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, 2022

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.)**

2042 Corte Del Nogal, Carlsbad, California 92011
(Address of principal executive offices) (Zip Code)

(760) 918-9165
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, 2022, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $21,943,148 based on the closing price for the common stock of $5.70 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 April 11, 2023, there were 5,052,463 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TABLE OF CONTENTS

		Page Number
Part I		
Item 1	Business	4
Item 1A	Risk Factors	13
Item 1B	Unresolved Staff Comments	30
Item 2	Properties	30
Item 3	Legal Proceedings	30
Item 4	Mine Safety Disclosures	30
Part II		
Item 5	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	31
Item 6	[Reserved]	31
Item 7	Management's Discussion and Analysis of Financial Condition and Results of Operations	31
Item 7A	Quantitative and Qualitative Disclosure About Market Risk	40
Item 8	Financial Statements and Supplementary Data	41
Item 9	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	78
Item 9A	Controls and Procedures	78
Item 9B	Other Information	79
Item 9C	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	79
Part III		
Item 10	Directors, Executive Officers and Corporate Governance	80
Item 11	Executive Compensation	83
Item 12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	90
Item 13	Certain Relationships and Related Transactions, and Director Independence	91
Item 14	Principal Accounting Fees and Services	92
Part IV		
Item 15	Exhibits and Financial Statement Schedules	93
Item 16	Form 10-K Summary	97
	Signatures	98

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 successfully develop any drugs or therapeutic devices;
- our ability to progress our drug candidates or therapeutic devices 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 or therapeutic devices;
- our ability to procure or earn sufficient working capital to complete the development, testing and launch of our prospective therapeutic products;
- the likelihood that patents will issue on our owned and in-licensed patent applications;
- our ability to protect our intellectual property;
- our ability to compete;
- our ability to maintain or expand market demand and/or market share for our diagnostic products;
- our ability to maintain our diagnostic sales and marketing engine without interruption once our distribution agreement with Sekisui expires.

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," "the Company" or "Qualigen" refer to Qualigen Therapeutics, Inc.

Item 1. Business

Overview

We are a diversified life sciences company focused on developing treatments for adult and pediatric cancers with potential for Orphan Drug designation, while also commercializing diagnostics.

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

Our lead oncology therapeutics 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 binding could, by stabilizing the G4s against DNA "unwinding," help inhibit cancer cell proliferation. QN-302 is currently undergoing Good Laboratory Practice (GLP) toxicology studies.

Our RAS portfolio 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. Preventing this binding could stop tumor growth, especially in RAS-driven tumors such as pancreatic, colorectal and lung cancers.

Our investigational QN-247 compound binds nucleolin, a key multi-functional regulatory phosphoprotein that is overexpressed in cancer cells. Such binding could inhibit the cancer cells' proliferation. The foundational aptamer of QN-247 is QN-165 (formerly referred to as AS1411), which the Company has deprioritized as a drug candidate for treating COVID-19 and other viral-based infectious diseases.

In addition to our oncology drug pipeline, we have an established diagnostics business.

Our revenue driver is our FastPack proprietary blood-based diagnostics platform which includes diagnostic instruments and test kits that are sold commercially primarily in the United States, as well as certain European countries. The FastPack System menu includes a rapid, highly accurate immunoassay diagnostic testing system for cancer, men's health, hormone function, and vitamin D status. We provide analyzers to our customers (physician offices, clinics and small hospitals) at low cost in order to increase sales volumes of higher-margin test kits.

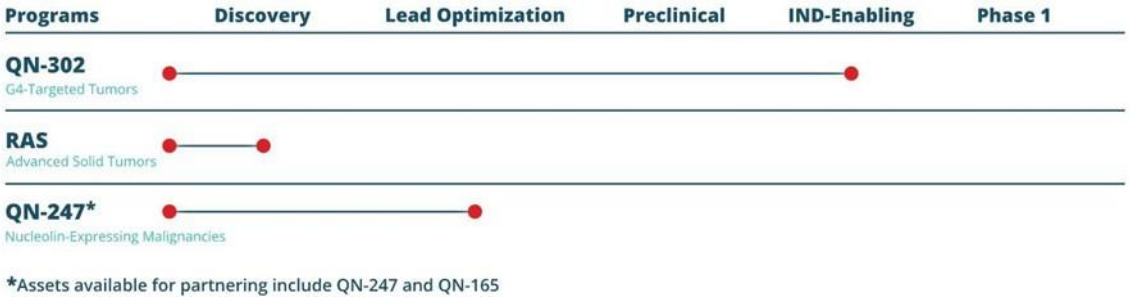
On May 26, 2022, we acquired a 52.8% interest in NanoSynex, Ltd. ("NanoSynex"). NanoSynex is a micro-biologics diagnostic company domiciled in Israel. NanoSynex's technology is an Antimicrobial Susceptibility Testing (AST) that aims to enable better targeting of antibiotics for their most suitable uses to ultimately result in faster and more efficacious treatment, hence reducing hospitals mortality and morbidity rates. See Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" for additional details.

Completion of Reverse Recapitalization Transaction with Ritter Pharmaceuticals, Inc.

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.

Cancer Drug Pipeline and Diagnostic Products

Therapeutics Pipeline



Our lead drug compound QN-302 (formerly SOP1812) is being developed to target regulatory regions of cancer genes that down-regulate gene expression in multiple cancer pathways for potential treatment of G4-targeted tumors (*e.g.*, pancreatic cancer). The investigational compounds within our RAS portfolio are designed to suppress the interaction of endogenous RAS with c-RAF, upstream of the KRAS, HRAS and NRAS effector pathways. Our anticancer drug candidate, QN-247 (formerly referred to as ALAN or AS1411-GNP) is aptamer-based and currently in development to treat a variety of cancer types, including liquid and solid tumors.

Our deprioritized programs (and thus not featured in the chart above) include QN-165 (formerly referred to as AS1411), a drug candidate for the potential broad-spectrum treatment of infectious diseases such as COVID-19, and our Selective Target Antigen Removal System (STARS), a therapeutic device product concept, currently in discovery stage, designed to remove circulating tumor cells, viruses, inflammation factors and immune checkpoints.

QN-302 (formerly referred to as SOP1812)

We exclusively in-licensed the global rights to the G4 selective transcription inhibitor platform from University College London ("UCL") in January 2022. The licensed technology comprises lead compound QN-302 (formerly 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 G-Quadruplex (G4) binding concept is derived from over 30 years in nucleic acid research, 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.

Pancreatic cancer is the tenth most common cancer and third deadliest cancer in the United States and has one of the lowest rates of survival of all cancer types, with 91% of those diagnosed dying from the disease and one in four dying within the first month of diagnosis. The chemotherapy drug Gemcitabine has been standard of care for patients with metastatic pancreatic cancer for more than 15 years. Numerous clinical trials have tested new drugs, either alone or in combination, with Gemcitabine. We believe that QN-302 has the potential to demonstrate superior efficacy and activity against pancreatic ductal adenocarcinoma ("PDAC") compared to existing agents, with a distinct mechanism of action and promising preclinical target profile.

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, which represents 98% of pancreatic cancers. 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 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 suggest no significant adverse toxic effects at proposed therapeutic doses in pancreatic cancer mouse *in-vivo* models.

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.

RAS (formerly RAS-F)

In July 2020, we entered into an exclusive worldwide license agreement with University of Louisville ("UofL") 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 in-licensed the "RAS" compound family of drug candidates and 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 RAS inhibitor licensed products.

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.

In March 2022 and October 2022, we signed amendments to our sponsored research agreement with UofL to extend our partnership. Under the amended agreement, the collaboration extends until the third quarter of 2023 and commits additional resources to support ongoing discovery and preclinical efforts for the RAS platform.

QN-247 (formerly referred to as ALAN or AS1411-GNP)

QN-247 is an oligonucleotide-based drug candidate that is designed to treat different types of nucleolin-expressing cancers, including liquid and solid tumors. QN-247 inhibits nucleolin, a key multi-functional regulatory phosphoprotein that is overexpressed in cancer cells, and may thereby be able to inhibit the cells' proliferation. QN-247 has shown promise in preclinical studies for the treatment of acute myeloid leukemia ("AML"). This novel technology may have several other potential applications, including enhancement of radiation therapy, enhancement of tumor imaging, and delivery of other anti-cancer compounds directly to tumor cells.

QN-247 is an enhanced version of QN-165 (which in turn was formerly referred to as AS1411), where the DNA oligonucleotide aptamer is conjugated. A key component of QN-247, DNA oligonucleotide aptamer QN-165, has been shown, primarily on a preclinical basis, to have the potential to target and destroy cancer cells. This component has been administered in Phase 1 and Phase 2 clinical trials to over 100 AML or renal cell carcinoma cancer patients and appears to be well tolerated with no evidence of severe adverse events in such trials, with at least seven patients appearing to have clinical responses.

An in vivo efficacy study with a triple negative breast cancer (TNBC) MDA-MB-231 xenograft mouse model was performed with 12 daily doses (1 mg/kg) of QN-247. This study showed statistically significant reductions in mean tumor volumes for all QN-247 formulations compared to baseline and to vehicle control. QN-247 formulations with higher oligonucleotide loading appeared to reduce tumor volumes more than lower oligonucleotide loading. No evidence of adverse toxicity was observed.

We entered into a sponsored research agreement with UofL in August 2018 which was subsequently amended in October 2020, pursuant to which UofL performed various animal studies to assess antitumor efficacy and safety of different QN-247 compositions. The sponsored research agreement with UofL for QN-247 expired on August 31, 2022, and the license agreement with UofL for QN-247 was amended on January 9, 2023.

QN-165 (formerly referred to as AS1411)

In June 2020, we entered into an exclusive royalty-bearing license agreement with UofL for UofL's intellectual property for the use of QN-165 as a drug candidate for the treatment of COVID-19. In September 2020 we and UofL jointly filed a U.S. provisional patent application, entitled "Methods of inhibiting or treating coronavirus infection, and methods for delivering an anti-nucleolin agent." The application was filed in conjunction with Drs. Paula J. Bates and Kenneth E. Palmer from UofL, and covers methods for using QN-165 as an antiviral drug candidate to prevent SARS-CoV-2 from entering the body through mucous membranes in the nose, mouth and eyes. As stated in the patent application, we believe that QN-165 could be administered by means of inhalers, nose spray or eye drops to individuals who have recently come in contact with SARS-CoV-2, or are at high risk of contracting the virus.

We believe that the mechanism by which QN-165 is believed to work, by blocking the ability of viruses to replicate in the body, may also make the drug candidate effective against future mutations in COVID-19 as well as against other dangerous viruses including seasonal influenza. Moreover, we believe that in addition to its proposed use as a therapeutic, QN-165 might be able to be used as a protective defense or prophylaxis against COVID-19 and/or other viral-based diseases such as seasonal influenza.

On July 13, 2021, we submitted an Investigational New Drug ("IND") application with the FDA seeking approval to commence Phase 1b/2a clinical studies of QN-165 in hospitalized COVID-19 patients. On August 11, 2021, the FDA informed us that additional preclinical studies would be required for the IND application to be cleared to proceed into the clinic with QN-165. We then decided to allocate our resources to focus on our oncology pipeline, and deprioritized the development of QN-165 program. Qualigen is seeking to out-license QN-165 to a partner that has interest and expertise in antiviral development, such as dengue, influenza, RSV and other infectious diseases. Due to its mechanism and in vivo potency, we believe that QN-165 could potentially be developed as a first-line treatment against emerging viruses and biothreats.

FastPack®

The FastPack System is a patent-protected rapid, onsite immunoassay testing system consisting of the FastPack Analyzer and the FastPack test pouch, a single-use, disposable, foil packet which includes the FastPack reagent chemistry. Since the initial conception of the system, we have developed successive versions of the analyzer and test pouch, known as "1.0," "IP" and "PRO", and have expanded our assay menu to nine tests, including tests for prostate cancer, thyroid function, metabolic disorders, and research applications. We have sold FastPack products in the United States and overseas for over 20 years, and since inception, our sales of FastPack products have exceeded $127 million. We manufacture the FastPack products at our FDA and International Standards Organization ("ISO") certified Carlsbad, California facility. As of April 2022 most FastPack sales are distributed through various distribution partners in North America as well as in Europe (primarily Axon Labs in Germany and Switzerland). We also sell direct to clinics and physician offices located throughout North America.

In July 2020, we submitted an official notification to the FDA to commence sales in the United States of our FastPack SARS-CoV-2 IgG test for COVID-19 antibodies, which was designed for use with our new FastPack PRO. The test was previously submitted to the FDA for Emergency Use Authorization ("EUA"). In April 2021, we withdrew this EUA. During the nine months during which the EUA was with the FDA, alternative tests and testing practices became widespread and we determined that there was no longer a viable business case for scale-up of the test.

Strategic Partners

In January 2022, we entered into a royalty-bearing license agreement with UCL, with respect to intellectual property and know-how covering lead and backup compounds for our G4 selective transcription inhibitor program, QN-302.

We are party to a royalty-bearing license agreement with UofL for the development of RAS and the QN-247 program.

We in-license patents from DIAsource ImmunoAssays S.A. and Future Diagnostics B.V., for reagents that are used in our FastPack Vitamin D assay.

Sales Channels

Prior to April 2022, most of our FastPack sales were through our diagnostics distribution partner Sekisui Diagnostics, LLC ("Sekisui") pursuant to a distribution agreement. The distribution agreement with Sekisui expired on March 31, 2022, at which time the activities formerly provided by Sekisui reverted to us. As of April 2022, most of our FastPack sales are through various distribution partners in North America, including McKesson Medical-Surgical, Henry Schein Medical, Medline Industries and National Distribution & Contracting, the largest distributors of physician office laboratory products in the United States. Outside of the United States, we sell the FastPack product line through a network of distributors in Europe (primarily Axon Labs in Germany and Switzerland). We also continue to sell our testosterone test kits directly to Low T Center, Inc. ("Low T"), the largest men's health group in the United States, with 40 locations. Low T was acquired by SynergenX in September 2022. The combined company currently operates 64 locations.

Product sales to McKesson accounted for 48% of our total revenues and product sales to Low T accounted for 26% of our total revenues during the fiscal year ended December 31, 2022. The remaining revenue was comprised of product sales and warranties to other distributors and direct sales accounts.

In October 2020, we entered into an agreement with Yi Xin Zhen Duan Jishu (Suzhou) Ltd ("Yi Xin"), pursuant to which we granted Yi Xin exclusive rights to manufacture and sell new generations of FastPack-based products as well as Yi Xin-manufactured versions of our existing FastPack 1.0, IP and PRO product lines in China. We are entitled to receive royalties on any such sales. After May 1, 2022, Yi Xin has the right to sell its new generations of FastPack-based diagnostic test systems throughout the world, other than to our then-current FastPack customers; and on a worldwide basis, except in the United States, Yi Xin also has the right to sell Yi Xin-manufactured versions of our existing FastPack 1.0, IP and PRO product lines. We are entitled to receive royalties on any of these sales. After March 31, 2022, Yi Xin has the right to buy Qualigen FastPack 1.0, IP and PRO products from us at distributor prices for resale in the United States, again excluding resales toward our then-current FastPack customers.

Manufacturing

We develop, manufacture and assemble our diagnostic products at our approximately 23,000 square feet facility in Carlsbad, California. Our laboratory and manufacturing practices are governed by a series of internally published Standard Operating Procedures, in accordance with FDA and ISO guidelines. While we produce many of our own raw materials and sub-components for diagnostic products, we also purchase certain materials from third-party suppliers such as Amcor, Enstrom, Gilson, Hi-Tech Products, Hamamatsu, Sigma Aldrich, Surmodics, 3M, Thermo Fisher Scientific, and VWR International.

We do not have in-house manufacturing capability for our therapeutics product candidates.

Research and Development

For research and development of our drug candidates, we are leveraging the scientific and technical resources and laboratory facilities of UofL and UCL, through technology licensing, sponsored research, and other consulting agreements, which are focused on aptamer technology and applications. We would engage contract research organizations ("CROs") for any clinical trials of our drug candidates. We intend to focus our internal research and development on oversight of these organizations and continuing support of the FastPack diagnostic line.

Regulatory Matters

We have obtained 17 FDA clearances/approvals and 28 CE Marks for our diagnostic products (FastPack analyzers, immunoassays, control kits, calibration kits and verifications kits) to date. We have not obtained FDA or other regulatory approval for any drug candidate.

Medical Device Regulatory Clearances and Approvals

The medical devices that we manufacture and market are subject to regulation by numerous worldwide regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing development, testing, manufacturing, labeling, marketing and distribution. Medical devices are also generally subject to varying levels of regulatory control based on the risk level of the device.

In the United States, unless an exemption applies, before we can commercially distribute medical devices, we must obtain, depending on the type of device, either premarket notification clearance or premarket approval ("PMA") from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either class I or II, which typically requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. Some low-risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared device, are placed in class III, generally requiring PMA.

The premarket notification process requires that a premarket notification (510(k)) be made to the FDA to demonstrate that a new device is as safe and effective as, or substantially equivalent to, a legally marketed device (the "predicate" device). This process is generally known as obtaining 510(k) clearance for a new device. Under this process, applicants must submit performance data to establish substantial equivalence. In some instances, data from human clinical trials must also be submitted in support of a 510(k) premarket notification. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption ("IDE") regulations. The FDA must issue a decision finding substantial equivalence before commercial distribution can occur. Changes to cleared devices that do not significantly affect the safety or effectiveness of the device can generally be made without additional 510(k) premarket notifications; otherwise, a new 510(k) is required.

The PMA approval process requires the submission of a PMA application to the FDA to demonstrate that the new device is safe and effective for its intended use. This approval process applies to most Class III devices and generally requires clinical data to support the safety and effectiveness of the device, obtained in adherence with IDE requirements. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose and that the proposed manufacturing is in compliance with the Quality System Regulation ("QSR"). For novel technologies, the FDA may seek input from an advisory panel of medical experts and seek their views on the safety, effectiveness and benefit-risk of the device. The PMA process is generally more detailed, lengthier and more expensive than the 510(k) process.

In the European Union ("EU"), we are required to comply with the In-Vitro Diagnostic Regulation ("IVDR"), which became effective May 2021, superseding existing Medical Device Directives. Medical devices that have a valid EC Certificate to the prior Directives (issued before May 2021) can continue to be sold until May 2025 or until the EC Certificate expires, whichever comes first, providing there are no significant changes to the design or intended use. The CE Mark, which is required to sell medical devices in the EU is affixed following a Conformity Assessment and either approval from the appointed independent Notified Body or through self-certification by the manufacturer. The selected pathway to CE marking is based on device risk classification. CE marking indicates conformity to the applicable General Safety and Performance Requirements ("GSPRs") for the IVDR. The IVDR changes multiple aspects of the regulatory framework for CE marking, such as increased clinical evidence requirements, changes to labeling, and new requirements, including Unique Device Identification ("UDI"), and many new post-market reporting obligations. IVDR also modifies and increases the compliance requirements for the medical device industry and will continue to require significant investment to transition all products by May 2025. The CE mark continues to be a prerequisite for successful registration in many other global geographies.

We are also required to comply with the regulations of every other country where we commercialize products before we can launch or maintain new products on the market.

The FDA and other worldwide regulatory agencies and competent authorities actively monitor compliance to local laws and regulations through review and inspection of design and manufacturing practices, record-keeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices, detain or seize adulterated or misbranded medical devices, order recall or market withdrawal of these devices and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain a company for certain violations of the Food, Drug and Cosmetic Act ("FDCA") and the Safe Medical Devices Act, pertaining to medical devices, or initiate action for criminal prosecution of such violations. Regulatory agencies and authorities in the countries where we do business can halt production in or distribution within their respective country or otherwise take action in accordance with local laws and regulations.

International sales of medical devices manufactured in the United States that are not approved by the FDA for use in the United States, or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Additionally, exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the United States due to differing regulatory requirements; however, other countries, require approval in the country of origin first. Most countries outside of the United States require that product approvals be recertified on a regular basis. The recertification process requires the evaluation of any device changes and any new regulations or standards relevant to the device and, where needed, conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

Medical Device Quality Assurance

We are committed to providing high quality products to our customers and the patients they serve. Our quality system starts with the initial product specification and continues through the design of the product, component specification process and the manufacturing, sale and servicing of the product. Our quality system is intended to build in quality and process control and to utilize continuous improvement concepts throughout the product life. Our quality system is also designed to enable us to satisfy various international quality system regulations, including those of the FDA with respect to products sold in the United States. All of our medical device manufacturing facilities and distribution centers are certified under the ISO 13485 quality system standard, established by the ISO for medical devices, which includes requirements for an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. This certification can be obtained only after a complete audit of a company's quality system by an independent outside auditor, and maintenance of the certification requires that these facilities undergo periodic re-examination.

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 FDCA 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 ("REMS"); 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, two 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 REMS 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 the issued patents and pending patent applications, as of December 31, 2022, is as follows:

Subject Matter	Issued	Pending	Geographic Scope	Patent Term
Qualigen Patents and Trademarks				
FastPack 1.0, IP, and PRO	2	0	U.S., Japan	2024-2032
FastPack 2.0	23	0	U.S., Europe, China, Japan	2032-2042
STARS	9	6	U.S., Europe, Canada, China, Japan, Korea	2030-2045
Qualigen Trademarks	13	9	U.S., Europe, Canada, China, Japan, Korea	N/A
Qualigen + Gen-Probe (Joint)	24	0	U.S., Austrialia, Canada, China, Japan	2028
Total Qualigen	**71**	**15**		
In-Licensed Patents				
FastPack 1.0, IP, and PRO	1	0	Europe	2030
Univ College London (UCL)				
QN-302	2	11	U.S., Europe, Australia, Canada, China, Hong Kong, India, Japan, Korea, Russia	2030-2040
Univ of Louisville (ULRF)				
RAS	0	12	U.S, Europe, Australia, Canada, China, Hong Kong, India, Israel, Japan, Korea, Mexico, Russia, South Africa	2039*
QN-247	44	3	U.S., Europe, Canada, China, Hong Kong, Japan	2032-2038
DiaSource				
Total In-Licensed	**47**	**26**		
TOTAL	**118**	**41**		

**Anticipated patent term*

Human Capital Management

As of March 31, 2023, we had 38 employees, 31 of whom were full-time employees. None of our employees is represented by a labor union or covered by a collective bargaining agreement.

Employee Engagement, Benefits & Development. We recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. Our employees are a significant asset and we aim to create an equitable, inclusive and empowering environment in which our employees can grow and advance their careers, with the overall goal of developing, retaining and expanding our workforce, as needed, to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our business and operations, our pipeline, and also protect the long-term interests of our shareholders. We frequently benchmark our compensation practices and benefits programs against those of comparable companies in our industry and in the geographic area where we are located. In our efforts to recruit and retain a diverse and exceptional workforce, we provide our employees with competitive cash compensation, opportunities to own equity, and an employee benefit program that promotes well-being, including healthcare, a 401(k) Plan, and paid time-off.

Diversity & Inclusion. Our success also depends on our ability to attract, engage and retain a diverse group of employees. We value diversity across our workforce and we will continue to focus on diversity and inclusion initiatives. With respect to our employees overall, approximately fifty percent (50%) are people of color and approximately forty-five percent (45%) are women. We seek to have an inclusive and positive culture that is centered on our shared corporate mission and values, and that is free from discrimination of any kind, including sexual or other discriminatory harassment. Our employees have multiple avenues available through which inappropriate behavior can be reported. All reports of inappropriate behavior are promptly investigated with appropriate action taken to stop such behavior.

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. 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. is now a wholly-owned subsidiary of the Company.

Our website address is *www.qualigeninc.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 primarily on development of therapeutic product candidates, which requires extensive cash needs for research and development activities. This is a high-risk strategy because there is no assurance that our products will ever become commercially viable, that we will prevent other companies from depriving us of market share and profit margins by selling products based on our inventions and developments, that we will successfully manage a company in a new area of business and on a different scale than we have operated in the past, that our product candidates will be able to achieve the desired therapeutic results, or that our cash resources will be adequate to develop our product candidates until we become profitable, if ever. This may make our stock an unsuitable investment for many investors.

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

We have suffered recurring losses from operations, and we will need capital to support our intended development of our therapeutics business. We believe that future financings will be necessary in order for us 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 securities, our stockholders may 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 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 Capital Anstalt ("Alpha"), a related party and the holder of our 8% Senior Convertible Debenture (the "Debenture"), and/or trigger certain adjustments to the Debenture or warrants held by Alpha. See Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" for additional details regarding the Debenture.

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

Our ability to make payments to Alpha of principal or interest on our indebtedness or to make any potential prepayments for the Debenture, to the extent applicable, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. If the assumptions underlying our cash flow guidance are incorrect, our business may not continue to generate cash flow from operations in the future sufficient to service our indebtedness and make necessary capital expenditures.

Commencing June 1, 2023 and continuing on the first day of each month thereafter until the earlier of (i) December 22, 2025 and (ii) the full redemption of the Debenture (each such date, a "Monthly Redemption Date"), we must redeem $110,000 plus accrued but unpaid interest, liquidated damages and any amounts then owing under the Debenture (the "Monthly Redemption Amount"). The Monthly Redemption Amount must be paid in cash; provided that after the first two monthly redemptions, we may elect to pay all or a portion of a Monthly Redemption Amount in shares of our common stock, based on a conversion price equal to the lesser of (i) the then applicable conversion price of the Debenture and (ii) 85% of the average of the VWAPs (as defined in the Debenture) for the five consecutive trading days ending on the trading day that is immediately prior to the applicable Monthly Redemption Date. We may also redeem some or all of the then outstanding principal amount of the Debenture at any time for cash in an amount equal to 105% of the then outstanding principal amount of the Debenture being redeemed plus accrued but unpaid interest, liquidated damages and any amounts then owing under the Debenture. These monthly redemption and optional redemptions are subject to the satisfaction of the Equity Conditions (as defined in the Debenture), which include a condition that we have obtained stockholder approval for such share issuances.

The Debenture accrues interest at the rate of 8% per annum, which begins 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 interest may only be paid in shares if the Equity Conditions have been satisfied, including the stockholder approval condition as described above.

If we are unable to obtain stockholder approval for the issuance of shares of common stock under the Debenture, we will required to make any required payments to Alpha in cash. If we are unable to generate cash flow sufficient to service our indebtedness and make necessary capital expenditures, 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.

Risks Related to Our Therapeutics and Diagnostics Pipeline

Our product candidates are still in the early stages of development. We have not begun clinical trials or obtained regulatory approval for any drug candidate. We may never obtain approval for any of our drug candidates.

We are still early in our development efforts and have not yet begun enrollment in any clinical trials evaluating QN-302, RAS, or QN-247. There can be no assurance that QN-302, RAS, and/or QN-247 will achieve success in their clinical trials or obtain regulatory approval.

Our ability to generate revenues from QN-302, RAS, and/or QN-247 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, RAS, QN-247, 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 QN-302, RAS, and/or QN-247.

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:

- 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 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 or IDE application or similar regulatory filing, and the FDA (or corresponding foreign regulatory body) must approve the application. We have not yet submitted our IND application for QN-302 for pancreatic cancer. While we expect to submit the IND application during the first half of 2023, we cannot guarantee the timing for submitting the IND application for QN-302, and we do not know when this IND application (or any other IND application) would be approved, if ever.

Before obtaining marketing approval from the FDA for the sale of QN-302, RAS, QN-247, 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:

- 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, RAS or QN-247, 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 QN-302, RAS, and/or QN-247 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 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 QN-302, RAS, QN-247 or any other 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 QN-302, RAS and QN-247, as well as any other product candidate that we may develop in the future, are subject to extensive regulation.

Regulatory approval of drugs in the United States requires the submission of an NDA to the FDA and we are not permitted to market any pharmaceutical product candidate in the United States until we obtain approval from the FDA of the NDA for that product. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls.

FDA approval of an NDA or PMA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for NDA or PMA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and any clinical trials of QN-302, RAS or QN-247 or any other future product candidate may not be predictive of the results of our later-stage clinical trials.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the pharmaceutical and device industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent regulatory approval.

Even if we are able to commercialize any drug candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if such drug candidates obtain regulatory approval.

Our ability to commercialize any drug candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government healthcare programs, private health insurers and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere has been cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any drug candidate for which we obtain regulatory approval. Obtaining and maintaining coverage and adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain regulatory approval.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may continue to result in more rigorous coverage criteria and in additional downward pressure on the price that providers receive for any approved therapeutics products of ours. This would adversely affect the prices we receive and could also adversely affect providers' willingness to prescribe our therapeutics products, if any.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as "orphan drugs." Under the Orphan Drug Act of 1983, as amended, the FDA may designate a drug candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making a drug product available in the United States for the type of disease or condition will be recovered from sales of the product.

Orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity. This means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in certain circumstances, including proving clinical superiority (*i.e.*, another product is safer, more effective or makes a major contribution to patient care) to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective.

We have received orphan drug designation in the United States for QN-302 for the indication of pancreatic cancer. Following having data that supports other rare cancer indications, we intend to seek orphan drug designation in the United States for QN-302 for additional indications, and will also seek orphan drug designations for RAS for one or more indications. Orphan drug status does not ensure that we will receive marketing exclusivity in a particular market, and there is no assurance that any application for orphan drug designation will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

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 QN-302, RAS and QN-247. 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, and expect to continue to rely, on UofL for preclinical studies related to RAS, and we expect to rely heavily on CROs and sponsored academic researchers for preclinical studies related to QN-302. As to any clinical trials, we expect to rely on CROs, sponsored academic researchers, clinical investigators and 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 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 QN-302, RAS and/or QN-247 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 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, RAS or QN-247.

We may enter into collaborations with third parties for the development and commercialization of our products. If those collaborations are not successful, we may not be able to capitalize on the market potential of these products. Even if they are successful, they may result in a limitation of our upside potential.

We may in the future seek third-party collaborators for the development and commercialization of some of our products on a selected basis. For example, we expect that we will require partners to continue the development of QN-247 which is in early-stage development.

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 collaboration will necessarily result in a sharing of economics with the collaborator, which might otherwise have been captured by us directly.

Even if any of our product candidates receives regulatory approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives regulatory approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments, such as existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA;

- the size of the target patient population;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the strength of marketing and distribution support;
- publicity for our product candidates and competing products and treatments;
- the existence of distribution and/or use restrictions, such as through a Risk Evaluation and Mitigation Strategy;
- the availability of third-party payor coverage and adequate reimbursement and the willingness of patients to pay for our products in the absence of such coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of pharmaceutical products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates that may be effective in developing therapeutics. Some of these competitive products, therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We expect that our oncology drug product candidates will face competition from traditional small or large molecule drugs that target specific cancers that are FDA-approved and marketed for the indications that we are pursuing, in addition to off-label use of current therapeutics and therapeutics in development; and from other drugs using targeted approaches to direct payloads to cancerous tumors, as well as newer approaches, such as immuno-oncology, which attempts to harness the patient's own immune system to fight cancer itself.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing and selling approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are approved for broader indications or patient populations, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than any approval we may obtain, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. The key competitive factors affecting the success of QN-302, RAS, QN-247 are likely to be efficacy, safety, scope and limitations of marketing approval, and availability of reimbursement.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe 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, we could lose all or a portion of amounts held in excess of such insurance limitations. The FDIC recently took control of two such banking institutions, Silicon Valley Bank ("SVB") on March 10, 2023 and Signature Bank ("Signature Bank") on March 12, 2023. While we did not have an account at either of these two banks, in the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Risks Related to Our Diagnostics Business

We may face challenges distributing our FastPack System.

Our distribution agreement with Sekisui for our FastPack System expired on March 31, 2022. We have and will continue to incur costs re-establishing and maintaining a direct sales force, and we may also face logistical issues and relationship issues with customers during the transition period. In addition, there is the risk that the direct sales force assembled and used by us will not be as efficient and effective as Sekisui's distribution efforts.

We may provide inadequate training to our sales force and/or fail to increase our sales and marketing capabilities.

We rely on our direct sales force to sell our FastPack System in targeted geographic regions, territories and distribution channels, and any failure to maintain our direct sales force could harm our business. The members of our direct sales force are specifically trained to market and sell our FastPack System and they possess technical expertise, which we believe is critical in driving the awareness and adoption of our product. The members of our sales force are at-will employees. The loss of these personnel to competitors, or otherwise, could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of comparable expertise and qualifications, or if we are unable to successfully instill such expertise in replacement personnel, our product sales, revenues and results of operations could be materially harmed.

Identifying and recruiting qualified sales and marketing professionals and training them on our FastPack System, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It can take several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing products that can utilize independent third parties, placing us at a competitive disadvantage. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in product sales and revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have material adverse effect on our business, financial condition and results of operations.

Our diagnostic products face heavy competition.

Our FastPack System is a mature technology and faces heavy competition from manufacturers of more complex immunoassay systems designed primarily for central laboratory use, but that also are sold to physician offices. Many of our competitors have substantially greater financial, technical, research and other resources and capabilities. We also face competition from companies that have developed or are developing newer blood testing systems for use in physician offices. The FastPack system may not continue to be competitive in light of future technological developments by others.

Our diagnostic products are disadvantaged by reduced Medicare reimbursement and third-party payer pricing.

As noted above, a primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical devices, especially mature ones such as ours. Decreases in Medicare and private-insurer reimbursement for diagnostic tests such as ours in recent years are a negative factor in our attempts to maintain and grow our diagnostics business. This factor constrains the price that we can charge to providers for our diagnostic products. Moreover, if adequate reimbursement is not available or reimbursement is available only to limited levels, some physician offices, clinics and small hospitals may choose not to offer (or to discontinue offering) some or all of our diagnostic products.

Yi Xin may not meet expectations in its China/overseas FastPack business.

Yi Xin is a new and untested company and there is no assurance that its financial and other capabilities will enable it to succeed in commercializing FastPack-based diagnostic products. We will receive royalties from Yi Xin if and only if Yi Xin achieves sales of FastPack-based diagnostic products.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our therapeutic product candidates and diagnostic technologies, 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.

To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates and technologies, their methods of manufacture and use. The patent application and approval process is expensive, time-consuming and complex. We may not be able to prepare, file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, depending on the terms of any future 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. We have not filed patent applications in every jurisdiction, and some filings are only pending in the United States.

Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file or invent (before March 16, 2013) the invention disclosed in any patent application related to our product candidates or technology.

Moreover, because the issuance of a patent, although presumptive, is not conclusive as to its inventorship, scope, validity or enforceability, our 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 our 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 and 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 our 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 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 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 patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have 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 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, 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, Managing Growth, 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, as well as other members of our management, scientific, operations and corporate development teams.

As previously disclosed, in January 2023, as part of certain cost-cutting measures, we approved a temporary 20% reduction to the base salaries of all executive officers of the Company, effective immediately. As part of these cost-cutting measures, we terminated the employment of certain employees, including our former Chief Operating Officer and former Vice President and Chief Scientific Officer. These cost-cutting measures could make us vulnerable to attrition among our current senior management team and other key employees, and may make it difficult for us to hire additional senior managers and other key 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 may limit our ability to continue 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 expect that we will need to expand our development and regulatory capabilities as our product candidates progress through the clinic, or additional product candidates are developed; if any products are approved, we would have to implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing growth, which could disrupt our operations.

As of March 31, 2023, we had 38 employees, 31 of whom were full-time employees. Although we outsource many drug development functions and may choose to continue to do so in the future, we expect to experience growth in the number of employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, and regulatory affairs as we progress QN-302, RAS and QN-247 through the clinic and develop additional product candidates. If any of our therapeutics product candidates receives regulatory approval, we may need to expand into sales, marketing and distribution. To manage anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert management and business development resources.

We currently rely, and for the foreseeable future will continue to rely, in substantial part, on certain third-party contract research organizations, sponsored academic researchers, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacture of QN-302, RAS and QN-247 or any future product candidates. We cannot assure that the services of such third-party contract research organizations, sponsored academic researchers, advisors 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, and we may not be able to obtain regulatory approval of QN-302, RAS and/or QN-247 or any of future product candidates or otherwise advance our business. 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. For example, as a result of annual goodwill impairment testing, we recognized a $4.2 million non-cash goodwill impairment charge in the valuation of our business acquisition of Nanosynex for the year ended December 31, 2022. 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 investment in NanoSynex, our majority owned indirect subsidiary, has a number of risks associated with it.

Our investment in NanoSynex, our majority owned indirect subsidiary domiciled in Israel, 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;
- 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, as a condition to our acquisition of NanoSynex, we agreed to provide NanoSynex with up to $10.4 million of future funding in the form of promissory notes to us based on NanoSynex's achievement of certain future development milestones and subject to other terms and conditions described in the funding agreement. See Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" for additional details. If we are unable to make these payments, if and when required, and if NanoSynex is unable to find alternative sources of funding, NanoSynex's operations may be negatively impacted, which would ultimately have a negative impact on us.

Our reported financial condition and results of operations 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. In particular, the warrant liabilities (and change in the fair value of warrant liabilities, over a reporting period) may result in distortions and sharp variability in reported periodic results. Accordingly, you should not blindly rely upon the results of any quarterly or annual periods as indications of future 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, 2022 there were 608,012 stock options outstanding under our equity incentive plans. and 4,575,617 outstanding warrants.

In addition, the Debenture issued to Alpha in December 2022 is convertible, at any time, and from time to time, at Alpha's option, into shares of our common stock, subject to our receipt of the necessary stockholder approvals and other terms and conditions described in the Debenture. Furthermore, subject to our receipt of the necessary stockholder approvals and other terms and conditions described in the Debenture, we may elect to pay all or a portion of the Monthly Redemption Amount and/or interest required by the Debenture in shares of our common stock.

The issuance of shares upon the exercise or conversion of outstanding stock options, warrants and the Debenture (or our election to pay amounts owed under the Debenture 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 complex IT 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, track inventory, provide services and customer support, 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.

The number and complexity of these security threats continue to increase over time. The costs of maintaining adequate protection against such threats are significant and are expected to continue to increase in the future and may be material to our financial statements. If a breach of our security systems or that of our partners occurs, the market perception of the effectiveness of our security measures could be harmed, we could lose business and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. We may also be required to comply with disparate state and foreign breach notification laws and otherwise subject to liability under laws that protect personal data, resulting in increased costs or loss of revenue. In addition, a data security breach or ransomware attack could distract management or other key personnel from performing their primary operational duties. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely.

Our business, financial condition, results of operations and growth have been adversely impacted by the effects of the COVID-19 pandemic and may be adversely impacted by COVID-19 or another pandemic, epidemic or infectious disease outbreak in the future.

The COVID-19 pandemic and related governmental and business responses had and may again have an adverse effect on the markets we derive project opportunities from, our customers, and our operations. The extent to which the COVID-19 pandemic could again impact us will depend on numerous evolving factors and future developments that are uncertain and that we are not able to predict at this time, including: the timing, extent, trajectory and duration of the pandemic; the emergence of new variants; the development, availability, distribution and effectiveness of vaccines and treatments; the imposition of protective public safety measures; and the impact of the pandemic on the global economy and demand for our products and services. Although the COVID-19 pandemic has subsided, we could again experience adverse impacts to our business as a result of any related economic recession that occurred or may occur in the future from COVID-19 or other similar global pandemics.

Adverse global conditions, including economic uncertainty, may negatively impact our financial results.

Global conditions, disruptions in the financial markets, or inflation could adversely impact our business. In addition, the global macroeconomic environment has been and may continue to be negatively affected by, among other things, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the war in Ukraine, the withdrawal of the United Kingdom from the European Union, and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets, which may adversely affect our business.

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 prevented Qualigen from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for Qualigen 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.

Moreover, 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.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. 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. However, 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 that the material weakness identified in connection with the 2021 audit has not been fully remediated and has 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 this Annual Report (see Item 9A. Controls and Procedures).

If we are unable to remediate the material weakness and achieve and maintain effective internal control over financial reporting and effective disclosure controls, our business could be adversely affected. Certain customers and/or suppliers may choose not to do business with us and the price of our common stock could be adversely impacted. This could, in turn, negatively affect our ability to access equity capital markets.

Our failure to be current in our filings with the SEC could pose significant risks to our business, which could materially and adversely affect our financial condition and results of operations.

We are required, as a public reporting company, to provide investors on a regular basis with periodic reports that contain important financial and business information, including annual reports on Form 10-K and other periodic reports. Periodic reports help investors to make informed investment decisions about the purchase or sale of a reporting company's securities. Our inability to timely file periodic reports with the SEC could have an adverse impact on our ability to, among other things, (i) raise funds in the public markets and (ii) attract and retain key employees, which could materially and adversely affect our financial condition and results of operations. In addition, the late filing of our Annual Report has also adversely affected our eligibility to use our Form S-3 registration statement. Use of that Form requires, among other things, that the issuer be current in its reports under the Exchange Act for at least 12 months. As a result of our being unable to use Form S-3, we will have to meet more demanding requirements to register our securities, so it will be more difficult for us to effect public offering transactions, and our range of available financing alternatives could be narrowed.

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 this 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 has no immediate effect on the listing or trading of our common stock on the Nasdaq Capital Market. The notification letter states that, under Nasdaq rules, we have 60 calendar days, or until June 20, 2023, to submit a plan to regain compliance with Nasdaq's continued listing requirements. Alternatively, we may also regain compliance with Nasdaq's continued listing requirements at any time before June 20, 2023, by filing this Annual Report with the SEC, as well as any subsequent periodic financial reports that may become due, and continuing to comply with Nasdaq's other continued listing requirements. We expect that the filing of this Annual Report will be sufficient to avoid the delisting of our common stock.

We have in the past been in noncompliance with other Nasdaq continued listing rules. For example, on November 23, 2022, we effected a 1-for-10 reverse stock split of our outstanding common stock to cure our noncompliance, for a period of more than 30 consecutive business days, with Nasdaq Listing Rule 5550(a)(2), which requires listed securities to maintain a minimum bid price of $1.00 per share.

If we are unable to maintain compliance with Nasdaq's continued listing requirements. 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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our wholly-owned subsidiary Qualigen, Inc. currently leases an all-purpose facility in Carlsbad, California. Our partially owned subsidiary NanoSynex currently leases an R&D facility in Ness Ziona, Israel.

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 April 11, 2023, there were 627 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

None.

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 a diversified life sciences company focused on developing treatments for adult and pediatric cancers with potential for Orphan Drug designation, while also commercializing diagnostics.

Our cancer therapeutics pipeline includes QN-302, RAS and QN-247.

Our lead oncology therapeutics program, QN-302, is an investigational small molecule G4-selective transcription inhibitor with strong binding affinity to G4s prevalent in cancer cells. Such binding could, by stabilizing the G4s against DNA "unwinding," help inhibit cancer cell proliferation. QN-302 is currently undergoing Good Laboratory Practice (GLP) toxicology studies.

Our RAS portfolio 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. Preventing this binding could stop tumor growth, especially in RAS-driven tumors such as pancreatic, colorectal and lung cancers.

Our investigational QN-247 compound binds nucleolin, a key multi-functional regulatory phosphoprotein that is overexpressed in cancer cells. Such binding could inhibit the cancer cells' proliferation. The foundational aptamer of QN-247 is QN-165 (formerly referred to as AS1411), which the Company has deprioritized as a drug candidate for treating COVID-19 and other viral-based infectious diseases.

On May 26, 2022, we acquired 2,232,861 shares of Series A-1 Preferred Stock of NanoSynex from Alpha in exchange for 3,500,000 shares of our common stock and a prefunded warrant to purchase 3,314,641 shares of our common stock at an exercise price of $0.001 per share. These warrants were subsequently exercised on September 13, 2022 and the shares of our common stock were subsequently subject to a 1 for 10 reverse split on November 23, 2022. Concurrently with this transaction, we also purchased 381,786 shares of Series B preferred stock from NanoSynex for a total purchase price of $600,000. The transactions resulted in our acquiring a 52.8% interest in NanoSynex. NanoSynex is a micro-biologics diagnostics company domiciled in Israel.

Because our therapeutic candidates are all still in the pre-clinical development stage, our only products that are currently commercially available are the for sale FastPack System diagnostic instruments and test kits. Our FastPack System diagnostic instruments and test kits are sold commercially primarily in the United States, as well as certain European countries. The FastPack System menu includes a rapid, highly accurate immunoassay diagnostic testing system for cancer, men's health, hormone function, and vitamin D status. We provide analyzers to our customers (physician offices, clinics and small hospitals) at low cost in order to increase sales volumes of higher-margin test kits.

We have always utilized a "razor and blades" pricing strategy, providing analyzers to our customers (physician offices, clinics and small hospitals) at low cost in order to increase sales volumes of higher-margin test kits. Through the first quarter of 2022, we relied on our diagnostics distribution partner, Sekisui, for most FastPack distribution worldwide pursuant to a distribution agreement. We maintained direct distribution for certain house accounts, including selling our total testosterone test kits to Low T, the largest men's health group in the United States, with 40 locations. The Distribution Agreement with Sekisui expired on March 31, 2022, and after that date the activities previously provided by Sekisui have reverted back to us and we have recognized 100% of the revenue from the sales of our FastPack diagnostic instruments and test kits. We have licensed and technology-transferred our FastPack System technology to Yi Xin Zhen Duan Jishu (Suzhou) Ltd. for the China diagnostics market.

We do not expect to be profitable before products from our therapeutics pipeline are commercialized, because we foresee that research and development expenses on the therapeutics programs will significantly exceed the profits, if any, that we will generate from our diagnostics products. To experience losses while therapeutic products are still under development is, of course, typical for biotechnology companies.

Our consolidated financial statements do not separate our diagnostics-related activities from our therapeutics-related activities. Although to date all of our reported revenue is diagnostics-related, our reported expenses represent the total of our diagnostics-related and therapeutics-related expenses

Reverse Stock Split

On November 23, 2022, we effected a 1-for-10, as determined by our board of directors, 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 payments were made to stockholders. All share and per share data for all periods presented in this section and the accompanying financial statements and 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.

Impact of COVID-19 Pandemic

The COVID-19 pandemic had, and it or similar pandemics, epidemics or infectious disease outbreaks may, in the future, have, adverse impacts on the U.S. and world economy, health care systems, personnel availability, supply chains, social and political assumptions, and capital markets. The impacts from the pandemic were particularly serious for smaller companies such as ours. Sales of our diagnostic products fell significantly during 2020 as deferral of patients' non-emergency visits to physician offices, clinics and small hospitals sharply reduced demand for our FastPack tests. While our FastPack sales began to rebound in 2021, the extent to which the COVID-19 pandemic, or similar pandemics, epidemic or infectious disease outbreak, could impact us in the future will depend on numerous evolving factors and future developments that we are unable to predict at this time, including: the timing, extent, trajectory and duration of the pandemic; the emergence of new variants; the development, availability, distribution and effectiveness of vaccines and treatments; the imposition of protective public safety measures; and the impact of the pandemic on the global economy and demand for our products and services. We could again experience adverse impacts to our business as a result of any related economic recession that may occur in the future from COVID-19 or other similar global pandemic, epidemic or infectious disease outbreak.

Critical Accounting Policies and Estimates

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, stock-based compensation, amortization and depreciation, inventory reserves, allowances for doubtful accounts and returns, and warranty costs. 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:

- Convertible debt
- Research and development
- Revenue recognition
- Allowance for doubtful accounts and returns
- Inventory
- Impairment of long-lived assets
- Business combination
- Goodwill
- In Process R&D
- 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 Qualigen, Inc. 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. The operation of the "double-ratchet" provisions in these warrants in connection with the NanoSynex acquisition and the convertible debenture financing transaction in 2022 now allow the holders to exercise for a significantly higher number of shares than before. Accounting principles generally accepted in the United States of America ("U.S. GAAP") require us to recognize the fair value of these warrants as warrant liabilities on our 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 $0.8 million and $1.7 million at December 31, 2022 and 2021, respectively. There were 1,349,571 of these warrants outstanding at December 31, 2022 and 248,162 of these warrants outstanding at December 31, 2021.

On December 22, 2022, as part of the convertible debenture financing, the Company issued to Alpha a common stock warrant to purchase a number of shares of the common stock of the Company equal to the number of Conversion Shares issuable upon conversion of the Debenture as of the closing date. The exercise price of the warrant is $1.65 (equal to 125% of the Conversion Price of the Debenture on the closing date). The warrant entitles Alpha to purchase up to 2,500,000 shares of common stock of the Company and may be exercised by Alpha, in whole or in part, at any time on or after June 22, 2023 and before June 22, 2028. U.S. GAAP requires 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 this warrant liability was $2.8 million and $0 at December 31, 2022 and 2021, respectively.

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

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

	For the Years Ended December 31,	
	2022	**2021**
REVENUES		
Net product sales	$ 4,983,556	$ 5,021,721
License revenue	—	632,004
Total revenues	4,983,556	5,653,725
EXPENSES		
Cost of product sales	4,302,755	4,332,485
General and administrative	10,835,647	11,724,964
Research and development	6,837,133	11,716,718
Sales and marketing	950,420	542,594
Goodwill and fixed asset impairment	4,239,000	—
Total expenses	27,164,955	28,316,761
LOSS FROM OPERATIONS	(22,181,399)	(22,663,036)
OTHER EXPENSE (INCOME), NET		
(Gain) loss on change in fair value of warrant liabilities	(907,203)	(4,723,187)
Interest (income) expense, net	26,646	(42,693)
Other income, net	(1,125)	(5,446)
Total other expense (income), net	(881,682)	(4,771,326)
LOSS BEFORE (BENEFIT) PROVISION FOR INCOME TAXES	(21,299,717)	(17,891,710)
(BENEFIT) PROVISION FOR INCOME TAXES	(265,074)	5,427
NET LOSS	(21,034,643)	(17,897,137)
Net loss attributable to noncontrolling interest	(2,394,100)	—
Net loss attributable to Qualigen Therapeutics, Inc.	$ (18,640,543)	$ (17,897,137)
Other comprehensive loss, net of tax		
Net loss	$ (21,034,643)	$ (17,897,137)
Foreign currency translation adjustment	50,721	—
Other comprehensive loss	(20,983,923)	(17,897,137)
Comprehensive loss attributable to noncontrolling interest	(2,394,100)	—
Comprehensive loss attributable to Qualigen Therapeutics, Inc.	$ (18,589,823)	$ (17,897,137)

Revenues

Our operating revenues are primarily generated from sales of our FastPack diagnostic tests. Revenues for the year ended December 31, 2022 were approximately $5.0 million compared to approximately $5.7 million for the year ended December 31, 2021, a decrease of $0.7 million. This decrease was primarily due to the recognition of approximately $0.6 million in license revenue from Yi Xin under the Technology Transfer Agreement for the year ended December 31, 2021, compared with no license revenue for the year ended December 31, 2022.

Net product sales

Net product sales are primarily generated from sales of our diagnostic tests. Net product sales for the year ended December 31, 2022 were $5.0 million, which remained largely consistent with $5.0 million for the year ended December 31, 2021.

License Revenue

License revenue for the year ended December 31, 2021 was $0.6 million, due to the recognition of revenue from Yi Xin under the Technology Transfer Agreement. There was no license revenue for the year ended December 31, 2022.

Expenses

Cost of Product Sales

Cost of product sales for the year ended December 31, 2022 were $4.3 million, which remained largely consistent with $4.3 million for the year ended December 31, 2021.

General and Administrative Expenses

General and administrative expenses decreased from $11.7 million for the year ended December 31, 2021 to $10.8 million the year ended December 31, 2022. This decrease was due to a $0.3 million decrease in professional fees, a $0.3 million decrease in payroll-related expenses, a $0.3 million decrease in insurance expenses, and a $0.3 million decrease in investor relations expenses, offset by increases of $0.2 million in legal expenses and $0.1 million in rent.

Research and Development Costs

Research and development costs include therapeutics and diagnostics research and product development costs. Research and development costs decreased from $11.7 million for the year ended December 31, 2021 to $6.8 million for the year ended December 31, 2022. Of the $6.8 million of research and development costs for year ended December 31, 2022, $4.5 million (66%) was attributable to therapeutics and $2.3 million (34%) was attributable to diagnostics. Of the $11.7 million of research and development costs for the year ended December 31, 2021, $10.3 million (88%) was attributable to therapeutics and $1.4 million (12%) was attributable to diagnostics.

The increase in diagnostic research and development costs was primarily due to $0.9 million in R&D expenses assumed in connection with the acquisition of NanoSynex. The decrease in therapeutics research and development costs was primarily due to a decrease of $6.4 million in expenses related to the potential application of QN-165 for the treatment of COVID-19 ($4.6 million in drug compound manufacturing costs, and $1.8 million in other pre-clinical research costs), as well as pre-clinical research and development cost decreases of $0.2 million for QN-247, a decrease in legal expenses of $0.3 million, a decrease of $0.3 million in payroll-related expenses, offset by an increase in QN-302 spending of $1.1 million and an increase in RAS expenses of $0.3 million.

For the future, we expect our therapeutic research and development costs to continue to significantly outweigh our diagnostic research and development costs, and to be relatively lower in periods when we are focusing on pre-clinical activities and meaningfully higher in periods when we are provisioning for and conducting clinical trials, if any.

Sales and Marketing Expenses

Sales and marketing expenses for the year ended December 31, 2022 increased to $1.0 million as compared to $0.5 million for the year ended December 31, 2021, primarily due to an increase in payroll-related expenses as a result of the termination of the Sekisui distribution agreement.

Goodwill and Fixed Asset Impairment

As a result of annual goodwill impairment testing, we recognized a $4.2 million non-cash goodwill and fixed asset impairment charge in the valuation of our business acquisition of NanoSynex for the year ended December 31, 2022. For more information, refer to Note 1 - Organization and Summary of Significant Accounting Policies and Estimates and Note 7 - Goodwill, IPR&D and other Intangibles of the consolidated financial statements.

Other Expense (Income)

Change in Fair Value of Warrant Liabilities

During the year ended December 31, 2022 we experienced (primarily due to a decrease in our stock price during the period) a $0.9 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 warrants increased to $3.6 million as of December 31, 2022 from $1.7 million as of December 31, 2021 primarily due to the issuance of a new warrant as part of the convertible debt-related party financing transaction, offset by a reduction in fair value of the other liability classified warrants. For the year ended December 31, 2021, the gain on change in fair value of warrant liabilities was $4.7 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.

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

Interest (Income) Expense, Net

There was $27,000 in net interest expense during the year ended December 31, 2022 compared to net interest income of $43,000 during the year ended December 31, 2021. During the year ended December 31, 2022, we issued convertible debt which resulted in an increase of $47,000 in interest expense offset by a reduction of $20,000 in interest income compared to the year ended December 31, 2021, primarily due to lower interest bearing cash balances.

Other Income, Net

Other income was immaterial during the years ended December 31, 2022 and 2021.

Liquidity and Going Concern

As of December 31, 2022, we had approximately $7.0 million in cash. We have incurred recurring losses from operations and have an accumulated deficit of $103.4 million at December 31, 2022. We expect to continue to incur losses subsequent to the consolidated balance sheet date of December 31, 2022. For the years ended December 31, 2022 and 2021, we used cash of $13.2 million and $14.7 million, respectively, in operations. We currently expect our cash balances to fund operations into the third quarter of 2023. As a pre-clinical development-stage therapeutics biotechnology company, we expect to continue to have net losses and negative cash flow from operations, which over time 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 these financial statements 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, clinical and pre-clinical testing for QN-302 clinical trials, to continue preclinical development of RAS, and to continue funding the NanoSynex operations (See Note 3-Acquisition), as well as commercialization activities.

Historically, our principal sources of cash have, in addition to revenue from FastPack product sales and license revenues, included proceeds from the issuance of common and preferred equity and proceeds from the issuance of debt. In December 2021, we raised $8.8 million from the issuance of common stock to several institutional investors, and in December 2022 we raised approximately $3.0 million from the sale of a convertible debenture 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, which could adversely affect our business prospects.

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 government or other 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 Debenture and/or trigger certain adjustments to the Debenture or warrants held by Alpha.

As a condition to the NanoSynex closing, the Company agreed to provide NanoSynex with up to $10.4 million of future funding based on NanoSynex's achievement of certain future development milestones and subject to other terms and conditions described in the Master Agreement for the Operational and Technological Funding of NanoSynex (the "Funding Agreement") entered into with NanoSynex. These funding commitments are in the form of convertible promissory notes to be issued to the Company with a face value equal to the amount paid by the Company to NanoSynex upon satisfaction of the applicable performance milestone, bearing interest at the rate of 9% per annum on the principal balance from time to time outstanding under the particular promissory note, convertible at the option of the Company into additional shares of NanoSynex in order for the Company to maintain at least a 50.1% controlling ownership interest in NanoSynex, should NanoSynex issue additional shares. The principal of the convertible notes are due and payable upon the sooner to occur of: i) five years from the date of issuance of the particular promissory note; ii) the acquisition by any person or entity of all or substantially all of the share capital of NanoSynex, through share purchase, issuance or shares or merger of NanoSynex, or the purchase of all or substantially all of the assets of NanoSynex; or iii) the initial public offering of NanoSynex. The Company provided funding to NanoSynex of $2.4 million during 2022 and an additional $0.5 million in February 2023 pursuant to this agreement. The Company may terminate the Funding Agreement upon 120 days' notice, but would still be liable for any payments due for milestones achieved prior to termination.

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 consolidated balance sheet at December 31, 2022 includes $3.6 million of current warrant liabilities. We do not consider the warrant liabilities to constrain our liquidity, as a practical matter. Our current liabilities at December 31, 2022 also include $0.9 million of accounts payable, $0.5 million of accrued vacation pay, $1.5 million of accrued expenses and other current liabilities, a $0.8 million R&D grant liability, $0.2 million in operating lease liabilities, $0.1 million of notes payable (convertible debt to a related party), and $1.0 million in short term 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.

Lease Agreement with Bond Ranch LP

On December 15, 2021, our wholly-owned subsidiary Qualigen, Inc. entered into a Second Amendment to Lease with Bond Ranch LP. This Amendment extended the Company's triple-net leasehold on its existing 22,624-square-foot headquarters/manufacturing facility at 2042 Corte del Nogal, Carlsbad, California for the 61-month period of November 1, 2022 to November 30, 2027. Over the 61 months, the base rent payable will total $1,950,710; however, the base rent for the first 12 months of the 61-month period will be only $335,966. Additionally, Qualigen, Inc. was entitled to a $339,360 tenant improvement allowance. See Note 13-Commitments and Contingencies of the consolidated financial statements for additional details.

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 UofL Research Foundation ("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 RAS. As of December 31, 2022 we had up to $748,000 remaining due under this sponsored research agreement for RAS. We also agreed to reimburse ULRF for sponsored research expenses of up to $830,000 and prior patent costs of up to $200,000 for QN-247. As of December 31, 2022, there were no remaining un-expensed amounts under this sponsored research agreement for QN-247 and the agreement was terminated effective August 31, 2022. We also agreed to reimburse ULRF for sponsored research expenses of up to $430,000 and prior patent costs of up to $24,000 for QN-165. As of December 31, 2022 we had no remaining un-expensed amounts under this sponsored research agreement for QN-165, and the agreement was terminated effective November 30, 2021. Under the terms of these agreements, we are required to make patent maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $5 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under these agreements, and we will be required to pay a percentage of any sublicense income.

On January 13, 2022, we entered into a License Agreement with UCL Business Limited to obtain an exclusive worldwide in-license of a genomic quadruplex (G4)-selective transcription inhibitor drug development program which had been developed at University College London, including lead and back-up compounds, preclinical data and a patent estate. (UCL Business Limited is the commercialization company for University College London.) The program's lead compound will be further developed at Qualigen under the name QN-302 as a candidate for treatment of pancreatic ductal adenocarcinoma (PDAC), which represents the vast majority of pancreatic cancers. The Agreement requires (if and when applicable) tiered royalty payments in the low to mid-single digits, clinical/regulatory/sales milestone payments, and a percentage of any non-royalty sublicensing consideration paid to Qualigen.

Termination of Sekisui Distribution Agreement

Following the expiration of the Sekisui Distribution Agreement on March 31, 2022, the Company has a commitment to purchase leased FastPack rental systems back from Sekisui at its net book value, in the amount of $154,000 which is included in equipment held for lease and accrued expenses and other current liabilities on the consolidated balance sheet.

Technology Transfer Agreement with Yi Xin

Through our wholly-owned diagnostics subsidiary Qualigen, Inc., we entered into a Technology Transfer Agreement dated as of October 7, 2020, with Yi Xin, of Suzhou, China, which authorizes Yi Xin to develop, manufacture and sell new generations of diagnostic test systems based on our core FastPack technology. In addition, the Technology Transfer Agreement authorizes Yi Xin to manufacture and sell our current generations of FastPack System diagnostic products (1.0, IP and PRO) in China. We have provided technology transfer and patent/know-how license rights to facilitate Yi Xin's development and commercialization.

Under the terms of the Technology Transfer Agreement, we have provided Yi Xin the exclusive rights for China – which is a market we have not otherwise entered – both for Yi Xin's new generations of FastPack-based products and for Yi Xin-manufactured versions of our existing FastPack product lines. Yi Xin has the right to sell its new generations of FastPack-based diagnostic test systems throughout the world (but not to or toward current customers of our existing generations of FastPack products); provided that any non-China sales would, until March 31, 2022, need to be through Sekisui. As of April 1, 2022, Yi Xin has right to sell Yi Xin-manufactured versions of existing FastPack 1.0, IP and PRO product lines worldwide (other than in the United States and other than to or toward current non-US customers of those products). Yi Xin also has the right, as of April 1, 2022, to buy Qualigen-manufactured FastPack 1.0, IP and PRO products from us at distributor prices for resale in and for the United States (but not to or toward current U.S. customers of those products). We did not license Yi Xin to sell in the United States market any Yi Xin-manufactured versions of those legacy FastPack product lines, even after March 31, 2022. We agreed in the Technology Transfer Agreement that we would not, after March 31, 2022, seek new FastPack customers outside the United States.

Under the Technology Transfer Agreement, we have received total net cash payments of approximately $670,000, of which approximately $632,000 was classified as license revenue, and approximately $38,000 is classified as product sales on the statement of operations for the fiscal year ended December 31, 2021. There were no revenues under this agreement for the fiscal year ended December 31, 2022. We will receive low- to mid-single-digit royalties on any future new-generations and current-generations product sales by Yi Xin.

Yi Xin is a newly-formed company and is subject to many risks. There can be no assurance that Yi Xin will successfully commercialize any products or that we will receive any royalties from Yi Xin.

Alpha Convertible Debt

On December 22, 2022, we issued an 8% Senior Convertible Debenture in the aggregate principal amount of $3,300,000 to Alpha for a purchase price of $3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022 (the "Alpha Purchase Agreement"). The Debenture is convertible, at any time, and from time to time, at Alpha's option, into shares of our common stock (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 Company's receipt of the requisite stockholder approvals.

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, we must redeem $110,000 plus accrued but unpaid interest, liquidated damages and any amounts then owing under the Debenture. The Monthly Redemption Amount must be paid in cash; provided that after the first two monthly redemptions, we may elect to pay all or a portion of a Monthly Redemption Amount in shares of our common stock, based on a conversion price equal to the lesser of (i) the then applicable conversion price of the Debenture and (ii) 85% of the average of the VWAPs (as defined in the Debenture) for the five consecutive trading days ending on the trading day that is immediately prior to the applicable Monthly Redemption Date. We may also redeem some or all of the then outstanding principal amount of the Debenture at any time for cash in an amount equal to 105% of the then outstanding principal amount of the Debenture being redeemed plus accrued but unpaid interest, liquidated damages and any amounts then owing under the Debenture. These monthly redemption and optional redemptions are subject to the satisfaction of the Equity Conditions (as defined in the Debenture), which includes a condition that we have obtained stockholder approval for such share issuances.

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

Nanosynex Funding Agreement

As a condition to the NanoSynex acquisition, 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 have agreed to fund NanoSynex up to an aggregate of approximately $10.4 million over the next three years, 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.

We will receive in exchange for any payment made to NanoSynex under the Funding Agreement one or more promissory notes (which may contain convertible features) with a face value equal to the amount paid by the Company to NanoSynex upon satisfaction of the applicable performance milestones. Any promissory notes issued to us by NanoSynex under the Funding Agreement will bear interest at a rate of 9.00% per annum on the principal balance from time to time outstanding under the promissory note. The principal and interest under any promissory note issued to us under the Funding Agreement will be due and payable upon the sooner to occur of: (i) five years from the date of the particular promissory note; (ii) the acquisition by any person or entity of all or substantially all of the share capital of NanoSynex, through share purchase, issuance of shares or merger of NanoSynex or the purchase of all or substantially all of the assets of NanoSynex; or (iii) the initial public offering of NanoSynex. If at any time, our ownership of the share capital of NanoSynex on an issued and outstanding basis falls or is reasonably expected to fall below 50.1%, solely as a result of the exercise of existing or future options (or an equivalent instrument) or as a result of issuance of restricted, shares, restricted stock units (or an equivalent instruments), we, in our sole discretion, may elect to convert all or any portion of the outstanding principal amount of any promissory note into shares of NanoSynex's most senior class of preferred shares existing immediately prior to such conversion, subject to the terms and conditions described in the promissory notes so that, following such conversion, we will regain 50.1% ownership of NanoSynex's issued and outstanding share capital. During the year ended December 31, 2022 a total of approximately $2.4 million was funded and in February 2023 and additional $0.5 million was funded to NanoSynex under the Funding Agreement.

Other Service Agreements

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

Cash Flows

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

	For the Years Ended December 31,	
	2022	**2021**
Net cash (used in) provided by:		
Operating activities	$ (13,247,540)	$ (14,730,742)
Investing activities	(183,763)	(141,364)
Financing activities	2,910,515	8,433,808
Effect of exchange rate on cash	22,639	—
Net decrease in cash and restricted cash	**$ (10,498,149)**	**$ (6,438,298)**

Net Cash Used in Operating Activities

During the year ended December 31, 2022, operating activities used $13.2 million of cash, primarily resulting from a net loss of $21.0 million. Cash flows from operating activities (as opposed to net loss) for the year ended December 31, 2022 were positively impacted by adjustments for $5.4 million in non cash stock-based compensation expense, a $4.2 million non cash goodwill impairment charge related to the acquisition of Nanosynex, $0.1 million in depreciation and amortization, as well as $0.4 million decrease in accounts receivable. Cash flows from operating activities (as opposed to net loss) for the year ended December 31, 2022 were negatively impacted by a $1.0 million gain on change in fair value of warrant liabilities (as described above), a $0.6 million increase in inventory and equipment held for lease, a $0.5 million decrease in R&D grant liability which was offset against NanoSynex R&D expenses, a $0.3 million decrease in deferred tax liability, a $0.1 million increase in prepaid expenses and other assets, and a $0.1 million decrease in accounts payable and accrued expenses.

During the year ended December 31, 2021, operating activities used $14.7 million of cash, primarily resulting from a net loss of $17.9 million. Cash flows from operating activities (as opposed to net loss) for the twelve months ended December 31, 2021 were positively impacted by adjustments for $5.6 million in non cash stock-based compensation expenses, a $1.3 million decrease in prepaid expenses and other assets, a $1.0 million increase in accrued expenses and other current liabilities and a $0.4 million increase in accounts payable, due to higher costs related to therapeutics research and development. The decrease in prepaid expenses reflected in the statements of cash flows from operating activities was primarily due to the expensing during the period of $1.2 million of previous prepayments to STA Pharmaceutical Co., Ltd., a subsidiary of WuXi AppTec, which was our manufacturer of QN-165 drug compounds. Cash flows from operating activities (as opposed to net loss) for the twelve months ended December 31, 2021 were negatively impacted by a $4.7 million gain on change in fair value of warrant liabilities (as described above), and a $0.4 million decrease in deferred revenue primarily resulting from recognition of Yi Xin license revenue.

Net Cash Used in Investing Activities

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.

During the year ended December 31, 2021, net cash used in investing activities was approximately $0.1 million, primarily related to the purchase of property and equipment.

Net Cash Provided by Financing Activities

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.

Net cash provided by financing activities for the year ended December 31, 2021 was approximately $8.4 million, due to $8.8 million of proceeds from sales of equity securities in a registered-direct offering to several institutional investors, and $0.5 million of net proceeds from warrant exercises, offset by $0.7 million in payments for offering costs related to the registered-direct offering and $0.1 million of principal payments on notes payable.

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

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID: 23)	42
Consolidated Balance Sheets	45
Consolidated Statements of Operations and Comprehensive Loss	46
Consolidated Statements of Stockholders' Equity	47
Consolidated Statements of Cash Flows	48
Notes to Consolidated Financial Statements	50

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM (PCAOB ID 23)

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, 2022 and December 31, 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and December 31, 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Intangible Assets – Business Combination

Critical Audit Matter Description

As described in Note 3 of the consolidated financial statements, the Company completed its majority interest acquisition of NanoSynex, Ltd. ("NanoSynex") on May 26, 2022, in a business combination. In connection with this acquisition, the Company recorded an in-process research and development ("IPR&D") intangible asset in the amount of $5.7 million based on the fair value of the IPR&D at the acquisition date. The fair value of this acquired intangible asset was estimated using the excess earnings method which is a form of an income-based approach. The excess earnings valuation model requires certain significant assumptions in estimating fair value of the IPR&D.

We identified the assessment of the fair value of the IPR&D intangible asset as a critical audit matter. This required a high degree of auditor judgment and an increased audit effort in determining the reasonableness of the fair value of the IPR&D due to the measurement uncertainty related to the selection of the valuation methodology and the significant assumptions used in the estimation.

How We Addressed the Matter in Our Audit

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

- Obtaining an understanding of the Company's process and control over the valuation of IPR&D intangible asset including the significant assumptions used in the valuation.
- Testing the clerical accuracy of the valuation model prepared by the Company's specialist.
- Evaluating the reasonableness of the key assumptions by considering past performance and third-party market data where appropriate, and whether such assumptions were consistent with our understanding and evidence obtained in other areas of the audit.
- Involving internal valuation professionals as an auditor's specialist to assist in evaluating the valuation methodology used by management by comparing with methodologies commonly used to value IPR&D intangible assets and to review and opine on significant assumptions utilized in the valuation model.

Goodwill and IPR&D Impairment Assessment

Critical Audit Matter Description

As described in Notes 1 and 7 to the consolidated financial statements, the Company recorded goodwill and indefinite-lived intangible assets in connection with its acquisition of majority ownership of NanoSynex. Goodwill represents the excess of the purchase price over the fair market value of assets acquired and liabilities assumed, and the intangible asset represents the estimated acquisition date fair value of acquired IPR&D. Goodwill and indefinite-lived intangible assets are tested for impairment at least annually, or more frequently if events or changes in circumstances indicate that these assets may be impaired. Goodwill is tested for impairment at the reporting unit level and indefinite-lived intangible assets are tested at the individual asset level. The Company determined that its goodwill was impaired and recorded an impairment loss of approximately $4.2 million.

Management's estimates of the fair value of the reporting unit and of the IPR&D were determined using the discounted cash flow method and excess earnings method, respectively. The determination of fair value using these income approach techniques involves significant assumptions which are highly subjective.

We identified goodwill and IPR&D impairment assessments as a critical audit matter due to the significant judgment and subjectivity exercised by management when developing the fair value measurements, and a high degree of auditor judgment and an increased audit effort required in evaluating management's significant assumptions.

How We Addressed the Matter in Our Audit

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

- Obtaining an understanding and evaluating the design of internal controls related to the impairment of goodwill and IPR&D.
- Evaluating the appropriateness of methods used in developing the fair value measurements by management.
- Testing the completeness and accuracy of underlying data used in management's fair value estimates, including mathematical accuracy.
- Evaluating the reasonableness of the key assumptions by considering past performance and third-party market data where appropriate, and whether such assumptions were consistent with our understanding and evidence obtained in other areas of the audit.

- Involving internal valuation professionals as an auditor's specialist to assist in evaluating the valuation methodologies used by management for the goodwill impairment assessment by comparing the methodologies to those utilized by other companies holding similar assets, and to review and opine on significant assumptions utilized in the valuation model.

Accounting for Financial Instruments – Convertible Debt with Warrants

Critical Audit Matter Description

As described in Notes 11 to the consolidated financial statements, the Company issued a convertible debenture and common stock purchase warrants in the principal amount of $3.3M during the year ended December 31, 2022.

We identified the accounting for 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 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. And 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:

- Obtaining an understanding of the Company's process and controls over the execution of complex financial instruments.

- Inspecting the agreements associated with the transactions and evaluating management's technical accounting analysis, including the identification of potential embedded derivatives, and 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
May 2, 2023

QUALIGEN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash	$ 7,034,434	$ 17,538,272
Accounts receivable, net	538,587	822,351
Inventory, net	1,586,297	1,055,878
Prepaid expenses and other current assets	1,661,220	1,379,896
Total current assets	10,820,538	20,796,397
Restricted cash	5,690	—
Right-of-use assets	1,422,538	1,645,568
Property and equipment, net	345,087	204,217
Intangible assets, net	5,845,702	171,190
Goodwill	625,602	—
Other assets	18,334	18,334
Total Assets	**$ 19,083,491**	**$ 22,835,705**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 857,311	$ 886,224
Accrued vacation	467,948	282,910
Accrued expenses and other current liabilities	1,511,856	1,510,990
R&D grant liability	780,682	—
Deferred revenue, current portion	116,161	135,063
Operating lease liability, current portion	240,645	134,091
Short term debt - related party	950,722	—
Warrant liabilities	788,100	1,686,200
Warrant liabilities - related party	2,834,547	—
Convertible debt - related party	60,197	—
Total current liabilities	8,608,169	4,635,479
Operating lease liability, net of current portion	1,301,919	1,542,564
Deferred revenue, net of current portion	49,056	92,928
Deferred tax liability	357,757	—
Total liabilities	10,316,901	6,270,971
Commitments and Contingencies (Note 13)		
Stockholders' equity		
Qualigen Therapeutics, Inc. stockholders' equity:		
Common stock, $0.001 par value; 225,000,000 shares authorized; 4,210,737 and 3,529,018 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	42,110	35,290
Additional paid-in capital	110,528,050	101,274,073
Accumulated other comprehensive income	50,721	—
Accumulated deficit	(103,385,172)	(84,744,629)
Total Qualigen Therapeutics, Inc. stockholders' equity	7,235,709	16,564,734
Noncontrolling interest	1,530,881	—
Total Stockholders' Equity	8,766,590	16,564,734
Total Liabilities & Stockholders' Equity	**$ 19,083,491**	**$ 22,835,705**

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,	
	2022	**2021**
REVENUES		
Net product sales	$ 4,983,556	$ 5,021,721
License revenue	—	632,004
Total revenues	4,983,556	5,653,725
EXPENSES		
Cost of product sales	4,302,755	4,332,485
General and administrative	10,835,647	11,724,964
Research and development	6,837,133	11,716,718
Sales and marketing	950,420	542,594
Goodwill and fixed asset impairment	4,239,000	—
Total expenses	27,164,955	28,316,761
LOSS FROM OPERATIONS	(22,181,399)	(22,663,036)
OTHER EXPENSE (INCOME), NET		
Gain on change in fair value of warrant liabilities	(907,203)	(4,723,187)
Interest (income) expense, net	26,646	(42,693)
Other income, net	(1,125)	(5,446)
Total other expense (income), net	(881,682)	(4,771,326)
LOSS BEFORE (BENEFIT) PROVISION FOR INCOME TAXES	(21,299,717)	(17,891,710)
(BENEFIT) PROVISION FOR INCOME TAXES	(265,074)	5,427
NET LOSS	(21,034,643)	(17,897,137)
Net loss attributable to noncontrolling interest	(2,394,100)	—
Net loss attributable to Qualigen Therapeutics, Inc.	$ (18,640,543)	$ (17,897,137)
Net loss per common share, basic and diluted	$ (4.85)	$ (6.10)
Weighted—average number of shares outstanding, basic and diluted	3,840,340	2,933,487
Other comprehensive loss, net of tax		
Net loss	$ (21,034,643)	$ (17,897,137)
Foreign currency translation adjustment	50,721	—
Other comprehensive loss	(20,983,922)	(17,897,137)
Comprehensive loss attributable to noncontrolling interest	(2,394,100)	—
Comprehensive loss attributable to Qualigen Therapeutics, Inc.	$ (18,589,822)	$ (17,897,137)

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 Paid-In	Accumulated Other Comprehensive	Accumulated	Total Qualigen Therapeutics, Inc. Stockholders'	Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity	Interest	Equity
Balance at December 31, 2021	3,529,018	$ 35,290	$ 101,274,073	$ —	$ (84,744,629)	$ 16,564,734	$ —	$ 16,564,734
Stock issued upon exercise of warrants	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

	Series Alpha Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2020	18	$ 1	2,729,606	$ 27,296	$ 85,114,755	$ (66,847,492)	$ 18,294,560
Stock issued upon cash-exercise of warrants	—	—	161,830	1,619	2,358,570	—	2,360,189
Stock issued upon net-exercise of warrants	—	—	22,740	227	(227)	—	—
Issuance of common stock for conversion of preferred stock	(18)	(1)	24,342	243	(243)	—	(1)
Fair value of warrants issued for professional services	—	—	—	—	298,651	—	298,651
Shares issued pursuant to Securities Purchase Agreements	—	—	588,000	5,880	8,814,120	—	8,820,000
Commission and offering costs of Securities Purchase Agreements	—	—	—	—	(2,960,465)	—	(2,960,465)
Fair value of warrant modifications pursuant to Securities Purchase Agreements	—	—	—	—	2,253,536	—	2,253,536
Stock issued for professional services	—	—	2,500	25	101,725	—	101,750
Stock-based compensation	—	—	—	—	5,293,651	—	5,293,651
Net Loss	—	—	—	—	—	(17,897,137)	(17,897,137)
Balance at December 31, 2021	—	$ —	3,529,018	$ 35,290	$101,274,073	$ (84,744,629)	$ 16,564,734

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	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (21,034,643)	$ (17,897,137)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	152,573	113,218
Amortization of right-of-use assets	223,030	225,059
Accounts receivable reserves and allowances	(59,982)	(247,845)
Inventory reserves	18,943	(108,138)
Common stock issued for professional services	—	101,750
Fair value of warrants issued for professional services	—	298,651
Stock-based compensation	5,484,044	5,293,651
Fair value of warrant modification for professional services	67,370	—
Goodwill and fixed asset impairment	4,239,000	—
Change in fair value of warrant liabilities	(906,345)	(4,723,187)
Changes in operating assets and liabilities:		
Accounts receivable	417,708	41,250
Inventory and equipment held for lease	(637,410)	111,422
Prepaid expenses and other assets	(99,251)	1,298,998
Accounts payable	(33,397)	385,455
Accrued expenses and other current liabilities	(76,266)	1,047,163
R&D grant liability	(534,426)	—
Operating lease liability	(134,091)	(254,740)
Deferred revenue	(62,775)	(416,312)
Deferred tax liability	(271,622)	—
Net cash used in operating activities	(13,247,540)	(14,730,742)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(164,684)	(134,471)
Purchases of equipment held for lease	(154,433)	—
Payments for patents and licenses	—	(6,893)
Net cash acquired in business combination	135,354	—
Net cash used in investing activities	(183,763)	(141,364)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from warrant exercises	7,173	459,476
Proceeds from issuance of shares and warrants pursuant to Securities Purchase Agreements	—	8,820,000
Proceeds from issuance of convertible debt - related party	2,903,847	—
Offering costs of Securities Purchase Agreements	—	(706,929)
Principal payments on notes payable	—	(138,739)
Fractional share payments related to the reverse stock split	(505)	—
Net cash provided by financing activities	2,910,515	8,433,808
Net change in cash and restricted cash	(10,520,787)	(6,438,298)
Effect of exchange rate changes on cash and restricted cash	22,639	—
Cash and restricted cash - beginning of period	17,538,272	23,976,570
Cash and restricted cash - end of period	$ 7,040,123	$ 17,538,272
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid during the year for:		
Interest	$ —	$ 1,233
Taxes	$ 5,571	$ 5,133

NONCASH FINANCING AND INVESTING ACTIVITIES:				
Issuance of common stock for conversion of preferred stock after closing of reverse recapitalization	$	—	$	243
Right-of-use assets obtained in exchange for operating lease liabilities	$	—	$	1,439,830
Fair value of shares issued for cashless warrant exercises	$	—	$	764,657
Net transfers to inventory from equipment held for lease	$	—	$	1,304
Fair value of warrant modifications pursuant to Securities Purchase Agreements	$	9,439	$	2,253,536
Fair value of warrant liabilities on date of exercise	$	858	$	1,900,713
Fair value of warrant modifications for business acquisition	$	33,543	$	—
ACQUISITION:				
Fair value of assets acquired	$	(5,896,278)		—
Fair value of liabilities assumed, net of goodwill		2,321,845		—
Fair value of Alpha Capital/Qualigen warrants repriced due to acquisition		696		—
Fair value of Qualigen prefunded warrant issued in exchange for NanoSynex stock		1,804,102		—
Fair value of Qualigen common stock issued in exchange for NanoSynex stock		1,904,989		—
Net cash acquired in business combination (Note 3)	$	135,354	$	—

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

Qualigen, Inc., now a subsidiary of Qualigen Therapeutics, Inc., was incorporated in Minnesota in 1996 to design, develop, manufacture and sell Physician Office Laboratory ("POL") market quantitative immunoassay diagnostic products for use in physician offices and other point-of-care settings worldwide, and was reincorporated in Delaware in 1999. In May 2020, Qualigen, Inc. completed a reverse recapitalization transaction with Ritter Pharmaceuticals, Inc. ("Ritter") and Ritter was renamed Qualigen Therapeutics, Inc. All shares of Qualigen, Inc.'s capital stock were exchanged for Qualigen Therapeutics, Inc.'s capital stock in the merger. Ritter/Qualigen Therapeutics common stock, which was previously traded on the Nasdaq Capital Market under the ticker symbol "RTTR," commenced trading on the Nasdaq Capital Market, on a post-reverse-stock-split adjusted basis, under the trading symbol "QLGN" on May 26, 2020. Qualigen Therapeutics, Inc. (the "Company") operates in one business segment.

.

On May 26, 2022, the Company acquired 2,232,861 shares of Series A-1 Preferred Stock of NanoSynex, Ltd. ("NanoSynex") from Alpha Capital Anstalt ("Alpha Capital"), a related party, in exchange for 350,000 reverse split adjusted shares of the Company's common stock and a prefunded warrant to purchase 331,464 reverse split adjusted shares of the Company's common stock at an exercise price of $0.001 per share. These warrants were subsequently exercised on September 13, 2022. Concurrently with this transaction, the Company also purchased 381,786 shares of Series B preferred stock from NanoSynex for a total purchase price of $600,000. The transactions resulted in the Company acquiring a 52.8% interest in NanoSynex. The Company envisions future synergies from the integration of its own proprietary results-proven FastPack diagnostics platform with the innovative NanoSynex technology. NanoSynex is a micro-biologics diagnostics company domiciled in Israel.

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 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, however for NanoSynex, the functional currency is the local currency, New Israeli Shekels (NIS). As such, assets and liabilities for NanoSynex are translated into U.S. dollars and the effects of foreign currency translation adjustments are reflected as a component of accumulated other comprehensive income within the Company's consolidated statements of changes in stockholders' equity.

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, stock-based compensation, amortization and depreciation, inventory reserves, allowances for doubtful accounts and returns, and warranty costs. Actual results could vary from the estimates that were used.

Reverse Stock Split

On November 23, 2022, the Company effected a 1-for-10, as determined by the Company's board of directors, 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 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 payments were made 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. Restricted cash includes cash that is restricted due to Israeli banking regulations.

The Company maintains the majority of its cash in accounts at banking institutions in the U.S. that are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, the Company could lose all or a portion of amounts held in excess of such insurance limitations. The FDIC recently took control of two such banking institutions, Silicon Valley Bank on March 10, 2023 and Signature Bank on March 12, 2023. While the Company did not have an account at either of these two banks, in the event of failure of any of the financial institutions where the Company maintains its cash and cash equivalents, there can be no assurance that the Company would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Inventory, Net

Inventory is recorded at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. The Company reviews the components of its inventory on a periodic basis for excess or obsolete inventory, and records reserves for inventory components identified as excess or obsolete.

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 fiscal year ending December 31, 2022 the Company recorded an impairment loss of $4,239,000 related to the NanoSynex acquisition.

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 Israel.

Accounts Receivable, Net

The Company grants credit to domestic physicians, clinics, and distributors. The Company performs ongoing credit evaluations of its customers and generally requires no collateral. Customers can purchase certain products through a financing agreement that the Company has with an outside leasing company. Under the agreement, the leasing company evaluates the credit worthiness of the customer. Upon acceptance of the product by the customer, the leasing company remits payment to the Company at a discount. This financing arrangement is without recourse to the Company.

The Company records an allowance for doubtful accounts and returns equal to the estimated uncollectible amounts or expected returns. The Company's estimates are based on historical collections and returns and a review of the current status of trade accounts receivable.

Accounts receivable is comprised of the following at:

	December 31, 2022	December 31, 2021
Accounts Receivable	$ 726,449	$ 958,448
Less Reserves and Allowances	(187,862)	(136,097)
	$ 538,587	$ 822,351

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.

R&D Grants

NanoSynex has received R&D grants from Israel Innovation Authority (IIA) and from the European Commission. These grants may provide cash funding to NanoSynex from time to time in advance of the applicable costs being incurred. When such cash funding is received from these grants in advance, the proceeds are recorded as a current or non-current R&D grant liability based on the time from the consolidated balance sheets date to the expected future date of recognition as a reduction to research and development expenses.

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.

Shipping and Handling Costs

The Company includes shipping and handling fees billed to customers in net sales. Shipping and handling costs associated with inbound and outbound freight are generally recorded in cost of sales; such shipping and handling costs totaled approximately $267,000 and $113,000, respectively, for the years December 31, 2022 and 2021. Other shipping and handling costs included in general and administrative, research and development, and sales and marketing expenses totaled approximately $14,000 and $12,000 for the years ended December 31, 2022 and 2021, respectively.

Revenue from Contracts with Customers

The Company applies the following five-step model in accordance with ASC 606, Revenue from Contracts with Customers, in order to determine revenue: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Product Sales

The Company generates revenue from selling FastPack System analyzers, accessories and disposable products used with the FastPack System. Disposable products include reagent packs, which are diagnostic tests for prostate-specific antigen, testosterone, thyroid disorders, pregnancy, and Vitamin D.

The Company provides disposable products and equipment in exchange for consideration, which occurs when a customer submits a purchase order and the Company provides disposable products and equipment at the agreed upon prices in the invoice. Generally, customers purchase disposable products using separate purchase orders after the equipment ("analyzer") has been provided to the customer. The initial delivery of the equipment and reagent packs represents a single performance obligation and is completed upon receipt by the customer. The delivery of each subsequent individual reagent pack represents a separate performance obligation because the reagent packs are standardized, are not interrelated in any way, and the customer can benefit from each reagent pack without any other product. There are no significant discounts, rebates, returns or other forms of variable consideration. Customers are generally required to pay within 30 days.

The performance obligation arising from the delivery of the equipment is satisfied upon the delivery of the equipment to the customer. The disposable products are shipped Free on Board ("FOB") shipping point. For disposable products that are shipped FOB shipping point, the customer has the significant risks and rewards of ownership and legal title to the assets when the disposable products leave the Company's shipping facilities, thus the customer obtains control and revenue is recognized at that point in time.

The Company has elected the practical expedient and accounting policy election to account for the shipping and handling as activities to fulfill the promise to transfer the disposable products and not as a separate performance obligation.

The Company's contracts with customers generally have an expected duration of one year or less, and therefore the Company has elected the practical expedient in ASC 606 to not disclose information about its remaining performance obligations. Any incremental costs to obtain contracts are recorded as selling, general and administrative expense as incurred due to the short duration of the Company's contracts.

License Revenue

The Company entered into an out-license agreement with Yi Xin to develop and/or commercialize its products in exchange for nonrefundable upfront license fees and/or sales-based royalties.

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from nonrefundable upfront fees allocated to the license when the license is transferred to the customer and the customer can benefit from the license. For licenses that are bundled with other performance obligations, management uses judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition. During years ended December 31, 2022 and 2021, the Company recognized license revenue of approximately $0 and $632,000, respectively.

Contract Asset and Liability Balances

The timing of the Company's revenue recognition may differ from the timing of payment by the Company's customers. The Company records a receivable when revenue is recognized prior to payment and there is an unconditional right to payment. Alternatively, when payment precedes the performance of the related services, the Company records deferred revenue until the performance obligations are satisfied.

Multiple performance obligations include contracts that combine both the Company's analyzer and a customer's future reagent purchases under a single contract. In some sales contracts, the Company provides analyzers at no charge to customers. Title to the analyzer is maintained by the Company and the analyzer is returned by the customer to the Company at the end of the purchase agreement.

During the years December 31, 2022 and 2021, product sales are stated net of an allowance for estimated returns of approximately $96,000 and $150,000, respectively.

Deferred Revenue

Payments received in advance from customers pursuant to certain collaborative research license agreements, deposits against future product sales, multiple element arrangements and extended warranties are recorded as a current or non-current deferred revenue liability based on the time from the Consolidated Balance Sheet date to the future date of revenue recognition.

Operating Leases

Effective April 1, 2020, the Company adopted Accounting Standards Update ("ASU") No. 2018-11, *Leases (Topic 842) Targeted Improvements* ("Topic 842"). In accordance with the guidance in Topic 842, the Company recognizes lease liabilities and corresponding right-of-use-assets for all leases with terms of greater than 12 months. Leases with a term of 12 months or less will be accounted for in a manner similar to the guidance for operating leases prior to the adoption of Topic 842. (See Note 13-Commitments and Contingencies).

Property and Equipment, Net

Property and equipment are stated at cost and are presented net of accumulated depreciation. Depreciation is provided for on a straight-line basis over the estimated useful lives of the related assets as follows:

Machinery and equipment	5 years
Computer equipment	3 years
Molds and tooling	5 years
Furniture and fixtures	5 years

Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or their estimated useful lives. The Company occasionally designs and builds its own machinery. The costs of these projects, which includes the cost of construction and other direct costs attributable to the construction, are capitalized as construction in progress. No provision for depreciation is made on construction in progress until the relevant assets are completed and placed in service.

The Company's policy is to evaluate the remaining lives and recoverability of long-term assets on at least an annual basis or when conditions are present that indicate impairment.

Business Combinations

The Company accounts for business combinations using the acquisition method pursuant to FASB ASC Topic 805. This method requires, among other things, that results of operations of acquired companies are included in Qualigen's financial results beginning on the respective acquisition dates, and that assets acquired and liabilities assumed and noncontrolling interests 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. We have third-party valuations completed for intangible assets in a business combination using a discounted cash flow analysis, incorporating various assumptions. 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. For more information, refer to Note 1 - Organization and Summary of Significant Accounting Policies and Estimates and Note 7 - Goodwill, IPR&D and other Intangibles.

Intangible Assets

In Process R&D

Acquired in process R&D (IPR&D) represents the fair value assigned to the research and development assets that have not reached technological feasibility. The value assigned to IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flow to present value. The revenue and cost projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success of developing the new product. Additionally, projections consider relevant market sizes and growth factors, expected trends in technology and the nature and expected timing of new product introductions. The rates utilized to discount the net cash flow to its present value are commensurate with the stage of development of the project and uncertainties in the economic estimates used in the projections. Upon the acquisition of acquired IPR&D, an assessment is completed as to whether the acquisition constitutes an acquisition of a single asset or a group of assets. Multiple factors are considered in this assessment, including the nature of the technology acquired, the presence or absence of separate cash flows, the development process and stage of completion, quantitative significance, and the Company's rationale for entering into the transaction.

If a business is acquired, as defined under the applicable accounting standards, then the acquired IPR&D is capitalized as an intangible asset. If an asset or group of assets is acquired that do not meet the definition under the applicable accounting standards, then the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense in the Company's consolidated statements of operations and comprehensive loss as they are incurred.

IPR&D is evaluated for impairment annually using the same methodology as described above for calculating fair value. If the carrying value of the acquired IPR&D exceeds the fair value, then the intangible asset is written down to its fair value, with the resulting adjustment recorded as a charge to operations. Changes in estimates and assumptions used in determining the fair value of acquired IPR&D could result in an impairment.

Other Intangible Assets, Net

Other intangible assets consist of patent-related costs and costs for license agreements. Management reviews the carrying value of other intangible assets that are being amortized on an annual basis or sooner when there is evidence that events or changes in circumstances may indicate that impairment exists. The Company considers relevant cash flow and profitability information, including estimated future operating results, trends and other available information, in assessing whether the carrying value of intangible assets being amortized can be recovered.

If the Company determines that the carrying value of other intangible assets will not be recovered from the undiscounted future cash flows expected to result from the use and eventual disposition of the underlying assets, the Company considers the carrying value of such intangible assets as impaired and reduces them by a charge to operations in the amount of the impairment.

Costs related to acquiring patents and licenses are capitalized and amortized over their estimated useful lives, which is generally 5 to 17 years, using the straight-line method. Amortization of patents and licenses commences once final approval of the patent or license has been obtained. Patent and license costs are charged to operations if it is determined that the patent or license will not be obtained.

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 10-Warrant Liabilities and Note 11- 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.

Advertising

Advertising expense consists primarily of print and digital media promotional materials for a distributor. Advertising costs are expensed as incurred. Advertising expense for the years ended December 31, 2022 and 2021 amounted to $50,000 and $0, respectively.

Comprehensive Loss

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

Stock-Based Compensation

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

Income Taxes

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

Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment. Realization of the deferred income tax asset is dependent on generating sufficient taxable income in future years. For more information, refer to Note 17-Income Taxes.

Sales and Excise Taxes

Sales and other taxes collected from customers and subsequently remitted to government authorities are recorded as accounts receivable with corresponding tax payable. These balances are removed from the consolidated balance sheet as cash is collected from customers and remitted to the tax authority.

Warranty Costs

The Company's warranty policy generally provides for one year of coverage against defects and nonperformance within published specifications for sold analyzers and for the term of the contract for equipment held for lease. The Company accrues for estimated warranty costs in the period in which the revenue is recognized based on historical data and the Company's best estimates of analyzer failure rates and costs to repair.

Accrued warranty liabilities were approximately $138,000 and $60,000, respectively, at December 31, 2022 and December 31, 2021 and are included in accrued expenses and other current liabilities on the Consolidated Balance Sheets. Warranty costs were approximately $69,000 and $57,000 for the years ended December 31, 2022 and 2021, respectively, and are included in cost of product sales in the Consolidated Statements of Operations.

Foreign Currency Translation

The functional currency for the Company is the U.S. dollar. The functional currency for NanoSynex, the Company's newly acquired majority owned subsidiary, is the New Israeli Shekel (NIS). The financial statements of NanoSynex are 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 is reflected as a separate component of other comprehensive income (loss).

Other comprehensive loss related to the effects of foreign currency translation adjustments attributable to NanoSynex was $50,721 and $0 at December 31, 2022 and 2021, respectively.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments*, which supersedes current guidance by requiring recognition of credit losses when it is probable that a loss has been incurred. The new standard requires the establishment of an allowance for estimated credit losses on financial assets including trade and other receivables at each reporting date. The new standard will result in earlier recognition of allowances for losses on trade and other receivables and other contractual rights to receive cash. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815)* and *Leases (Topic 842)*, which extended the effective date of Topic 326 for certain companies until fiscal years beginning after December 15, 2022. The new standard will be effective for the Company in the first quarter of fiscal year beginning January 1, 2023, and early adoption is permitted. The Company adopted ASU 2016-13 on January 1, 2023. Adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

Global Economic Conditions

War in Ukraine

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.

Inflationary Cost Environment

During the year ended 2022 and continuing into the current fiscal year, global commodity and labor markets experienced significant inflationary pressures attributable to ongoing economic recovery and supply chain issues. The Company is subject to inflationary pressures with respect to raw materials, labor and transportation. Accordingly, the Company continues to take actions with its customers and suppliers to mitigate the impact of these inflationary pressures in the future. Actions to mitigate inflationary pressures with suppliers include aggregation of purchase requirements to achieve optimal volume benefits, negotiation of cost-reductions and identification of more cost competitive suppliers. While these actions are designed to offset the impact of inflationary pressures, the Company cannot provide assurance that it will be successful in fully offsetting increased costs resulting from inflationary pressure.

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. Sales of diagnostic products fell significantly during 2020 and the Company's net loss increased significantly, as deferral of patients' non-emergency visits to physician offices, clinics and small hospitals sharply reduced demand for FastPack tests. Since then we have experienced some recovery in demand.

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, 2022, the Company had approximately $7.0 million in cash and an accumulated deficit of $103.4 million. For the years ended December 31, 2022 and 2021, the Company used cash of $13.2 million and $14.7 million, respectively, in operations. The Company's cash balances are expected to fund operations into the third quarter of 2023. As a pre-clinical development-stage therapeutics biotechnology company, the Company expects to continue to have net losses and negative cash flow from operations, which over time will challenge its liquidity. These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period following the date that these financial statements were issued.

There is no assurance that profitable operations will ever be achieved, or, if achieved, could be sustained on a continuing basis. In order to fully execute its business plan, the Company will require significant additional financing for planned research and development activities, capital expenditures, clinical and pre-clinical testing for its QN-302 clinical trials, preclinical development of RAS and QN-247, and funding for NanoSynex operations (See Note 3-Acquisition), as well as commercialization activities.

Historically, the Company's principal sources of cash have included proceeds from the issuance of common and preferred equity and proceeds from the issuance of debt. In December 2021, the Company raised $8.8 million from the issuance of common stock to several institutional investors, and in December 2022 the Company raised $3.0 million from the sale of a convertible debt - related party (see Note 11-Convertible Debt - Related Party).

There can be no assurance that further financing can be obtained on favorable terms, or at all. If we are unable to obtain funding, we could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect our business prospects.

As a condition to the NanoSynex closing, the Company agreed to provide NanoSynex with up to $10.4 million of future funding based on NanoSynex's achievement of certain future development milestones and subject to other terms and conditions described in the Master Agreement for the Operational and Technological Funding of NanoSynex (the "Funding Agreement") entered into with NanoSynex. These funding commitments are in the form of convertible promissory notes to be issued to the Company with a face value equal to the amount paid by the Company to NanoSynex upon satisfaction of the applicable performance milestone, bearing interest at the rate of 9% per annum on the principal balance from time to time outstanding under the particular promissory note, convertible at the option of the Company into additional shares of NanoSynex in order for the Company to maintain at least a 50.1% controlling ownership interest in NanoSynex, should NanoSynex issue additional shares. The principal of the convertible notes are due and payable upon the sooner to occur of: i) five years from the date of issuance of the particular promissory note; ii) the acquisition by any person or entity of all or substantially all of the share capital of NanoSynex, through share purchase, issuance or shares or merger of NanoSynex, or the purchase of all or substantially all of the assets of NanoSynex; or iii) the initial public offering of NanoSynex. The Company provided funding to NanoSynex of $2.4 million during 2022 pursuant to this agreement. The Company may terminate the Funding Agreement upon 120 days' notice, but would still be liable for any payments due for milestones achieved prior to termination.

To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interests of its common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises additional funds through government or other third-party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company. Additional funding may not be available to the Company on acceptable terms, or at all. In addition, any future financing (depending on the terms and conditions) may be subject to the approval of Alpha Capital, the holder of the Company's 8% Senior Convertible Debenture (the "Debenture"), or trigger certain adjustments to the Debenture or warrants held by Alpha Capital.

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

NOTE 3 — ACQUISITION

Business Combination

The Company acquired a 52.8% voting equity interest in NanoSynex on May 26, 2022 (the "NanoSynex Acquisition Date") through: (1) the purchase of 2,232,861 shares Preferred A-1 Stock of NanoSynex from Alpha Capital (a related party) 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 a purchase price of $0.001 per share (these warrants were subsequently exercised on September 13, 2022), and (2) the purchase of 381,786 shares of Series B preferred stock of NanoSynex from NanoSynex in exchange for $600,000 (collectively, the "NanoSynex Acquisition").

The acquisition of the majority interest of NanoSynex was accounted for as a business combination using the acquisition method, in accordance with FASB ASC Topic 805. Identifiable assets acquired, liabilities assumed and any noncontrolling interest in the acquiree are recognized and measured as of the acquisition date at fair value. Determining the fair value of assets acquired, liabilities assumed and noncontrolling interest requires management's judgment and often involves the use of significant estimates and assumptions, including assumptions with respect to future cash flows, discount rates and asset lives among other items. The Company uses third-party valuations for intangible assets in a business combination using a discounted cash flow analysis, incorporating various assumptions.

A summary of the consideration transferred and fair value of assets acquired and liabilities assumed in the NanoSynex Acquisition is as follows (all shares shown post 1 for 10 reverse split on November 23, 2022):

Consideration transferred, net of cash acquired		
Cash paid for NanoSynex preferred stock:	$	600,000
FMV of 350,000 shares of Qualigen stock issued to Alpha Capital Anstalt	$	1,904,989
FMV of 331,464 shares of Qualigen stock related to prefunded warrant issued to Alpha Capital Anstalt (See Note 15)	$	1,804,102
Total consideration paid for NanoSynex preferred stock	$	3,709,091
FMV of consideration related to related to repricing of 7,048 shares of Alpha Capital/Qualigen warrants *	$	696
NanoSynex cash acquired		**(735,354)**
Total consideration transferred, net of cash acquired	**$**	**3,574,433**

*See disclosure under *Noncompensatory Equity Classified Warrants* regarding May 26, 2022 transaction-Note 15-Stockholders' Equity

	Purchase Price Allocation
Accounts receivable	$ 75,336
Property and equipment	120,942
In process R&D	5,700,000
Accounts payable	(4,588)
Accrued expenses and other payables	(291,093)
R&D grant liability	(1,362,264)
Short term debt	(941,898)
Deferred tax liability	(629,379)
Noncontrolling interest assumed	(3,882,225)
Identifiable net assets acquired	(1,215,169)
Goodwill	4,789,602
Total consideration transferred, net of cash acquired	**$ 3,574,433**

During the year ended December 31, 2022, the Company made measurement period adjustments to the preliminary purchase price allocation which included: (i) a decrease to noncontrolling interest of $117,775, (ii) a decrease to goodwill of $106,621. The measurement period adjustments were made to reflect facts and circumstances that existed as of the acquisition date and is reflected in the table above.

Company transaction costs, which were immaterial, have been expensed as incurred and charged to the Company's consolidated statements of operations and comprehensive loss. There was no provision for reimbursement of transaction costs from the Company to NanoSynex.

Goodwill represents the excess of the purchase price over the fair value of the net assets acquired as of the acquisition date. Goodwill represents the value of the future technology to be developed in excess of the identifiable assets as well as the operational synergies of the combined companies to be recognized. Goodwill has an indefinite useful life and is not amortized. None of the Goodwill is expected to be deductible for tax purposes.

As a condition to the closing, the Company agreed to provide NanoSynex with up to $10.4 million of future funding based on NanoSynex's achievement of certain future development milestones and subject to other terms and conditions described in the Funding Agreement entered into with NanoSynex. (See Note 2-Liquidity for further details regarding the terms and conditions of the Funding Agreement).

The Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021 include approximately $5.1 million and $0, respectively, of net loss associated with the results of operations of NanoSynex from the NanoSynex Acquisition Date.

The following proforma information has been prepared as if the NanoSynex Acquisition occurred on January 1, 2021. The following unaudited supplemental proforma consolidated results do not purport to reflect what the combined Company's results of operations would have been, nor do they project the future results of operations of the combined Company. The unaudited supplemental proforma consolidated results reflect the historical financial information of the Company and NanoSynex, adjusted to give effect to the NanoSynex Acquisition as if it had occurred on January 1, 2021, as well as to record NanoSynex stock compensation expense and to record the net loss related to the non-controlling interest, in accordance with generally accepted accounting principles:

	Consolidated Pro Forma Financial Results for the Years Ending December 31,	
	2022	**2021**
Net revenue	$ 4,983,556	$ 5,653,725
Net loss attributable to Qualigen Therapeutics, Inc.	$ (19,538,959)	$ (17,897,137)

NOTE 4 — INVENTORY, NET

Inventory, net consisted of the following at December 31, 2022 and December 31, 2021:

	December 31, 2022	**December 31, 2021**
Raw materials	$ 949,796	$ 823,315
Work in process	200,318	188,135
Finished goods	436,183	44,428
	$ 1,586,297	$ 1,055,878

NOTE 5 — PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following at December 31, 2022 and December 31, 2021:

	December 31, 2022	**December 31, 2021**
Prepaid insurance	$ 1,377,323	$ 1,197,726
Prepaid manufacturing expenses	43,820	67,410
Other prepaid expenses	227,451	111,183
Other current assets	12,626	3,577
	$ 1,661,220	$ 1,379,896

NOTE 6 — PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following at December 31, 2022 and December 31, 2021:

	December 31, 2022	**December 31, 2021**
Machinery and equipment	$ 2,510,148	$ 2,482,841
Computer equipment	395,836	345,117
Leasehold improvements	333,271	333,271
Molds and tooling	260,002	260,002
Furniture and fixtures	144,832	143,013
Equipment held for lease	1,399,444	1,181,211
	5,043,533	4,745,455
Accumulated depreciation	(4,623,446)	(4,541,238)
Fixed asset impairment	(75,000)	—
	$ 345,087	$ 204,217

Depreciation expense relating to property and equipment was approximately $92,000 and $73,000 for the years ended December 31, 2022 and 2021, respectively.

Upon termination of the Sekisui Distribution Agreement on March 31, 2022, the Company had a commitment to purchase leased FastPack rental systems back from Sekisui at Sekisui's net book value, which was determined to be approximately $154,000. This amount is included in equipment held for lease in the table above and in accrued expenses at December 31, 2022. An assignment agreement is to be executed by both parties to legally transfer title to this equipment from Sekisui to Qualigen.

NOTE 7 — GOODWILL, IPR&D AND OTHER INTANGIBLES

	Estimated Useful Lives	December 31, 2022 Gross carrying amounts	December 31, 2021 Gross carrying amounts
Goodwill		$ 625,602	$ —
Finite-lived intangible assets:			
Developed-product-technology rights	8 - 17 years	$ 479,103	$ 479,103
Licensing rights	10 years	418,836	418,836
Less: Accumulated amortization		(752,237)	(726,749)
Total finite-lived intangible assets, net		145,702	171,190
Indefinite-lived intangible assets:			
In-process research and development		5,700,000	—
Total other intangible assets, net		$ 5,845,702	$ 171,190

The Company periodically reviews goodwill for impairment in accordance with relevant accounting standards. Goodwill is attributable to the NanoSynex Acquisition. Goodwill and intangible assets are recognized at fair value during the period in which an acquisition is completed, from updated estimates during the measurement period, or when they are considered to be impaired. These non-recurring fair value measurements, primarily for goodwill and intangible assets acquired, were based on Level 3 inputs. The Company estimates the fair value of long-lived assets on a non-recurring basis based on a market valuation approach, engaging independent valuation experts to assist in the determination of fair value. In the fourth quarter of fiscal 2022, in conjunction with the annual impairment assessment, the Company determined that the fair value of the reporting unit was less than the carrying value. In addition to continued losses in the reporting unit, the Company considered macroeconomic conditions including a deterioration in the equity markets evidenced by sustained declines in the Company's stock price, peer companies, and major market indices since the acquisition date. The Company engaged independent valuation experts to assist in determining the fair value of the reporting unit. As a result of this analysis, the Company recorded a $4,239,000 goodwill and fixed asset impairment charge associated with the reporting unit. There were no impairments to intangible assets and goodwill during the year ended December 31, 2021.

The carrying value of the patents of approximately $140,000 and $159,000 at December 31, 2022 and December 31, 2021, respectively, are stated net of accumulated amortization of approximately $339,000 and $320,000, respectively. Amortization of patents charged to operations for the year ended December 31, 2022 and December 31, 2021 were approximately $18,000 and $17,000, respectively. Total future estimated amortization of patent costs for the five succeeding years is approximately $18,000 for the year ending December 31, 2023, approximately $15,000 for the year ending December 31, 2024, approximately $14,000 for years 2025, 2026 and 2027, and approximately $65,000 thereafter.

The carrying value of the licenses of approximately $5,000 and $12,000 at December 31, 2022 and December 31, 2021 are stated net of accumulated amortization of approximately $414,000 and $407,000, respectively. Amortization of licenses charged to operations for the year ended December 31, 2022 and December 31, 2021 was approximately $7,000 and $7,000, respectively. Total future estimated amortization of license costs for the five succeeding years is approximately $5,000 for the year ending December 31, 2023.

NOTE 8 — ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following at December 31, 2022 and December 31, 2021:

	December 31, 2022	December 31, 2021
Board compensation	$ 70,000	$ 17,500
Equipment held for lease	154,433	—
Franchise, sales and use taxes	27,531	14,090
Income taxes	4,663	3,620
Interest (Convertible debt - related party)	2,829	—
Payroll	209,303	682,036
Professional fees	238,211	225,308
Research and development	322,987	232,712
Royalties	13,158	10,152
Warranty liability	137,568	60,281
License fees	150,130	—
Other	181,043	265,292
	$ 1,511,856	$ 1,510,990

NOTE 9 – SHORT TERM DEBT - RELATED PARTY

NanoSynex has four separate Notes Payable (the "Notes") outstanding to Alpha Capital, dated between March 26, 2020 and September 2, 2021, aggregating to a total principal outstanding balance of $905,000, and aggregate accrued interest of $45,722 for a total outstanding balance of $950,722 as of December 31, 2022. The Notes all accrue interest at 2.62% per annum, accrued daily, and provide that the full amount of principal and interest under each Note shall be due immediately prior to a Liquidation Event (the Maturity Date) unless due earlier in accordance with the terms of the Notes. "Liquidation Event" means either i) the merger or consolidation of NanoSynex into any other entity, other than one in control or under control of NanoSynex or NanoSynex's majority shareholder; ii) a transaction or series of transactions resulting in the transfer of all or substantially all of NanoSynex's assets or issued and outstanding share capital (other than to a company under the control of NanoSynex or NanoSynex's majority shareholders; or iii) an underwritten public offering by NanoSynex of its ordinary shares. Notwithstanding the above, if NanoSynex receives subsequent debt, convertible debt, or equity funding with gross proceeds of USD $3,000,000 or more, then these Notes shall be due and payable upon the actual receipt of such funding.

NOTE 10 – 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, pursuant to the Series C Warrant terms as adjusted.

In exchange for the Series C Warrants, upon closing of the merger with Ritter, the holders received warrants to purchase shares of the Company's common stock at $7.195 per share, subject to adjustment. As of December 31, 2022, the warrants have remaining terms ranging from 0.90 to 1.49 years. The warrants were determined to be liability-classified pursuant to the guidance in ASC 480 and ASC 815-40, resulting from inclusion of a leveraged ratchet provision for subsequent dilutive issuances. On April 25, 2022 the warrants were repriced from $7.195 to $6.00 with an additional 49,318 ratchet shares issued, and on May 26 2022 the warrants were repriced from $6.00 to $5.136 with an additional 49,952 ratchet shares issued. On December 22, 2022 the warrants were repriced again from $5.136 to $1.32 with an additional 1,002,717 ratchet shares issued.

Additionally, on December 22, 2022, in conjunction with the issuance of Convertible Debt - Related Party (Note 11), the Company issued to Alpha Capital a warrant to purchase 2,500,000 shares of the Company's common stock. The exercise price of the warrant is $1.65 (equal to 125% of the conversion price of the Debenture on the closing date). The warrant may be exercised by Alpha, in whole or in part, at any time on or after June 22, 2023 and before June 22, 2028, subject to certain terms conditions described in the warrant, including the Company's receipt of the necessary stockholder approvals.

The following table summarizes the activity in liability classified 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 summarizes the activity in the Common Stock Warrants received in exchange for the Series C Warrants for the year ended December 31, 2021:

	Common Stock Warrants			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding –December 31, 2020	337,860	$ 7.20		
Exercised	(80,731)	7.20		
Forfeited	(8,967)	7.20		
Expired	—	—		
Granted	—	—		
Total outstanding – December 31, 2021	248,162	$ 7.20		
Exercisable	248,162	$ 7.20	$ 7.20	2.00

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, 2022:

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, 2021	$ —	$ —	**$ 1,686,200**	**$ 1,686,200**
Exercises	—	—	**(858)**	**(858)**
Issuance of Alpha warrants	**—**	**—**	**2,834,547**	**2,834,547**
Gain on change in fair value of warrant liabilities	**—**	**—**	**(897,242)**	**(897,242)**
Balance as of December 31, 2022	**$ —**	**$ —**	**$ 3,622,647**	**$ 3,622,647**

The following table presents the Company's fair value hierarchy for its Common Stock Warrant liabilities (all of which arose under the warrants received in exchange for the Series C Warrants) measured at fair value on a recurring basis as of December 31, 2021:

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, 2020	$ —	$ —	**$ 8,310,100**	**$ 8,310,100**
Exercises	—	—	**(1,900,713)**	**(1,900,713)**
Gain on change in fair value of warrant liabilities	**—**	**—**	**(4,723,187)**	**(4,723,187)**
Balance as of December 31, 2021	**$ —**	**$ —**	**$ 1,686,200**	**$ 1,686,200**

There were no transfers of financial assets or liabilities between category levels for the year ended December 31, 2022.

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

The following are the weighted average and the range of assumptions used in estimating the fair value of warrant liabilities (weighted average calculated based on the number of outstanding warrants on each issuance) as of December 31, 2022 and December 31, 2021:

	December 31, 2022		December 31, 2021	
	Range	Weighted Average	Range	Weighted Average
Risk-free interest rate	3.906% — 4.628 %	4.15%	0.69% — 0.84%	0.72%
Expected volatility (peer group)	88% — 103%	98%	84% — 87%	85%
Term of warrants (in years)	.90 — 5.48	3.9	1.90 — 2.50	2.01
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

The value of the warrant liabilities is based on a valuation received from an independent valuation firm determined using a Monte-Carlo simulation.

NOTE 11 — CONVERTIBLE DEBT - RELATED PARTY

On December 22, 2022, the Company issued to Alpha Capital, an 8% Senior Convertible Debenture in the aggregate principal amount of $3,300,000 for a purchase price of $3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022 (the "Alpha Purchase Agreement"). The Debenture is convertible, at any time, and from time to time, 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 Company's receipt of the requisite stockholder approvals. Additionally, on December 22, 2022, the Company issued to Alpha Capital a liability classified warrant to purchase 2,500,000 shares of the Company's common stock (see Note 10-Warrant Liabilities). The exercise price of the warrant is $1.65 (equal to 125% of the conversion price of the Debenture on the closing date). The warrant may be exercised by Alpha Capital, in whole or in part, at any time on or after June 22, 2023 and before June 22, 2028, subject to certain terms conditions described in the warrant, including the Company's receipt of the necessary stockholder approvals.

The proceeds from the transaction will be dedicated to the Company's efforts of advancing its 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 will 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 will 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. These monthly redemption and optional redemptions are subject to the satisfaction of the Equity Conditions (as defined in the Debenture), which includes a condition that we have obtained stockholder approval for such share issuances.

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

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

The Company filed a registration statement on Form S-3 (No. 333-269088) with the Securities and Exchange Commission on December 30, 2022 registering the resale by Alpha Capital of an aggregate of 5,157,087 shares of our common stock, which may be issuable to the selling stockholder pursuant to the terms of the Debenture and Alpha Warrant.

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

The proceeds were allocated to the initial fair value of the Warrants, 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 at proceeds received after allocating the proceeds to the Warrants, 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 ($0.3 million), the initial fair value of the Warrant ($2.8 million), the initial fair value of the suite of bifurcated embedded derivative features ($0), and the fees and costs paid to Alpha Capital and other third parties ($0.1 million) comprise the debt discount.

The debt discount shall be 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.

The senior secured convertible debt comprises the following:

	December 31, 2022	December 31, 2021
Senior secured convertible debenture	$ 3,300,000	$ —
Discount on convertible debenture	(3,239,803)	—
Total convertible debt - related party	$ 60,197	$ —

As of December 31, 2022, there were no events of default or violation of any covenants under our financing obligations.

NOTE 12 — EARNINGS (LOSS) PER SHARE

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

The following table reconciles net loss and the weighted-average shares used in computing basic and diluted EPS in the respective periods:

	For the Years Ended December 31,	
	2022	**2021**
Net loss used for basic earnings per share	$ (18,640,543)	$ (17,897,137)
Basic weighted-average common shares outstanding	3,840,340	2,933,487
Dilutive potential shares issuable from stock options and warrants	—	—
Diluted weighted-average common shares outstanding	3,840,340	2,933,487

	As of December 31,	
	2022	**2021**
Shares of common stock subject to outstanding options	608,012	484,186
Shares of common stock subject to outstanding warrants	4,575,617	982,140
Total common stock equivalents	5,183,629	1,466,326

Potentially dilutive common shares excluded from the calculation above represent stock options and warrants because their effect would be anti-dilutive.

NOTE 13 — COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its facilities under a long-term operating lease agreement. On December 15, 2021, our wholly-owned subsidiary Qualigen, Inc. entered into a Second Amendment to Lease with Bond Ranch LP. This Amendment extended the Company's triple-net leasehold on the Company's existing 22,624-square-feet headquarters/manufacturing facility at 2042 Corte del Nogal, Carlsbad, California for the 61-month period of November 1, 2022 to November 30, 2027. Over the 61 months, the base rent payable by Qualigen, Inc. will total $1,950,710; however, the base rent for the first 12 months of the 61-month period is only $335,966. Additionally, under the Second Amendment to Lease Qualigen, Inc. is entitled to a $339,360 tenant improvement allowance.

The tables below show the operating lease right-of-use assets and operating lease liabilities and the balances as of December 31, 2022 and 2021, including the changes during the periods:

	Operating lease right-of-use assets
Net right-of-use assets at December 31, 2021	$ 1,645,568
Less amortization of operating lease right-of-use assets	(223,030)
Operating lease right-of-use assets at December 31, 2022	$ 1,422,538

	Operating lease liabilities
Lease liabilities at December 31, 2021	$ 1,676,655
Less principal payments on operating lease liabilities	(134,091)
Lease liabilities at December 31, 2022	1,542,564
Less non-current portion	(1,301,919)
Current portion at December 31, 2022	$ 240,645

As of December 31, 2022, the Company's operating leases have a weighted-average remaining lease term of 4.9 years and a weighted-average discount rate of 8.9%.

As of December 31, 2022, the maturities of operating lease liabilities are as follows:

Year Ending December 31,	Amount
2023	368,341
2024	379,392
2025	390,773
2026	402,497
2027	379,164
Total	1,920,168
Less present value discount	(377,604)
Operating lease liabilities	$ 1,542,564

Total lease expense was approximately $462,000 and $342,000, respectively, for the years ended December 31, 2022 and December 31, 2021. Lease expense was recorded in cost of product sales, general and administrative expenses, research and development and sales and marketing expenses.

Termination of Sekisui Distribution Agreement

Sekisui's Distribution Arrangement expired on March 31, 2022. Following the expiration of the Sekisui Distribution Agreement on March 31, 2022, the Company had a commitment to purchase leased FastPack rental systems back from Sekisui at Sekisui's net book value, in the amount of $154,000 which is included in equipment held for lease and accrued expenses on the consolidated balance sheet.

NanoSynex Funding Commitment

As a condition to the NanoSynex Acquisition, the Company agreed to provide NanoSynex with up to $10.4 million of future funding in the form of promissory notes to the Company based on NanoSynex's achievement of certain future development milestones and subject to other terms and conditions described in the Funding Agreement entered into with NanoSynex. Of this amount approximately $2.4 million was funded during the year ended December 31, 2022, and an additional $0.5 million was funded in February 2023 (See Note 2-Liquidity for further details regarding the terms and conditions of the Funding Agreement).

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 14 — RESEARCH AND LICENSE AGREEMENTS

The University of Louisville Research Foundation

In March 2019, the Company entered into a sponsored research agreement and an option for a license agreement with ULRF for development of several small-molecule RAS interaction inhibitor drug candidates. Under the terms of this agreement, the Company was to reimburse ULRF for sponsored research expenses of up to $693,000 for this program. In February 2021, March 2022, and October 2022, the Company extended the term of this agreement until September 2023 and increased the amount that the Company will reimburse ULRF for sponsored research expenses to approximately $2.7 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 will take over development, regulatory approval and commercialization of the candidates from ULRF and is responsible for maintenance of the related intellectual property portfolio. In return, ULRF received approximately $112,000 for an upfront license fee and reimbursement of prior patent costs. In addition, the Company has agreed to pay ULRF (i) royalties, on patent-covered net sales associated with the commercialization, of 4% (on net sales up to a cumulative $250,000,000) or 5% (on net sales above a cumulative $250,000,000), until expiration of the licensed patent, and 2.5% (on net sales for any sales not covered by Licensed Patents), (ii) 30% to 50% of any non-royalty sublicensee income received (50% for sublicenses granted in the first two years of the ULRF license agreement, 40% for sublicenses granted in the third or fourth years of the ULRF license agreement, and 30% for sublicenses granted in the fifth year of the ULRF license agreement or thereafter), (iii) reimbursements for ongoing costs associated with the preparation, filing, prosecution and maintenance of licensed patents, incurred prior to July 2020, and (iv) payments ranging from $50,000 to $5,000,000 upon the achievement of certain regulatory and commercial milestones. Milestone payments for the first therapeutic indication would be $50,000 for first dosing in a Phase 1 clinical trial, $100,000 for first dosing in a Phase 2 clinical trial, $150,000 for first dosing in a Phase 3 clinical trial, $300,000 for regulatory marketing approval and $5,000,000 upon achieving a cumulative $500,000,000 of Licensed Product sales. The Company also must pay ULRF shortfall payments if the total amounts actually paid with respect to royalties and non-royalty sublicensee income for any year is less than the applicable annual minimum (ranging from $20,000 to $100,000) for such year.

Sponsored research expenses related to these agreements for the years ended December 31, 2022 and December 31, 2021 were approximately $758,000 and $646,000, 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, 2022 and December 31, 2021 were approximately $40,000 and $60,000, respectively, and are included in research and development expenses in the Consolidated Statements of Operations.

Between June 2018 and September 2020, the Company entered into license and sponsored research agreements with the University of Louisville Research Foundation ("ULRF") for QN-247, a novel aptamer-based compound that has shown promise as an anticancer drug. Under the agreements, the Company took over development, regulatory approval and commercialization of the compound from ULRF and is responsible for maintenance of the related intellectual property portfolio. In return, ULRF received a $50,000 convertible promissory note in payment of an upfront license fee, which was subsequently converted into the Company's common stock, and the Company agreed to reimburse ULRF for sponsored research expenses of up to $830,000 and prior patent costs of up to $200,000. The sponsored research agreement ended on August 31, 2022. 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 would also pay another $500,000 milestone payment for any additional regulatory marketing approval for each additional therapeutic (or diagnostic) indication. 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 $10,000 to $50,000) for such year.

Sponsored research expenses related to these agreements for the years ended December 31, 2022 and December 31, 2021 were approximately $164,000 and $325,000, respectively, and these amounts are recorded in research and development expenses in the Consolidated Statements of Operations. Minimum annual royalties of $0 and $0 related to these agreements are included in research and development expenses in the Consolidated Statements of Operations for the years ended December 31, 2022 and December 31, 2021, respectively. License costs related to these agreements were approximately $94,000 and $118,000 for the years ended December 31, 2022 and December 31, 2021, respectively, and are included in research and development expenses in the Consolidated Statements of Operations.

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 was 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 executed a sponsored research agreement with ULRF (for QN-165 as a treatment for COVID-19) supporting up to $430,000. This sponsored research agreement expired in November 2021 and effective October 31, 2022 the license agreement for QN-165 was terminated.

Sponsored research expenses related to these agreements for the years ended December 31, 2022 and December 31, 2021 were approximately $14,000 and $243,000, 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, 2022 and December 31, 2021 were approximately $2,000 and $28,000, respectively, and are included in research and development expenses in the Consolidated Statements of Operations.

Advanced Cancer Therapeutics

In December 2018, the Company entered into a license agreement with Advanced Cancer Therapeutics, LLC ("ACT"), granting the Company exclusive rights to develop and commercialize QN-165, an aptamer-based drug candidate. In return, ACT received a $25,000 convertible promissory note in payment of an upfront license fee, which was subsequently converted into the Company's common stock. In addition, the Company agreed to pay ACT (i) royalties, on net sales associated with the commercialization of QN-165, of 2% (only if patent-covered and only on net sales above a cumulative $3,000,000) or 1% (if not patent-covered, but only on net sales above a cumulative $3,000,000), until the 15th anniversary of the ACT license agreement and (ii) milestone payments of $100,000 for the Company raising a cumulative total of $2,000,000 in new equity financing after the date of the ACT license agreement, $100,000 upon any first QN-165-based licensed product receiving the CE Mark or similar FDA status, and $500,000 upon cumulative worldwide QN-165-based licensed product net sales reaching $3,000,000. For the years ended December 31, 2022 and December 31, 2021, there were approximately $0 and $2,000, respectively in costs related to this agreement which are included in research and development expenses in the Consolidated Statements of Operations.

Yi Xin

In October 2020, through our wholly-owned diagnostics subsidiary Qualigen, Inc. we entered into a Technology Transfer Agreement with Yi Xin Zhen Duan Jishu (Suzhou) Ltd. ("Yi Xin"), of Suzhou, China, for Yi Xin to develop, manufacture and sell new generations of diagnostic test systems based on the Company's core FastPack technology. In addition, the Technology Transfer Agreement authorized Yi Xin to manufacture and sell the Company's current generations of FastPack System diagnostic products (1.0, IP and PRO) in China.

The Company will receive low- to mid-single-digit royalties on any future new-generations and current-generations product sales by Yi Xin. We received total net cash payments of approximately $670,000, of which approximately $632,000 is classified as license revenue, and approximately $38,000 is classified as product sales on the Consolidated Statements of Operations for the fiscal year ended December 31, 2021. The Company provided technology transfer and patent/know-how license rights to facilitate Yi Xin's development and commercialization.

The Company gave Yi Xin the exclusive rights for China – which is a market we have not otherwise entered – both for Yi Xin's new generations of FastPack-based products and for Yi Xin-manufactured versions of our existing FastPack product lines. Yi Xin also has the right to sell its new generations of FastPack-based diagnostic test systems throughout the world (but not to or toward current customers of our existing generations of FastPack products). After March 31, 2022, Yi Xin has the right to sell Yi Xin-manufactured versions of existing FastPack 1.0, IP and PRO product lines worldwide (other than in the United States and other than to or toward current non-US customers of those products), as well as the right to buy Qualigen-manufactured FastPack 1.0, IP and PRO products from us at distributor prices for resale in and for the United States (but not to or toward current U.S. customers of those products). The Company did not license Yi Xin to sell in the U.S. market any Yi Xin-manufactured versions of those legacy FastPack 1.0, IP and PRO product lines. In the Technology Transfer Agreement the Company also confirmed that after March 31, 2022 it would not seek new FastPack customers outside the U.S.

STA Pharmaceutical

In November 2020, the Company entered into a contract with STA Pharmaceutical Co., Ltd., a subsidiary of WuXi AppTec, for GMP production of QN-165, which was the Company's lead drug candidate for the treatment of COVID-19 and other viral diseases. In connection with this agreement, the Company paid an upfront deposit of approximately $1.1 million which was classified as a prepaid expense on the December 31, 2020 Consolidated Balance Sheet date, and all of which was included in research and development expenses in the statement of operations for the year ended December 31, 2021.

Research and development expenses related to this agreement for the years ended December 31, 2022 and December 31, 2021 were approximately $9,000 and $3.2 million, respectively, and are recorded in research and development expenses in the Consolidated Statements of Operations.

UCL Business Limited

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

For the years ended December 31, 2022 and 2021 there were license costs of approximately $338,000 and $0, respectively, related to this agreement which are included in research and development expenses in the Consolidated Statements of Operations.

NOTE 15 — STOCKHOLDERS' EQUITY

As of December 31, 2022, and 2021 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.

On December 1, 2021, the Company closed a Securities Purchase Agreement (dated November 29, 2021) with several institutional investors for the purchase and sale of 588,000 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $15.00 per share, for aggregate gross proceeds of $8.82 million.

On December 22, 2022, the Company issued to Alpha Capital, an 8% Senior Convertible Debenture in the aggregate principal amount of $3,300,000 for a purchase price of $3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022. The Debenture is convertible, at any time, and from time to time, at Alpha's option, into shares of common stock of the Company, at a price equal to $1.32 per share, and other terms and conditions described in the Debenture (see Note 11 -Convertible Debt - Related Party). As part of this transaction, the Company issued to Alpha Capital a warrant to purchase 2,500,000 shares of the Company's common stock (see Note 10-Warrant Liabilities).

At December 31, 2022, the Company has reserved 5,183,629 shares of authorized but unissued common stock for possible future issuance. At December 31, 2022, 5,183,629 shares were reserved as follows:

Exercise of issued and future grants of stock options	608,012
Exercise of stock warrants	4,575,617
Total	5,183,629

Preferred Stock

At December 31, 2022 and 2021, there were no shares of preferred stock outstanding. All shares of Series A, B, C, D, D-1 convertible preferred stock were converted into common stock at the time of the May 2020 reverse recapitalization transaction.

During the year ended December 31, 2021, the holder of Series Alpha convertible preferred stock converted 180 of its shares of Series Alpha convertible preferred stock into an aggregate of 243,416 shares of the Company's common stock.

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, 2022 and December 31, 2021 there were 608,012 and 484,186 outstanding stock options, respectively, under the 2020 Plan and there were 147,690 and 280,916 of 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, 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

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, 2021, 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, 2020	401,136	$ 70.50	$35.20 — $14,657.50	9.29
Granted	83,500	13.70	12.40 — 32.90	9.79
Expired	—	—	—	—
Forfeited	(450)	36.80	35.20 — 49.70	—
Total outstanding – December 31, 2021	484,186	$ 60.70	$12.40 — $14,657.50	8.52
Exercisable (vested)	140,820	$ 108.80	$35.20 — $14,657.50	7.94
Non-Exercisable (non-vested)	343,366	$ 41.00	$12.40 — $51.30	8.81

There was approximately $5.4 million and $5.3 million of compensation costs related to outstanding options for the year ended December 31, 2022 and December 31, 2021, respectively. As of December 31, 2022, there was approximately $3.3 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements. This cost is expected to be recognized over a weighted average period of 0.93 years.

No stock options were exercised during the year ended December 31, 2022 or 2021.

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. 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 and during the year ended December 31, 2021 was $11.00.

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,	
	2022	**2021**
Expected dividend yield	0.00%	0.00%
Expected stock-price volatility	103%	102%
Risk-free interest rate	1.58% — 3.77%	0.84% — 1.51%
Expected average term of options (in years)	5.99	6.27
Stock price	5.14 - 10.50	12.40 — 32.90

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

	For the Years Ended December 31,	
	2022	**2021**
General and administrative	$ 4,649,649	$ 4,465,911
Research and development	834,395	827,740
Total	$ 5,484,044	$ 5,293,651

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 10- Warrant Liabilities.

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

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

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	—	$ —	$ —	—

The following table summarizes the equity classified compensatory warrant activity for the year ended December 31, 2021:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2020	129,403	$ 16.60		
Granted to advisor and its designees	60,000	13.20		
Exercised	(3,839)	20.90		
Expired	—	—		
Forfeited	(6,518)	20.70		
Total outstanding – December 31, 2021	179,046	$ 15.20	$11.10 — $25.40	2.64
Exercisable	179,046	$ 15.20	$11.10 — $25.40	2.64
Non-Exercisable	—	$ —	$ —	—

There were $67,370 in compensation costs related to outstanding warrants for the year ended December 31, 2022 and $0.3 million for the year ended December 31, 2021. As of December 31, 2022 and December 31, 2021, 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 Capital (a related party) for the purchase of 27,048 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $11.10 per share (of which warrants for 20,000 shares were subsequently exercised in December 2020). In July 2020 the Company issued noncompensatory equity classified warrants to Alpha Capital for the purchase of 78,019 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $0.01 per share (which were subsequently exercised in July 2020), and 192,068 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $52.50 per share. In August 2020, the Company issued noncompensatory equity classified warrants to Alpha Capital for the purchase of 128,783 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $60.00 per share. In December 2020, the Company issued noncompensatory equity classified warrants to Alpha Capital for the purchase of 100,000 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $0.10 per share (which were exercised in February 2021) and 219,101 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $40.70 per share. In May 2022, the Company issued noncompensatory equity classified warrants to Alpha Capital for the purchase of 331,464 reverse split adjusted shares of Company common stock at a reverse split adjusted exercise price of $0.01 per share (See Note 3 -Acquisition).

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. These warrants were subsequently exercised during the period ended September 30, 2022.

In conjunction with the NanoSynex Acquisition (See Note 3-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.

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
Granted	331,464	0.01	0.01	
Exercised	(331,464)	0.01	0.01	
Expired	(7,911)	37.78	37.78	
Forfeited	—	—	—	
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	—	$ —	$ —	—

The following table summarizes the noncompensatory equity classified warrant activity for the year ended December 31, 2021:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2020	654,978	$ 43.60		
Granted	—	—		
Exercised	(100,000)	0.01		
Expired	(64)	23,250.00		
Forfeited	—	—		
Total outstanding – December 31, 2021	554,914	20.10		
Exercisable	554,914	20.10	11.10— 37.78	1.32
Non-Exercisable	—	$ —	$ —	—

NOTE 16 — RELATED PARTY TRANSACTIONS

Convertible Debt

On December 22, 2022, the Company issued to Alpha Capital, an 8% Senior Convertible Debenture in the aggregate principal amount of $3,300,000 for a purchase price of $3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022 (the "Alpha Purchase Agreement"). The Debenture is convertible, at any time, and from time to time, 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 Company's receipt of the requisite stockholder approvals (See Note 11 -Convertible Debt - Related Party).

Short-Term Debt

NanoSynex has four separate notes payable (the "Notes") outstanding to Alpha Capital, dated between March 26, 2020 and September 2, 2021, aggregating to a total principal outstanding balance of $905,000, and aggregate accrued interest of $45,722 for a total outstanding balance of $950,722 as of December 31, 2022. The Notes all accrue interest at 2.62% per annum, accrued daily, and provide that the full amount of principal and interest under each Note shall be due immediately prior to a Liquidation Event (the Maturity Date) unless due earlier in accordance with the terms of the Notes. "Liquidation Event" means either i) the merger or consolidation of NanoSynex into any other entity, other than one in control or under control of NanoSynex or NanoSynex's majority shareholder; ii) a transaction or series of transactions resulting in the transfer of all or substantially all of NanoSynex's assets or issued and outstanding share capital (other than to a company under the control of NanoSynex or NanoSynex's majority shareholders; or iii) an underwritten public offering by NanoSynex of its ordinary shares. Notwithstanding the above, if NanoSynex receives subsequent debt, convertible debt, or equity funding with gross proceeds of USD $3,000,000 or more, then these Notes shall be due and payable upon the actual receipt of such funding (See Note 9 -Short-term Debt - Related Party).

Nanosynex Acquisition

The Company acquired a 52.8% voting equity interest in NanoSynex on May 26, 2022 (the "NanoSynex Acquisition Date") through: (1) the purchase of 2,232,861 shares Preferred A-1 Stock of NanoSynex from Alpha Capital (a related party) 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 a purchase price of $0.001 per share (these warrants were subsequently exercised on September 13, 2022), and (2) the purchase of 381,786 shares of Series B preferred stock of NanoSynex from NanoSynex in exchange for $600,000 (See Note 3 - Acquisition).

NOTE 17 — INCOME TAXES

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

	December 31, 2022	December 31, 2021
Domestic	$ (15,954,750)	$ (17,891,710)
Foreign	(5,344,967)	—
Loss before provision for income taxes	$ (21,299,717)	$ (17,891,710)

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

	December 31, 2022	December 31, 2021
Statutory federal income tax rate	21.00%	21.00%
State taxes, net of federal tax benefit	5.46%	6.63%
Non-deductible expenses	-1.36%	-1.19%
NOL expiration	-12.96%	-2.71%
Tax credit	2.42%	0.86%
Goodwill impairment	-4.50%	0.00%
Foreign rate differential	0.50%	0.00%
Change in FV of warrant liability	0.89%	5.54%
True-up	1.47%	-2.72%
Change in valuation allowance	-11.68%	-27.44%
Income taxes provision (benefit)	1.24%	-0.03%

Income tax expense for the year ended December 31, 2022 and 2021 consisted of the following:

	For the Years Ended	
	December 31, 2022	December 31, 2021
Current		
US Federal	$ —	$ —
US State	7,000	5,000
Foreign	—	—
Total current provision	7,000	5,000
Deferred		
US Federal	(236,000)	(1,268,000)
US State	(2,252,000)	(3,641,000)
Foreign	(272,000)	—
Total deferred benefit	(2,760,000)	(4,909,000)
Change in valuation allowance	2,488,000	4,909,000
Total provision (benefit) for income taxes	$ (265,000)	$ 5,000

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

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Net operating loss	$ 33,540,000	$ 33,362,000
Research and development credits	7,857,000	6,185,000
Accrued expenses	1,020,000	757,000
Patent	—	262,000
Stock compensation	3,069,000	2,747,000
Research and development expenses	1,196,000	—
Fixed assets	280,000	282,000
Total deferred income tax assets	46,962,000	43,595,000
Deferred tax liabilities:		
Intangible assets	(1,324,000)	(34,000)
Right-of-use asset	(382,000)	(436,000)
Total deferred income tax liabilities	(1,706,000)	(470,000)
Net deferred income tax assets	45,256,000	43,125,000
Valuation allowance	(45,614,000)	(43,125,000)
Deferred tax asset, net of allowance	$ (358,000)	$ —

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, 2022 and December 31, 2021.

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. This results in $272,000 of foreign deferred tax benefit recorded to the income statement in 2022.

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 2022 consolidated financial statements, noting that the impact on the Company's consolidated financial statements was immaterial.

At December 31, 2022, the Company has U.S. federal and state net operating loss carryforwards of approximately $119,254,000 and $110,227,000, 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. At December 31, 2022, the Company has foreign net operating loss carryforwards of approximately $953,000, which are available to offset future taxable income. Foreign net operating loss carryovers are indefinite lived and do not expire.

The Company also has research and development credit carryforwards for federal and state tax purposes of approximately $5,484,000 and $2,373,000, 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 not have any unrecognized tax benefits as of December 31, 2022 and December 31, 2021 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, 2022, the Company has not accrued any interest or penalties related to uncertain tax positions.

NOTE 18 — SUBSEQUENT EVENTS

Between January 9 and 12, 2023 Alpha Capital voluntarily converted $1,111,078 of its outstanding Senior Convertible Debenture principal into 841,726 shares of common stock at a conversion price of $1.32 per share.

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 and a 20% reduction to the non-employee directors' annual cash compensation. The Company also terminated the employment of certain employees, including its Senior Vice President/Chief Operating Officer and Vice President/Chief Scientific Officer.

The Company filed a Notification of Late Filing on Form 12b-25 on March 31, 2023, indicating that the filing of this Annual Report would be delayed on account of the Company and its registered public accounting firm requiring additional time to complete the accounting and disclosures related to the Company's acquisition of a majority interest in NanoSynex, Ltd., which accounting and disclosures have been included in this Annual Report. On April 20, 2023, the Company received a notification letter from the Listing Qualifications Department of Nasdaq indicating that, as a result of the Company's delay in filing this Annual Report, the Company was not in compliance with the timely filing requirements for continued listing under Nasdaq Listing Rule 5250(c)(1). The notification letter has no immediate effect on the listing or trading of the Company's common stock on the Nasdaq Capital Market. The notification letter stated that, under Nasdaq rules, the Company has 60 calendar days, or until June 20, 2023, to submit a plan to regain compliance with Nasdaq's continued listing requirements. The Company may also regain compliance with Nasdaq's continued listing requirements at any time before June 20, 2023, by filing this Annual Report with the SEC, as well as any subsequent periodic financial reports that may become due, and continuing to comply with Nasdaq's other continued listing requirements. The filing of this Annual Report was the Company's action to regain compliance.

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, 2022, 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, 2022, our disclosure controls and procedures were not effective due to the continuing material weakness described below. 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, 2022, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on the continuing material weakness described below, our management concluded that as of December 31, 2022, our internal control over financial reporting was not effective.

Description of Material Weakness

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 and registered independent public accounting firm 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. However, 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 that the material weakness identified in connection with the 2021 audit has 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 this Annual Report.

Remediation of Material Weakness

As described above, following the 2021 audit, we evaluated and implemented additional procedures in order to remediate this material weakness, including 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. However, due, in part, to a number of unfortunate staffing adjustments and departures at the consulting firms we utilized, these changes have not completely remediated the material weakness identified and reported. 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.

However, 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 indicated adjustments having been made) 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, 2022 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 seven members, each of whose current term of office as a director expires at the 2023 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	67	2020
Amy Broidrick	President, Chief Strategy Officer and Director	64	2020
Richard David	Director	63	2020
Sidney Emery, Jr.	Director	76	2020
Matthew Korenberg	Director	48	2020
Kurt Kruger	Director	67	2020
Ira Ritter	Director	74	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.

Amy S. Broidrick. Ms. Broidrick has served as our President, Chief Strategy and Operating Officer since February 2023. She previously served as our President and Chief Strategy Officer since December 2021, and Executive Vice President/Chief Strategy Officer since December 2020. From 2016 to July 2020, Ms. Broidrick served as Senior Vice President, Global Head of Corporate Development of Viking Therapeutics, Inc. (Nasdaq: VKTX), a clinical-stage biopharmaceutical company. Before that, she was Vice President, Head of Global Marketing Excellence and Business Innovation with EMD Serono (part of Merck KGaA). Earlier, she was Vice President, Head of Marketing and Commercialization at Arena Pharmaceuticals, Inc., and had significant roles and responsibilities at Merck & Co., Inc. and G.D. Searle & Company.

Ms. Broidrick's executive experience with large and smaller public companies in the therapeutics industry contributed to our board of directors' conclusion that she 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 acquired Supply Chain Services in 2010 and, as its Chief Executive Officer, grew it into a premier provider of automatic identification and data capture and factory automation solutions before selling the business to Sole Source Capital LLC in May 2020. Before Supply Chain Services, 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 School 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. He served for 10 years in the US Navy (including on gunboats in Vietnam).

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 showed perspicuity leading Hambrecht & Quist in providing venture funds for, and then taking public, Ventritex, which was later acquired by St. Jude Medical. After Hambrecht & Quist, 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, including leadership of 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 our predecessor, Ritter Pharmaceuticals, Inc., from its inception in 2004 through the formation of Ritter Pharmaceuticals, Inc. 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.qualigeninc.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	67	Chairman and Chief Executive Officer
Amy Broidrick	64	President and Chief Strategy Officer
Christopher Lotz	58	Chief Financial Officer, Vice President of Finance
Tariq Arshad	53	Chief Medical Officer and Senior Vice President

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 biographies of Mr. Poirier and Ms. Broidrick, please see "Board of Directors - The Board of Directors in General".

Christopher L. Lotz | Chief Financial Officer, Vice President of Finance. Mr. Lotz joined Qualigen as Director of Finance in 2002 and was promoted to his current role of Chief Financial Officer, Vice President of Finance in 2003. Before joining Qualigen, 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.

Tariq Arshad, MD, MBA | Chief Medical Officer and Senior Vice President. Dr. Arshad brings more than 20 years of biotech and pharmaceutical experience to Qualigen. He is an oncologist with expertise in both early and late-stage clinical development at several leading and emergent biopharmaceutical companies. Prior to joining Qualigen in May 2021, Dr. Arshad was Global Head of Medical Affairs and Clinical Research with Becton Dickinson Biosciences in San Jose, California from 2019-2021, where he led a team of MDs and PHDs driving scientific strategy for a cutting-edge immuno-oncology focused portfolio. From 2018-2019, Dr. Arshad served as Head of Medical Affairs, Immunology, Global Markets for Sanofi Genyzyme, and Chief Medical Officer, Head of Clinical Research and Medical Affairs for Humanigen, Inc. from 2016-2018. Prior to that, he held leadership positions with XOMA Corporation, Genentech, Inc., Merck & Co., Inc., and Pfizer Inc. Dr. Arshad holds a M.B.B.S (Bachelor of Medicine, Bachelor of Surgery) from University of Punjab, MD from Educational Commission for Foreign Medical Graduates (ECFMG), and a M.B.A. degree from George Washington 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, 2022, all Section 16(a) filing requirements applicable to such persons were met in a timely manner, except as described below.

Each of Michael Poirier, Amy Broidrick, Christopher Lotz, Shishir Sinha, Wajdi Abdul-Ahad, Tariq Arshad, Richard David, Sidney Emery, Jr., Matthew Korenberg, Kurt Kruger and Ira Ritter filed one late Form 4 report with respect to a grant of stock options that each of them received on July 11, 2022 as follows: Michael Poirier (37,000 options), Amy Broidrick (130,000 options), Christopher Lotz (100,000 options), Shishir Sinha (100,000 options), Wajdi Abdul-Ahad (80,000 options), Tariq Arshad (102,000 options), Richard David (40,000 options), Sidney Emery (40,000 options), Jr., Matthew Korenberg (40,000 options), Kurt Kruger (40,000 options) and Ira Ritter (40,000 options).

Item 11. Executive Compensation.

EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table (2022 and 2021)

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	2022	575,000	—	145,274	8,180	728,454
	2021	517,788	218,740	—	5,751	742,279
Amy Broidrick, President and Chief Strategy Officer	2022	450,000	—	50,359	7,642	508,001
	2021	403,077	155,000	296,170	4,055	858,302
Tariq Arshad, Chief Medical Officer and Senior Vice President [3]	2022	400,000	—	39,512	138	439,650
	2021	253,846	80,212	430,569	69	764,696

(1) The amounts reported in this column reflect the aggregate grant date fair value of the option awards granted during 2022 and 2021, computed in accordance with Financial Accounting Standard 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.

(2) Represents life insurance premiums paid by us for each named executive officer in addition to 401(k) matching contributions paid by us for Mr. Poirier and Ms. Broidrick.

(3) Dr. Arshad joined Qualigen in May 2021.

Executive Employment Agreements

Employment Agreement with Michael Poirier

Mr. Poirier, is party to an Executive Employment Agreement with Qualigen 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.

Employment Agreement with Amy Broidrick

Upon her promotion to the position of President and Chief Strategy Officer in December 2021, Ms. Broidrick is party to an Executive Employment Agreement with Qualigen dated December 10, 2021 (the "Broidrick Employment Agreement"). The Broidrick Employment Agreement had an initial term expiring on April 30, 2022 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 Broidrick Employment Agreement, Ms. Broidrick is entitled to an annual base salary of at least $450,000, is eligible to participate in the Company's bonus plans, benefit programs and medical benefits, is eligible for certain event-based bonuses, and is entitled to four weeks of vacation per year. If Ms. Broidrick's employment is terminated without Cause or she resigns for Good Reason (as such terms are defined in the Broidrick Employment Agreement), and she provides a general release to the Company, she will be entitled to one year of salary continuation plus the cost of COBRA coverage continuation for such one year period. 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, Ms. Broidrick's base salary was reduced to $360,000.

The following definitions are used in each of the Employment Agreements described above:

"Cause" means any of the following: (i) a material breach by the employee of any of the trade secret/proprietary information, confidential information of intellectual property ownership sections of the Employment Agreement; (ii) a material breach by the employee of any other provision of the Employment Agreement, if such material breach (if susceptible to cure) has continued uncured for a period of at least 15 days following delivery by Qualigen to the employee of written notice of such material breach; (iii) fraud, dishonesty or other breach of trust whereby the employee obtains personal gain or benefit at the expense of or to the detriment of Qualigen or any of Qualigen's subsidiaries or affiliates; (iv) a conviction of or plea of nolo contendere or similar plea by the employee of any felony; (v) a conviction of or plea of nolo contendere or similar plea by of any other crime involving theft, misappropriation of property, dishonesty or moral turpitude; (vi) a willful and material violation of applicable law by the employee in connection with the performance of his/her duties under the Employment Agreement; (vii) chronic or repeated substance abuse by the employee, or any other use by the employee of alcohol, drugs or illegal substances in such a manner as to interfere with the performance of his/her material duties hereunder; or (viii) failure to comply with the lawful directions of Qualigen's board of directors which are otherwise consistent with the terms of this Agreement, which failure has continued for a period of at least 10 days after delivery by Qualigen to the employee of written demand by Qualigen's board of directors.

"Good Reason" means the occurrence of any of the following circumstances, without the employee's express consent: the employee resigns due to (i) a material reduction of the employee's title or authority, (ii) a material reduction in the employee's salary or benefits (other than a reduction that generally applies to the officers at the employee's level in Qualigen or, as applicable, after a transaction in which Qualigen or substantially all its assets is acquired, in the successor entity at that time), (iii) any material breach of this Agreement by Qualigen which is not cured within 30 days after written notice by the employee; or (iv) a change of the principal non-temporary location in which the employee is required to perform the employee's services to any location exceeding 35 miles from Carlsbad, California. In no event shall a resignation be considered to be with Good Reason unless the resignation occurs after but within 30 days after the initiation of the item of Good Reason.

The foregoing description of the employment agreements does not purport to be complete and is qualified in its entirety by reference to the employment agreements.

Offer Letter with Tariq Arshad

Under the terms of his offer letter with the Company, dated May 17, 2021, Dr. Arshad is 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, is 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 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 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. Arshad's annual base salary was reduced to $320,000.

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 filed as an exhibit to the Original Report and 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, 2022

The following table presents the outstanding stock options and compensatory warrants held by each of the named executive officers as of December 31, 2022. There were no direct stock awards, restricted stock units or stock appreciation rights outstanding at December 31, 2022. 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	—	37,500(1)	5.14	7/11/2032
	6/5/2020	66,667	33,333(1)	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	770	—	20.66	8/2/2024
	8/2/2014	2,214	—	20.66	8/2/2024
	1/31/2014	2,214	—	20.66	1/31/2024
Amy Broidrick.....	7/11/2022	—	13,000(1)	5.14	7/11/2032
	12/8/2021	10,000	20,000(1)	12.40	12/8/2031
	12/7/2020	10,000	5,000(1)	35.20	12/7/2030
	8/27/2020	3,333	1,666(1)	47.00	8/27/2030
Tariq Arshad	7/11/2022	—	10,200(1)	5.14	7/11/2032
	12/8/2021	10,000	20,000(2)	12.40	5/17/2031
	5/17/2021	3,333	6,666(1)	18.00	5/17/2031

(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.

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 PEO and NEOs for each of the fiscal years ended December 31, 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, 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)**
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 2022 and 2021 is Michael Poirier, our Chairman and Chief Executive Officer. The Non-PEO NEOs in 2022 and 2021 are Amy Broidrick, our President, Chief Strategy and Operating Officer and Tariq Arshad, 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						
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						
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 103%, 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%.

Analysis of Information Presented in the Pay versus Performance Table

The Company's executive compensation program reflects a variable pay-for-performance philosophy. While the Company utilizes 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, the Company generally seeks to incentivize long-term performance, and therefore does not specifically align the Company's performance measures with compensation that is actually paid (as computed in accordance with SEC rules) for a particular year. In accordance with SEC rules, the Company is providing the following narrative disclosure regarding the relationships between information presented in the Pay versus Performance table.

Compensation Actually Paid and Cumulative Total Stockholder Return

During 2021 and 2022, compensation actually paid to our PEO increased from ($753,431) in 2021 to $262,274 in 2022 for Mr. Poirier, and average compensation actually paid to our named executive officers other than our PEO decreased from $609,691 in 2021 to $121,235 in 2022. 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, and further decreased by $34.12 to $4.09 during 2022, for a total decrease over 2021 and 2022 of $95.91.

Compensation Actually Paid and Net Loss

During 2021 and 2022, compensation actually paid to our PEO increased from ($753,431) in 2021 to $262,274 in 2022 for Mr. Poirier, and average compensation actually paid to our named executive officers other than our PEO decreased from $609,691 in 2021 to $121,235 in 2022. Over the same period, our net loss decreased by $1.6 million during 2021 (from a net loss in 2020 of $19.5 million to a net loss in 2021 of $17.9 million), and 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).

Compensation of Directors

For 2022, our non-employee directors received $35,000 in cash for their services. The Audit Committee chair received additional cash compensation of $15,000 and the other Board committee chairs received additional cash compensation of $10,000. Each non-chair member of each Board committee received additional cash compensation of $7,500 (Audit Committee) and $5,000 (other Committees). Non-employee directors each received a grant of 4,000 stock options (adjusted for the Reverse Stock Split) during 2022.

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.

Compensation paid to Mr. Poirier and to 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 Earned and Paid in Cash ($)	Option Awards[(1)] ($)	All other compensation[(2)] ($)	Total ($)
Richard David	54,167	15,496	—	69,663
Sidney Emery, Jr.	62,292	15,496	—	77,788
Matthew Korenberg	56,875	15,496	—	72,371
Kurt Kruger	54,167	15,496	—	69,663
Ira Ritter	—	15,496	80,000	95,496

(1) The amounts reported in this column reflects the aggregate grant date fair value of the option awards granted during the year ending December 31, 2022, computed in accordance with 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 our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 17, 2023. These amounts do not reflect the actual economic value that may be realized by the directors upon the exercise of the stock options or the sale of the common stock underlying such stock options.

(2) Represents amounts paid for consulting services.

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 also intend to adopt a formal claw-back policy for the recovery of incentive-based executive compensation erroneously awarded to executive officers based on misstated financial reporting measures once Nasdaq's listing standards become effective.

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 April 28, 2023 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 April 28, 2023, 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 5,052,463 shares outstanding as of April 28, 2023.

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., 2042 Corte Del Nogal, Carlsbad, California 92011 USA.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned
Five Percent Stockholders		
Alpha Capital Anstalt (1)	555,155	9.99%
Executive Officers, Directors and Director Nominees		
Michael Poirier (2)	96,543	1.9%
Amy Broidrick (3)	26,784	*%
Tariq Arshad (4)	13,334	*%
Richard David (5)	4,219	*%
Sidney Emery, Jr. (6)	5,302	*%
Matthew Korenberg (7)	3,334	*%
Kurt Kruger (8)	6,019	*%
Ira Ritter (9)	3,738	*%
All current executive officers and directors as a group (9 persons)(10)	208,293	4.0%

* 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; Alpha Capital Anstalt would not be permitted to convert or exercise all or any portion of its warrants 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 Qualigen 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 66,667 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 23,334 shares of common stock exercisable within 60 days under outstanding stock options.

(4) Includes 13,334 shares of common stock exercisable within 60 days under outstanding stock options.

(5) Includes 3,334 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.

(6) Includes 3,334 shares of common stock exercisable within 60 days under outstanding stock options.

(7) Includes 3,334 shares of common stock exercisable within 60 days under outstanding stock options.

(8) Includes 3,334 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.

(9) Includes 3,334 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.

(10) Includes 160,005 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, 2022:

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	608,012	$ 35.02	147,690
Equity compensation plans not approved by stockholders (1)	179,046	$ 9.12	—
Total	787,058	$ 29.13	2,809,157

(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 Capital Anstalt (“Alpha Capital”), a related party, in exchange for 350,000 reverse split adjusted shares of the Company’s common stock and a prefunded warrant to purchase 331,464 reverse split adjusted shares of the Company’s common stock at an exercise price of $0.001 per share. These warrants were subsequently exercised on September 13, 2022.

On December 22, 2022, the Company issued to Alpha Capital, an 8% Senior Convertible Debenture (the "Debenture") in the aggregate principal amount of $3,300,000 for a purchase price of $3,000,000 pursuant to the terms of a Securities Purchase Agreement, dated December 21, 2022. The Debenture is convertible, at any time, and from time to time, at Alpha's option, into shares of common stock of the Company, at a price equal to $1.32 per share, subject to adjustment as described in the Debenture and other terms and conditions described in the Debenture, including the Company's receipt of the requisite stockholder approvals. Additionally, on December 22, 2022, the Company issued to Alpha Capital a liability classified warrant to purchase 2,500,000 shares of the Company's common stock (see Note 10-Warrant Liabilities to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K). The exercise price of the warrant is $1.65 (equal to 125% of the conversion price of the Debenture on the closing date). The warrant may be exercised by Alpha Capital, in whole or in part, at any time on or after June 22, 2023 and before June 22, 2028, subject to certain terms conditions described in the warrant, including the Company's receipt of the necessary stockholder approvals.

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 and Kruger 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 2022 or 2021.

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, 2022 and 2021:

	2022	2021
Audit Fees(1)	$ 411,362	$ 267,020
Audit-Related Fees	—	—
Tax Fees (2)	35,050	25,175
All Other Fees	—	—
Total	$ 446,412	$ 292,195

(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, 2022 and 2021, 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:

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID 23)	42
Financial Statements:	
Consolidated Balance Sheets as of December 31, 2022 and December 31, 2021	45
Consolidated Statements of Operations and Comprehensive Loss for the Year Ended December 31, 2022 and Year Ended December 31, 2021	46
Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the Year Ended December 31, 2022 and Year Ended December 31, 2021	47
Consolidated Statements of Cash Flows for the Year Ended December 31, 2022 and Year Ended December 31, 2021	48
Notes to Consolidated Financial Statements	50

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	Contingent Value Rights Agreement, dated May 22, 2020, among the Company, John Beck in the capacity of CVR Holders' Representative and Andrew J. Ritter in his capacity as a consultant to the Company.	8-K	001-37428	2.4	5/29/2020
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, as amended.	8-K	001-37428	3.1	11/22/2022
4.1	Warrant, issued by the Company in favor of Alpha Capital Anstalt, dated May 22, 2020	8-K	001-37428	10.13	5/29/2020
4.2	Form of Warrant, issued by the Company in favor of GreenBlock Capital LLC and its designees, dated May 22, 2020 [post-Merger]	8-K	001-37428	10.10	5/29/2020
4.3	Common Stock Purchase Warrant in favor of Alpha Capital Anstalt, dated July 10, 2020	8-K	001-37428	10.2	7/10/2020
4.4	Common Stock Purchase Warrant in favor of Alpha Capital Anstalt, dated August 4, 2020	8-K	001-37428	10.3	8/4/2020
4.5	"Two-Year" Common Stock Purchase Warrant for 1,348,314 shares in favor of Alpha Capital Anstalt, dated December 18, 2020	8-K	001-37428	10.3	12/18/2020
4.6	"Deferred" Common Stock Purchase Warrant 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	001-37428	4.7	3/31/2020
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
10.3+	Executive Employment Agreement dated December 10, 2021 with Amy Broidrick	10-K	001-37428	10.53	3/31/2022
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
10.6+	Form of Indemnification Agreement – Qualigen, Inc.	8-K	001-37428	10.21	5/29/2020
10.7	Exclusive Agreement (QN-24), by and between Qualigen, Inc. and University of Louisville Research Foundation, Inc. dated as of June 8, 2018	S-4/A	001-37428	10.58	3/13/2020
10.8*	Amendment 1 to the Exclusive License Agreement (QN-247), by and between Qualigen, Inc. and University of Louisville Research Foundation, Inc., dated March 16, 2021				
10.9*	Amendment 2 to the Exclusive License Agreement (QN-247), by and between Qualigen, Inc. and University of Louisville Research Foundation, Inc., dated January 17, 2023				
10.10*	Exclusive License Agreement between the Company and University of Louisville Research Foundation (RAS), Inc., dated as of July 17, 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				

10.12	License Agreement between Qualigen, Inc. and Advanced Cancer Therapeutics, LLC dated December 17, 2018	S-4/A	001-37428	10.59	3/13/2020
10.13	Novation Agreement among the Company, Qualigen, Inc. and Advanced Cancer Therapeutics, LLC dated July 29, 2020	10-K	001-37428	10.31	3/31/2021
10.14	Technology Transfer Agreement dated as of October 7, 2020 between Qualigen, Inc. and Yi Xin Zhen Duan Jishu (Suzhou) Ltd.	8-K	001-37428	10.1	10/9/2020
10.15	Novation Agreement 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
10.16	Novation Agreement among the Company, Qualigen, Inc. and University of Louisville Research Foundation, Inc. dated March 1, 2021	10-Q	001-37428	10.2	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
10.18	Amendment to Technology Transfer Agreement between Yi Xin Zhen Duan Jishu (Suzhou) Ltd. and Qualigen, Inc., dated August 5, 2021	10-Q	001-37428	10.2	11/15/2021
10.19	Amendment to 2020 Stock Incentive Plan (approved by the Board of Directors on April 27, 2021 and by the Stockholders on August 9, 2021)	10-Q	001-37428	10.3	11/15/2021
10.20	Second Amendment to Lease with Bond Ranch LP dated December 15, 2021	10-K	001-37428	10.54	3/31/2022
10.21*	First Deed of Variation to License Agreement with UCL Business Limited dated March 30, 2022				
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	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 P. Poirier, dated January 13, 2023, regarding compensatory changes				
10.32+*	Letter to Amy Broidrick, dated January 13, 2023, regarding compensatory changes				
10.33+*	Letter to Tariq Arshad, dated January 13, 2023, regarding compensatory changes				
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.				
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*
Michael S. Poirier
Chairman of the Board, Chief Executive Officer

Date: May 2, 2023

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)	May 2, 2023
/s/ Christopher L. Lotz Christopher L. Lotz	Vice President of Finance, Chief Financial Officer (Principal Financial and Accounting Officer)	May 2, 2023
/s/ Amy S. Broidrick Amy S. Broidrick	President, Chief Strategy and Operating Officer	May 2, 2023
/s/ Richard A. David Richard A. David	Director	May 2, 2023
/s/ Sidney W. Emery, Jr. Sidney W. Emery, Jr.	Director	May 2, 2023
/s/ Matthew E. Korenberg Matthew E. Korenberg	Director	May 2, 2023
/s/ Kurt H. Kruger Kurt H. Kruger	Director	May 2, 2023
/s/ Ira E. Ritter Ira E. Ritter	Director	May 2, 2023