A Participant who exercises an incentive stock option will not be taxed at the time he or she exercises his or her options or a portion thereof. Instead, he or she will be taxed at the time he or she sells the common stock purchased pursuant to the option. The Participant will be taxed on the excess of the amount for which he or she sells the stock over the price he or she had paid for the stock. If the Participant does not sell the stock prior to two years from the date of grant of the option and one year from the date the stock is transferred to him or her upon exercise, the gain will be capital gain and we will not get a corresponding deduction. If the Participant sells the stock at a gain prior to that time, the difference between the amount the Participant paid for the stock and the lesser of the fair market value on the date of the exercise or the amount for which the stock is sold, will be taxed as ordinary income and we will be entitled to a corresponding deduction. If the Participant sells the stock for less than the amount he or she paid for the stock prior to the one or two year periods indicated, no amount will be taxed as ordinary income and the loss will be taxed as a capital loss.

A Participant generally will not recognize income upon the grant of a stock appreciation right or a restricted stock unit. At the time a Participant receives shares or cash payment under any such award, he or she generally will recognize compensation taxable as ordinary income in an amount equal to the cash or the fair market value of the common stock received, less any amount paid for the stock, and we will then be entitled to a corresponding deduction. Upon a subsequent sale of the shares received under the stock appreciation right or restricted stock unit, if any, the difference between the amount realized on the sale and the Participant's tax basis (the amount previously included in income) is generally taxable as a capital gain or loss, which will be short-term or long-term depending on the Participant's holding time of such shares.

The taxation of restricted stock is dependent on the actions taken by the Participant. Generally, absent an election to be taxed currently under Section 83(b) of the Code, or an 83(b) election, there will be no federal income tax consequences to the Participant upon the grant of a restricted stock award. At the lapse of the restrictions or satisfaction of the conditions on the restricted stock, the Participant will recognize ordinary income equal to the fair market value of our common stock at that time. If the Participant makes an 83(b) election within 30 days of the date of grant, he or she will recognize ordinary income equal to the fair market value of our common stock at the time of grant, determined without regard to the applicable restrictions. If an 83(b) election is made, no additional income will be recognized by the Participant upon the lapse of the restrictions or satisfaction of the conditions on the restricted stock award. We generally should be entitled to a deduction equal to the amount of ordinary income recognized by the Participant, at the same time as the ordinary income is recognized by the Participant. Upon a subsequent sale of the formerly restricted stock, the difference between the amount realized on the sale and the Participant's tax basis (the amount previously included in income) is generally taxable as a capital gain or loss, which will be short-term or long-term depending on the Participant's holding time of such shares.

The tax consequences to Participants who receive performance-based awards depend on the particular type of award issued. Our ability to take a deduction for such awards similarly depends on the terms of the awards and the limitations of Section 162(m) of the Code, if applicable. Section 162(m) of the Code currently imposes a $1 million limit on the amount that a public company may deduct for compensation paid to an employee who is chief executive officer, chief financial officer, or another "covered employee" (as defined by Section 162(m)), or was such an employee beginning in any year after 2017. The Compensation Committee retains the discretion to establish the compensation paid or intended to be paid or awarded to the executive officers as the Compensation Committee may determine is in the best interest of us and our stockholders, and without regard to any limitation provided in Section 162(m). This discretion is an important feature of the Compensation Committee's compensation practices because it provides the Compensation Committee with sufficient flexibility to respond to specific circumstances facing us.

Outstanding Equity Awards at December 31, 2023

The following table presents the outstanding stock options and compensatory warrants held by each of the named executive officers as of December 31, 2023. There were no direct stock awards, restricted stock units or stock appreciation rights outstanding at December 31, 2023. All pre-2020 "option" awards shown were initially issued as Qualigen, Inc. Series C Warrants, and became warrants exercisable instead for our common stock

(at an adjusted exercise price) upon the Reverse Recapitalization Transaction. The share numbers and exercise prices in the table below reflect the reverse stock split, which was effected by the Company on November 23, 2022 (the "Reverse Stock Split").

	Equity Awards				
Name	Grant Date	Number of Securities Underlying Unexercised Awards (#) Exercisable	Number of Securities Underlying Unexercised Awards (#) Unexercisable	Exercise Price ($)	Expiration Date
Michael Poirier	7/11/2022	12,500	25,000(1)	5.14	7/11/2032
	6/5/2020	100,000	—	51.30	6/5/2030
	9/22/2016	1,443	—	25.41	9/22/2026
	3/3/2015	2,214	—	25.41	3/2/2025
	8/2/2014	2,984	—	20.66	8/2/2024
	1/31/2014	2,214	—	20.66	1/31/2024
Tariq Arshad	7/11/2022	3,400	6,800(1)	5.14	7/11/2032
	12/8/2021	20,000	10,000(2)	12.40	5/17/2031
	5/17/2021	6,667	3,333(1)	18.00	5/17/2031
Amy Broidrick	7/11/2022	—	13,000(3)	5.14	7/11/2032
	12/8/2021	—	30,000(3)	12.40	12/8/2031
	12/7/2020	—	15,000(3)	35.20	12/7/2030
	8/27/2020	—	5,000(3)	47.00	8/27/2030

(1) Shares underlying the stock option vest over three years in three equal annual installments from the date of grant.

(2) Shares underlying the stock option vest over three years in three equal annual installments from the vesting commencement date of May 17, 2021.

(3) Following Ms. Broidrick's termination of employment on June 16, 2023, she did not exercise any vested stock options, and all of her equity awards were subsequently forfeited.

Pay Versus Performance (PVP)

In accordance with the SEC's disclosure requirements regarding pay versus performance, or PVP, this section presents the SEC-defined "Compensation Actually Paid," or CAP of our principal executive officer ("PEO") and named executive officers ("NEOs") for each of the fiscal years ended December 31, 2023, 2022, and 2021, and our financial performance. Also as required by the SEC, this section compares CAP to various measures used to gauge performance at the Company for each such fiscal year.

Pay versus Performance Table - Compensation Definitions

Salary, Bonus, Stock Awards, and All Other Compensation are each calculated in the same manner for purposes of both CAP and Summary Compensation Table, or SCT values. The primary difference between the calculation of CAP and SCT total compensation is the calculation of the value of "Stock Awards," with the table below describing the differences in how these awards are valued for purposes of SCT total and CAP:

	SCT Total	CAP
Stock Awards	Grant date fair value of stock awards granted during the year	Fair value of stock awards that are unvested as of the end of the year, or vested during the year

Pay Versus Performance Table

In accordance with the SEC's new PVP rules, the following table sets forth information concerning the compensation of our NEOs for each of the fiscal years ended December 31, 2023, 2022, and 2021, and our financial performance for each such fiscal year:

Year	Summary Compensation Table Total for PEO	Compensation Actually Paid to PEO	Average Summary Compensation Table Total for non-PEO Named Executive Officers	Average Compensation Actually Paid to non-PEO Named Executive Officers	Value of Initial Fixed $100 Investment Based On Total Shareholder Return	Net Loss Attributable to Qualigen Therapeutics, Inc. (millions)
2023	$ 632,698	$ 612,865	$ 514,321	$ 488,856	$ 1.83	$ (13.4)
2022	728,454	262,274	473,826	121,235	4.29	(18.6)
2021	742,279	(753,431)	811,499	609,691	38.21	(17.9)

The principal executive officer ("PEO") in 2023, 2022, and 2021 was Michael Poirier, our Chairman and Chief Executive Officer. The Non-PEO NEOs in 2023, 2022, and 2021 were Amy Broidrick, who was our President, Chief Strategy and Operating Officer, and Tariq Arshad, who was our Chief Medical Officer and Senior Vice President. The CAP was calculated beginning with the NEOs SCT total. The following amounts were deducted from and added to the applicable SCT total compensation:

		SCT Total (A)	Stock awards deducted from SCT (B)	Increase for fair value of awards granted during the year that remain unvested as of year end (C)	Decrease in fair value from prior year-end to current year-end for awards granted in prior years and unvested as of year end (D)	Decrease in fair value from prior year-end to current year vesting date for awards granted in prior years (E)	Total CAP A-B+C+D+E
PEO							
	2023	$ 632,698	$ -	$ -	$ (13,650)	$ (6,183)	$ 612,865
	2022	728,454	(145,274)	31,387	(218,695)	(133,598)	262,274
	2021	742,279	-	-	(1,236,534)	(259,176)	(753,431)
Average Non-PEO NEO							
	2023	$ 514,321	$ -	$ -	$ (23,708)	$ (1,757)	$ 488,856
	2022	473,826	(44,936)	9,709	(218,541)	(98,823)	121,235
	2021	811,499	(363,370)	314,858	(104,300)	(48,997)	609,691

The fair value of stock options reported for CAP purposes in columns (B), (C), (D) and (E) above was estimated using a Black-Scholes option pricing model for the purposes of this PVP calculation in accordance with SEC rules. This model uses both historical data and current market data to estimate the fair value of options and requires several assumptions. The assumptions used in estimating fair value for awards granted during 2022 were as follows: volatility 102%, expected life 5.99 years, expected dividend yield 0%, risk-free rate 3.04%. The assumptions used in estimating fair value for awards granted during 2021 and prior were as follows: volatility 102%, expected life 5.99 years, expected dividend yield 0%, risk-free rate 0.42% - 1.43%. There were no awards granted in 2023.

Analysis of Information Presented in the Pay versus Performance Table

Our executive compensation program reflects a variable pay-for-performance philosophy. While we utilize several performance measures to align executive compensation with Company performance, all of those Company measures are not presented in the Pay versus Performance table. Moreover, we generally seek to incentivize long-term performance, and therefore we do not specifically align our performance measures with compensation that is actually paid (as computed in accordance with SEC rules) for a particular year. Further, we do not have the right to (without the executive's consent) reduce an executive's salary for a particular year to an amount lower than is provided for in any employment agreement with the executive which covers such year. In accordance with SEC rules, we provide the following narrative disclosure:

Compensation Actually Paid and Cumulative Total Stockholder Return

Compensation actually paid to our PEO increased from ($753,431) in 2021 to $262,274 in 2022, and further increased to $612,865 in 2023. Average compensation actually paid to our named executive officers other than our PEO decreased from $609,691 in 2021 to $121,235 in 2022, and increased to $488,856 in 2023. Over the same period, the value of an investment of $100 in our common stock on the last trading day of 2020 decreased by $61.79 to $38.21 during 2021, further decreased by $33.92 to $4.29 during 2022, and further decreased by $2.46 during 2023, for a total decrease over 2021, 2022, and 2023 of $98.17.

Compensation Actually Paid and Net Loss

Compensation actually paid to our PEO increased from ($753,431) in 2021 to $262,274 in 2022, and further increased to $612,865 in 2023. Average compensation actually paid to our named executive officers other than our PEO decreased from $609,691 in 2021 to $121,235 in 2022, and increased to $488,856 in 2023. Over the same period, our net loss increased by $0.7 million during 2022 (from a net loss in 2021 of $17.9 million to a net loss in 2022 of $18.6 million), and decreased by $5.2 million during 2023 (from a net loss in 2022 of $18.6 million to a net loss in 2023 of $13.4 million).

Compensation of Directors

For 2023, our non-employee directors were eligible to receive $35,000 in annual cash compensation. The Audit Committee chair was eligible to receive additional annual cash compensation of $15,000 and the other Board committee chairs were eligible to receive additional annual cash compensation of $10,000. Each non-chair member of each Board committee was eligible to receive additional annual cash compensation of $7,500 (Audit Committee) and $5,000 (other Committees). On January 13, 2023, the Company's board of directors, as part of certain cost-cutting measures, approved a temporary 20% reduction to the compensation of all directors of the Company effective January 1, 2023. On August 1, 2023 the Company's board of directors approved the reinstatement of the compensation of all directors of the Company to the above amounts effective August 1, 2023. Non-employee directors did not receive stock option grants during 2023. The amounts in the table below represent fees actually paid in cash during 2023 and include some fees earned in 2022.

Compensation paid to Mr. Poirier and Ms. Broidrick is presented as part of the "Summary Compensation Table" above, rather than here. Our employee directors do not receive compensation for their service as directors.

Name of Director	Fees Paid in Cash ($)	Option Awards ($)	All other compensation ($)	Total ($)
Richard David	40,000	—	—	40,000
Sidney Emery, Jr.	46,000	—	—	46,000
Matthew Korenberg	42,000	—	—	42,000
Kurt Kruger	40,000	—	—	40,000
Ira Ritter	16,333	—	—	16,333

As of December 31, 2023, all non-employee directors had been paid for compensation earned through July 31, 2023.

Hedging or Offsetting Against Compensatory Securities

We have adopted a policy that our employees (including officers) and directors shall not purchase securities or other financial instruments, or otherwise engage in transactions, that hedge or offset, or are designed to hedge or offset, any decrease in the market value of equity securities granted as compensation to, or held directly or indirectly by, those persons.

We have adopted a formal claw-back policy for the recovery of incentive-based executive compensation erroneously awarded to executive officers based on misstated financial reporting measures.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information regarding the beneficial ownership of our common stock as of March 25, 2024 by:

- our named executive officers;
- our directors;
- all of our current directors and executive officers as a group; and
- each stockholder known by us to own beneficially more than 5% of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days after March 25, 2024, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. The percentage of beneficial ownership of our common stock is calculated based on an aggregate of 6,307,371 shares outstanding as of March 25, 2024.

Except as indicated in the footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Qualigen Therapeutics, Inc., 5857 Owens Avenue, Suite 300, Carlsbad, California 92008 USA.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned
Five Percent Stockholders		
Alpha Capital Anstalt [(1)]	700,041	9.99%
Executive Officers, Directors and Director Nominees		
Michael Poirier [(2)]	142,376	2.2%
Christopher Lotz [(3)]	72,353	1.1%
Richard David [(4)]	7,219	*%
Sidney Emery, Jr. [(5)]	8,302	*%
Matthew Korenberg [(6)]	6,334	*%
Kurt Kruger [(7)]	9,019	*%
Ira Ritter [(8)]	6,738	*%
All current executive officers and directors as a group (7 persons) [(9)]	252,341	3.9%

* Represents beneficial ownership of less than 1% of the shares of common stock.

(1) Includes shares of common stock issuable upon the exercise of warrants or conversion of its convertible debentures; Alpha Capital Anstalt would not be permitted to convert or exercise all or any portion of its warrants or debentures to the extent that such conversion or exercise would result in Alpha Capital Anstalt (and its affiliates) beneficially owning more than 9.99% of the number of shares of Company common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion/exercise. Konrad Ackermann has voting and investment power over the shares held by Alpha Capital Anstalt.

(2) Includes 112,500 shares of common stock exercisable within 60 days under outstanding stock options and 8,855 shares of common stock exercisable within 60 days under outstanding warrants.

(3) Includes 63,333 shares of common stock exercisable within 60 days under outstanding stock options and 7,766 shares of common stock exercisable within 60 days under outstanding warrants.

(4) Includes 6,334 shares of common stock exercisable within 60 days under outstanding stock options and 885 shares of common stock exercisable within 60 days under outstanding warrants.

(5) Includes 6,334 shares of common stock exercisable within 60 days under outstanding stock options.

(6) Includes 6,334 shares of common stock exercisable within 60 days under outstanding stock options.

(7) Includes 6,334 shares of common stock exercisable within 60 days under outstanding stock options and 885 shares of common stock exercisable within 60 days under outstanding warrants.

(8) Includes 6,334 shares of common stock exercisable within 60 days under outstanding stock options. Also includes shares of common stock held in a retirement plan trust of which Ira Ritter and his spouse are trustees; and also includes shares beneficially owned by Stonehenge Partners. As a managing partner of Stonehenge Partners, Ira Ritter may be deemed the beneficial owner of these shares.

(9) Includes 207,503 shares of common stock exercisable within 60 days under outstanding stock options and 18,391 shares of common stock exercisable within 60 days under outstanding warrants.

Equity Compensation Plan Information

The following table presents information regarding securities authorized for issuance under equity compensation plans as of December 31, 2023:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders	398,924	$ 35.21	356,791
Equity compensation plans not approved by stockholders (1)	119,046	$ 10.35	—
Total	517,970	$ 29.50	356,791

(1) Consists of shares of common stock issuable upon the exercise of compensatory warrants granted to service providers.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Certain Relationships and Related Party Transactions

Our Audit Committee is responsible for reviewing, approving and overseeing any transaction between the Company and its directors, director nominees, executive officers, greater than 5% beneficial owners, and each of their respective immediate family members, where the amount involved exceeds the lesser of (i) $120,000 and (ii) 1% of the average of our total assets at year-end for the prior two fiscal years. Since January 1, 2021, there have been no such transactions except as described below.

On May 26, 2022, the Company acquired 2,232,861 shares of Series A-1 Preferred Stock of NanoSynex, Ltd. ("NanoSynex") from Alpha a related party, in exchange for 350,000 reverse split adjusted shares of the Company's common stock and a prefunded warrant to purchase 331,464 reverse split adjusted shares of the Company's common stock at an exercise price of $0.001 per share. These warrants were subsequently exercised on September 13, 2022.

On December 21 and 22, 2022, we entered into a Securities Purchase Agreement with Alpha and in exchange for $3,000,000 in cash (less $50,000 for expense reimbursement) issued to Alpha the 2022 Debenture, plus 2,500,000 common stock warrants exercisable (from June 22, 2023 through June 22, 2028) at $1.65 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 2022 Debenture (each such date, a "Monthly Redemption Date"), we must redeem $110,000 plus accrued but unpaid interest, liquidated damages and any amounts then owing under the 2022 Debenture (the "Monthly Redemption Amount"). The Monthly Redemption Amount must be paid in cash; provided that after the first two monthly redemptions, we may (if the Equity Conditions, as defined in the 2022 Debenture, are then satisfied or have been waived) elect to pay all or a portion of a Monthly Redemption Amount in shares of our common stock, based on a conversion price equal to the lesser of (i) the then applicable conversion price of the 2022 Debenture and (ii) 85% of the average of the VWAPs (as defined in the 2022 Debenture) for the five consecutive trading days ending on the trading day that is immediately prior to the applicable Monthly Redemption Date.

The 2022 Debenture accrues interest at the rate of 8% per annum, which began accruing on December 1, 2023, and will be payable on a quarterly basis. Interest may be paid in cash or shares of common stock or a combination thereof at our option; provided that the Equity Conditions have been satisfied.

The 2022 Debenture is convertible into our common stock at any time at the holder's option; the conversion price was originally $1.32.

Other than the Monthly Redemption Amounts, the 2022 Debenture does not call for scheduled payments of principal before the scheduled maturity date.

Both the 2022 Debenture and the accompanying warrants provide for "ratchet" antidilution adjustments to their conversion price and exercise price.

Both the 2022 Debenture and the accompanying warrants include a beneficial ownership blocker of 9.99%, which may only be waived by Alpha upon 61 days' notice to the Company.

On December 5, 2023, we and Alpha entered into an Amendment No. 1 with regard to Securities Purchase Agreement, under which the conversion price of the 2022 Debenture and the exercise price of the associated warrants were reduced to $0.73 per share, in exchange for Alpha permitting us to make certain Monthly Redemption Amount payments in the form of our stock rather than in cash even though the Equity Conditions were not satisfied (which would otherwise have prevented payment in the form of stock). In addition, such Amendment revised certain provisions of the 2,500,000 common stock warrants to (i) limit the circumstances which would trigger a potential adjustment to the exercise price of the 2,500,000 common stock warrants and (ii) clarify the treatment of the 2,500,000 common stock warrants upon a "Fundamental Transaction." (The purpose of these revisions was to remove the terms that caused the 2,500,000 common stock warrants to be liability-classified under U.S. GAAP).

The new $0.73 per share conversion/exercise price triggered a "ratchet" antidilution adjustment in the Company's outstanding "exploding" "Series C Warrants," resulting in such Series C Warrants becoming exercisable for 455,623 common shares (at an exercise price of $0.73 per share), as opposed to the 251,971 common shares into which such outstanding Series C Warrants would have been exercisable (at $1.32 per share) pre-adjustment. Finally, the $0.73 per share price triggered a "ratchet" antidilution adjustment in the exercise price of other outstanding Company common stock warrants, including 7,084 warrants held by Alpha and 67,620 warrants held by other persons, all of which were previously exercisable at $1.32 per share.

In February 26 and 27, 2024, we entered into a Securities Purchase Agreement with Alpha and in exchange for $500,000 in cash (less $25,000 for expense reimbursement) issued to Alpha an 8% Convertible Debenture with a face amount of $550,000 due on December 31, 2024 (the "2024 Debenture"), plus 900,016 5-year common stock warrants exercisable at $0.26 per share. In addition, per this Securities Purchase Agreement Alpha obtained an option to purchase additional 8% Convertible Debentures, of like tenor, with face amounts of up to an aggregate of $1,100,000 (and with a proportional number of accompanying common stock warrants of like tenor, up to a total of 1,800,032 additional warrants), which would (if and when Alpha exercises such option) provide us up to an additional $1.0 million in cash proceeds (less expense reimbursement, and not including any possible cash proceeds from any future exercise of the additional warrants). This option is valid through July 1, 2024.

The 2024 Debenture has a maturity date of December 31, 2024 and is convertible, at any time, and from time to time, at Alpha's option, into shares of our common stock, at $0.6111 per share. The 2024 Debenture does not call for scheduled payments of principal or interest before the

scheduled maturity date. Interest on the 2024 Debenture accrues on its outstanding principal balance at the rate of 8% per annum.

Both the 2024 Debenture and the accompanying warrants provide for “ratchet” antidilution adjustments to their conversion price/exercise price.

Both the 2024 Debenture and the accompanying warrants include a beneficial ownership blocker of 9.99%, which may only be waived by Alpha upon 61 days’ notice to the Company.

We granted Alpha “piggyback” registration rights for the common shares underlying the 2024 Debenture and the accompanying warrants.

The $0.26 exercise price of the warrants issued with the 2024 Debenture triggered a “ratchet” antidilution adjustment in the 2022 Debenture, resulting in the then current $1,198,922 principal amount thereof becoming convertible into 4,611,238 shares of Company common stock (as opposed to the 1,642,359 shares into which such outstanding principal amount were convertible pre-adjustment). Also, the $0.26 exercise price of the warrants issued with the 2024 Debenture triggered a “ratchet” antidilution adjustment in the Company’s outstanding “exploding” “Series C Warrants,” resulting in such Series C Warrants becoming exercisable for 1,279,261 common shares (at an exercise price of $0.26 per share), as opposed to the 455,623 common shares into which such outstanding Series C Warrants would have been exercisable (at $0.73 per share) pre-adjustment. Finally, the $0.26 exercise price of the warrant triggered a “ratchet” antidilution adjustment in the exercise price of other outstanding Company common stock warrants, including 2,507,048 warrants held by Alpha and 67,620 warrants held by other persons, all of which were previously exercisable at $0.73 per share.

In connection with her termination of employment, on June 20, 2023, Qualigen, Inc., a former wholly-owned subsidiary of the Company, signed a separation agreement and general release (the “Separation Agreement”) with Amy Broidrick, which became effective on June 24, 2023.

Under the terms of the Separation Agreement, Qualigen, Inc. provided Ms. Broidrick with (i) $16,637 in cash compensation, less applicable withholdings for federal and state income and employment taxes, which represented Ms. Broidrick’s accrued but unpaid salary and vacation pay through the Separation Date, and reimbursement of certain expenses incurred by Ms. Broidrick, (ii) severance in the form of continued salary pay to Ms. Broidrick at the rate then in effect on the Separation Date ($360,000 per annum) for a period of 12 months following the Separation Date, subject to applicable withholding, and (iii) payment or reimbursement for the cost of COBRA continuation medical and dental insurance coverage for 12 months following the Separation Date, less any required taxes or withholdings. In addition, Ms. Broidrick is entitled to any rights or benefits under Qualigen Inc.’s employee benefit plans, to the extent earned and vested, and had three months from the Separation Date to exercise any vested stock options. Ms. Broidrick did not exercise any vested stock options.

Director Independence

Under Nasdaq’s continued listing requirements, a majority of a listed company’s board of directors must be comprised of independent directors, subject to certain exceptions. In addition, Nasdaq’s continued listing requirements require that, subject to certain exceptions, each member of a listed company’s audit, compensation and governance and nominating committees must be independent. Audit Committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Nasdaq’s continued listing requirements, a director will only qualify as an “independent director” if, in the opinion of that company’s board of directors, such person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our board of directors determined that each of Messrs. David, Emery, Korenberg, Kruger and Ritter are independent under the applicable rules and regulations of Nasdaq. In making such determinations, the board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances the board of directors deemed relevant in determining their independence.

Item 14. Principal Accounting Fees and Services.

Baker Tilly US, LLP (“Baker Tilly”) serves as the Company’s independent registered public accounting firm and has served in that capacity since June 2018.

The Audit Committee considered the independence of Baker Tilly and whether the audit services Baker Tilly provided to the Company are compatible with maintaining that independence. The Audit Committee has adopted procedures by which the Audit Committee must approve in advance all services provided by and fees paid to the Company’s independent registered public accounting firm. The advance approval requirement was not waived in any instance during 2023 or 2022.

Fees and Services of Baker Tilly US, LLP

The following table sets forth the aggregate fees billed to the Company by Baker Tilly for the years ended December 31, 2023 and 2022:

	2023	2022
Audit Fees(1)	$ 495,955	$ 411,362
Audit-Related Fees	—	—
Tax Fees (2)	18,789	35,050
All Other Fees	—	—
Total	$ 514,744	$ 446,412

(1) Audit fees consisted of fees for audit work performed in the audit of financial statements, as well as fees for quarterly reviews and registration statements.

(2) These fees were incurred for professional services rendered in connection with tax compliance, tax advice, and tax planning. These services included income tax compliance and related tax services.

The Audit Committee has adopted a formal policy on auditor independence requiring the advance approval by the Audit Committee of all audit and non-audit services provided by our independent registered public accounting firm. In determining whether to approve any services by our independent registered public accounting firm, the Audit Committee reviews the services and the estimated fees, and considers whether approval of the proposed services will have a detrimental impact on the auditor’s independence. On an annual basis, our management reports to the Audit Committee all audit services performed during the previous 12 months and all fees billed by our independent registered public accounting firm for such services.

For the years ended December 31, 2023 and 2022, all audit services and the corresponding fees were approved by our Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report:

1. *Financial Statements.* The following documents are included in Part II, Item 8 of this Annual Report and are incorporated by reference herein:

2. *Financial Statement Schedules.* Financial statement schedules have been omitted because they are not required or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

3. *Exhibits.* See EXHIBIT INDEX

EXHIBIT INDEX

Exhibit No.	Description	Form	File No.	Exhibit	Filing Date
2.1	Stock Purchase Agreement dated July 20, 2023 with 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 of Ritter Pharmaceuticals, Inc.	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 29, 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	8-K	001-37428	3.4	5/29/2020
3.8	Amended and Restated Bylaws of the Company, as of 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, filed with the Delaware Secretary of State on November 21, 2022	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 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+	Executive Employment Agreement, by and between Qualigen, Inc. and Michael Poirier, dated as of February 1, 2017 and as amended on January 9, 2018	8-K	001-37428	10.1	5/29/2020
10.2+	Executive Employment Agreement, by and between Qualigen, Inc. and Christopher Lotz, dated as of February 1, 2017 and as amended on January 9, 2018	8-K	001-37428	10.2	5/29/2020
10.4+	2020 Stock Equity Incentive Plan	8-K	001-37428	10.20	5/29/2020
10.5+	Standard template of Stock Option Agreement for use under 2020 Stock Incentive Plan	8-K	001-37428	10.1	6/11/2020
10.10	Exclusive License Agreement (RAS) between the Company and University of Louisville Research Foundation, Inc., dated as of July 17, 2020	8-K	001-37428	10.4	8/4/2020
10.11	Amendment 1 to the Exclusive License Agreement (RAS), by and between Qualigen, Inc. and University of Louisville Research Foundation, Inc., dated March 16, 2021	10-K	001-37428	10.11	5/2/2023
10.15	Novation Agreement (RAS) among the Company, Qualigen, Inc. and University of Louisville Research Foundation, Inc. dated January 30, 2021	10-Q	001-37428	10.1	5/14/2021
10.17+	Hire offer letter from the Company to Tariq Arshad, dated April 22, 2021	10-Q	001-37428	10.1	8/16/2021
10.20	License Agreement with UCL Business Limited dated January 12, 2022	10-K	001-37428	10.55	3/31/2022
10.21	First Deed of Variation to License Agreement with UCL Business Limited dated March 30, 2022	10-K	001-37428	10.21	5/2/2023
10.22	Series B Preferred Share Purchase Agreement between the Company and NanoSynex Ltd. dated April 29, 2022	10-Q	001-37428	10.1	5/13/2022
10.23	Share Purchase Agreement between the Company and Alpha Capital Anstalt dated April 29, 2022	10-Q	001-37428	10.2	5/13/2022

10.24	Master Agreement for the Operational and Technological Funding of NanoSynex between Qualigen Therapeutics, Inc. and NanoSynex Ltd., dated May 26, 2022	8-K	001-37428	10.1	6/2/2022
10.25+	Qualigen Therapeutics, Inc. 2022 Employee Stock Purchase Plan	10-Q	001-37428	10.1	11/14/2022
10.26+	Amendment No. 2 to the 2020 Stock Incentive Plan of Qualigen Therapeutics, Inc.	8-K	001-37428	10.1	11/22/2022
10.27+	Amendment No. 1 to the 2022 Employee Stock Purchase Plan of Qualigen Therapeutics, Inc.	8-K	001-37428	10.2	11/22/2022

10.28	Securities Purchase Agreement, dated December 21, 2022, by and between Qualigen Therapeutics, Inc. and Alpha Capital Anstalt	8-K	001-37428	10.1	12/22/2022
10.29	8% Senior Convertible Debenture Due December 22, 2025 in favor of Alpha Capital Anstalt	8-K	001-37428	10.2	12/22/2022
10.30	Registration Rights Agreement, dated December 22, 2022, by and between Qualigen Therapeutics, Inc. and Alpha Capital Anstalt	8-K	001-37428	10.3	12/22/2022
10.31+	Letter to Michael Poirier, dated January 13, 2023, regarding compensatory changes	10-K	001-37428	10.31	5/2/2023
10.32+	Letter to Amy Broidrick, dated January 13, 2023, regarding compensatory changes	10-K	001-37428	10.32	5/2/2023
10.33+	Letter to Tariq Arshad, dated January 13, 2023, regarding compensatory changes	10-K	001-37428	10.33	5/2/2023
10.34	Amendment No. 1 with regard to Securities Purchase Agreement dated December 5, 2023 with Alpha Capital Anstalt	8-K	001-37428	10.1	12/7/2023
10.35	Amendment and Settlement Agreement dated July 19, 2023 with NanoSynex, Ltd.	8-K	001-37428	10.1	7/26/2023
10.36+	Separation Agreement and General Release dated June 20, 2023 with Amy Broidrick	10-Q	001-37428	10.1	8/14/2023
14.1	Code of Business Conduct and Ethics	8-K	001-37428	14.1	5/29/2020
21.1*	Subsidiaries of the Registrant				
23.1*	Consent of Baker Tilly US, LLP, independent registered public accounting firm				
24.1	Power of Attorney (included on signature page)				

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.
97.1*	Clawback Policy
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 or furnished herewith.
** Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedules will be furnished to the SEC upon request.
+ 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.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Qualigen Therapeutics, Inc.

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

Date: April 5, 2024

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

Date: April 5, 2024

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Michael S. Poirier and Christopher L. Lotz, and each of them individually, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael S. Poirier Michael S. Poirier	Chairman of the Board, Chief Executive Officer (Principal Executive Officer)	April 5, 2024
/s/ Christopher L. Lotz Christopher L. Lotz	Vice President of Finance, Chief Financial Officer (Principal Financial and Accounting Officer)	April 5, 2024
/s/ Richard A. David Richard A. David	Director	April 5, 2024
/s/ Sidney W. Emery, Jr. Sidney W. Emery, Jr.	Director	April 5, 2024
/s/ Matthew E. Korenberg Matthew E. Korenberg	Director	April 5, 2024
/s/ Kurt H. Kruger Kurt H. Kruger	Director	April 5, 2024
/s/ Ira E. Ritter Ira E. Ritter	Director	April 5, 2024

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

None.

Exhibit 23.1

CONSENT OF BAKER TILLY US, LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-265691, 333-266430, and 333-269088) and Form S-8 (File No. 333-249280, 333-249281 and 333-262090) of Qualigen Therapeutics, Inc. of our report dated April 5, 2024, relating to the consolidated financial statements, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern and appears on page 33 of this annual report on Form 10-K for the year ended December 31, 2023.

/s/ Baker Tilly US, LLP

San Diego, CA
April 5, 2024

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 Annual Report on Form 10-K 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.

April 5, 2024

By: */s/ Michael S. Poirier*
Name: Michael S. Poirier
Title: Chief 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 Annual report on Form 10-K 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.

April 5, 2024

By: */s/ Christopher L. Lotz*
Name: Christopher L. Lotz
Title: Chief Financial Officer (Principal Financial 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 Annual Report on Form 10-K of the Company for the year ended December 31, 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.

April 5, 2024

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

April 5, 2024

By: */s/ Christopher L. Lotz*
Name: Christopher L. Lotz
Title: Chief Financial Officer (Principal Financial 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.

Exhibit 97.1

CLAWBACK POLICY

QUALIGEN THERAPEUTICS, INC.

Purpose

Qualigen Therapeutics, Inc. (the "Company") is establishing this policy to align the interests of executive officers of the Company with those of shareholders, to create and maintain a culture that emphasizes integrity and accountability and to enforce the Company's pay-for-performance compensation philosophy. This policy provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the "**Policy**"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934 (the "**Exchange Act**"), Rule 10D-1 promulgated under the Exchange Act (" **Rule 10D-1**"), and Nasdaq Listing Rule 5608 (the "**Listing Standards**").

Administration

This Policy shall be administered by the Board of Directors (the " **Board**") of the Company or, if so designated by the Board, a committee thereof including the Compensation Committee, in which case references herein to the Board shall be deemed references to such committee. The Board is authorized to interpret and construe this Policy and to make all determinations and rules as it deems to be necessary or advisable for its administration. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the Securities and Exchange Commission or The Nasdaq Stock Market ("**Nasdaq**"). Any determinations made by the Board shall be final and binding on all affected individuals.

Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Board in accordance with Section 10D of the Exchange Act, the definition of executive officer set forth in Rule 10D-1 and the Listing Standards ("**Covered Executives**"), and such other employees who may from time to time be deemed subject to the Policy by the Board. For this purpose, an "executive officer" includes the Company's president, principal financial officer, principal accounting officer (or controller), any vice president in charge of a principal business unit, division or function or any other officer or person who performs a "policy-making" function for the Company.

Recoupment; Accounting Restatement

In the event that the Company is required to prepare an Accounting Restatement, as defined herein, the Board will promptly require reimbursement or forfeiture of any Excess Incentive Compensation, as defined herein, received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an Accounting Restatement, and including any transition period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years, except that a transition period comprising a period of at least nine months shall count as a full fiscal year. The Policy applies to all Incentive-Based Compensation received by a Covered Executive (i) after beginning service as an executive officer; (ii) who served as an executive officer at any time during the performance period for that Incentive-Based Compensation; and (iii) while the Company has a listed class of securities. Recovery of amounts under this Policy with respect to a Covered Executive shall not require the finding of any misconduct by such Covered Executive or that such Covered Executive is responsible for any error associated with an Accounting Restatement.

For purposes of this Policy, an "**Accounting Restatement**" means an accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. Also for purposes of this Policy, the date on which the Company is required to prepare an accounting restatement is the earlier of (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement, in each case regardless of whether or when the restated financial statements are filed.

Excess Incentive Compensation: Amount Subject to Recovery

The amount subject to recovery (the "**Excess Incentive Compensation**") is the excess of the Incentive-Based Compensation paid to the Covered Executive based on the erroneous data over the Incentive-Based Compensation that would have been paid to the Covered Executive had it been based on the restated results. Excess Incentive Compensation shall be determined by the Board without regard to any taxes paid by the Covered Executive with respect to the Excess Incentive Compensation.

For Incentive-Based Compensation based on stock price or total shareholder return: (i) the Board shall determine the amount of the Excess Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received; and (ii) the Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq.

"**Incentive-Based Compensation**" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation is received for purposes of this Policy in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period.

A "**Financial Reporting Measure**" means any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived in whole or in part from such measure. For purposes of this Policy, Financial Reporting Measures include, but are not limited to, the following, and any measures derived from the following: revenues; earnings before interest, taxes, depreciation and amortization; net income; Company stock price; and total shareholder return. A Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the Securities and Exchange Commission.

Method of Recoupment

The Board shall determine, in its sole discretion, the timing and method for promptly recouping Excess Incentive Compensation, which may include without limitation:

(a) seeking reimbursement of all or part of any cash or equity Incentive-Based Compensation previously paid,

(b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards,

(c) cancelling prior cash or equity-based awards, whether vested or unvested or paid or unpaid,

(d) cancelling or offsetting against any planned future cash or equity-based awards,

(e) forfeiture of deferred compensation, subject to compliance with Section 409A of the Internal Revenue Code (the " **Code**") and the regulations promulgated thereunder, and

(f) any other method authorized by applicable law or contract.

Subject to compliance with any applicable law, the Board may recover amounts under this Policy from any amount otherwise payable to the Covered Executive.

The Company is authorized and directed pursuant to this Policy to recoup Excess Incentive Compensation in compliance with this Policy unless the Compensation Committee of the Board has determined that recovery would be impracticable solely for the following limited reasons, and subject to the following procedural and disclosure requirements:

- The direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered; provided that prior to concluding that it would be impracticable to recover any amount of Excess Incentive Compensation based on expense of enforcement, the Board must make a reasonable attempt to recover such erroneously awarded compensation, document such reasonable attempt(s) to recover and provide that documentation to Nasdaq; or

- Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

No Indemnification of Covered Executives

The Company shall not indemnify any Covered Executives against the loss of any incorrectly awarded Excess Incentive Compensation. The Company is prohibited from paying or reimbursing a Covered Executive for purchasing insurance to cover any such loss.

Board Indemnification

Any members of the Board or its delegates shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be fully indemnified by the Company to the fullest extent under applicable law and Company organizational documents and policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board or its delegates under applicable law or Company organizational documents and policy.

Effective Date

This Policy shall be effective as of the effective date of the Listing Standards (the " **Effective Date**"). The terms of this Policy shall apply to any Incentive-Based Compensation that is received by Covered Executives on or after the Effective Date and during the applicable clawback period described herein, even if such Incentive-Based Compensation was approved, awarded, granted or paid to Covered Executives prior to the Effective Date.

Amendment and Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect final regulations adopted by the Securities and Exchange Commission under Section 10D of the Exchange Act, to comply with any rules or standards adopted by Nasdaq, and to comply with (or maintain an exemption from the application of) Section 409A of the Code. The Board may terminate this Policy at any time.

Other Recoupment Rights

The Board intends that this Policy will be applied to the fullest extent of the law. The Board may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.

Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law. To the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision shall be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

Governing Law

This Policy and all rights and obligations hereunder are governed by and construed in accordance with the internal laws of the State of Delaware, excluding any choice of law rules or principles that may direct the application of the laws of another jurisdiction.

Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

Exhibit Filing Requirement

A copy of this Policy and any amendments thereto shall be posted on the Company's website and filed as an exhibit to the Company's annual report on Form 10-K.

[FOR SIGNATURE BY THE COMPANY'S COVERED EXECUTIVES]

Clawback Policy Acknowledgment

I, the undersigned, agree and acknowledge that I am fully bound by, and subject to, all of the terms and conditions of the Clawback Policy (as may be amended, restated, supplemented or otherwise modified from time to time, the "Policy"). In the event of any inconsistency between the Policy and the terms of any employment agreement to which I am a party, or the terms of any compensation plan, program or agreement under which any compensation has been granted, awarded, earned or paid, the terms of the Policy shall govern. In the event it is determined by the Board, or such committee thereof that is charged with administration of the Policy, that any amounts granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. Any capitalized terms used in this Acknowledgment without definition shall have the meaning set forth in the Policy.

By: Date:
[Name]
[Title]