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 September 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 November 5, 2020, there were 23,060,906 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)

	September 30, 2020	March 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 14,465,541	$ 153,121
Accounts receivable, net	179,870	417,122
Accounts receivable — related party, net	189,474	290,180
Inventory, net	805,383	660,138
Prepaid expenses and other current assets	1,925,446	98,385
Total current assets	17,565,714	1,618,946
Right-of-use asset	483,643	—
Property and equipment, net	1,565,275	1,447,514
Equipment held for lease, net	32,726	64,005
Intangible assets, net	1,009,453	571,270
Other assets	18,334	18,279
Total Assets	$ 20,675,145	$ 3,720,014
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 408,254	$ 879,264
Accrued expenses and other current liabilities	726,542	1,243,764
Notes payable, current portion	787,478	1,913,255
Deferred revenue, current portion	58,773	105,416
Deferred revenue — related party	95,160	271,206
Due to related party	176,046	926,385
Lease liability	247,050	—
Warrant liabilities	20,596,700	—
Total current liabilities	23,096,003	5,339,290
Notes payable, net of current portion	159,670	305,805
Lease liability, net of current portion	303,894	—
Deferred revenue, net of current portion	4,219	2,689
Total liabilities	23,563,786	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 September 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 September 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 September 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 September 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 September 30, 2020 and March 31, 2020	—	6,435
Series Alpha convertible preferred stock, $0.001 par value; 7,000 shares authorized; 698 shares and 0 shares issued and outstanding as of September 30, 2020 and March 31, 2020	1	—
Common stock, post-merger $0.001 par value; 225,000,000 shares authorized; 22,529,905 shares issued and outstanding as of September 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	22,530	56,026
Additional paid-in capital	71,082,072	45,161,599
Accumulated deficit	(73,993,244)	(47,301,126)
Total stockholders' deficit	(2,888,641)	(1,927,770)
Total Liabilities and Stockholders' Deficit	$ 20,675,145	$ 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)

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
REVENUES				
Net product sales	$ 361,218	$ 526,865	$ 845,641	$ 1,087,516
Net product sales—related party	476,496	634,262	896,140	1,584,446
Collaborative research revenue	—	40,000	—	40,000
Total revenues	837,714	1,201,127	1,741,781	2,711,962
EXPENSES				
Cost of product sales	318,460	408,203	673,887	724,716
Cost of product sales—related party	603,015	603,890	1,055,510	1,265,157
General and administrative	2,664,658	202,679	4,644,272	471,696
Research and development	870,876	200,217	1,468,221	347,858
Research and development—related party	—	1,193	—	540,618
Sales and marketing	98,045	74,518	186,889	176,912
Total expenses	4,555,054	1,490,700	8,028,779	3,526,957
LOSS FROM OPERATIONS	(3,717,340)	(289,573)	(6,286,998)	(814,995)
OTHER EXPENSE (INCOME), NET				
Change in fair value of warrant liabilities	4,395,300	—	20,596,700	—
Interest expense, net	715	65,480	58,079	135,465
Other income, net	(2,447)	(248)	(252,561)	(1,240)
Total other expense (income), net	4,393,568	65,232	20,402,218	134,225
LOSS BEFORE PROVISION FOR INCOME TAXES	(8,110,908)	(354,805)	(26,689,216)	(949,220)
PROVISION FOR INCOME TAXES	2,305	1,420	2,902	1,570
NET LOSS	(8,113,213)	(356,225)	(26,692,118)	(950,790)
Net loss per common share, basic and diluted	$ (0.41)	$ (0.06)	$ (1.87)	$ (0.17)
Weighted—average number of shares outstanding, basic and diluted	19,799,468	5,602,214	14,303,058	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 Series Alpha preferred shares upon closing of private placement	—	—	—	—	—	—	—	—	—	—	5,010	5	—	—	4,009,995	—	4,010,000
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
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)
Issuance of common stock for conversion of preferred stock	—	—	—	—	—	—	—	—	—	—	(3,922)	(3)	5,303,773	5,303	(5,300)	—	—
Shares and (exercised) warrants issued pursuant to Securities Purchase Agreements	—	—	—	—	—	—	—	—	—	—	—	—	3,637,874	3,639	17,997,142	—	18,000,781
Commission and offering costs of Securities Purchase Agreements	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(835,904)	—	(835,904)
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,212,451	—	1,212,451
Net Loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(8,113,213)	(8,113,213)
Balance at September 30, 2020	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	698	$ 1	22,529,905	$ 22,530	$ 71,082,072	$ (73,993,244)	$ (2,888,641)

	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)
Net Loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	45,153,733	(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	$ —	$ (46,108,179)	$ (742,689)
Net Loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(356,225)	(356,225)
Balance at September 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	$ (46,464,404)	$ (1,098,914)

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 Six Months Ended September 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (26,692,118)	$ (950,790)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	60,010	110,792
Amortization of debt issuance costs	—	20,834
Amortization of right-of-use assets	101,869	—
Accounts receivable reserves and allowances	4,112	(20,069)
Inventory reserves	(127,455)	(32,402)
Stock-based compensation	1,571,076	—
Change in fair value of warrant liabilities	20,596,700	—
Changes in operating assets and liabilities:		
Accounts receivable	233,140	111,398
Accounts receivable — related party	100,706	291,710
Inventory and equipment held for lease	(17,790)	124,970
Prepaid expenses and other assets	(627,783)	(10,255)
Accounts payable	(471,010)	185,161
Accrued expenses and other current liabilities	(353,861)	(28,447)
Due to related party	(750,339)	392,353
Lease liability	(112,166)	—
Deferred revenue	(221,159)	(14,711)
Net cash (used in) provided by operating activities	(6,706,068)	180,544
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(136,217)	—
Payments for patents and licenses	(448,458)	(92,843)
Net cash used in investing activities	(584,675)	(92,843)
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
Proceeds from issuance of shares and warrants pursuant to Securities Purchase Agreements	18,000,781	—
Commission and offering costs of securities purchase agreements	(835,904)	—
Payments on capital lease obligations	—	(15,462)
Principal payments on notes payable	(964,177)	(430,181)
Net cash provided by (used in) financing activities	21,603,163	(187,989)
Net change in cash and cash equivalents	14,312,420	(100,288)
CASH AND CASH EQUIVALENTS – beginning of period	153,121	125,123
CASH AND CASH EQUIVALENTS – end of period	$ 14,465,541	$ 24,835
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 28,256	$ 48,564
Taxes	$ 4,772	$ 4,763
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 before closing of reverse recapitalization	$ 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	$ —
Issuance of common stock for conversion of preferred stock after closing of reverse recapitalization	$ 5,300	$ —
Initial measurement of operating lease right-of-use assets	$ 663,110	$ —
Net transfers to inventory from equipment held for lease	$ —	$ 2,352

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

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

NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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 and six months periods ended September 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 the estimated fair value of warrant liabilities, 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.

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 and six months ended September 30, 2020 and 2019, 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:

	September 30, 2020	March 31, 2020
Accounts Receivable	$ 202,299	$ 443,663
Less Allowance	(22,429)	(26,541)
	$ 179,870	$ 417,122

Research and Development

The Company expenses research and development costs as incurred.

Shipping and Handling Costs

The Company includes shipping and handling fees billed to customers in net sales. Shipping and handling costs associated with inbound and outbound freight are generally recorded in cost of sales which totaled approximately $29,000 and $28,000, respectively, for the three months ended September 30, 2020 and 2019, and approximately $55,000 and $59,000, respectively, for the six months ended September 30, 2020 and 2019. Other shipping and handling costs included in general and administrative, research and development, and sales and marketing expenses totaled approximately $2,000 and $1,000 for the three months ended September 30, 2020 and 2019, respectively, and approximately $7,000 and $2,000 for the six months ended September 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 generates revenue from selling FastPack System analyzers, accessories and disposable products used with the FastPack System. Disposable products include reagent packs which are diagnostic tests for 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 and six months ended September 30, 2020 and 2019, product sales are stated net of an allowance for estimated returns of approximately $1,000 and $19,000, 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 September 30, 2020 and 2019, the Company recognized collaborative research revenue of $0 and $40,000, respectively. During the six months ended September 30, 2020 and 2019, the Company recognized collaborative research revenue of $0 and $40,000, respectively.

Operating Leases

Effective April 1, 2020, the Company adopted ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements* ("Topic 842"). 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 and licenses are capitalized and amortized over their estimated useful lives, which is generally 5 to 17 years, using the straight-line method. Amortization of patents and licenses commences once final approval of the patent has been obtained. Patent and licenses costs are charged to operations if it is determined that the patent will not be obtained.

The carrying value of the patents of approximately $769,000 and $715,000 at September 30, 2020 and March 31, 2020, respectively, are stated net of accumulated amortization of approximately $300,000 and $293,000, respectively. Amortization of patents charged to operations for the three months ended September 30, 2020 and 2019 were approximately $3,000 for each period, and approximately $7,000 and $6,000 for the six months ended September 30, 2020 and 2019, respectively. Total future estimated amortization of patent costs for the five succeeding years is approximately $7,000 for the remaining six months in 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 $412,000 thereafter.

The carrying value of the licenses of approximately $939,000 and $544,000 at September 30, 2020 and March 31, 2020 are stated net of accumulated amortization of approximately $398,000 and $395,000, respectively. Amortization of licenses charged to operations for each of the three month periods ended September 30, 2020 and 2019 was approximately $2,000, and approximately $3,000 for each of the six month periods ended September 30, 2020 and 2019. Total future estimated amortization of license costs is approximately $4,000 for the remaining six months in 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 $520,000 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 8).

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

- Level 1 - Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that 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

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.

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 September 30, 2020 and March 31, 2020 and are included in accrued expenses and other current liabilities on the balance sheets. Warranty costs were approximately $28,000 and $27,000 for the three months ended September 30, 2020 and 2019, respectively, and approximately $59,000 and $55,000 for the six months ended September 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 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 incurred recurring losses from operations and has a net working capital deficit and an accumulated deficit at September 30, 2020, and the Company continued to incur losses subsequent to the balance sheet date of September 30, 2020. 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 12). Based on our current cash position, and assuming currently planned expenditures and level of operations, we believe we have sufficient capital to fund operations for the twelve-month period subsequent to the issuance of the interim financial information. However, there is no assurance that profitable operations will ever be achieved, or if achieved, could be sustained on a continuing basis. Also, beyond such 12-month period, planned research and development activities, capital expenditures, clinical and pre-clinical testing, and commercialization activities of the Company's products are expected to require significant additional financing. Additional financing may not be available on acceptable terms or at all.

NOTE 3 — INVENTORY, NET

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

	September 30, 2020	March 31, 2020
Raw materials	$ 537,502	$ 457,425
Work in process	156,679	117,729
Finished goods	111,202	84,984
	$ 805,383	$ 660,138

NOTE 4 — PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following at September 30, 2020 and March 31, 2020:

	September 30, 2020	March 31, 2020
Prepaid insurance	$ 1,643,060	$ 26,981
Other prepaid expenses and current assets	282,386	71,404
	$ 1,925,446	$ 98,385

NOTE 5 — PROPERTY AND EQUIPMENT, NET

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

	September 30, 2020	March 31, 2020
Machinery and equipment	$ 2,364,471	$ 2,355,165
Construction in progress–equipment	1,480,400	1,376,000
Computer equipment	431,091	420,552
Leasehold improvements	317,157	307,539
Molds and tooling	260,002	260,002
Office furniture and equipment	137,374	136,275
	4,990,495	4,855,533
Less Accumulated depreciation	(3,425,220)	(3,408,019)
	$ 1,565,275	$ 1,447,514

Depreciation expense relating to property and equipment was approximately $10,000 and $17,000 for the three months ended September 30, 2020 and 2019, respectively, and approximately $18,000 and $34,000 for the six months ended September 30, 2020 and 2019, respectively.

NOTE 6 — ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	September 30, 2020	March 31, 2020
Board compensation	$ 53,809	$ —
Vacation	221,866	160,024
Royalties	11,361	26,099
Research and development	152,815	288,184
Professional fees	101,647	277,900
Office rent	10,544	—
Deferred rent	—	77,597
Warranty costs	28,978	30,119
Payroll	55,031	35,052
Patent and license fees	—	51,007
Sales and use taxes	12,800	16,755
Income taxes	6,230	8,100
Interest	1,820	247,569
Other	69,641	25,358
	$ 726,542	$ 1,243,764

NOTE 7 — NOTES PAYABLE

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

	September 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	$ 475,269	$ —
An unsecured promissory note with a bank, pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act	449,050	—
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	16,706	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	6,123	9,441
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	—	489,051
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
	947,148	2,219,060
Less current portion, net of debt issuance costs	(787,478)	(1,913,255)
Notes Payable, net of current portion	$ 159,670	$ 305,805

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

Year Ending March 31,	Amount
2021 (six months)	$ 668,505
2022	235,955
2023	42,688
Total balance	$ 947,148

NOTE 8 – WARRANT LIABILITIES

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

In exchange for the Series C Warrants, upon closing of the merger with Ritter, the holders received warrants to purchase an aggregate of 4,713,490 shares of the Company's common stock at $0.72 per share, subject to adjustment. As of September 30, 2020, the warrants have received in exchange for the Series C Warrants remaining terms ranging from 2.9 to 5.0 years. The warrants were determined to be liability-classified pursuant to the guidance in ASC 480 and ASC 815-40, resulting from inclusion of a leveraged ratchet provision for subsequent dilutive issuances.

The following table summarizes the activity in the warrants received in exchange for the Series C Warrants for the six months ended September 30, 2020:

	Common Stock Warrants (received in exchange for the Series C Warrants)			
	Shares	Weighted–Average Exercise Price	Range of Exercise Price	Weighted–Average Remaining Life (Years)
Total outstanding – 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 – September 30, 2020	4,713,490	$ 0.72		
Exercisable	4,713,490	$ 0.72	$ 0.72	3.25
Non-Exercisable	—	$ —	$ —	—

The following table summarizes the Series C Warrants activity for the six months ended September 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	1,441,180	$ 2.35		
Forfeited	—	—		
Expired	—	—		
Granted	—	—		
Total outstanding – September 30, 2019	1,441,180	$ 2.35		
Exercisable	1,441,180	$ 2.35	$ 2.25 – $2.70	5.35
Non-Exercisable	—	$ —	$ —	—

The following table presents the Company's fair value hierarchy for its warrant liabilities (all of which arise under the warrants received in exchange for the Series C Warrants) measured at fair value on a recurring basis as of September 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 September 30, 2020	$ -	$ -	$ 20,596,700	$ 20,596,700

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

Warrant liabilities	As of September 30, 2020
Balance, March 31, 2020	$ —
Fair value at issuance date	—
Change in fair value included in the statement of comprehensive loss	20,596,700
Balance, September 30, 2020	$ 20,596,700

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

The value of the warrant liabilities (all of which arise under the warrants received in exchange for the Series C Warrants), as of the dates set forth in the table above, was based on upon the following assumptions:

	September 30, 2020
Stock price	$ 4.95
Exercise price per share	$ 0.72
Risk-free interest rate	0.16% — 0.28%
Expected volatility (peer group)	82.00% — 85.00%
Expected life (in years)	2.85 — 5.02
Expected dividend yield	0.00%
Number outstanding	4,713,490

NOTE 9 — 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 September 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	(101,870)
Operating lease right-of-use assets at September 30, 2020	$ 483,643

	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	(112,166)
Lease liabilities at September 30, 2020	550,944
Less non-current portion	303,894
Current portion at September 30, 2020	$ 247,050

As of September 30, 2020, the Company's operating leases have a weighted-average remaining lease term of 2.1 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 September 30, 2020 and 2019, and approximately $173,000 for each of the six month periods ended September 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 10 — 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 September 30, 2020 and 2019 and approximately $129,000 for each of the six month periods ended September 30, 2020 and 2019.

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

Year Ending March 31,	Amount
2021 (six months)	$ 142,398
2022	290,492
2023	173,315
Total	606,205
Less present value discount	(55,261)
Operating lease liabilities	$ 550,944

NOTE 11 — RESEARCH AND LICENSE AGREEMENTS

Between June 2018 and September 2020, the Company entered into license and sponsored research agreements with the University of Louisville Research Foundation ("ULRF") for ALAN (AS1411-GNP), 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, which was subsequently converted into the Company's common stock, and the Company will reimburse ULRF for sponsored research expenses of up to $805,000 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 ongoing costs associated with the preparation, filing, prosecution and maintenance of licensed patents, incurred prior to June 2018, and (iv) payments ranging from $100,000 to $5,000,000 upon the achievement of certain regulatory and commercial milestones. Milestone payments for the first therapeutic indication would be $100,000 for first dosing in a Phase 1 clinical trial, $200,000 for first dosing in a Phase 2 clinical trial, $350,000 for first dosing in a Phase 3 clinical trial, $500,000 for regulatory marketing approval and $5,000,000 upon achieving a cumulative $500,000,000 of Licensed Product sales; the Company would also pay another $500,000 milestone payment for any additional regulatory marketing approval for each additional therapeutic (or diagnostic) indication. The Company also must pay ULRF shortfall payments if the total amounts actually paid with respect to royalties and non-royalty sublicensee income for any year is less than the applicable annual minimum (ranging from $10,000 to $50,000) for such year.

Sponsored research expenses related to these agreements for the three months ended September 30, 2020 and 2019 were approximately $0 and $93,000, and approximately $2,000 and $126,000 for the six months ended September 30, 2020 and 2019, respectively, and are recorded in research and development expenses in the statements of operations. Patent costs related to these agreements for the three months ended September 30, 2020 and 2019 were approximately $17,000 and $6,000 respectively, and approximately $164,000 and $66,000 for the six months ended September 30, 2020 and 2019, respectively. These amounts are included in intangible assets on the balance sheets.

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, which was subsequently converted into the Company's common stock. In addition, the Company agreed to pay ACT (i) royalties, on net sales associated with the commercialization of 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 as of September 30, 2020. Between April and August 2020, the Company purchased drug compounds from ACT for $10,000, and an Investigational New Drug (IND) application from ACT for an additional $100,000. Upon successful recertification of the drug compounds, ACT will receive an additional $50,000. Of these amounts, for the three and six months ended September 30, 2020, $100,000 and $110,000 respectively, are included in research and development expenses in the statements of operations.

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

Sponsored research expenses related to these agreements for the three months ended September 30, 2020 and 2019 were approximately $50,000 and $39,000, and approximately $189,000 and $59,000 for the six months ended September 30, 2020 and 2019, respectively, and are recorded in research and development expenses in the statements of operations. Patent costs related to these agreements for the three and six months ended September 30, 2020 and 2019 were approximately $112,000 and $14,000, respectively. These amounts are included in intangible assets on the balance sheets.

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 received approximately $24,000 for an upfront license fee and reimbursement of prior patent costs. For the three and six months ended September 30, 2020, the Company also incurred approximately $490,000 and $678,000 in costs respectively, related to this agreement which are included in research and development expenses in the statement of operations. In addition, the Company was required to enter into a separate sponsored research agreement with ULRF for at least $250,000. In November 2020, the Company executed a sponsored research agreement supporting up to approximately $430,000 in research (see Note 14).

In addition, the Company has agreed to pay ULRF (i) royalties, on patent-covered net sales associated with the commercialization, of 4% (on net sales up to a cumulative $250,000,000) or 5% (on net sales above a cumulative $250,000,000), until expiration of the licensed patent, and 2.5% (on net sales for any sales not covered by Licensed Patents), (ii) 30% to 50% of any non-royalty sublicensee income received (50% for sublicenses granted in the first two years of the ULRF license agreement, 40% for sublicenses granted in the third or fourth years of the ULRF license agreement, and 30% for sublicenses granted in the fifth year of the ULRF license agreement or thereafter), (iii) reimbursements for ongoing costs associated with the preparation, filing, prosecution and maintenance of licensed patents, incurred prior to 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.

In November 2015, the Company entered into a long-term development and supply agreement with Prediction Biosciences, SAS, an unrelated party, to develop and manufacture diagnostic tests for use in the stroke point-of-care market. The Company recognizes development revenue and product sales over the performance period of the contract. For the three and six months ended September 30, 2020, there was no collaborative research revenue, and for the three and six months ended September 30, 2019, there was $40,000 collaborative research revenue related to this agreement.

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

There were product sales of approximately $476,000 and $634,000 for the three months ended September 30, 2020 and 2019, and product sales of approximately $896,000 and $1,584,000 for the six months ended September 30, 2020 and 2019, respectively, related to this agreement.

NOTE 12 — STOCKHOLDERS' DEFICIT

As of September 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 September 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 September 30, 2020, the Company has reserved 14,418,983 shares of authorized but unissued common stock for possible future issuance. At September 30, 2020, shares were reserved in connection with the following:

Exercise of issued and future grants of stock options	3,723,356
Exercise of stock warrants	9,751,712
Conversion of Series Alpha preferred stock	943,915
Total	14,418,983

Series A, B, C, D, D-1, Alpha 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.

In the six-month period ended September 30, 2020, the holder of 4,662 shares of Series Alpha preferred stock converted its shares of Series Alpha preferred stock into an aggregate of 6,304,485 shares of the Company's common stock, and there were 698 shares of Series Alpha preferred stock outstanding at September 30, 2020.

Alpha Securities Purchase Agreements

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

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

Stock Options and Warrants

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

In April 2020, the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan") which provides for the granting of incentive or nonstatutory common stock options to qualified employees, officers, directors, consultants and other service providers. At September 30, 2020 and 2019 there were 3,629,500 and 0 outstanding options respectively under the 2020 Plan and there were 427,657 and 0 options available respectively for future grant.

The Company has in 2017 and earlier 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. These are to be differentiated from the Series C Warrants described in Note 8.

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-employee service providers that are outstanding at September 30, 2020, and changes during the six-month 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	1.65
Granted	3,629,500	5.09	$ 4.70—$5.10	9.70
Expired	(1,268)	34.54	$ 15.00 — 562.50	
Forfeited	—	—		
Total outstanding – September 30, 2020	3,723,356	$ 7.33	$ 4.70—$1,465.75	9.49
Exercisable (vested)	108,856	$ 2.72	$ 4.70—$1,465.75	2.76
Non-Exercisable (non-vested)	3,614,500	$ 5.09	$ 4.70—$5.10	9.70

There was approximately $1.2 million and $0 of compensation costs related to outstanding options for the three months ended September 30, 2020 and 2019, and approximately $1.6 million and $0 for the six months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, there was approximately $13.1 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 2.69 years.

No stock options were exercised during the three months ended September 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 six months ended September 30, 2020 was $5.09.

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 six months ended September 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	$ 4.70 — 5.13

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

	For the six months ended September 30,	
	2020	2019
General and administrative	$ 1,312,433	$ —
Research and development	258,643	—
Total	$ 1,571,076	$ —

Compensatory Warrants

In the six months ended September 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 cost of these warrants was charged to additional paid-in capital, and did not result in expense on the Company's statements of operations.

In addition, various service providers hold equity classified compensatory warrants issued in 2017 and earlier (originally exercisable to purchase Series C convertible preferred stock, and now instead exercisable to purchase common stock) for the purchase of 668,024 shares of Company common stock at a weighted average exercise price of $2.34 per share. These are to be differentiated from the Series C Warrants described in Note 8. No compensatory warrants were issued in the six months ended September 30, 2019.

The following table summarizes the equity classified compensatory warrant activity for the six months ended September 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 compensatory warrants exchanged for common stock warrants upon reverse recapitalization	668,024	2.34		
Granted to advisor and its designees	811,431	1.11		
Expired	—	—		
Forfeited	—	—		
Total outstanding – September 30, 2020	1,479,455	$ 1.67		
Exercisable	664,428	$ 2.34	$ 2.07 —$2.54	3.78
Non-Exercisable	815,027	$ 1.11	$ 1.11 —$2.54	4.65

The following table summarizes the compensatory warrant activity for the six months ended September 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	756,262	$ 1.99		
Forfeited	(2,000)	2.25		
Expired	—	—		
Granted	—	—		
Total outstanding – September 30, 2019	754,262	$ 1.99		
Exercisable	746,142	$ 1.99	$ 1.83 – $2.25	5.09
Non-Exercisable	8,120	$ 2.25	$ 2.25	6.98

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

Noncompensatory Equity Classified Warrants

In the six months ended September 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. In addition, in July 2020 the Company issued noncompensatory equity classified warrants to an investor for the purchase of 2,700,966 shares of Company common stock at an exercise price of $5.25 per share, and in August 2020 the Company issued noncompensatory equity classified warrants to such investor for the purchase of 1,287,829 shares of Company common stock at an exercise price of $6.00 per share. No noncompensatory equity classified warrants were issued in the six months ended September 30, 2019.

The following table summarizes the noncompensatory equity classified warrant activity for the six months ended September 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	3,478,985	5.21		
Expired	(1,673)	1,562.50		
Forfeited	—	—		
Total outstanding – September 30, 2020	3,558,767	$ 5.59		
Exercisable	3,558,767	$ 5.59	$ 1.11 – $2,325.00	2.03
Non-Exercisable	—	$ —	—	—

NOTE 13 — RELATED PARTY TRANSACTIONS

In October 2017, Sekisui purchased all outstanding shares of the Company's Series D and Series D-1 preferred stock from Gen-Probe Incorporated. As such, Sekisui became a related party as of October 2017. These Series D and Series D-1 preferred stock shares were converted into 1,980,233 shares of the Company's common stock in connection with the reverse recapitalization transaction in May 2020. The following are transactions made between the Company and Sekisui as of and for the three and six months ended September 30, 2020 and 2019.

- The Company sells products and provides collaborative research & development ("R&D") services to Sekisui. As of September 30, 2020 and March 31, 2020, the Company had a receivable from Sekisui of approximately $189,000 and $290,000, respectively. The Company recorded product sales of approximately $476,000 and $634,000 for the three months ended September 30, 2020 and 2019, and approximately $896,000 and $1,584,000 for the six months ended September 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 and six months ended September 30, 2020 and 2019. The Company had cost of product sales relating to Sekisui of approximately $603,000 and $604,000 for the three months ended September 30, 2020 and 2019, and approximately $1.1 million and $1.3 million for the six months ended September 30, 2020 and 2019, respectively. R&D expenses relating to Sekisui were approximately $0 and $1,000 for the three months ended September 30, 2020 and 2019, and approximately $0 and $541,000 for the six months ended September 30, 2020 and 2019, respectively.

- As of September 30, 2020 and March 31, 2020, the Company had approximately $0.2 million and $0.9 million, respectively, classified as due to related party (Sekisui) on the accompanying balance sheets. The Company satisfied the $0.9 million obligation at March 31, 2020 (related to product development financing payments made by Sekisui) by payment in full on July 21, 2020. The $0.2 million obligation at September 30, 2020 represents amounts due related to the distribution portion of our strategic partnership with Sekisui.

- As of September 30, 2020 and March 31, 2020, the Company had approximately $95,000 and $271,000 of deferred revenue from Sekisui classified as deferred revenue on the accompanying balance sheets, respectively.

NOTE 14 — SUBSEQUENT EVENTS

The Company entered into a Technology Transfer Agreement dated as of October 7, 2020 with Yi Xin Zhen Duan Jishu (Suzhou) Ltd. ("Yi Xin"), of Suzhou, China, for Yi Xin to develop, manufacture and sell new generations of diagnostic test systems based on the Company's core FastPack® "laboratory in a pouch" technology. In addition, the Technology Transfer Agreement authorized Yi Xin to manufacture and sell the Company's current generations of rapid point-of-care FastPack diagnostic products in China.

Under the Technology Transfer Agreement, the Company is to receive certain cash payments in the third and fourth quarters of the Company's 2021 fiscal year, plus royalties on all future new-generations and current-generations product sales by Yi Xin.

The Company agreed to provide technology transfer and patent/know-how license rights to facilitate Yi Xin's development and commercialization.

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

On October 14, 2020, the Company issued 30,645 shares of its common stock upon the exercise of 30,645 warrants exercisable at $0.72 per share.

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

On November 1, 2020, the Company entered into a contract with STA Pharmaceutical Co., Ltd. (WuXi STA), a subsidiary of WuXi AppTec, for GMP production of AS1411, the Company's lead drug candidate for the treatment of COVID-19 and other viral diseases, for potential clinical trials in 2021.

On November 11, 2020, the Company entered into a Sponsored Research Agreement with ULRF in connection with its license agreement for the use of AS1411 as a treatment for COVID-19 (see Note 11).

On November 12, 2020, the Company issued 1,000 shares of its common stock upon the exercise of 1,000 warrants exercisable at $0.72 per share.

Risks Related to COVID-19 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 two quarters 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 owned and in-licensed patent applications;
- there can be no assurance that such patents, if any, and our current owned and in-licensed patents would prevent competition;
- there can be no assurance that 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 a drug candidate for treating COVID-19 and other viral-based infectious diseases. 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. ("Low T"), 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 and six month periods ended September 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 Liabilities

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 liabilities. The size of these warrant liabilities at September 30, 2020 was quite large ($20.6 million) and caused a significant distortion of our balance sheet at September 30, 2020 and our results of operations for the three and six month periods ended September 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 September 30, 2020 and 2019

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

	For the Three Months Ended September 30,		Dollar
	2020	2019	Change
REVENUES			
Net product sales	$ 361,218	$ 526,865	(165,647)
Net product sales—related party	476,496	634,262	(157,766)
Collaborative research revenue	—	40,000	(40,000)
Total revenues	837,714	1,201,127	(363,413)
EXPENSES			
Cost of product sales	318,460	408,203	(89,743)
Cost of product sales—related party	603,015	603,890	(875)
General and administrative	2,664,658	202,679	2,461,979
Research and development	870,876	200,217	670,659
Research and development—related party	—	1,193	(1,193)
Sales and marketing	98,045	74,518	23,527
Total expenses	4,555,054	1,490,700	3,064,354
LOSS FROM OPERATIONS	(3,717,340)	(289,573)	(3,427,767)
OTHER EXPENSE, NET			
Change in fair value of warrant liabilities	4,395,300	—	4,395,300
Interest expense, net	715	65,480	(64,765)
Other (income) expense, net	(2,447)	(248)	(2,199)
Total other expense, net	4,393,568	65,232	4,328,336
LOSS BEFORE PROVISION FOR INCOME TAXES	(8,110,908)	(354,805)	(7,756,103)
PROVISION FOR INCOME TAXES	2,305	1,420	885
NET LOSS	(8,113,213)	(356,225)	(7,756,988)

Revenues

Our operating revenues are primarily generated from sales of diagnostic tests. Revenues during the three-month period ended September 30, 2020 were $0.8 million compared to $1.2 million during the same period in 2019, a decrease of $0.4 million, or 30%. This decrease of $0.4 million was due to a reduction in sales to Sekisui, our primary distributor, of about $0.2 million due to an excess of Sekisui's FastPack instrument and diagnostic kit inventory levels primarily caused by the COVID-19 pandemic, and a $0.2 million decrease in sales to Low T, our largest direct customer, primarily due to the COVID-19 pandemic as well as an unrelated reduction in sales of our Total PSA assay to Low T. (As of October 2020, Low T has discontinued usage of our Total PSA assay due to unsatisfactory Medicare and private-insurer reimbursement pricing, which is expected to cause reduced sales to this customer in the future.) 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 use (or to discontinue use of) 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 currently deemed to be a related party) are primarily generated from sales of diagnostic tests. Net product sales during the three-month periods ended September 30, 2020 and 2019 were approximately $361,000 and $527,000, respectively, representing a decrease of approximately $166,000, or 31%. This decrease was due primarily to a reduction in sales to Low T, due to the effect of the COVID-19 pandemic and Low T's phase-out of our Total PSA assay, 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 September 30, 2020 and 2019 decreased by approximately $158,000 to approximately $476,000 from approximately $634,000, or 25%, with the reduction in sales to Sekisui being primarily due to the effect of the COVID-19 pandemic, as described above.

Collaborative research revenue

Collaborative research revenue is recognized as research services are performed over the related development periods for each agreement. Collaborative research revenue during the three-month periods ended September 30, 2020 and 2019 decreased by $40,000 to $0, due to the lack of activity in the current period.

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 currently deemed to be a related party) decreased from approximately $408,000 or 77% of net product sales, during the three-month period ended September 30, 2019, to $318,000, or 88% of net product sales, during the three-month period ended September 30, 2020. The decrease in dollars and increase in percentage of net product sales were primarily due to the effect of the COVID-19 pandemic. The increase in percentage of net product sales was due to lower sales volume and higher allocated manufacturing overhead costs, resulting in diseconomies of scale.

Cost of Product Sales-related party

Cost of product sales-related party (i.e., our cost of products sold to our distributor Sekisui) stayed at the same level at approximately $603,000, however, it increased as a percentage of net product sales-related party from 95% during the three-month period ended September 30, 2019, to 127% of net product sales-related party during the three-month period ended September 30, 2020. The increase in percentage of net product sales-related party was due to lower net product sales volume, resulting in diseconomies of scale.

General and Administrative Expenses

General and administrative expenses increased from $0.2 million, during the three-month period ended September 30, 2019, to $2.7 million during the three-month period ended September 30, 2020. This increase was primarily due to $1.0 million in employee/director stock-based compensation expense, a $0.6 million increase in professional fees including legal and accounting services, a $0.4 million increase in insurance expenses and a $0.3 million increase in bonus and payroll expenses all related to the Company's public-company status in the current period.

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 currently deemed to be a related party) increased from approximately $200,000 for the three months ended September 30, 2019 to approximately $871,000 for the three months ended September 30, 2020. Of the research and development costs for the three months ended September 30, 2019, approximately $69,000 was attributable to diagnostics and approximately $133,000 was attributable to therapeutics. Of the research and development costs for the three months ended September 30, 2020, approximately $284,000 was attributable to diagnostics and approximately $587,000 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 $2,000 for the three months ended September 30, 2019 to $0 for the same period ended September 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 as well as increased stock-based compensation expense related to the Company's public-company status in the current period. The increase in therapeutics costs was primarily due to expenses related to the potential application of AS1411 to treatment of COVID-19 ($490,000 for the three months ended September 30, 2020 as compared to $0 for the same period ended in 2019) and research costs related to RAS-F ($62,000 for the three months ended September 30, 2020 as compared to $39,000 for the same period ended in 2019), offset by a $59,000 decrease in research costs associated with ALAN and other ($35,000 for the three months ended September 30, 2020 as compared to $94,000 for the same period in 2019). 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 increased by $23,000 from approximately $75,000 to $98,000 for the three-month period ended September 30, 2020 over the three-month period ended September 30, 2019, primarily due to an increase in royalty expense related to increased Vitamin D assay sales during the current period.

Other Expense

There was approximately $4.4 million in other expense during the three-month period ending September 30, 2020 versus approximately $0.1 million during the three-month period ended September 30, 2019. This change was due primarily to the change in the fair value of warrant liabilities of $4.4 million 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 a $0.1 million 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.

Comparison of the Six Months Ended September 30, 2020 and 2019

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

	For the Six Months Ended September 30,		Dollar
	2020	2019	Change
REVENUES			
Net product sales	$ 845,641	$ 1,087,516	(241,875)
Net product sales—related party	896,140	1,584,446	(688,306)
Collaborative research revenue	—	40,000	(40,000)
Total revenues	1,741,781	2,711,962	(970,181)
EXPENSES			
Cost of product sales	673,887	724,716	(50,829)
Cost of product sales—related party	1,055,510	1,265,157	(209,647)
General and administrative	4,644,272	471,696	4,172,576
Research and development	1,468,221	347,858	1,120,363
Research and development—related party	—	540,618	(540,618)
Sales and marketing	186,889	176,912	9,977
Total expenses	8,028,779	3,526,957	4,501,822
LOSS FROM OPERATIONS	(6,286,998)	(814,995)	(5,472,003)
OTHER EXPENSE, NET			
Change in fair value of warrant liabilities	20,596,700	—	20,596,700
Interest expense, net	58,079	135,465	(77,386)
Other (income) expense, net	(252,561)	(1,240)	(251,321)
Total other expense, net	20,402,218	134,225	20,267,993
LOSS BEFORE PROVISION FOR INCOME TAXES	(26,689,216)	(949,220)	(25,739,996)
PROVISION FOR INCOME TAXES	2,902	1,570	1,332
NET LOSS	(26,692,118)	(950,790)	(25,741,328)

Revenues

Our operating revenues are primarily generated from sales of diagnostic tests. Revenues during the six-month period ended September 30, 2020 were $1.7 million compared to $2.7 million during the same period in 2019, a decrease of $1.0 million, or 36%. This decrease of $1.0 million was primarily due to a reduction in sales to Sekisui, our primary distributor, of about $0.7 million caused by the COVID-19 pandemic, and a $0.2 million decrease in sales to Low T, Inc., our largest direct customer, also due to the COVID-19 pandemic as well as an unrelated reduction in sales of our Total PSA assay to Low T. (As of October 2020, Low T has discontinued usage of our Total PSA assay due to unsatisfactory Medicare and private-insurer reimbursement pricing, which is expected to cause reduced sales to this customer in the future.) 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 currently deemed to be a related party) are primarily generated from sales of diagnostic tests. Net product sales during the six-month periods ended September 30, 2020 and 2019 were approximately $846,000 and $1,088,000, respectively, representing a decrease of approximately $242,000, or 22%. This decrease was due primarily to a reduction in sales to Low T, due to the effect of the COVID-19 pandemic and reduced sales of our Total PSA assay, 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 six-month periods ended September 30, 2020 and 2019 decreased by approximately $688,000 to approximately $896,000 from approximately $1,584,000, or 43%, with the reduction in sales to Sekisui being primarily due to the effect of the COVID-19 pandemic, as described above, as well as Sekisui's inventory-purchase timing factors.

Collaborative research revenue

Collaborative research revenue is recognized as research services are performed over the related development periods for each agreement. Collaborative research revenue during the six-month periods ended September 30, 2020 and 2019 decreased by $40,000 to $0, due to the lack of activity in the current period.

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 currently deemed to be a related party) decreased from approximately $725,000 or 67% of net product sales, during the six-month period ended September 30, 2019, to $674,000, or 80% of net product sales, during the six-month period ended September 30, 2020. The decrease in dollars and increase in percentage of net product sales were due to higher allocated manufacturing overhead costs and lower net product sales volume, resulting in diseconomies of scale.

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 $1.3 million or 80% of net product sales-related party, during the six-month period ended September 30, 2019, to $1.1 million, or 118% of net product sales-related party, during the six-month period ended September 30, 2020. The decrease in dollars and increase in percentage of net product sales-related party were due to lower net product sales volume, resulting in diseconomies of scale.

General and Administrative Expenses

General and administrative expenses increased from $0.5 million, during the six-month period ended September 30, 2019, to $4.6 million during the six-month period ended September 30, 2020. This increase was primarily due to a $1.5 million increase in professional fees including legal and accounting services, a $1.3 million in employee/director stock-based compensation expense, a $0.8 million increase in bonus and payroll expenses and a $0.5 million increase in insurance expense, all due to the reverse recapitalization transaction which closed on May 22, 2020 and, following that, the Company's public-company status in the current period.

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 currently deemed to be a related party) increased from approximately $348,000 for the six months ended September 30, 2019 to approximately $1,468,000 for the six months ended September 30, 2020. Of the research and development costs for the six months ended September 30, 2019, approximately $668,000 was attributable to diagnostics and approximately $221,000 was attributable to therapeutics. Of the research and development costs for the six months ended September 30, 2020, approximately $534,000 was attributable to diagnostics and approximately $934,000 was attributable to therapeutics.

Research and development costs—related party includes the diagnostics costs associated with the FastPack 2.0 project with Sekisui, which decreased from approximately $541,000 for the six months ended September 30, 2019 to $0 for the same period ended September 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 as well as increased stock based compensation expense related to the Company's public-company status in the current period. The increase in therapeutics costs was primarily due to expenses related to the potential application of AS1411 to COVID-19 treatment ($678,000 for the six months ended September 30, 2020 as compared to $0 for the same period ended in 2019) and research costs with respect to RAS-F ($201,000 for the six months ended September 30, 2020 as compared to $59,000 for the same period ended in 2019), offset by a $106,000 decrease in research costs associated with ALAN and other ($56,000 for the six months ended September 30, 2020 as compared to $162,000 for the same period in 2019). 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 increased from approximately $177,000 to $187,000 for the six-month period ended September 30, 2020 over the three-month period ended September 30, 2019, primarily due to a modest increase in payroll costs.

Other Expense

There was approximately $20.4 million in other expense during the six-month period ending September 30, 2020 versus approximately $0.1 million during the six-month period ended September 30, 2019. This change was due primarily to the change in fair value of warrant liabilities of $20.6 million 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 six-month period ending September 30, 2020 of a $0.3 million license option for the Company's FastPack 2.0 technology for China. 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

As of September 30, 2020, we had $14.5 million of cash and cash equivalents. Our liquidity improved very significantly since March 31, 2020, due to a $4.0 million equity capital raise and sales of equity securities for a total of $18.0 million in two registered-direct offerings of common stock and warrants to an institutional investor (see Note 12). However, we have suffered recurring losses from operations and actually had a net working capital deficit of approximately $5.5 million at September 30, 2020 compared to a net working capital deficit of $3.7 million at March 31, 2020. Included in the working capital deficit at September 30, 2020 was $20.6 million of warrant liabilities. We do not consider that the warrant liabilities constrain our liquidity, as a practical matter. Based on our current cash position, and assuming currently planned expenditures and level of operations, we believe we have sufficient capital to fund operations for the twelve-month period subsequent to the issuance of the interim financial information. However, we operate in a rapidly evolving and unpredictable business environment that may change the timing or amount of expected future cash receipts and expenditures.

Our current liabilities at September 30, 2020 included $0.9 million in principal on financing agreements and a CARES Act loan. (We are seeking to have the CARES Act loan be forgiven.) In addition, at September 30, 2020 we had $0.4 million in accounts payable and $0.7 million and accrued expenses and other current liabilities.

As a development-stage therapeutics biotechnology company, we expect to continue to have net losses and negative cash flow from operations, which over time will 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.

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

Cash Flows

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

	For the Six Months Ended September 30,	
	2020	**2019**
Net cash provided by (used in):		
Operating activities	$ (6,706,068)	$ 180,544
Investing activities	(584,675)	(92,843)
Financing activities	21,603,163	(187,989)
Net increase (decrease) in cash and cash equivalents	**$ 14,312,420**	**$ (100,288)**

Net Cash Used in Operating Activities

During the six months ended September 30, 2020, operating activities used $6.7 million of cash, resulting from a net loss of $26.7 million, largely offset by $20.6 million change in fair value of warrant liabilities. Changes in net cash used in operating activities for the six months ended September 30, 2020 included the $20.6 million change in fair value of warrant liabilities (as described above), a $1.6 million increase in employee/director stock-based compensation expense, a $0.3 million decrease in accounts receivable and accounts receivable-related party, a $0.1 million increase in depreciation and amortization, partially offset by a $0.8 million decrease in due to related party, a $0.6 million increase in prepaid expenses and other assets, a $0.5 million decrease in accounts payable, a $0.4 million decrease in accrued expenses and other current liabilities, a $0.2 million decrease in deferred revenue and a $0.1 million decrease in lease liabilities. The decreases in accounts receivable and accounts receivable-related party were due to lower receivable balances from Sekisui and from Low T, 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 six months ended September 30, 2019, operating activities provided $0.2 million of cash, resulting from a net loss of $0.9 million, offset by $1.1 million in depreciation and amortization and changes in our operating assets and liabilities. Changes in net cash used in operating activities for the six months ended September 30, 2019 included a $0.4 million increase in accrued expenses and other current liabilities, a $0.4 million decrease in accounts receivable and accounts receivable-related party, a $0.2 million increase in accounts payable and a $0.1 million in depreciation and amortization. The increase in accrued expenses and other current liabilities and 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 Low T, our largest direct customer. In the 2019 period, the change in fair value of warrant liabilities was $0.

Net Cash Used in Investing Activities

During the six months ended September 30, 2020, net cash used in investing activities was $0.6 million, primarily related to payments for patents and licenses and secondarily for purchase of property and equipment.

During the six months ended September 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 six months ended September 30, 2020 was $21.6 million, due to $21.1 million of net proceeds from a reverse-recapitalization-time equity capital raise and later sales of equity securities in two registered-direct offerings to an institutional investor and the $1.4 million proceeds from the pre- reverse-recapitalization issuance of notes payable, offset by a $1.0 million principal payment of notes payable. Net cash used in financing activities for the six months ended September 30, 2019 was $0.2 million, primarily due to $0.4 million of principal payments on notes payable offset by $0.2 million of proceeds from the issuance of notes payable.

3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 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 September 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

None

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

On August 20, 2020, we issued a press release reporting the United States Patent and Trademark Office's issuance to us of a patent entitled "Devices and Methods for On-Line Whole Blood Treatment" regarding our Selective Target Antigen Removal System (STARS™) technology. The correct United States patent number for such patent is actually 10,744,258.

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	Securities Purchase Agreement between the Company and certain Purchasers, dated July 8, 2020 [corrected]	8-K		10.1	July 10, 2020
10.2	Common Stock Purchase Warrant for 1,920,768 shares, dated July 10, 2020	8-K		10.2	July 10, 2020
10.3	Pre-Funded Common Stock Purchase Warrant for 1,920,768 shares, dated July 10, 2020	8-K		10.3	July 10, 2020
10.4	Placement Agency Agreement between the Company and A.G.P./Alliance Global Partners, dated July 8, 2020	8-K		10.4	July 9, 2020

10.5	Securities Purchase Agreement between the Company and certain Purchasers, dated August 2, 2020	8-K	10.1	August 4, 2020
10.6	Placement Agency Agreement between the Company and A.G.P./Alliance Global Partners, dated August 2, 2020	8-K	10.2	August 4, 2020
10.7	Common Stock Purchase Warrant for 1,287,829 shares, dated August 4, 2020	8-K	10.3	August 4, 2020
10.8	Exclusive License Agreement between the Company and University of Louisville Research Foundation, Inc., dated as of July 17, 2020	8-K	10.4	August 4, 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.

November 12, 2020

QUALIGEN THERAPEUTICS, INC.

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

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.

November 12, 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.

November 12, 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 six months ended September 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.

November 12, 2020

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

November 12, 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.