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 June 30, 2020

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	[X]

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 August 7, 2020, there were 21,028,837 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)

	June 30, 2020	March 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,306,422	$ 153,121
Restricted cash	75,696	—
Accounts receivable, net	282,170	417,122
Accounts receivable — related party, net	55,292	290,180
Inventory, net	640,260	660,138
Prepaid expenses and other current assets	2,318,057	98,385
Total current assets	5,677,897	1,618,946
Right-of-use asset	535,194	—
Property and equipment, net	1,547,380	1,447,514
Equipment held for lease, net	45,411	64,005
Intangible assets, net	855,132	571,270
Other assets	18,279	18,279
Total Assets	$ 8,679,293	$ 3,720,014
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 892,182	$ 879,264
Accrued expenses and other current liabilities	1,315,899	1,243,764
Notes payable, current portion	1,106,518	1,913,255
Deferred revenue, current portion	69,571	105,416
Deferred revenue — related party	271,206	271,206
Due to related party	1,144,513	926,385
Lease liability	239,549	—
Warrant liabilities	16,201,400	—
Total current liabilities	21,240,838	5,339,290
Notes payable, net of current portion	218,832	305,805
Lease liability, net of current portion	368,785	—
Deferred revenue, net of current portion	3,594	2,689
Total liabilities	21,832,049	5,647,784
Stockholders' deficit		
Series A convertible preferred stock, $0.01 par value; 2,500,000 shares authorized; 0 and 2,412,887 shares issued and outstanding as of June 30, 2020 and March 31, 2020	—	24,129
Series B convertible preferred stock, $0.01 par value; 9,000,000 shares authorized; 0 and 7,707,736 shares issued and outstanding as of June 30, 2020 and March 31, 2020	—	77,077
Series C convertible preferred stock, $0.01 par value; 5,500,000 shares authorized; 0 and 3,300,715 shares issued and outstanding as of June 30, 2020 and March 31, 2020	—	33,007
Series D convertible preferred stock, $0.01 par value; 2,151,816 shares authorized; 0 and 1,508,305 shares issued and outstanding as of June 30, 2020 and March 31, 2020	—	15,083
Series D-1 convertible preferred stock, $0.01 par value; 848,184 shares authorized; 0 and 643,511 shares issued and outstanding as of June 30, 2020 and March 31, 2020	—	6,435
Series Alpha convertible preferred stock, $0.001 par value; 7,000 shares authorized; 4,620 shares and 0 shares issued and outstanding as of June 30, 2020 and March 31, 2020	4	—
Common stock, post-merger $0.001 par value; 225,000,000 shares authorized; 13,588,258 shares issued and outstanding as of June 30, 2020 and pre-merger $0.01 par value; 40,000,000 shares authorized; 5,602,214 shares issued and outstanding as of March 31, 2020	13,588	56,026
Additional paid-in capital	52,713,683	45,161,599
Accumulated deficit	(65,880,031)	(47,301,126)
Total stockholders' deficit	(13,152,756)	(1,927,770)
Total Liabilities and Stockholders' Deficit	$ 8,679,293	$ 3,720,014

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

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

	Three Months Ended June 30,	
	2020	**2019**
REVENUES		
Net product sales	$ 484,423	$ 560,651
Net product sales—related party	419,644	950,184
Total revenues	904,067	1,510,835
EXPENSES		
Cost of product sales	355,427	316,513
Cost of product sales—related party	452,495	661,267
General and administrative	1,979,614	269,017
Research and development	597,345	147,641
Research and development—related party	—	539,425
Sales and marketing	88,844	102,394
Total expenses	3,473,725	2,036,257
LOSS FROM OPERATIONS	(2,569,658)	(525,422)
OTHER EXPENSE (INCOME), NET		
Change in fair value of warrant liabilities	16,201,400	—
Interest expense, net	57,364	69,985
Other income, net	(250,114)	(992)
Total other expense (income), net	16,008,650	68,993
LOSS BEFORE PROVISION FOR INCOME TAXES	(18,578,308)	(594,415)
PROVISION FOR INCOME TAXES	597	150
NET LOSS	$ (18,578,905)	$ (594,565)
Net loss per common share, basic and diluted	$ (2.12)	$ (0.11)
Weighted—average number of shares outstanding, basic and diluted	8,746,250	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' DEFICIT
(Unaudited)

	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 Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $			
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)
Issuance of common stock for conversion of preferred stock	(2,412,887)	(24,129)	(7,707,736)	(77,077)	(3,300,715)	(33,007)	(1,508,305)	(15,083)	(643,511)	(6,435)	(740)	(1)	7,042,660	7,042	148,690	—	—
Issuance of common stock for conversion of notes payable and accrued interest	—	—	—	—	—	—	—	—	—	—	—	—	1,775,096	1,775	1,582,633	—	1,584,408
Issuance of Series Alpha preferred shares upon closing of private placement	—	—	—	—	—	—	—	—	—	—	5,010	5		-	4,009,995	—	4,010,000
Effect of reverse recapitalization	—	—	—	—	—	—	—	—	—	—	—	—	(2,095,826)	(52,519)	863,405	—	810,886
Issuance of Series Alpha preferred stock for conversion of notes payable	—	—	—	—	—	—	—	—	—	—	350	—	—	—	350,000	—	350,000
Shares and warrants issued to advisor upon closing of private placement	—	—	—	—	—	—	—	—	—	—	—	—	1,217,147	1,217	1,103,891	—	1,105,108
Fair value of shares issued to advisor upon closing of private placement	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(902,250)	—	(902,250)
Fair value of warrants issued to advisor upon closing of private placement	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(202,858)	—	(202,858)
Stock issued for professional services	—	—	—	—	—	—	—	—	—	—	—	—	46,967	47	239,953	—	240,000
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	358,625	—	358,625
Net Loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(18,578,905)	(18,578,905)
Balance at June 30, 2020	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	4,620	$ 4	13,588,258	$ 13,588	$ 52,713,683	$ (65,880,031)	$ (13,152,756)

	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 Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $	Shares	Amount $			
Balance at March 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	$ (45,513,614)	$ (148,124)
Stock-based compensation															-		-
Net Loss																(594,565)	(594,565)
Balance at June 30, 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	$ (46,108,179)	$ (742,689)

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 June 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (18,578,905)	$ (594,565)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	32,565	57,891
Amortization of debt issuance costs	—	11,849
Amortization of right-of-use assets	50,318	—
Accounts receivable reserves and allowances	(27,282)	—
Inventory reserves	(23,132)	24,081
Stock-based compensation	358,625	—
Change in fair value of warrant liabilities	16,201,400	—
Changes in operating assets and liabilities:		
Accounts receivable	162,234	167,476
Accounts receivable — related party	234,888	(335,478)
Inventory and equipment held for lease	43,010	(1,349)
Prepaid expenses and other assets	(1,020,339)	(37,038)
Accounts payable	12,918	216,589
Accrued expenses and other current liabilities	235,495	(81,425)
Due to related party	218,128	392,353
Lease liability	(54,776)	—
Deferred revenue	(34,940)	(34,951)
Net cash used in operating activities	(2,189,793)	(214,567)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(108,699)	—
Payments for patents and licenses	(289,000)	(72,817)
Net cash used in investing activities	(397,699)	(72,817)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of Series Alpha preferred shares upon closing of private placement	4,010,000	—
Net proceeds from the issuance of notes payable	1,392,463	257,654
Payments on capital lease obligations	—	(7,625)
Principal payments on notes payable	(585,974)	(16,585)
Net cash provided by financing activities	4,816,489	233,444
Net change in cash, cash equivalents and restricted cash	2,228,997	(53,940)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH – beginning of period	153,121	125,123
CASH, CASH EQUIVALENTS AND RESTRICTED CASH – end of period	$ 2,382,118	$ 71,183
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 12,145	$ 24,051
Taxes	$ 597	$ 3,343
NONCASH FINANCING AND INVESTING ACTIVITIES:		
Issuance of common stock for professional services	$ 240,000	$ —
Issuance of common stock for conversion of debt	$ 1,350,198	$ —
Issuance of common stock for conversion of accrued interest	$ 234,210	$ —
Issuance of common stock for conversion of preferred stock	$ 148,690	$ —
Issuance of preferred stock for conversion of debt	$ 350,000	$ —
Fair value of shares issued to advisor upon closing of private placement	$ 902,250	$ —
Fair value of warrants issued to advisor upon closing of private placement	$ 202,858	$ —
Effect of reverse recapitalization	$ 810,886	$ —
Right-of-use assets obtained in exchange for lease liabilities	$ 585,512	$ —
Lease liabilities arising from obtaining right-of-use assets	$ 663,110	$ —
Net transfers to inventory from equipment held for lease	$ —	$ 103,112

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

NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Qualigen, Inc., the predecessor of and 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. Qualigen, Inc. 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' capital stocks 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 ticker 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 as of March 31, 2020 and for the three-months period ended June 30, 2019 are those of Qualigen, Inc.

Basis of Presentation

The Company's unaudited interim condensed consolidated financial statements included herein have been prepared in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X and the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted pursuant to such rules and regulations. In management's opinion, the accompanying statements reflect adjustments necessary to present fairly the financial position, results of operations, and cash flows for those periods indicated, and contain adequate disclosure to make the information presented not misleading. Adjustments included herein are of a normal, recurring nature unless otherwise disclosed in the footnotes. The condensed consolidated financial statements and notes thereto should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended March 31, 2020 included on Form 8-K/A, as filed with the SEC on June 29, 2020. The accompanying condensed balance sheet at March 31, 2020 has been derived from the audited balance sheet at March 31, 2020 contained in the above referenced Form 8-K/A. Results of operations for interim periods are not necessarily indicative of the results of operations for a full year.

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 amortization and depreciation, deferred revenue, 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.

Restricted Cash

Restricted cash includes funds that are held in a bank account that are restricted as to withdrawal until certain conditions are met pursuant to Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act").

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported on the Company's condensed consolidated statements of cash flows for the three months ended June 30, 2020 and 2019:

	June 30, 2020	June 30, 2019
Cash and cash equivalents	$ 2,306,422	$ 71,183
Restricted cash	75,696	—
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	**$ 2,382,118**	**$ 71,183**

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 June 30, 2020 and year ended March 31, 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:

	June 30, 2020	March 31, 2020
Accounts Receivable	$ 335,993	$ 443,663
Less Allowance	(53,823)	(26,541)
	$ 282,170	$ 417,122

Research and Development

The Company expenses research and development costs as incurred.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising expense was approximately $9,000 and $1,000, respectively, for the three months ended June 30, 2020 and 2019.

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 $26,000 and $27,000, respectively, for the three months ended June 30, 2020 and 2019. Other shipping and handling costs included in general and administrative, research and development, and sales and marketing expenses totaled approximately $4,000 and $1,000 for the three months ended June 30, 2020 and 2019, respectively.

Revenue from Contracts with Customers

Effective April 1, 2020, the Company adopted Accounting Standard 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 the new revenue standard 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. The following five steps are applied to achieve that core principle:

Step 1: Identify the contract with the customer
Step 2: Identify the performance obligations in the contract
Step 3: Determine the transaction price
Step 4: Allocate the transaction price to the performance obligations in the contract
Step 5: Recognize revenue when the company satisfies a performance obligation

The Company places its medical diagnostic equipment, FastPack System analyzers and accessories, at customer sites under loan agreements as well as generating revenue from direct sales to customers and sells disposable products for use with the equipment. In instances where the equipment is loaned to the customer, the customer is required to make minimum purchases of disposable products. The Company generates revenue from selling disposable products used with the FastPack System. Disposable products include reagent packs which are diagnostic tests for Total PSA, testosterone, thyroid disorders, pregnancy, and Vitamin D.

The Company provides the 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 has been provided to the customer. The delivery of the equipment represents a separate performance obligation and is completed upon receipt of the equipment by the customer. The delivery of each 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. The Company's contracts for equipment and disposable products only include fixed consideration. There are no discounts, rebates, returns or other forms of variable consideration. Customers are generally required to pay within 30 days.

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

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

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

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, the Company accounted for its revenue arrangements under ASC 605, *Revenue Recognition* ("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.

Revenues from product sales which included both the Company's proprietary diagnostic equipment ("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 June 30, 2020 and 2019, product sales are stated net of an allowance for estimated returns of approximately $31,000 and $45,000, respectively.

Deferred Revenue

Prior to the adoption of ASC 606, payments received in advance from customers pursuant to certain collaborative research license agreements, deposits against future product sales, multiple element arrangements and extended warranties are recorded as a current or non-current deferred revenue liability based on the time from the balance sheet date to the future date of revenue recognition.

Research and Licenses

Prior to the adoption of ASC 606, the Company recognized research revenue over the term of various agreements, as negotiated contracted amounts are earned or reimbursable costs are incurred related to those agreements. Negotiated contracted amounts are earned in relative proportion to the performance required under the applicable contracts. Nonrefundable license fees are recognized over the related performance period or at the time that the Company has satisfied all performance obligations. Any amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

During the three months ended June 30, 2020 and 2019, the Company did not recognize any collaborative research revenue.

Operating Leases

Effective April 1, 2020, the Company adopted ASU No. 2018-11, *Leases (Topic 842) ("Topic 842") Targeted Improvements*. The Company determines if a contract contains a lease at inception. The Company's material operating lease consists of a single office/manufacturing/warehouse/laboratory space. Operating lease assets and liabilities are recognized at the lease commencement date. Operating lease liabilities represent the present value of lease payments not yet paid. Operating lease assets represent the Company's right to use an underlying asset and are based upon the operating lease liabilities adjusted for prepayments or accrued lease payments, initial direct costs, lease incentives, and impairment of operating lease assets. To determine the present value of lease payments not yet paid, the Company used the incremental secured borrowing rate for an existing secured loan corresponding to the maturities of the leases.

The Company's leases typically contain rent escalations over the lease term. The Company recognizes expense for these leases on a straight-line basis over the lease term. Additionally, tenant incentives used to fund leasehold improvements are recognized when earned and reduce the Company's right-of-use ("ROU") asset related to the lease. These are amortized through the ROU asset as reductions of expense over the lease term. The Company's office/manufacturing/warehouse/laboratory lease agreement does not contain any material residual value guarantees or material restrictive covenants. The Company has no lease agreements with lease and non-lease components.

Related to the adoption of Topic 842, the Company's policy elections were as follows:

- The Company has availed itself of this practical expedient for under U.S. GAAP, along with the other practical expedients such as grandfathering lease classifications, and treatment of indirect costs;
- The Company has elected to exclude short-term leases having initial terms of 12 months or less, if any;
- The Company has elected not to separate non-lease components from its leases to account for them separately;
- The Company has elected not to avail itself of the practical expedient of using hindsight to determine the lease term; and
- The Company has elected the alternative transition option, by recognizing a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption (as of April 1, 2020, however, the adoption of the Topic 842 did not have an effect on retained earnings).

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 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 are capitalized and amortized over their estimated useful lives, which is generally 5 to 17 years, using the straight-line method. Amortization of patents commences once final approval of the patent has been obtained. Patent costs are charged to operations if it is determined that the patent will not be obtained. The cost of the patents of approximately $739,000 and $715,000 at June 30, 2020 and March 31, 2020, respectively, are stated net of accumulated amortization of approximately $297,000 and $293,000, respectively. Amortization of patents charged to operations for the three months ended June 30, 2020 and 2019 were approximately $3,000 for each period. Total future estimated amortization of patent costs for the five succeeding years is approximately $10,000 for the year ending March 31, 2021, approximately $14,000 for each of the years ending March 31, 2022 through 2023, approximately $13,000 for year 2024, approximately $9,000 for year 2025 and approximately $382,000 thereafter.

The cost of the licenses of approximately $810,000 and $544,000 at June 30, 2020 and March 31, 2020 are stated net of accumulated amortization of approximately $396,000 and $395,000, respectively. Amortization of licenses charged to operations for each of the three month periods ended June 30, 2020 and 2019 was approximately $2,000. Total future estimated amortization of license costs is approximately $5,000 for the year ending March 31, 2021, approximately $7,000 for each of the years ending March 31, 2022 through 2023 and approximately $3,000 for year 2024, $0 for year 2025 and approximately $390,000 thereafter.

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 7).

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 we have 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

Financial instruments, which include 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 we determine that other methods are more reasonable, or other methods for calculating these assumptions are prescribed by regulators, the fair value calculated for our 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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, enacted in March 2010, required medical device manufacturers to pay an excise tax of 2.3% on the sales price of medical devices sold in the United States beginning in January 2013.

The Further Consolidated Appropriations Act, 2020 H.R. 1865 (Pub.L.116-94), signed into law on December 20, 2019, has repealed the medical device excise tax previously imposed by Internal Revenue Code section 4191. Prior to the repeal, the tax was on a 4-year moratorium. As a result of the repeal and the prior moratorium, sales of taxable medical devices after December 31, 2015, are not subject to the tax. Accordingly, for the three months ended June 30, 2020 and 2019, the Company did not incur any medical device excise tax expenses.

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 $29,000 and $35,000, respectively, at June 30, 2020 and March 31, 2020 and are included in accrued expenses and other current liabilities on the balance sheets. Warranty costs were approximately $31,000 and $28,000 for the three months ended June 30, 2020 and 2019, respectively, and are included in cost of product sales in the statements of operations.

Recent Accounting Pronouncements

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 July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements*, 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 most significant impact was the recognition of a ROU asset and lease liability for the Company's sole operating lease—the Company had no finance leases. Adoption of the standard 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 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 will be 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 did not have a material impact on the Company's condensed consolidated 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 suffered recurring losses from operations and has a net working capital deficit and an accumulated deficit at June 30, 2020, and the Company continued to incur losses subsequent to the balance sheet date. The Company's reverse recapitalization transaction with Ritter Pharmaceuticals, Inc. ("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 and August 2020, the Company raised an additional $18.0 million through two Securities Purchase Agreements with a single institutional investor (see Note 13). Planned future research and development activities, capital expenditures, clinical and pre-clinical testing, and commercialization activities of the Company's products will require significant additional financing. Additional financing may not be available on acceptable terms or at all. There is no assurance that profitable operations will ever be achieved, or if achieved, could be sustained on a continuing basis.

NOTE 3 — INVENTORY, NET

Inventory, net consisted of the following at June 30, 2020 and March 31, 2020:

	June 30, 2020	March 31, 2020
Raw materials	$ 437,728	$ 457,425
Work in process	167,849	117,729
Finished goods	34,683	84,984
	$ 640,260	$ 660,138

NOTE 4 — PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following at June 30, 2020 and March 31, 2020:

	June 30, 2020	March 31, 2020
Machinery and equipment	$ 2,355,165	$ 2,355,165
Construction in progress–equipment	1,480,400	1,376,000
Computer equipment	424,851	420,552
Leasehold improvements	307,539	307,539
Molds and tooling	260,002	260,002
Office furniture and equipment	136,275	136,275
	4,964,232	4,855,533
Less Accumulated depreciation	(3,416,852)	(3,408,019)
	$ 1,547,380	$ 1,447,514

Depreciation expense relating to property and equipment was approximately $9,000 and $17,000 for the three months ended June 30, 2020 and 2019, respectively.

NOTE 5 — ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following at June 30, 2020 and March 31, 2020:

	June 30, 2020	March 31, 2020
Bonus	$ 362,500	$ —
Vacation	226,881	160,024
Royalties	1,008	26,099
Research and development	105,064	288,184
Legal	82,019	151,357
Accounting	166,965	126,543
Deferred rent	—	77,597
Warranty costs	29,165	30,119
Payroll	96,501	35,052
Patent and license fees	134,025	51,007
Sales and use taxes	21,590	16,755
Income taxes	8,100	8,100
Interest	689	247,569
Other	81,392	25,358
	$ 1,315,899	$ 1,243,764

NOTE 6 — NOTES PAYABLE

Notes payable consisted of the following at June 30, 2020 and March 31, 2020:

	June 30, 2020	March 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; due January 2021	$ 827,039	$ —
An unsecured promissory note with a bank, pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act	449,050	—
A Factoring and Security Agreement for up to $2,000,000 with a bank, interest at Prime plus 2% of the amount of advances outstanding and a factoring fee of 0.01% per day of the face amount of each invoice for each calendar day that a factored invoice is outstanding	22,912	489,051
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	18,554	20,370
Equipment Financing Agreement with a bank, monthly payments of $596 including imputed interest at 6.590% per annum; secured by manufacturing equipment; due July 2021	7,795	9,441
An unsecured convertible note with an investor including interest at 10% per annum; due September 2019, which was extended by the noteholder until May 2020	—	1,000,000
A series of unsecured convertible bridge notes with investors, including interest of 8% per annum; due between June 2020 and February 2021	—	410,000
A series of unsecured convertible bridge notes with investors, including interest of 8% per annum; due between January and February 2022	—	290,198
	1,325,350	2,219,060
Less current portion, net of debt issuance costs	(1,106,518)	(1,913,255)
Notes Payable, net of current portion	$ 218,832	$ 305,805

Future maturities of notes payable are as follows as of June 30, 2020:

Year Ending March 31,	Amount
2021 (nine months)	$ 1,106,518
2022	215,994
2023	2,838
Total balance	$ 1,325,350

NOTE 7 – WARRANT LIABILITIES

In 2004, the Company issued warrants to various investors and brokers for the purchase of Series C preferred stock in connection with a private placement (the "Series C Warrants"). The Series C Warrants were subsequently extended and, upon closing of the reverse recapitalization transaction with Ritter, exchanged for warrants to purchase common stock of the Company, 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 June 30, 2020, the warrants have remaining terms ranging from 3.1 to 5.3 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 warrant activity for the year ended June 30, 2020:

	Common Stock Warrants			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – March 31, 2020	—	$ —		
Series C preferred stock warrants exchanged for common stock warrants upon reverse recapitalization	4,713,490	0.72		
Forfeited	—	—		
Expired	—	—		
Granted	—	—		
Total outstanding – June 30, 2020	4,713,490	$ 0.72		
Exercisable	4,713,490	$ 0.72	$ 0.72	3.82
Non-Exercisable	—	$ —	$ —	—

The following table summarizes the warrant activity for the year ended June 30, 2019:

	Series C Preferred Stock Warrants			
	Shares	Weighted– Average Exercise Price	Range of Exercise Price	Weighted– Average Remaining Life (Years)
Total outstanding – March 31, 2019	2,197,442	$ 2.23		
Forfeited	(2,000)	2.25		
Expired	—	—		
Granted	—	—		
Total outstanding – June 30, 2019	2,195,442	$ 2.23		
Exercisable	2,187,322	$ 2.23	$ 1.83 – $2.70	4.61
Non-Exercisable	8,120	$ 2.25	$2.25	7.24

The following table presents the Company's fair value hierarchy for its warrant liabilities measured at fair value on a recurring basis as of June 30, 2020:

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 June 30, 2020	$ -	$ -	$ 16,201,400	$ 16,201,400

The following table is a reconciliation for those items measured at fair value on a recurring basis using Level 3 inputs during the three months ended June 30, 2020:

Warrant liabilities	As of June 30, 2020
Balance, beginning of period	$ —
Fair value at issuance date	—
Change in fair value included in the statement of comprehensive loss	16,201,400
Balance, end of period	$ 16,201,400

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

The value as of the dates set forth in the table above, was based on upon following assumptions:

	June 30, 2020
Stock price	$ 3.97
Risk-free interest rate	0.17% — 0.32%
Expected volatility (peer group)	81.00% — 87.00%
Expected life (in years)	3.10 — 5.27
Expected dividend yield	0.00%
Number outstanding	4,713,490
Warrant liabilities (current), end of period	$ 16,201,400

NOTE 8 — LEASE OBLIGATIONS

The tables below show the initial measurement of the operating lease right-of-use assets and liabilities as of April 1, 2020 and the balances as of June 30, 2020, including the changes during the periods:

	Operating lease right-of-use assets
Operating lease right-of-use-assets obtained in exchange for lease obligation at April 1, 2020:	$ 585,513
Less amortization of operating lease right-of-use assets	(50,319)
Operating lease right-of-use assets at June 30, 2020	$ 535,194

	Operating lease liabilities
Lease liabilities arising from obtaining right-of-use assets at April 1, 2020:	$663,110
Less principal payments on operating lease liabilities	(54,776)
Lease liabilities at June 30, 2020	608,334
Less non-current portion	368,785
Current portion at June 30, 2020	$ 239,549

As of June 30, 2020, the Company's operating leases have a weighted-average remaining lease term of 2.3 years and a weighted-average discount rate of 8.9%.

Total lease expense was approximately $86,000 and $84,000, respectively, for the three month periods ended June 30, 2020 and 2019. Lease expense was recorded in cost of product sales, general and administrative expenses, research and development and sales and marketing expenses.

NOTE 9 — COMMITMENTS

The Company leases its facilities under a long-term operating lease agreement expiring in October 2022. The agreement generally requires the payment of utilities, real estate taxes, insurance, and repairs. Rent expense was approximately $65,000 for the three month periods ended June 30, 2020 and 2019.

As of June 30, 2020, future minimum payments during the next five fiscal years and thereafter are as follows:

Year Ending March 31,	Amount
2021 (nine months)	$ 212,906
2022	290,492
2023	173,315
Total	676,713
Less present value discount	(68,379)
Operating lease liabilities	$ 608,334

NOTE 10 — RESEARCH AND LICENSE AGREEMENTS

In June and August 2018, the Company entered into license and sponsored research agreements with the University of Louisville Research Foundation ("ULRF") for a novel molecular-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 and the Company will reimburse ULRF for sponsored research expenses of up to $348,000 and prior patent costs of up to $200,000. In addition, the Company has 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 costs associated with the preparation, filing, prosecution and maintenance of licensed patents, incurred prior to June 2018, and (iv) payments ranging from $100,000 to $5,000,000 upon the achievement of certain regulatory and commercial milestones. Milestone payments for the first therapeutic indication would be $100,000 for first dosing in a Phase 1 clinical trial, $200,000 for first dosing in a Phase 2 clinical trial, $350,000 for first dosing in a Phase 3 clinical trial, $500,000 for regulatory marketing approval and $5,000,000 upon achieving a cumulative $500,000,000 of Licensed Product sales; the Company would also pay another $500,000 milestone payment for any additional regulatory marketing approval for each additional therapeutic (or diagnostic) indication. The Company also must pay ULRF shortfall payments if the total amounts actually paid with respect to royalties and non-royalty sublicensee income for any year is less than the applicable annual minimum (ranging from $10,000 to $50,000) for such year.

Sponsored research expenses related to these agreements for the three months ended June 30, 2020 and 2019 were approximately $2,000 and $33,000 and are recorded in research and development expenses in the statements of operations.

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 a novel aptamer-based anticancer technology. In return, ACT received a $25,000 convertible promissory note in payment of an upfront license fee. In addition, the Company has agreed to pay ACT (i) royalties, on net sales associated with the commercialization of ACT-GRO-777/AS1411, 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 AS1411-based licensed product receiving the CE Mark or similar FDA status, and $500,000 upon cumulative worldwide AS1411-based licensed product net sales reaching $3,000,000. In May 2020, the $100,000 milestone payment for the Company raising a cumulative total of $2,000,000 in new equity financing was triggered. This amount is included in intangible assets and accrued expenses as of June 30, 2020.

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 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 from April 2019 through September 2020.

Sponsored research expenses related to this agreement for the three months ended June 30, 2020 and 2019 were approximately $139,000 and $20,000 and are recorded 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 AS1411 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 will receive a $20,000 upfront license fee. In addition, the Company will execute a sponsored research agreement with ULRF supporting at least $250,000 in research by December 31, 2020.

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 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 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 $5,000 to $50,000) for such year.

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. In exchange for up to $7.2 million in future product development financing payments over the term of the agreement, the Company has appointed Sekisui as its commercial partner and exclusive worldwide distributor with the exception of certain customer accounts retained by Qualigen. The agreement contains an exclusivity period and right of first refusal for a potential acquisition of the Company by Sekisui.

For the three months ended June 30, 2020 and 2019, there was no collaborative research revenue, and product sales of approximately $420,000 and $950,000 related to this agreement, respectively.

NOTE 11 — STOCKHOLDERS’ DEFICIT

As of June 30, 2020, the Company had two classes of capital stock: common stock and Series Alpha convertible preferred stock. As of March 31, 2020, the Company had two classes of capital stock with one being divided into five series: common stock and preferred stock (Series A convertible preferred stock, Series B convertible preferred stock, Series C convertible preferred stock, Series D convertible preferred stock and Series D-1 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, 2020 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 C convertible preferred stock, Series D convertible preferred stock and Series D-1 convertible preferred stock) upon liquidation, dissolution or winding up of the affairs of the Company. Following payment of the liquidation preference of the preferred stock, as of June 30, 2020 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 June 30, 2020, the Company has reserved 16,465,518 shares of authorized but unissued common stock for possible future issuance. At June 30, 2020, shares were reserved in connection with the following:

Exercise of issued and future grants of stock options	3,674,624
Exercise of stock warrants	6,543,205
Conversion of Series Alpha preferred stock	6,247,689
Total	16,465,518

Series A, B, C, D, D-1 Convertible Preferred Stock

At March 31, 2020, there were 2,412,887, 7,707,736, 3,300,715, 1,508,305, 643,511 shares of Series A, B, C, D, D-1 convertible preferred stock outstanding respectively. All shares of Series A, B, C, D, D-1 convertible preferred stock were converted into common stock at the time of the May 2020 reverse recapitalization transaction.

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. There was approximately $359,000 and $0 of compensation costs related to outstanding options and warrants for the three months ended June 30, 2020 and 2019, respectively.

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 June 30, 2020 and 2019 there were 3,579,500 and 0 outstanding options respectively under the 2020 Plan and there were 477,657 and 0 options available respectively for future grant.

The Company has also granted equity classified warrants (originally exercisable to purchase Series C convertible preferred stock, and now instead exercisable to purchase common stock) to service providers, as compensation for services.

In addition, the Company has granted warrants for purposes other than compensation for services.

The following represents a summary of the options granted to employees and non-employees that are outstanding at June 30, 2020, and changes during the period then ended:

	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – March 31, 2020	—	$ —		
Legacy Ritter options	95,124	92.80	$ 5.75—$1,465.75	1.87
Granted	3,579,500	5.10	$ 4.97—$5.13	9.94
Expired	—	—		
Forfeited	—	—		
Total outstanding – June 30, 2020	3,674,624	$ 7.37	$ 4.97—$1,465.75	9.73
Exercisable (vested)	110,124	$ 80.84	$ 4.97—$1,465.75	2.97
Non-Exercisable (non-vested)	3,564,500	$ 5.10	$ 4.97—$5.13	9.94

There was approximately $0.4 million and $0 of compensation costs related to outstanding options for the three months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, there was approximately $14.1 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 2.94 years.

No stock options were exercised during the three months ended June 30, 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 June 30, 2020 was $5.10.

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 June 30, 2020
Expected dividend yield	0.00%
Expected stock-price volatility	102%
Risk-free interest rate	0.33% — 0.59%
Expected average term of options	6.0
Stock price	$ 4.97 — 5.13

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

	For the three months ended June 30,	
	2020	2019
General and administrative	$ 272,978	$ —
Research and development	85,647	—
Total	$ 358,625	$ —

Compensatory Warrants

In the three months ended June 30, 2020, 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 of these warrants did not result in expense on the Company's statements of operations. In addition, various service providers hold compensatory warrants issued in 2017 and earlier for the purchase of 668,024 shares of Company common stock at a weighted exercise price of $2.34 per share. No compensatory warrants were issued in the three month ended June 30, 2019.

The following table summarizes the compensatory warrant activity for the three months ended June 30, 2020:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – March 31, 2020	—	$ —		
Series C preferred stock warrants exchanged for common stock warrants upon reverse recapitalization	668,024	2.34		
Legacy Ritter warrants	—	—		
Granted	811,431	1.11		
Expired	—	—		
Forfeited	—	—		
Total outstanding – June 30, 2020	1,479,455	$ 1.67		
Exercisable	660,832	$ 2.34	$2.07 —$2.54	3.82
Non-Exercisable	818,623	$ 1.12	$1.11 —$2.54	4.91

Noncompensatory Equity Classified Warrants

In the three months ended June 30, 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. No noncompensatory equity classified warrants were issued in the three months ended June 30, 2019.

The following table summarizes the noncompensatory equity classified warrant activity for the three months ended June 30, 2020:

	Common Stock			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – March 31, 2020	—	$ —		
Legacy Ritter warrants	81,455	54.04		
Granted	270,478	1.11		
Expired	(1,673)	1,562.50		
Forfeited	—	—		
Total outstanding – June 30, 2020	350,260	$ 1.08		
Exercisable	350,260	$ 5.96	$1.11 – $2,325.00	4.31
Non-Exercisable	—	$ —	—	—

There were no compensation costs related to outstanding warrants for the three months ended June 30, 2020 and 2019. As of June 30, 2020 and 2019, there was approximately $0 and $11,000 of unrecognized compensation cost related to nonvested warrants, respectively.

NOTE 12 — RELATED PARTY TRANSACTIONS

In October 2017, Sekisui purchased all outstanding shares of 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. The following are transactions made between the Company and Sekisui as of and for the three months ended June 30, 2020 and 2019.

- The Company sells products and provides collaborative research & development ("R&D") services to Sekisui. As of June 30, 2020 and March 31, 2020, the Company had a receivable from Sekisui of approximately $55,000 and $290,000, respectively. The Company recorded product sales of approximately $420,000 and $950,000 for the three months ended June 30, 2020 and 2019, respectively. In May 2019 the Company and Sekisui terminated the R&D portion of their distribution and development agreement. There was no collaborative R&D revenue from Sekisui for the three months ended June 30, 2020 and 2019. The Company had cost of product sales relating to Sekisui of approximately $452,000 and $661,000, respectively, and R&D expenses relating to Sekisui of approximately $0 and $539,000, respectively, for the three months ended June 30, 2020 and 2019.

- As of June 30, 2020 and March 31, 2020, the Company had approximately $1.1 million and $0.9 million, respectively, classified as due to related party (Sekisui) on the accompanying balance sheets. The Company satisfied the financial obligation by payment in full on July 21, 2020.

- A s of June 30, 2020 and March 31, 2020, the Company had approximately $271,000 of deferred revenue from Sekisui classified as deferred revenue on the accompanying balance sheets.

NOTE 13 — SUBSEQUENT EVENTS

On July 1, 2020, an aggregate of 1,554 shares of Series Alpha preferred stock were converted into 2,101,495 shares of the Company's common stock.

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 Qualigen common stock, (ii) 780,198 pre-funded warrants (i.e., warrants to purchase shares of Qualigen common stock, for which the exercise price is almost entirely prepaid) and (iii) 1,920,768 two-year warrants to purchase shares of Qualigen 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 July 17, 2020, the Company entered into a license agreement with ULRF for RAS Inhibitor compounds.

On July 21, 2020, the Company paid Sekisui approximately $1.0 million to fully satisfy the Company's R&D-related financial obligations to Sekisui.

On July 23, 2020, 444 shares of Series Alpha preferred stock were converted into 600,427 shares of the Company's common stock.

On July 27, 2020, 444 shares of Series Alpha preferred stock were converted into 600,427 shares of the Company's common stock.

On July 29, 2020, 370 shares of Series Alpha preferred stock were converted into 500,356 shares of the Company's common stock.

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 Qualigen common stock, and (ii) 1,287,829 two-year warrants to purchase shares of Qualigen common stock for an exercise price of $6.00 per share. The warrants included a 9.99% beneficial-ownership blocker provision.

Risks Related to COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect the Company's operations and those of third parties on which the Company relies. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic are difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, financing or other activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which the Company relies. For example, the Company believes the COVID-19 pandemic was a primary cause of the Company's decline in diagnostic product sales in the first quarter of fiscal 2021. Deferral of patients' non-emergency visits to the facilities of the Company's physician-office, clinic and small-hospital users sharply reduced their use of the Company's tests and their need to place further orders. This phenomenon is expected to continue for the duration of the pandemic, although the degree of it will probably vary depending on progress toward suppressing the pandemic, lockdowns and similar responses, and personal and societal behavior changes arising from psychological factors.

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 year ended March 31, 2020, which are contained in our amended Current Report on Form 8-K/A filed with the Securities and Exchange Commission ("SEC") on June 29, 2020. 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 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 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 adoption and placement of FastPack PRO System analyzers (which are the only FastPack analyzers on which our SARS-CoV-2 IgG and cFN test kits can be run) will be widespread;
- there can be no assurance that we will be able to manufacture our FastPack PRO System analyzers and the SARS-CoV-2 IgG test kits successfully;
- there can be no assurance that any commercialization of the FastPack PRO System analyzers and SARS-CoV-2 IgG test kits will be profitable; that the FDA will ultimately approve an Emergency Use Authorization for our SARS-CoV-2 IgG test;
- 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.

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 Securities and Exchange Commission, 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.

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 almost 20 years. Our cancer therapeutics pipeline includes ALAN (AS1411-GNP), RAS-F and STARS™. ALAN (AS1411-GNP) is a DNA coated gold nanoparticle cancer drug candidate that has the potential to target various types of cancer with minimal side effects; the nanoparticle coating technology is similar to the core nanoparticle coating technology used in our blood-testing diagnostic products. The foundational aptamer of ALAN, AS1411, is also being studied on our behalf for use in treating viral-based infectious diseases, including COVID-19. RAS-F is a family of RAS oncogene protein-protein interaction inhibitor small molecules for preventing mutated RAS genes' proteins from binding to their effector proteins; preventing this binding could stop tumor growth, especially in pancreatic, colorectal and lung cancers. STARS is a DNA/RNA-based treatment device 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, vitamin D status and antibodies against SARS-CoV-2. Since inception, 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 Low T Center, Inc., the largest men's health group in the US, with more than 47 locations.

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 as of March 31, 2020 and for the three-months period ended June 30, 2019 are those of Qualigen, Inc., and the corresponding figures of Ritter Pharmaceuticals, Inc. have been disregarded. Moreover, references in this Quarterly Report to "our" pre-May 22, 2020 history, securities and agreements in this Item are references to the pre-May 22, 2020 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, 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 be 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.

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.

Warrant Liability

In 2004, we 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. Although the fair value of the warrants was immaterial at March 31, 2020, the operation of the double-ratchet provisions in these 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. U.S. GAAP requires us to recognize the fair value of these warrants as warrant liability. The size of this warrant liability at June 30, 2020 was quite large ($16.2 million) and caused a significant distortion of our balance sheet at June 30, 2020 and our results of operations for the three month period ended June 30, 2020. 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 quarter statements of operations and balance sheets based on changes in our public market common stock price.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019, together with the changes in those items in dollars:

	For the Three Months Ended June 30,		Dollar
	2020	2019	Change
REVENUES			
Net product sales	$ 484,423	$ 560,651	(76,228)
Net product sales—related party	419,644	950,184	(530,540)
Total revenues	904,067	1,510,835	(606,768)
EXPENSES			
Cost of product sales	355,427	316,513	38,914
Cost of product sales—related party	452,495	661,267	(208,772)
General and administrative	1,979,614	269,017	1,710,597
Research and development	597,345	147,641	449,704
Research and development—related party	—	539,425	(539,425)
Sales and marketing	88,844	102,394	(13,550)
Total expenses	3,473,725	2,036,257	1,437,468
LOSS FROM OPERATIONS	(2,569,658)	(525,422)	(2,044,236)
OTHER EXPENSE, NET			
Change in fair value of warrant liabilities	16,201,400	—	16,201,400
Interest expense, net	57,364	69,985	(9,781)
Other (income) expense, net	(250,114)	(992)	(249,122)
Total other expense, net	16,008,650	68,993	15,939,657
LOSS BEFORE PROVISION FOR INCOME TAXES	(18,578,308)	(594,415)	(17,983,893)
PROVISION FOR INCOME TAXES	597	150	447
NET LOSS	(18,578,905)	(594,565)	(17,984,340)

Revenues

Our operating revenues are primarily generated from sales of diagnostic tests. Revenues during the three-month period ended June 30, 2020 were $0.9 million compared to $1.5 million during the same period in 2019, a decrease of $0.6 million, or 40%. This decrease of $0.6 million was due to a reduction in sales to Sekisui, our primary distributor, of about $0.5 million due to an excess of Sekisui's FastPack instrument and diagnostic kit inventory levels primarily caused by the COVID-19 pandemic, and a $0.1 million decrease in sales to Low T Center, Inc., our largest direct customer, also due to the COVID-19 pandemic. Deferral of patients' non-emergency visits to the facilities of our physician-office, clinic and small-hospital users sharply reduced their use of our tests and their need to place further orders. This phenomenon is expected to continue for the duration of the pandemic, although the degree of it will probably vary depending on progress toward suppressing the pandemic, lockdowns and similar responses, and personal and societal behavior changes arising from psychological factors. In addition, decreases in Medicare and private-insurer reimbursement for tests such as ours in recent years are a negative factor in our attempts to maintain and grow our diagnostics business. This factor constrains the price that we can charge for our diagnostic products and may induce some physician offices, clinics and small hospitals not to offer (or to discontinue offering) our diagnostic products or particular ones of our diagnostic products.

Net product sales

Net product sales (which is a category defined by excluding sales to Sekisui, because Sekisui is a related party) are primarily generated from sales of diagnostic tests. Net product sales during the three-month periods ended June 30, 2020 and 2019 were approximately $484,000 and $561,000, respectively, representing a decrease of approximately $76,000, or 14%. This decrease was due primarily to a reduction in sales to Low T Center, Inc., due to the effect of the COVID-19 pandemic, as described above.

Net product sales—related party

Net product sales—related party are primarily generated from sales of diagnostic tests to our primary distributor, Sekisui. Net product sales—related party during the three-month periods ended June 30, 2020 and 2019 decreased by approximately $531,000 to approximately $420,000 from approximately $950,000, or 56%, with the reduction in sales to Sekisui being primarily due to the effect of the COVID-19 pandemic, as described above.

Expenses

Cost of Product Sales

Cost of product sales (which is a category defined by excluding the cost of products sold to our distributor Sekisui, because Sekisui is a related party) increased from $317,000 or 56% of product sales, during the three-month period ended June 30, 2019, to $355,000, or 73% of product sales, during the three-month period ended June 30, 2020. The increase in dollars and increase in percentage of product sales were due to higher overhead costs and lower product sales volume.

Cost of Product Sales-related party

Cost of product sales-related party (i.e., our cost of products sold to our distributor Sekisui) decreased from $661,000 or 70% of product sales-related party, during the three-month period ended June 30, 2019, to $452,000, or 108% of product sales-related party, during the three-month period ended June 30, 2020. The decrease in dollars and increase in percentage of product sales-related party were due to lower product sales volume, resulting in diseconomies of scale. Because the percentage decline in our Sekisui sales was much greater than the percentage decline in our non-Sekisui sales, our absolute cost of product sales-related party decreased in the 2020 period despite the increase in higher allocable overhead costs.

General and Administrative Expenses

General and administrative expenses increased from $0.3 million, during the three-month period ended June 30, 2019, to $2.0 million during the three-month period ended June 30, 2020. This increase was primarily due to $0.3 million in employee/director stock-based compensation expense, a $0.8 million increase in professional fees including legal and accounting services related to the reverse-recapitalization transaction, a $0.5 million increase in payroll expense and a $0.1 million increase in insurance expense. For the future, the reverse-recapitalization transaction costs will be behind us.

Research and Development Costs

Research and development costs (and research and development costs—related party) include diagnostic and therapeutic research and product development costs. We have shifted our focus in this category toward therapeutics. Research and development costs (which is a category defined by excluding the cost of our R&D project for Sekisui, because Sekisui is a related party) increased from approximately $148,000 for the three months ended June 30, 2019 to approximately $597,000 for the three months ended June 30, 2020. Of the research and product development costs for the three months ended June 30, 2019, approximately $60,000 was attributable to diagnostics and approximately $88,000 was attributable to therapeutics. Of the research and product development costs for the three months ended June 30, 2020, approximately $214,000 was attributable to diagnostics and approximately $383,000 was attributable to therapeutics.

Research and development costs—related party includes the diagnostics costs associated with the FastPack 2.0 project with Sekisui, and decreased from approximately $539,000 for the three months ended June 30, 2019 to $0 for the same period ended June 30, 2020. The FastPack 2.0 project with Sekisui was terminated in May 2019.

The increase in non-Sekisui-related diagnostic costs was primarily due to COVID-19 antibody diagnostic test and FastPack PRO instrument development costs. The increase in therapeutics costs was primarily due to expenses related to the potential application of AS1411 to COVID-19 ($189,000 for the three months ended June 30, 2020 as compared to $0 for the same period ended in 2019) and sponsored therapeutics research at the University of Louisville with respect to RAS-F ($139,000 for the three months ended June 30, 2020 as compared to $20,000 for the same period ended in 2019), offset by a modest decrease in sponsored therapeutics research at the University of Louisville with respect to ALAN. 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 were not materially changed from the three-month period ended June 30, 2020 (approximately $89,000) versus the three-month period ended June 30, 2019 (approximately $102,000). Our sales and marketing expenses (which all pertain to our diagnostic products) are relatively low because we rely on Sekisui for all sales efforts except for sales to our specified house accounts.

Other Expense

There was approximately $16.0 million in other expense during the three-month period ending June 30, 2020 versus approximately $0.1 million in other expenses during the three-month period ended June 30, 2019. This change was due primarily to the recognition in the 2020 period of $16.2 million of warrant liabilities related to warrants (containing a “double-ratchet” provision) issued many years ago to brokers and investors in connection with a 2004 private placement (as described above), partially offset by expiration during the three-month period ending June 30, 2020 of a $0.3 million license option for the Company’s FastPack 2.0 technology. The 2020 period also benefited from a reduction in interest expense due to the automatic conversion of $1.7 million principal amount of convertible notes payable, upon the closing of the reverse recapitalization transaction in May 2020.

Liquidity and Capital Resources

After June 30, 2020, our liquidity improved very significantly due to sales of equity securities for a total of $18.0 million in two registered-direct offerings to an institutional investor (see Note 13).

As of June 30, 2020, our liquidity and cash positions had not been so strong. We have suffered recurring losses from operations and had a net working capital deficit of approximately $15.6 million at June 30, 2020 compared to a net working capital deficit of $3.7 million at March 31, 2020. Included in the working capital deficit at June 30, 2020 was $16.2 million of warrant liability. We had cash of approximately $2.3 million at June 30, 2020, which was not comfortably sufficient for a development-stage therapeutics biotechnology company – although it was much improved over our March 31, 2020 cash position of approximately $0.2 million.

The increase in our cash position, during the three months ended June 30, 2020, was primarily due to a $4.0 million equity capital raise in May 2020. Our current liabilities at June 30, 2020 included $1.3 million in principal and accrued interest on factoring/financing agreements and a CARES Act loan. In addition, at June 30, 2020 we had a payment of $0.9 million plus accrued interest due to Sekisui in September 2020 related to the Distribution Agreement; we prepaid this obligation in full in July 2020.

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

Cash Flows

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

	For the Three Months Ended June 30,	
	2020	**2019**
Net cash provided by (used in):		
Operating activities	$ (2,189,793)	$ (214,567)
Investing activities	(397,699)	(72,817)
Financing activities	4,816,489	233,444
Net increase (decrease) in cash, cash equivalents and restricted cash	**$ 2,228,997**	**$ (53,940)**

Net Cash Used in Operating Activities

During the three months ended June 30, 2020, operating activities used $2.2 million of cash, resulting from a net loss of $18.6 million, partially offset by $16.2 million change in fair value of warrant liabilities and changes in our operating assets and liabilities. Changes in net cash used in operating activities for the three months ended June 30, 2020 included the $16.2 million change in fair value of warrant liabilities (as described above), a $0.4 million increase in employee/director stock-based compensation expense, a $0.4 million decrease in accounts receivable and accounts receivable-related party, a $0.2 million increase in due to related party and a $0.2 million increase in accrued expenses and other current liabilities, partially offset by a $1.0 million increase in prepaid expenses and other assets. The decreases in accounts receivable and accounts receivable-related party were due to lower receivable balances from Sekisui and from our largest direct customer, while the increase in prepaid expenses and other assets was due to prepaid director and officer insurance policies purchased in connection with the reverse recapitalization transaction.

During the three months ended June 30, 2019, operating activities used $0.2 million of cash, resulting from a net loss of $0.6 million, offset by $0.4 million in depreciation and amortization and changes in our operating assets and liabilities. Changes in net cash used in operating activities for the three months ended June 30, 2019 included a $0.4 million increase in due to related party and a $0.2 million increase in accounts payable, partially offset by a $0.2 million increase in accounts receivable. The 2019 period's increase in due to related party was from the discontinuation of the FastPack 2.0 project with Sekisui, the increase in accounts payable was due to higher payables related to therapeutics research and development, and the increase in accounts receivable was due to higher receivables from our largest house-account customer. In the 2019 period, the change in fair value of warrant liabilities was $0.

Net Cash Used in Investing Activities

During the three months ended June 30, 2020, net cash used in investing activities was $0.4 million, primarily related to payments for patents and licenses and purchase of property and equipment.

During the three months ended June 30, 2019, net cash used in investing activities was $0.1 million, primarily related to payments for patents and licenses.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended June 30, 2020 and 2019 was $4.8 million and $0.2 million, respectively. The 2020 period's financings were in direct anticipation of the reverse-recapitalization transaction.

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 June 30, 2020, 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 June 30, 2020 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

In connection with the reverse recapitalization transaction of May 22, 2020, the financial team of Qualigen, Inc. became the financial team of the Company, and the internal control policies of Qualigen, Inc. were accordingly implemented for the Company. We do not believe that these changes materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We 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 arising in the normal course of business. 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.

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

Unregistered Sales of Equity Securities

On June 29, 2020, we issued 46,967 shares of common stock to SRAX, Inc. pursuant to a Platform Account Contract dated June 18, 2020, in exchange for services valued at $240,000. No underwriter was involved. This was an issuance to a single purchaser and accordingly was 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

Exhibit No.	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1**	Agreement and Plan of Merger, dated January 15, 2020, by and among the Company, Qualigen, Inc. and RPG28 Merger Sub, Inc.	S-4/A		Annex A	April 6, 2020
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated February 1, 2020, by and among the Company, Qualigen, Inc. and RPG28 Merger Sub, Inc.	S-4/A		Annex B	April 6, 2020
2.3	Amendment No. 2 to Agreement and Plan of Merger, dated March 26, 2020, by and among the Company, Qualigen, Inc. and RPG28 Merger Sub, Inc.	S-4/A		Annex C	April 6, 2020
2.4	Contingent Value Rights Agreement, dated May 22, 2020, by and among the Company, John Beck in the capacity of CVR Holders' Representative and Andrew J. Ritter in his capacity as a consultant to the Company	8-K		2.4	May 29, 2020
3.1	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
3.2	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
3.3	Certificate of Merger, filed with the Delaware Secretary of State on May 22, 2020	8-K		3.3	May 29, 2020
3.4	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
3.5	Amended and Restated Bylaws of the Company, as of May 22, 2020	8-K		3.5	May 29, 2020
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series Alpha Preferred Stock of Qualigen, filed with the Delaware Secretary of State on May 20, 2020	8-K		3.6	May 29, 2020
10.1+	Amendment No. 2 to Consulting Agreement, by and between Qualigen, Inc. and GreenBlock Capital LLC, dated as of May 3, 2020	8-K		10.8	May 29, 2020
10.2+	Form of Warrant, issued by Qualigen, Inc. in favor of GreenBlock Capital LLC and its designees, dated May 22, 2020 [pre-Merger]	8-K		10.9	May 29, 2020

10.3+	Form of Warrant, issued by the Company in favor of GreenBlock Capital LLC and its designees, dated May 22, 2020 [post-Merger]	8-K	10.10	May 29, 2020
10.4**	Securities Purchase Agreement, by and between Qualigen, Inc. and Alpha Capital Anstalt, dated May 20, 2020	8-K	10.11	May 29, 2020
10.5	Warrant, issued by Qualigen, Inc. in favor Alpha Capital Anstalt, dated May 22, 2020 [pre-Merger]	8-K	10.12	May 29, 2020
10.6	Warrant, issued by the Company in favor of Alpha Capital Anstalt, dated May 22, 2020 [post-Merger]	8-K	10.13	May 29, 2020
10.7+	Notice of Grant of Stock Option / Stock Option Agreement, by and between the Company and Andrew J. Ritter, dated as of May 18, 2020	8-K	10.14	May 29, 2020
10.8+	Notice of Grant of Stock Option / Stock Option Agreement, by and between the Company and Ira E. Ritter, dated as of May 18, 2020	8-K	10.15	May 29, 2020
10.9+	Notice of Grant of Stock Option / Stock Option Agreement, by and between the Company and John Beck, dated as of May 18, 2020	8-K	10.16	May 29, 2020
10.10+	Consulting Agreement, by and between the Company and Andrew J. Ritter, dated as of May 22, 2020	8-K	10.17	May 29, 2020
10.11+	Consulting Agreement, by and between the Company and Stonehenge Partners, LLC, dated as of May 22, 2020	8-K	10.18	May 29, 2020
10.12+	Consulting Agreement, by and between the Company and CFB Financial, Inc., dated as of May 22, 2020	8-K	10.19	May 29, 2020
10.13+	2020 Stock Equity Incentive Plan	Form S-4/A	Annex G	April 6, 2020
10.14	Form of Indemnification Agreement - Qualigen, Inc.	8-K	10.21	May 29, 2020
10.15	Form of Lock-Up Agreement	8-K	10.22	May 29, 2020
10.16	Standard template of Stock Option Agreement for use under 2020 Stock Incentive Plan.	8-K	10.1	June 11, 2020
10.17	Letter agreement amending M&A Advisory Agreement between the Company and A.G.P./Alliance Global Partners dated May 20, 2020.			
10.18	Exclusive License Agreement, by and between the Company and University of Louisville Research Foundation, Inc. dated as of June 9, 2020.			
10.19	Letter agreement (for payment date extension) between the Company and Sekisui Diagnostics, LLC dated June 23, 2020.			
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.

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

+ Management contract or compensatory plans or arrangements

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.

August 14, 2020

QUALIGEN THERAPEUTICS, INC.

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

Exhibit 10.17

May 20, 2020

A.G.P./Alliance Global Partners
Attention: David Bocchi
Head of Investment Banking
590 Madison Ave 28th Floor
New York, NY 10022

Dear David:

We refer to the M&A Advisory Agreement (the "Advisory Agreement"), dated October 1, 2019, by and between Ritter Pharmaceuticals, Inc. (the "Company") and A.G.P./Alliance Global Partners ("A.G.P."), with respect to A.G.P.'s exclusive engagement as financial advisor to the Company in connection with a possible transaction with the Targets (as defined in the Advisory Agreement). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Advisory Agreement.

1. The Company and A.G.P. hereby agree to amend the Advisory Agreement as follows:

   a. Paragraph B(1) shall be amended and restated in its entirety as follows:

      i. Transaction Fee. If during the term of this engagement or after termination of this engagement as set forth in Paragraph C below, a Transaction is consummated, the Company shall pay, or cause to be paid, to A.G.P., at the time of the closing (the " Closing") of the Transaction, in immediately available funds, a transaction fee (the "Transaction Fee") of $1,200,000.

   b. Paragraph B(2) shall be deleted in its entirety.

   c. Paragraph B(5) shall be deleted in its entirety.

2. The Company and A.G.P. agree that (a) the payment of the Transaction Fee shall satisfy all payment obligations of the Company under the Advisory Agreement, as amended hereby, and (b) the Advisory Agreement shall immediately terminate upon payment to A.G.P. of the Transaction Fee in accordance with the Advisory Agreement, as amended hereby. Other than with respect to Paragraphs E, G, H, I and J, which shall survive in accordance with their terms, following such payment and termination, neither party shall have any outstanding obligation to the other party pursuant to or with respect to the Advisory Agreement, as amended hereby.

Please confirm that the foregoing is in accordance with your understanding by signing and returning to us the enclosed copy of this letter, which shall become a binding agreement upon our receipt.

Very truly yours,

/s/Andrew J. Ritter
Ritter Pharmaceuticals, Inc.
Name: Andrew J. Ritter
Title: CEO

Confirmed:

ALLIANCE GLOBAL PARTNERS

By: */s/ Thomas J. Higgins*
Name: Thomas J. Higgins
Title: Managing Director
Investment Banking
Date: May 21st 2020

EXCLUSIVE LICENSE AGREEMENT

This exclusive license agreement ("**Agreement**") is dated and effective as of the date of last signature (the "**Effective Date**") and is made by and between University of Louisville Research Foundation, Inc. ("**ULRF**"), a Kentucky 501(c)3 non-profit corporation having an office at 300 East Market Street, Suite 300, Louisville, Kentucky, 40202, as the agent of the University of Louisville ("**UofL**") for licensing intellectual property owned and controlled by ULRF on behalf of UofL, and Qualigen Therapeutics, Inc. ("**Licensee**"), a Delaware corporation with a principal place of business at 2042 Corte Del Nogal, Carlsbad, California 92011. ULRF and Licensee are referred to herein, on occasion, separately as a "**Party**" or together as the "**Parties**".

BACKGROUND

1. ULRF was established by UofL to enter into and administer research agreements with external funding sources and to own, control, and license intellectual property on behalf of UofL in order to foster the transfer and development of technology for public benefit.

2. A valuable invention or inventions as described in ULRF Case No. 20050 ("**Invention**"), was/were developed during the course of research conducted at UofL by the individuals hereinafter listed in Section 1.4 ("**Inventors**").

3. ULRF has acquired through assignment all rights, title and interest of said Inventors in said valuable Invention and the related Licensed Patents, as hereinafter defined and identified.

4. ULRF has acquired and owns, as of the Effective Date of this Agreement, certain technical knowledge ("**Technical Knowledge**") relating to schematics, formulas, processes, data, methods, and other information suitable for manufacturing and using the invention for various uses and applications, as hereinafter defined and identified.

5. Qualigen, Inc., which is now a wholly owned subsidiary of Licensee, and ULRF signed an Exclusive Option Agreement effective March 31, 2020 (ULRF ref. 20291-OA) hereinafter the "**Option Agreement**," allowing Qualigen, Inc. to evaluate the Invention, potential products arising therefrom, and markets therefor.

6. In accordance with the terms of the Option Agreement, Qualigen, Inc. has exercised its option to negotiate a license to the Invention; and Qualigen, Inc. has (with ULRF's consent) assigned its optionee rights under the Option Agreement to Licensee.

7. ULRF and Licensee desire to have the Invention developed and commercialized so that products and services resulting therefrom may be available for public use and benefit.

8. Licensee desires to receive and utilize ULRF's Technical Knowledge for the development of the Invention, and acquire a license under the Licensed Patents to make, have made, use, sell, offer for sale, and import products, methods, and services in accordance with the terms herein, and ULRF is willing to make such Technical Knowledge available and grant a license under the Licensed Patents to Licensee in accordance with the terms herein.

Now, therefore, the Parties agree as follows:

1. DEFINITIONS

1.1 "**Affiliate**" of Licensee (or of a Sublicensee, respectively) means any entity that, as of the applicable point in time during the term of this Agreement, directly or indirectly controls Licensee (or a Sublicensee, respectively), is controlled by Licensee (or a Sublicensee, respectively), or is under common control with Licensee (or a Sublicensee, respectively) and is under obligations of or otherwise bound to terms of confidentiality with Licensee (or Sublicensee, repectively). For purposes of this definition, "control" means (a) having the actual, present capacity to elect a majority of the directors of such entity, or (b) having the power to direct at least fifty percent (50%) of the voting rights entitled to elect directors of such entity.

1.2 "**Change of Control**" means (a) the sale of all or substantially all the assets of a Party; (b) any merger, consolidation or acquisition of a Party with, by or into another corporation, entity or person; or (c) any change in the ownership of more than fifty percent (50%) of the voting capital stock of a Party in one or more related transactions.

1.3 "**Field of Use**" means: all fields.

1.4 "**Inventors**" means: Paula J. Bates and Kenneth Palmer.

1.5 "**Licensed Method**" means any process or method, the use or practice of which, absent the license granted pursuant to this Agreement, infringes or contributes to or induces the infringement of a Licensed Patent or relies on Licensed Technical Knowledge.

1.6 "**Licensed Patents**" means: (a) the United States and foreign patents and/or patent applications identified in Exhibit A; (b) any and all patents issuing from the foregoing; (c) any and all claims of continuation-in-part applications that claim priority to the United States patent applications identified in Exhibit A, but only where such claims are directed to inventions disclosed in the manner provided in 35 U.S.C. § 112(a) in the United States patent applications identified in Exhibit A, and such claims in any patents issuing from such continuation-in-part applications; (d) any and all foreign patent applications, foreign patents or related foreign patent documents that claim priority to the patents and/or patent applications identified in Exhibit A; and (e) any and all divisionals, continuations, reissues, reexaminations, renewals, substitutions, and extensions of the foregoing. Any claim of a pending or of an issued and unexpired Licensed Patent is presumed to be valid unless it has been held to be invalid by a final judgment of a patenting authority or a court of competent jurisdiction from which no appeal can be or is taken.

1.7 "**Licensed Product**" means any product, material, kit, or other article of manufacture or composition of matter, the making, use, Sale, or offer for Sale, or import of which, absent the license granted pursuant to this Agreement, infringes, induces infringement, or contributes to infringement of a Licensed Patent and/or embodies, contains, uses, is used or made through the use of, or was in whole or part derived from Licensed Technical Information.

1.8 "**Licensed Service**" means a service provided using Licensed Products or Licensed Methods, including, without limitation, any such service provided in the form of contract research or other research performed by Licensee on behalf of a third party.

1.9 "**Licensed Technical Knowledge**" means proprietary data and information which are not generally known that are acquired and controlled by ULRF and are provided to Licensee by ULRF in order to practice the Licensed Patents. Technical Knowledge shall be limited only to those proprietary data and information to which ULRF has an ownership or other interest during the term of this Agreement; all to the extent and only to the extent that ULRF has the right to grant licenses or other rights thereunder.

1.10 "**License Year**" means a year in which this Agreement is in effect. The first License Year will begin on the Effective Date and run until December 31 of the same calendar year. Thereafter, each subsequent License Year will mean each subsequent calendar year, beginning January 1 and ending December 31, provided that the final License Year will end on the date of expiration or termination of this Agreement.

1.11 "**Net Sales**" means the gross amount of any payments, and the fair market value of any non-cash consideration, received by Licensee, Affiliates or Sublicensees for the use, Sale or other transfer of Licensed Products and Licensed Services, less the following deductions:

a. Trade, cash and quantity discounts actually allowed from billed amounts;

b. Discounts, refunds, rebates actually taken, chargebacks, retroactive price adjustments, and any other allowances which effectively reduce the net selling price (other than such which have already diminished the gross amount invoiced), including, without limitation, Medicaid, HMO, institutional and governmental rebates (other than such which have already diminished the gross amount invoiced);

c. Credits or allowances granted on returns or rejections of Licensed Products/Licensed Services actually Sold;

d. Amounts invoiced for Licensed Products/Licensed Services sales but actually written off in good faith as uncollectible (net of any recoveries on written-off debt);

e. Shipping, freight, postage, insurance and transportation charges, but all only to the extent included as a separate line item in the gross amount invoiced; and

f. Any tax imposed on the production, sale, delivery or use of the Licensed Products/Licensed Services, including, without limitation, import, export, sales, use, excise or value added taxes and customs and duties, but all only to the extent included as a separate line item (e.g., "taxes") in the gross amount invoiced. Before deducting value added taxes, Licensee will inform ULRF of the value added taxes to give ULRF, as a non-profit entity, the opportunity to follow procedures to eliminate the need for value added taxes.

Net Sales will not include transfers among Licensee, its Affiliates, or Sublicensees unless the recipient is the end purchaser.

If Licensed Products/Licensed Services are Sold as part of a combination product or bundle, the Net Sales of such Licensed Products/Licensed Services for the purpose of calculating royalties owed under this Agreement, shall be determined as follows: first, Licensee shall determine the actual Net Sales of such combination product or bundle (using the above provisions) and then such amount shall be multiplied by the fraction A/(A+B), where A is the average gross selling price in the applicable country of such Licensed Products/Licensed Services sold separately, and B is the sum of the average gross selling prices in the applicable country of each other component/constituent in the combination product or bundle sold separately. For clarity, the other component/constituent as B must be an active ingredient and not merely a buffer or formulation substance. If the Licensed Products/Licensed Services and/or the other component/constituent(s) in the combination product or bundle are not sold separately in the applicable country, the adjustment to Net Sales shall be determined by the Parties in good faith to reasonably reflect the fair market value of the contribution of the Licensed Products/Licensed Services in the combination product or bundle to the total fair market value of such combination product or bundle. If the Parties cannot agree on such relative value, such disagreement shall be referred to an independent expert.

1.12 "**Non-Royalty Sublicensing Income**" means the gross amount of any payments, and the fair market value of all other consideration, received by Licensee for the grant of rights under a Sublicense, excluding payments made to Licensee as a royalty based on Sales by the Sublicensee. For avoidance of doubt, amounts received by Licensee or its securities holders upon a Change of Control do not constitute Non-Royalty Sublicensing Income.

1.13 "**Sale**" means the act of selling, leasing, or otherwise transferring or providing Licensed Products or Licensed Services for any consideration. Correspondingly, "**Sell**" means to make or cause to be made a Sale, and "**Sold**" means to have made or cause to be made a Sale.

1.14 "**Sublicense**" means any agreement between Licensee and a third party that contains a grant to Licensed Patents and/or Licensed Technical Knowledge regardless of the name given to the agreement by the parties.

1.15 "**Sublicensee**" means any third party to whom Licensee has granted a Sublicense.

1.16 "**Term**" has the meaning set forth in Section 15.1.

2. GRANT

ARTICLE 2

2.1 **Grant**. Subject to Licensee's compliance with the terms and conditions of this Agreement, ULRF grants to Licensee an exclusive (subject to Section 2.2), worldwide license under the Licensed Patents in the Field of Use to (a) make, have made, use, offer for Sale, import, and Sell Licensed Products and Licensed Services, and (b) to practice Licensed Methods.

2.2 **Grant to Licensed Technical Knowledge**. Subject to Licensee's compliance with the terms and conditions of this Agreement, ULRF grants to Licensee a nonexclusive, royalty-fee bearing, worldwide license for Licensed Technical Knowledge to manufacture, have made, use, offer for Sale, import, and Sell Licensed Products and Licensed Services. In furtherance of the foregoing, ULRF will not grant a license to the Licensed Technical Knowledge to any third party to commercialize a product in the Field of Use that would be competitive with the Licensed Patents or Licensee's use or proposed use of the Licensed Patents and/or Licensed Technical Knowledge, absent Licensee's prior written consent.

2.3 **Retained Rights**. Regarding ULRF's Licensed Patents and Licensed Technical Knowledge, ULRF reserves to itself and UofL and to the Inventors to do any one or more of the following: (a) publish any information resulting from research relating to the Invention; (b) practice the Licensed Patents and Licensed Technical Knowledge for any not-for-profit purposes, including education, research, teaching, and public service; (c) make, use, and import the Invention, Licensed Technical Knowledge and associated technology for educational and research purposes; and (d) allow other non-profit academic research institutions to do any one or more of the activities of the preceding clauses (a), (b), and (c) of this Section for educational and research purposes.

2.4 **Government Rights**. It is understood that if the United States Government (through any of its agencies or otherwise) has funded research, during the course of or under which any inventions of the Licensed Patents were conceived or made, the United States Government is entitled, as a right, under the provisions of 35 U.S.C. §§ 200–212 and applicable regulations of Chapter 37 of the Code of Federal Regulations, to a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the invention of such Licensed Patents for governmental purposes. These provisions also impose the obligation that Licensed Products Sold or produced in the United States be "manufactured substantially in the United States." Licensee will ensure that all obligations under these provisions are met.

2.5 **Specific Exclusions**. Nothing in this Agreement is or will be construed as: (a) conferring by implication, estoppel, or otherwise any license or rights under any patent applications or patents of ULRF other than the Licensed Patents, regardless of whether such patent applications or patents are dominant or subordinate to the Licensed Patents; or (b) an obligation to furnish to Licensee any know-how not provided in the patents and patent applications of the Licensed Patents other than to the extent it constitutes Licensed Methods, Licensed Products, Licensed Services or Licensed Technical Knowledge.

3. SUBLICENSING

ARTICLE 3

3.1 **Permitted Sublicensing**. Subject to the requirements of Section 3.3 and for so long as Licensee remains in good standing with all terms and conditions of this Agreement, Licensee may grant Sublicenses in the Field of Use. For this consideration, Licensee will pay to ULRF the fees and other amounts specified in Exhibit B. For purposes of this Agreement, the operations of any Sublicensee under their respective Sublicense will be deemed to be the operations of Licensee, for which Licensee will be responsible. Affiliates will have no licenses under the Licensed Patents or Licensed Technical Knowledge except as granted by Licensee in a Sublicense.

3.2 **Required Sublicensing**.

(a) In the event that ULRF and Licensee each own an undivided interest in any Licensed Patent (a "**Jointly Owned Licensed Patent**"), Licensee will not attempt to separately grant a license to any third party under its rights in such Jointly Owned Licensed Patent without concurrently granting a Sublicense under ULRF's rights in the same, and ULRF will not attempt to separately grant a license to any third party under its rights in such Jointly Owned Licensed Patent without concurrently granting a sublicense under Licensee's rights in the same.

(b) If Licensee licenses patent rights assigned to or otherwise acquired by it ("**Licensee's Patent Rights**"), and it believes, in good faith, that the recipient of such license will infringe Licensed Patents in practicing Licensee's Patent Rights, then Licensee will not separately grant a license to such recipient under Licensee's Patent Rights without concurrently granting a Sublicense.

(c) If Licensee is unable or unwilling to develop potential Licensed Products or Licensed Services (within the parameters set forth in this Agreement) or to serve a market territory and Licensee has not, after an appropriate search period, identified a Sublicensee candidate therefor reasonably acceptable to Licensee, and ULRF has identified to Licensee an experienced, competent and reliable organization willing to be a Sublicensee therefor, Licensee will, at ULRF's request, negotiate in good faith a Sublicense with any such potential Sublicensee on reasonable commercial terms.

3.3 **Sublicense Requirements**. Any Sublicense: (a) is subject to this Agreement, (b) will not permit the grant of further Sublicenses by the Sublicensee, and (c) will, as a condition of validity, expressly include the provisions of Articles 7, 8 and 10 for the benefit of ULRF and UofL.

3.4 **Notice and Copy of Sublicense**. Within thirty (30) days of execution of each Sublicense, or amendment thereof, Licensee will notify ULRF of such executed Sublicense or amendment and provide to ULRF a copy of such Sublicense or amendment with no portion which is relevant to ULRF's rights hereunder redacted. Such Sublicense or amendment shall be Confidential Information of Licensee hereunder.

3.5 **License Termination**. Upon termination of this Agreement for any reason, all Sublicenses will automatically terminate, unless ULRF, at its sole discretion, agrees in writing to an assignment to ULRF of any Sublicense. In the event of termination of this Agreement and if ULRF accepts assignment of any Sublicense, ULRF will not be bound by any grant of rights broader than, and will not be required to perform any obligation other than, those rights and obligations contained in this Agreement. ULRF will have the sole right to modify each such assigned Sublicense to include all of the rights of ULRF contained in this Agreement.

4. DILIGENCE

ARTICLE 4

4.1 **Best Efforts by Licensee**. Licensee will use good-faith efforts to effect introduction of Licensed Products and (if applicable) Licensed Services into the commercial market as soon as possible; thereafter, and until the expiration or termination of this Agreement, Licensee will use commercially reasonable efforts to keep Licensed Products and (if applicable) Licensed Services reasonably available to the public.

4.2 **Milestones**. In addition to Licensee's obligations under Section 4.1, Licensee will accomplish the diligence milestones ("**Milestones**") set forth in Exhibit C. Licensee agrees that said Milestones are reasonable and that it will take all reasonable steps to meet its diligence obligations.

4.3 Licensee's failure to perform in accordance with Sections 4.1 or 4.2 will be grounds for ULRF to terminate this Agreement pursuant to Section 15.3.

5. PAYMENTS AND ACCOUNTING

ARTICLE 5

5.1 **Fees and Royalties**. In partial consideration for the rights granted herein, Licensee will pay to ULRF the fees, royalties and other amounts specified in Exhibit B, and will reimburse ULRF for costs incurred in connection with the Licensed Patents as provided in Section 9.2.

5.2 **Payment Procedures**. All payments due to ULRF will be made in United States currency preferably by electronic funds transfer (EFT), e.g., ACH, wire or book transfer. Bank information will be provided upon request. Alternatively, payments due to ULRF hereunder may be made by check or money order payable to "University of Louisville Research Foundation, Inc." with reference to tax identification number 61-1029626, and remitted to the address for ULRF specified in Section 14.1. Licensee or its Sublicensees will be responsible for payments of any fees associated with the transfer or other delivery of amounts payable to ULRF hereunder.

5.3 **Calculation and Payment of Royalties**. When Licensed Products or Licensed Services are Sold for monies other than United States dollars, Royalties will first be determined in the foreign currency of the country in which the Sale was made and then converted into equivalent United States dollars. The exchange rate will be that rate quoted in the Wall Street Journal on the last business day of the reporting period. Royalties will be paid to the ULRF free and clear of all foreign taxes. If any Licensed Patent, or any claim thereof, expires or is held invalid by a final decision of a patenting authority or a court of competent jurisdiction from which no appeal can be or is taken, all obligations to pay Royalties based on such Licensed Patent, or claim, will cease as of the date of such expiration or final decision, and in addition (in the case of invalidity but not in the case of expiration), Licensee shall be relieved of all accrued within the previous nine (9) months but unpaid obligations to pay Royalties based on such Licensed Patent, or claim. For clarity, Royalties based on Licensed Technical Knowledge will still apply. Licensee will not, however, be relieved from paying any Royalties that accrued before such expiration or that are based on another Licensed Patent, or claim within any Licensed Patent, which is not expired, or which is not held invalid or unpatentable in such final decision.

5.4 **Books and Records**. Licensee will keep full, true, and accurate books of accounts containing all particulars that may be necessary for the purpose of showing (a) the amount of Royalties payable to ULRF, and (b) Licensee's compliance with obligations under this Agreement. For six (6) years following the end of the calendar year to which they pertain, said books and the supporting data will be open, during normal business hours upon reasonable notice, to inspection and audit by an independent certified public accountant as well as an internal ULRF auditor for purposes of verifying Licensee's Development and Royalty Reports under Article 6 and compliance in other respects with this Agreement. Such representatives will be required to hold all information in confidence except as necessary to communicate Licensee's non-compliance with this Agreement to ULRF. The fees and expenses of the representatives performing such an examination will be borne by ULRF, provided that if an error in underpaid Royalties or other payments to ULRF of more than five percent (5%) for any calendar year is discovered, then the fees and expenses of these representatives in conducting such examination will be borne by Licensee.

5.5 **Self-audit**. Licensee will conduct an independent audit of Sales and Royalties at least every two (2) years if Net Sales exceed five million dollars ($5,000,000) in any given calendar year. The audit will address, at a minimum, the amount of Net Sales by or on behalf of Licensee during the audit period, the amount of funds owed to ULRF under this Agreement, and whether the amount owed has been paid to ULRF and is reflected in Licensee's records. Licensee will submit the auditor's report promptly to ULRF upon completion. Licensee will pay for the entire cost of the audit.

5.6 **Auditing and Review of Development Records**. ULRF reserves the right to audit Licensee's records relating to the development of Licensed Products and Licensed Services as required hereunder. Such requirements for Licensee's record keeping and ULRF's audit thereof will be subject to the same procedures and restrictions set forth in Section 5.4 for audit of financial records of Licensee.

5.7 **Late Payments**. In the event any payment due hereunder is not made when due, the payment will accrue interest, calculated at the monthly rate of one and one-half percent (1.5%), the interest being compounded on the last day of each calendar month. Each such payment when made will be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof will not negate or waive the right of ULRF to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment including, but not limited to, termination of this Agreement as provided in Article 15.

6. DEVELOPMENT AND ROYALTY REPORTS

ARTICLE 6

6.1 **Development Reports**. Until the first Sale occurs in the United States, Licensee will submit to ULRF a semi-annual development report ("**Development Report**") within sixty (60) days of each June 30 and December 31 following the end of such six (6) month period. Development Reports will cover Licensee's activities related to the development and testing of Licensed Products, Licensed Services, and Licensed Methods, including efforts related to obtaining necessary government approvals, if any, for marketing in the United States and foreign countries. Each Development Report will provide a sufficiently detailed summary of activities of Licensee and any Sublicensees so that ULRF may evaluate and determine Licensee's progress in the development of Licensed Products, Licensed Services, and Licensed Methods, and in meeting Licensee's diligence obligations under Article 4, and include at least the following: (a) summary of work completed and in progress; (b) current schedule of anticipated events and milestones, including the diligence Milestones under Article 4; (c) anticipated market introduction dates; (d) names and addresses of Sublicensees for any new Sublicenses entered into during the reporting period; (e) Sublicensees' known activities during the reporting period; and (f) description of any Non-Royalty Sublicensing Income received by Licensee. In the Development Report immediately subsequent to the first Sale by Licensee or by a Sublicensee, Licensee will report the date of such first Sale.

6.2 **Royalty Reports**. After the first Sale, within sixty (60) days of each June 30 and December 31 following the end of such six (6) month period, Licensee will submit to ULRF a semi-annual royalty report ("**Royalty Report**"), accompanied by the corresponding Royalty payment as required in Exhibit B, Section 2. Each Royalty Report will include at least the following: (a) the volume of Licensed Products and Licensed Services Sold (if no Sales have occurred during the report period, the Royalty Report will contain a statement to this effect); (b) gross amounts of any payments or other consideration received in connection with Sales, (c) Net Sales pursuant to Section 1.10, and the calculation of Net Sales, including all deductions taken, so that ULRF can confirm the calculation; (d) total Royalties due to ULRF; (e) description of any Non-Royalty Sublicensing Income received by Licensee; and (f) names and addresses of Sublicensees for any new Sublicenses entered into during the reporting period.

6.3 **Submission of Development and Royalty Reports**. All Development and Royalty Reports will be submitted electronically via email with reference to this Agreement (ULRF ref. 20337-LA) to the UofL Commercialization EPI-Center service account at thinker@louisville.edu.

7. EXCLUSIONS AND NEGATIONS OF WARRANTIES, AND LIMITATION OF LIABILITY

ARTICLE 7

7.1 **Negation of Warranties**. ULRF provides Licensee the rights granted in this Agreement AS IS and WITH ALL FAULTS. ULRF makes no representations and extends no warranties of any kind, either express or implied, except a representation that ULRF owns the Licensed Patents and that neither ULRF nor any of the Inventors have granted any licenses in the Licensed Patents to any commercial or for-profit entities. Among other things, ULRF disclaims any express or implied warranty: (a) of merchantability, or of fitness for a particular purpose; (b) of non-infringement; or (c) arising out of any course of dealing.

7.2 **No Representation of Licensed Patent**. Licensee also acknowledges that ULRF does not represent or warrant: (a) the validity or scope of any Licensed Patent; or (b) that the exploitation of the Invention or Licensed Patents or Licensed Technical Knowledge will be successful.

7.3 **No Warranties to Third Parties**. Licensee will not make any statements, representations or warranties or accept any liabilities or responsibilities whatsoever to or with regard to any person or entity that are inconsistent with any disclaimer or limitation included in this Article.

7.4 **Limitation of Liability**. THE ENTIRE RISK AS TO PERFORMANCE OF LICENSED PRODUCTS, LICENSED SERVICES, LICENSED METHODS AND UNDERLYING RESEARCH IS ASSUMED BY LICENSEE OR ANY SUBLICENSEES. IN NO EVENT (OTHER THAN WILLFUL MISCONDUCT OR FRAUD AND TO THE EXTENT PERMITTED BY LAW) WILL ULRF, UOFL, INCLUDING ITS TRUSTEES, FELLOWS, OFFICERS, EMPLOYEES, STUDENTS AND AGENTS, BE RESPONSIBLE OR LIABLE FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL OR OTHER DAMAGES WHATSOEVER, OR LOST PROFITS OR OTHER ECONOMIC LOSS OR DAMAGE WITH RESPECT TO THE PRACTICE OF THE INVENTION OR LICENSED PATENTS (INCLUDING MAKING, USING, SELLING, OFFERING TO SELL, OR IMPORTING LICENSED PRODUCTS, LICENSED SERVICES, OR LICENSED METHODS) WHETHER GROUNDED IN TORT (INCLUDING NEGLIGENCE AND PRODUCT LIABILITY), STRICT LIABILITY, CONTRACT OR OTHERWISE. THE ABOVE LIMITATIONS ON LIABILITY APPLY EVEN THOUGH ULRF, UOFL, ITS TRUSTEES, FELLOWS, OFFICERS, EMPLOYEES, STUDENTS OR AGENTS MAY HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

8. INDEMNITY AND INSURANCE

ARTICLE 8

8.1 **Indemnity**. Licensee will indemnify, hold harmless, and defend ULRF, UofL, and its trustees, fellows, officers, employees, students, and agents from and against any and all claims, suits, losses, damage, costs, fees, expenses (including attorneys' fees), and claims resulting from or arising out of the exercise of the license granted hereunder, or any Sublicense thereof, by Licensee, Affiliates or Sublicensees. This indemnification will include, but not be limited to, any product liability. This Section 8.1 shall not apply to the extent the claims, suits, losses, damage, costs, fees, and/or expenses are due to any indemnitee's breach of this Agreement, violation of law, willful misconduct or fraud.

8.2 **Insurance**. During the Term, Licensee will obtain and maintain at all times and will require Sublicensees, and any subcontractors of any of the foregoing, to obtain and maintain (a) insurance for all statutory workers' compensation and employers' liability requirements covering any and all employees with respect to activities performed under this Agreement; and (b) commercial general liability insurance, with limits of insurance not less than $1,000,000 per occurrence and $3,000,000 aggregate, including products liability insurance, written on an occurrence bases, from reputable and financially secure insurance carriers (having an A.M. Best rating of A IX or above) to cover their respective activities. Such insurance will provide an appropriate and standard level of coverage considering the size of the company and for the product and industry, and will list ULRF, UofL, its trustees, fellows, officers, employees, students, and agents as additional insureds. Such insurance will be written to cover claims resulting from or arising out of the exercise of the licenses granted hereunder, or any Sublicense thereof, by Licensee or Sublicensees incurred, discovered, manifested, or made at any time during or after the expiration or termination of this Agreement. At ULRF's request, Licensee will furnish a certificate of insurance evidencing primary coverage, indicating that ULRF and UofL have been listed as an additional insured under commercial general liability, and requiring thirty (30) days prior written notice to ULRF of cancellation or material change. All such insurance of Licensee will be primary coverage; the insurance of ULRF will be deemed to be excess and noncontributory. ULRF will notify Licensee in writing of any claim brought against ULRF in respect to which ULRF intends to invoke the provisions of this Section. Licensee will keep ULRF informed in writing and on a current basis of Licensee's defense(s) of any known claim under this Section.

9. PATENT PROSECUTION AND MAINTENANCE

ARTICLE 9

9.1 **Responsibility for Licensed Patents**. ULRF will prosecute and maintain the Licensed Patents, subject to Licensee's reimbursement of ULRF's Patent Costs under Section 9.2. ULRF will have sole responsibility for retaining and instructing patent counsel (which from and after the Effective Date shall be selected by Licensee but reasonably acceptable to ULRF), and will promptly provide Licensee with copies of all official patent office correspondence. ULRF will seek and consider comments from Licensee prior to taking any substantive prosecution action in any Licensed Patent, provided that if Licensee has not commented on such prosecution action prior to the deadline for filing a response with the relevant government patent office, ULRF will be free to respond appropriately without consideration of Licensee's comments. ULRF will use reasonable efforts to prepare or amend any patent application within the Licensed Patents to include claims reasonably requested by Licensee to protect the Licensed Products or Licensed Services contemplated to be Sold or Licensed Methods to be practiced under this Agreement. Licensee will make all reasonable efforts to advise ULRF and its patent counsel in order to secure the broadest patent protection possible with respect to envisioned Licensed Products and (if any) Licensed Services.

9.2 **Patent Costs**. Subject to Section 9.3, Licensee will reimburse ULRF for all out-of-pocket costs incurred before, on, or after the Effective Date in connection with preparing, filing, prosecuting and maintaining Licensed Patents (including, without limitation, the cost of any reexaminations, oppositions, post-grant review, inter partes review, supplemental examinations, and other patent office administrative proceedings, and their appeals), which have not been previously reimbursed to ULRF ("**Patent Costs**").

(a) **Prior Patent Costs**. Licensee will reimburse ULRF for all Patent Costs incurred prior to the Effective Date in the amount stated in Exhibit B at such time and in such manner as stated in Exhibit B.
(b) **Ongoing Patent Costs**. Licensee will reimburse ULRF for all Patent Costs incurred on or after the Effective Date within thirty (30) days of receipt by Licensee of invoice from ULRF for the same.
(c) **Advances**. If a specific Patent Cost is estimated to be greater than ten thousand dollars ($10,000) or if Licensee has not timely reimbursed ULRF for ongoing Patent Costs, then ULRF, at its sole discretion, may require that Licensee deposit with ULRF a reasonable amount, as based on patent counsel's estimate or invoice, as an advance against anticipated significant Patent Costs, such as new patent application filings, maintenance fees, or annuities. Unless otherwise agreed, such funds will be applied against invoices ULRF receives in connection with such Patent Costs until the funds are depleted. Upon expiration or termination of this Agreement, or at such time that no additional Patent Costs are reasonably anticipated, the remaining balance, if any, will be returned to Licensee at Licensee's written request, or at Licensee's election, may be credited against other amounts then due and payable to ULRF hereunder.

9.3 **Surrender of Rights**. Licensee's obligation to pay Patent Costs will continue for so long as this Agreement remains in effect, provided that Licensee may terminate Licensee's obligations with respect to any given patent application or patent within the Licensed Patents in any designated country upon ninety (90) days written notice to ULRF. In the event of such notice to ULRF, ULRF will undertake to curtail applicable Patent Costs reimbursable by Licensee pursuant to Section 9.2. ULRF may continue prosecution and maintenance of such patent applications or patents at ULRF's sole discretion and expense, provided that Licensee will have no further rights thereunder.

10. CONTEST OF PATENT VALIDITY

ARTICLE 10

10.1 Licensee and Sublicensees must provide ULRF at least ninety (90) days prior written notice before filing any action that contests the validity of any Licensed Patent during the Term.

10.2 In the event Licensee, a Sublicensee, or an Affiliate files any action contesting the validity of any Licensed Patent, the Royalty rate applicable to Sales made during the pendency of such action will be two (2) times the Royalty rate specified in Exhibit B. Should the outcome of such contest determine that any claim of a Licensed Patent challenged is valid and would be infringed by Licensee's or a Sublicensee's Sales if not for the license granted by this Agreement, the applicable Royalty rate for Sales made thereafter and for the remainder of the Term will be three (3) times the Royalty rate specified in Exhibit B. In the event that Licensee, a Sublicensee, or an Affiliate contests the validity of any Licensed Patent during the Term, Licensee agrees (and will require its Sublicensees to agree) to pay to ULRF all royalties due under this Agreement during the period of challenge. For the sake of clarity, such amounts will not be paid into any escrow or other account, but directly to ULRF, and will not be refunded.

11. INFRINGEMENT

ARTICLE 11

11.1 **Infringement Procedure**. Each Party will promptly notify the other Party if it believes a third party infringes a Licensed Patent in the Field of Use. So long as the license granted herein remains exclusive, Licensee may have the right to institute a suit against such third party as provided in Sections 11.2 through 11.6.

11.2 **ULRF Suit**. ULRF will have the first right to institute suit, and may name Licensee as a party to such suit for standing purposes. If ULRF decides in good faith to institute suit, it will notify Licensee in writing. If Licensee does not notify ULRF in writing that it desires to jointly prosecute the suit within fifteen (15) days after the date of the notice, Licensee will assign and hereby does assign to ULRF all rights, causes of action, and damages resulting from the alleged infringement. ULRF will bear the entire cost of the litigation, and from any recovery or damages derived therefrom, ULRF will first be reimbursed its out-of-pocket costs and attorney fees, and the remaining sums will be split, with seventy-five percent (75%) of such sums going to ULRF, and twenty-five percent (25%) of such sums going to Licensee. In the event that a non-cash cross license is awarded or a non-cash settlement is reached, both Parties agree to negotiate appropriate compensation in good faith.

11.3 **Joint Suit**. If ULRF and Licensee so agree (or if Licensee so elects pursuant to Section 11.2), they may institute suit jointly. If so, they will: (a) prosecute the suit in both their names; (b) bear the out-of-pocket costs equally; (c) share any recovery or settlement equally; and (d) agree in a separate written document how they will exercise control over the action. In the event that a non-cash cross license is awarded or a non-cash settlement is reached, both Parties agree to negotiate appropriate compensation in good faith

11.4 **Licensee Suit**. If ULRF does not elect to, within 45 days after Licensee notifies ULRF pursuant to Section 11.1 of a particular infringement, pursue a suit pursuant to either of Sections 11.2 or 11.3, Licensee may institute and prosecute a suit so long as it conforms with the requirements of this Section and Licensee or a Sublicensee is diligently developing or making Sales of Licensed Products or Licensed Services. Licensee will diligently pursue the suit and will bear the entire cost of the litigation, and will indemnify ULRF for any costs, expenses, and counsel fees incurred by ULRF. Licensee will keep ULRF reasonably apprised of all developments in the suit, and will seek ULRF's input and approval on any substantive submissions or positions taken in the litigation regarding the scope, validity and enforceability of the Licensed Patent. Licensee will not prosecute, settle or otherwise compromise any such suit in a manner that adversely affects the interests of ULRF or UofL without ULRF's prior written consent. ULRF may be named as a party only if: (a) Licensee's, ULRF's and UofL's respective counsel recommend that such action is necessary in their reasonable opinion to achieve standing; (b) ULRF is not the first named party in the action; and (c) the pleadings and any public statements about the action state that Licensee is pursuing the action and that Licensee has the right to join ULRF as a party plaintiff thereto.

11.5 **Recovery**. If Licensee institutes suit pursuant to Section 11.4, any recovery in excess of any unrecovered litigation costs and fees will be shared with ULRF as follows: Any recovery will be split, with seventy-five percent (75%) of such sums going to Licensee, and twenty-five (25%) of such sums going to ULRF. In the event that a non-cash cross license is awarded or a non-cash settlement is reached, both Parties agree to negotiate appropriate compensation to ULRF in good faith.

11.6 **Abandonment of Suit**. If either ULRF or Licensee commences a suit and thereafter intends to abandon the suit, it will give timely notice to the other Party. The other Party may continue prosecution of the suit after ULRF and Licensee agree on the sharing of expenses and any recovery in the suit.

12. DECLARATORY JUDGMENT

ARTICLE 12

12.1 In the event a declaratory judgment action alleging invalidity or noninfringement of any Licensed Patent is brought against Licensee, then ULRF, at its option and sole discretion, will have the right, within thirty (30) days after commencement of such action, to (in good faith) intervene and take over and conduct the sole defense of the action at its own expense.

13. CONFIDENTIALITY

ARTICLE 13

13.1 With respect to disclosures by one Party or its Affiliates ("**Disclosing Party**") to the other Party or its Affiliates ("**Receiving Party**") under this Agreement or under the Option Agreement identified in the above Background Section, effective March 31, 2020, the Receiving Party will, subject to Sections 13.2 and 13.3, keep any information identified as confidential by the Disclosing Party confidential using methods at least as stringent as each Party uses to protect its own confidential information. "**Confidential Information**" will include the negotiated terms of this Agreement as set forth in Exhibits B and C, Licensee's Development Reports, Royalty Reports, Sublicenses, the Licensed Patents (until publication of the Licensed Patents), information regarding any prior/on-going/future research or the review of such research and all information concerning them and any other information that which a reasonable person would understand to be confidential in natureor which is marked confidential or accompanied by correspondence indicating such information is exchanged in confidence between the Parties. Except as may be authorized in advance in writing by ULRF, Licensee will grant access to ULRF's Confidential Information only to its own employees or agents involved in research relating to the Licensed Patents and Licensee will require such employees to be bound by terms of confidentiality no less restrictive than those set forth in this Article.

13.2 The confidentiality and non-use obligations set forth above apply to all or any part of the Confidential Information disclosed hereunder except to the extent that the information:

(a) was already in the Receiving Party's possession on a non-confidential basis prior to receipt from the Disclosing Party;
(b) was in the public domain by public use, general knowledge or the like, or after disclosure hereunder, becomes general or public knowledge through no fault of the Receiving Party or its disclosees;
(c) was properly obtained by the Receiving Party from a third party not under a confidentiality obligation to or for the benefit of the Disclosing Party;
(d) is explicitly approved for release by written authorization of the Disclosing Party;
(e) is independently developed by employees or agents of the Receiving Party who had no knowledge of or access to the Confidential Information as evidenced by the Receiving Party's business records;
(f) is required to be disclosed to the public pursuant to federal securities laws or regulations; or
(g) five (5) years have elapsed from the expiration of this Agreement.

13.3 ULRF will be free to release to the Inventors, and to ULRF and UofL senior administrators, the terms and conditions of this Agreement upon their request. If such release is made, ULRF will inform such individuals of the confidentiality obligations set forth above that require that such individuals not disclose such terms and conditions to others.

13.4 The Receiving Party may disclose Confidential Information of the Disclosing Party pursuant to a requirement to so disclose under applicable laws or regulations or a valid order of a court or other governmental authority of competent jurisdiction, including an opinion issued by the Kentucky Attorney General which carries the force of law in Kentucky open-records cases, provided that the Receiving Party: (a) provides the Disclosing Party with prompt notice of such disclosure requirement if legally permitted, (b) reasonably affords the Disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure (and reasonably cooperates with such effort) and (c) to the extent that the Disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the Receiving Party is legally required to disclose. For the avoidance of doubt, the Confidential Information disclosed by said law or legal process remains confidential unless and until it falls under one of the exceptions set forth in Sections 13.2(a)-(g). (For avoidance of doubt: if Confidential Information disclosed by said law or legal process becomes general or public knowledge thereby, Section 13.2(b) would be applicable.)

14. NOTICES AND INVOICES

ARTICLE 14

14.1 **Notices**. All notices required or permitted to be given hereunder will be effective when given in writing, with reference to this Agreement and when (a) sent by email, (b) sent by registered or certified mail, return receipt requested, or (c) by overnight courier, such as Federal Express or UPS, to the other Party at its respective address set forth below or to such other address as one Party may designate by written notice from time to time hereunder. Notices will be deemed effective when received.

If to Licensee: Qualigen Therapeutics, Inc.
2042 Corte Del Nogal
Carlsbad, CA 92011
Email: mpoirier@qualigeninc.com
Attn.: Michael S. Poirier, President/CEO

If to ULRF: Commercialization EPI-Center
University of Louisville
300 East Market Street, Suite 300
Louisville, KY 40202
Email: thinker@louisville.edu
Attn.: Director
ULRF ref. #20337-LA

14.2 **Invoices**. ULRF may submit invoices for any payments due in electronic form via email sent to the email address supplied by Licensee from time to time. An invoice directed to the last email address provided by Licensee to ULRF will be deemed received by Licensee when sent by ULRF.

15. TERM AND TERMINATION

ARTICLE 15

15.1 **Term**. This Agreement will continue in full force and effect from the Effective Date until the expiration of the last to expire Licensed Patents, unless sooner terminated by operation of law or by acts of either Party in accordance with the terms of this Agreement (the "**Term**").

15.2 **Termination by Licensee**. Licensee may terminate this Agreement by providing written notice to ULRF in accordance with Section 14.1 at least ninety (90) days in advance of the effective date of termination selected by Licensee.

15.3 **Termination by ULRF**. If Licensee should materially violate or fail to perform any material term or provision of this Agreement, then ULRF may give written notice of such default ("**Notice of Default**") to Licensee. If Licensee should fail to repair such default within thirty (30) days of the effective date of such Notice of Default, ULRF will have the right to terminate this Agreement by a second written notice ("**Notice of Termination**") to Licensee. If a Notice of Termination is sent to Licensee, this Agreement will automatically terminate on the effective date of such notice. Such termination will not relieve Licensee of Licensee's obligation to pay any Royalty or fees owing at the time of such termination and will not impair any accrued rights of ULRF. Notices given under this Section will be subject to Section 14.1.

(a) Notwithstanding Section 15.3, ULRF may, to the extent permitted by applicable law, terminate this Agreement immediately upon written notice to Licensee if Licensee files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or for reorganization or for an arrangement or for the appointment of a receiver or trustee of Licensee or of its assets, or if Licensee is served with an involuntary petition against it, filed in any proceeding of such sort, and such petition is not dismissed within 60 days after the filing thereof, or if Licensee overtly proposes to dissolve or liquidate, or if Licensee makes an assignment for the benefit of its creditors.

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15.4 **Consequences of Termination**. Upon termination of this Agreement for any reason, nothing herein is to be construed to release either Party from any obligation that matured prior to the effective date of such termination. Licensee may, however, for one (1) year following the date of termination, Sell inventoried Licensed Products, provided that Licensee pays to ULRF Royalties thereon as required under Article 5 and submits the related reports as required under Article 6. Upon termination, Licensee will remain obligated to provide, in the form specified in Section 6.2, an accounting for and pay Royalties earned up to the date of termination and for the one (1) year period thereafter, as specified above, and any Annual Minimums prorated as of the date of termination based on the number of days elapsed in the applicable License Year. Any such payments or reports due hereunder will be sent to ULRF within thirty (30) days of termination. In the event of termination, ULRF will have no obligation to as a result of such termination refund any royalties, fees, or other amounts paid to ULRF under this Agreement or any other agreement between the Parties.

15.5 **Surviving Provisions**. Surviving any termination or expiration are: (a) Licensee's obligation to pay royalties or other amounts accrued; (b) any claim of Licensee or ULRF, accrued or to accrue, because of any breach or default by the other Party; and (c) the provisions of Articles 5, 6, 7, 8, 12, 13 and 17, Section 3.5, and any other provision that by its nature is intended to survive.

16. ASSIGNMENT

ARTICLE 16

16.1 **Permitted Assignment by Licensee**. Subject to Section 16.3, Licensee may assign this Agreement to its successor in interest as part of a Change of Control, provided that, if Licensee is in material breach of any material provision of this Agreement, Licensee must obtain ULRF's prior written consent to such assignment.

16.2 **Any Other Assignment by Licensee**. Any other attempt to assign this Agreement by Licensee is null and void.

16.3 **Conditions of Assignment**. Prior to any assignment, the following conditions must be met:

(a) Licensee must give ULRF simultaneous or prior written notice of the assignment, including the assignee's contact information; and
(b) the assignee must agree in writing to ULRF to be bound by this Agreement.

16.4 **After the Assignment**. Upon a permitted assignment of this Agreement pursuant to this Article, the term "Licensee" in this Agreement will mean the assignee.

17. MISCELLANEOUS

ARTICLE 17

17.1 **Marking**. Licensee will mark all Licensed Products made, used, offered for Sale, imported, or Sold under this Agreement, or their containers, in accordance with applicable patent marking laws.

17.2 **Use of Names and Trademarks**. Licensee will not, without the prior written consent of ULRF, identify ULRF, UofL, or any of their affiliated entities in any promotional statement or use the name of any Inventor (with the exception of any Inventors who are employed by, partners in, or consultants of Licensee) or any UofL employee or student, or any trademark, service mark, trade name, or symbol of ULRF or UofL. Notwithstanding the foregoing or anything to the contrary herein, Licensee may state that it is a licensee of ULRF with respect to the Licensed Patents; likewise, ULRF or UofL may state that the Licensed Patents are licensed to Licensee.

17.3 **Entire Agreement; Amendment**. This Agreement, including the attached Exhibits, constitutes the entire agreement and the understanding of the Parties with respect to the subject matter contained herein, and supersedes all prior or contemporaneous communications, agreements, commitments, representations, or understandings, whether oral or written, between the Parties relating to the same. For avoidance of doubt: the Exclusive Agreement dated June 8, 2018 (and as thereafter amended) between ULRF and Qualigen, Inc. (ULRF ref. #18255-LA), sponsored research agreement dated August 15, 2018 between ULRF and Qualigen, Inc. (ULRF ref. #OIEN190151-SRA), and the other agreements referred to therein are not superseded hereby. Any confidential information which was disclosed under the Option Agreement or under any written confidentiality agreement between the Parties (and/or an Affiliate of a Party) before the Term shall remain confidential and shall be subject to the nondisclosure and nonuse provisions set forth in Article 13 of this Agreement. This Agreement may be modified only by an instrument duly executed by authorized officials of the Parties and only if such instrument specifically states that it is an amendment to this Agreement.

17.4 **Severability**. In the event any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable, that provision will be curtailed, limited or deleted, but only to the extent necessary to remove such invalidity, illegality or unenforceability, and the remaining provisions are not in any way to be affected or impaired thereby. In the event such curtailment, limitation or deletion is not allowed by relevant law or if such curtailment, limitation or deletion changes any essential basis of the bargain set forth in this Agreement, the Parties agree to substitute a new provision as similar in effect to the deleted provision as may be allowed by relevant law.

17.5 **Interpretation**. Any reference herein to any defined term includes both the singular and the plural, whether or not both forms are included in the reference. References to any statutes or regulations mean such statutes or regulations as amended at the time of interpretation and include any successor legislation or regulations. All references to particular Exhibits, Articles or Sections mean the Exhibits to, and Articles and Sections of, this Agreement, unless otherwise specified. Any Exhibits are hereby incorporated by reference and deemed a part of this Agreement. Unless the context otherwise requires, capitalized terms used herein will have the respective meanings specified or referred to in Article 1, or elsewhere herein. Any words not herein defined will have their ordinary meaning.

17.6 **Waiver**. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that (or any other) right or excuse a similar subsequent failure to perform any such (or any other) term or condition by the other Party. None of the terms and conditions of this Agreement can be waived except by the written consent of the Party waiving compliance.

17.7 **No Agency**. The relationship between the Parties is that of independent contractors. Neither Party will be deemed an agent of the other in connection with the exercise of any rights hereunder, nor will either Party have any right or authority to assume or create any obligation or responsibility on behalf of the other.

17.8 **Governing Law**. This Agreement will be governed solely by the laws of the Commonwealth of Kentucky, without applying any law that would result in the application of a different body of law; provided that questions affecting the construction and effect of any patent will be determined by the law of the country in which the patent has been granted. The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

17.9 **Jurisdiction and Forum**. The state courts located in the Commonwealth of Kentucky will have exclusive jurisdiction over any claim or dispute concerning or arising out of this Agreement. The Parties hereby irrevocably consent to the exclusive jurisdiction of such courts and irrevocably waive any claim of inconvenient forum; provided that, notwithstanding the foregoing, either Party will have the right to seek injunctive relief and the enforcement of judgments in any court of competent jurisdiction.

17.10 **Compliance with Laws**. This Agreement will be subject to all United States laws and regulations now or hereafter applicable to the subject matter of this Agreement. Licensee will comply with all applicable international, national, state, regional, and local laws and regulations in performing its obligations hereunder and in Licensee's use, manufacture, Sale, offer for Sale, or import of Licensed Products or Licensed Services, or in Licensee's practice of Licensed Methods. Without limitation, Licensee will observe all applicable United States and foreign laws and regulations governing the transfer to other countries of technical data related to Licensed Products, Licensed Services, or Licensed Methods, including, without limitation, the International Traffic in Arms Regulations (ITAR) and the Export Administration Regulations (EAR). Licensee will obtain, and will require Affiliates (if applicable) and Sublicensees to obtain, such written assurances regarding export and re-export of technical data (including Licensed Products made by use of technical data) as may be required by EAR, and any similar foreign laws or regulations, and Licensee hereby gives such written assurances as may be required under those Regulations to ULRF.

17.11 **Export Controls**. Licensee understands that ULRF and UofL are subject to United States laws and regulations (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979) controlling the export of technical data, computer software, laboratory prototypes, and other commodities, and ULRF's obligations to Licensee under this Agreement are contingent on and subject to compliance with such laws and regulations. The transfer of certain technical data or commodities may require a license from an agency of the United States Government or written assurances by Licensee or a Sublicensee that Licensee or a Sublicensee will not export such technical data or commodities to certain foreign countries without prior approval of such agency. ULRF neither represents that such a license will not be required nor that, if required, it will be issued.

Therefore, the Parties have executed this Exclusive License Agreement in duplicate originals by their duly authorized officers or representatives.

Signatures appear on the following page.

UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC.

/s/ T. Allen Morris

T. Allen Morris, Ph.D., MBA
Executive Director
Commercialization EPI-Center

Date June 9, 2020

QUALIGEN THERAPEUTICS, INC.

/s/ Michael S. Poirier

Michael S. Poirier
President/CEO

Date June 9, 2020

Attachments:

Exhibit A: Licensed Patents
Exhibit B: Fees and Royalties
Exhibit C: Diligence Milestones

ULRF Initials */s/ AM*
Licensee Initials */ s/ MSP*

EXHIBIT A – LICENSED PATENTS

- United States Provisional Patent Application no. 63/001,308; *Methods of Inhibiting or Treating a Coronavirus Infection*; Filing date: March 28, 2020; ULRF ref. #20050.

EXHIBIT B – FEES AND ROYALTIES

NOTICE

THIS EXHIBIT B CONTAINS FINANCIAL AND COMMERCIAL INFORMATION DEEMED BUSINESS SENSITIVE AND CONFIDENTIAL. THE PARTIES AGREE NOT TO DISCLOSE THE TERMS OF THIS EXHIBIT TO ANY THIRD PARTY WITHOUT THE WRITTEN CONSENT OF THE OTHER PARTY, EXCEPT AS NECESSARY TO ENABLE THE PARTIES TO PERFORM UNDER THIS AGREEMENT OR AS MAY BE REQUIRED AND CONTEMPLATED IN ARTICLE 13 HEREOF.

1. **License Issue Fee**. Within ten (10) calendar days of the Effective Date, Licensee will pay to ULRF a License Issue Fee of Twenty Thousand dollars ($20,000).

2. **Royalties**. Licensee agrees to pay to ULRF earned royalties ("**Royalties**") as a percentage of Net Sales for all Licensed Products and Licensed Services Sold during the Term by Licensee, Affiliates, Sublicensees or any third party otherwise authorized by Licensee to Sell Licensed Products and/or Licensed Services according to the following schedule:

    a. Licensee agrees to pay to ULRF Royalties at the rate of four percent (4%) of Net Sales up to and equal to two hundred fifty million dollars ($250,000,000) cumulative gross Sales in which Licensed Products are produced and/or Sold or Licensed Services are conducted in countries or regions where there are valid claims for Licensed Patents covering such Licensed Patents or Licensed Services.
    b. Licensee agrees to pay to ULRF Royalties at the rate of five percent (5%) of Net Sales for any Sales exceeding two hundred fifty million dollars ($250,000,000) cumulative gross Sales in which Licensed Products are produced and/or Sold or Licensed Services are conducted in countries or regions where there are valid claims for Licensed Patents covering such Licensed Patents or Licensed Services.
    c. Licensee agrees to pay to ULRF Royalties at the rate of two and a half percent (2.5%) of Net Sales for any Sales not covered by Licensed Patents.

    Amounts owed under this Section will be paid and reported on a semi-annual basis, as described in Section 6.2.

    For clarity, Royalties are payable to ULRF if Licensed Products are produced in a country covered by Licensed Patents but Sold in a country not covered by Licensed Patents. Conversely, Royalties are payable to ULRF if Licensed Products are produced in a country not covered by Licensed Patents buy Sold in a country that is covered by Licensed Patents.

3. **Sharing of Non-Royalty Sublicensing Income**. In addition to but not in duplication of paragraph 2 above, with respect to any Sublicenses granted by Licensee under Article 3, Licensee will pay Non-Royalty Sublicensing Income to ULRF according to the following schedule for Non-Royalty Sublicensing Income actually received by Licensee:

    a. Fifty percent (50%) if sublicensed in the first or second License Year of the Agreement;
    b. Forty percent (40%) if sublicensed in the third or fourth License Year of the Agreement; and
    c. Thirty percent (30%) if sublicensed in the fifth License Year or any subsequent License Year of the Agreement.

Amounts owed under this Section will be paid to ULRF within thirty (30) days of Licensee's receipt of any Non-Royalty Sublicensing Income. No payments owed under this Section will be prorated, regardless of whether or not the Sublicense is bundled with other licenses or sublicenses, without ULRF's written consent. It is contemplated that any Sublicensee of the Licensed Patents or Licensed Technical Knowledge, or any third party acquiring Licensee would continue the performance of relevant activities and obligations under this Agreement, including the payment of all royalties and fees, pursuant to this Agreement.

4. **Annual Minimums**. If total amounts actually paid under Sections 2 and 3 of this Exhibit for any calendar year are less than the applicable minimum amount set forth in the following subsections (the "**Annual Minimum**"), Licensee will pay to ULRF an amount for that calendar year equal to the shortfall. Such payment will be made within sixty (60) days from the first day following the end of the applicable calendar year (i.e. the first payment will be due sixty (60) days from January 1, 2025). If this Agreement expires or terminates for any reason during any calendar year, the Annual Minimum for such License Year will be reduced pro-rata.

Calendar Year(s)	Annual Minimum	Due as of:
2024	Five thousand dollars ($5,000)	Jan. 1, 2025
2025	Ten thousand dollars ($10,000)	Jan. 1, 2026
2026	Ten thousand dollars ($10,000)	Jan. 1, 2027
2027	Twenty thousand dollars ($20,000)	Jan. 1, 2028
2028	and each calendar year thereafter. Fifty thousand dollars ($50,000)	Jan. 1, 2029 and each Jan. 1 thereafter.

5. **Prior Patent Costs**. Licensee will reimburse ULRF the balance of Patent Costs incurred and invoiced prior to the Effective Date which equals the total of any and all Patent Costs incurred and invoiced prior to the Effective Date minus the amount paid under the Option Agreement. Licensee's payment of such prior Patent Costs will be due and payable as of the Effective Date of this Agreement.

Balance of Prior Patent Costs:	$	3,006.00

Any Patent Costs incurred prior but invoiced after the Effective Date will be reimbursed to ULRF by Licensee in accordance with Section 9.2 of the Agreement.

6. **Milestone Payments**. Licensee will pay to ULRF the following non-creditable, non-refundable license milestone payments:

To be paid by Licensee to ULRF for the first Licensed Product:

● Upon first dosing of any Licensed Product to the first subject or patient for the first phase I clinical trial:	$	50,000
● Upon first dosing of any Licensed Product to the first subject or patient for the first phase II clinical trial:	$	100,000
● Upon first dosing of any Licensed Product to the first subject or patient for the first phase III clinical trial:	$	150,000
● Market approval*:	$	300,000
● Achieving $500,000,000 in sales of Licensed Product:	$	5,000,000

**Market approval is regulatory approval by a major regulatory entity, such as the FDA.*

Payment for the above milestones shall be paid within thirty (30) days from the date that specific milestone occurs. None of the milestone payments is payable more than one-time-only.

EXHIBIT C – DILIGENCE MILESTONES

NOTICE

THIS EXHIBIT C CONTAINS COMMERCIAL AND PROPRIETARY INFORMATION DEEMED BUSINESS SENSITIVE AND CONFIDENTIAL. THE PARTIES AGREE NOT TO DISCLOSE THE TERMS OF THIS EXHIBIT TO ANY THIRD PARTY WITHOUT THE WRITTEN CONSENT OF THE OTHER PARTY, EXCEPT AS NECESSARY TO ENABLE THE PARTIES TO PERFORM UNDER THIS AGREEMENT OR AS MAY BE REQUIRED AND CONTEMPLATED IN ARTICLE 13 HEREOF.

Non-Fee-Based, Diligence Milestones: If Licensee fails to meet a diligence milestone by the milestone due date, Licensee may request an extension or modification of the diligence milestone, and ULRF will consider a reasonable extension or modification provided that Licensee demonstrates that it has diligently, vigorously and in good faith made progress in the applicable milestone.

- **December 31, 2020:** Execution of a sponsored research agreement supporting at least $250,000 in research.
- **January 31, 2021:** Licensee to have obtained or retained sufficient funding for Phase I clinical trial.
- **July 1, 2021:** Dosing of first patient in Phase I clinical trial.
- **November 1, 2022: Dosing of first patient in Phase II clinical trial.**
- [Date to be determined in the future by the Parties after good faith discussions in light of the actual results of the Phase II clinical trial, the perceived necessity for a Phase III clinical trial, the regulatory pathway toward any necessary Phase III clinical trial and the expected duration of any necessary Phase III clinical trial]: Regulatory submission.
- [Date to be determined in the future by the Parties after good faith discussions in light of the actual results of the Phase II clinical trial, the perceived necessity for a Phase III clinical trial, the regulatory pathway toward any necessary Phase III clinical trial, the expected duration of any necessary Phase III clinical trial and the expected timeline (under the circumstances) from the end of such Phase III clinical trial to regulatory approval]: Date of first commercial sale.
- Following the first commercial sale, Licensee shall use best efforts to fill the market demand for the Licensed Products at all times.

Exhibit 10.19

June 23, 2020

Qualigen, Inc.
2042 Corte Del Nogal
Carlsbad, CA 92011
Attention: Michael S. Poirier, (Chairman, President and CEO)

Re: Letter of Intent by and between Sekisui Diagnostics, LLC ("Sekisui") and Qualigen, Inc. ("Qualigen") dated as of March 16, 2018, as amended and restated as of August 22, 2018, as amended (the "LOI"). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the LOI.

Dear Michael:

With respect to the above-referenced LOI, this letter will confirm certain understandings of Qualigen, and Sekisui as follows:

(1) Qualigen and Sekisui confirm and agree that pursuant to the terms of the LOI, Qualigen owes Sekisui for the R&D Payment and the Sekisui Vitamin D Costs the aggregate principal amount of 890,000.00, together with interest thereon, which sum was due and payable in full on December 6th, 2019 and payment was extended to January 6th, 2020 March 6th, 2020 and then to June 1st 2020, without offset or demand.

(2) Qualigen and Sekisui agree to extend the due date for payment of the R&D Payment and the Sekisui Vitamin D Costs in the aggregate principal amount of $890,000.00, together with interest thereon, to September 1st, 2020, on which date Qualigen shall pay to Sekisui such sum in full without offset or demand.

(3) Except as specifically set forth herein, all terms and conditions of the Distribution Agreement remain in full force and effect.

If you agree with the terms of this letter agreement, please sign a counterpart copy of this letter and return to me.

Very truly yours,

Sekisui Diagnostics, LLC

By: */s/ Bill Faranda*
William Faranda

AGREED TO:

QUALIGEN, INC.
By: */s/ Michael Poirier* */s/ RDR*

Michael S. Poirier, (Chairman, President and CEO) Legal Approval

Sekisui Diagnostics, LLC
1 Wall Street
Burlington, MA 01803
Tel: 800 332 1042 Fax: 800 762 6311
www.sekisuidiagnostics.com

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.

August 14, 2020

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.

August 14, 2020

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 June 30, 2020, 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.

August 14, 2020

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

August 14, 2020

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.