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

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2021

Or

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

For the transition period from _____ to _____

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

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

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

(760) 918-9165
(Registrant's telephone number, including area code)

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

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

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

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

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

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		Emerging growth company	[ ]

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

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

As of May 7, 2021, there were 28,833,059 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	March 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 21,947,912	$ 23,976,570
Accounts receivable, net	862,235	615,757
Inventory, net	885,855	953,458
Prepaid expenses and other current assets	1,219,759	2,678,894
Total current assets	24,915,761	28,224,679
Right-of-use assets	376,616	430,795
Property and equipment, net	224,932	247,323
Equipment held for lease, net	10,687	17,947
Intangible assets, net	189,294	187,694
Other assets	18,334	18,334
Total Assets	**$ 25,735,624**	**$ 29,126,772**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 485,551	$ 500,768
Accrued expenses and other current liabilities	1,869,424	746,738
Notes payable, current portion	10,683	131,766
Deferred revenue, current portion	381,366	486,031
Lease liability, current portion	262,601	254,739
Warrant liabilities	6,187,200	8,310,100
Total current liabilities	9,196,825	10,430,142
Notes payable, net of current portion	4,923	6,973
Lease liability, net of current portion	168,254	236,826
Deferred revenue, net of current portion	135,235	158,271
Total liabilities	9,505,237	10,832,212
Stockholders' equity		
Series Alpha convertible preferred stock, $0.001 par value; 7,000 shares authorized; 180 shares issued and outstanding as of March 31, 2021 and December 31, 2020	1	1
Common stock, $0.001 par value; 225,000,000 shares authorized; 28,833,059 shares and 27,296,061 shares issued and outstanding as of March 31, 2021 and December 31, 2020	28,833	27,296
Additional paid-in capital	86,721,672	85,114,755
Accumulated deficit	(70,520,119)	(66,847,492)
Total stockholders' equity	16,230,387	18,294,560
Total Liabilities and Stockholders' Equity	**$ 25,735,624**	**$ 29,126,772**

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

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

	For the Three Months Ended March 31,	
	2021	**2020**
REVENUES		
Net product sales	$ 1,420,842	$ 1,411,755
License revenue	478,654	—
Collaborative research revenue	—	45,000
Total revenues	1,899,496	1,456,755
EXPENSES		
Cost of product sales	1,202,479	991,651
General and administrative	2,873,939	918,379
Research and development	3,499,373	238,059
Sales and marketing	136,587	92,262
Total expenses	7,712,378	2,240,351
LOSS FROM OPERATIONS	(5,812,882)	(783,596)
OTHER (INCOME) EXPENSE, NET		
Gain on change in fair value of warrant liabilities	(2,122,900)	—
Interest (income) expense, net	(17,343)	90,757
Other income, net	(542)	(1,158)
Total other (income) expense, net	(2,140,785)	89,599
LOSS BEFORE PROVISION FOR INCOME TAXES	(3,672,097)	(873,195)
PROVISION FOR INCOME TAXES	530	(619)
NET LOSS	(3,672,627)	(872,576)
Net loss per common share, basic and diluted	$ (0.13)	$ (0.16)
Weighted—average number of shares outstanding, basic and diluted	28,165,796	5,602,214

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

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

	Series Alpha Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount $	Shares	Amount $			
Balance at December 31, 2020	180	$ 1	27,296,061	$ 27,296	$ 85,114,755	$ (66,847,492)	$ (18,294,560)
Stock issued upon cash-exercise of warrants	—	—	1,319,625	1,320	243,261	—	244,581
Stock issued upon net-exercise of warrants	—	—	192,373	192	(192)	—	—
Stock issued for professional services	—	—	25,000	25	101,725	—	101,750
Stock-based compensation	—	—	—	—	1,262,123	—	1,262,123
Net Loss	—	—	—	—	—	(3,672,627)	(3,672,627)
Balance at March 31, 2021	180	$ 1	28,833,059	$ 28,833	$ 86,721,672	$ (70,520,119)	$ 16,230,387

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Series D-1 Convertible Preferred Stock		Series Alpha Convertible Preferred Stock		Common Stock		Additional		
	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Paid-In Capital	Accumulated Deficit	Total
Balance at December 31, 2019	2,412,887	$ 24,129	7,707,736	$ 77,077	3,300,715	$ 33,007	1,508,305	$ 15,083	643,511	$ 6,435	—	$ —	5,602,214	$ 56,026	$ 45,153,733	$ (46,428,550)	$ (1,063,060)
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	7,866	—	7,866
Net Loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(872,576)	(872,576)
Balance at March 31, 2020	2,412,887	$ 24,129	7,707,736	$ 77,077	3,300,715	$ 33,007	1,508,305	$ 15,083	643,511	$ 6,435	—	$ —	5,602,214	$ 56,026	$ 45,161,599	$ (47,301,126)	$ (1,927,770)

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

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

	For the Three Months Ended March 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,672,627)	$ (872,576)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	27,453	50,269
Amortization of right-of-use assets	54,179	—
Accounts receivable reserves and allowances	8,490	7,329
Inventory reserves	29,615	25,960
Common stock issued for professional services	101,750	—
Stock-based compensation	1,262,123	7,866
Gain on change in fair value of warrant liabilities	(2,122,900)	—
Changes in operating assets and liabilities:		
Accounts receivable	(254,968)	441,369
Inventory and equipment held for lease	107,588	(28,430)
Prepaid expenses and other assets	1,459,135	4,136
Accounts payable	(15,217)	175,922
Accrued expenses and other current liabilities	1,122,686	618,597
Lease liability	(60,710)	—
Deferred revenue	(127,701)	(22,728)
Net cash (used in) provided by operating activities	(2,081,104)	407,714
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(62,265)	(1,729)
Payments for patents and licenses	(6,737)	(93,732)
Net cash used in investing activities	(69,002)	(95,461)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from the issuance of notes payable	—	290,198
Proceeds from warrant exercises	244,581	—
Principal payments on notes payable	(123,133)	(578,026)
Net cash provided by (used in) financing activities	121,448	(287,828)
Net change in cash and cash equivalents	(2,028,658)	24,425
CASH AND CASH EQUIVALENTS – beginning of period	23,976,570	128,696
CASH AND CASH EQUIVALENTS – end of period	$ 21,947,912	$ 153,121
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 831	$ 19,473
Taxes	$ 100	$ 500
NONCASH FINANCING AND INVESTING ACTIVITIES:		
Net transfers to inventory from equipment held for lease	$ —	$ 5,439

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

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

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

Organization

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

Qualigen, Inc. was determined to be the accounting acquirer in a reverse recapitalization based upon the terms of the merger and other factors. All references to financial figures of the Company presented in the accompanying condensed consolidated financial statements and in these Notes through May 22, 2020 are to those of Qualigen, Inc. All references to financial figures after May 22, 2020 are to those of Qualigen Therapeutics, Inc. and Qualigen, Inc.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules of the Securities and Exchange Commission ("SEC") applicable to interim reports of companies filing as a smaller reporting company. These financial statements should be read in conjunction with the audited financial statements and notes thereto contained in the Company's Transition Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC on March 31, 2021. In the opinion of management, the accompanying condensed consolidated interim financial statements include all adjustments necessary in order to make the financial statements not misleading. The results of operations for interim periods are not necessarily indicative of the results to be expected for the full year or any other future period. Certain notes to the financial statements that would substantially duplicate the disclosures contained in the audited financial statements for the most recent fiscal year as reported in the Company's Transition Report on Form 10-K have been omitted. The accompanying condensed consolidated balance sheet at March 31, 2021 has been derived from the audited balance sheet at December 31, 2020 contained in such Form 10-K.

Principles of Consolidation

The Company's unaudited interim condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP. The Company views its operations and manages its business in one operating segment. All long-lived assets of the Company reside in the US.

Accounting Estimates

Management uses estimates and assumptions in preparing its condensed consolidated financial statements in accordance with U.S. GAAP. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. The most significant estimates relate to the estimated fair value of warrant liabilities, stock-based compensation, write-off of patents and licenses, amortization and depreciation, inventory reserves, allowances for doubtful accounts and returns, and warranty costs. Actual results could vary from the estimates that were used.

Cash and Cash Equivalents

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

The Company maintains its cash and cash equivalents in bank deposits which at times may exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risks on cash and cash equivalents.

Inventory, Net

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

Long-Lived Assets

The Company assesses potential impairments to its long-lived assets when there is evidence that events or changes in circumstances indicate that assets may not be recoverable. An impairment loss would be recognized when the sum of the expected future undiscounted cash flows is less than the carrying amount of the assets. The amount of impairment loss, if any, will generally be measured as the difference between the net book value of the assets and their estimated fair values. During the three months ended March 31, 2021 and 2020, no such impairment losses have been recorded.

Accounts Receivable, Net

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

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

Accounts receivable is comprised of the following at:

	March 31, 2021	December 31, 2020
Accounts Receivable	$ 867,617	$ 629,630
Less Allowance	(5,382)	(13,873)
	$ 862,235	$ 615,757

Research and Development

The Company expenses research and development costs as incurred.

Shipping and Handling Costs

The Company includes shipping and handling fees billed to customers in net sales. Shipping and handling costs associated with inbound and outbound freight are generally recorded in cost of sales which totaled approximately $30,000 and $31,000, respectively, for the three months ended March 31, 2021 and 2020. Other shipping and handling costs included in general and administrative, research and development, and sales and marketing expenses totaled approximately $1,000 and $2,000 for the three months ended March 31, 2021 and 2020, respectively.

Revenue from Contracts with Customers

Effective April 1, 2020, the Company adopted Accounting Standards Codification ("ASC") Topic 606 ("ASC 606"), Revenue from Contracts with Customers, using the modified retrospective approach. The adoption of ASC 606 did not have a material impact on the measurement or on the recognition of revenue of contracts for which all revenue had not been recognized as of April 1, 2020. Therefore, no cumulative adjustment has been made to the opening balance of accumulated deficit at April 1, 2020. The comparative information has not been restated and continues to be reported under the accounting standards in effect for the periods presented.

The core principle of ASC 606 is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services.

Product Sales

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

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

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

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

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

License Revenue

The Company enters into out-license agreements with counterparties to develop and/or commercialize its products in exchange for nonrefundable upfront license fees and/or sales-based royalties.

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from nonrefundable upfront fees allocated to the license when the license is transferred to the customer and the customer can benefit from the license. For licenses that are bundled with other performance obligations, management uses judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition. During the three months ended March 31, 2021 and 2020, the Company recognized license revenue of $479,000 and $0, respectively.

Collaborative Research Revenue

Prior to the adoption of ASC 606, the Company recognized research revenue over the term of various agreements, as negotiated contracted amounts were earned or reimbursable costs were incurred related to those agreements. Negotiated contracted amounts were earned in relative proportion to the performance required under the applicable contracts. Any amounts received prior to satisfying these revenue recognition criteria were recorded as deferred revenue.

To determine revenue recognition for contracts with customers within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies the relevant performance obligations.

Collaborative research revenue is recognized as research services are performed over the development periods for each agreement. During the three months ended March 31, 2021 and 2020, the Company recognized collaborative research revenue of $0 and $45,000, respectively.

Contract Balances

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

Prior to the adoption of ASC 606 effective April 1, 2020 (using the modified retrospective approach), the Company accounted for its revenue arrangements under ASC 605, Revenue Recognition ("ASC 605"). Under ASC 605, revenue arrangements with multiple deliverables were evaluated for proper accounting treatment. In these arrangements, the Company recorded revenue as separate units of accounting if the delivered items have value to the customer on a stand-alone basis, if the arrangement includes a general right of return relative to the delivered items, and if delivery or performance of the undelivered items is considered probable and substantially within the Company's control.

Under ASC 605, revenues from product sales which included both the analyzer and various immunoassay products ("reagents") were generally recognized upon shipment, as no significant continuing performance obligations remained post shipment. Cash payments received in advance were classified as deferred revenue and recorded as a liability. The Company was generally not contractually obligated to accept returns, except for defective products. Revenue was recorded net of an allowance for estimated returns.

Multiple element arrangements included contracts that combined both the Company's analyzer and a customer's future reagent purchases under a single contract. In some sales contracts, the Company provided analyzers at no charge to customers. Title to the analyzer was maintained by the Company and the analyzer was returned by the customer to the Company at the end of the purchase agreement.

During the three months ended March 31, 2021 and 2020, product sales are stated net of an allowance for estimated returns of approximately $0 and $12,000, respectively.

Deferred Revenue

Prior to the adoption of ASC 606, payments received in advance from customers pursuant to certain collaborative research and license agreements, deposits against future product sales, multiple element arrangements and extended warranties are recorded as a current or non-current deferred revenue liability based on the time from the balance sheet date to the future date of revenue recognition. The adoption of ASC 606 had no material effect on deferred revenue.

Operating Leases

The Company adopted ASC Topic 842, *Leases* ("Topic 842") in the nine-months transition period ended December 31, 2020. In accordance with the guidance in Topic 842, the Company recognizes lease liabilities and corresponding right-of-use-assets for all leases with terms of greater than 12 months. Leases with a term of 12 months or less will be accounted for in a manner similar to the guidance for operating leases prior to the adoption of Topic 842. Refer to Recent Accounting Pronouncements below and Note 9, Leases for more information.

Property and Equipment, Net

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

Machinery and equipment	5 years
Computer equipment	3 years
Molds and tooling	5 years
Office furniture and equipment	5 years

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

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

Intangible Assets, Net

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

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

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

The carrying value of the patents of approximately $172,000 and $169,000 at March 31, 2021 and December 31, 2020, respectively, are stated net of accumulated amortization of approximately $307,000 and $303,000, respectively. Amortization of patents charged to operations for the three months ended March 31, 2021 and 2020 were approximately $3,000 for each period. Total future estimated amortization of patent costs for the five succeeding years is approximately $11,000 for the remaining nine months in the year ending December 31, 2021, approximately $15,000 for each of the years ending December 31, 2022 through 2023, approximately $14,000 for year 2024, approximately $11,000 for year 2025 and approximately $106,000 thereafter.

The carrying value of the in-licenses of approximately $17,000 and $19,000 at March 31, 2021 and December 31, 2020 are stated net of accumulated amortization of approximately $402,000 and $400,000, respectively. Amortization of licenses charged to operations for each of the three month periods ended March 31, 2021 and 2020 was approximately $2,000. Total future estimated amortization of license costs is approximately $5,000 for the remaining nine months in the year ending December 31, 2021, approximately $7,000 for the year ending December 31, 2022 and approximately $5,000 for the year ending December 31, 2023.

Derivative Financial Instruments and Warrant Liabilities

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

Fair Value Measurements

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

- Level 1 - Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date;
- Level 2 - Inputs other than quoted prices that are observable for the assets or liability either directly or indirectly, including inputs in markets that are not considered to be active; and
- Level 3 - Inputs that are unobservable.

Fair Value of Financial Instruments

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

Stock-Based Compensation

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

Income Taxes

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

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

Sales and Excise Taxes

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

Warranty Costs

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

Accrued warranty liabilities were approximately $51,000 and $25,000, respectively, at March 31, 2021 and December 31, 2020 and are included in accrued expenses and other current liabilities on the balance sheets. Warranty costs were approximately $25,000 and $27,000 for the three months ended March 31, 2021 and 2020, respectively, and are included in cost of product sales in the statements of operations.

Recent Accounting Pronouncements

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

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. ASU 2020-06 is effective for the Company for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020 and adoption must be as of the beginning of the Company's annual fiscal year. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) ("Topic 606"). The guidance in Topic 606 provides that an entity should recognize revenue to depict the transfer of goods or services provided and establishes the following steps to be applied by an entity: (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies the performance obligation. Topic 606 was effective for fiscal years beginning after December 15, 2019 for the Company, based on the issuance of ASU 2020-05, which provided deferral of the effective date for an additional one year in response to the coronavirus (COVID-19) pandemic. The Company adopted the new revenue standard as of April 1, 2020 using the modified retrospective approach. The adoption of ASU 2014-09/Topic 606 did not have a material impact on its financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, which expands the scope of Topic 718, Compensation—Stock Compensation, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU No. 2018-07 supersedes Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees. The amendments in ASU No. 2018-07 are effective beginning in 2020, with early adoption permitted, but no earlier than a company's adoption date of Topic 606 Revenue from Contracts with Customers. The Company elected to adopt ASU 2018-07 as of April 1, 2020. The adoption did not require the Company to restate previously reported results.

In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842) Targeted Improvements ("Topic 842"), which provides for an alternative transition method by allowing companies to continue to use the legacy guidance in Topic 840, Leases, including its disclosure requirements, in the comparative periods presented in the year of adoption of the new leases standard and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption rather than the earliest period presented. The Company adopted the standard as of April 1, 2020 and the most significant impact was the recognition of a right-of-use asset and lease liability for the Company's sole operating lease—the Company had no finance leases. Adoption of Topic 842 did not require the Company to restate previously reported results as it elected to apply a modified retrospective approach at the beginning of the period of adoption rather than at the beginning of the earliest comparative period presented.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement," an amendment to the accounting guidance on fair value measurements. The guidance modifies the disclosure requirements on fair value measurements, including the removal of disclosures of the amount of and reasons for transfers between Level 1 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation processes for Level 3 fair value measurements. The guidance also adds certain disclosure requirements related to Level 3 fair value measurements. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company adopted ASU No. 2018-13 on April 1, 2020 and the adoption of this guidance did not have a material impact on its financial statements.

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

NOTE 2 — LIQUIDITY

The Company has incurred recurring losses from operations and has an accumulated deficit at March 31, 2021, and the Company expects to continue to incur losses subsequent to the balance sheet date of March 31, 2021. The Company's reverse recapitalization transaction with Ritter closed in May 2020 together with an associated new equity capital raise of approximately $4.0 million, and approximately $1.9 million in convertible notes payable were converted into shares of the Company's capital stock. In July, August and December 2020, the Company raised an additional $30.0 million through three Securities Purchase Agreements with a single institutional investor (see Note 11). Based on the Company's current cash position, currently planned expenditures and level of operations, the Company believes it has sufficient capital to fund operations for the 12-month period subsequent to the issuance of the interim financial information. However, there is no assurance that profitable operations will ever be achieved, or if achieved, could be sustained on a continuing basis. Also, beyond such 12-month period, planned research and development activities, capital expenditures, clinical and pre-clinical testing, and commercialization activities of the Company's products are expected to require significant additional financing. Additional financing may not be available on acceptable terms or at all.

NOTE 3 — INVENTORY, NET

Inventory, net consisted of the following at March 31, 2021 and December 31, 2020:

	March 31, 2021	December 31, 2020
Raw materials	$ 614,926	$ 579,765
Work in process	182,550	309,826
Finished goods	88,379	63,867
	$ 885,855	$ 953,458

NOTE 4 — PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following at March 31, 2021 and December 31, 2020:

	March 31, 2021	December 31, 2020
Prepaid insurance	$ 955,019	$ 1,307,864
Prepaid manufacturing expenses	57,117	1,181,029
Prepaid investor relations expenses	133,501	150,000
Other prepaid expenses	74,122	40,001
	$ 1,219,759	$ 2,678,894

NOTE 5 — PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following at March 31, 2021 and December 31, 2020:

	March 31, 2021	December 31, 2020
Machinery and equipment	$ 2,401,470	$ 2,401,470
Construction in progress–equipment	89,122	104,400
Computer equipment	451,808	443,865
Leasehold improvements	321,033	321,033
Molds and tooling	260,002	260,002
Office furniture and equipment	138,699	138,699
	3,662,134	3,669,469
Less Accumulated depreciation	(3,437,202)	(3,422,146)
	$ 224,932	$ 247,323

Depreciation expense relating to property and equipment was approximately $15,000 and $10,000 for the three months ended March 31, 2021 and 2020, respectively.

NOTE 6 — ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following at March 31, 2021 and December 31, 2020:

	March 31, 2021	December 31, 2020
Board compensation	$ 15,833	$ 15,091
Vacation	248,071	230,457
Royalties	17,193	491
Research and development	882,040	237,504
Professional fees	181,636	58,261
Warranty costs	51,487	24,871
Payroll	69,358	4,566
Patent and license fees	—	7,204
Franchise, Sales and use taxes	139,257	30,353
Income taxes	6,256	3,326
Interest	—	—
Other	258,293	134,614
	$ 1,869,424	$ 746,738

NOTE 7 — NOTES PAYABLE

Notes payable consisted of the following at March 31, 2021 and December 31, 2020:

	March 31, 2021	December 31, 2020
Insurance Financing Agreement with a finance company, monthly payments of $119,943 including interest of 4.54% per annum; secured by an insurance policy; paid January 2021	$ —	$ 119,491
Equipment Financing Agreement with a bank, monthly payments of $720 including imputed interest at 6.95% per annum; secured by laboratory equipment; due October 2022	12,913	14,826
Equipment Financing Agreement with a bank, monthly payments of $596 including imputed interest at 6.59% per annum; secured by manufacturing equipment; due July 2021	2.693	4,422
	15,606	138,739
Less current portion	(10,683)	(131,766)
Notes Payable, net of current portion	$ 4,923	$ 6,973

Future maturities of notes payable are as follows as of March 31, 2021:

Year Ending December 31,	Amount
2021 (nine months)	$ 8,633
2022	6,973
Total balance	$ 15,606

NOTE 8 – WARRANT LIABILITIES

In 2004, the Company issued warrants to various investors and brokers for the purchase of Series C preferred stock in connection with a private placement (the "Series C Warrants"). The Series C Warrants were subsequently extended and, upon closing of the reverse recapitalization transaction with Ritter, exchanged for warrants to purchase common stock of the Company, pursuant to the Series C Warrant terms as adjusted. The Series C Warrants were classified as liabilities, but had minimal fair value prior to the merger with Ritter.

In exchange for the Series C Warrants, upon closing of the merger with Ritter, the holders received warrants to purchase an aggregate of 4,713,490 shares of the Company's common stock at $0.72 per share, subject to adjustment. As of March 31, 2021, the warrants received in exchange for the Series C Warrants have remaining terms ranging from 2.7 to 3.2 years. The warrants were determined to be liability-classified pursuant to the guidance in ASC 480 and ASC 815-40, resulting from inclusion of a leveraged ratchet provision for subsequent dilutive issuances.

The following table summarizes the activity in the warrants received in exchange for the Series C Warrants for the three months ended March 31, 2021:

	Common Stock Warrants (received in exchange for the Series C Warrants)			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2020	3,378,596	$ 0.72		
Exercised	(473,608)	0.72		
Forfeited	(36,097)	0.72		
Expired	—	—		
Granted	—	—		
Total outstanding – March 31, 2021	2,868,891	$ 0.72		
Exercisable	2,868,891	$ 0.72	$ 0.72	2.75

Of the 473,608 shares issued upon the exercise of warrants during the three months ended March 31, 2021, 192,373 shares were issued upon net-exercises rather than upon exercises for cash.

The following table summarizes the Series C Warrants activity for the three months ended March 31, 2020:

	Series C Preferred Stock Warrants			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted– Average Remaining Life (Years)
Total outstanding – December 31, 2019	1,441,180	$ 2.35		
Forfeited	—	—		
Expired	—	—		
Granted	—	—		
Total outstanding – March 31, 2020	1,441,180	$ 2.35		
Exercisable	1,441,180	$ 2.35	$ 2.25 – 2.70	4.85

The following table presents the Company's fair value hierarchy for its warrant liabilities (all of which arise under the warrants received in exchange for the Series C Warrants) measured at fair value on a recurring basis using Level 3 inputs as of March 31, 2021:

Warrant liabilities	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Balance as of March 31, 2021	$ —	$ —	$ 6,187,200	$ 6,187,200

There were no transfers of financial assets or liabilities between category levels for the three months ended March 31, 2021.

During the three months ended March 31, 2021 the Company experienced $2.1 million in other income because the fair value of the warrant liabilities declined to $6.2 million from $8.3 million at December 31, 2020, primarily due to warrant exercises. For the three months ended March 31, 2020, change in fair value of warrant liabilities was $0 because the fair value was immaterial at both the beginning and the end of the three months ended March 31, 2020.

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

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

	March 31, 2021	
	Range	Weighted Average
Risk-free interest rate	0.28% — 0.42%	0.30%
Expected volatility (peer group)	81.00 — 84.00%	83.52%
Term of warrants (in years)	2.65 — 3.24	2.75
Expected dividend yield	0.00%	0.00%

NOTE 9 — LEASES

The Company leases its facilities under a long-term operating lease agreement expiring in October 2022. The tables below show the operating lease right-of-use assets and operating lease liabilities as of December 31, 2020 and the balances as of March 31, 2021, including the changes during the periods:

	Operating lease right-of-use assets
Net right-of-use assets at December 31, 2020	430,795
Less amortization of operating lease right-of-use assets	(54,179)
Operating lease right-of-use assets at March 31, 2021	$ 376,616

	Operating lease liabilities
At December 31, 2020	$ 491,565
Less principal payments on operating lease liabilities	(60,710)
Operating lease liabilities at March 31, 2021	430,855
Less non-current portion	(168,254)
Current portion at March 31, 2021	$ 262,601

As of March 31, 2021, the Company's operating leases have a weighted-average remaining lease term of 1.6 years and a weighted-average discount rate of 8.9%.

As of March 31, 2021, future minimum payments during the next five fiscal years and thereafter are as follows:

Year Ending December 31,	Amount
2021 (nine months)	$ 217,156
2022	246,650
Total	463,806
Less present value discount	(32,951)
Operating lease liabilities	$ 430,855

Total lease expense was approximately $86,000 and $84,000, respectively, for the three month periods ended March 31, 2021 and 2020. Lease expense was recorded in cost of product sales, general and administrative expenses, research and development and sales and marketing expenses.

NOTE 10 — RESEARCH AND LICENSE AGREEMENTS

The University of Louisville Research Foundation

Between June 2018 and September 2020, the Company entered into license and sponsored research agreements with the University of Louisville Research Foundation ("ULRF") for QN-247, a novel aptamer-based compound that has shown promise as an anticancer drug. Under the agreements, the Company will take over development, regulatory approval and commercialization of the compound from ULRF and is responsible for maintenance of the related intellectual property portfolio. In return, ULRF received a $50,000 convertible promissory note in payment of an upfront license fee, which was subsequently converted into the Company's common stock, and the Company agreed to reimburse ULRF for sponsored research expenses of up to $805,000 and prior patent costs of up to $200,000. In addition, the Company agreed to pay ULRF (i) royalties, on patent-covered net sales associated with the commercialization of anti-nucleolin agent-conjugated nanoparticles, of 4% (on net sales up to a cumulative $250,000,000) or 5% (on net sales above a cumulative $250,000,000), until expiration of the last to expire of the licensed patents, (ii) 30% to 50% of any non-royalty sublicensee income received (50% for sublicenses granted in the first two years of the ULRF license agreement, 40% for sublicenses granted in the third or fourth years of the ULRF license agreement, and 30% for sublicenses granted in the fifth year of the ULRF license agreement or thereafter), (iii) reimbursements for ongoing costs associated with the preparation, filing, prosecution and maintenance of licensed patents, incurred prior to June 2018, and (iv) payments ranging from $100,000 to $5,000,000 upon the achievement of certain regulatory and commercial milestones. Milestone payments for the first therapeutic indication would be $100,000 for first dosing in a Phase 1 clinical trial, $200,000 for first dosing in a Phase 2 clinical trial, $350,000 for first dosing in a Phase 3 clinical trial, $500,000 for regulatory marketing approval and $5,000,000 upon achieving a cumulative $500,000,000 of Licensed Product sales; the Company would also pay another $500,000 milestone payment for any additional regulatory marketing approval for each additional therapeutic (or diagnostic) indication. The Company also must pay ULRF shortfall payments if the total amounts actually paid with respect to royalties and non-royalty sublicensee income for any year is less than the applicable annual minimum (ranging from $10,000 to $50,000) for such year.

There was approximately $62,000 and $0 in sponsored research expenses related to these agreements for the three months ended March 31, 2021 and 2020, respectively, and these amounts are recorded in research and development expenses in the statements of operations. Minimum annual royalties of $0 and $10,000 related to these agreements are included in research and development expenses in the statements of operations for the three months ended March 31, 2021 and 2020, respectively. License costs were approximately $36,000 and $0 related to these agreements for the three months ended March 31, 2021 and 2020, respectively, and are included in research and development expenses in the statements of operations.

In March 2019, the Company entered into a sponsored research agreement and an option for a license agreement with ULRF for development of several small-molecule RAS interaction inhibitor drug candidates. Under the terms of this agreement, the Company will reimburse ULRF for sponsored research expenses of up to $693,000 for this program. In February 2021, the Company extended the term of this agreement for an additional 18 months (expires July 2022) and increased the amount that the Company will reimburse ULRF for sponsored research expenses from $693,000 to approximately $1.4 million. In July 2020, the Company entered into an exclusive license agreement with ULRF for RAS interaction inhibitor drug candidates. Under the agreement, the Company will take over development, regulatory approval and commercialization of the candidates from ULRF and is responsible for maintenance of the related intellectual property portfolio. In return, ULRF received approximately $112,000 for an upfront license fee and reimbursement of prior patent costs. In addition, the Company has agreed to pay ULRF (i) royalties, on patent-covered net sales associated with the commercialization, of 4% (on net sales up to a cumulative $250,000,000) or 5% (on net sales above a cumulative $250,000,000), until expiration of the licensed patent, and 2.5% (on net sales for any sales not covered by Licensed Patents), (ii) 30% to 50% of any non-royalty sublicensee income received (50% for sublicenses granted in the first two years of the ULRF license agreement, 40% for sublicenses granted in the third or fourth years of the ULRF license agreement, and 30% for sublicenses granted in the fifth year of the ULRF license agreement or thereafter), (iii) reimbursements for ongoing costs associated with the preparation, filing, prosecution and maintenance of licensed patents, incurred prior to July 2020, and (iv) payments ranging from $50,000 to $5,000,000 upon the achievement of certain regulatory and commercial milestones. Milestone payments for the first therapeutic indication would be $50,000 for first dosing in a Phase 1 clinical trial, $100,000 for first dosing in a Phase 2 clinical trial, $150,000 for first dosing in a Phase 3 clinical trial, $300,000 for regulatory marketing approval and $5,000,000 upon achieving a cumulative $500,000,000 of Licensed Product sales. The Company also must pay ULRF shortfall payments if the total amounts actually paid with respect to royalties and non-royalty sublicensee income for any year is less than the applicable annual minimum (ranging from $20,000 to $100,000) for such year.

Sponsored research expenses related to these agreements for the three months ended March 31, 2021 and 2020 were approximately $107,000 and $108,000, respectively, and are recorded in research and development expenses in the statements of operations. License costs related to these agreements for the three months ended March 31, 2021 and 2020 were approximately $46,000 and $0, respectively, and are included in research and development expenses in the statements of operations.

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

In addition, the Company has agreed to pay ULRF (i) royalties, on patent-covered net sales associated with the commercialization of QN-165 as a treatment for COVID-19, of 4% (on net sales up to a cumulative $250,000,000) or 5% (on net sales above a cumulative $250,000,000), until expiration of the licensed patents, and 2.5% (on net sales for any sales not covered by Licensed Patents), (ii) 30% to 50% of any non-royalty sublicensee income received (50% for sublicenses granted in the first two years of the ULRF license agreement, 40% for sublicenses granted in the third or fourth years of the ULRF license agreement, and 30% for sublicenses granted in the fifth year of the ULRF license agreement or thereafter), (iii) reimbursements for ongoing costs associated with the preparation, filing, prosecution and maintenance of licensed patents, incurred prior to June 2020, and (iv) payments ranging from $50,000 to $5,000,000 upon the achievement of certain regulatory and commercial milestones. Milestone payments would be $50,000 for first dosing in a Phase 1 clinical trial, $100,000 for first dosing in a Phase 2 clinical trial, $150,000 for first dosing in a Phase 3 clinical trial, $300,000 for regulatory marketing approval and $5,000,000 upon achieving a cumulative $500,000,000 of Licensed Product sales. The Company also must pay ULRF shortfall payments if the total amounts actually paid with respect to royalties and non-royalty sublicensee income for any year is less than the applicable annual minimum (ranging from $5,000 to $50,000) for such year.

Sponsored research expenses related to these agreements for the three months ended March 31, 2021 and 2020 were approximately $69,000 and $0, respectively, and are recorded in research and development expenses in the statements of operations. License costs related to these agreements for the three months ended March 31, 2021 and 2020 were $0 for each period.

Advanced Cancer Therapeutics

In December 2018, the Company entered into a license agreement with Advanced Cancer Therapeutics, LLC ("ACT"), granting the Company exclusive rights to develop and commercialize QN-165, an aptamer-based drug candidate. In return, ACT received a $25,000 convertible promissory note in payment of an upfront license fee, which was subsequently converted into the Company's common stock. In addition, the Company agreed to pay ACT (i) royalties, on net sales associated with the commercialization of QN-165, of 2% (only if patent-covered and only on net sales above a cumulative $3,000,000) or 1% (if not patent-covered, but only on net sales above a cumulative $3,000,000), until the 15th anniversary of the ACT license agreement and (ii) milestone payments of $100,000 for the Company raising a cumulative total of $2,000,000 in new equity financing after the date of the ACT license agreement, $100,000 upon any first QN-165-based licensed product receiving the CE Mark or similar FDA status, and $500,000 upon cumulative worldwide QN-165-based licensed product net sales reaching $3,000,000. For the three months ended March 31, 2021 and 2020, license costs of approximately $2,000 and $0 related to this agreement, respectively, are included in research and development expenses in the statements of operations.

Prediction Biosciences

In November 2015, the Company entered into a long-term development and supply agreement with Prediction Biosciences SAS to develop and manufacture diagnostic tests for use in the stroke point-of-care market. The Company recognizes development revenue and product sales over the performance period of the contract. For the three months ended March 31, 2021 and 2020, there was $0 and $45,000, respectively, in collaborative research revenue related to this agreement.

Sekisui Diagnostics

During the year ended March 31, 2018, the Company extended a strategic partnership entered into in May 2016 with Sekisui Diagnostics, LLC ("Sekisui") until May 2022. The Company appointed Sekisui as its diagnostics commercial partner and exclusive worldwide distributor with the exception of certain customer accounts retained by Qualigen. The agreement contains a right of first refusal for Sekisui against any potential acquisition of the Company until May 2022.

There were product sales to Sekisui of approximately $1.0 million for both of the three month periods ended March 31, 2021 and 2020, related to this agreement.

Yi Xin

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

Under the Technology Transfer Agreement, the Company received net cash payments of $250,000 in the final quarter of the year ended December 31, 2020, classified as deferred revenue on the December 31, 2020 balance sheet, and a cash payment of $420,000 during the three months ended March 31, 2021. The Company will also receive low- to mid-single-digit royalties on any future new-generations and current-generations product sales by Yi Xin. Of these amounts, the Company recognized approximately $38,000 in product sales and $479,000 in license revenue included in the statement of operations for the three months ended March 31, 2021. The Company provided technology transfer and patent/know-how license rights to facilitate Yi Xin's development and commercialization.

The Company gave Yi Xin the exclusive rights for China – which is a market the Company has not otherwise entered – both for Yi Xin's new generations of FastPack-based products and for Yi Xin-manufactured versions of the Company's existing FastPack product lines. Yi Xin will also have the right to sell its new generations of FastPack-based diagnostic test systems throughout the world (but not to or toward current customers of the Company's existing generations of FastPack products); any such non-China sales would, until May 1, 2022, need to be through Sekisui. In addition, after May 1, 2022, Yi Xin will have the right to sell Yi Xin-manufactured versions of existing FastPack 1.0, IP and PRO product lines worldwide (other than in the United States and other than to or toward current non-US customers of those products). Also, after May 1, 2022, Yi Xin will have the right to buy Company-manufactured FastPack 1.0, IP and PRO products from the Company at distributor prices for resale in and for the United States (but not to or toward current US customers of those products); the Company did not license Yi Xin to sell in the United States market any Yi Xin-manufactured versions of those legacy FastPack 1.0, IP and PRO product lines, even after May 1, 2022. In the Technology Transfer Agreement, the Company confirmed that it would not, after May 1, 2022, seek new FastPack customers outside the United States.

STA Pharmaceutical

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

NOTE 11 — STOCKHOLDERS' EQUITY

As of March 31, 2021 and December 31, 2020, the Company had two classes of capital stock: common stock and Series Alpha convertible preferred stock.

Common Stock

Holders of common stock generally vote as a class with the holders of the preferred stock and are entitled to one vote for each share held. Subject to the rights of the holders of the preferred stock to receive preferential dividends, the holders of common stock are entitled to receive dividends when and if declared by the Board of Directors. Following payment of the liquidation preference of the preferred stock, as of March 31, 2021 any remaining assets would be distributed ratably among the holders of the common stock and, on an as-if-converted basis, the holders of Series Alpha convertible preferred stock upon liquidation, dissolution or winding up of the affairs of the Company. The holders of common stock have no preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions.

At March 31, 2021, the Company has reserved 13,886,590 shares of authorized but unissued common stock for possible future issuance. At March 31, 2021, shares were reserved in connection with the following:

Exercise of outstanding stock options and future grants of stock options	4,033,856
Exercise of outstanding stock warrants	9,609,316
Conversion of outstanding Series Alpha preferred stock	243,418
Total	13,886,590

Series Alpha Preferred Stock

In the three-month period ended March 31, 2021, no shares of Series Alpha convertible preferred stock were converted into shares of the Company's common stock, and there were 180 shares of Series Alpha preferred stock outstanding at March 31, 2021.

Alpha Securities Purchase Agreements

On July 10, 2020, the Company closed a Securities Purchase Agreement (dated July 8, 2020) with a single institutional investor for the purchase and sale for $8.0 million for (i) 1,140,570 shares of Company common stock, (ii) 780,198 pre-funded warrants (i.e., warrants to purchase shares of Company common stock, for which the exercise price is almost entirely prepaid) and (iii) 1,920,768 two-year warrants to purchase shares of Company common stock for an exercise price of $5.25 per share. Both sets of warrants included a 9.99% beneficial-ownership blocker provision. The 780,198 pre-funded warrants were then exercised on July 21 and 22, 2020.

On August 4, 2020, the Company closed a Securities Purchase Agreement (dated August 2, 2020) with a single institutional investor for the purchase and sale for $10.0 million for (i) 1,717,106 shares of Company common stock, and (ii) 1,287,829 two-year warrants to purchase shares of Company common stock for an exercise price of $6.00 per share. The warrants included a 9.99% beneficial-ownership blocker provision.

On December 18, 2020, the Company closed a Securities Purchase Agreement (dated December 16, 2020) with a single institutional investor for the purchase and sale for $12,000,000 of (i) 2,370,786 shares of Company common stock, (ii) 1,000,000 pre-funded warrants (i.e., warrants to purchase shares of Company common stock, for which the exercise price is almost entirely prepaid) (iii) 1,348,314 two-year warrants to purchase shares of Company common stock for an exercise price of $4.07 per share, and (iv) 842,696 warrants (first exercisable 6 months after issuance, and with an expiration date 30 months after issuance) to purchase shares of Company common stock for an exercise price of $4.07 per share. The warrants included a 9.99% beneficial-ownership blocker provision. The 1,000,000 pre-funded warrants were exercised on February 4, 2021.

Stock Options and Warrants

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

In April 2020, the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan") which provides for the granting of incentive or nonstatutory common stock options to qualified employees, officers, directors, consultants and other service providers. At March 31, 2021 and 2020 there were 3,940,000 and 0 outstanding options respectively under the 2020 Plan and there were 117,157 and 0 options available respectively for future grant.

The following represents a summary of the options granted (under the 2020 Plan and otherwise) to employees and non-employee service providers that are outstanding at March 31, 2021, and changes during the three-month period then ended:

	Shares	Weighted– Average Exercise Price	Range of Exercise Price	Weighted– Average Remaining Life (Years)
Total outstanding – December 31, 2020	4,011,356	$ 7.05	$ 3.52—1,465.75	9.29
Granted	27,000	3.29	3.29	9.91
Expired	—	—	—	—
Forfeited	(4,500)	3.68	3.52—4.97	9.78
Total outstanding – March 31, 2021	4,033,856	$ 7.03	$ 3.29—1,465.75	9.04
Exercisable (vested)	108,856	$ 81.38	$ 4.97—1,465.75	2.26
Non-Exercisable (non-vested)	3,925,000	$ 4.96	$ 3.29—5.13	9.23

There was approximately $1.3 million and $0 of compensation costs related to outstanding options for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, there was approximately $11.4 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements. This cost is expected to be recognized over a weighted average period of 2.22 years.

No stock options were exercised during the three months ended March 31, 2021 and 2020.

The exercise price for an option issued under the 2020 Plan is determined by the Board of Directors, but will be (i) in the case of an incentive stock option (A) granted to an employee who, at the time of grant of such option, is a 10% stockholder, no less than 110% of the fair market value per share on the date of grant; or (B) granted to any other employee, no less than 100% of the fair market value per share on the date of grant; and (ii) in the case of a non-statutory stock option, no less than 100% of the fair market value per share on the date of grant. The options awarded under the 2020 Plan will vest as determined by the Board of Directors but will not exceed a ten-year period. The weighted average grant date fair value per share of options granted during the three months ended March 31, 2021 was $3.29.

Fair Value of Equity Awards

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

- *Expected dividend yield.* The expected dividend is assumed to be zero, as the Company has never paid dividends and has no current plans to pay any dividends on the Company's common stock.

- *Expected stock-price volatility.* The Company's expected volatility is derived from the average historical volatilities of publicly traded companies within the Company's industry that the Company considers to be comparable to the Company's business over a period approximately equal to the expected term.

- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the expected term.

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

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

	For the three months ended March 31, 2021
Expected dividend yield	0.00%
Expected stock-price volatility	102%
Risk-free interest rate	0.84% — 1.04%
Average expected remaining years of life of options	6.0
Stock price	$ 3.29

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

	For the three months ended March 31,	
	2021	2020
General and administrative	$ 1,092,228	$ —
Research and development	169,895	—
Total	$ 1,262,123	$ —

Equity Classified Compensatory Warrants

In connection with the $4.0 million equity capital raise as part of the May 2020 reverse recapitalization transaction, the Company issued common stock warrants to an advisor and its designees for the purchase of 811,431 shares of the Company's common stock at an exercise price of $1.11 per share. The issuance cost of these warrants was charged to additional paid-in capital, and did not result in expense on the Company's statements of operations.

In addition, various service providers hold equity classified compensatory warrants issued in 2017 and earlier (originally exercisable to purchase Series C convertible preferred stock, and now instead exercisable to purchase common stock) for the purchase of 668,024 shares of Company common stock at a weighted average exercise price of $2.34 per share. These are to be differentiated from the Series C Warrants described in Note 8.

No compensatory warrants were issued during the three months ended March 31, 2021.

The following table summarizes the equity classified compensatory warrant activity for the three months ended March 31, 2021:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2020	1,294,217	$ 1.66		
Granted	—	—		
Exercised	(38,390)	2.09		
Expired	—	—		
Forfeited	(65,179)	2.07		
Total outstanding – March 31, 2021	1,190,648	$ 1.61		
Exercisable	1,187,052	$ 1.60	$ 1.11 —2.54	4.00
Non-Exercisable	3,596	$ 2.54	$ 2.54	5.48

The following table summarizes the compensatory warrant activity for the three months ended March 31, 2020:

	Series C Preferred Stock Warrants			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted– Average Remaining Life (Years)
Total outstanding – December 31, 2019	754,262	$ 1.99		
Forfeited	—	—		
Expired	—	—		
Granted	—	—		
Total outstanding – March 31, 2020	754,262	$ 1.99		
Exercisable	746,142	$ 1.99	$ 1.83 – $2.25	4.59
Non-Exercisable	8,120	$ 2.25	$ 2.25	6.48

There were no compensation costs related to outstanding warrants for the three months ended March 31, 2021 and approximately $8,000 for the three months ended March 31, 2020. As of March 31, 2021 and 2020, there was no unrecognized compensation cost related to nonvested warrants.

Noncompensatory Equity Classified Warrants

In May 2020, as a commitment fee, the Company issued noncompensatory equity classified warrants to an investor for the purchase of 270,478 shares of Company common stock at an exercise price of $1.11 per share (of which warrants for 200,000 shares were subsequently exercised in December 2020). In July 2020 the Company issued noncompensatory equity classified warrants to such investor for the purchase of 780,198 shares of Company common stock at an exercise price of $0.001 per share (which were subsequently exercised in July 2020), and 1,920,678 shares of Company common stock at an exercise price of $5.25 per share. In August 2020 the Company issued noncompensatory equity classified warrants to such investor for the purchase of 1,287,829 shares of Company common stock at an exercise price of $6.00 per share. Lastly, in December 2020, the Company issued noncompensatory equity classified warrants to such investor for the purchase of 1,000,000 shares of Company common stock at an exercise price of $0.01 per share (which were exercised in February 2021) and 2,191,010 shares of Company common stock at an exercise price of $4.07 per share. No noncompensatory equity classified warrants were issued during the three months ended March 31, 2021.

The following table summarizes the noncompensatory equity classified warrant activity for the three months ended March 31, 2021:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – December 31, 2020	6,549,777	$ 4.36		
Exercised	(1,000,000)	0.01		
Granted	—	—		
Expired	—	—		
Forfeited	—	—		
Total outstanding – March 31, 2021	5,549,777	$ 5.15		
Exercisable	4,707,081	$ 5.34	$ 1.11 – 2,325.00	1.47
Non-Exercisable	842,696	$ 4.07	4.07	2.72

NOTE 12 — RELATED PARTY TRANSACTIONS

In October 2017, Sekisui purchased all outstanding shares of the Company's Series D and Series D-1 preferred stock from Gen-Probe Incorporated. As such, Sekisui became a related party as of October 2017. These Series D and Series D-1 preferred stock shares were converted into 1,980,233 shares of the Company's common stock in connection with the reverse recapitalization transaction in May 2020. During the nine months ended December 31, 2020, Sekisui ceased to be a related party as to the Company. In the attached financial statements, information for 2020 periods and dates is presented without distinct "related party" treatment for items pertaining to Sekisui.

NOTE 13 — SUBSEQUENT EVENTS

Management has evaluated subsequent events pursuant to the requirements of ASC Topic 855—*Subsequent Events*, from the balance sheet date through the date the financial statements were available to be issued, and has determined that there are no material subsequent events that require disclosure in these financial statements.

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

The following discussion and analysis should be read in conjunction with our interim unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q ("Quarterly Report") and the audited financial statements and notes thereto as of and for the nine-months transition period ended December 31, 2020, which are contained in our Transition Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 31, 2021. As used in this Quarterly Report, unless the context suggests otherwise, "we," "us," "our," or "Qualigen" refer to Qualigen Therapeutics, Inc. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions.

Cautionary Note Regarding Forward Looking Statements

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

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

- there can be no assurance that we will successfully develop any drugs or therapeutic devices;
- there can be no assurance that preclinical or clinical development of our candidate drugs or therapeutic devices will be successful;
- there can be no assurance that clinical trials will be approved to begin by or will actually begin by or will proceed as contemplated by any projected timeline;
- there can be no assurance that clinical trials will complete enrollment as contemplated by any projected timeline;
- there can be no assurance that future clinical trial data will be favorable or that such trials will confirm any improvements over other products or lack negative impacts;
- there can be no assurance that any drugs or therapeutic devices will receive required regulatory approvals or that they will be commercially successful;
- there can be no assurance that we will be able to procure or earn sufficient working capital to complete the development, testing and launch of our prospective therapeutic products;
- there can be no assurance that patents will issue on our owned and in-licensed patent applications;
- there can be no assurance that such patents, if any, and our current owned and in-licensed patents would prevent competition;
- there can be no assurance that we will be able to maintain or expand market demand and/or market share for our diagnostic products generally, particularly in view of COVID-19-related deferral of patients' physician-office visits and in view of FastPack reimbursement pricing challenges.
- there can be no assurance that adoption and placement of FastPack PRO System analyzers will be widespread; and
- there can be no assurance that we will be able to manufacture our FastPack PRO System analyzers successfully.

Our stock price could be harmed if any of the events or trends contemplated by the forward-looking statements fails to occur or is delayed or if any actual future event otherwise differs from expectations. Additional information concerning these and other risk factors affecting our business (including events beyond our control, such as epidemics and resulting changes) can be found in our prior filings with the SEC (including our Transition Report on Form 10-K for the nine-months transition period ended December 31, 2020), available at www.sec.gov. Any forward-looking statement that we make in this Quarterly Report speaks only as of the date of this Quarterly Report, and we disclaim any intent or obligation to update these forward-looking statements beyond the date of this Quarterly Report, except as required by law. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate, are consistent in some future periods with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in other future periods.

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

Overview

We are a biotechnology company focused on developing novel therapeutics for the treatment of cancer and infectious diseases, as well as maintaining and expanding our core FDA-approved FastPack® System, which has been used successfully in diagnostics for 20 years. Our cancer therapeutics pipeline includes QN-247, RAS-F and STARS™. QN-247 (formerly referred to as ALAN or 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 nanoparticle coating technology is similar to the core nanoparticle coating technology used in our blood-testing diagnostic products. The foundational aptamer of QN-247, QN-165 (formerly referred to as AS1411), is also a drug candidate for treating COVID-19 and other viral-based infectious diseases; we currently plan that our first clinical trial would be a trial of QN-165 against 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 candidate for removal from circulating blood of precisely targeted tumor-produced and viral compounds.

Because our therapeutic candidates are still in the development stage, our only products that are currently commercially available are the FastPack System diagnostic instruments and test kits. The FastPack System menu includes rapid point-of-care diagnostic tests for cancer, men's health, hormone function and vitamin D status. Since inception, our sales of FastPack products have exceeded $100 million. We have always utilized a "razor and blades" pricing strategy, providing analyzers to our customers (physician offices, clinics and small hospitals) at low cost in order to increase sales volumes of higher-margin test kits. Pursuant to a distribution agreement, we are required to rely on our diagnostics distribution partner Sekisui Diagnostics, LLC ("Sekisui") for most FastPack distribution worldwide until May 2022. We maintain direct distribution for certain house accounts, including selling our total testosterone test kits to Low T Center, Inc. ("Low T"), the largest men's health group in the US, with 44 locations. We have licensed and technology-transferred our FastPack System technology to Yi Xin Zhen Duan Jishu (Suzhou) Ltd., for the China diagnostics market.

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

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

Completion of Reverse Recapitalization Transaction with Ritter

On May 22, 2020, we completed a "reverse recapitalization" transaction with Qualigen, Inc. (not to be confused with the Company); the Company's merger subsidiary merged with and into Qualigen, Inc. with Qualigen, Inc. surviving as a wholly owned subsidiary of the Company. The Company, which had previously been known as Ritter Pharmaceuticals, Inc., was renamed Qualigen Therapeutics, Inc., and the former stockholders of Qualigen, Inc. acquired, via the recapitalization, a substantial majority of the shares of the Company. Ritter/Qualigen Therapeutics common stock, which was previously traded on the Nasdaq Capital Market under the ticker symbol "RTTR," commenced trading on Nasdaq, on a post-reverse-stock-split adjusted basis, under the ticker symbol "QLGN" on May 26, 2020.

Because Qualigen, Inc. was the accounting acquirer in the reverse recapitalization transaction, all references to financial figures of "the Company" presented in the accompanying condensed consolidated financial statements and Notes are those of Qualigen, Inc.; the corresponding figures of Ritter Pharmaceuticals, Inc. have been disregarded. Moreover, references in this Quarterly Report to "our" pre-May 22, 2020-merger history, securities and agreements are references to the pre-May 22, 2020-merger history, securities and agreements of Qualigen, Inc., except where otherwise expressly specified.

We are no longer pursuing the gastrointestinal disease treatment business on which Ritter Pharmaceuticals, Inc. had focused before the reverse recapitalization transaction.

Distribution and Development Agreement with Sekisui

In May 2016, through our wholly-owned diagnostics subsidiary Qualigen, Inc., we entered into a Distribution and Development Agreement (the "Distribution Agreement") with Sekisui. Under the Distribution Agreement, Sekisui serves as the exclusive worldwide distributor for FastPack products (although we retain certain specific accounts for direct transactions). Sekisui's exclusive distribution arrangements are effective until May 2022.

Under the Distribution Agreement, we began development of a proposed "FastPack 2.0" product line, which if successfully introduced by us would have been distributed by Sekisui. Between May 2016 and January 2018, Sekisui paid us a total of approximately $5.5 million upon the achievement of specified development milestones.

Under this program, we developed a FastPack 2.0 diagnostic test for a new whole blood vitamin D assay, and we then conducted a clinical trial of it in March 2019. We determined in May 2019 that it was uncertain whether the results of the trial would enable the test to receive FDA approval, and our FastPack 2.0 project with Sekisui was discontinued. Currently no further FastPack 2.0 analyzer or test development is ongoing, and we have licensed and transferred our FastPack 2.0 technology to Yi Xin Zhen Duan Jishu (Suzhou) Ltd. for them to further develop and commercialize.

We became obligated to pay Sekisui $0.9 million for $0.5 million in research and development costs advanced by Sekisui to us and for the reimbursement of $0.4 million in certain out-of-pocket development and preclinical study expenses incurred by Sekisui. We satisfied these amounts (plus interest) by payment in full on July 21, 2020.

Our expectation is that when we regain FastPack distribution rights from Sekisui, we will be able to improve the profitability of our diagnostics business.

Technology Transfer Agreement with Yi Xin

Through our wholly-owned diagnostics subsidiary Qualigen, Inc., we entered into a Technology Transfer Agreement dated as of October 7, 2020 with Yi Xin Zhen Duan Jishu (Suzhou) Ltd. ("Yi Xin"), of Suzhou, China, for Yi Xin to develop, manufacture and sell new generations of diagnostic test systems based on our core FastPack technology. In addition, the Technology Transfer Agreement authorized Yi Xin to manufacture and sell our current generations of FastPack System diagnostic products (1.0, IP and PRO) in China.

Under the Technology Transfer Agreement, we received net cash payments of $250,000 in the final quarter of calendar 2020, classified as deferred revenue as of the balance sheet date of December 31, 2020, and a cash payment of $420,000 during the three months ended March 31, 2021. In addition, we will receive low- to mid-single-digit royalties on any future new-generations and current-generations product sales by Yi Xin. Of these amounts, we recognized approximately $38,000 in product sales and $479,000 in license revenue included in the statement of operations for the three months ended March 31, 2021.

We provided technology transfer and patent/know-how license rights to facilitate Yi Xin's development and commercialization.

We gave Yi Xin the exclusive rights for China – which is a market we have not otherwise entered – both for Yi Xin's new generations of FastPack-based products and for Yi Xin-manufactured versions of our existing FastPack product lines. Yi Xin will also have the right to sell its new generations of FastPack-based diagnostic test systems throughout the world (but not to or toward current customers of our existing generations of FastPack products); any such non-China sales would, until May 1, 2022, need to be through Sekisui. In addition, after May 1, 2022, Yi Xin will have the right to sell Yi Xin-manufactured versions of existing FastPack 1.0, IP and PRO product lines worldwide (other than in the United States and other than to or toward current non-US customers of those products). Also, after May 1, 2022, Yi Xin will have the right to buy Qualigen-manufactured FastPack 1.0, IP and PRO products from us at distributor prices for resale in and for the United States (but not to or toward current US customers of those products); we did not license Yi Xin to sell in the United States market any Yi Xin-manufactured versions of those legacy FastPack product lines, even after May 1, 2022.

In the Technology Transfer Agreement, we confirmed that we would not, after May 1, 2022, seek new FastPack customers outside the United States.

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

Warrant Liabilities

In 2004, Qualigen, Inc. issued a series of Series C preferred stock warrants to investors and brokers in connection with a private placement. These warrants were subsequently extended and survived the May 2020 Ritter reverse recapitalization transaction and are now exercisable for Qualigen Therapeutics common stock. These warrants were so-called "exploding warrants" – they contained a provision that if Qualigen, Inc. issued shares (except in certain defined scenarios) at a price below the warrants' exercise price, the exercise price would be re-set to such new price and the number of shares underlying the warrants would be increased in the same proportion as the exercise price decrease. For accounting purposes, such "exploding warrants" give rise to "warrant liabilities" (even though there is not any "liability" in the sense that we would be obligated to pay any cash sum to anyone). Although the fair value of the warrants was immaterial at March 31, 2020, the operation of the "double-ratchet" provisions in these "exploding warrants" in connection with the reverse-recapitalization transaction now allow the holders to exercise for a significantly higher number of shares than before and at a significantly lower price than the current market price of our shares. Accounting principles generally accepted in the United States ("U.S. GAAP") require us to recognize the fair value of these warrants as warrant liabilities on our balance sheets and to reflect period-to-period changes in the fair value of the warrant liabilities on our statements of operations. The size of these warrant liabilities at March 31, 2021 was quite large ($6.2 million) and caused a significant distortion of our balance sheet at March 31, 2021 and our results of operations for the three months period ended March 31, 2021. Because this fair value will be determined each quarter on a "mark-to-market" basis, this item could result in significant variability in our future quarterly and annual statements of operations and balance sheets based on changes in our public market common stock price. Pursuant to U.S. GAAP, a quarter-to-quarter increase in our stock price would result in a (possibly quite large) increase in the fair value of the warrant liabilities and a quarter-to-quarter decrease in our stock price would result in a (possibly quite large) decrease in the fair value of the warrant liabilities. Approximately 39% of these "exploding warrants" were exercised or forfeited as of the balance sheet date at March 31, 2021, which will tend to reduce the amplitude of this variability. (There were 2,868,891 and 3,378,596 of these "exploding warrants" outstanding at March 31, 2021 and December 31, 2020, respectively.) We will continue to encourage the holders of these warrants to exercise them, and if the number of outstanding "exploding warrants" is further reduced the potential amplitude of the changes in the warrant liabilities will correspondingly be further reduced.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020:

	For the Three Months Ended March 31,	
	2021	**2020**
REVENUES		
Net product sales	$ 1,420,842	$ 1,411,755
License revenue	478,654	—
Collaborative research revenue	—	45,000
Total revenues	1,899,496	1,456,755
EXPENSES		
Cost of product sales	1,202,479	991,651
General and administrative	2,873,939	918,379
Research and development	3,499,373	238,059
Sales and marketing	136,587	92,262
Total expenses	7,712,378	2,240,351
LOSS FROM OPERATIONS	(5,812,882)	(783,596)
OTHER EXPENSE (INCOME), NET		
Gain on change in fair value of warrant liabilities	(2,122,900)	—
Interest (income) expense, net	(17,343)	90,757
Other income, net	(542)	(1,158)
Total other expense (income), net	(2,140,785)	89,599
LOSS BEFORE PROVISION FOR INCOME TAXES	(3,672,097)	(873,195)
PROVISION FOR INCOME TAXES	530	(619)
NET LOSS	$ (3,672,627)	$ (872,576)

Revenues

Our operating revenues are primarily generated from sales of diagnostic tests. Revenues during the three months ended March 31, 2021 were $1.9 million compared to $1.5 million during the three months ended March 31, 2020, an increase of $0.4 million. This increase was primarily due to recognition of license revenue from Yi Xin under the Technology Transfer Agreement, an item which had no counterpart in the quarter ended March 31, 2020.

Net product sales

Net product sales are primarily generated from sales of diagnostic tests. Net product sales remained level at approximately $1.4 million during the three months ended March 31, 2021 and 2020, but improved in the first quarter of 2021 compared to the later calendar 2020 quarters which were negatively impacted by the COVID-19 pandemic.

License revenue

License revenue during the three months ended March 31, 2021 was $0.5 million, due to the recognition of revenue from Yi Xin under the Technology Transfer Agreement. There was $0 of license revenue during the three months ended March 31, 2020.

Collaborative research revenue

Collaborative research revenue is recognized as research services are performed over the development period for each agreement. Collaborative research revenue during the three months ended March 31, 2021 was $0, as compared to less than $0.1 million during the three months ended March 31, 2020. Collaborative research revenue during the three months ended March 31, 2020 arose from our development work toward a cellular fibronectin assay for Prediction BioSciences SAS.

Expenses

Cost of Product Sales

Cost of product sales increased during the three months ended March 31, 2021, to $1.2 million, or 85% of net product sales, versus approximately $1.0 million, or 68% of net product sales, during the three months ended March 31, 2020. The increase of $0.2 million, and increase in percentage, were primarily due to higher manufacturing labor costs and higher allocated manufacturing-support costs of research and development personnel.

General and Administrative Expenses

General and administrative expenses increased sharply from $0.9 million, during the three months ended March 31, 2020, to $2.9 million during the three months ended March 31, 2021. This increase was primarily due to $1.1 million in employee/director stock-based compensation expense, a $0.3 million increase in insurance expenses, a $0.3 million increase in payroll expenses, and a $0.3 million increase in other overhead expenses, all primarily related to our public-company status during the three months ended March 31, 2021 in contrast to our private-company status during the three months ended March 31, 2020.

Research and Development Costs

Research and development costs include diagnostic and therapeutic research and product development costs. We have shifted our focus in this category toward therapeutics. Research and development costs increased from $0.2 million for the three months ended March 31, 2020 to $3.5 million for the three months ended March 31, 2021. Of the $0.2 million of research and development costs for the three months ended March 31, 2020, 35% was attributable to diagnostics and 65% was attributable to therapeutics. Of the $3.5 million of research and development costs for the three months ended March 31, 2021, $0.3 million (or 9%) was attributable to diagnostics and $3.2 million (or 91%) was attributable to therapeutics.

The increase in diagnostic research and development costs was primarily due to increased stock-based compensation expense related to our public-company status, and wind-down costs related to the withdrawn COVID-19 antibody diagnostic test during the three months ended March 31, 2021. The increase in therapeutics research and development costs was primarily due to $2.7 million in expenses related to the potential application of QN-165 to treatment of COVID-19 ($1.8 million in drug compound manufacturing costs, and $0.9 million in other pre-clinical research costs for the three months ended March 31, 2021, as compared to $0 for the three months ended March 31, 2020), as well as pre-clinical research and development cost increases of about $0.2 million for QN-247 and about $0.1 million for RAS. Of the $1.8 million in drug compound manufacturing costs during the three months ended March 31, 2021, $1.1 million consisted of deposits which had been placed in 2020 with STA Pharmaceutical Co., Ltd., a subsidiary of WuXi AppTec, our manufacturer of QN-165 for our anticipated clinical trials; these deposits were recognized as a 2021 first quarter expense.

For the future, we expect our therapeutic research and development costs to continue to increase and to significantly outweigh our diagnostic research and development costs.

Sales and Marketing Expenses

Sales and marketing expenses during the three months ended March 31, 2021 increased to approximately $137,000 as compared to $92,000 during the three months ended March 31, 2020 and are primarily due to an increase in payroll and recruiting expenses related to our diagnostics business.

Other Expense (Income)

Change in Fair Value of Warrant Liabilities

During the three months ended March 31, 2021 we experienced $2.1 million in other income because the fair value of the warrant liabilities arising from our "exploding warrants" series (containing a "double-ratchet" provision) issued by Qualigen, Inc. many years ago to brokers and investors in connection with a 2004 private placement declined to $6.2 million from $8.3 million at December 31, 2020. For the three months ended March 31, 2020, change in fair value of warrant liabilities was $0 because the fair value was immaterial at both the beginning and the end of the three months ended March 31, 2020.

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

Interest (Income) Expense, Net

There was about $17,000 in net interest income during the three months ended March 31, 2021 versus net interest expense of approximately $0.1 million during the three months ended March 31, 2020. Interest on $1.7 million principal amount of convertible notes payable ceased to accrue when they automatically converted in May 2020 upon the closing of the reverse recapitalization transaction. In addition, between April 1, 2020 and December 31, 2020 we paid off our revolving factoring line of credit facility and repaid approximately $0.9 million to Sekisui.

Liquidity and Capital Resources

As of March 31, 2021, we had $21.9 million of cash and cash equivalents. However, we have suffered recurring losses from operations. Based on our current cash position, and assuming currently planned expenditures and level of operations, we believe we have sufficient capital to fund operations for the twelve-month period subsequent to the date of this Quarterly Report. However, we operate in a rapidly evolving and unpredictable business environment that may change the timing or amount of expected future cash receipts and expenditures. If we are unable to obtain funding, we could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect our business prospects.

Our balance sheet at March 31, 2021 included $6.2 million of warrant liabilities. We do not consider that the warrant liabilities constrain our liquidity, as a practical matter. Our current liabilities at March 31, 2021 included $0.5 million of accounts payable and $1.9 million of accrued expenses and other current liabilities.

As a development-stage therapeutics biotechnology company, we expect to continue to have net losses and negative cash flow from operations, which over time will challenge our liquidity. There is no assurance that profitable operations will ever be achieved, or, if achieved, could be sustained on a continuing basis.

In order to fully execute our business plan, including full clinical trials of therapeutic drug candidates, we will require additional financing. There can be no assurance that further financing can be obtained on favorable terms, or at all.

Cash Flows

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

	For the Three Months Ended March 31,	
	2021	**2020**
Net cash provided by (used in):		
Operating activities	$ (2,081,104)	$ 407,714
Investing activities	(69,002)	(95,461)
Financing activities	121,448	(287,828)
Net increase (decrease) in cash and cash equivalents	**$ (2,028,658)**	**$ 24,425**

Net Cash Used in (Provided by) Operating Activities

During the three months ended March 31, 2021, operating activities used $2.1 million of cash, primarily resulting from a net loss of $3.7 million. Cash flows from operating activities (as opposed to net loss) for the three months ended March 31, 2021 benefitted from the $1.6 million decrease in prepaid expenses and other assets, a $1.3 million increase in employee/director stock-based compensation expense and a $1.1 million increase in accrued expenses and other current liabilities. On the other hand, cash flows from operating activities (as opposed to net loss) for the three months ended March 31, 2021 were disadvantaged by a $2.1 million decrease in fair value of warrant liabilities and a $0.2 million increase in accounts receivable, net. The decrease in prepaid expenses was primarily due to the expensing during the period of $1.1 million of upfront deposits paid to STA Pharmaceutical Co., Ltd., a subsidiary of WuXi AppTec, our manufacturer of QN-165 for our anticipated clinical trials.

During the three months ended March 31, 2020, operating activities provided $0.4 million of cash, despite a net loss of $0.9 million. Cash flows from operating activities (as opposed to net loss) for the three months ended March 31, 2020 benefitted from a $0.4 million decrease in accounts receivable and a $0.8 million increase in accrued expenses and other current liabilities and accounts payable due to higher payables related to therapeutics research and development. During the three months ended March 31, 2020, the warrant liabilities fair value was zero.

Net Cash Used in Investing Activities

During the three months ended March 31, 2021, net cash used in investing activities was approximately $69,000, primarily related to the purchase of property and equipment.

During the three months ended March 31, 2020, net cash used in investing activities was $95,000, primarily related to payments for patents and licenses.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2021 was $0.1 million, due to $0.2 million of net proceeds from exercise of warrants, offset by a $0.1 million principal payment on notes payable. Net cash used in financing activities for the three months ended March 31, 2020 was $0.3 million, primarily due to $0.6 million of principal payments on notes payable offset by $0.3 million of proceeds from the issuance of notes payable.

3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Smaller reporting companies are not required to respond to this Item.

4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021, the end of the period covered by this Quarterly Report.

Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures as of March 31, 2021 were effective to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. We believe that a disclosure controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the disclosure controls system are met, and no evaluation of disclosure controls can provide absolute assurance that all disclosure control issues, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. As of December 31, 2020, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework, or 2013 Framework. Based on this assessment, our management concluded that, as of December 31, 2020, our internal control over financial reporting was not effective because of a material weakness in our internal control over financial reporting related to the lack of accounting department resources and/or policies and procedures to ensure recording and disclosure of items in compliance with generally accepted accounting principles. We have taken and are taking steps to remediate the material weakness, including implementing additional procedures and utilizing external consulting resources with experience and expertise in U.S. GAAP and public company accounting and reporting requirements to assist management with its accounting and reporting of complex and/or non-recurring transactions and related disclosures.

We do not believe that during the quarter ended March 31, 2021 there was yet any change in our internal control over financial reporting that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

Smaller reporting companies are not required to respond to this Item.

Please refer to the Risk Factors section of our Transition Report on Form 10-K for the nine-months transition period ended December 31, 2020.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

On February 10 and 11, 2021, we issued an aggregate of 25,000 shares of our common stock to Atlanta Capital Partners, LLC, and Investor Awareness, Inc. in exchange for services valued at $101,750. No underwriter was involved. These were issuances to only two purchasers and accordingly were exempt, by virtue of Section 4(a)(2) of the Securities Act, from the registration requirements of the Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

		Incorporated by Reference			
Exhibit No.	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation	8-K	001-37428	3.1	July 1, 2015
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-37428	3.1	September 15, 2017
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-37428	3.1	March 22, 2018
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series Alpha Preferred Stock of the Company, filed with the Delaware Secretary of State on May 20, 2020	8-K		3.1	May 29, 2020
3.5	Certificate of Amendment to the Certificate of Incorporation of the Company, filed with the Delaware Secretary of State on May 22, 2020 [reverse stock split]	8-K		3.2	May 29, 2020
3.6	Certificate of Merger, filed with the Delaware Secretary of State on May 22, 2020	8-K		3.3	May 29, 2020
3.7	Certificate of Amendment to the Certificate of Incorporation of the Company, filed with the Delaware Secretary of State on May 22, 2020 [name change]	8-K		3.4	May 29, 2020
3.8	Amended and Restated Bylaws of the Company, as of May 22, 2020	8-K		3.5	May 29, 2020
10.1	Novation Agreement among the Company, Qualigen, Inc. and University of Louisville Research Foundation, Inc. dated January 30, 2021				
10.2	Novation Agreement among the Company, Qualigen, Inc. and University of Louisville Research Foundation, Inc. dated March 1, 2021				
31.1	Certificate of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certificate of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1	Certificate of principal executive officer and principal financial officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS#	XBRL Instance Document.				
101.SCH#	XBRL Taxonomy Extension Schema Document.				
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document.				

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

SIGNATURES

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

May 14, 2021

QUALIGEN THERAPEUTICS, INC.

By: */s/ Michael S. Poirier*

Name: Michael S. Poirier

Title: Chief Executive Officer

Exhibit 10.1

NOVATION AGREEMENT

This Novation Agreement (this "**Agreement**") is made as of January 30, 2021 among the University of Louisville Research Foundation, Inc. ("**ULRF**"), a Kentucky non-profit corporation as the agent of the University of Louisville ("**UofL**") for receiving grants and research agreements from external funding sources and which owns and controls intellectual property on behalf of UofL, Qualigen, Therapeutics, Inc., a Delaware corporation ("**QLGN**") and Qualigen, Inc., a Delaware corporation ("**Qualigen**"). This Agreement is made with respect to the Sponsored Research Agreement executed and effective on March 5, 2019, and subsequently amended on October 6, 2019 (collectively, "**Sponsored Research Agreement**") by and between ULRF and Qualigen. The parties intend this Agreement to constitute a novation of the Sponsored Research Agreement.

In consideration of the following promises and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the parties, intending to be legally bound, agree as follows:

1. Assignment and Novation. Qualigen hereby grants, conveys, assigns, transfers and delivers unto QLGN, and QLGN hereby accepts and assumes, all of Qualigen's right, title and interest in, to and under the Sponsored Research Agreement, as if it were the original party to the Sponsored Research Agreement in place of Qualigen. In addition, Qualigen hereby assigns, and QLGN hereby assumes and agrees to satisfy and perform if due or when coming due as a direct obligation to ULRF, all of Qualigen's obligations under the Sponsored Research Agreement, regardless of whether arising before or after the Effective Date, without any further liability to Qualigen, and ULRF agrees to look only to QLGN for satisfaction of all such obligations (collectively, the "***Novation***").

2. Release. ULRF hereby agrees to the Novation under this Agreement and releases and forever discharges Qualigen from all of its obligations and liabilities under the Sponsored Research Agreement as of and from the date of this Agreement. Qualigen hereby releases and forever discharges ULRF from all of its obligations and liabilities under the Sponsored Research Agreement on and from the date of this Agreement.

3. Substitution. ULRF recognizes QLGN as Qualigen's successor-in-interest in and to the Sponsored Research Agreement as of and after the date of this Agreement. ULRF and QLGN shall be bound by the terms of the Sponsored Research Agreement in every way as if QLGN is and had always been named in the novated Sponsored Research Agreement in place of Qualigen as a party thereto.

4. General Provisions.

4.1 Full Force and Effect. Except as expressly set forth in this Agreement, the Sponsored Research Agreement remains unchanged and in full force and effect.

4.2 Further Assurances. The parties hereby covenant and agree, without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and instruments and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

4.3 Entire Agreement. This Agreement is the entire agreement of the parties relating to the subject matter hereof.

4.4 Signatories. Each individual executing this Agreement on behalf of a party hereby represents and warrants to the other parties that he is fully and duly empowered and authorized by the first party to so execute and deliver this Agreement to the other parties on behalf of the first party.

4.5 Counterparts. This Agreement may be executed and delivered in counterparts (portable document format (.pdf)/electronic transmission included), each of which shall constitute an original document, but all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed and delivered this Novation Agreement as of the Effective Date.

UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC.

By: */s/ Brennan S. Cox*
Name: Brennan S. Cox
Title: Asst. Dir. – Office of Sponsored Programs

QUALIGEN THERAPEUTICS, INC.

By: */s/ Michael Poirier*
Name: Michael Poirier
Title: President & CEO

QUALIGEN, INC.

By: */s/ Michael Poirier*
Name: Michael Poirier
Title: President & CEO

Exhibit 10.2

NOVATION AGREEMENT

This Novation Agreement (this "**Agreement**") is made as of March 1, 2021 (the "**Effective Date**") among the University of Louisville Research Foundation, Inc. ("**ULRF**"), a Kentucky non-profit corporation as the agent of the University of Louisville ("**UofL**") for receiving grants and research agreements from external funding sources and which owns and controls intellectual property on behalf of UofL, Qualigen, Therapeutics, Inc., a Delaware corporation ("**QLGN**") and Qualigen, Inc., a Delaware corporation ("**Qualigen**"). This Agreement is made with respect to the Exclusive License Agreement June 8, 2018 ("**Exclusive License Agreement**") by and between ULRF and Qualigen. The parties intend this Agreement to constitute a novation of the Exclusive License Agreement.

In consideration of the following promises and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the parties, intending to be legally bound, agree as follows:

1. Assignment and Novation. Qualigen hereby grants, conveys, assigns, transfers and delivers unto QLGN, and QLGN hereby accepts and assumes, all of Qualigen's right, title and interest in, to and under the Exclusive License Agreement, as if it were the original party to Exclusive License Agreement in place of Qualigen. In addition, Qualigen hereby assigns, and QLGN hereby assumes and agrees to satisfy and perform if due or when coming due as a direct obligation to ULRF, all of Qualigen's obligations under the Exclusive License Agreement, regardless of whether arising before or after the Effective Date, without any further liability to Qualigen, and ULRF agrees to look only to QLGN for satisfaction of all such obligations (collectively, the "***Novation***").

2. Release. ULRF hereby agrees to the Novation under this Agreement and releases and forever discharges Qualigen from all of its obligations and liabilities under the Exclusive License Agreement as of and from the date of this Agreement. Qualigen hereby releases and forever discharges ULRF from all of its obligations and liabilities under the Exclusive License Agreement on and from the date of this Agreement.

3. Substitution. ULRF recognizes QLGN as Qualigen's successor-in-interest in and to the Exclusive License Agreement as of and after the date of this Agreement. ULRF and QLGN shall be bound by the terms of the Exclusive License Agreement in every way as if QLGN is and had always been named in the novated Exclusive License Agreement in place of Qualigen as a party thereto.

4. General Provisions.

4.1 Full Force and Effect. Except as expressly set forth in this Agreement, the Exclusive License Agreement remains unchanged and in full force and effect.

4.2 Further Assurances. The parties hereby covenant and agree, without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and instruments and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

4.3 Entire Agreement. This Agreement is the entire agreement of the parties relating to the subject matter hereof.

4.4 Signatories. Each individual executing this Agreement on behalf of a party hereby represents and warrants to the other parties that he is fully and duly empowered and authorized by the first party to so execute and deliver this Agreement to the other parties on behalf of the first party.

4.5 Counterparts. This Agreement may be executed and delivered in counterparts (portable document format (.pdf)/electronic transmission included), each of which shall constitute an original document, but all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed and delivered this Novation Agreement as of the Effective Date.

UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC.

By: */s/ T. Allen Morris*
Name: T. Allen Morris, PhD, MBA
Title: Executive Director, Commercialization EPI-Center

QUALIGEN THERAPEUTICS, INC.

By: */s/ Michael S. Poirier*
Name: Michael S. Poirier
Title: President & CEO

QUALIGEN, INC.

By: */s/ Michael S. Poirier*
Name: Michael S. Poirier
Title: President & CEO

Exhibit 31.1

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

I, Michael S. Poirier, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Qualigen Therapeutics, Inc., a Delaware corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of condensed consolidated financial statements for external purposes with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 14, 2021

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

Exhibit 31.2

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

I, Christopher L. Lotz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Qualigen Therapeutics, Inc., a Delaware corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of condensed consolidated financial statements for external purposes with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 14, 2021

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

Exhibit 32.1

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

Each of the undersigned, Michael S. Poirier, Chief Executive Officer of Qualigen Therapeutics, Inc., a Delaware corporation (the "Company"), and Christopher L. Lotz, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes- Oxley Act of 2002, that, to his knowledge (1) the quarterly report on Form 10-Q of the Company for the three months ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 14, 2021

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

May 14, 2021

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

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