**Filed Pursuant to Rule 424(b)(5)**
**Registration No. 333-232798**

**Prospectus Supplement to Prospectus dated August 1, 2019**

**1,717,106 Shares of Common Stock**

**Warrants to Purchase 1,287,829 Shares of Common Stock**

**1,287,829 Shares of Common Stock Underlying Warrants**

# QUALIGEN THERAPEUTICS, INC.

We (Qualigen Therapeutics, Inc.) are offering, for a total gross purchase price of $10,000,000, 1,717,106 shares of our common stock and warrants to purchase up to 1,287,829 shares of our common stock to an institutional investor. The shares of our common stock and warrants are immediately separable and will be issued separately, but will be purchased together in this offering.

This prospectus supplement supplements, modifies and supersedes, only to the extent indicated herein, certain information contained in our base prospectus dated August 1, 2019, which, together with this prospectus supplement, we refer to as this prospectus. This prospectus supplement should be read in conjunction with, is not complete without, and may not be delivered or utilized except in connection with, the base prospectus. If there is any inconsistency between the information in the base prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement. Any information that is modified or superseded in the base prospectus shall not be deemed to constitute a part of this prospectus, except as modified or superseded by this prospectus supplement.

The shares of our common stock issuable from time to time upon exercise of the warrants are also being offered pursuant to this prospectus.

Our common stock is listed on The Nasdaq Capital Market under the symbol "QLGN." The last reported sale price of our common stock on The Nasdaq Capital Market on July 31 and August 3, 2020, respectively, was $5.72 and $5.48, respectively, per share.

There is no established public trading market for the warrants and we do not expect a market to develop. Without an active trading market, we expect the liquidity of the warrants will be limited.

Pursuant to a Placement Agency Agreement dated August 2, 2020 that we entered into with A.G.P./Alliance Global Partners, or A.G.P., we have retained A.G.P. to act as our placement agent in connection with the sale of securities offered by this prospectus supplement. The placement agent is not required to arrange for the sale of any specific number of securities or dollar amount but will use its reasonable best efforts to sell the securities offered by this prospectus supplement. We have agreed to pay the placement agent the placement agent fees set forth in the table below, which assumes we sell all of the securities we are offering.

**Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page S-8 of this prospectus supplement and in our reports and other documents filed with the Securities and Exchange Commission which are incorporated by reference into this prospectus supplement for an important discussion of risks and uncertainties relevant to an investment in our common stock and warrants.**

| | Per Share | Per Warrant (exclusive of underlying warrant shares) | Total[1] |
|---|---|---|---|
| Offering price | $ 5.73 | 0.125 | $ 10,000,000 |
| Placement agent fees[2] | $ 0.20055 | 0.004375 | $ 350,000 |
| Proceeds, before expenses, to us for securities other than the underlying warrant shares | $ 5.52945 | 0.1245625 | $ 9,650,000 |

(1) 1,717,106 shares of common stock and warrants to purchase up to 1,287,829 shares of common stock.
(2) See "Plan of Distribution" for additional disclosure regarding placement agent fees and estimated offering expenses.

| | Total |
|---|---|
| Aggregate exercise price of the warrants (if and when exercised)[1] | $ 7,726,974 |
| Placement agent fees[2] | $ — |
| Proceeds, before expenses, to us for the underlying warrant shares if and when the warrants are exercised | $ 7,726,974 |

(1) Each warrant will have an exercise price of $6.00 per share.

(2) No placement agent fees would be payable in connection with the exercise of the warrants.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**A.G.P.**

The date of this prospectus supplement is August 2, 2020.

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## ABOUT THIS PROSPECTUS SUPPLEMENT

On July 24, 2019, we filed with the Securities and Exchange Commission, or the SEC, a registration statement on Form S-3. That registration statement was declared effective on August 1, 2019.

This prospectus supplement describes the specific terms of the securities we are offering and adds to, and updates information in, the base prospectus and the documents incorporated by reference into it or this prospectus supplement. If there is a conflict between the information contained in this prospectus supplement and the information contained in the base prospectus or any document incorporated by reference into this prospectus supplement that was filed with the SEC before the date of this prospectus supplement, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date, the statement in the document having the later date modifies or supersedes the earlier statement.

Neither the delivery of this prospectus nor any sale made using this prospectus implies that there has been no change in our affairs or that information in this prospectus is correct as of any date after the date of this prospectus. You should assume that the information appearing in this prospectus, the documents incorporated by reference into this prospectus, and in any free writing prospectus that we may authorize for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

You should carefully read this prospectus, the documents incorporated by reference into this prospectus and any free writing prospectus that we may authorize for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled “Where You Can Find More Information” and “Incorporation of Certain Documents by Reference.”

We are offering to sell, and seeking offers to buy, securities only in jurisdictions where offers and sales are permitted. The distribution of this prospectus and the offering of our securities in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement or the base prospectus must inform themselves about, and observe any restrictions relating to, the offering of our securities and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

You should rely only on the information contained in, or incorporated by reference into, this prospectus and in any free writing prospectus that we may authorize for use in connection with this offering. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it.

We have filed or incorporated by reference exhibits to the registration statement of which this prospectus is a part. You should read the exhibits carefully for provisions that may be important to you.

When we refer to “Qualigen,” “the Company,” “we,” “our” and “us” in this prospectus, we mean Qualigen Therapeutics, Inc., a Delaware corporation, unless otherwise specified. References to our “common stock” refer to the common stock, par value $0.001 per share, of Qualigen Therapeutics, Inc.

## PROSPECTUS SUPPLEMENT SUMMARY

*This prospectus supplement summary discusses the key aspects of the offering and highlights certain information appearing elsewhere in this prospectus, and in the documents we incorporate by reference herein and therein. However, as this is a summary, it does not contain all of the information that you should consider before deciding to invest in our common stock and warrants. You are encouraged to carefully read the entire prospectus, including the information provided in our reports and other documents filed with the SEC, and our financial statements and the related notes, in our Current Report on Form 8-K/A, filed with the SEC on June 29, 2020, and the other periodic report filings we make with the SEC after the date of this prospectus supplement.*

### Overview

Qualigen is a biotechnology company focused on developing novel therapeutics for the treatment of cancer and infectious diseases, as well as maintaining and expanding its core FDA-approved FastPack® System, which has been used in diagnostics for almost 20 years. The FastPack menu includes tests for cancer, men's health, hormone function, vitamin D status and antibodies against SARS-CoV-2. The Company's cancer therapeutics pipeline includes ALAN (AS1411-GNP), RAS-F and STARS™. ALAN (AS1411-GNP) is a DNA coated gold nanoparticle cancer drug candidate that has the potential to target various types of cancer with minimal side effects. The foundational aptamer of ALAN, AS1411, is also being studied for use in treating viral-based infectious diseases, including COVID-19. RAS-F is a family of RAS oncogene protein-protein interaction inhibitor small molecules for preventing mutated RAS genes' proteins from binding to their effector proteins; preventing this binding could stop tumor growth, especially in pancreatic, colorectal and lung cancers. STARS is a DNA/RNA-based treatment device product candidate for removal from circulating blood of precisely targeted tumor-produced and viral compounds. Qualigen's only products that are currently commercially available are its FastPack System diagnostic instruments and test kits. Qualigen's facility in Carlsbad, California is FDA and ISO Certified and its FastPack product line is sold worldwide by its commercial partner Sekisui Diagnostics, LLC, or Sekisui.

Qualigen, Inc., a wholly owned subsidiary of Qualigen, was incorporated in Minnesota in 1996 and reincorporated in Delaware in 1999. The Company was formed as a Nevada limited liability company on March 29, 2004 under the name Ritter Natural Sciences, LLC. In September 2008, the Company was converted into a Delaware corporation under the name Ritter Pharmaceuticals, Inc. In May 2020, Ritter Pharmaceuticals, Inc. entered into a reverse merger transaction with Qualigen, Inc. pursuant to which Qualigen, Inc. became a wholly-owned subsidiary of Ritter Pharmaceuticals, Inc. Following the reverse merger transaction, Ritter Pharmaceuticals, Inc. changed its name to Qualigen Therapeutics, Inc. The Company is no longer pursuing the gastrointestinal disease treatment business on which it had focused before the reverse merger transaction.

Qualigen, Inc. began operations at its current Carlsbad, California facility in 2000. Qualigen's first FastPack cancer diagnostic product, Total PSA, was introduced in 2002. Since then, Qualigen's FastPack test menu has expanded to include additional tests for cancer, men's health, hormones and metabolic biomarkers.

As a strategic matter, Qualigen now views its diagnostics business as not having a particularly high ceiling. To increase stockholder value, Qualigen has recently revised its strategy toward a primary focus on developing its therapeutic device and drug opportunities (particularly in the cancer area), while maintaining its diagnostics business.

Qualigen, Inc.'s transition into cancer therapeutics could be said to have begun as far back as 2007 with the issuance of Qualigen, Inc.'s first STARS patent. In 2018, Qualigen, Inc. accelerated its transition into cancer therapeutics with development and licensing partnerships with the University of Louisville, or UofL, and Advanced Cancer Therapeutics, LLC. Today, Qualigen has a pipeline of cancer therapeutics product candidates to complement its commercialized diagnostic-device products.

### Products and Solutions

Since its introduction in 2000, Qualigen's FastPack System diagnostic instruments and kits have demonstrated the ability to detect cancer, other diseases and medical conditions, and biological factors. Qualigen's anticancer drug candidates, ALAN and RAS-F, are designed to destroy tumors (or stop tumor growth) with minimal side effects. STARS is a therapeutic device product candidate, currently in the preclinical development stage, which is designed to remove circulating tumor cells, viruses, inflammation factors and immune checkpoints. Qualigen's only products that are currently commercially available are its FastPack System diagnostic instruments and test kits.

#### *FastPack®*

The FastPack System is a 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, Qualigen has developed two successive versions of the analyzer and test pouch, known as "1.0" and "IP", and has expanded its assay menu to 10, including tests for prostate cancer, thyroid function, metabolic disorders and research applications. Qualigen has sold FastPack products in the United States and overseas for almost 20 years, and FastPack products are now in place in approximately 1,000 physician offices worldwide. Since inception, sales of FastPack products have exceeded $100 million. Qualigen manufactures the FastPack products at its FDA and ISO certified Carlsbad, California facility. Pursuant to a distribution agreement, Qualigen is required to rely on its diagnostics distribution partner Sekisui for most FastPack distribution worldwide until 2022. Qualigen maintains direct distribution for certain house accounts, including Low T Center, Inc.

Qualigen plans to carry forward its FastPack System business, including supporting the late-July-2020 launch of its new immunoassay test for COVID-19 antibodies.

Qualigen seeks and maintains patent protection for its FastPack products in the United States and selected foreign jurisdictions. For example, in 2018 Qualigen was granted patents in China for the FastPack system.

***ALAN (AS1411-GNP) and AS1411***

ALAN (Aptamer-Linked Anti-Nucleolin or AS1411-GNP) is an aptamer-based anticancer drug candidate that is designed to treat different types of cancer. This novel technology potentially has several additional applications, including enhancement of radiation therapy, enhancement of tumor imaging, and delivery of other anti-cancer compounds directly to tumor cells. A key component of this drug candidate, DNA aptamer AS1411, 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 cancer patients and appears to be well tolerated with no evidence of severe side effects, with at least seven patients appearing to have long-lasting clinical responses where their cancers disappeared or shrank substantially.

ALAN is an enhanced version of AS1411 where the DNA aptamer is attached to a gold nanoparticle.

In a Qualigen-sponsored UofL in-vitro preclinical study involving tumor-associated macrophages, ALAN was shown to have stronger anti-cancer activity versus AS1411. Tumor-associated macrophages are a class of immune cells present in high numbers around solid tumors and affect most aspects of tumor cell biology; they drive pathological phenomena including tumor cell proliferation, tumor angiogenesis, invasion and metastasis, immunosuppression, and drug resistance. In most cancers, the tumor-associated macrophages have an M2 phenotype, which may inhibit the anti-tumor effects of immune checkpoint inhibitor drugs, such as Merck's Keytruda (pembrolizumab). Converting these M2 macrophages to the M1 phenotype could enhance the activity of these immune checkpoint inhibitors. In this study, ALAN increased the conversion of M2 macrophages to the M1 phenotype, while also reducing the overall proliferation of macrophages.

Moreover, a UofL in-vitro preclinical study with triple negative breast cancer cells (MDA-MB-231) indicated that ALAN, in combination with radiation therapy, resulted in reduced tumor cell colony size (i.e., resulted in increased tumor cell necrosis) compared to radiation alone.

Qualigen believes that, in addition to its potential use as a stand-alone anticancer drug, ALAN could potentially be used as a component of the STARS device or used as a combination treatment with it.

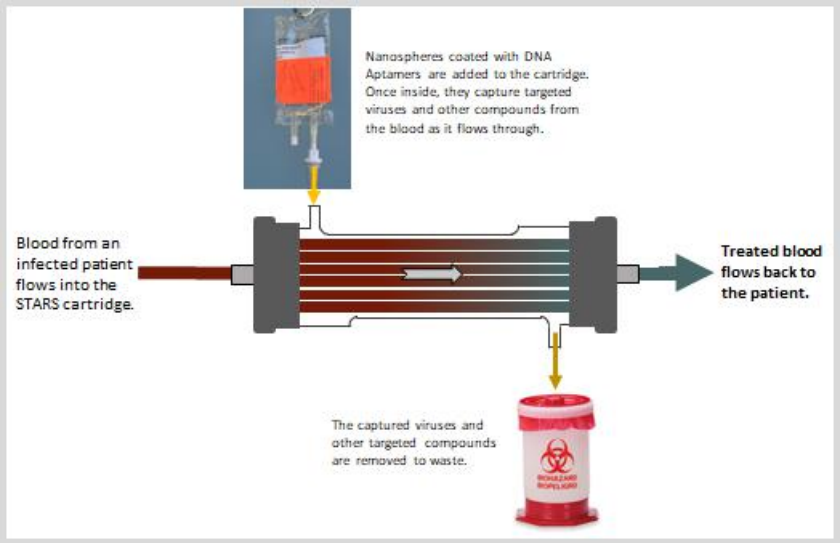
In addition, Qualigen plans to advance clinical trials with AS1411 for the treatment of certain infectious diseases. AS1411 has been shown to be effective in halting the replication of viruses in proof-of-concept in vivo studies performed at the UofL, and Qualigen believes that clinical trials may show it could be used to treat patients who have COVID-19 or other similar viral-based diseases.

***RAS-F***

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 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 US and cause more than 120,000 deaths. There is currently no FDA-approved direct RAS protein inhibitor available. Although drugs that target downstream signaling of RAS are available, they have shown limited clinical activity (most likely because RAS acts like a hub that activates multiple effectors). As such, blocking any single pathway, or even two, typically provides disappointing clinical effect. By contrast, the RAS-F small molecules' intended mechanism of action is to inhibit or block the binding of mutated RAS to their effector proteins, thereby leaving the proteins from mutated RAS unable to cause further harm. Qualigen believes that preventing this binding could stop tumor growth, especially in pancreatic, colorectal and lung cancers.

***STARS™***

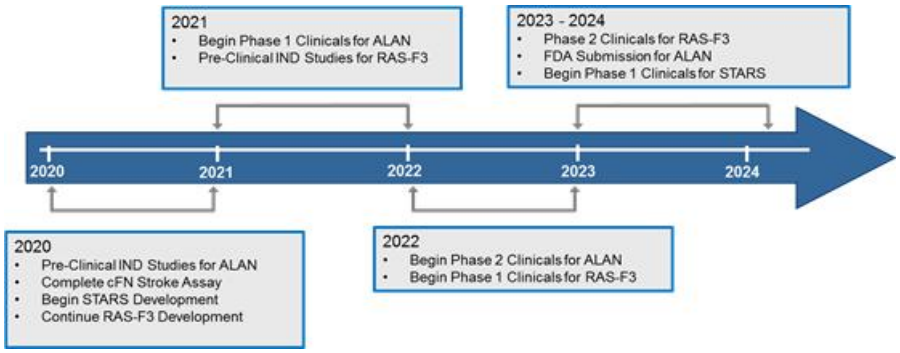
Since its inception, Qualigen's initial research and development focus has been on its FastPack diagnostic system and related core technologies. These same technologies are now the basis for Qualigen's planned expansion into therapeutic applications for the treatment of cancer and infectious disease. Qualigen's Selective Target Antigen Removal System, or STARS, is designed to utilize core expertise in advanced reagents and coatings to remove disease associated agents, including viruses and tumor-produced compounds, directly from a patient's blood. The key components of STARS, membranes coated with target capture reagents, utilize several proprietary processes developed and used in the FastPack product lines. Proprietary STARS cartridges are expected to be designed for use with conventional dialysis or hemofiltration machines to remove immune checkpoints, metastatic cells and inflammation factors from cancer patients' bloodstreams. Qualigen believes STARS can also be used to treat infectious diseases, by removing circulating viruses sufficiently to facilitate patient stabilization and recovery.




*How STARS would remove viruses and tumor-produced compounds from blood.*

**Timeline & Milestones**

Qualigen's expected key milestones for the next several years are listed in the timeline below, which will involve Qualigen's cancer therapeutics product candidates. Phase 1 clinical human trials for ALAN are scheduled to take place in 2021. Assuming that these trials are successful, Qualigen believes that Phase 2 trials could begin as early as 2021. Qualigen expects RAS-F and STARS trials to follow in 2022 and 2023, respectively.



**Regulatory Matters**

Qualigen has demonstrated success in regulatory affairs, having obtained 17 FDA approvals and 26 CE-Marks for its diagnostic products (FastPack analyzers, immunoassays, control kits, calibration kits and verifications kits) to date. However, Qualigen has not obtained FDA or other regulatory approval for any drug candidate.

Qualigen plans to seek to obtain Orphan Drug status for ALAN, which is expected to confer several advantages including faster review and increased market protection, for one or more indications, such as pancreatic cancer, acute myeloid leukemia (AML) and pediatric neuroblastoma.

**Strategic Partners**

Qualigen has licensed key components of and intellectual property covering ALAN and RAS-F and their uses from UofL and Qualigen's scientists are working closely with UofL's development team in order to optimize and prepare ALAN for human trials. A separate team at UofL, funded by Qualigen, is developing RAS-F. In addition, Qualigen has secured the rights to the core AS1411 aptamer from Advanced Cancer Therapeutics, LLC.

In 2016, Qualigen entered into an agreement with Sekisui whereby Sekisui distributes Qualigen's FastPack diagnostic product line worldwide. Qualigen is also developing a novel stroke assay, FastPack cFN, for Prediction Sciences LLC, or Prediction Sciences, to be used as a companion diagnostic for Prediction Science's new stroke drug, and to be launched in Europe in 2020. Qualigen in-licenses several patents from DiaSource Immuno Assays, s.a., and Future Diagnostics, b.v., for reagents that are used in its FastPack Vitamin D Assay.

**Sales Channels**

Qualigen sells its FastPack diagnostic product line worldwide through its distribution partner Sekisui. In the US, Sekisui commercializes the FastPack product line through its own direct sales force and distribution agreements with McKesson Medical-Surgical, Henry Schein Medical, Medline Industries and National Distribution & Contracting, the largest distributors of physician office laboratory products in the US. Outside of the US, Sekisui commercializes the FastPack product line through a network of distributors in Europe, Asia, Middle East, and North Africa. In addition, among its other direct sales accounts, Qualigen sells FastPack products directly to Low T Center, Inc., the largest men's health group in the US, with over 47 locations. Sales to Sekisui accounted for 61% of Qualigen's total revenues during the fiscal year ended March 31, 2020 and sales to Low T Center, Inc. accounted for 34% of Qualigen's total revenues during the fiscal year ended March 31, 2020.

**Manufacturing**

Qualigen conducts internal immunoassay development and production and instrument engineering and assembly at its approximately 25,000 square feet facility in Carlsbad, CA. Qualigen's laboratory and manufacturing practices are governed by a series of internally published Standard Operating Procedures, in accordance with FDA and ISO guidelines. While Qualigen produces many of its own raw materials and sub-components, it also purchases certain materials from third-party suppliers such as Thermo Fisher Scientific, Equitech-Bio, Surmodics, OYC Americas, PerfecSeal, 3M, VWR, Gilson, Impact Project Management, Enstrom, Hi-Tech Products, and Hamamatsu.

**Research and Development**

Qualigen intends to focus its internal research and development on the STARS therapeutic device, while continuing to support the FastPack diagnostic line. In addition, Qualigen is leveraging the scientific and technical resources and laboratory facilities of UofL, through technology licensing and sponsored research agreements, which are focused on Aptamer technology and applications in the field of cancer treatment.

**Competition**

The biotechnology and biopharmaceutical industries, including the oncology subsector, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. Any product candidates that Qualigen successfully develops and commercializes will have to compete with existing products and therapies, as well as new ones that may become available in the future. While Qualigen believes that its ALAN and RAS-F oncology drug candidates, as well as its STARS therapeutic system, along with Qualigen's scientific expertise, provide it with competitive advantages, a wide variety of institutions, including large biopharmaceutical companies, specialty biotechnology companies, academic research departments and public and private research institutions, are actively developing potentially competitive products and technologies. Qualigen expects that its 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 Qualigen is pursuing, in addition to off-label use of current therapeutics and therapeutics in development; newer approaches, such as immunotherapies like chimeric antigen receptor (CAR-T), which attempts to harness the patient's own immune system to fight cancer itself. Many of Qualigen's competitors, either alone or with strategic partners, have substantially greater financial, technical and human resources than it does. Accordingly, its competitors may be more successful than it in obtaining approval for treatments and achieving widespread market acceptance, rendering Qualigen's treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of its competitors. These companies also compete with Qualigen in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient enrollment in clinical studies and acquiring technologies complementary to, or necessary for, Qualigen's programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Qualigen's commercial opportunity could be substantially limited in the event that its competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or less expensive than its comparable products. Competitors may also obtain regulatory approvals before Qualigen, resulting in its competitors building a strong market position in advance of its products' entry, if any. Qualigen believes the factors determining the success of its therapeutics product pipeline will be the efficacy, safety, cost and convenience of its therapeutic product candidates.

The medical diagnostics industry is highly competitive and many companies in this market have substantially greater capital resources, sales, distribution and research and development programs than Qualigen. Although Qualigen believes that it has developed the only automated system designed specifically for performing a broad menu of rapid quantitative immunoassays in physician offices and other point-of-care locations, Qualigen faces competition from companies that currently manufacture larger immunoassay systems used in commercial and hospital laboratories. These systems also are sold to larger physician practices that have their own laboratories and laboratory staff. Qualigen believes that these systems do not offer the ease-of-use and rapid test time that are necessary to effectively penetrate the point-of-care market. In addition, Qualigen believes that some of its competitors are not meeting the same quality and dedication that Qualigen has been known for in this market segment, and rather treat the segment as a venue to "dump" excess inventory.

Qualigen also faces competition in the services sector of the diagnostics market from clinical laboratory companies that currently process the bulk of immunoassay tests performed by office-based physicians.

**Intellectual Property**

Qualigen believes that a considerable portion of its value resides in its intellectual property. Qualigen has developed proprietary methodologies and processes in connection with delivering its products and services. Qualigen protects its intellectual property through a combination of patents, copyrights, trademarks, trade secrets, licenses, non-disclosure agreements and contractual provisions. Qualigen enters into a non-disclosure and confidentiality agreement with each of its employees, consultants and third parties that have access to Qualigen's proprietary technology. Pursuant to assignment of inventions agreements, all of Qualigen's employees and consultants assign to Qualigen all intellectual property rights for the relevant inventions created in connection with their employment or contract with Qualigen. Qualigen currently maintains a patent portfolio of 60 issued, allowed, in-licensed or pending patents covering various aspects of its products and product candidates, in the United States, Europe, Japan, China, Canada and Australia. In addition, Qualigen has two trademark registrations in the United States. There are currently no contested proceedings or third party claims against any Qualigen intellectual property.

**Employees**

As of July 31, 2020, Qualigen had 35 employees, 29 of whom were full-time employees. None of Qualigen's employees is represented by a labor union or covered by a collective bargaining agreement.

**Implications of Being an Emerging Growth Company**

We qualify as an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- we are exempt from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- we are permitted to provide less extensive disclosure about our executive compensation arrangements; and
- we are not required to give our stockholders non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions until such time that we no longer qualify as an emerging growth company.

We may choose to take advantage of some but not all of these reduced burdens. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from our competitors that are public companies, or other public companies in which you have made an investment.

**THE OFFERING**

| | |
|---|---|
| Issuer: | Qualigen Therapeutics, Inc. |
| Common Stock offered by us: | 1,717,106 shares of common stock |
| Warrants offered by us: | Warrants to purchase up to 1,287,829 shares of common stock<br><br>Each warrant will have an exercise price of $6.00 per share, will be exercisable during the period commencing from the date of their issuance and will expire two years from the date of issuance.<br><br>This prospectus also includes the offering of the shares of common stock issuable upon exercise of the warrants. |
| Common Stock to be outstanding immediately after this offering: | 21,028,837 shares |
| Use of proceeds: | We intend to use the net proceeds from this offering primarily for working capital and other general corporate purposes. See the information included under the heading "Use of Proceeds." |
| Risk factors: | Investing in our common stock and warrants involves a high degree of risk. See "Risk Factors" beginning on page S-8 of this prospectus supplement and in our reports and other documents filed with the SEC which are incorporated by reference into this prospectus supplement for an important discussion of risks and uncertainties relevant to an investment in our common stock and warrants. |
| Nasdaq Capital Market Symbol: | Our common stock is listed on The Nasdaq Capital Market under the symbol "QLGN."<br><br>There is no established public trading market for the warrants and we do not expect a market to develop. Without an active trading market, we expect the liquidity of the warrants will be limited. |

The number of shares of our common stock to be outstanding immediately after this offering is based on 19,311,731 shares of our common stock outstanding as of July 31, 2020 and excludes:

- 1,287,829 shares of common stock issuable upon exercise of the warrants issued in connection with this offering;
- 2,444,984 shares of common stock issuable upon the conversion of outstanding Series Alpha Preferred Stock; and
- 12,138,592 shares of common stock issuable upon the exercise of outstanding options and warrants as of immediately before this offering (which figure does not include the 1,287,829 shares of common stock issuable upon exercise of the warrants issued in connection with this offering).

Unless otherwise indicated, this prospectus supplement reflects and assumes the following:

- no exercise of the outstanding warrants and options described above and no exercise of the warrants to be issued in connection with this offering.

## RISK FACTORS

*Investing in our common stock and warrants involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below, together with all of the other information included in this prospectus and the information incorporated by reference herein and therein, including the risks described under similar headings in our reports and other documents filed with the SEC which are incorporated by reference into this prospectus supplement, as may be updated by other filings we make with the SEC after the date of this prospectus supplement.*

*If any of the risks described below, or incorporated by reference into this prospectus, actually occur, our business, financial condition, results of operations and prospects could suffer. In that case, the trading price of our common stock, or the value of our warrants, may decline and you may lose all or part of your investment. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business, financial condition results of operations and prospects. Certain statements below are forward-looking statements. See the information included under the heading "Cautionary Note Regarding Forward-Looking Information."*

**Risks Related to Qualigen's Business, Capital Structure and Strategy**

***Qualigen's future success depends on its ability to keep pace with rapid technological changes that could make its products less competitive or obsolete.***

The biotechnology, pharmaceutical and medical device industries are subject to increasingly rapid technological changes. Qualigen's competitors or others might develop technologies or products that are more effective or commercially attractive than Qualigen's current or future technologies or products, or that render Qualigen's technologies or products less competitive or obsolete. If competitors introduce superior technologies or products and Qualigen cannot make enhancements to its technologies or products to remain competitive, its competitive position, and in turn its business, revenues and financial condition, would be materially and adversely affected. Many of Qualigen's competitors have superior financial and human resources deployed toward research and development efforts. Qualigen's relatively constrained financial and human resources may limit its ability to effectively keep pace with relevant technological changes.

***Qualigen does not currently have enough working capital to execute fully its strategic plan***

Qualigen has a working capital deficit (approximately $3.7 million at March 31, 2020) and will need capital to support its intended development of its therapeutics and drug businesses. Qualigen believes that future financings will be necessary in order for Qualigen to properly execute its strategic plan, which includes not only the development of its therapeutics and drug businesses but also making necessary investments to maintain its legacy diagnostic products business (for example, implementation of a new FastPack pouch production manufacturing line to replace the existing production line). There can be no assurance that such future financings will be able to be obtained (or, if they can be obtained, that they can be obtained on desirable terms).

***Qualigen's financial situation creates substantial doubt whether Qualigen will be able to continue as a going concern.***

Qualigen has suffered recurring losses from operations and has a net working capital deficit and an accumulated deficit at March 31, 2020. Qualigen has ongoing cash needs for its business, such as the need to complete the assembly of the new FastPack pouch production manufacturing line (to replace the existing production line and also enable manufacturing of any FastPack 2.0 pouches). The audit report on Qualigen's audited financial statements include an emphasis of matter paragraph stating that such factors raise substantial doubt about Qualigen's ability to continue as a going concern for a period of one year from June 29, 2020. There is no assurance that the needed additional financing would be available on acceptable terms or at all.

***Qualigen relies on its distribution partner Sekisui. The loss (by Qualigen or by Sekisui as distributor) of one or more key customers may adversely affect Qualigen's operating results.***

Pursuant to a distribution agreement, Qualigen is required to rely on its diagnostics distribution partner Sekisui for most FastPack® distribution worldwide. Qualigen maintains direct distribution for certain house accounts, including Low T Center, Inc. The loss of a significant amount of business from one of Qualigen's major direct or indirect customers would materially and adversely affect its results of operations until such time, if ever, as Qualigen is able to replace the lost business. Significant customers in any one period may not continue to be significant customers in other periods. In any given year, there is a possibility that a customer may account for a significant percentage of Qualigen's total revenue. To the extent that Qualigen is dependent on any single customer, Qualigen is subject to the risks faced by that customer if such risks impede the customer's ability to stay in business and make timely payments to Qualigen.

Under the existing distribution arrangement, which currently extends to May 2022, Sekisui's distributor margin curtails, in effect, Qualigen's actual and potential profitability. So long as the existing distribution arrangement continues, Qualigen will not be able to achieve optimal profitability, and the absence of such additional profits will negatively affect Qualigen's working capital and its ability to pursue its therapeutics opportunities and support its diagnostics business. In addition, third-party distributors are inherently not as motivated to market products and maximize sales as a direct-selling manufacturer would be, and this factor may also negatively affect Qualigen's ability to tap the full potential of its diagnostics business.

On the other hand, if and when Sekisui ceases its distribution of FastPack products, Qualigen would need to incur the costs of re-establishing and maintaining a full direct sales force, and there might also be logistical issues and relationship issues with customers during any transition period. In addition, there would be the risk that a direct sales force assembled and used by Qualigen would not be as efficient and effective as Sekisui's distribution efforts.

***Qualigen's diagnostic products are disadvantaged by reduced Medicare reimbursement and third-party payer pricing.***

Decreases in Medicare and private-insurer reimbursement for diagnostic tests such as Qualigen's in recent years are a negative factor in Qualigen's attempts to maintain and grow its diagnostics business. This factor constrains the price that Qualigen can charge for its diagnostic products and may induce some physician offices, clinics and small hospitals not to offer (or to discontinue offering) Qualigen diagnostic products or particular Qualigen diagnostic products.

***Qualigen's new immunoassay test for COVID-19 antibodies will run only on a new line of FastPack analyzers which is not widely available at the time of launch.***

After submitting notification to the FDA in July 2020 that we intend to commence commercial distribution of our new SARS-CoV-2 IgG antibodies test, we began commercial shipments of the new test in late July 2020. (This test has already been submitted to the FDA for Emergency Use Authorization, but the notification enabled Qualigen to commence sales even before the FDA considers or formally grants Emergency Use Authorization for the test.) However, this new immunoassay test will run only on FastPack PRO System point-of-care diagnostic instruments, which are a new upgraded version of Qualigen's flagship FastPack IP rapid immunoassay diagnostic point-of-care system line. The FastPack PRO System is not expected to achieve wide distribution in the near term, and until it achieves wide distribution the new test will have limited commercial potential.

***COVID -19 adversely affects Qualigen's business and prospects.***

COVID-19 has had, and will continue to have, adverse impacts on the U.S. and world economy, health care systems, personnel availability, supply chains, social and political assumptions, and capital markets. Those impacts are expected to be especially serious for smaller companies such as Qualigen. If another such infectious disease arises and spreads, similar serious impacts could arise. Qualigen's sales of diagnostic products fell significantly in the first quarter of fiscal year 2021 (and net loss increased significantly), as deferral of patients' non-emergency visits to physician offices, clinics and small hospitals sharply reduced demand for FastPack tests; this phenomenon will likely continue to some extent for the duration of the pandemic, although the degree of it will probably vary depending on progress toward suppressing the pandemic, lockdowns and similar responses, and personal and societal behavior changes arising from psychological factors.

**Risks Related to the Design and Development of Qualigen's Therapeutic and Pharmaceutical Product Candidates**

***Qualigen is early in its development efforts of ALAN, RAS-F, and STARS. Qualigen has not successfully completed clinical trials or obtained regulatory approval for any drug candidate or STARS. Qualigen may never obtain approval for any of its drug candidates or STARS.***

Qualigen is early in its development efforts and has not yet begun enrollment in the Phase 1 clinical trials evaluating ALAN, RAS-F or STARS. There can be no assurance that ALAN, RAS-F or STARS will achieve success in their clinical trials or obtain regulatory approval.

Qualigen's ability to generate revenues from drug candidates or STARS will depend on the successful development and eventual commercialization of ALAN, RAS-F or STARS. 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 by the FDA or other clinical trial or similar applications from foreign regulatory authorities for Qualigen's future clinical trials for its 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 its 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 its products;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing and distribution capabilities and launching commercial sales of its products, if and when approved, whether alone or in collaboration with others;
- acceptance of Qualigen's drugs or STARS, 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;

- protecting and enforcing its rights in its intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

Many of these factors are beyond Qualigen's control, and it is possible that none of its drug candidates or STARS will ever obtain regulatory approval even if Qualigen expends substantial time and resources seeking such approval. If Qualigen does not achieve one or more of these factors in a timely manner or at all, it could experience significant delays or an inability to successfully commercialize its drug candidates or STARS, which would materially harm its business. For example, Qualigen's business could be harmed if results of the clinical trials of ALAN, RAS-F, any other drug candidates or STARS vary adversely from its expectations.

***Drug and product development involves a lengthy and expensive process. Qualigen may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of ALAN, RAS-F or STARS.***

Qualigen is unable to predict when or if its drug candidates or STARS 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, Qualigen 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.

Qualigen may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to obtain marketing approval or commercialize its drug candidates or STARS, including:

- regulators or IRBs or ethics committees, or ECs, may not authorize Qualigen or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- Qualigen 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 Qualigen's drug candidates and STARS may produce negative or inconclusive results, and Qualigen may decide, or regulators may require it, to conduct additional clinical trials, delay clinical trials or abandon product development programs;
- the number of patients required for clinical trials for its drug candidates and STARS may be larger than Qualigen anticipates, enrollment in these clinical trials may be slower than Qualigen anticipates, participants may drop out of these clinical trials at a higher rate than Qualigen anticipates or the duration of these clinical trials may be longer than Qualigen anticipates;
- competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in Qualigen's clinical trials;
- Qualigen's third-party contractors may fail to meet their contractual obligations to it in a timely manner, or at all, or may fail to comply with regulatory requirements;
- Qualigen may have to suspend or terminate clinical trials for its drug candidates or STARS for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- Qualigen's drug candidates or STARS may have undesirable or unexpected side effects or other unexpected characteristics, causing it or its investigators, regulators or IRBs/ECs to suspend or terminate the trials;
- the cost of clinical trials for Qualigen's drug candidates and STARS may be greater than it anticipates; and
- the supply or quality of Qualigen's drug candidates, STARS or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of its clinical trials.

Qualigen's product development costs will increase if it experiences delays in preclinical studies or clinical trials or in obtaining marketing approvals. Qualigen does not know whether any of its 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 Qualigen's clinical trials for a variety of reasons.

Significant preclinical or clinical trial delays also could shorten any periods during which Qualigen may have the exclusive right to commercialize its drug candidates or STARS or allow Qualigen's competitors to bring products to market before it does and impair Qualigen's ability to successfully commercialize its drug candidates or STARS and may harm its business and results of operations.

***Any delays in the commencement or completion, or termination or suspension, of Qualigen's future clinical trials, if any, could result in increased costs to Qualigen, delay or limit its ability to generate revenue and adversely affect its commercial prospects.***

Before Qualigen can initiate clinical trials of a drug candidate or STARS, Qualigen must submit the results of preclinical studies to the FDA along with other information as part of an IND or similar regulatory filing.

Before obtaining marketing approval from the FDA for the sale of ALAN, RAS-F, any other drug candidate or STARS, Qualigen 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 Qualigen to conduct additional preclinical studies for any drug candidate or STARS before it allows Qualigen to initiate clinical trials under any IND, which may lead to additional delays and increase the costs of its preclinical development programs.

Any delays in the commencement or completion of Qualigen's ongoing, planned or future clinical trials could significantly affect its product development costs. Qualigen does not know whether its 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 Qualigen's clinical trials or with its recommended dose for any of its 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, STARS or, if applicable, combination therapies for use in clinical trials;
- patients failing to enroll or remain in Qualigen's trial at the rate it expects, 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 Qualigen's drug candidates, STARS or any of their components, including without limitation, Qualigen's 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 Qualigen's clinical trial material or any quality issues that arise with the clinical trial material;
- any changes to Qualigen's manufacturing process that may be necessary or desired;
- Qualigen, or its 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 Qualigen may need to find a substitute contractor, and Qualigen may not be able to use some or all of the data produced by such contractors in support of its marketing applications.

Qualigen could also encounter delays if a clinical trial is suspended or terminated by it, 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 its 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 a pharmaceutical, 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 Qualigen may need to amend clinical trial protocols to comply with these changes. Amendments may require Qualigen to resubmit its clinical trial protocols to IRBs/ECs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

If Qualigen experiences the termination of, or delays in the completion of, any clinical trial of ALAN or RAS-F, or STARS, the commercial prospects of such product will be harmed, and Qualigen's ability to generate product revenues will be delayed. Moreover, any delays in completing its clinical trials will increase its costs, slow down its development and approval process and jeopardize Qualigen's ability to commence product sales and generate revenues, which may harm its business, financial condition, results of operations and prospects significantly.

***If Qualigen experiences delays or difficulties in enrolling patients in its ongoing or planned clinical trials, its receipt of necessary regulatory approval could be delayed or prevented.***

Qualigen may not be able to initiate or continue its ongoing or planned clinical trials for its products if it is 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 Qualigen's competitors may have ongoing clinical trials for products that would treat the same patients as ALAN, RAS-F or STARS, and patients who would otherwise be eligible for Qualigen's clinical trials may instead enroll in clinical trials of its competitors' products. In addition, introduction of new drugs to the market place may have an effect on the number of patients available or timing of the availability of the patients. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- Qualigen's ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of Qualigen's target indications;
- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of Qualigen's products in relation to other available therapies, including any new drugs that may be approved for the indications it is investigating;
- invasive procedures required to enroll patients and to obtain evidence of the product's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;

- whether Qualigen is subject to a partial or full clinical hold on any of its clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- Qualigen's ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Qualigen's inability to enroll a sufficient number of patients for its clinical trials would result in significant delays or may require it to abandon one or more clinical trials altogether. Enrollment delays in its clinical trials may result in increased development costs, which would cause the value of the company to decline and limit its ability to obtain additional financing.

***Adverse side effects or other safety risks associated with ALAN, RAS-F or STARS product candidates could delay or preclude approval, cause Qualigen 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 marketing approval, if any.***

Results of Qualigen's planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by Qualigen's products could result in the delay, suspension or termination of clinical trials by Qualigen or the FDA for a number of reasons. Additionally, due to the high mortality rates of certain cancers and the pretreated nature of many patients in Qualigen's planned clinical trials of ALAN, RAS-F and STARS, a material percentage of patients in these clinical trials may die during a trial. The percentage of patient death, timing of patient death, or cause thereof could impact development of ALAN, RAS-F or STARS. If Qualigen elects or is required to delay, suspend or terminate any clinical trial, the commercial prospects of these products will be harmed and its ability to generate product revenues from these products will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of these products. Any of these occurrences may harm Qualigen's business, prospects, financial condition and results of operations significantly.

Moreover, if Qualigen's products are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, Qualigen 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 its products, if approved. Qualigen may also be required to modify its study plans based on findings in its clinical trials. Many drugs 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 Qualigen tests its drug candidates and STARS in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of its drug candidates and STARS 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. If such side effects become known later in development or upon approval, if any, such findings may harm Qualigen's business, financial condition, results of operations and prospects significantly.

In addition, if any of Qualigen's drug candidates or STARS receives marketing approval, and it or others later identify undesirable side effects caused by treatment with such product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the product;
- Qualigen may be required to recall a product or change the way the product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- Qualigen may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;

- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- Qualigen could be sued and held liable for harm caused to patients;
- the drug could become less competitive; and
- Qualigen's reputation may suffer.

Any of these events could prevent Qualigen from achieving or maintaining market acceptance of its drug candidates or STARS, if approved, and could significantly harm its business, financial condition, results of operations and prospects.

***Qualigen may not be able to obtain or maintain orphan drug designation or exclusivity for its 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 Qualigen seeks 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.

Qualigen intends to obtain orphan drug designation in the United States for use of ALAN for one or more indications, such as pancreatic cancer, acute myeloid leukemia, or AML, and pediatric neuroblastoma. Orphan drug status does not ensure that Qualigen 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.

**Risks Related to Qualigen's Dependence on Third Parties**

***Qualigen relies, and intends to continue to rely, on third parties to conduct its clinical trials and perform some of its 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, Qualigen's development programs may be delayed or subject to increased costs or it may be unable to obtain regulatory approval, each of which may have an adverse effect on its business, financial condition, results of operations and prospects.***

Qualigen is dependent on third parties to conduct its planned clinical trials of ALAN, RAS-F and STARS and preclinical studies, and any preclinical studies and clinical trials of any other products. 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 its development programs. Specifically, Qualigen expects CROs, clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, Qualigen will not be able to control all aspects of their activities. Nevertheless, Qualigen is responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and its reliance on the CROs and other third parties does not relieve it of its regulatory responsibilities. Qualigen and its CROs are required to comply with Good Clinical Practices, or GCP, requirements, which are regulations and guidelines enforced by the FDA for products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If Qualigen or any of its CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in its clinical trials may be deemed unreliable, and the FDA may require Qualigen to perform additional clinical trials before approving its marketing applications. Qualigen cannot assure you that, upon inspection, the FDA will determine that its clinical trials comply with GCPs. In addition, Qualigen's clinical trials must be conducted with product produced under cGMP regulations. Qualigen's failure or the failure of third parties on whom it relies to comply with these regulations may require it to stop and/or repeat clinical trials, which would delay the marketing approval process.

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

Furthermore, these third parties may also have relationships with other entities, some of which may be Qualigen's competitors for whom they may also be conducting clinical trials or other pharmaceutical product development activities that could harm its competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct its clinical trials in accordance with regulatory requirements or Qualigen's stated protocols, Qualigen will not be able to obtain, or may be delayed in obtaining, marketing approvals for ALAN, RAS-F or STARS and will not be able to, or may be delayed in its efforts to, successfully commercialize its products.

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

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

Qualigen may be unable to establish any agreements with third-party manufacturers or to do so on favorable terms. Even if Qualigen is 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 Qualigen's third-party manufacturers or suppliers could be disrupted by conditions unrelated to its 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;
- the possible misappropriation of Qualigen's proprietary information, including its trade secrets and know how;
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for Qualigen;
- carrier disruptions or increased costs that are beyond Qualigen's control; and
- failure to deliver Qualigen's drugs under specified storage conditions and in a timely manner.

Qualigen has only limited arrangements in place with respect to acquiring and manufacturing necessary for clinical trials, and these arrangements do not extend to commercial supply. Qualigen acquires many key materials on a purchase order basis. As a result, it does not have long-term committed arrangements with respect to its product candidates and other materials. If Qualigen obtains marketing approval for any of its product candidates, it will need to establish an agreement for commercial manufacture with a third-party.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Qualigen's failure, or the failure of its third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on Qualigen, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of its products. In addition, Qualigen's third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, Qualigen's clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm its business.

Qualigen's product candidates that it may develop may compete with other product candidates for access to manufacturing facilities. As a result, Qualigen may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for Qualigen.

As Qualigen prepares for later-stage clinical trials and potential commercialization, Qualigen will need to take steps to increase the scale of production of its product candidates. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in its product candidates or in the manufacturing facilities in which its product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any performance failure on the part of Qualigen's existing or future manufacturers could delay clinical development or marketing approval. Qualigen does not currently have arrangements in place for redundant supply or a second source for bulk drug substance for ALAN or RAS-F. If Qualigen's current contract manufacturers for preclinical and clinical testing cannot perform as agreed, Qualigen may be required to replace such manufacturers. Although Qualigen believes that there are several potential alternative manufacturers who could manufacture its product candidates, Qualigen may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer.

Qualigen's current and anticipated future dependence upon others for the manufacture of its product candidates may adversely affect its future profit margins and ability to commercialize any products that obtain marketing approval on a timely and competitive basis.

***Qualigen may enter into collaborations with third parties for the development and commercialization of its products. If those collaborations are not successful, it may not be able to capitalize on the market potential of these products.***

Qualigen may in the future seek third-party collaborators for the development and commercialization of some of its products on a selected basis. Qualigen's likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Qualigen faces significant competition in seeking appropriate collaborators. Its ability to reach a definitive agreement for a collaboration will depend, among other things, upon its 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 Qualigen does enter into any such arrangements with any third parties, it will likely have limited control over the amount and timing of resources that such collaborators dedicate to the development or commercialization of its products. Qualigen's ability to generate revenues from these arrangements will depend on its collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving Qualigen's products would pose numerous risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of Qualigen's products or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product, repeat or conduct new clinical trials or require a new formulation of a product for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Qualigen's products or products if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of its product relative to other products;

- collaborators may not properly obtain, maintain, defend or enforce its intellectual property rights or may use Qualigen's proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate its proprietary information and intellectual property or expose Qualigen to potential litigation or other intellectual property related proceedings;

- disputes may arise between the collaborators and Qualigen that result in the delay or termination of the research, development or commercialization of its products or products or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products;

- collaboration agreements may not lead to development or commercialization of products in the most efficient manner or at all; and

- if a collaborator of were to be involved in a business combination, the continued pursuit and emphasis on Qualigen's product development or commercialization program could be delayed, diminished or terminated.

**Risks Related to Regulatory Approval and Marketing of Qualigen's Product Candidates and Other Legal Compliance Matters**

***The development and commercialization of pharmaceutical products are subject to extensive regulation, and Qualigen may not obtain regulatory approvals for ALAN, RAS-F, STARS 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 ALAN, RAS-F and STARS, as well as any other product candidate that Qualigen may develop in the future, are subject to extensive regulation. Marketing approval of drugs in the United States requires the submission of a NDA to the FDA and Qualigen is not permitted to market any pharmaceutical product candidate in the United States until it obtains 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 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 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 early clinical trials of ALAN, RAS-F, STARS or any other product candidate may not be predictive of the results of Qualigen's 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 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, Qualigen may decide, or regulators may require it, 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 Qualigen's data as favorably as it does, which may further delay, limit or prevent marketing approval.

The FDA could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem Qualigen's product candidate to be adequately safe and effective as compared to available therapies;

- may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of a NDA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in Qualigen's clinical trials represent an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which Qualigen seeks approval;
- may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes or facilities associated with Qualigen's product candidate;
- may change approval policies or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Generally, public concern regarding the safety of pharmaceutical products could delay or limit Qualigen's ability to obtain regulatory approval, result in the inclusion of unfavorable information in its labeling, or require it to undertake other activities that may entail additional costs. Qualigen has not obtained FDA approval for any product other than diagnostic products. This lack of experience may impede its ability to obtain FDA approval in a timely manner, if at all, for ALAN and RAS-F.

If Qualigen experiences delays in obtaining approval or if it fails to obtain approval of ALAN, RAS-F or STARS, its commercial prospects will be harmed and its ability to generate revenues will be materially impaired which would adversely affect its business, prospects, financial condition and results of operations.

***Qualigen's failure to obtain marketing approval in foreign jurisdictions would prevent its product candidates from being marketed abroad, and any approval it is granted for its product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.***

In order to market and sell its products in any jurisdiction outside the United States, Qualigen must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Qualigen may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Qualigen may not be able to submit for marketing approvals and may not receive necessary approvals to commercialize its products in any market.

***Even if Qualigen obtains marketing approval for its product candidates, the terms of approvals and ongoing regulation of its products may limit how it manufactures and markets its products and compliance with such requirements may involve substantial resources, which could materially impair its ability to generate revenue.***

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, which may include the requirement to implement a REMS or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. Qualigen must also comply with requirements concerning advertising and promotion for any of its product candidates for which it obtains marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, Qualigen will not be able to promote any products it develops for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. Qualigen and its contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming Qualigen obtains marketing approval for one or more of its product candidates, it and its contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If Qualigen is not able to comply with post-approval regulatory requirements, it could have the marketing approvals for its products withdrawn by regulatory authorities and its ability to market any future products could be limited, which could adversely affect Qualigen's ability to achieve or sustain profitability. As a result, the cost of compliance with post-approval regulations may have a negative effect on Qualigen's operating results and financial condition.

***Any product candidate for which Qualigen obtains marketing approval will be subject to ongoing enforcement of post-marketing requirements and Qualigen could be subject to substantial penalties, including withdrawal of its product from the market, if Qualigen fails to comply with all regulatory requirements or if it experiences unanticipated problems with its products, when and if any of them are approved.***

Any product candidate for which Qualigen obtains marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the Food, Drug, and Cosmetic Act, or the FDCA, and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Qualigen's failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with its products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking Qualigen's products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that it submits;
- recall of products;
- significant fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- imprisonment or exclusion from participation in federal healthcare programs;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to Qualigen's reputation;

- refusal to permit the import or export of its products;
- product seizure; and/or
- injunctions or the imposition of significant civil, administrative or criminal penalties.

Non-compliance by Qualigen or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, can also result in significant financial penalties.

***Qualigen's relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose it to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which Qualigen obtains marketing approval. Qualigen's current and future arrangements with healthcare providers, third-party payors and customers may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which it conducts research, markets, sells and distributes any products for which it obtains marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the False Claims Act, which can be enforced by civil whistleblower or qui tam actions on behalf of the government, and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also impose obligations, including mandatory contractual terms, on certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act, or ACA, requires certain manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare and Medicaid Services, or CMS, information related to physician payments and other transfers of value and ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to drug pricing. State and local laws require manufacturers to report information related to transfers of value to physicians and other healthcare providers, marketing expenditures and require the registration of pharmaceutical sales representatives. State and non-U.S. laws that also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that Qualigen's business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that its business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Qualigen's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, Qualigen may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of its operations, any of which could adversely affect its ability to operate its business and its results of operations. If any of the physicians or other healthcare providers or entities with whom Qualigen expects to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on Qualigen's business, results of operations, financial condition and prospects.

***Recently enacted and future legislation may increase the difficulty and cost for Qualigen to obtain marketing approval of and commercialize its product candidates and decrease the prices it may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of Qualigen's product candidates, restrict or regulate post-approval activities and affect its ability to profitably sell any product candidates for which it obtains marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that Qualigen receives for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private third-party payors.

In March 2010, the ACA was signed into law and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to Qualigen's potential product candidates are the following:

- annual fees and taxes on manufacturers of certain branded prescription drugs;
- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;

- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report financial arrangements with physicians and teaching hospitals;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges as well as recent efforts by the current U.S. President's administration to repeal or replace certain aspects of the ACA. Since January 2017, the current U.S. President has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas district court judge, as well as the current U.S. President's administration and the CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and Qualigen's business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction, or the Joint Select Committee, to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, triggering the legislation's automatic reduction to several government programs. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, or the ATRA, was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding.

Further, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the current U.S. President's administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. In addition, the current U.S. President's administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although some of these and other measures may require additional authorization to become effective, Congress and the current U.S. President's administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Qualigen expects that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that it receives for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent Qualigen from being able to generate revenue, attain profitability, or commercialize its products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Qualigen cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of its product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject Qualigen to more stringent product labeling and post-marketing testing and other requirements.

***Governments outside of the United States tend to impose strict price controls, which may adversely affect Qualigen's revenues, if any.***

In some countries, particularly the countries of the European Union, or the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, Qualigen may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidate to other available therapies. If reimbursement of Qualigen's products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, its business could be harmed. In addition, the recent United Kingdom referendum on its membership in the EU resulted in a majority of United Kingdom voters voting to exit the EU, often referred to as Brexit. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the United Kingdom determines which EU laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, Qualigen could face significant new costs. It is unclear what the effects of Brexit will be on the successful conduct of future clinical trials in the United Kingdom, and how Brexit may affect the acceptability and use of the results of such clinical trials in the EU. As a result, Brexit could impair Qualigen's ability to transact business in the EU and the United Kingdom, as well as its conduct of future clinical trials in these regions.

***Laws and regulations governing any international operations Qualigen may have in the future may preclude it from developing, manufacturing and selling certain product candidates outside of the United States and require Qualigen to develop and implement costly compliance programs.***

If Qualigen expands its operations outside of the United States, it must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which it plans to operate. The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such third-party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If Qualigen expands its presence outside of the United States, it will require Qualigen to dedicate additional resources to comply with these laws, and these laws may preclude it from developing, manufacturing or selling certain product candidates outside of the United States, which could limit its growth potential and increase its development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***If Qualigen fails to comply with environmental, health and safety laws and regulations, it could become subject to fines or penalties or incur costs that could harm its business.***

Qualigen is subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Qualigen's operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Qualigen's operations also produce hazardous waste products. Qualigen generally contracts with third parties for the disposal of these materials and wastes. Qualigen cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from its use of hazardous materials, Qualigen could be held liable for any resulting damages, and any liability could exceed its resources, including any available insurance.

In addition, Qualigen's leasing and operation of real property may subject it to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

Qualigen could incur significant costs and liabilities which may adversely affect its financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to its facilities or changes to its operating procedures, or injunctions limiting or altering its operations.

Although Qualigen maintains workers' compensation insurance to cover it for costs and expenses it may incur due to injuries to its employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Qualigen does not maintain insurance for environmental liability or toxic tort claims that may be asserted against it in connection with its storage or disposal of biological, hazardous or radioactive materials.

In addition, Qualigen may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations, which are becoming increasingly more stringent, may impair its research, development or production efforts. Qualigen's failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Qualigen is subject to certain U.S. and certain foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. Qualigen can face serious consequences for violations.***

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. Qualigen has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. Qualigen also expects its non-U.S. activities to increase over time. Qualigen expects to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing approvals. Qualigen can be held liable for the corrupt or other illegal activities of its personnel, agents, or partners, even if it does not explicitly authorize or have prior knowledge of such activities.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

**Risks Related to Qualigen's Intellectual Property**

***If Qualigen is unable to obtain and maintain sufficient patent protection for its product candidates and platform technologies, or if the scope of the patent protection is not sufficiently broad, third parties, including its competitors, could develop and commercialize products similar or identical to Qualigen's, and its ability to commercialize its product candidates successfully may be adversely affected.***

Qualigen's commercial success depends significantly on its ability to protect its proprietary technologies that it believes are important to Qualigen's business, including pursuing, obtaining and maintaining patent protection in the United States and other countries intended to cover the composition of matter of its product candidates, for example, ALAN, RAS-F and STARS, the methods of use, related technologies, and other inventions that are important to its business. In addition to patent protection, Qualigen also relies on trade secrets to protect aspects of its business that are not amenable to, or that it does not consider appropriate for, patent protection. If Qualigen does not adequately pursue, obtain, maintain, protect or enforce its intellectual property, third parties, including its competitors and/or collaborators, may be able to erode or negate any competitive advantage Qualigen may have, which could harm its business and ability to achieve profitability.

To protect its proprietary position, Qualigen files patent applications in the United States and abroad related to its product candidates, their methods of manufacture and use. The patent application and approval process is expensive, time-consuming and complex. Qualigen 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 Qualigen will fail to identify patentable aspects of its 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 it may become a party, Qualigen 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 its business.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of Qualigen's patent rights are highly uncertain. Thus, it 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. While Qualigen has filed many patent applications covering aspects of its product candidates and platform technologies, it currently has or has in-licensed 54 issued patents and 13 pending patent applications. Qualigen has not filed its patent applications in every jurisdiction, and some filings are only pending in the United States.

Qualigen's pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until at least one patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. 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, Qualigen cannot be certain that it was the first to file or invent (prior to March 16, 2013) the invention disclosed in any patent application related to its product candidates or technology. In addition, Qualigen enters into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of its research and development output, such as its employees, collaborators, CROs, contract manufacturers, hospitals, independent treatment centers, consultants, independent contractors, suppliers, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing Qualigen's ability to seek patent protection. Furthermore, if third parties have filed patent applications related to Qualigen's product candidates or technology, it may not be able to obtain its own patent rights to those product candidates or technology.

Moreover, because the issuance of a patent, although presumptive, is not conclusive as to its inventorship, scope, validity or enforceability, Qualigen's patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, Qualigen may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging its patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, Qualigen's patent rights, allow third parties to commercialize its technology or products and compete directly with Qualigen, without payment to Qualigen, or result in an inability to manufacture or commercialize products without infringing third-party rights. Moreover, Qualigen may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of exclusivity or in Qualigen's patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit its ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of its technology and products. Such challenges also may result in substantial cost and require significant time from Qualigen's scientists and management, even if the eventual outcome is favorable to it. Any of the foregoing could have a material adverse effect on Qualigen's business, financial condition, results of operations, and prospects.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, Qualigen's patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, Qualigen's intellectual property may not provide it with sufficient rights to exclude others from commercializing products similar or identical to its products. Moreover, some of Qualigen's patents and patent applications may in the future be co-owned with third parties. If Qualigen is unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including Qualigen's competitors, and its competitors could market competing products and technology. In addition, Qualigen may need the cooperation of any such co-owners of its patents in order to enforce such patents against third parties, and such cooperation may not be provided to Qualigen. Any of the foregoing could have a material adverse effect on Qualigen's competitive position, business, financial conditions, results of operations, and prospects.

Qualigen's pending and future patent applications may not result in patents being issued that protect its product candidates, in whole or in part, or that effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of Qualigen's patents or narrow the scope of its patent protection. In addition, the laws of foreign countries may not protect its rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does.

Even if Qualigen's patent applications issue as patents, they may not issue in a form that will provide it with any meaningful protection, prevent competitors or other third parties from competing with it or otherwise provide Qualigen with any competitive advantage. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Consequently, Qualigen does not know whether any of its product candidates or platform technologies will be protectable or remain protected by valid and enforceable patents. Qualigen's competitors and other third parties may be able to circumvent its patents by developing similar or alternative technologies or products in a non-infringing manner. Qualigen's competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with its products. Alternatively, Qualigen's 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 Qualigen are invalid, unenforceable or not infringed. In these circumstances, Qualigen may need to defend or assert its 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 Qualigen's patents invalid or unenforceable, or that its competitors are competing in a non-infringing manner. Thus, even if Qualigen has valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve its business objectives. Any of the foregoing could have a material adverse effect on Qualigen's competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, future patents may be subject to a reservation of rights by one or more third parties. For example, to the extent the research resulting in future patent rights or technologies is funded in the future in part by the U.S. government, the government could have certain rights in any resulting patents and technology, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non-commercial purposes. If the U.S. government then decides to exercise these rights, it is not required to engage Qualigen as its contractor in connection with doing so. These rights may also permit the government to disclose Qualigen's confidential information to third parties and to exercise march-in rights to use or allow third parties to use its licensed technology. The government may also exercise its march-in rights if it determines that action is necessary because Qualigen failed to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, Qualigen's rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of aforementioned proprietary rights could harm Qualigen's competitive position, business, financial condition, results of operations, and prospects.

***Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing Qualigen's ability to protect its products.***

As is the case with other pharmaceutical companies, Qualigen's success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. For example, the Leahy-Smith Act allows third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system from a "first-to-invent" system to a "first-to-file" system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of Qualigen's business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for Qualigen's inventions and increase the uncertainties and costs surrounding the prosecution of its or its collaboration partners' patent applications and the enforcement or defense of or collaboration partners' issued patents, all of which could harm Qualigen's business, results of operations, financial condition and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact Qualigen's ability to enforce its proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on Qualigen's existing patent portfolio and weaken its ability to obtain new patents or to enforce its existing patents and patents that it might obtain in the future.

***Qualigen may become involved in lawsuits or administrative disputes to protect or enforce its patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors and other third parties may infringe, misappropriate or otherwise violate Qualigen's patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement, misappropriation or other violations, Qualigen may be required to file infringement, misappropriation or other violation claims, which can be expensive and time consuming and divert the time and attention of its management and business and scientific personnel. In addition, many of Qualigen's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than it can.

Any claims Qualigen asserts against perceived infringers could provoke these parties to assert counterclaims against Qualigen alleging that it infringes, misappropriates or otherwise violates their patents or their other intellectual property, in addition to counterclaims asserting that Qualigen's patents are invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate or threaten legal proceedings against Qualigen seeking a declaration that certain of its intellectual property is non-infringed, invalid or unenforceable. The outcome of any such proceeding is generally unpredictable. Given the costs involved to litigate, Qualigen may decide to settle rather than dispute such claims if it is more economical to do so.

In any patent infringement proceeding, there is a risk that a court will decide that a patent is invalid or unenforceable, in whole or in part, and that Qualigen does not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that Qualigen does not have the right to stop the other party from using the invention at issue on the grounds that its patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving Qualigen's patents could limit its ability to assert its patents against those parties or other competitors, and may curtail or preclude its ability to exclude third parties from making and selling similar or competitive products. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of Qualigen's patents covering one of its product candidates, Qualigen could lose at least a part, and perhaps all, of the patent protection covering such a product candidate. Competing drugs may also be sold in other countries in which its patent coverage might not exist or be as strong. If Qualigen loses a foreign patent lawsuit alleging its infringement of a competitor's patents, Qualigen could be prevented from marketing its drugs in one or more foreign countries. Any of these occurrences could adversely affect its competitive business position, business prospects and financial condition. Similarly, if Qualigen asserts trademark infringement claims, a court may determine that the marks Qualigen has asserted are invalid or unenforceable, or that the party against whom it has asserted trademark infringement has superior rights to the marks in question. In this case, Qualigen could ultimately be forced to cease use of such trademarks.

Even if Qualigen establishes infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Qualigen's confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If these results are perceived to be negative, it could have a material adverse effect on your investment. Moreover, there can be no assurance that Qualigen will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if Qualigen ultimately prevails in such claims, the monetary cost of such litigation and the diversion of the attention of management and scientific personnel could outweigh any benefit it receives as a result of the proceedings.

Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the United States or foreign authorities, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to Qualigen's patents in such a way that they no longer cover and protect its product candidates or platform technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution of the patent. With respect to the validity of Qualigen's patents, for example, it cannot be certain that there is no invalidating prior art of which Qualigen, its licensors, patent counsel and the patent examiner were unaware during prosecution. Moreover, it is possible that prior art may exist that it is aware of but does not believe is relevant to its current or future patents, but that could nevertheless be determined to render its patents invalid. If a third-party were to prevail on a legal assertion of invalidity or unenforceability, Qualigen could lose at least part, and perhaps all, of the patent protection on one or more of its product candidates. Any such loss of patent protection could have a material adverse impact on Qualigen's business, financial condition, results of operations and prospects.

***Qualigen may not be able to effectively enforce its intellectual property and proprietary rights throughout the world.***

Filing, prosecuting and defending patents with respect to its product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect Qualigen's rights to the same extent as the laws of the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, any future intellectual property license agreements may not always include worldwide rights. Consequently, competitors and other third parties may use Qualigen's technologies in jurisdictions where it has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where Qualigen may obtain patent protection, but where patent enforcement is not as strong as that in the United States and where its ability to enforce patents to stop infringing activities may be inadequate. These products may compete with Qualigen's products in such territories and in jurisdictions where it does not have any patent rights or where any future patent claims or other intellectual property or proprietary rights may not be effective or sufficient to prevent them from competing with Qualigen, which could have a material adverse effect on its business, financial condition, results of operations and prospects.

Moreover, Qualigen's ability to protect and enforce its intellectual property and proprietary rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property and proprietary rights in certain foreign jurisdictions. The legal systems of some countries, including, for example, India, China and other developing countries, do not favor the enforcement of patents and other intellectual property or proprietary rights, particularly those relating to biotechnology products, which could make it difficult for Qualigen to stop the infringement, misappropriation or other violation of its patents or other intellectual property or proprietary rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, Qualigen may not be able to prevent third parties from practicing its inventions in certain countries outside the United States and Europe. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If Qualigen is forced to grant a license to third parties with respect to any patents relevant to its business, its competitive position may be impaired, and its business, financial condition, results of operations, and prospects may be adversely affected. Proceedings to enforce Qualigen's intellectual property and proprietary rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert efforts and resources from other aspects of its business, could put its patents, trademarks or other intellectual property and proprietary rights at risk of being invalidated or interpreted narrowly, could put its patent applications at risk of not issuing, and could provoke third parties to assert claims against it. Qualigen may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while Qualigen intends to protect its intellectual property and proprietary rights in major markets for its products, it cannot ensure that it will be able to initiate or maintain similar efforts in all jurisdictions in which it may wish to market its products. Accordingly, Qualigen's efforts to protect its intellectual property and proprietary rights in such countries may be inadequate.

***If Qualigen is sued for infringing, misappropriating or otherwise violating intellectual property or proprietary rights of third parties, such litigation or disputes could be costly and time consuming and could prevent or delay it from developing or commercializing its product candidates.***

Qualigen's commercial success depends, in part, on its ability to develop, manufacture, market and sell its product candidates and use its proprietary platform and other technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. If any third-party patents, patent applications or other proprietary rights are found to cover Qualigen's product candidates or their compositions, methods of use or manufacturing, Qualigen may be required to pay damages, which could be substantial, and Qualigen would not be free to manufacture or market its product candidates or to do so without obtaining a license, which may not be available on commercially reasonable terms, or at all.

Qualigen may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property or proprietary rights with respect to its product candidates and platform and other technologies it uses in its business. Qualigen's competitors or other third parties may assert infringement claims, alleging that Qualigen's product candidates or platform or other technologies are covered by their patents. Qualigen cannot be certain that it does not infringe existing patents or that it will not infringe patents that may be granted in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because patent claims can be revised before issuance, there may be applications now pending that may later result in issued patents that may be infringed by the manufacture, use or sale of its product candidates. If a patent holder believes Qualigen's product candidates or technology infringes its patent rights, the patent holder may sue even if Qualigen has received patent protection for its technology. Moreover, Qualigen may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom its own patent portfolio may thus have no deterrent effect.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and Qualigen may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property or proprietary rights with respect to its product candidates and platform technologies, including interference proceedings before the USPTO. Third parties may assert infringement, misappropriation or other claims against Qualigen based on existing or future intellectual property or proprietary rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including Qualigen, which patents cover various types of products or methods of using or manufacturing products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If Qualigen were sued for patent infringement, Qualigen would need to demonstrate that its product candidates, products or methods of use, manufacturing or other applicable activities either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and Qualigen may not be successful in doing so. However, proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if Qualigen believes third-party intellectual property claims are without merit, there is no assurance that a court would find in Qualigen's favor on questions of infringement, validity, or enforceability. Even if Qualigen is successful in these proceedings, it may incur substantial costs and the time and attention of management and business and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm its business and operating results. In addition, Qualigen may not have sufficient resources to bring these actions to a successful conclusion.

If Qualigen is found to infringe, misappropriate or otherwise violate a third-party's intellectual property or proprietary rights and is unsuccessful in demonstrating that such intellectual property or proprietary rights are invalid or unenforceable, Qualigen could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate. Alternatively, Qualigen may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, Qualigen may not be able to obtain any required license on commercially reasonable terms or at all. Even if Qualigen were able to obtain such a license, it could be granted on non-exclusive terms, thereby giving its competitors and other third parties access to the same technologies licensed to it. In addition, Qualigen could be found liable for significant monetary damages, including treble damages and attorneys' fees if it is found to have willfully infringed such third-party patent rights. A finding of infringement could prevent Qualigen from commercializing its product candidates or force it to cease some of its business operations, which could materially harm its business. Claims that Qualigen has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business, financial condition, results of operations and prospects.

***Qualigen may be subject to claims by third parties asserting that its employees or consultants or it has misappropriated their intellectual property, or claiming ownership of what Qualigen regards as its own intellectual property.***

Some of Qualigen's employees and consultants are currently or have been previously employed at universities or at other biotechnology or pharmaceutical companies, including its competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although Qualigen tries to ensure that its employees and consultants do not use the proprietary information or know-how of others in their work for it, Qualigen may be subject to claims that it or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties. Litigation may be necessary to defend against such claims. If Qualigen fails in defending any such claims, in addition to paying monetary damages, Qualigen may lose valuable intellectual property or personnel or sustain damages. Such intellectual property could be awarded to a third-party, and Qualigen could be required to obtain a license from such third-party to commercialize its technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if Qualigen is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing would have a material adverse effect on Qualigen's business, financial condition, results of operations and prospects.

In addition, while it is Qualigen's policy to require its employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to it, Qualigen may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that it regards as its own, which may result in claims by or against Qualigen related to the ownership of such intellectual property. In addition, such agreements may not be self-executing such that the intellectual property subject to such agreements may not be assigned to Qualigen without additional assignments being executed, and Qualigen may fail to obtain such assignments. In addition, such agreements may be breached. Accordingly, Qualigen may be forced to bring claims against third parties, or defend claims that they may bring against it to determine the ownership of what it regards as its intellectual property. If Qualigen fails in prosecuting or defending any such claims, in addition to paying monetary damages, Qualigen may lose valuable intellectual property. Even if Qualigen is successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to its senior management and scientific personnel, which would have a material adverse effect on its business, financial condition, results of operations and prospects.

***Rights to improvements to Qualigen's product candidates may be held by third parties.***

In the course of testing its product candidates, Qualigen may enter into agreements with third parties to conduct preclinical and clinical testing, which may provide that improvements to its product candidates may be owned solely by a party or jointly between the parties. If Qualigen determines that rights to such improvements owned solely by a third-party are necessary to commercialize its product candidates or maintain its competitive advantage, Qualigen may need to obtain a license from such third-party in order to use the improvements and continue developing, manufacturing or marketing the product candidates. However, Qualigen may not be able to obtain any required license on commercially reasonable terms or at all. Even if Qualigen were able to obtain such a license, it could be granted on non-exclusive terms, thereby giving its competitors and other third parties access to the same technologies licensed to it. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent Qualigen from commercializing its product candidates or force it to cease some of its business operations, which could materially harm its business. If Qualigen determines that rights to improvements jointly owned between Qualigen and a third-party are necessary to commercialize its product candidates or maintain its competitive advantage, Qualigen may need to obtain an exclusive license from such third-party. If Qualigen is unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other third parties, including its competitors, and Qualigen's competitors could market competing products and technology. In addition, Qualigen may need the cooperation of any such co-owners of its intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided. Any of the foregoing could have a material adverse effect on Qualigen's competitive position, business, financial conditions, results of operations, and prospects.

***The term of Qualigen's patents may be inadequate to protect its competitive position on its products.***

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and other factors relating to any FDA marketing approval Qualigen receives for any of its product candidates, one or more of its U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. Qualigen expects to seek extensions of patent terms in the United States and, if available, in other countries where it is prosecuting patents. In the United States, the Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the normal expiration of the patent, limited to the approved indication (or any additional indications approved during the period of extension), as compensation for patent term lost during the regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug is eligible for the extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with Qualigen's assessment of whether such extensions are available for its patents, may refuse to grant extensions to its patents, or may grant more limited extensions than Qualigen requests. Qualigen may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. If Qualigen is unable to obtain patent term extension or the term of any such extension is less than it requests, its competitors and other third parties may be able to obtain approval of competing products following patent expiration and take advantage of Qualigen's investment in development and clinical trials by referencing its clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on Qualigen's business, financial condition, results of operations and prospects.

***Obtaining and maintaining patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, and Qualigen's patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. In the future, Qualigen may rely on licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to comply with these other requirements with respect to any future licensed patents and patent applications. While an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, Qualigen's competitors and other third parties might be able to enter the market with similar or identical products of technology, which would have a material adverse effect on its business, financial condition, results of operations and prospects.

***If Qualigen is unable to protect the confidentiality of its trade secrets, the value of its technology could be materially adversely affected and its business would be harmed.***

In addition to patent protection and licenses, Qualigen relies on proprietary know-how and trade secret protection and confidentiality agreements to protect proprietary know-how or trade secrets that are not patentable or that it elects not to patent. Qualigen seeks to protect its proprietary know-how in part by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as its employees, consultants, independent contractors, advisors, contract manufacturers, CROs, hospitals, independent treatment centers, suppliers, collaborators and other third parties. Qualigen also enters into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, Qualigen cannot guarantee that it has entered into such agreements with each party that may have or have had access to its trade secrets or proprietary know-how. Additionally, Qualigen's confidentiality agreements and other contractual protections may not be adequate to protect its intellectual property from unauthorized disclosure, third-party infringement or misappropriation. Any party with whom it has executed such an agreement may breach that agreement and disclose Qualigen's proprietary information, including its trade secrets, and Qualigen may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of Qualigen's trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, Qualigen would have no right to prevent such third-party, or those to whom they communicate such technology or information, from using that technology or information to compete with Qualigen. If any of Qualigen's trade secrets were to be disclosed to or independently developed by a competitor or other third-party, its business, financial condition, results of operations and prospects and competitive position could be materially harmed.

***Intellectual property rights do not necessarily address all potential threats.***

The degree of future protection afforded by Qualigen's intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect its business or permit it to maintain its competitive advantage. For example:

- others may be able to make products similar to any product candidates Qualigen may develop or utilize similarly related technologies that are not covered by the claims of the patents that Qualigen may license or may own in the future;

- Qualigen, or any future license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that it licenses or may own in the future;

- Qualigen, or any future license partners or current or future collaborators, might not have been the first to file patent applications covering certain of its or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of Qualigen's technologies without infringing, misappropriating or otherwise violating any of its owned or licensed intellectual property rights;
- it is possible that Qualigen's pending patent applications or those that it may own in the future will not lead to issued patents;
- issued patents that Qualigen holds rights to may be held invalid or unenforceable, including as a result of legal challenges by its competitors or other third parties;
- its competitors or other third parties might conduct research and development activities in countries where Qualigen does not have patent rights and then use the information learned from such activities to develop competitive products for sale in its major commercial markets;
- Qualigen may not develop additional proprietary technologies that are patentable;
- the patents of others may harm Qualigen's business; and
- Qualigen may choose not to file a patent in order to maintain certain trade secrets or know how, and a third-party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on Qualigen's business, financial condition, results of operations and prospects.

**Risks Related to the Commercialization of Qualigen's Product Candidates**

***The incidence and prevalence for target patient populations of Qualigen's drug candidates have not been established with precision. If the market opportunities for its drug candidates are smaller than it estimates or if any approval that Qualigen obtains is based on a narrower definition of the patient population, its revenue potential and ability to achieve profitability will be adversely affected.***

The total addressable market opportunity for ALAN, RAS-F and any other drug candidates Qualigen may develop will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each such drug candidate if its drug candidates are approved for sale for these indications, acceptance by the medical community and patient access, drug pricing and their reimbursement. The number of patients in Qualigen's targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with its drugs, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect its results of operations and its business.

***Even if any of Qualigen's product candidates receives marketing approval, it 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 Qualigen's product candidates receives marketing approval, it 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 Qualigen's product candidates do not achieve an adequate level of acceptance, Qualigen may not generate significant product revenues and it may not become profitable. The degree of market acceptance of its 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 Qualigen's 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;

- Qualigen's ability to offer its 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 Qualigen's 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 Qualigen's 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 Qualigen's products together with other medications.

***Qualigen faces substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than it.***

The development and commercialization of pharmaceutical and therapeutics products is highly competitive. Qualigen faces competition with respect to its current drug candidates, its FastPack and STARS systems, and will face competition with respect to any product candidates that it may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies 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 Qualigen is developing its product candidates and other platform technologies that may be effective in developing therapeutics. Some of these competitive products, therapies and technologies are based on scientific approaches that are similar to Qualigen's 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.

Qualigen's currently marketed FastPack system faces competition from other diagnostic systems and laboratories and Qualigen expects that its oncology drug product candidates and its STARS system will face competition from traditional small or large molecule drugs that target specific cancers that are FDA-approved and marketed for the indications that Qualigen is pursuing, in addition to off-label use of current therapeutics and therapeutics in development; other drug 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 Qualigen is competing or against which it may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing and selling approved products than it does. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of its 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 Qualigen 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, its programs.

Qualigen's commercial opportunity could be reduced or eliminated if its 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 it may develop. Qualigen's competitors also may obtain FDA or other marketing approval for their products more rapidly than any approval it may obtain, which could result in its competitors establishing a strong market position before Qualigen is able to enter the market. In addition, Qualigen's 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 ALAN, RAS-F and STARS are likely to be efficacy, safety, scope and limitations of marketing approval, and availability of reimbursement.

***Even if Qualigen is 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 its 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, Qualigen may be required to conduct a clinical trial that compares the cost-effectiveness of its 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, Qualigen 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, it is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder Qualigen's ability to recoup its investment in one or more drug candidates, even if such drug candidates obtain marketing approval.

Qualigen's 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 is 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 Qualigen commercializes 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 it obtains marketing approval. Obtaining and maintaining coverage and adequate reimbursement for its products may be difficult. Qualigen 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, Qualigen may not be able to successfully commercialize any drug candidate for which it obtains marketing 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 Qualigen's 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 Qualigen's 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. Qualigen's inability to promptly obtain coverage and adequate reimbursement rates from third-party payors for any approved products that it develops could have a material adverse effect on its operating results, ability to raise capital needed to commercialize products and overall financial condition.

In addition, diagnostic tests, such as the screening tests that are used to identify genetic mutations associated with various cancer types, require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, apply to diagnostics.

***Product liability lawsuits against Qualigen could cause it to incur substantial liabilities and to limit commercialization of any products that it may develop.***

Qualigen faces an inherent risk of product liability exposure related to the testing of its drug candidates or products in human clinical trials and will face an even greater risk if it commercializes any products that it may develop. If Qualigen cannot successfully defend itself against any claims that its drug candidates or products caused injuries, it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidates or products that it may develop;
- injury to its reputation and significant negative media attention;

- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of management to pursue its business strategy; and
- the inability to commercialize any products that Qualigen may develop.

Qualigen's current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that it may incur. Qualigen likely will need to increase its insurance coverage as it expands its clinical trials or if it commences commercialization of its product candidates. Insurance coverage is increasingly expensive. Qualigen may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

**Risks Related to Employee Matters, Managing Growth and Other Risks Related to Qualigen's Business**

***Qualigen's future success depends on its ability to retain key employees and to attract, retain and motivate qualified personnel.***

Qualigen is highly dependent on Michael Poirier, its President, Chief Executive Officer and Chairman, Christopher Lotz, its Chief Financial Officer and Vice President of Finance, Dr. Wajdi Abdul-Ahad, its Chief Scientific Officer and Vice President of Research & Development, and Shishir Sinha, its Vice President of Operations, as well as other members of scientific and operations teams. Although Qualigen has entered into employment agreements with its executive officers, each of them may terminate their employment with Qualigen at any time.

Qualigen's ability to compete in the highly competitive pharmaceuticals and therapeutics industries depends upon its ability to attract, retain and motivate highly skilled and experienced personnel with scientific, clinical, regulatory, manufacturing and management skills and experience. Qualigen conducts its operations in Southern California, a region that is home to many other pharmaceutical and therapeutics companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. Qualigen may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical and therapeutics companies. Many of the other pharmaceutical and therapeutics companies against which it competes have greater financial and other resources, different risk profiles and a longer history in the industry than it does. Qualigen's competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit its ability to continue to attract and retain high quality personnel, which could negatively affect its ability to successfully develop and commercialize its product candidates and to grow its business and operations as currently contemplated.

***Qualigen expects that it will need to expand its development and regulatory capabilities as its product candidates progress through the clinic, or additional product candidates are developed; if any products are approved, Qualigen would have to implement sales, marketing and distribution capabilities, and as a result, it may encounter difficulties in managing growth, which could disrupt its operations.***

As of July 31, 2020, Qualigen had 29 full-time employees. Qualigen expects to experience growth in the number of employees and the scope of its operations, particularly in the areas of clinical development, clinical operations, manufacturing, and regulatory affairs as it progresses its ALAN, RAS-F and STARS through the clinic and develops additional product candidates. If any of Qualigen's product candidates receives marketing approval, Qualigen would potentially need to expand into sales, marketing and distribution. To manage anticipated future growth, Qualigen must continue to implement and improve its managerial, operational and financial systems, expand its facilities and continue to recruit and train additional qualified personnel. Qualigen may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. The expansion of Qualigen's operations may lead to significant costs and may divert management and business development resources.

Further, Qualigen currently relies, and for the foreseeable future will continue to rely, in substantial part, on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of its clinical trials and the manufacture of ALAN, RAS-F, STARS or any of its other current or future product candidates. Qualigen cannot assure that the services of such third-party contract organizations, advisors and consultants will continue to be available to it on a timely basis when needed, or that it can find qualified replacements. In addition, if Qualigen is unable to effectively manage its outsourced activities or if the quality or accuracy of the services provided by its vendors or consultants is compromised for any reason, its clinical trials may be extended, delayed or terminated, and Qualigen may not be able to obtain marketing approval of ALAN, RAS-F, STARS or any of its other current or future product candidates or otherwise advance its business. Qualigen cannot assure that it will be able to properly manage its existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If Qualigen is not able to effectively manage growth and expand its organization, it may not be able to successfully implement the tasks necessary to further develop and commercialize ALAN, RAS-F, STARS, or any other product candidates and, accordingly, may not achieve its research, development and commercialization goals.

***Qualigen's employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

Qualigen is exposed to the risk of fraud or other misconduct by its employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to it that violates: (i) FDA regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct, or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to Qualigen's reputation. Qualigen maintains a written code of business conduct and ethics that applies to its directors, officers and employees, including its principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions it takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Qualigen from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against Qualigen, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of its operations, any of which could adversely affect its ability to operate its business and its results of operations.

***Qualigen's internal information technology systems, or those of its third-party CROs or other vendors, contractors or consultants, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of its development programs, compromise sensitive information related to its business or prevent it from accessing critical information, potentially exposing it to liability or otherwise adversely affecting its business.***

Qualigen is increasingly dependent upon information technology systems, infrastructure and data to operate its business. In the ordinary course of business, Qualigen collects, stores and transmits confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that Qualigen does so in a secure manner to maintain the confidentiality and integrity of such confidential information. Qualigen also has outsourced elements of its operations to third parties, and as a result it manages a number of third-party CROs, vendors, and other contractors and consultants who have access to its confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, Qualigen's internal information technology systems and those of its third-party CROs, vendors and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by its employees, third-party CROs, vendors, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise Qualigen's system infrastructure, or that of its third-party CROs, vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Qualigen may not be able to anticipate all types of security threats, nor may it be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. To the extent that any disruption or security breach were to result in a loss of, or damage to, its data or applications, or those of its third-party CROs, vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, Qualigen could incur liability and reputational damage and the further development and commercialization of ALAN, RAS-F, STARS or any other product candidates could be delayed. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance Qualigen maintains against such risks. If the information technology systems of its third-party CROs, vendors and other contractors and consultants become subject to disruptions or security breaches, Qualigen may have insufficient recourse against such third parties and it may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

While Qualigen has not experienced any such system failure, accident or security breach to date, and believes that its data protection efforts and investment in information technology reduce the likelihood of such incidents in the future, it cannot assure you that its data protection efforts and investment in information technology will prevent significant breakdowns, data leakages, breaches in its systems, or those of its third-party CROs, vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon its reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in Qualigen's operations, or those of its third-party CROs, vendors and other contractors and consultants, it could result in a material disruption of its programs and the development of its product candidates could be delayed. In addition, the loss of clinical trial data for ALAN, RAS-F, STARS or any other product candidates could result in delays in Qualigen's marketing approval efforts and significantly increase its costs to recover or reproduce the data. Furthermore, significant disruptions of its internal information technology systems or those of third-party CROs, vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to Qualigen. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding Qualigen's clinical trial subjects or employees, could harm its reputation directly, compel it to comply with federal and/or state breach notification laws and foreign law equivalents, subject it to mandatory corrective action, and otherwise subject it to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on its business.

***Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect Qualigen's operating results and business.***

Qualigen and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (*i.e.*, laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (*e.g.*, Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to Qualigen's operations or the operations of its collaborators. In addition, it may obtain health information from third parties (including research institutions from which it obtains clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, Qualigen could be subject to criminal penalties if it knowingly obtains, uses, or discloses individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation, or the GDPR, may also apply to health-related and other personal information obtained outside of the United States. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the EU, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfer. The GDPR will increase Qualigen's responsibility and liability in relation to personal data that it processes, and it may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. Further, Brexit has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

In addition, California recently enacted the California Consumer Privacy Act, or the CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA will require covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General may now bring enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact Qualigen's business activities and exemplifies the vulnerability of its business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require Qualigen to take on more onerous obligations in its contracts, restrict its ability to collect, use and disclose data, or in some cases, impact its ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect its operating results and business. Moreover, clinical trial subjects about whom Qualigen or its potential collaborators obtain information, as well as the providers who share this information with it, may contractually limit Qualigen's ability to use and disclose the information. Claims that Qualigen has violated individuals' privacy rights, failed to comply with data protection laws, or breached its contractual obligations, even if it is not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm its business.

***Qualigen or the third parties upon whom it depends may be adversely affected by natural disasters and its business continuity and disaster recovery plans may not adequately protect it from a serious disaster.***

Qualigen is located in southern California, and is subject to risks posed by natural disasters, including wildfires, earthquakes and severe weather that may interfere with its operations. Extreme weather events and other natural disasters could severely disrupt its operations, and have a material adverse effect on its 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 its headquarters, that damaged critical infrastructure, such as the manufacturing facilities of its third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for Qualigen to continue its business for a substantial period of time. Any disaster recovery and business continuity plans Qualigen has in place may prove inadequate in the event of a serious disaster or similar event. Qualigen may incur substantial expenses as a result of the limited nature of its disaster recovery and business continuity plans, which could have a material adverse effect on its business.

***U.S. tax legislation may materially adversely affect Qualigen's financial condition, results of operations and cash flows.***

The Tax Act has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate. Many of these changes became effective beginning in 2018, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury Department and the IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

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

From time to time, Qualigen may consider strategic transactions, such as acquisitions of companies, businesses or assets and out-licensing or in-licensing of products, drug candidates or technologies. Additional potential transactions that it may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require it 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 Qualigen's operations and financial results. For example, 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 goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations, systems and personnel of any acquired businesses with its 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.

**Risks Related to this Offering and Ownership of Qualigen's Securities**

***Our use of the offering proceeds may not yield a favorable return on your investment.***

We currently intend to use the net proceeds of this offering for general corporate purposes, including working capital and potential acquisitions. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree. Pending the use of the proceeds in this offering, we intend to invest them. However, the proceeds may not be invested in a manner that yields a favorable or any return. The failure of our management to use such funds effectively could have a material adverse effect on our business, results of operations and financial condition.

***There is no public market for the warrants being offered in this offering.***

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any securities exchange or nationally recognized trading system, including The Nasdaq Stock Market. Without an active market, the liquidity of the warrants will be limited.

***Holders of warrants purchased in this offering will have no rights as common stockholders until such holders exercise their warrants and acquire shares of our common stock.***

Until holders of the warrants being offered in this offering acquire shares of our common stock upon exercise of the warrants, such holders will have no rights with respect to the shares of our common stock underlying the warrants. Upon exercise of the warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

***Certain provisions of the warrants may discourage potential acquisition transactions.***

The "Fundamental Transaction" provisions of the warrants provide advantages to the holders of the warrants (which would not be shared by other Company securityholders) if the Company is acquired or engages in a similar transaction. Such provisions might therefore discourage the Company from being acquired or engaging in a similar transaction, even if such acquisition or transaction would otherwise be in the best interest of the Company and its securityholders generally.

***Qualigen's financial condition and results of operations may fluctuate from quarter to quarter and year to year, which makes them difficult to predict.***

Qualigen expects its 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 Qualigen's control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***Investors purchasing in this offering will incur immediate and substantial dilution.***

If you invest in our common stock and warrants in this offering, your ownership interest will be diluted to the extent of the difference between the combined offering price per share of our common stock and related warrants in this offering and the pro forma net tangible book value per share of our common stock upon completion of this offering.

***Qualigen's reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.***

United States generally accepted accounting principles are subject to interpretation by the Financial Accounting Standards Board or the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on Qualigen's reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations and may require it to make costly changes to its operational processes and accounting systems.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Information set forth in this prospectus and the information incorporated by reference herein and therein may contain various "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All information relative to future markets for our products and trends in and anticipated levels of revenue, gross margins and expenses, as well as other statements containing words such as "believe," "project," "may," "will," "anticipate," "target," "plan," "estimate," "expect" and "intend" and other similar expressions constitute forward-looking statements. These forward-looking statements are subject to business, economic and other risks and uncertainties, both known and unknown, and actual results may differ materially from those contained in the forward-looking statements. Examples of risks and uncertainties that could cause actual results to differ materially from historical performance and any forward-looking statements include, but are not limited to, the risks described under the heading "Risk Factors" on page S-8 of this prospectus supplement and past and subsequent reports filed with the SEC. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. You should read carefully this prospectus, the information incorporated by reference herein and therein and any related free writing prospectus that we have authorized for use in connection with this offering, as described under the heading "Where You Can Find Additional Information," completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify all of our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

## USE OF PROCEEDS

We estimate that our net proceeds from this offering will be approximately $9,525,000, after deducting the placement agent fees and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering, including any net proceeds to us from the exercise of warrants, for working capital and other general corporate purposes and potential acquisitions.

Our expected use of the net proceeds from this offering is based upon our present plans and business condition. As of the date of this prospectus supplement, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of proceeds will vary depending on numerous factors, including the factors described in the section entitled "Risk Factors" beginning on page S-8 of this prospectus supplement. As a result, management will retain broad discretion over the allocation of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

Pending the use of the net proceeds of this offering, we intend to invest the net proceeds in high-quality, short-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## DESCRIPTION OF THE SECURITIES WE ARE OFFERING

### General

Our authorized capital stock consists of 225,000,000 shares of our common stock, $0.001 par value per share, and 15,000,000 shares of preferred stock, $0.001 par value per share, including 7,000 shares that have been designated as Series Alpha Preferred Stock. As of July 31, 2020, there were 19,311,731 shares of our common stock outstanding and 1,808 shares of our Series Alpha Preferred Stock outstanding.

### Common Stock

Our common stock is listed on The Nasdaq Capital Market under the symbol "QLGN." The last reported sale price of our common stock on The Nasdaq Capital Market on July 31, 2020 was $5.72 per share.

Pursuant to the terms of our Certificate of Incorporation, the holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders, except on matters relating solely to terms of preferred stock. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock will be entitled to receive ratably such dividends, if any, as may be declared from time to time by our Board of Directors out of funds legally available therefor. In the event of liquidation, dissolution or winding up, the stockholders will be entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The holders of our common stock will have no preemptive or conversion rights or other subscription rights. There will be no redemption or sinking fund provisions applicable to our common stock.

### Warrants

The shares of our common stock and warrants to be sold in this offering are immediately separable and will be issued separately, but will be purchased together in this offering. The shares of our common stock issuable from time to time upon exercise of the warrants are also being offered pursuant to this prospectus.

The following description summarizes the material terms and provisions of the warrants that we are offering pursuant to this prospectus.

*Number of Warrants*

We are offering warrants to purchase up to 1,287,829 shares of our common stock.

*Exercise Price*

Each warrant has an exercise price of $6.00.

*Term*

The warrants are exercisable commencing from the date of their issuance and will expire two years from the date of issuance.

*Exercisability*

The warrants may be exercised, in whole or in part, by delivering to the Company a facsimile or PDF copy of a written notice of election to exercise the warrant and delivering to the Company cash payment of the exercise price, in the manner set forth in the applicable warrant agreement. The exercise price and the number of shares of our common stock issuable upon exercise of the warrants is subject to adjustment in the event of certain subdivisions and combinations, including by any stock split or reverse stock split, stock dividend, recapitalization or otherwise. In addition, subject to the rules and regulations of Nasdaq, the Company has the right at any time during the term of the warrants to reduce the then-existing exercise price to any amount and for any period of time deemed appropriate by our board of directors.

*Transferability*

Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent. However, as of the date of this prospectus supplement there is no established trading market for the warrants and it is not expected that a trading market for the warrants will develop in the future.

*Listing*

We do not intend to apply for the listing of the warrants on any national securities exchange or other trading market.

*Rights as a Stockholder*

Except as set forth in the warrants or by virtue of such holders' ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise the warrants.

*Limitations on Exercise*

The warrants contain a "blocker" provision such that the warrants cannot be exercised if, after giving effect to such exercise, the holder or any of its affiliates would beneficially own more than 9.99% (which threshold may be decreased or increased, but not above 9.99%, at the election of the holder upon prior written notice to us) of our outstanding common stock immediately after giving effect to the exercise.

*Purchase Rights*

If at any time prior to the expiration of the warrants the Company grants, issues or sells any purchase rights (including options, convertible securities or rights to purchase stock, warrants, securities or other property) pro rata to the record holders of our common stock, each warrant holder will be entitled to acquire the aggregate purchase rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon exercise of his or her warrant. The holder's participation in any such purchase right is subject to the beneficial ownership limitations described above.

*Fundamental Transactions*

In the event of a fundamental transaction, as described in the warrants and generally including any merger or consolidation with or into another entity, the holders of the warrants shall have the right to exercise the warrant after the closing of the fundamental transaction and receive, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock for which the warrant is exercisable immediately prior to such fundamental transaction (without regard to the 9.99% limitation on exercise described above). The Company will cause any successor entity in a fundamental transaction in which the Company is not the survivor to assume in writing all of the obligations of the Company under the warrants.

*Dividends and Other Distributions*

If we declare or make any dividend or other distribution of our assets to holders of shares of our common stock (including any distribution of cash, stock or other securities, property, options, evidence of indebtedness or any other assets), then, subject to certain limitation on exercise described in the warrants, each holder of a warrant shall receive the distributed assets that such holder would have been entitled to receive in the distribution had the holder exercised the warrant immediately prior to the record date for the distribution.

**Holders**

As of July 31, 2020, there were approximately 900 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We have no current plans to declare or pay any dividends and intend to retain all of our future earnings, if any, generated by our operations for the development and growth of our business. Any future decision to pay dividends will be made by our board of directors in its sole discretion and will depend upon our results of operations, financial condition, capital requirements and other factors that our board of directors deems relevant in its informed business judgment.

## DILUTION

If you invest in our common stock and warrants in this offering, your ownership interest will be diluted to the extent of the difference between the combined offering price per share of our common stock and related warrants in this offering and the pro forma net tangible book value per share of our common stock upon completion of this offering, assuming no value is attributed to the warrants, and such warrants are accounted for and classified as equity. Investors purchasing in this offering will incur immediate and substantial dilution.

Our warrant holders and option holders may exercise their respective warrants and options in the future or we may make future equity grants under stock incentive plans. In addition, we may choose to raise additional capital through the sale of common stock, or securities exercisable for or convertible into common stock. To the extent any of these warrants or options are exercised, any new equity awards are issued under the plans, we issue additional shares of common stock (or securities exercisable for or convertible into common stock) in the future, or any of the warrants sold in this offering are exercised, there will be further dilution to investors purchasing in this offering.

## PLAN OF DISTRIBUTION

Pursuant to a Placement Agency Agreement dated as of August 2, 2020, we have engaged A.G.P. to act as our placement agent in connection with this offering pursuant to this prospectus. Under the terms of the Placement Agency Agreement, the placement agent has agreed to be our placement agent, on a reasonable best efforts basis, in connection with the issuance and sale by us of our securities in this takedown from our shelf registration statement. The terms of this offering were subject to market conditions and negotiations between us, the placement agent and prospective investor(s). The Placement Agency Agreement does not give rise to any commitment by the placement agent to purchase any of our securities, and the placement agent will have no authority to bind us by virtue of the Placement Agency Agreement. Further, the placement agent does not guarantee that it will be able to raise new capital in any prospective offering. The placement agent may engage sub-agents or selected dealers to assist with the offering.

The placement agent proposes to arrange for the sale of the securities we are offering pursuant to this prospectus to one or more investors through securities purchase agreements directly between the purchasers and us.

We expect to deliver the shares of our common stock and warrants being offered pursuant to this prospectus supplement on or about August 4, 2020.

We have agreed to pay the placement agent a cash fee equal to 7.0% of the gross proceeds of this offering (or, in the case of one identified investor, 3.5% of the gross proceeds). We anticipate that no investor other than such identified investor will be participating in this offering. We will also pay all costs, fees and expenses incurred by us in connection with the performance of our obligations in connection with this offering. We estimate the total expenses payable by us for this offering will be approximately $475,000, which amount includes, among other things, the placement agent's fees and certain legal fees and expenses of prospective investor(s).

We have agreed to indemnify the placement agent and specified other persons against certain liabilities relating to or arising out of the placement agent's activities under the Placement Agency Agreement and to contribute to payments that the placement agent may be required to make in respect of such liabilities.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants by the placement agent acting as principal. Under these rules and regulations, the placement agent:

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

From time to time, the placement agent may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which it has received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with the placement agent for any further services other than under an "at-the-market" facility. The placement agent also served as a placement agent for us in a previous 2020 registered-direct offering.

Our common stock trades on the Nasdaq Capital Market under the symbol "QLGN."

## LEGAL MATTERS

Certain legal matters relating to this offering will be passed upon for us by Stradling Yocca Carlson & Rauth, a Professional Corporation, San Diego, California.

## FINANCIAL STATEMENTS

The financial statements of Qualigen, Inc. at March 31, 2020 and 2019, and for each of the two years in the period ended March 31, 2020, have been incorporated by reference into this prospectus.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate" into this prospectus information that we file with the SEC in other documents. This means that we can disclose important information to you by referring to other documents that contain that information. Any information that we incorporate by reference into this prospectus is considered part of this prospectus.

Information contained in this prospectus, and information that we file with the SEC in the future and incorporate by reference in this prospectus automatically modifies and supersedes previously filed information, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information. Any statement so modified will be deemed to constitute a part of this prospectus only as so modified, and any statement so superseded will be deemed not to constitute a part of this prospectus.

We incorporate by reference, as of their respective dates of filing, the documents listed below that we have filed with the SEC and any future documents (excluding information furnished pursuant to Items 2.02 and 7.01 of Form 8-K) that we file with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, between the date of this prospectus supplement and the termination of the offering of the securities described in this prospectus supplement, other than, in each case, documents or information deemed to have been "furnished" and not "filed" in accordance with SEC rules:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 31, 2020, as amended by Amendment No. 1 to Form 10-K, filed with the SEC on April 24, 2020;

- our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, as filed with the SEC on May 1, 2020;
- our Current Reports on Form 8-K filed with the SEC on each of January 21, 2020, February 7, 2020, February 21, 2020, March 3, 2020, March 11, 2020, April 16, 2020, May 11, 2020, May 14, 2020, May 19, 2020, May 29, 2020 (as amended June 3, 2020), May 29, 2020 (as amended June 29, 2020), June 11, 2020, July 9 and July 10, 2020; and
- the description of our common stock contained in our registration statement on Form S-4 declared effective April 9, 2020, as amended (File No. 333-236235), and any amendments or reports filed for the purpose of updating such description, including with respect to the 1:25 reverse stock split effected on May 22, 2020.

You may request a free copy of any of the documents incorporated by reference into this prospectus. Requests should be made to:

Christopher L. Lotz
Vice President of Finance, Chief Financial Officer
Qualigen Therapeutics, Inc.
2042 Corte Del Nogal
Carlsbad, California 92011

Exhibits to the filings will not be sent, however, unless those exhibits have specifically been incorporated by reference in this prospectus.

You should rely only on the information contained in this prospectus, any document incorporated by reference herein or therein, or any free writing prospectuses we may provide to you in connection with this offering. Neither we nor the placement agent have authorized anyone to provide you with any different information. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide to you.

The information contained in this prospectus, any document incorporated by reference herein or therein, and in any free writing prospectuses we may provide to you in connection with this offering is accurate only as of the date such information is presented. Our business, financial condition, results of operations and prospects may have changed since those respective dates.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports and other information with the SEC. Our filings with the SEC also are available from the SEC's internet site at http://www.sec.gov, which contains reports, proxy and information statements, and other information regarding issuers that file electronically.

This prospectus is part of a registration statement that we filed with the SEC. As permitted by SEC rules, this prospectus forms a part of the registration statement, but does not contain all of the information that is included in the registration statement. The registration statement contains more information regarding us and our securities, including certain exhibits. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC's website.

**1,717,106 Shares of Common Stock**

**Warrants to Purchase 1,287,829 Shares of Common Stock**

**1,287,829 Shares of Common Stock Underlying Warrants**


**QUALIGEN THERAPEUTICS, INC.**

**PROSPECTUS SUPPLEMENT**

# A.G.P.

August 2, 2020