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

FORM 10-Q

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

For the quarterly period ended: **June 30, 2020**

OR

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

For the transition period from _____ to _____

Commission File No. 001-36268

AKERS BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

New Jersey	**22-2983783**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)

201 Grove Road
Thorofare, NJ 08086
(Address of principal executive offices)

(856) 848-8698
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered**
Common Stock, no par value	AKER	NASDAQ

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 past 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes [X] 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 (Sec.232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ]

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

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

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

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

As of August 13, 2020 there were 8,724,283 shares outstanding of the registrant's common stock.

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Part I - Financial Information

Item 1 - Financial Statements

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

	As of	
	June 30, 2020	**December 31, 2019**
	(unaudited)	**(audited)**
ASSETS		
Current Assets		
Cash	$ 11,446,717	$ 517,444
Marketable Securities	6,856,805	9,164,273
Trade Receivables, net	2,301	42,881
Inventories, net	-	198,985
Prepaid expenses	172,096	387,231
Total Current Assets	18,477,919	10,310,814
Non-Current Assets		
Prepaid Expenses	-	252,308
Restricted Cash	115,094	115,094
Property, Plant and Equipment, net	4,783	33,574
Operating Lease Right-of-Use Asset	79,942	-
Intangible Assets, net	-	170,423
Other Assets	-	2,722
Total Non-Current Assets	199,819	574,121
Total Assets	$ 18,677,738	$ 10,884,935
LIABILITIES		
Current Liabilities		
Trade and Other Payables	$ 2,625,572	$ 1,529,765
Operating Lease Liability	80,018	-
Total Current Liabilities	2,705,590	1,529,765
Operating Lease Liability - non-current	-	-
Total Liabilities	$ 2,705,590	$ 1,529,765
Commitments and Contingencies		
SHAREHOLDERS' EQUITY		
Preferred Stock, No par value, 50,000,000 total preferred shares authorized	-	-
Series C Convertible Preferred Stock, 1,990,000 shares designated, no par value and a stated value of $4.00 per share, 0 and 0 shares issued and outstanding as of June 30, 2020 and December 31, 2019	-	-
Series D Convertible Preferred Stock, 211,353 shares designated, no par value and a stated value of $0.01 per share, 208,577 and 0 shares issued and outstanding as of June 30, 2020 and December 31, 2019	412,982	-
Common stock, No par value, 100,000,000 shares authorized 6,125,039 and 1,738,837 issued and outstanding as of June 30, 2020 and December 31, 2019	142,330,116	128,920,414
Accumulated Other Comprehensive Income (Loss)	(21,153)	17,886
Accumulated Deficit	(126,749,797)	(119,583,130)
Total Shareholders' Equity	15,972,148	9,355,170
Total Liabilities and Shareholders' Equity	$ 18,677,738	$ 10,884,935

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Product Revenue	$ (1,888)	$ 464,513	$ 361,627	$ 1,076,634
Product Cost of Sales	(377,169)	(219,864)	(550,040)	(465,801)
Gross Income (Loss)	(379,057)	244,649	(188,413)	610,833
Research and Development Expenses	1,916,161	-	4,399,218	-
Administrative Expenses	736,708	981,309	1,894,440	1,964,265
Sales and Marketing Expenses	7,240	14,139	21,703	163,979
Regulatory and Compliance Expenses	67,667	60,909	139,758	149,300
Litigation Settlement Expenses	81,717	-	81,717	75,000
Amortization of Non-Current Assets	8,727	10,002	17,601	20,004
Impairment of Prepaid Royalties	291,442	-	291,442	-
Impairment of Production Equipment	18,680	-	18,680	-
Impairment of Intangible Assets	149,870	-	152,822	-
Loss from Operations	(3,657,269)	(821,710)	(7,205,794)	(1,761,715)
Other (Income) Expenses				
Foreign Currency Transaction (Gain) Loss	(93)	219	(93)	4,878
Loss on Investments	-	543	36,714	4,258
Interest and Dividend Income	(29,045)	(27,581)	(75,748)	(59,002)
Total Other Income	(29,138)	(26,819)	(39,127)	(49,866)
Loss Before Income Taxes	(3,628,131)	(794,891)	(7,166,667)	(1,711,849)
Income Tax Benefit	-	-	-	-
Net Loss	(3,628,131)	(794,891)	(7,166,667)	(1,711,849)
Other Comprehensive Income (Loss)				
Net Unrealized Gain (Loss) on Marketable Securities	201,898	18,059	(39,039)	47,402
Total Other Comprehensive Income (Loss)	201,898	18,059	(39,039)	47,402
Comprehensive Loss	$ (3,426,233)	$ (776,832)	$ (7,205,706)	$ (1,664,447)
Basic and Diluted loss per common share	$ (0.69)	$ (1.47)	$ (1.92)	$ (3.16)
Weighted average basic and diluted common shares outstanding	5,252,211	541,367	3,739,529	541,000

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statement of Changes in Shareholders' Equity

	For the Six Months Ended June 30, 2019						
	Series D Convertible Preferred Stock		Common Stock			Accumulated Other	
	Shares	Series D	Shares	Common Stock	Accumulated Deficit	Comprehensive Income/(Loss)	Total Equity
Balance at December 31, 2018 (audited)	-	$ -	540,607	$ 121,554,547	$ (115,694,881)	$ (25,913)	$ 5,833,753
Net loss	-	-	-	-	(916,958)	-	(916,958)
Issuance of stock grants to key employees	-	-	625	15,874	-	-	15,874
Share-based compensation - Directors - restricted stock units	-	-	-	3,906	-	-	3,906
Net unrealized gain on marketable securities	-	-	-	-	-	29,343	29,343
Balance at March 31, 2019 (unaudited)	-	$ -	541,232	$ 121,574,327	$ (116,611,839)	$ 3,430	$ 4,965,918
Net loss	-	-	-	-	(794,891)	-	(794,891)
Issuance of stock grants to key employees	-	-	470	6,570	-	-	6,570
Share-based compensation - Directors - restricted stock units	-	-	-	118,478	-	-	118,478
Net unrealized gain on marketable securities	-	-	-	-	-	18,059	18,059
Balance at June 30, 2019 (unaudited)	-	$ -	541,702	$ 121,699,375	$ (117,406,730)	$ 21,489	$ 4,314,134

	For the Six Months Ended June 30, 2020						
	Series D Convertible Preferred Stock		Common Stock			Accumulated Other	
	Shares	Series D	Shares	Common Stock	Accumulated Deficit	Comprehensive Income/(Loss)	Total Equity
Balance at December 31, 2019 (audited)	-	$ -	1,738,837	$ 128,920,414	$ (119,583,130)	$ 17,886	$ 9,355,170
Net loss	-	-	-	-	(3,538,536)	-	(3,538,536)
Exercise of prepaid equity forward contracts for common stock	-	-	765,000	77	-	-	77
Share-based compensation - Directors - restricted stock units	-	-	-	1,302	-	-	1,302
Shares issued for the purchase of license	211,353	418,479	411,403	814,578	-	-	1,233,057
Share-based compensation - shares issued to vendors	-	-	-	7,318	-	-	7,318
Net unrealized loss on marketable securities	-	-	-	-	-	(240,937)	(240,937)
Balance at March 31, 2020 (unaudited)	211,353	$ 418,479	2,915,240	$ 129,743,689	$ (123,121,666)	$ (223,051)	$ 6,817,451
Net loss	-	-	-	-	(3,628,131)	-	(3,628,131)
Exercise of prepaid equity forward contracts for common stock	-	-	30,000	3	-	-	3
Exercise of Series C Convertible Preferred warrants for common stock	-	-	1,043,500	4,174,000	-	-	4,174,000
Conversion of Series D Convertible Preferred Shares for common stock	(2,776)	(5,497)	2,776	5,497	-	-	-
Registered direct offering of common stock net of offering costs of $513,795	-	-	766,667	4,086,207	-	-	4,086,207
Registered direct offering of common stock net of offering costs of $504,281	-	-	1,366,856	4,320,720	-	-	4,320,720
Net unrealized gain on marketable securities	-	-	-	-	-	201,898	201,898
Balance at June 30, 2020 (unaudited)	208,577	$ 412,982	6,125,039	$ 142,330,116	$ (126,749,797)	$ (21,153)	$ 15,972,148

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(unaudited)

	For the Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (7,166,667)	$ (1,711,849)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on sale of securities	36,714	4,258
Accrued (income)/loss on marketable securities	348	3,514
Depreciation and amortization	27,712	34,979
Impairment of Prepaid Royalties	291,442	-
Impairment of Production Equipment	18,680	-
Impairment of intangible assets	152,822	-
Inventory adjustment for net realizable value	197,723	-
Reserve for doubtful trade receivables	1,273	4,247
Share based compensation to an employee - common stock	-	22,444
Share based compensation to directors - restricted stock units	1,302	122,384
Share based compensation - shares issued to vendors	7,318	-
Shares issued for the purchase of a license	1,233,057	-
Change in assets and liabilities		
(Increase)/Decrease in trade receivables	63,548	(94,781)
Decrease in deposits and other receivables	-	9,347
Decrease in inventories	1,262	41,026
Decrease in prepaid expenses	176,001	305,531
Decrease in other assets	2,722	4,330
(Increase)/Decrease in trade and other payables	1,071,566	(355,782)
Increase in operating lease liability	76	-
Net cash used by operating activities	(3,883,101)	(1,610,352)
Cash flows from investing activities:		
Purchases of marketable securities	(76,095)	(62,516)
Proceeds from sale of marketable securities	2,307,462	1,354,646
Net cash provided by investing activities	2,231,367	1,292,130
Cash flows from financing activities		
Net proceeds from issuance of common stock	8,406,927	-
Net proceeds from the exercise of Series C Convertible Preferred warrants and conversion into common stock	4,174,000	-
Net proceeds from the exercise of prepaid equity forward contracts for the purchase of common stock	80	-
Net cash provided by financing activities	12,581,007	-
Net increase/(decrease) in cash and restricted cash	10,929,273	(318,222)
Cash and restricted cash at beginning of period	632,538	681,755
Cash and restricted cash at end of period	$ 11,561,811	$ 363,533
Supplemental cash flow information		
Cash paid for:		
Interest	$ -	$ -
Income Taxes	$ -	$ -
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Net unrealized gains/(losses) on marketable securities	$ (39,039)	$ 47,402
Operating lease right-of-use asset obtained in exchange for lease obligation	$ (79,942)	$ -

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

Note 1 – Organization and Description of Business

Akers Biosciences, Inc. ("Akers"), is a New Jersey corporation. These consolidated financial statements include three wholly owned subsidiaries, Cystron Biotech, LLC, Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation, (together, the "Company"). All material intercompany transactions have been eliminated in consolidation.

The Company was historically a developer of rapid health information technologies but since March 2020, has been primarily focused on the development of a vaccine candidate against SARS-CoV-2, a coronavirus currently causing a pandemic throughout the world. In response to the global pandemic, the Company is pursuing rapid development and manufacturing of its COVID-19 vaccine candidate, or combination product candidate (the "COVID-19 Vaccine Candidate") in collaboration with Premas Biotech PVT Ltd. ("Premas"). With Premas, the Company is currently conducting animal studies for its COVID-19 Vaccine Candidate in India with different dose amounts, including amounts that would be applicable to humans. The Company and Premas are currently engaged in communications with the U.S. Food and Drug Administration ("FDA") and the office of the drug controller in India.

On July 7, 2020, the Company immediately ceased the production and sale of its rapid, point-of-care screening and testing products. The Company will continue to provide support for these testing products that remain in the market through respective product expiration dates. For a more detailed discussion of the Company's cessation of its screening and testing products, see Note 3 herein.

Note 2 – Significant Accounting Policies

(a) Basis of Presentation

The Condensed Consolidated Financial Statements of the Company are prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the United States of America (US GAAP).

Certain information and note disclosures normally included in the financial statements prepared in accordance with US GAAP have been condensed. As such, the information included in these financial statements should be read in conjunction with the audited financial statements as of and for the years ended December 31, 2019 and 2018 included in the Company's 2019 Form 10-K, as filed on March 25, 2020. In the opinion of the Company's management, these condensed consolidated financial statements include all adjustments, which are of only a normal and recurring nature, necessary for a fair statement of the financial position of the Company as of June 30, 2020 and its results of operations and cash flows for the three and six months ended June 30, 2020 and 2019. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results to be expected for the full fiscal year ending December 31, 2020.

Note 2 - Significant Accounting Policies, continued

(b) Use of Estimates and Judgments

The preparation of financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. Information about significant areas of estimation, uncertainty and critical judgments in applying accounting policies that have the most significant effect on the amounts recognized in the financial statements is included in the following notes for revenue recognition, recording research and development expenses, allowances for doubtful accounts, inventory and prepaid asset write-downs, impairment of equipment and intangible assets and valuation of share-based payments.

(c) Functional and Presentation Currency

These condensed consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. All financial information has been rounded to the nearest dollar. Foreign Currency Transaction Gains or Losses, resulting from cash balances denominated in Foreign Currencies, are recorded in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

(d) Comprehensive Income (Loss)

The Company follows Financial Accounting Standards Board Accounting Standards Codification ("FASB ASC") 220 in reporting comprehensive income (loss). Comprehensive income is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income.

(e) Cash and Cash Equivalents

The Company considers all highly liquid investments, which include short-term bank deposits (up to three months from date of deposit) that are not restricted as to withdrawal date or use, to be cash equivalents.

(f) Restricted Cash

At June 30, 2020, restricted cash included in non-current assets on the Company's Condensed Consolidated Balance Sheet was $115,094 representing cash in trust for the purpose of funding legal fees for certain litigations.

Note 2 - Significant Accounting Policies, continued

(g) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, receivables and trade and other payables. The carrying value of cash and cash equivalents, receivables and trade and other payables approximate their fair value because of their short maturities.

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under FASB ASC 820 are described as follows:

Level 1 Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access.

Level 2 Inputs to the valuation methodology include:

- quoted prices for similar assets or liabilities in active markets;
- quoted prices for identical or similar assets or liabilities in inactive markets;
- inputs other than quoted prices that are observable for the asset or liability;
- inputs that are derived principally from or corroborated by observable market data by correlation or other means

If the asset or liability has a specified (contractual) term, the Level 2 input must be observable for substantially the full term of the asset or liability.

Level 3 Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Valuation techniques maximize the use of relevant observable inputs and minimize the use of unobservable inputs.

Note 2 - Significant Accounting Policies, continued

(g) Fair Value of Financial Instruments, continued

Following is a description of the valuation methodologies used for assets measured at fair value as of June 30, 2020 and December 31, 2019.

Marketable Securities: Valued using quoted prices in active markets for identical assets.

	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Quoted Prices for Similar Assets or Liabilities in Active Markets (Level 2)	Significant Unobservable Inputs (Level 3)
Fixed Income Bonds at June 30, 2020	$ 6,856,805	$ -	$ -
Fixed Income Bonds at December 31, 2019	$ 9,164,273	$ -	$ -

Marketable securities are classified as available for sale. The debt securities are valued at fair market value. Maturities of the securities are less than one year. Unrealized gains and losses relating to the available for sale investment securities were recorded in the Condensed Consolidated Statement of Changes in Shareholders' Equity as other comprehensive (loss) income. These amounts were an unrealized gain of $201,898 and $18,059 for the three months ended June 30, 2020 and 2019, respectively and an unrealized loss of $39,039 and an unrealized gain of $47,402 for the six months ended June 30, 2020 and 2019, respectively.

Losses resulting from the sales of marketable securities were $0 and $543 for the three months ended June 30, 2020 and 2019, respectively and were a loss of $36,714 and $4,258 for the six months ended June 30, 2020 and 2019, respectively

Proceeds from the sales of marketable securities in the three and six months ended June 30, 2020 were $3,572 and $2,307,462, respectively and were $502,126 and $1,354,646 for the three and six months ended June 30, 2019, respectively.

Note 2 - Significant Accounting Policies, continued

(h) Trade Receivables and Allowance for Doubtful Accounts

The carrying amounts of current trade receivables are stated at cost, net of allowance for doubtful accounts and approximates their fair value given their short-term nature.

The normal credit terms extended to customers range between 30 and 90 days. Credit terms longer than these may be extended after considering the credit worthiness of the customers and the business requirements. The Company reviews all receivables that exceed terms and establishes an allowance for doubtful accounts based on management's assessment of the collectability of trade and other receivables. A considerable amount of judgment is required in assessing the amount of allowance. The Company considers the historical level of credit losses, makes judgments about the credit worthiness of each customer based on ongoing credit evaluations and monitors current economic trends that might impact the level of credit losses in the future.

As of June 30, 2020 and December 31, 2019, allowances for doubtful accounts for trade receivables were $1,273 and $458,902, respectively. Bad debt expenses for trade receivables were $1,273 and $0 for the three months ended June 30, 2020 and 2019 and $1,273 and $4,247 for the six months ended June 30, 2020 and 2019, respectively. During the three and six months ended June 30, 2020, the Company charged off accounts receivable of $458,902 against the allowance for doubtful accounts.

(i) Prepaid Expenses

For expenses paid prior to the date that the related services are rendered or used are recorded as prepaid expenses. Prepaid expenses are comprised principally of prepaid insurance and prepaid royalties.

As of June 30, 2020, the Company determined that, on account of the unfavorable factors existing within its rapid, point-of-care screening and testing products business, prepaid royalties in the amount of $291,442 would be fully impaired. For the three and six months ended June 30, 2020, this charge was reflected within Impairment of Prepaid Royalties in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

Note 2 - Significant Accounting Policies, continued

(j) Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash on deposit with financial institutions. At times, the Company's cash in banks is in excess of the FDIC insurance limit. The Company has not experienced any loss as a result of these cash deposits. These cash balances are maintained with two banks.

Major Customers

For the three months ended June 30, 2020, revenues net of discounts and allowances, was a negative amount of $1,888. For the three months ended June 30, 2019, three customers generated 42%, 20% and 19%, or 81% in the aggregate, of the Company's revenue.

For the six months ended June 30, 2020, two customers generated 58% and 35%, or 93% in the aggregate, of the Company's revenues. For the six months ended June 30, 2019, two customers generated 44% and 34%, or 78% in the aggregate, of the Company's revenue.

One customer accounted for 100%, and five customers accounted for 30%, 18%, 12%, 12% and 11%, or 83% in the aggregate, of trade receivables net of customer credits and allowances for doubtful accounts as of June 30, 2020 and December 31, 2019, respectively.

Major Suppliers

Three suppliers accounted for 37%, 28% and 11%, or 76% in the aggregate and two suppliers accounted for 70% and 11% or 81% in aggregate, of the Company's purchases for the three months ended June 30, 2020 and 2019, respectively.

Two suppliers accounted for 49% and 17%, or 66% in the aggregate and one supplier accounted for 63% of the Company's purchases for the six months ended June 30, 2020 and 2019, respectively.

None of the Company's suppliers accounted for more than 10% of the Company's outstanding accounts payable as of June 30, 2020 and December 31, 2019.

(k) Property, Plant and Equipment

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Costs include expenditures that are directly attributable to the acquisition of the asset.

Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amounts of property, plant and equipment and are recognized within "other income" in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

Depreciation is recognized in profit and loss on an accelerated basis over the estimated useful lives of the property, plant and equipment. Leased assets are depreciated over the shorter of the lease term or their useful lives.

Depreciation expense totaled $3,214 and $10,111 for the three and six months ended June 30, 2020, respectively and $9,542 and $14,975 for the three and six months ended June 30, 2019, respectively. Impairment expense totaled $18,680 for the three and six months ended June 30, 2020, respectively and $0 for the three and six months ended June 30, 2019, respectively, in connection with the determination as of June 30, 2020 that equipment utilized in the production of the Company's rapid, point-of-care screening and testing products was fully impaired.

Note 2 - Significant Accounting Policies, continued

(l) Right-of-Use Assets

The Company leases its facility in West Deptford, New Jersey (the "Thorofare Facility") under an operating lease ("Thorofare Lease") with annual rentals of $132,000 plus common area maintenance (CAM) charges. The Thorofare Facility houses the Company's office, manufacturing, laboratory and warehouse space. The Thorofare Lease took effect on January 1, 2008. On January 7, 2013, the Company extended the Thorofare Lease extending the term to December 31, 2019. On November 11, 2019, the Company entered into another extension of the Thorofare Lease, extending the term to December 31, 2021, effective January 1, 2020, and providing for an early termination option with a 150-day notice period. On July 16, 2020, the Company exercised the early termination option under the lease agreement, with the effect of the post exercise lease maturity date changing to December 13, 2020.

On January 1, 2020 ("Effective Date"), the Company adopted FASB Accounting Standards Codification, or ASC, Topic 842, Leases ("ASC 842"), which increases transparency and comparability by recognizing a lessee's rights and obligations resulting from leases by recording them on the balance sheet as lease assets and lease liabilities. The new guidance requires the recognition of the right-of-use ("ROU") assets and related operating and finance lease liabilities on the balance sheet. The Company adopted the new guidance using the modified retrospective approach on January 1, 2020. As a result, the consolidated balance sheet as of December 31, 2019 was not restated and is not comparative.

The adoption of ASC 842 resulted in the recognition of ROU assets of $306,706 and lease liabilities for an operating lease of $306,706 on the Company's Condensed Consolidated Balance Sheet as of January 1, 2020.

The Company elected the package of practical expedients permitted within the standard, which allows an entity to forgo reassessing (i) whether a contract contains a lease, (ii) classification of leases, and (iii) whether capitalized costs associated with a lease meet the definition of initial direct costs. Also, the Company elected the expedient allowing an entity to use hindsight to determine the lease term and impairment of ROU assets and the expedient to allow the Company to not have to separate lease and non-lease components. The Company has also elected the short-term lease accounting policy under which the Company would not recognize a lease liability or ROU asset for any lease that at the commencement date has a lease term of twelve months or less and does not include a purchase option that the Company is more than reasonably certain to exercise.

For contracts entered into on or after the Effective Date, at the inception of a contract, the Company will assess whether the contract is, or contains, a lease. The Company's assessment is based on: (i) whether the contract involves the use of a distinct identified asset, (ii) whether the Company obtained the right to substantially all the economic benefit from the use of the asset throughout the period, and (iii) whether the Company has the right to direct the use of the asset. Leases entered into prior to January 1, 2020, which were accounted for under ASC 840, were not reassessed for classification.

For operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments. The Company generally uses its incremental borrowing rate as the discount rate for leases, unless an interest rate is implicitly stated in the lease. The present value of the lease payments is calculated using the incremental borrowing rate for operating leases, which was determined using a portfolio approach based on the rate of interest that the Company would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term. The lease term for all of the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend the lease that the Company is reasonably certain to exercise, or an option to extend the lease controlled by the lessor. All ROU assets are reviewed for impairment.

Lease expense for operating leases consists of the lease payments plus any initial direct costs and is recognized on a straight-line basis over the lease term.

Note 2 - Significant Accounting Policies, continued

(m) Right-of-Use Assets - continued

Effective June 30, 2020, the Company recorded an adjustment to its right-of-use asset and liability in the amounts of $153,709 and $155,737, respectively, to adjust for the effect of the Company having elected to exercise the early termination option under the lease agreement, as discussed earlier. The following information reflects the effect of the adjustments discussed above in connection with the Company's exercise of the early termination option.

The Company's operating lease is comprised solely of the lease of its Thorofare Facility. Condensed Consolidated Balance Sheet information related to its lease is presented below:

Balance Sheet Location	June 30, 2020	January 1, 2020	December 31, 2019
Operating Lease			
Right-of-use asset	$ 79,942	$ 306,706	$ -
Liability, current	80,018	143,018	-
Liability, net of current	-	163,688	-

The following provides details of the Company's lease expense, including CAM charges:

	Three months ended June 30, 2020	Six months ended June 30, 2020
Lease cost		
Operating lease	$ 40,132	$ 83,076

Other information related to leases is presented below:

Other information	As of June 30, 2020
Operating cash used by operating leases	$ 83,000
Weighted-average remaining lease term – operating leases (in months)	6
Weighted-average discount rate – operating leases	10.00%

As of June 30, 2020, the annual minimum lease payments of the Company's operating lease liabilities were as follows:

For Years Ending December 31,	Operating leases
2020 (excluding the six months ended June 30, 2020)	$ 82,368
Total future minimum lease payments, undiscounted	$ 82,368
Less: Imputed interest	(2,350)
Present value of future minimum lease payments	$ 80,018

Note 2 - Significant Accounting Policies, continued

(m) Intangible Assets

The Company's long-lived intangible assets, other than goodwill, are assessed for impairment when events or circumstances indicate there may be an impairment. These assets were initially recorded at their estimated fair value at the time of acquisition and assets not acquired in acquisitions were recorded at historical cost. However, if their estimated fair value is less than the carrying amount, other intangible assets with indefinite lives are reduced to their estimated fair value through an impairment charge to the Company's Condensed Consolidated Statements of Operations and Comprehensive Loss.

As of June 30, 2020, on account of the unfavorable factors existing within its rapid, point-of-care screening and testing products business, the Company determined that the intellectual property comprising the remaining intangible assets was fully impaired. Accordingly, during the three and six months ended June 30, 2020, the Company recorded impairment charges of $149,870 and $152,822, respectively. There were no impairment charges of intangible assets during the three and six months ending June 30, 2019.

Intangible assets as of June 30, 2020 and December 31, 2019 were $0 and $170,423, respectively. Intangible assets at June 30, 2020 consisted of patents, trademarks and customer lists of $3,897,635, net of accumulated amortization and impairment of $3,897,635. Intangible assets at December 31, 2019 consisted of patent, trademarks and customer lists of $3,897,635, net of accumulated amortization and impairment of $3,727,212.

Amortization is recognized on a straight-line basis over the estimated useful lives of intangible assets, other than goodwill, from the date that they are available for use. Amortization expense was $8,727 and $10,002 for the three months ended June 30, 2020 and 2019 and $17,601 and $20,004 for the six months ended June 30, 2020 and 2019, respectively.

Note 2 - Significant Accounting Policies, continued

(n) Revenue Recognition

Beginning on January 1, 2019, the Company recognizes revenue under ASC 606, Revenue from Contracts with Customers. The core principle of this 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 Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods and services transferred to the customer. 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 does not have any significant contracts with customers requiring performance beyond delivery. Shipping and handling activities are performed before the customer obtains control of the goods and therefore represent a fulfillment activity rather than a promised service to the customer. Revenue and costs of sales are recognized when control of the product transfers to the Company's customer, which generally occurs upon delivery to the customer but can also occur when goods are shipped by the Company, depending on the shipment terms of the contract. The Company's performance obligations are satisfied at that time.

The Company uses the most likely amount approach to determine the variable consideration of the transaction price in order to account for the contractual rebates and incentives that are estimated and adjusted for over time. The Company provides for rebates to its distributors. The Company had accrued for rebates and incentives of $200 and $20,002 as of June 30, 2020 and December 31, 2019, respectively. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized credits of $536 and $1,199 for the three and six months ended June 30, 2020 and rebates and incentives of $7,679 and $16,377 during the three and six months ended June 30, 2019. The Company recognized sales discounts of $10,632 and $11,366 for the three and six months ended June 30, 2020, and $7,406 and $20,957 for the three and six months ended June 30, 2019. These components are included as product revenue in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

(o) Research and Development Costs

In accordance with FASB ASC 730, research and development costs are expensed as incurred and consist of fees paid to third parties that conduct certain research and development activities on the Company's behalf. These costs included costs incurred to acquire and develop the license for the COVID-19 vaccine project (See Note 3).

Note 2 - Significant Accounting Policies, continued

(p) Income Taxes

The Company utilizes an asset and liability approach for financial accounting and reporting for income taxes. The provision for income taxes is based upon income or loss after adjustment for those permanent items that are not considered in the determination of taxable income. Deferred income taxes represent the tax effects of differences between the financial reporting and tax basis of the Company's assets and liabilities at the enacted tax rates in effect for the years in which the differences are expected to reverse.

The Company evaluates the recoverability of deferred tax assets and establishes a valuation allowance when it is more likely than not that some portion or all the deferred tax assets will not be realized. Management makes judgments as to the interpretation of the tax laws that might be challenged upon an audit and cause changes to previous estimates of tax liability. In management's opinion, adequate provisions for income taxes have been made. If actual taxable income by tax jurisdiction varies from estimates, additional allowances or reversals of reserves may be necessary.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for "unrecognized tax benefits" is recorded for any tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards. As of June 30, 2020, and December 31, 2019, no liability for unrecognized tax benefits was required to be reported.

There is no income tax benefit for the losses for the three and six months ended June 30, 2020 and 2019 since management has determined that the realization of the net deferred assets is not assured and has created a valuation allowance for the entire amount of such tax benefits.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of general and administrative expense. There were no amounts accrued for penalties and interest for the three and six months ended June 30, 2020 and 2019. The Company does not expect its uncertain tax position to change during the next twelve months. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

(q) Shipping and Handling Fees and Costs

The Company charges actual shipping costs plus a handling fee to customers, which amounted to $1,511 and $10,568 for the three and six months ended June 30, 2020 and $9,511 and $21,997 for the three and six months ended June 30, 2019, respectively. These fees are classified as part of product revenue in the Condensed Consolidated Statement of Operations and Comprehensive Loss. Shipping and other related delivery costs, including those for incoming raw materials are classified as product cost of sales, which amounted to $5,261 and $17,918 for the three and six months ended June 30, 2020 and $15,660 and $27,579 for the three and six months ended June 30, 2019.

Note 2 - Significant Accounting Policies, continued

(r) Basic and Diluted Earnings per Share of Common Stock

Basic earnings per common share is based on the weighted average number of shares outstanding during the periods presented. Diluted earnings per share is computed using the weighted average number of common shares plus dilutive common share equivalents outstanding during the period. Potential common shares that would have the effect of increasing diluted earnings per share are considered anti-dilutive.

The calculation of basic and diluted loss per share for the three months ended June 30, 2020 and 2019 was based on the net loss of $3,628,131 and $794,891, respectively and $7,166,667 and $1,711,849 for the six months ended June 30, 2020 and 2019, respectively. The basic and diluted weighted average number of common shares outstanding for the three months ended June 30, 2020 and 2019 was 5,252,211 and 541,367, respectively and 3,739,529 and 541,000 for the six months ended June 30, 2020, respectively.

Diluted net loss per share is computed using the weighted average number of common and dilutive potential common shares outstanding during the period.

As the Company reported a net loss for the three and six months ended June 30, 2020 and 2019, common share equivalents were anti-dilutive. Therefore, the amounts report for basic and diluted loss per share were the same.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	For the Three and Six Months Ended June 30,	
	2020	2019
Stock Options	40	291
RSUs	15,603	15,603
Warrants to purchase common stock	417,896	88,015
Series D Preferred Convertible Stock	208,577	-
Warrants to purchase Series C Preferred stock	946,500	-
Total potentially dilutive shares	1,588,616	103,909

(s) Reclassifications

Certain prior year amounts have been reclassified to conform to the current year's presentation.

Note 2 - Significant Accounting Policies, continued

(t) Recently Issued Accounting Pronouncements

Recently Issued Accounting Pronouncements Adopted

In February 2016, the FASB issued ASU 2016-02—Leases (Topic 842) ("ASU-2016-02"), which requires an entity to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU 2016-02 offers specific accounting guidance for a lessee, a lessor, and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The Company has adopted ASU-2016-02, effective January 1, 2020, and, as a result of this implementation, has recorded an operating lease right-of-use asset and an operating lease liability as of June 30, 2020.

Recently Issued Accounting Pronouncements Not Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments ("ASU-2016-13"). ASU 2016-13 affects loans, debt securities, trade receivables, and any other financial assets that have the contractual right to receive cash. The ASU requires an entity to recognize expected credit losses rather than incurred losses for financial assets. ASU 2016-13 is effective for the fiscal year beginning after December 15, 2022, including interim periods within that fiscal year. The Company expects that there would be no material impact on the Company's condensed consolidated financial statements upon the adoption of this ASU.

Note 3 – Recent Developments, Liquidity and Management's Plans

Ceasing Production and Sale of Rapid, Point-Of-Care Screening and Testing Products

As previously disclosed, in light of the unfavorable factors persistent in our rapid, point-of-care screening and testing product business and the progress the Company has made in its partnership with Premas, the Company conducted a strategic review of the screening and testing products business. Following such review, in early July 2020, the Company ceased the production and sale of its rapid, point-of-care screening and testing products. The Company will continue to provide support for these testing products that remain in the market through their respective product expiration dates. The Company had been experiencing declining sales revenue and production backlogs for these products and, as it previously reported, had eliminated its sales force for such products. The Company intends to devote its attention to its partnership with Premas for the development of its COVID-19 Vaccine Candidate and will continue to explore strategic alternatives that the Company believes will increase shareholder value. In connection with the ceasing production and sale of its existing product line, on July 16, 2020, the Company decided to close the Thorofare Facility and exercised the early termination option under the Thorofare Lease, which provided for a 150-day notice to terminate the lease. Pursuant to the early termination option, the Thorofare Lease will mature on December 13, 2020.

Exploration of Strategic Alternatives

In addition, the Company's board of directors (the "Board") continues to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations. The Company does not plan to disclose or comment on developments regarding the strategic review process until it is complete or further disclosure is deemed appropriate. There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

August Offering

On August 13, 2020, pursuant to a securities purchase agreement with certain institutional and accredited investors, dated August 11, 2020, the Company issued and sold in a registered direct offering (the "August Offering") an aggregate of 1,207,744 shares of its common stock at an offering price of $5.67 per share, for gross and net proceeds of approximately $6.8 million and $6.2 million, respectively. The Company issued to the placement agent or its designees warrants to purchase up to 96,620 shares of common stock at an exercise price of $7.0875 as compensation in connection with the August Offering. Such warrants are exercisable immediately and will expire on August 11, 2025.

ChubeWorkx Settlement Agreement and General Release

On August 3, 2020, the Company entered into a Settlement Agreement and General Release (the "SAGR") with ChubeWorkx Guernsey Limited ("ChubeWorkx"). The Company and ChubeWorkx entered into the SAGR to terminate a prior Settlement Agreement, dated August 17, 2016, by and among the Company and ChubeWorkx, pursuant to which the Company granted ChubeWorkx a security interest in substantially all of the Company's assets, and to fully and finally settle and compromise any and all current and future claims and liabilities of any nature arising between the Company and ChubeWorkx in relation to, or otherwise connected with, the Prior Agreements, on the terms set forth in the SAGR. For a more detailed discussion of the ChubeWorkx Settlement, see Note 7 herein.

Corporate Governance Reforms

On May 28, 2020, the United States District Court for the District of New Jersey approved that certain Amended Stipulation and Agreement of Settlement, dated October 1, 2019 (the "Settlement") among the settling parties in connection with a consolidated shareholder derivative action, Case No.: 2:18-cv-15992. Pursuant to the Settlement, effective as of July 21, 2020, the Company made various modifications to its corporate governance and business ethics practices as further discussed below.

Note 3 – Recent Developments, Liquidity and Management's Plans - continued

On July 21, 2020, the Board adopted amended and restated bylaws (the "A&R Bylaws") that became effective as of July 21, 2020 pursuant to the Settlement. The A&R Bylaws were adopted to require that, among other things: (i) each member of the Board attend each annual meeting of our shareholders in person, absent extraordinary circumstances; (ii) the role of the Chairman of the Board be rotated among our independent directors every five years; (iii) at least half (50%) of the Board be comprised of directors who qualify as independent directors under applicable listing standards of The Nasdaq Stock Market LLC; (iv) our independent directors to meet in executive session following each Board meeting, in no event less than four (4) times per year; (v) following November 27, 2020, the positions of Chairman of the Board and Chief Executive Officer are to be held by different individuals, and (vi) following November 27, 2020, no one person shall serve the positions of the chief executive officer and the chief financial officer. Pursuant to the Settlement, these changes will remain in place for at least four years.

In addition, pursuant to the Settlement, on July 21, 2020, the Board formed a risk and disclosure committee (the "Risk and Disclosure Committee") and adopted a new whistleblower policy (the "Whistleblower Policy") and a charter for the Risk and Disclosure Committee (the "Risk and Disclosure Committee Charter") to govern the Risk and Disclosure Committee. In order to align the Company's Code of Ethics (the "Code") that applies to all of its directors, officers, and employees with the newly adopted Whistleblower Policy and the Risk and Disclosure Committee Charter, the Board revised the Code. As required by the Settlement, any waivers of any provision of the Code may be granted only by the Risk and Disclosure Committee. In addition, the Code was revised to clarify the enforcement mechanism for violations of the Code. Furthermore, pursuant to the Settlement, the Board approved and adopted revised charters of our standing committees.

Departure of Interim Chief Financial Officer

On July 19, 2020, the Company and Howard R. Yeaton, our Interim Chief Financial Officer, agreed by mutual understanding that Mr. Yeaton's employment as the Company's officer and employee will cease effective August 19, 2020, in accordance with the terms of his employment agreement dated January 6, 2020.

Appointment of Chief Financial Officer

On July 21, 2020, the Company entered into a CFO Consulting Agreement (the "Consulting Agreement") with Brio Financial Group ("Brio"), pursuant to which the Company appointed Mr. Stuart Benson as Chief Financial Officer, effective August 19, 2020, with a term ending June 30, 2021. Pursuant to the Consulting Agreement, the Company will pay Brio an initial retainer fee of $7,500 and a fixed monthly payment of $13,500, commencing August 15, 2020. The Company will also be billed for travel and other out-of-pocket costs, such as report production, postage, etc.

Acquisition of Cystron

On March 23, 2020, the Company acquired Cystron pursuant to that certain Membership Interest Purchase Agreement (the "MIPA"). Cystron was incorporated on March 10, 2020. Upon the Company's purchase of Cystron, Cystron's sole asset consisted of an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other coronavirus infections. Since its formation and through the date of its acquisition by the Company, Cystron did not have any employees. The acquisition of Cystron was accounted for as the purchase of an asset.

As consideration for the Membership Interests (as defined in the MIPA), the Company delivered to the members of Cystron (the "Sellers"): (1) that number of newly issued shares of its common stock equal to 19.9% of the issued and outstanding shares of its common stock and pre-funded warrants as of the date of the MIPA, but, to the extent that the issuance of its common stock would have resulted in any Seller owning in excess of 4.9% of the Company's outstanding common stock, then, at such Seller's election, such Seller received "common stock equivalent" preferred shares with a customary 4.9% blocker (with such common stock and preferred stock collectively referred to as "Common Stock Consideration"), and (2) $1,000,000 in cash. On March 24, 2020 the Company paid $1,000,000 to the Sellers and delivered 411,403 shares of common stock and 211,353 shares of Series D Convertible Preferred Stock with a customary 4.9% blocker, with an aggregate fair market value of $1,233,057, and recorded $2,233,057 as a charge to research and development expense within the Condensed Consolidated Statements of Operations and Comprehensive Loss. On April 22, 2020, Premas, one of the Sellers, returned to us $299,074 representing its portion of the cash purchase price to acquire Cystron. Premas has advised us that these funds were returned temporarily for Premas to meet certain regulatory requirements in India.

Note 3 – Recent Developments, Liquidity and Management's Plans - continued

Additionally, the Company shall (A) make an initial payment to the Sellers of up to $1,000,000 upon its receipt of cumulative gross proceeds from the consummation of an initial equity offering after the date of the MIPA of $8,000,000, and (B) pay to Sellers an amount in cash equal to 10% of the gross proceeds in excess of $8,000,000 raised from future equity offerings after the date of the MIPA until the Sellers have received an aggregate additional cash consideration equal to $10,000,000 (collectively, the "Equity Offering Payments"). On May 14, 2020, the Company and the Sellers entered into an Amendment No. 1 to the MIPA (the "Amendment"), which provided that any Equity Offering Payments in respect of an equity offering that is consummated prior to September 23, 2020, shall be accrued, but shall not be due and payable until September 24, 2020. The other provisions of the MIPA remain unmodified and in full force and effect. Upon the achievement of certain milestones, including the completion of a Phase 2 study for a COVID-19 Vaccine Candidate that meets its primary endpoints, Sellers will be entitled to receive an additional 750,000 shares of the Company's common stock or, in the event the Company is unable to obtain stockholder approval for the issuance of such shares, 750,000 shares of non-voting preferred stock that are valued following the achievement of such milestones and shall bear a 10% annual dividend (the "Milestone Shares"). Sellers will also be entitled to contingent payments from the Company of up to $20,750,000 upon the achievement of certain milestones, including the approval of a new drug application by the FDA.

Pursuant to the MIPA, upon the Company's consummation of the registered direct equity offering closed on April 8, 2020, the Company paid the Sellers $250,000 on April 20, 2020 (the "April Payment"). On April 30, 2020, Premas, one of the Sellers, returned to us $83,334, representing their portion of the $250,000 amount paid to the Sellers on April 20, 2020. Premas has advised us that these funds were returned temporarily for Premas to meet certain regulatory requirements in India. The Company recorded liabilities of $892,500 (the "May Payment") and $684,790 to the Sellers upon the consummation of the registered direct equity offering closed on May 18, 2020 and the consummation of the August Offering, respectively, which are payable on September 24, 2020 pursuant to the Amendment. For the three months period ended June 30, 2020, $1,142,500 is included in research and development expense within the Condensed Consolidated Statements of Operations and Comprehensive Loss for the April Payment and the May Payment.

The Company shall also make quarterly royalty payments to Sellers equal to 5% of the net sales of a COVID-19 vaccine or combination product by the Company (the "COVID-19 Vaccine") for a period of five (5) years following the first commercial sale of the COVID-19 Vaccine; provided, that such payment shall be reduced to 3% for any net sales of the COVID-19 Vaccine above $500 million.

In addition, Sellers shall be entitled to receive 12.5% of the transaction value, as defined in the MIPA, of any change of control transaction, as defined in the MIPA, that occurs prior to the fifth (5th) anniversary of the closing date of the MIPA, provided that the Company is still developing the COVID-19 Vaccine Candidate at that time. Following the consummation of any change of control transaction, the Sellers shall not be entitled to any payments as described above under the MIPA.

Note 3 – Recent Developments, Liquidity and Management's Plans - continued

License Agreement

Cystron is a party to a License and Development Agreement (the "Initial License Agreement") with Premas. As a condition to the Company's entry into the MIPA, Cystron amended and restated the Initial License Agreement on March 19, 2020 (as amended and restated, the "License Agreement"). Pursuant to the License Agreement, Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other coronavirus infections.

Upon the achievement of certain developmental milestones by Cystron, Cystron shall pay to Premas a total of up to $2,000,000. On April 16, 2020, the Company paid Premas $500,000 for the achievement of the first two development milestones of which $250,000 was accrued as research and development expense for the three months ended March 31, 2020. On May 18, 2020, the Company paid Premas $500,000 for the achievement of the third development milestone. On July 7, 2020, the Company and Premas agreed that the fourth milestone under the License Agreement had been satisfied. Due to the achievement of this milestone, Premas is entitled to receive a payment of $1,000,000.

Cystron Medical Panel

On April 10, 2020, the Company established the Cystron Medical Panel and appointed its first member to the panel. Each member shall be compensated with an initial grant of the Company's common stock with an aggregate fair market value of $25,000 and a monthly cash stipend in the initial amount of $2,500. During the three and six months ended June 30, 2020, the Company recorded $10,274 as a charge to research and development expense within the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Note 3 – Recent Developments, Liquidity and Management's Plans, continued

Series D Convertible Preferred Stock

On March 24, 2020, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of New Jersey. Pursuant to the Certificate of Designation, in the event of the Company's liquidation or winding up of its affairs, the holders of its Series D Convertible Preferred Stock (the "Preferred Stock") will be entitled to receive the same amount that a holder of the Company's common stock would receive if the Preferred Stock were fully converted (disregarding for such purposes any conversion limitations set forth in the Certificate of Designation) to common stock which amounts shall be paid pari passu with all holders of the Company's common stock. Each share of Preferred Stock has a stated value equal to $0.01 (the "Stated Value"), subject to increase as set forth in Section 7 of the Certificate of Designation.

A holder of Preferred Stock is entitled at any time to convert any whole or partial number of shares of Preferred Stock into shares of the Company's common stock determined by dividing the Stated Value of the Preferred Stock being converted by the conversion price of $0.01 per share.

A holder of Preferred Stock will be prohibited from converting Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of the Company's common stock then issued and outstanding (with such ownership restriction referred to as the "Beneficial Ownership Limitation"). However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. In addition, a holder of Preferred Stock is prohibited from converting any portion of the Preferred Stock if, as a result of such conversion, the holder, together with its affiliates, would exceed the aggregate number shares of our common stock which we may issue under the MIPA without breaching our obligations under the rules or regulations of the Nasdaq Stock Market (the number of shares which may be issued without violating such rules and regulations, the "Exchange Cap").

Subject to the Beneficial Ownership Limitation and the Exchange Cap, on any matter presented to the Company's stockholders for their action or consideration at any meeting of the Company's stockholders (or by written consent of stockholders in lieu of a meeting), each holder of Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of the Company's common stock into which the shares of Preferred Stock beneficially owned by such holder are convertible as of the record date for determining stockholders entitled to vote on or consent to such matter (taking into account all Preferred Stock beneficially owned by such holder). Except as otherwise required by law or by the other provisions of the Company's certificate of incorporation, the holders of Preferred Stock will vote together with the holders of the Company's common stock and any other class or series of stock entitled to vote thereon as a single class.

A holder of Preferred Stock shall be entitled to receive dividends as and when paid to the holders of the Company's common stock on an as-converted basis.

During the three and six months ended June 30, 2020, 2,776 shares of Preferred Stock were converted to 2,776 common shares. As of June 30, 2020, 208,577 shares of Series D Preferred Stock were issued and outstanding.

Note 3 – Recent Developments, Liquidity and Management's Plans - continued

Liquidity

As of June 30, 2020, the Company's cash on hand was $11,561,811 (which included restricted cash of $115,094), and its marketable securities were $6,856,805. The Company has incurred net losses of $7,166,667 for the six months ended June 30, 2020. As of June 30, 2020, the Company had working capital of $15,772,329 and stockholder's equity of $15,972,148. During the six months ended June 30, 2020, cash flows used in operating activities were $3,883,101, consisting primarily of a net loss of $7,166,667, which includes, principally, research and development costs in connection with the purchase of a license and milestone license fees of $4,375,557. Since its inception, the Company has met its liquidity requirements principally through the sale of its common stock in public and private placements.

On April 8, 2020, pursuant to a securities purchase agreement with certain institutional and accredited investors, the Company issued and sold in a registered direct offering (the "April Offering") an aggregate of 766,667 shares of common stock of the Company at an offering price of $6.00 per share, for gross and net proceeds of $4,600,002 and $4,086,207, respectively.

In connection with the April Offering, the Company issued to the placement agent or designees warrants to purchase up to 61,333 shares of its common stock at an exercise price of $7.50 (the "April Placement Agent Warrants") in a private placement. The April Placement Agent Warrants will be exercisable at any time and from time to time, in whole or in part, following the date of issuance and for a term of five years from the effective date of the April Offering.

On April 20, 2020, the Company recorded $250,000 of the net proceeds from the April Offering to the former members of Cystron Biotech, LLC, pursuant to the terms of that certain MIPA as a charge to research and development expense within the Condensed Consolidated Statements of Operations and Comprehensive Loss.

During the period of April 6, 2020 through April 16, 2020, warrants to purchase an aggregate of 1,043,500 shares of Series C Convertible Preferred Stock were exercised at an exercise price of $4.00 per share, yielding proceeds of $4,174,000.

On May 18, 2020, pursuant to a securities purchase agreement with certain institutional and accredited investors, the Company issued and sold in a registered direct offering (the "May Offering") an aggregate of 1,366,856 shares of its common stock at an offering price of $3.53 per share, for gross and net proceeds of $4,825,002 and $4,320,720, respectively.

In connection with the May Offering, the Company issued to the placement agent or designees warrants to purchase up to 109,348 shares of its common stock at an exercise price of $4.4125 (the "May Placement Agent Warrants") in a private placement. The May Placement Agent Warrants will be exercisable at any time and from time to time, in whole or in part, following the date of issuance and for a term of five years from the effective date of the May Offering.

During the period subsequent to June 30, 2020 and through August 11, 2020, warrants to purchase an aggregate of 891,500 shares of Series C Convertible Preferred Stock were exercised at an exercise price of $4.00 per share, yielding proceeds of $3,566,000.

In connection with the August Offering, the Company issued and sold an aggregate of 1,207,744 shares of its common stock at an offering price of $5.67 per share, for gross and net proceeds of $6,847,908 and approximately $6,178,000, respectively.

In connection with the August Offering, the Company issued to the placement agent or designees warrants to purchase up to 96,620 shares of its common stock at an exercise price of $7.0875 (the "August Placement Agent Warrants") in a private placement. The August Placement Agent Warrants will be exercisable at any time and from time to time, in whole or in part, following the date of issuance and for a term of five years from the effective date of the August Offering.

Note 3 – Recent Developments, Liquidity and Management's Plans - continued

Liquidity

The Company's current cash resources will not be sufficient to fund the development of its COVID-19 Vaccine candidate through all of the required clinical trials to receive regulatory approval and commercialization. While the Company does not currently have an estimate of all of the costs that it will incur in the development of the COVID-19 Vaccine, the Company anticipates that it will need to raise significant additional funds in order to continue the development of the Company's COVID-19 Vaccine candidate during the next 12-months. In addition, the Company could also have increased capital needs if it were to engage in strategic alternatives. The Company's ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond its control. The COVID-19 pandemic has caused an unstable economic environment globally, and the ultimate impact of the COVID-19 pandemic on the Company's operations is unknown and will depend on future developments, which are highly uncertain and cannot be predicted with confidence. These include but are not limited to the duration of the COVID-19 pandemic, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that regulators, or the board or management of the Company, may determine are needed. Disruptions in the global financial markets may adversely impact the availability and cost of credit, as well as the Company's ability to raise money in the capital markets. Current economic conditions have been and continue to be volatile. Continued instability in these market conditions may limit the Company's ability to access the capital necessary to fund and grow its business.

The Company believes that its current financial resources as of the date of the issuance of these consolidated financial statements, are sufficient to fund its current twelve month operating budget, alleviating any substantial doubt raised by the Company's historical operating results and satisfying its estimated liquidity needs for twelve months from the issuance of these consolidated financial statements.

Note 4 – Inventories

Inventories are measured at the lower of cost or net realizable value. The cost of inventories is based on the weighted-average principle, and includes expenditures incurred in acquiring the inventories, production or conversion costs and other costs incurred in bringing them to their existing location and condition. In the case of manufactured inventories and work in progress, costs include an appropriate share of production overhead based on normal operating capacity.

Inventories consist of the following:

	June 30, 2020	December 31, 2019
Raw Materials	$ -	$ 274,551
Sub-Assemblies	-	303,461
Finished Goods	-	28,223
Reserve for Obsolescence	-	(407,250)
	$ -	$ 198,985

As of June 30, 2020, on account of the unfavorable factors existing within its rapid, point-of-care screening and testing products business, the Company determined that inventory would be written down to a net realizable value of $0. Accordingly, during the three and six months ended June 30, 2020, the Company recorded charges of $193,839 and $197,723, respectively, to adjust inventory to net realizable value. During the three and six months ended June 30, 2019, the Company recorded charges of $41,849 and $45,946, respectively, to adjust for obsolete inventory. These amounts were reflected within product cost of sales in the condensed consolidated statement of operations and comprehensive loss.

Note 5 - Trade and Other Payables

Trade and other payables consist of the following:

	June 30, 2020	December 31, 2019
Accounts Payable – Trade	$ 561,578	$ 657,293
Obligations to Cystron Sellers	1,274,906	-
Accrued Expenses	789,088	812,722
Deferred Compensation	-	59,750
	$ 2,625,572	$ 1,529,765

See also Note 8 for related party information.

Note 6 - Share-based Payments

Equity Incentive Plans

2013 Stock Incentive Plan

On January 23, 2014, the Company adopted the 2013 Stock Incentive Plan ("2013 Plan"). The 2013 Plan was amended by the Board on January 9, 2015 and September 30, 2016, and such amendments were ratified by shareholders on December 7, 2018. The 2013 Plan provides for the issuance of up to 4,323 shares of the Company's common stock. As of June 30, 2020, grants of restricted stock and options to purchase 2,853 shares of common stock have been issued pursuant to the 2013 Plan, and 1,470 shares of common stock remain available for issuance.

2017 Stock Incentive Plan

On August 7, 2017, the shareholders approved, and the Company adopted the 2017 Stock Incentive Plan ("2017 Plan"). The 2017 Plan provides for the issuance of up to 7,031 shares of the Company's common stock. As of June 30, 2020, grants of restricted stock and options to purchase 3,064 shares of common stock have been issued pursuant to the 2017 Plan, and 3,967 shares of common stock remain available for issuance.

2018 Stock Incentive Plan

On December 7, 2018, the shareholders approved, and the Company adopted the 2018 Stock Incentive Plan ("2018 Plan"). The 2018 Plan provides for the issuance of up to 78,125 shares of the Company's common stock. As of June 30, 2020, grants of RSUs to purchase 15,603 shares of common stock have been issued pursuant to the 2018 Plan, and 62,522 shares of common stock remain available for issuance.

Note 6 - Share-based Payments, continued

Stock Options

The following table summarizes the option activities for the six months ended June 30, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2019	40	$ 236.16	$ 151.68	0.99	$ -
Granted	-	-	-	-	-
Exercised	-	-	-	-	-
Forfeited	-	-	-	-	-
Canceled/Expired	-	-	-	-	-
Balance at June 30, 2020	40	$ 236.16	$ 151.68	0.50	$ -
Exercisable as of June 30, 2020	40	$ 236.16	$ 151.68	0.50	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $3.48 for the Company's common stock on June 30, 2020. As the closing stock price on June 30, 2020 is lower than the exercise price, there is no intrinsic value to disclose.

As of June 30, 2020, all the Company's outstanding stock options were fully vested and exercisable.

During the three and six months ended June 30, 2020 and 2019, the Company did not incur any stock option expenses.

Note 6 - Share-based Payments, continued

Restricted Stock Units

On March 29, 2019, the Compensation Committee of the Company's board of directors approved the grant of 5,201 Restricted Stock Units ("RSUs") to each of the three directors. Each RSU had a grant date fair value of $23.28 which was amortized on a straight-line basis over the vesting period into administrative expenses within the Condensed Consolidated Statement of Operations and Comprehensive Loss. Such RSUs were granted under the 2018 Plan and vested on January 1, 2020. Such RSUs are expected to be settled with the issuance of common stock during the three months ending September 30, 2020.

At June 30, 2020, the unamortized value of the RSUs was $0. A summary of activity related to RSUs for the six months ended June 30, 2020 is presented below:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at December 31, 2019	15,603	$ 23.28
Granted	-	-
Exercised	-	-
Forfeited	-	-
Canceled/Expired	-	-
Balance at June 30, 2020	15,603	$ 23.28
Exercisable as of June 30, 2020	15,603	$ 23.28

The Company incurred RSU expense of $0 and $118,478 during the three months ended June 30, 2020 and 2019, respectively and $1,302 and $122,384 during the six months ended June 30, 2020 and 2019, respectively.

Note 6 - Share-based Payments, continued

Common Stock Warrants

The table below summarizes the warrant activity for the six month period ended June 30, 2020:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)
Balance at December 31, 2019	247,215	$ 29.79	4.32
Granted	170,681	5.52	4.85
Exercised	-	-	-
Forfeited	-	-	-
Canceled/Expired	-	-	-
Balance at June 30, 2020	417,896	$ 19.88	4.24
Exercisable as of June 30, 2020	417,896	$ 19.88	4.24

All common stock warrants were vested on date of grant.

Pre-funded Common Stock Warrants

The table below summarizes the pre-funded warrant activity for the six month period ended June 30, 2020:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)
Balance at December 31, 2019	795,000	$ 0.0001	-
Granted	-	-	-
Exercised	(795,000)	0.0001	-
Forfeited	-	-	-
Canceled/Expired	-	-	-
Balance at June 30, 2020	-	$ -	-
Exercisable as of June 30, 2020	-	$ -	-

All pre-funded warrants were vested on the date of grant and are exercisable at any time. During the six months ended June 30, 2020, pre-funded warrants to purchase 795,000 shares of common stock issued on December 9, 2019 were exercised at an exercise price of $0.0001 per share, yielding net proceeds of $80.00.

Note 6 - Share-based Payments, continued

Warrants for the purchase of Series C Convertible Preferred Stock

The table below summarizes the activity during the six month period ended June 30, 2020 for warrants issued in December 2019 for the purchase of Series C Convertible Preferred Stock:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)
Balance at December 31, 2019	1,990,000	$ 4.00	4.95
Granted	-	-	-
Exercised	(1,043,500)	4.00	4.45
Forfeited	-	-	-
Canceled/Expired	-	-	-
Balance at June 30, 2020	946,500	$ 4.00	4.45
Exercisable as of June 30, 2020	946,500	$ 4.00	4.45

All warrants to purchase Series C Convertible Preferred Stock were vested on the date of grant. During the six months ended June 30, 2020, 1,043,500 warrants to purchase 1,043,500 share of Series C Convertible Preferred Stock issued on December 9, 2019 were exercised and such shares of Series C Convertible Preferred Stock were immediately converted to 1,043,500 shares of common stock at an exercise price of $4.00 per share, yielding net proceeds of $4,174,000 (See Note 3).

Note 7 – Commitments and Contingencies

Advisory Board

On December 4, 2019, the Company established a cannabinoid and hemp (“CBD”) Advisory Board, whose role was to provide input to management and the board of directors regarding the identification and assessment of business opportunities in the cannabinoid and hemp industry. The Company is no longer pursuing opportunities in the cannabinoid and hemp industry, and as such, the CBD Advisory Board will be disbanded during the third quarter of 2020. Each member was compensated for their initial 24 months of service with the issuance of Company stock with a fair market value of $25,000. Pursuant to the agreement, such shares, when issued, were fully vested. During the three and six months ended June 30, 2020, the Company recorded a charge of $8,333 and $50,000, respectively which is reflected in administrative expense within the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Note 7 – Commitments and Contingencies, continued

Commitments

ChubeWorkx Settlement Agreement and General Release

On August 3, 2020, the Company entered into a Settlement Agreement and General Release (the "SAGR") with ChubeWorkx. The Company and ChubeWorkx entered into the SAGR to terminate a prior Settlement Agreement, dated August 17, 2016, by and among the Company and ChubeWorkx, pursuant to which the Company granted ChubeWorkx a security interest in substantially all of the Company's assets, and to fully and finally settle and compromise any and all current and future claims and liabilities of any nature arising between the Company and ChubeWorkx in relation to, or otherwise connected with, the Prior Agreements, on the terms set forth in the SAGR.

As consideration for the settlement of claims pursuant to the SAGR, on August 5, 2020, the Company (i) paid to ChubeWorkx an amount equal to $300,000 and (ii) delivered to ChubeWorkx 500,000 shares of the Company's common stock (the "Shares"). The Company granted ChubeWorkx registration rights with respect to the Shares. In the event that the Company fails to file a resale registration statement covering the Shares by August 18, 2020 (the "Filing Deadline"), or fails to cause such registration statement to be declared effective by the earlier of October 2, 2020 or 45 days after the filing of such registration statement (the "Effectiveness Deadline"), then, on each of the Filing Deadline and the Effectiveness Deadline, as the case may be, and on each monthly anniversary thereof (if the such registration statement shall not have been filed or declared effective by such date, as the case may be) until such registration statement is filed or declared effective, the Company shall pay to ChubeWorkx an amount in cash, as partial liquidated damages equal to 1.0% of the market value of the Shares.

As of the earlier to occur, following and subject to delivery and complete full effective legal transfer to ChubeWorkx of the Shares and delivery of the cash payment to ChubeWorkx in full in accordance with the provisions of the SAGR, of (i) the date that the resale registration statement covering the Shares is declared effective by the U.S. Securities and Exchange Commission and (ii) the date that all of the Shares may be resold by ChubeWorkx under Rule 144 of the Securities Act of 1933, as amended, without restriction (the "Release Date"), any and all claims, differences, and disputes of any current and/or future claims and/or liabilities arising between the Company and ChubeWorkx in relation to, or otherwise connected with, the Prior Agreements shall be deemed fully and finally settled and compromised (with the exception of any claims arising under the SAGR or the Leak-Out and Support Agreement as described below). As of the Release Date, each of the Prior Agreements will be terminated, and ChubeWorkx will automatically and irrevocably release all security interests and liens created under the Security Agreement or otherwise as security for the Company obligations under the Prior Agreements.

ChubeWorkx Leak-Out and Support Agreement

On August 3, 2020, as an inducement to enter into the SAGR, and as one of the conditions to the consummation of the transactions contemplated by the SAGR, ChubeWorkx entered into a Leak-Out and Support Agreement with the Company (the "Support Agreement"), pursuant to which ChubeWorkx agreed to vote the Shares in favor of each matter proposed and recommended for approval by the Company's board of directors or management at every meeting of the stockholders and on any action or approval by written consent of the stockholders and (ii) limit sales of its shares of common stock issued pursuant to the SAGR per day to no more than 10% of our daily traded volume per day on the Nasdaq Capital Market and we agreed to register the resale of such shares pursuant to a registration statement.

Note 7 – Commitments and Contingencies, continued

Litigation

Watts v. Gormally, et al., No. 2:18-15992 (D.N.J.) *and Chan v. Gormally, et al*., No. 2:19-cv-4989 (D.N.J.)

On November 9, 2018, Cale Watts ("Watts Plaintiff") filed a verified shareholder derivative complaint alleging violations of the Securities Exchange Act of 1934, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on alleged material weaknesses in controls, management, and documentation (the "Watts Action"). On January 14, 2019, the parties reached an agreement in principle to settle the Watts Action that included corporate reforms and a payment of attorneys' fees of $200,000. The parties finalized a Stipulation of Settlement on March 4, 2019. On February 7, 2019, Tiffany Chan, Jasmine Henderson, and Don Danesh ("Chan Plaintiffs") filed a verified shareholder derivative complaint alleging violations of Section 14(a) of the Exchange Act and SEC Rule 14a-9, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on the same circumstances as the Watts Action (the "Chan Action"). The Chan Action further alleged that the Company should not have settled the Watts Action because the Watts Action plaintiffs lacked standing and the settlement would cause irreparable harm to the Company and its shareholders. On March 22, 2019, the Watts Plaintiff filed a motion for preliminary approval of the proposed settlement, approving the proposed form and method of providing notice of the settlement, scheduling a hearing for final approval of the settlement ("Watts Motion for Preliminary Approval"). On April 1, 2019, the Chan Plaintiffs filed an Opposition to the Motion for Preliminary Approval and a Motion to Intervene and Stay Proceedings ("Motion to Intervene and Stay"). Subsequently, the Watts Plaintiff, Chan Plaintiffs, and Defendants reached an agreement in principle to settle the Watts and Chan Actions that included corporate reforms and a payment of attorneys' fees of $325,000. On October 2, 2019, the Watts Plaintiff filed an Unopposed Motion for Preliminary Approval of the Settlement (the "Omnibus Motion for Preliminary Approval"). The Omnibus Motion for Preliminary Approval was granted on January 8, 2020. Plaintiffs filed their motion for final approval of the proposed settlement on May 7, 2020. The Motion for Final Approval was approved on May 28, 2020.

NovoTek Therapeutics Inc. and NovoTek Pharmaceuticals Limited v. Akers Biosciences, Inc.

On June 21, 2019, the Company received a complaint, filed by Novotek Therapeutics Inc., and Novotek Pharmaceuticals Limited (collectively, "Novotek"), Beijing-based entities, in the United States District Court for the District of New Jersey, alleging, among other things, breach of contract. Novotek is seeking, among other things, damages in the amount of $1,551,562, plus interest, disbursements and attorneys' fees. The Company vigorously disputes the allegations in the complaint and has retained counsel to defend it. On September 16, 2019, the Company filed a partial motion to dismiss the complaint, which was fully submitted as of November 4, 2019. On June 9, 2020, the Court denied the Company's motion. The Company's Answer to the Complaint is currently due on September 8, 2020. The Company is not yet able to determine the amount of the Company's exposure, if any.

Note 7 – Commitments and Contingencies, continued

Litigation, continued

Neelima Varma v. Akers Biosciences, Inc. and St. David's Healthcare Partnership, L.P., LLP CAUSE NO: D-1-GN-19-004262

On July 25, 2019, the Company was notified that on July 23, 2019, a complaint was filed by Neelima Varma, against the Company and St. David's Healthcare Partnership, L.P., LLP ("St. David's"), in the district court of Travis County, Texas, alleging, among other things, negligence, gross negligence and strict product liability, breach of express warranty, breach of implied warranty and fraudulent misrepresentation and omission, with respect to a medical device which the Company had sold through one its distributors to St. David's. Ms. Varma was seeking aggregate monetary relief from the Company and St. David's in excess of $1,000,000. The Company carries product liability insurance. On July 29, 2020, this matter was resolved. The resolution of this matter had no significant impact on the condensed consolidated financial statements of the Company.

Douglas Carrara v. Akers Biosciences, Inc., John Does 1-10, and XYZ Corp. 1-10, Docket No. ESX-L-5272-19 (N.J. Super. Ct., Essex County):

Douglas Carrara, a former executive, sued the Company for breach of contract in connection with the termination of his employment. In his operative Complaint, filed August 9, 2019, Carrara primarily alleged that the Company breached the terms of his employment agreement by failing to pay "severance" after terminating his employment "without cause." Based on this alleged breach, Carrara sought compensatory damages and damages for lost wages and benefits. Carrara also sought punitive and/or liquidated damages and attorneys' fees. On August 29, 2019, the Company filed an answer to the operative complaint, denying all substantive allegations of wrongdoing. As of July 23, 2020, the parties have resolved all material disputes. The parties are in the process of preparing the appropriate documentation to effectuate this resolution and expect to file a stipulation of dismissal with prejudice shortly. The resolution of this matter had no significant impact on the condensed consolidated financial statements of the Company.

Note 8 – Related Parties

Interim CFO

Effective on October 5, 2018 and through December 31, 2019, the Board appointed Howard R. Yeaton, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company. Effective on January 1, 2020, Mr. Yeaton entered into a new agreement with the Company whereby he serves as the Company's Interim Chief Financial Officer. Mr. Yeaton is the managing principal of Financial Consulting Strategies ("FCS"), and the Company had an ongoing relationship with FCS as of June 30, 2020, with FCS continuing to provide accounting services to the Company, and the Company may continue to utilize the services of FCS in the future. FCS is considered to be a related party. During the three months ended June 30, 2020 and 2019, the Company incurred costs of $9,250 and $0, respectively and during the six months ended June 30, 2020 and 2019, the Company incurred costs of $9,250 and $23,506, respectively with FCS in connection with these services. As of June 30, 2020 and December 31, 2019 the Company had an obligation to FCS in the amounts of $9,250 and $18,323, respectively, for these services which is included in trade and other payables in the Condensed Consolidated Balance Sheet. On July 19, 2020, the Company and Mr. Yeaton agreed by mutual understanding that Mr. Yeaton's employment as Interim Chief Financial Officer will cease as of August 19, 2020.

During the six months ended June 30, 2020 and 2019, pursuant to his October 2018 employment agreement, the Company issued 0 and 1,095 shares of common stock under the 2017 Plan to Mr. Yeaton, with a fair value on the date of grant, of $0 and $22,444, respectively.

As of June 30, 2020, included in accounts payable and accrued expenses was an obligation of $3,173, representing an obligation to issue 471 shares of common stock to Mr. Yeaton, earned during 2019, but not issued. The accrual is reflected in trade and other payables on the Condensed Consolidated Balance Sheet.

Note 9 – Revenue Information

Revenue by product lines was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
Product Line	**2020**	**2019**	**2020**	**2019**
MicroParticle Catalyzed Biosensor ("MPC")	$ -	$ 65,344	$ -	$ 88,664
Particle ImmunoFiltration Assay ("PIFA")	(3,399)	304,658	351,059	880,973
Rapid Enzymatic Assay ("REA")	-	85,000	-	85,000
Other	1,511	9,511	10,568	21,997
Total Revenue	$ (1,888)	$ 464,513	$ 361,627	$ 1,076,634

The total revenue by geographic area determined based on the location of the customers was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
Geographic Region	**2020**	**2019**	**2020**	**2019**
United States	$ (1,888)	$ 447,013	$ 361,627	$ 1,059,134
Rest of World	-	17,500	-	17,500
Total Revenue	$ (1,888)	$ 464,513	$ 361,627	$ 1,076,634

The Company had long-lived assets totaling $0 and $9,823 located in the People's Republic of China and $4,783 and $194,174 located in the United States as of June 30, 2020 and December 31, 2019, respectively.

Note 10 – Employee Benefit Plan

The Company maintains a defined contribution benefit plan under section 401(k) of the Internal Revenue Code covering substantially all qualified employees of the Company (the "401(k) Plan"). Under the 401(k) Plan, the Company matches 100% up to a 3% contribution, and 50% over a 3% contribution, up to a maximum of 5%.

The Company made matching contributions to the 401(k) Plan during the three months ended June 30, 2020 and 2019 of $5,097 and $7,425, respectively and $22,924 and $16,888 during the six months ended June 30, 2020 and 2019, respectively.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This quarterly report on Form 10-Q and other reports filed by Akers Biosciences, Inc. ("Akers," "Akers Bio," "we" or the "Company") from time to time with the SEC (collectively, the "Filings") contain or may contain forward-looking statements and information that are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by Company's management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. When used in the Filings, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions as they relate to the Company or the Company's management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions, and other factors, including the risks relating to the Company's business, industry, and the Company's operations and results of operations. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

Important factors that could cause actual results to differ materially from the results and events anticipated or implied by such forward-looking statements include, but are not limited to:

- our ability to achieve the expected benefits and costs of the transactions related to the acquisition of Cystron Biotech, LLC ("Cystron"), including:
    - the timing of, and our ability to, obtain and maintain regulatory approvals for clinical trials of our COVID-19 vaccine or combination product candidate (the "COVID-19 Vaccine Candidate");
    - the timing and results of our planned clinical trials for our COVID-19 Vaccine Candidate;
    - the amount of funds we require for our COVID-19 Vaccine Candidate; and
    - our ability to maintain our existing license with Premas Biotech PVT Ltd. ("Premas").
- our ability to develop a COVID-Vaccine Candidate in a timely manner;
- our ability to effectively execute and deliver our plans related to commercialization, marketing and manufacturing capabilities and strategy;
- emerging competition and rapidly advancing technology in our industry;
- our ability to obtain adequate financing in the future on reasonable terms, as and when we need it;
- challenges we may face in identifying, acquiring and operating new business opportunities;
- our ability to retain and attract senior management and other key employees;
- our ability to quickly and effectively respond to new technological developments;
- the outcome of litigation or other proceedings to which we are subject as described in the "Legal Proceedings" sections of our annual report on Form 10-K filed with the SEC on March 25, 2020 and our subsequent filings with the SEC or which we may become subject to in the future;
- changes in political, economic or regulatory conditions generally and in the markets in which we operate;
- delisting of our common stock from the Nasdaq capital market;
- our ability to protect our trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on our proprietary rights;
- our compliance with all laws, rules, and regulations applicable to our business and COVID-19 Vaccine Candidate; and
- the impact of the recent COVID-19 outbreak on our results of operations, business plan and the global economy.

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Our financial statements would be affected to the extent there are material differences between these estimates and actual results. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP and does not require management's judgment in its application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result. The following discussion should be read in conjunction with our financial statements and notes thereto appearing elsewhere in this report.

Overview

We were historically a developer of rapid health information technologies but since March 2020, have been primarily focused on the development of a vaccine candidate against SARS-CoV-2, a coronavirus currently causing a pandemic throughout the world. In response to the global pandemic, we are pursuing rapid development and manufacturing of our COVID-19 Vaccine Candidate, in collaboration with Premas. With Premas, we are currently conducting animal studies for our COVID-19 Vaccine Candidate in India with different dose amounts, including amounts that would be applicable to humans. We and Premas are currently engaged in communications with the U.S. Food and Drug Administration ("FDA") and the office of the drug controller in India.

Coronavirus and COVID-19 Pandemic

In December 2019, SARS-CoV-2 was reported to have surfaced in Wuhan, China, and on March 12, 2020, the World Health Organization ("WHO") declared the global outbreak of COVID-19, the disease caused by SARS-CoV-2, to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada, China, and India, have imposed unprecedented restrictions on travel, quarantines, and other public health safety measures. According to the WHO situation report, dated as of August 6, 2020, approximately 18 million cases were reported globally and 700,000 of these were deadly, making the development of effective vaccines to prevent this disease a major global priority. Although multiple vaccine candidates against SARS-CoV-2 are under development, there is currently no known or approved vaccine or specific antiviral treatment, with the primary treatment being symptomatic and supportive therapies.

Competition

We face, and will continue to face, intense competition from large pharmaceutical companies, specialty pharmaceutical and biotechnology companies as well as academic and research institutions pursing research and development of technologies, drugs or other therapies that would compete with our products or product candidates. The pharmaceutical market is highly competitive, subject to rapid technological change and significantly affected by existing rival drugs and medical procedures, new product introductions and the market activities of other participants. Our competitors may develop products more rapidly or more effectively than us. If our competitors are more successful in commercializing their products than us, their success could adversely affect our competitive position and harm our business prospects.

Specifically, the competitive landscape of potential COVID-19 vaccines and treatment therapies has been rapidly developing since the beginning of the COVID-19 pandemic, with several hundreds of companies claiming to be investigating possible candidates and approximately 3,000 studies registered worldwide as investigating COVID-19 (source: clinicaltrials.gov). Given the global footprint and the widespread media attention on the COVID-19 pandemic, there are efforts by public and private entities to develop a COVID-19 vaccine as soon as possible, including large, multinational pharmaceutical companies such as AstraZeneca, GlaxoSmithKline, Johnson & Johnson, Moderna, Pfizer, and Sanofi, with vaccine candidates that are currently at more advanced stage of development than our vaccine candidate. Those other entities may develop COVID-19 vaccines that are more effective than any vaccine we may develop, may develop a COVID-19 vaccine that becomes the standard of care, may develop a COVID-19 vaccine at a lower cost or earlier than we are able to jointly develop any COVID-19 vaccine, or may be more successful at commercializing a COVID-19 vaccine. Many of these other organizations are much larger than we are and have access to larger pools of capital, and as such, able to fund and carry on larger research and development initiatives. Such other entities may have greater development capabilities than we do and have substantially greater experience in undertaking nonclinical and clinical testing of vaccine candidates, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products. Our competitors may also have greater name recognition and better access to customers. In addition, based on the competitive landscape, multiple COVID-19 vaccines or therapeutics may be approved to be marketed. Should another party be successful in producing a more efficacious vaccine for COVID-19, such success could reduce the commercial opportunity for our COVID-19 vaccine candidate and could have a material adverse effect on our business, financial condition, results of operations and future prospects. Moreover, if we experience delayed regulatory approvals or disputed clinical claims, we may not have a commercial or clinical advantage over competitors' products that we believe we currently possess. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our vaccine development efforts or for us to ultimately commercialize and market any vaccine candidate, if approved. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

Coronavirus Vaccine Development

On March 23, 2020, we entered into that certain membership interest purchase agreement (as subsequently amended, the "MIPA") with the members (the "Sellers") of Cystron Biotech, LLC ("Cystron"), pursuant to which we acquired 100% of the membership interests (the "Membership Interests") of Cystron. Cystron is a party to a license agreement with Premas whereby Premas granted Cystron, among other things, an exclusive license with respect to Premas' genetically engineered yeast (S. cerevisiae)-based vaccine platform, D-Crypt™, for the development of a vaccine against COVID-19 and other coronavirus infections. We have partnered with Premas on this initiative as we seek to advance this COVID-19 Vaccine Candidate through the regulatory process, both with the FDA and the office of the drug controller in India. Premas is primarily responsible for the development of the COVID-19 Vaccine Candidate through proof of concept and is entitled to receive milestone payments upon achievement of certain development milestones through proof of concept.

Premas' D-Crypt platform has been developed to express proteins that are difficult to clone, express and manufacture and are a key component in vaccine development. Premas has identified three major structural proteins of SARS-CoV-2 as antigens for potential vaccine candidates for COVID-19: spike protein or S protein, envelope protein or E protein, and membrane protein or M protein. In April 2020, Premas used its D-Crypt platform to recombinantly express all three of such antigens, which we considered as a significant milestone for development of a triple antigen vaccine. We believe including a combination of all three antigens will provide advantages against the likelihood of protein mutation, in which case a single-protein vaccine can be rendered non-efficacious, and therefore, enhance efficacy of our vaccine candidates. We believe the D-Crypt provides us advantages in vaccine production and manufacturing, as the technology platform is highly scalable with a robust process, which we expect will ultimately result in significant cost savings compared to other similar vaccine platforms. Based on genetically engineered baker's yeast S. cerevisiae, the platform is highly scalable into commercial production quantities and has been previously utilized for the production of multiple human and animal health vaccines candidates during its 10-year development track record. Yeast has a large endoplasmic reticulum, or ER, which is a desirable attribute for expressing membrane protein. In complex cells, ER is where the protein is formed. The larger the surface, the more membrane protein that can attach to the ER inside the cell. Yeast is also generally believed to be easily manipulated and allow for results to be gathered quickly. Yeast multiplies faster than mammalian cells and is cheaper to work with than mammalian systems, which are much more complex and slower to grow comparatively. Yeast has received Generally Recommended as Safe status from the FDA.

As of May 14, 2020, Premas has successfully completed its vaccine prototype and obtained transmission electron microscopic (TEM) images of the recombinant virus like particle (VLP) assembled in yeast. A manufacturing protocol has also been established and large-scale production studies have been initiated for our COVID-19 Vaccine Candidate. Though the prototype is complete, the COVID-19 Vaccine Candidate is still in early stages of development, and, accordingly, must undergo preclinical testing and all phases of clinical trials before we can submit a marketing application (in this case, a biologics license application, or "BLA") to the FDA. The BLA must be approved by the FDA before any biological product, including vaccines, may be lawfully marketed in the United States. We believe the most pivotal, yet difficult, stage in our anticipated development of the contemplated COVID-19 Vaccine Candidate is the requisite conduct of extensive clinical trials to demonstrate the safety and efficacy of our COVID-19 Vaccine Candidate. Additionally, after we complete the necessary preclinical testing, but before we may begin any clinical studies in the United States, we must submit an Investigational New Drug ("IND") application to the FDA, as this is required before any clinical studies may be conducted in the United States. In some cases, clinical studies may be conducted in other countries; however, the FDA may not accept data from foreign clinical studies in connection with a BLA (or other marketing application) submission.

In July 2020, animal studies for our COVID-19 Vaccine Candidate were initiated in India. In addition, we announced that Premas has successfully completed the manufacturing process for the VLP vaccine candidate. Clinical testing is expensive, time consuming, and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed in a timely manner, or at all. Failures in connection with one or more clinical trials can occur at any stage of testing.

Premas owns, and has exclusively licensed rights to us, two provisional Indian patent applications filed in January and March 2020. The scope of these Indian provisional patent applications is directed, respectively, to (i) a platform for the expression of difficult to express proteins (DTE-Ps), which might provide coverage for a method of making the to-be-developed vaccine; and (ii) an expression platform for SARS-CoV-2-like virus proteins, methods relevant thereto, and a relevant vaccine. If non-provisional patent rights are pursued claiming priority to each of these two provisional applications, any resulting patent rights that issue might not expire until approximately January 20, 2041 and March 4, 2041, if all annuities and maintenance fees are timely paid. The expiration dates may be extendable beyond these dates depending on the jurisdiction and the vaccine development process. As we do not own the patents or patent applications that we license, we may need to rely upon Premas to properly prosecute and maintain those patent applications and prevent infringement of those patents.

Impact of the COVID-19 Pandemic on Our Business

The ultimate impact of the global COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to future developments. These include but are not limited to the duration of the COVID-19 pandemic, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that regulators, or the board or management of the Company, may determine are needed. We do not yet know the full extent of potential delays or impacts on our business, our vaccine development efforts, healthcare systems or the global economy as a whole. However, the effects are likely to have a material impact on our operations, liquidity and capital resources, and we will continue to monitor the COVID-19 situation closely.

In response to public health directives and orders, we have implemented work-from-home policies for many of our employees and temporarily modified our operations to comply with applicable social distancing recommendations. The effects of the orders and our related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Similar health directives and orders are affecting third parties with whom we do business, including Premas, whose operations are located in India. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our operations.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways, as well. Specifically, we anticipate that the stress of COVID-19 on healthcare systems generally around the globe will negatively impact regulatory authorities and the third parties that we and Premas may engage in connection with the development and testing of our vaccine candidate.

In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Government Regulation and Product Approval

Federal, state, and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those we are developing. Our prospective vaccine candidate(s) must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act, Public Health Service Act, and their respective implementing regulations. Products are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to FDA's good laboratory practices (the "GLPs"), and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice, or GCP, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with current Good Manufacturing Process ("cGMP"), to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA.

Before testing any biological vaccine candidate in humans, the vaccine candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the vaccine candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

● Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in subjects having the specific disease.

● Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

● Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to subjects.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as "off-label" use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our prospective vaccine candidate(s).

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA, as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the HITECH Act, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Additionally, the Federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures". Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

U.S. Healthcare Reform

We anticipate that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our prospective vaccine candidate(s). In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations.

Recent Developments

Discontinuation of Screening and Testing Products

As previously disclosed, in light of the unfavorable factors persistent in our rapid, point-of-care screening and testing product business and the progress we have made in our partnership with Premas, we conducted a strategic review of the screening and testing products business. Following such review, in early July 2020, we ceased the production and sale of our rapid, point-of-care screening and testing products. We will continue to provide support for these testing products that remain in the market through their respective product expiration dates. We had been experiencing declining sales revenue and production backlogs for these products and, as we previously reported, had eliminated our sales force for such products. We intend to devote our attention to our partnership with Premas for the development of our COVID-19 Vaccine Candidate and will continue to explore strategic alternatives that we believe will increase shareholder value. In connection with the discontinuation of our existing product line, on July 16, 2020, we decided to close our facility in West Deptford, New Jersey (the "Thorofare Facility") and exercised the early termination option under the lease agreement, which provided for a 150-day notice to terminate the lease. Pursuant to the early termination option, the lease for the Thorofare Facility will mature on December 13, 2020.

Exploration of Strategic Alternatives

In addition, our board of directors (the "Board") continues to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations. We do not plan to disclose or comment on developments regarding the strategic review process until it is complete or further disclosure is deemed appropriate. There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

August Offering

On August 13, 2020, pursuant to a securities purchase agreement with certain institutional and accredited investors, dated August 11, 2020, we issued and sold in a registered direct offering (the "August Offering") an aggregate of 1,207,744 shares of our common stock at an offering price of $5.67 per share, for gross and net proceeds of approximately $6.8 million and $6.2 million, respectively. We issued to the placement agent or its designees warrants to purchase up to 96,620 shares of common stock at an exercise price of $7.0875 as compensation in connection with the August Offering. Such warrants are exercisable immediately and will expire on August 11, 2025. The August Offering triggered an accrued payment to the Sellers of $684,790 (equal to 10% of the gross proceeds raised from the August Offering), which will be due and payable on September 24, 2020.

ChubeWorkx Settlement Agreement and General Release

On August 3, 2020, we entered into a Settlement Agreement and General Release (the "SAGR") with ChubeWorkx Guernsey Limited ("ChubeWorkx"). We and ChubeWorkx entered into the SAGR to terminate a prior Settlement Agreement, dated August 17, 2016, by and among us and ChubeWorkx (the "Prior Settlement Agreement" and, collectively with all other contracts, agreements and understandings by and between us and ChubeWorkx, whether written or oral, the "Prior Agreements"), pursuant to which we granted ChubeWorkx a security interest in substantially all of our assets, and to fully and finally settle and compromise any and all current and future claims and liabilities of any nature arising between us and ChubeWorkx in relation to, or otherwise connected with, the Prior Agreements, on the terms set forth in the SAGR.

As consideration for the settlement of claims pursuant to the SAGR, we agreed to (i) pay to ChubeWorkx an amount equal to $300,000 and (ii) deliver to ChubeWorkx with 500,000 shares of our common stock. We granted ChubeWorkx registration rights with respect to such shares. In the event that the we fail to file a resale registration statement covering the such shares by August 18, 2020 (the "Filing Deadline"), or fails to cause such registration statement to be declared effective by the earlier of October 2, 2020 or 45 days after the filing of such registration statement (the "Effectiveness Deadline"), then, on each of the Filing Deadline and the Effectiveness Deadline, as the case may be, and on each monthly anniversary thereof (if the such registration statement shall not have been filed or declared effective by such date, as the case may be) until such registration statement is filed or declared effective, we shall pay to ChubeWorkx an amount in cash, as partial liquidated damages equal to 1.0% of the market value of 500,000 shares of our common stock issued to ChubeWorkx pursuant to the SAGR.

As of the earlier to occur, following and subject to delivery and complete full effective legal transfer to ChubeWorkx of the shares of our common stock and delivery of the cash payment to ChubeWorkx in full in accordance with the provisions of the SAGR, of (i) the date that the resale registration statement covering the such shares is declared effective by the SEC and (ii) the date that all of such shares may be resold by ChubeWorkx under Rule 144 of the Securities Act of 1933, as amended, without restriction (the "Release Date"), any and all claims, differences, and disputes of any current and/or future claims and/or liabilities arising between us and ChubeWorkx in relation to, or otherwise connected with, the Prior Agreements shall be deemed fully and finally settled and compromised (with the exception of any claims arising under the SAGR or the Leak-Out and Support Agreement described below). As of the Release Date, each of the Prior Agreements will be terminated, and ChubeWorkx will automatically and irrevocably release all security interests and liens created under the Security Agreement or otherwise as security for our obligations under the Prior Agreements.

Chubeworkx Leak-Out and Support Agreement

On August 3, 2020, as an inducement to enter into the SAGR, and as one of the conditions to the consummation of the transactions contemplated by the SAGR, ChubeWorkx entered into a Leak-Out and Support Agreement with us, pursuant to which ChubeWorkx agreed to vote its shares of common stock issued pursuant to the SAGR in favor of each matter proposed and recommended for approval by the Board or management at every meeting of the stockholders and on any action or approval by written consent of the stockholders and (ii) limit sales of its shares of common stock issued pursuant to the SAGR per day to no more than 10% of our daily traded volume per day on the Nasdaq Capital Market and we agreed to register the resale of such shares pursuant to a registration statement.

Corporate Governance Reforms

On May 28, 2020, the United Stated District Court for the District of New Jersey approved that certain Amended Stipulation and Agreement of Settlement, dated October 1, 2019 (the "Settlement") among the settling parties in connection with a consolidated shareholder derivative action, Case No.: 2:18-cv-15992. Pursuant to the Settlement, effective as of July 21, 2020, we made various modifications to our corporate governance and business ethics practices as further discussed below.

On July 21, 2020, our Board adopted amended and restated bylaws (the "A&R Bylaws") that became effective as of July 21, 2020 pursuant to the Settlement. The A&R Bylaws were adopted to require that, among other things: (i) each member of the Board attend each annual meeting of our shareholders in person, absent extraordinary circumstances; (ii) the role of the Chairman of the Board be rotated among our independent directors every five years; (iii) at least half (50%) of the Board be comprised of directors who qualify as independent directors under applicable listing standards of The Nasdaq Stock Market LLC; (iv) our independent directors to meet in executive session following each Board meeting, in no event less than four (4) times per year; (v) following November 27, 2020, the positions of Chairman of the Board and Chief Executive Officer are to be held by different individuals, and (vi) following November 27, 2020, no one person shall serve the positions of the chief executive officer and the chief financial officer. Pursuant to the Settlement, these changes will remain in place for at least four years.

In addition, pursuant to the Settlement, on July 21, 2020, the Board formed a risk and disclosure committee (the "Risk and Disclosure Committee") and adopted a new whistleblower policy (the "Whistleblower Policy") and a charter for the Risk and Disclosure Committee (the "Risk and Disclosure Committee Charter") to govern the Risk and Disclosure Committee. In order to align our Code of Ethics (the "Code") that applies to all of our directors, officers, and employees with the newly adopted Whistleblower Policy and the Risk and Disclosure Committee Charter, the Board revised the Code. As required by the Settlement, any waivers of any provision of the Code may be granted only by the Risk and Disclosure Committee. In addition, the Code was revised to clarify the enforcement mechanism for violations of the Code. Furthermore, pursuant to the Settlement, the Board approved and adopted revised charters of our standing committees.

Departure of Interim Chief Financial Officer

On July 19, 2020, we and Howard R. Yeaton, our Interim Chief Financial Officer, agreed by mutual understanding that Mr. Yeaton's employment as our officer and employee will cease effective August 19, 2020, in accordance with the terms of his employment agreement dated January 6, 2020.

Appointment of Chief Financial Officer

On July 21, 2020, we entered into a CFO Consulting Agreement (the "Consulting Agreement") with Brio Financial Group ("Brio"), pursuant to which we appointed Mr. Stuart Benson as Chief Financial Officer, effective August 19, 2020, with a term ending June 30, 2021. Pursuant to the Consulting Agreement, we will pay Brio an initial retainer fee of $7,500 and a fixed monthly payment of $13,500, commencing August 15, 2020. We will also be billed for travel and other out-of-pocket costs, such as report production, postage, etc.

Summary of Statements of Operations for the Three Months Ended June 30, 2020 and 2019

On July 7, 2020, after the completion of a review of our medical device business by our Board, we immediately ceased the production and sale of our rapid, point-of-care screening and testing products and determined to devote our attention and resources to our partnership with Premas for the development of a COVID-19 Vaccine Candidate. The Board's evaluation included an assessment of our product lineup and features, our market presence and the profit potential of our medical device products along with their fit within the market as analog devices within a principally digital product marketplace. Additionally, we had been experiencing declining sales revenue and significant production delays resulting in shipment backlogs for these products. We will continue to provide support for our medical devices that remain in the marketplace through their respective expiration dates.

Product Revenue

Akers' product revenue for the three months ended June 30, 2020 totaled ($1,888), a 100% decrease from the same period in 2019. The table below summarizes our revenue by product line for the three months ended June 30, 2020 and 2019, as well as the percentage of change year-over-year:

	For the Three Months Ended June 30,		
Product Lines	2020	2019	Percent Change
Particle ImmunoFiltration Assay ("PIFA")	$ (3,399)	$ 304,658	(101)%
MicroParticle Catalyzed Biosensor ("MPC")	-	65,344	(100)%
Repid Enzymatic Assay ("REA")	-	85,000	(100)%
Other	1,511	9,511	(84)%
Total Product Revenue	$ (1,888)	$ 464,513	(100)%

Product revenue (negative revenue) from our PIFA products decreased 101% to ($3,399) (2019: $304,658) during the three months ended June 30, 2020, as compared to the same period of 2019. The decrease in the 2020 quarter was principally attributable to product supply issues encountered in 2020 that resulted in only minimal shipments during the quarter.

MPC product sales decreased by 100% to $0 (2019: $65,344) during the three months ended June 30, 2020, on account of a decline in customer demand.

REA product sales decreased by 100% to $0 (2019: $85,000) during the three months ended June 30, 2020, as this product was discontinued during 2019.

Other revenue decreased to $1,511 (2019: $9,511) during the three months ended June 30, 2020 due to a decline in shipping/handling revenue.

Gross Income (Loss)

The gross margin percentage declined to a negative 255% (2019: 53%), principally due to negative net revenues for the period and the impact of fixed and variable production costs, as well as the impact of the charge to adjust inventory to net realizable value. The gross loss was ($379,057) (2019: gross income of $244,649) for the three months ended June 30, 2020.

Product cost of sales for the three months ended June 30, 2020 increased to $377,169 (2019: $219,864). During the three months ended June 30, 2020, fixed costs associated with production amounted to $104,955 (2019: $110,246) (principally including personnel and facilities costs), variable production costs were $78,375 (2019: $107,571) (principally costs for raw materials, testing and production consumables) and on account of the unfavorable factors existing within its rapid, point-of-care screening and testing products business, as described above, we recorded a charge of $193,839 (2019: $2,047) to adjust inventory to a net realizable value of $0.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2020 totaled $1,916,161, which was a 100% increase as compared to $0 for the three months ended June 30, 2019, as we are currently focused on the development of the COVID-19 Vaccine Candidate.

The table below summarizes our research and development expenses for the three months ended June 30, 2020 and 2019 as well as the percentage of change year-over-year:

	For the Three Months Ended June 30,		
Description	2020	2019	Percent Change
Professional Service Costs	$ 23,661	$ -	100%
Vaccine License and Development Costs	1,892,500	-	100%
Total Research and Development Expenses	$ 1,916,161	$ -	100%

Professional services costs are associated with the Cystron Medical Advisory Board established by the Board on April 10, 2020.

Vaccine license and development costs increased by 100%, for the three months ended June 30, 2020, as compared to the same period of 2019.

Pursuant to the terms of the MIPA, upon the closing of our registered direct equity offering on April 8, 2020, we paid the Sellers $250,000, and upon the closing of our registered direct offering on May 18, 2020, we incurred obligations to pay the Sellers $892,500. Pursuant to that certain license agreement, dated March 29, 2020, during the three months ended June 30, 2020, we incurred development costs of $750,000 upon Premas having achieved certain development milestones.

Administrative Expenses

Administrative expenses for the three months ended June 30, 2020, totaled $736,708, which was a 25% decrease as compared to $981,309 for the three months ended June 30, 2019.

The table below summarizes our administrative expenses for the three months ended June 30, 2020 and 2019 as well as the percentage of change year-over-year:

	For the Three Months Ended June 30,		
Description	2020	2019	Percent Change
Personnel Costs	$ 254,076	$ 169,960	49%
Professional Service Costs	133,051	345,282	(61)%
Stock Market & Investor Relations Costs	37,818	63,407	(40)%
Other Administrative Costs	311,763	402,660	(23)%
Total Administrative Expense	$ 736,708	$ 981,309	(25)%

Personnel expenses increased by 49% for the three months ended June 30, 2020 as compared to the same period of 2019 due to the addition of an executive staff member.

Professional service costs decreased 61% for the three months ended June 30, 2020 as compared to the same period of 2019, principally due to decreased legal fees.

Stock market and investor costs decreased 40% for the three months ended June 30, 2020. The decrease in these costs was principally associated with the Company having delisted from the London Stock Exchange during the first half of 2019, and thereafter avoiding the costs associated with a presence on the London Stock Exchange.

Other administrative expenses decreased by 23%, principally attributable to decreased stock-based compensation.

Sales and Marketing Expenses

Sales and marketing expenses for the three months ended June 30, 2020 totaled $7,240 which was a 49% decrease compared to $14,139 for the three months ended June 30, 2019.

Sales and marketing expenses decreased 49% for the three months ended June 30, 2020, as compared to the same period of 2019, principally on account of reduced marketing service fees and reduced royalty expenses due to lower sales revenue.

Regulatory and Compliance Expenses

Regulatory and Compliance expenses for the three months ended June 30, 2020 totaled $67,667, which was an 11% increase, as compared to $60,909 for the three months ended June 30, 2019.

The table below summarizes our regulatory and compliance expenses for the three months ended June 30, 2020 and 2019, as well as the percentage of change year-over-year:

	For the Three Months Ended June 30,		
Description	2020	2019	Percent Change
Personnel Costs	$ 56,439	$ 59,237	(5)%
Professional Service Costs	10,800	1,299	731%
Other Regulatory and Compliance Costs	428	373	15%
Total Regulatory and Compliance Expenses	$ 67,667	$ 60,909	11%

Professional service costs increased by 731% for the three months ended June 30, 2020, as compared to the same period of 2019, principally due to increased third party consultant costs.

Impairment of Prepaid Expenses

We determined that on account of the unfavorable factors existing within its rapid, point-of-care screening and testing products business that prepaid royalties of $291,442, which are based upon future revenues, were not recoverable, and as such, were fully impaired during the three months ended June 30, 2020.

Impairment of Production Equipment

We determined that as of June 30, 2020 equipment with a net book value of $18,680 utilized in the production of our rapid, point-of-care screening and testing products was fully impaired.

Impairment of Intangible Assets

We determined that on account of the unfavorable factors existing within its rapid, point-of-care screening and testing products business, that the intellectual property comprising the remaining intangible assets with a net book value of $149,870 was fully impaired during the three months ended June 30, 2020.

Other Income and Expense

Other income, net of expenses, for the three months ended June 30, 2020, totaled $29,138. Other income, net of expense, for the three months ended June 30, 2019 totaled $26,819.

The table below summarizes our other income and expenses for the three months ended June 30, 2020 and 2019, as well as the percentage of change year-over-year:

	For the Three Months Ended June 30,		
Description	2020	2019	Percent Change
Currency Translation (Gains)/Losses	$ (93)	$ 219	(142)%
Losses on Investments	-	543	(100)%
Interest and Dividend Income	(29,045)	(27,581)	5%
Total Other Income, Net of Expenses	$ (29,138)	$ (26,819)	9%

Summary of Statements of Operations for the Six Months Ended June 30, 2020 and 2019

Product Revenue

Akers' product revenue for the six months ended June 30, 2020 totaled $361,627, a 66% decrease from the same period in 2019. The table below summarizes our revenue by product line for the six months ended June 30, 2020 and 2019, as well as the percentage of change year-over-year:

	For the Six Months Ended June 30,		
Product Lines	2020	2019	Percent Change
PIFA	$ 351,059	$ 880,973	(60)%
MPC	-	88,664	(100)%
REA	-	85,000	(100)%
Other	10,568	21,997	(52)%
Total Product Revenue	$ 361,627	$ 1,076,634	(66)%

Product revenue from our PIFA products decreased 60% to $351,059 (2019: $880,973) during the six months ended June 30, 2020, as compared to the same period of 2019. The decrease in the 2020 period was principally attributable to product supply issues encountered that resulted in reduced shipments during the period.

MPC product sales decreased by 100% to $0 (2019: $88,664) during the six months ended June 30, 2020, on account of the decline in customer demand.

REA product sales decreased by 100% to $0 (2019: $85,000) during the six months ended June 30, 2020, as this product was discontinued during 2019.

Other revenue decreased to $10,568 (2019: $21,997) during the six months ended June 30, 2020 due to a decline in shipping/handling revenue.

Gross Income (Loss)

The gross margin percentage declined to a negative 131% (2019: 57%), principally due to a substantially lower net revenues for the period and the impact of fixed and variable production costs, as well as the impact of the charge to adjust inventory to net realizable value. The gross loss was ($188,413) (2019: gross income of $610,833) for the six months ended June 30, 2020.

Product cost of sales for the six months ended June 30, 2020 increased to $550,040 (2019: $465,801). During the six months ended June 30, 2020, fixed costs associated with production amounted to $225,365 (2019: $270,325) (principally including personnel and facilities costs), variable production costs were $126,951 (2019: $193.429) (principally costs for raw materials, testing and production consumables) and on account of the unfavorable factors existing within its rapid, point-of-care screening and testing products business, as described above, we recorded a charge of $197,724 (2019: $2,047) to adjust inventory to a net realizable value of $0.

Research and Development Expenses

Research and development expenses for the six months ended June 30, 2020 totaled $4,399,218 which was a 100% increase as compared to $0 for the six months ended June 30, 2019.

The table below summarizes our research and development expenses for the six months ended June 30, 2020 and 2019 as well as the percentage of change year-over-year:

	For the Six Months Ended June 30,		
Description	2020	2019	Percent Change
Professional Service Costs	$ 23,661	$ -	100%
Vaccine License and Development Costs	4,375,557	-	100%
Total Research and Development Expenses	$ 4,399,218	$ -	100%

Professional services costs are associated with the Cystron Medical Advisory Board established by the Board on April 10, 2020.

Vaccine license and development costs increased by 100%, for the six months ended June 30, 2020, as compared to the same period of 2019.

On March 24, 2020 we paid $1,000,000 to the Sellers and delivered 411,403 shares of common stock and 211,353 shares of Series D Convertible Preferred Stock, with an aggregate fair market value of $1,233,057, which in the aggregate was $2,233,057, which was recorded as a charge to vaccine license and development costs. Pursuant to the terms of the MIPA, upon the closing of our registered direct equity offerings on April 8, 2020 and May 18, 2020, we incurred obligations to pay the Sellers $250,000, and $892,500 respectively. Pursuant to that certain license agreement, dated March 29, 2020, during the six months ended June 30, 2020, we incurred development costs of $1,000,000 upon Premas having achieved certain development milestones.

Administrative Expenses

Administrative expenses for the six months ended June 30, 2020, totaled $1,894,440, which was a 4% decrease as compared to $1,964,265 for the six months ended June 30, 2019.

The table below summarizes our administrative expenses for the six months ended June 30, 2020 and 2019 as well as the percentage of change year-over-year:

	For the Six Months Ended June 30,		
Description	2020	2019	Percent Change
Personnel Costs	$ 537,583	$ 377,999	42%
Professional Service Costs	680,407	575,165	18%
Stock Market & Investor Relations Costs	85,700	277,961	(69)%
Other Administrative Costs	590,750	733,140	(19)%
Total Administrative Expense	$ 1,894,440	$ 1,964,265	(4)%

Personnel expenses increased by 42% for the six months ended June 30, 2020 as compared to the same period of 2019 due to the addition of an executive staff member.

Professional service costs increased 18% for the six months ended June 30, 2020 as compared to the same period of 2019, principally due to increased legal fees and accounting & audit fees.

Stock market and investor costs decreased 69% for the six months ended June 30, 2020. The decrease in these costs was principally associated with the Company having delisted from the London Stock Exchange during the first half of 2019, and thereafter avoiding the costs associated with a presence on the London Stock Exchange.

Other administrative expenses decreased by 19%, principally attributable to decreased stock-based compensation.

Sales and Marketing Expenses

Sales and marketing expenses for the six months ended June 30, 2020 totaled $21,703 which was an 87% decrease compared to $163,979 for the six months ended June 30, 2019.

The table below summarizes our sales and marketing expenses for the six months ended June 30, 2020 and 2019 as well as the percentage of change year-over-year:

	For the Six Months Ended June 30,		
Description	2020	2019	Percent Change
Personnel Costs	$ -	$ 65,717	(100)%
Professional Service Costs	(9,462)	33,103	(129)%
Royalties and Outside Commission Costs	20,748	40,750	(49)%
Other Sales and Marketing Costs	10,417	24,409	(57)%
Total Sales and Marketing Expenses	$ 21,703	$ 163,979	(87)%

During 2019, as part of our cost savings measures, we eliminated the personnel within the sales and marketing department.

Professional service costs decreased 129% for the six months ended June 30, 2020, as compared to the same period of 2019, principally on account of reductions in the services provided by third party vendors and the reversal of a charge for a marketing program.

Royalties and outside commission costs decreased 49% for the six months ended June 30, 2020, as compared to the same period of 2019, principally on account of reduced royalty expenses due to lower sales revenue and the elimination of the independent sales representatives in 2019.

Other sales and marketing costs declined 57% principally due to the elimination of the support and maintenance of the OxiChek platform.

Regulatory and Compliance Expenses

Regulatory and Compliance expenses for the six months ended June 30, 2020 totaled $139,758, which was an 6% decrease, as compared to $149,300 for the six months ended June 30, 2019.

The table below summarizes our regulatory and compliance expenses for the six months ended June 30, 2020 and 2019, as well as the percentage of change year-over-year:

	For the Six Months Ended June 30,		
Description	2020	2019	Percent Change
Personnel Costs	$ 118,175	$ 130,403	(9)%
Professional Service Costs	18,155	10,043	81%
Other Regulatory and Compliance Costs	3,428	8,854	(61)%
Total Regulatory and Compliance Expenses	$ 139,758	$ 149,300	(6)%

Personnel costs decreased by 9% for the six months ended June 30, 2020 as compared to the same period of 2019. In January 2019, our headcount was reduced by one full-time employee.

Professional service costs increased by 81% for the six months ended June 30, 2020, as compared to the same period of 2019, principally due to an increase in third party consultant costs.

Other regulatory and compliance costs decreased 61%, for the six months ended June 30, 2020, as compared to the same period of 2019, principally due to a decrease in the cost of lab supplies.

Impairment of Prepaid Expenses

We determined that on account of the unfavorable factors existing within its rapid, point-of-care screening and testing products business that prepaid royalties of $291,442, which are based upon future revenues, were not recoverable, and as such, were fully impaired during the six months ended June 30, 2020.

Impairment of Production Equipment

We determined that as of June 30, 2020 equipment with a net book value of $18,680 utilized in the production of our rapid, point-of-care screening and testing products was fully impaired.

Impairment of Intangible Assets

We determined that on account of the unfavorable factors existing within its rapid, point-of-care screening and testing products business, that the intellectual property comprising the remaining intangible assets with a net book value of $152,822 was fully impaired during the six months ended June 30, 2020.

Other Income and Expense

Other income, net of expenses, for the six months ended June 30, 2020, totaled $39,127. Other income, net of expense, for the six months ended June 30, 2019 totaled $49,866.

The table below summarizes our other income and expenses for the six months ended June 30, 2020 and 2019, as well as the percentage of change year-over-year:

Description	For the Six Months Ended June 30, 2020	2019	Percent Change
Currency Translation (Gains)/Losses	(93)	4,878	(102)%
Losses on Investments	36,714	4,258	762%
Interest and Dividend Income	(75,748)	(59,002)	28%
Total Other Income, Net of Expenses	$ (39,127)	$ (49,866)	(22)%

Loss on investments of $36,714 (2019 $4,258) was principally due to the impact of COVID-19 on the financial markets.

Interest and dividend income increased to $75,748 (2019 $59,002) principally due to the increase in funds available for investment.

Liquidity and Capital Resources

As of June 30, 2020, the Company's cash on hand was $11,561,811 (which included restricted cash of $115,094), and its marketable securities were $6,856,805. The Company has incurred net losses of $7,166,667 for the six months ended June 30, 2020 and $3,888,249 for the year ended December 31, 2019, respectively. As of June 30, 2020, the Company had working capital of $15,772,329 and stockholder's equity of $15,972,148. During the six months ended June 30, 2020, cash flows used in operating activities were $3,883,101, consisting primarily of a net loss of $7,166,667, which includes, principally, research and development costs in connection with the purchase of a license and milestone license fees in the aggregate amount of $4,375,557. Since its inception, the Company has met its liquidity requirements principally through the sale of its common stock in public and private placements.

On April 8, 2020, pursuant to a Securities Purchase Agreement with certain institutional and accredited investors, we issued and sold in a registered direct offering (the "April Offering") an aggregate of 766,667 shares of common stock at an offering price of $6.00 per share, for gross and net proceeds of $4,600,002 and $4,086,207, respectively. Pursuant to the terms of the MIPA, we paid $250,000 of the net proceeds from the April Offering to pay the Sellers.

During the period of April 6, 2020 through April 16, 2020, warrants to purchase an aggregate of 1,043,500 shares of Series C Convertible Preferred Stock were exercised at an exercise price of $4.00 per share, yielding proceeds of $4,174,000.

On May 18, 2020, pursuant to a Securities Purchase Agreement with certain institutional and accredited investors, we issued and sold in a registered direct offering (the "May Offering") an aggregate of 1,366,856 shares of its common stock at an offering price of $3.53 per share, for gross and net proceeds of $4,825,002 and $4,320,720, respectively. Pursuant to the terms of the MIPA, we incurred an obligation to pay the Sellers $892,500 by September 24, 2020 in connection with the May Offering.

During the period subsequent to June 30, 2020 and through August 11, 2020, warrants to purchase an aggregate of 891,500 shares of Series C Convertible Preferred Stock were exercised at an exercise price of $4.00 per share, yielding proceeds of $3,566,000.

In connection with the August Offering, we issued and sold an aggregate of 1,207,744 shares of its common stock at an offering price of $5.67 per share, for gross and net proceeds of $6,847,908 and approximately $6,178,000, respectively. Pursuant to the terms of the MIPA, we incurred an obligation to pay the Sellers $684,790 by September 24, 2020 in connection with the August Offering.

Our current cash resources will not be sufficient to fund the development of our COVID-19 Vaccine candidate through all of the required clinical trials to receive regulatory approval and commercialization. While we do not currently have an estimate of all of the costs that it will incur in the development of the COVID-19 Vaccine, we anticipate that we will need to raise significant additional funds in order to continue the development of the our COVID-19 Vaccine candidate during the next 12-months. In addition, we could also have increased capital needs if we were to engage in strategic alternatives. Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond our control. The COVID-19 pandemic has caused an unstable economic environment globally, and the ultimate impact of the COVID-19 pandemic on the our operations is unknown and will depend on future developments, which are highly uncertain and cannot be predicted with confidence. These include, but are not limited to, the duration of the COVID-19 pandemic, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that regulators, or the board or management of the Company, may determine are needed. Disruptions in the global financial markets may adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Current economic conditions have been and continue to be volatile. Continued instability in these market conditions may limit our ability to access the capital necessary to fund and grow its business.

We believe that that our current financial resources as of the date of the issuance of these condensed consolidated financial statements are sufficient to fund our current twelve month operating budget, and satisfying our estimated liquidity needs for twelve months from the issuance of these condensed consolidated financial statements.

Operating Activities

Our net cash used by operating activities totaled $3,883,101 during the six months ended June 30, 2020. Net cash used consisted principally of the net loss of $7,166,667, offset by a non-cash adjustment principally consisting of the fair value of shares issued for the purchase of a license of $1,233,057, impairment charges of $462,944, a charge to reduce inventory to net realizable value $197,723, and an increase in trade and other payables of $1,071,566.

Our net cash consumed by operating activities totaled $1,610,352 during the six months ended June 30, 2019. Cash was consumed by the loss of $1,711,849 reduced by non-cash adjustments principally consisting of $3,514 for accrued interest on marketable securities, $34,979 for depreciation and amortization of non-current assets, $4,247 for the allowance of doubtful accounts, $4,258 for loss on sales of securities and $144,828 for share based compensation. For the six months ended June 30, 2019, within changes of assets and liabilities, cash provided consisted of a decrease in inventories of $41,026, a decrease in prepaid expenses of $305,531, a decrease in deposits and other receivables of $9,347, a decrease in other assets of $4,330, off-set by an increase in trade receivables of $94,781 and a decrease in trade and other payables of $355,782.

Investing Activities

The Company's net cash provided by investing totaled $2,231,367, as compared to $1,292,130 during the six months ended June 30, 2020 and 2019, respectively. Net cash provided by investing activities for the six months ended June 30, 2020 consisted of proceeds from the sale of marketable securities of $2,307,462, offset by $76,095 for the purchase of marketable securities. During the six months ended June 30, 2019, investing activities consisted of proceeds from the sale of marketable securities of $1,354,646, offset by $62,516 for the purchase of marketable securities and capital expenditures.

Financing Activities

The Company's net cash provided by financing activities during the six months ended June 30, 2020 was $12,581,007 (2019: $0). Net cash provided during the 2020 period reflected the net proceeds from the April Offering and May Offering of $8,406,927, the net proceeds from the exercise of Series C Convertible Preferred Warrants of $4,174,000, the net proceeds from exercise of pre-funded equity forward contracts for the purchase of common stock of $80.

Critical Accounting Policies

See accounting policies in Note 2 of the condensed consolidated financial statements included in Part I, Item 1 of this report.

Off-Balance Sheet Arrangements

We have no significant known off balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We do not hold any derivative instruments and do not engage in any hedging activities.

Item 4. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in paragraph (e) of Rules 13a-15 and 15d-15 under the Exchange Act) designed to ensure that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified under the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our Executive Chairman and our Interim Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures. As required by paragraph (b) of Rules 13a-15 and 15d-15 under the Exchange Act, our Executive Chairman (Principal Executive Officer) and our Interim Chief Financial Officer (Principal Financial Officer) carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2020. Based on this evaluation, our Executive Chairman and our Interim Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2020.

(b) Changes in Internal Control over Financial Reporting

During the three months ended June 30, 2020, there were no material changes in internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Watts v. Gormally, et al., No. 2:18-15992 (D.N.J.) *and Chan v. Gormally, et al*., No. 2:19-cv-4989 (D.N.J.)

On November 9, 2018, Cale Watts ("Watts Plaintiff") filed a verified shareholder derivative complaint alleging violations of the Securities Exchange Act of 1934, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on alleged material weaknesses in controls, management, and documentation (the "Watts Action"). On January 14, 2019, the parties reached an agreement in principle to settle the Watts Action that included corporate reforms and a payment of attorneys' fees of $200,000. The parties finalized a Stipulation of Settlement on March 4, 2019. On February 7, 2019, Tiffany Chan, Jasmine Henderson, and Don Danesh ("Chan Plaintiffs") filed a verified shareholder derivative complaint alleging violations of Section 14(a) of the Exchange Act and SEC Rule 14a-9, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on the same circumstances as the Watts Action (the "Chan Action"). The Chan Action further alleged that the Company should not have settled the Watts Action because the Watts Action plaintiffs lacked standing and the settlement would cause irreparable harm to the Company and its shareholders. On March 22, 2019, the Watts Plaintiff filed a motion for preliminary approval of the proposed settlement, approving the proposed form and method of providing notice of the settlement, scheduling a hearing for final approval of the settlement ("Watts Motion for Preliminary Approval"). On April 1, 2019, the Chan Plaintiffs filed an Opposition to the Motion for Preliminary Approval and a Motion to Intervene and Stay Proceedings ("Motion to Intervene and Stay"). Subsequently, the Watts Plaintiff, Chan Plaintiffs, and Defendants reached an agreement in principle to settle the Watts and Chan Actions that included corporate reforms and a payment of attorneys' fees of $325,000. On October 2, 2019, the Watts Plaintiff filed an Unopposed Motion for Preliminary Approval of the Settlement (the "Omnibus Motion for Preliminary Approval"). The Omnibus Motion for Preliminary Approval was granted on January 8, 2020. Plaintiffs filed their motion for final approval of the proposed settlement on May 7, 2020. The Motion for Final Approval was approved on May 28, 2020.

NovoTek Therapeutics Inc. and NovoTek Pharmaceuticals Limited v. Akers Biosciences, Inc.

On June 21, 2019, the Company received a complaint, filed by Novotek Therapeutics Inc., and Novotek Pharmaceuticals Limited (collectively, "Novotek"), Beijing-based entities, in the United States District Court for the District of New Jersey, alleging, among other things, breach of contract. Novotek is seeking, among other things, damages in the amount of $1,551,562, plus interest, disbursements and attorneys' fees. The Company vigorously disputes the allegations in the complaint and has retained counsel to defend it. On September 16, 2019, the Company filed a partial motion to dismiss the complaint, which was fully submitted as of November 4, 2019. On June 9, 2020, the Court denied the Company's motion. The Company's Answer to the Complaint is currently due on September 8, 2020. The Company is not yet able to determine the amount of the Company's exposure, if any.

Neelima Varma v. Akers Biosciences, Inc. and St. David's Healthcare Partnership, L.P., LLP CAUSE NO: D-1-GN-19-004262

On July 25, 2019, the Company was notified that on July 23, 2019, a complaint was filed by Neelima Varma, against the Company and St. David's Healthcare Partnership, L.P., LLP ("St. David's"), in the district court of Travis County, Texas, alleging, among other things, negligence, gross negligence and strict product liability, breach of express warranty, breach of implied warranty and fraudulent misrepresentation and omission, with respect to a medical device which the Company had sold through one its distributors to St. David's. Ms. Varma was seeking aggregate monetary relief from the Company and St. David's in excess of $1,000,000. The Company carries product liability insurance. On July 29, 2020, this matter was resolved. The resolution of this matter had no significant impact on the condensed consolidated financial statements of the Company.

Douglas Carrara v. Akers Biosciences, Inc., John Does 1-10, and XYZ Corp. 1-10, Docket No. ESX-L-5272-19 (N.J. Super. Ct., Essex County):

Douglas Carrara, a former executive, sued the Company for breach of contract in connection with the termination of his employment. In his operative Complaint, filed August 9, 2019, Carrara primarily alleged that the Company breached the terms of his employment agreement by failing to pay "severance" after terminating his employment "without cause." Based on this alleged breach, Carrara sought compensatory damages and damages for lost wages and benefits. Carrara also sought punitive and/or liquidated damages and attorneys' fees. On August 29, 2019, the Company filed an answer to the operative complaint, denying all substantive allegations of wrongdoing. As of July 23, 2020, the parties have resolved all material disputes. The parties are in the process of preparing the appropriate documentation to effectuate this resolution and expect to file a stipulation of dismissal with prejudice shortly. The resolution of this matter had no significant impact on the condensed consolidated financial statements of the Company.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings before making an investment decision. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and stock price.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding other statements in this Form 10-Q. The following information should be read in conjunction with the condensed consolidated financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-Q.

Those risk factors below denoted with a "*" are newly added or have been materially updated from our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 25, 2020.

RISKS RELATED TO OUR ACQUISITION

We may fail to realize the anticipated benefits of our acquisition of Cystron and those benefits may take longer to realize than expected.

On March 23, 2020, we entered into the MIPA with the Sellers, pursuant to which we will acquire the Membership Interests of Cystron. Cystron is a party to a License and Development Agreement (the "Initial License Agreement") with Premas. As a condition to the Company's entry into the MIPA, Cystron amended and restated the Initial License Agreement on March 19, 2020 (as amended and restated, the "License Agreement"). Pursuant to the License Agreement, Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of the COVID-19 Vaccine Candidate. Our ability to realize the anticipated benefits of the acquisition will depend, to a large extent, on our ability to produce an effective vaccine against COVID-19. The development of the COVID-19 Vaccine Candidate is in very early stages and there is no assurance that we will be able to produce an effective vaccine. The failure to produce the COVID-19 Vaccine Candidate could adversely affect our business, financial condition and results of operations. In addition, we expect to incur significant expenses related to the acquisition. These expenses include, but are not limited to, the Common Stock Consideration (as defined in the MIPA), a cash consideration of $1.0 million, related contingent fees, legal fees and other related fees and expenses. Many of these expenses will be payable by us regardless of our ability to successfully develop the COVID-19 Vaccine Candidate, and we will not be able to recover these expenses in the event that we fail to develop the COVID-19 Vaccine Candidate.

Our acquisition of Cystron could result in additional costs, integration or operating difficulties, dilution and other adverse consequences.

In connection with the acquisition of the Cystron and in pursuit of developing the COVID-19 Vaccine Candidate, we may:

- issue equity securities that may substantially dilute our stockholders' percentage of ownership;
- be obligated to make milestone, royalty or other contingent or non-contingent payments; and
- incur debt or non-recurring and other charges, or assume liabilities.

In addition, the process of integrating Cystron's business may create operating difficulties and expenditures and pose numerous additional risks to our operations, including:

- failure to develop, manufacture or supply the COVID-19 Vaccine Candidate economically or successfully commercialize or achieve market acceptance of the COVID-19 Vaccine Candidate;
- exposure to liabilities of Cystron, including known or unknown risks relating to the validity or enforceability of exclusivity rights and generic competition;
- adverse effects on our operating results or financial condition, including due to expenditures or acquisition-related costs, costs of commercialization or amortization or impairment costs for acquired goodwill and other intangible assets;

- impairment of relationships with key suppliers and manufacturers due to changes in management and ownership and difficulty in maintaining existing agreements, licenses and other arrangements or rights on substantially similar terms as existed prior to the acquisition;

- regulatory changes and market dynamics after the acquisition; and

- potential loss of key employees, particularly those of the acquired entity.

If any of the above events (or more) occur, or if we cannot effectively manage or respond to such events following the acquisition, they may have material adverse effect on our business, results of operations and financial condition.

Cystron is dependent on technologies that it has licensed, and Cystron may need to license in the future, and if Cystron fails to obtain licenses it needs, or fails to comply with its payment obligations in the agreements under which Cystron in-license intellectual property and other rights from third parties, Cystron could lose its ability to develop a COVID-19.

Cystron currently is dependent on a license from Premas for its key technologies. Any failure to make the payments required by the License Agreement may permit Premas to terminate the license. If Cystron were to lose or otherwise be unable to maintain the license for any reason, it would halt Cystron's ability to develop a COVID-19 Vaccine Candidate. The foregoing could result in a material adverse effect on our business or results of operations.

In addition, Cystron does not own the patents or patent applications that it licenses, and as such, Cystron may need to rely upon Premas to properly prosecute and maintain those patent applications and prevent infringement of those patents. If Premas is unable to adequately protect their proprietary intellectual property Cystron licenses from legal challenges, or Cystron is unable to enforce such licensed intellectual property against infringement or alternative technologies, we will not be able to compete effectively in the drug discovery and development business.

RISKS RELATED TO OUR BUSINESS

**** We have a history of operating losses and we cannot guarantee that we can ever achieve sustained profitability.***

We have recorded a net loss attributable to common stockholders in most reporting periods since our inception. Our net losses for the years ended December 31, 2019 and 2018 were $3,888,249 and $10,849,034, respectively. We had a net loss of $7,166,667 million during the six months ended June 30, 2020. Our accumulated deficit at June 30, 2020 was $126,749,797. On account of the unfavorable factors existing within our rapid, point-of-care screening and testing products business, we ceased the production and sale of our screening testing products. We intend to focus on the development of the COVID-19 Vaccine Candidate in partnership with Premas and expect to incur additional operating losses for the foreseeable future. We also plan to continue to explore strategic alternatives that we believe will increase shareholder value. However, there can be no assurance of success in reducing our loss, becoming profitable, or having sufficient cash to develop a COVID-19 Vaccine Candidate or to complete a strategic alternative transaction.

****Our pursuit of the COVID-19 Vaccine Candidate is at an early stage. We have not previously tested our rapid response capability and may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all.***

In response to the COVID-19 pandemic, we are pursuing the rapid development of the COVID-19 Vaccine. Our development of the vaccine is in early stages, and we may be unable to produce a vaccine candidate against SARS-CoV-2, a coronavirus causing the COVID-19 pandemic in a timely manner, if at all. Additionally, our ability to develop an effective vaccine depends on the success of our rapid response capability, which we have not previously tested and which will need to be funded by third parties in order to enable us to have sufficient capacity to respond to a global health challenge. If the pandemic is effectively contained or the risk of coronavirus infection is diminished or eliminated before we can successfully develop and manufacture the COVID-19 Vaccine, we may be unable to successfully generate revenue from the manufacturing of the COVID-19 Vaccine. We are also committing financial resources and personnel to the development of the COVID-19 Vaccine Candidate which may divert resources from other strategic alternative transactions, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

****We operate in a highly competitive industry.***

We face, and will continue to face, intense competition from large pharmaceutical companies, specialty pharmaceutical and biotechnology companies as well as academic and research institutions pursing research and development of technologies, drugs or other therapies that would compete with our products or product candidates. The pharmaceutical market is highly competitive, subject to rapid technological change and significantly affected by existing rival drugs and medical procedures, new product introductions and the market activities of other participants. Our competitors may develop products more rapidly or more effectively than us. If our competitors are more successful in commercializing their products than us, their success could adversely affect our competitive position and harm our business prospects and may also lead to the diversion of funding away from us and toward other companies.

Specifically, the competitive landscape of potential COVID-19 vaccines and treatment therapies has been rapidly developing since the beginning of the COVID-19 pandemic, with several hundreds of companies claiming to be investigating possible candidates and approximately 3,000 studies registered worldwide as investigating COVID-19 *(source: clinicaltrials.gov)*. Given the global footprint and the widespread media attention on the COVID-19 pandemic, there are efforts by public and private entities to develop a COVID-19 Vaccine Candidate as soon as possible, including large, multinational pharmaceutical companies such as AstraZeneca, GlaxoSmithKline, Johnson & Johnson, Moderna, Pfizer, and Sanofi, with vaccine candidates that are currently at more advanced stage of development than our vaccine candidate. Those other entities may develop COVID-19 vaccines that are more effective than any vaccine we may develop, may develop a COVID-19 Vaccine Candidate that becomes the standard of care, may develop a COVID-19 Vaccine Candidate at a lower cost or earlier than we are able to jointly develop any COVID-19 vaccine, or may be more successful at commercializing a COVID-19 Vaccine. Many of these other organizations are much larger than we are and have access to larger pools of capital, and as such, able to fund and carry on larger research and development initiatives. Such other entities may have greater development capabilities than we do and have substantially greater experience in undertaking nonclinical and clinical testing of vaccine candidates, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products. Our competitors may also have greater name recognition and better access to customer. In addition, based on the competitive landscape, multiple COVID-19 vaccines or therapeutics may be approved to be marketed. Should another party be successful in producing a more efficacious vaccine for COVID-19, such success could reduce the commercial opportunity for our COVID-19 Vaccine Candidate and could have a material adverse effect on our business, financial condition, results of operations and future prospects. Moreover, if we experience delayed regulatory approvals or disputed clinical claims, we may not have a commercial or clinical advantage over competitors' products that we believe we currently possess. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our vaccine development efforts or for us to ultimately commercialize and market any vaccine candidate, if approved. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

Our business may be materially adversely affected by the COVID-19 pandemic.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures, including in the United States and India. On March 12, 2020, the WHO declared COVID-19 to be a global pandemic. The various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 has had and may continue to have an adverse effect on the global markets and global economy. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases.

The ultimate impact of the global COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our vaccine development efforts, healthcare systems or the global economy as a whole. However, the effects are likely to have a material impact on our operations, liquidity and capital resources, and we will continue to monitor the COVID-19 situation closely.

In response to public health directives and orders, we have implemented work-from-home policies for many of our employees and temporarily modified our operations to comply with applicable social distancing recommendations. The effects of the orders and our related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Similar health directives and orders are affecting third parties with whom we do business, including Premas, whose operations are located in India. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our operations.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways, as well. Specifically, we anticipate that the stress of COVID-19 on healthcare systems generally around the globe will negatively impact regulatory authorities and the third parties that we and Premas may engage in connection with the development and testing of our vaccine candidate.

The anticipated economic consequences of the COVID-19 pandemic have adversely impacted financial markets, resulting in high share price volatility, reduced market liquidity, and substantial declines in the market prices of the shares of most publicly traded companies, including Akers. Volatile or declining markets for equities could adversely affect our ability to raise capital when needed through the sale of shares of common stock or other equity securities. Should these market conditions persist when we need to raise capital, and if we are able to sell shares of our common stock under then prevailing market conditions, we might have to accept lower prices for our shares and issue a larger number of shares than might have been the case under better market conditions, resulting in significant dilution of the interests of our shareholders.

With regard to our contemplated coronavirus vaccine candidate, we must conduct preclinical testing, prepare and submit an IND to the FDA, and conduct all phases of clinical studies (which may include postmarket or "Phase 4" studies), which will likely take several years and substantial expenses to complete, before we can submit an application for marketing approval to the FDA, and there is no guarantee that we will complete such clinical development in a timely manner or at all or that our BLA will be approved, if submitted.

We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our contemplated vaccine candidate for coronavirus. Accordingly, our business currently depends heavily on the successful development, FDA approval, and commercialization of such candidate, which may never receive FDA approval or be successfully commercialized even if FDA approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing, and distribution of our contemplated vaccine candidate are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, as applicable. We are not permitted to market our tablet vaccines in the United States until we receive FDA approval of our applicable BLA. To date, we have not-yet begun any preclinical studies for the COVID-19 Vaccine Candidate, nor have we prepared or submitted an IND. Accordingly, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future, as there are numerous developmental steps that must be completed before we can prepare and submit a BLA.

In the United States, the FDA regulates pharmaceutical and biological products (including vaccines and vaccine candidates, such as the COVID-19 Vaccine Candidate currently in early stages of development) under the Federal Food, Drug and Cosmetic Act and the Public Health Service Act, as well as their respective implementing regulations. Such products and product candidates are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies in accordance with FDA's good laboratory practices ("GLPs") and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials in the United States may begin;
- performance of adequate and well-controlled human clinical trials in accordance with FDA's IND regulations, good clinical practices ("GCPs"), and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of preclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with current cGMPs and assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or denial, of the BLA.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. Our vaccine candidate is in the earliest stages of clinical development and, therefore, a long way from BLA submission. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for our vaccine candidate or whether any such BLA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For example, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also lengthy and requires substantial time and effort. We estimate that the clinical trials we need to conduct to be in a position to submit a BLA for our vaccine candidate for coronavirus will take several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Also, the results of early preclinical and clinical testing of the COVID-19 Vaccine Candidate may not be predictive of the results of subsequent clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their vaccine candidates performed satisfactorily in preclinical studies and clinical trials have, nonetheless, failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. Any failure or substantial delay in our vaccine development plans may have a material adverse effect on our business.

We may opt to conduct future clinical studies for our contemplated vaccine candidate outside the United States, which could heighten the risk of delay and/or failure, as the FDA may not accept data from such studies in support of any BLA we may submit after completing the applicable developmental and regulatory prerequisites, if ever.

We are still in the earliest stages of development with respect to our contemplated coronavirus vaccine candidate and may ultimately decide to conduct preclinical and/or clinical studies in one or more countries outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States that are not conducted under an IND, the FDA's acceptance of such data is subject to certain conditions. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles and all applicable FDA regulations. The trial population must also adequately represent the intended U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to market the vaccine candidate in the United States, if approved. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its ability to verify the data and its determination that the trials also complied with all applicable U.S. laws and regulations. We cannot guarantee that the FDA will accept data from trials we conduct outside of the United States, if any. If the FDA does not accept the data from such clinical trials, it would likely result in the need for additional trials and the completion of additional regulatory steps, which would be costly and time-consuming and could delay or permanently halt our development of the contemplated candidate.

If we are successful in producing the COVID-19 Vaccine Candidate, we may need to devote significant resources to its scale-up and development including for use by the U.S. government.

In the event that the preclinical and clinical trials for the COVID-19 Vaccine Candidate are perceived to be successful, we may need to work toward the large scale technical development, manufacturing scale-up and larger scale deployment of this potential vaccine through a variety of U.S. government mechanisms such as an Expanded Access Program or an Emergency Use Authorization program. In this case we may need to divert significant resources to this program, which would require diversion of resources from our other businesses. In addition, since the path to licensure of any vaccine against COVID-19 is unclear, if use of the vaccine is mandated by the U.S. government, we may have a widely used vaccine in circulation in the United States or another country prior to our full validation of the overall long term safety and efficacy profile of our vaccine platform and technology. Unexpected safety issues in these circumstances could lead to significant reputational damage for the Company going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

We may be unable to advance the COVID-19 Vaccine Candidate successfully through the preclinical and clinical development process.

Our ability to develop, obtain regulatory approval for, and ultimately commercialize, the COVID-19 Vaccine Candidate effectively will depend on many factors, including the following:

- successful completion of preclinical studies and clinical trials;
- successful achievement of the objectives of planned preclinical studies and clinical trials;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;
- establishing efficient and effective commercial manufacturing, supply and distribution arrangements;
- establishing sufficient market share and promoting acceptance of the product by patients, the medical community and third-party payors;
- successfully executing an effective pricing and reimbursement strategy;
- maintaining a continued acceptable safety and adverse event profile following regulatory approval; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims.

The COVID-19 Vaccine Candidate will require additional non-clinical and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can be in a position to generate any revenue from product sales. We are not permitted to market or promote any vaccine before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. If we are unable to develop or receive marketing approval in a timely manner or at all, we could experience significant delays or an inability to commercialize the COVID-19 Vaccine Candidate, which would materially and adversely affect our business, financial condition and results of operations.

Government involvement may limit the commercial success of our COVID-19 Vaccine Candidate.

The COVID-19 pandemic has been classified as a pandemic by public health authorities, and it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities.

Various government entities, including the U.S. government, are offering incentives, grants, and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against coronavirus, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share, if any, for our COVID-19 Vaccine Candidate even if we succeed in developing one.

We expect to require additional capital in the future in order to develop our vaccine candidate and to pursue strategic alternative transactions. If we do not obtain any such additional financing, it may be difficult to effectively realize our long-term strategic goals and objectives.

Our current cash resources will not be sufficient to fund the development of our vaccine candidate through all of the required clinical trials to receive regulatory approval and commercialization. While we do not currently have an estimate of all of the costs that it will incur in the development of the COVID-19 Vaccine, we anticipate that it will need to raise significant additional funds in order to continue the development of our vaccine candidate during the next 12-months. In addition, we could also have increased capital needs if it were to engage in a strategic alternative transaction. If we cannot secure this additional funding when such funds are required, we may fail to develop a COVID-19 Vaccine Candidate or be forced to forego certain strategic opportunities.

Any additional capital raised through the sale of equity or equity-backed securities may dilute our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

The terms of any securities issued by us in future capital transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

If we fail to obtain regulatory approval in foreign jurisdictions, then we cannot market our COVID-19 Vaccine in those jurisdictions.

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. Companies are now required to obtain a CE Mark, which shows conformance with the requirements of applicable European Conformity directives, prior to the sale of some medical devices within the European Union. Some of our products that require CE Markings have them. We may be required to conduct additional testing or to provide additional information, resulting in additional expenses, to obtain necessary approvals. If we fail to obtain approval in such foreign jurisdictions, we would not be able to sell our products in such jurisdictions, thereby reducing the potential revenue from the sale of our products.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions which may materially affect our business operations.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions and civil penalties;
- recall, detention or seizure of our products;
- the issuance of public notices or warnings;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for a 510(k) clearance of new products;
- withdrawing a 510(k) clearance already granted; and
- criminal prosecution.

Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

Even if we are able to commercialize our prospective or future product candidates, the products may not receive coverage or adequate reimbursement from third-party payors in the United States or in other countries in which we seek to commercialize such products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such products will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment.

Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain regulatory approval.

We may not have the resources to conduct clinical protocols sufficient to yield data suitable for publication in peer-reviewed journals and our inability to do so in the future could have an adverse effect on marketing our products effectively.

In order for our products targeted for use by hospital laboratory professionals and healthcare providers to be widely adopted, we would have to conduct clinical protocols that are designed to yield data suitable for publication in peer-reviewed journals. These studies are often time-consuming, labor-intensive and expensive to execute. We have not had the resources to effectively implement such clinical programs within our clinical development activities and may not be able to do so in the future. In addition, if a protocol is initiated, the results of which may ultimately not support the anticipated positioning and benefit proposition for the product. Either of these scenarios could hinder our ability to market our products and revenue may decline.

We may experience delays in any phase of the preclinical or clinical development of a product, including during its research and development.

The completion of any of these studies may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical study protocol or place a clinical study on hold;
- patients do not enroll in a clinical study or results from patients are not received at the expected rate;
- patients discontinue participation in a clinical study prior to the scheduled endpoint at a higher than expected rate;
- patients experience adverse events from a product we develop;

- third-party clinical investigators do not perform the studies in accordance with the anticipated schedule or consistent with the study protocol and good clinical practices or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;

- third-party clinical investigators engage in activities that, even if not directly associated with our studies, result in their debarment, loss of licensure, or other legal or regulatory sanction;

- regulatory inspections of manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend the preclinical or clinical studies;

- changes in governmental regulations or administrative actions;

- the interim results of the preclinical or clinical study, if any, are inconclusive or negative; and

- the study design, although approved and completed, is inadequate to demonstrate effectiveness and safety.

If the preclinical and clinical studies that we are required to conduct to gain regulatory approval are delayed or unsuccessful, we may not be able to market any product that we develop in the future. Preclinical studies and clinical trials are expensive and difficult to design and implement and any delays or prolongment in our preclinical and clinical studies will require additional capital. There is no assurance that we will be able to acquire additional capital to support our studies. The failure to obtain additional capital would have a material adverse effect on the Company.

We anticipate that we will rely completely on third parties to manufacture certain preclinical and all clinical drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in the conduct of our clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. In order to develop products, apply for regulatory approvals and commercialize our products, we will need to develop, contract for, or otherwise arrange for access to the necessary manufacturing capabilities. We anticipate that we will rely on CMOs, or contract manufacturing organizations, and other third party contractors, some of whom may have limited cGMP experience, to manufacture formulations and produce larger scale amounts of drug substance and the drug product required for any clinical trials that we initiate.

The manufacturing process for any vaccine candidate is subject to the FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. In addition, if we receive the necessary regulatory approval for any product candidate, we also expect to rely on third parties to produce materials required for commercial supply. We may experience difficulty in obtaining adequate manufacturing capacity for our needs. Furthermore, it is our responsibility to ensure that all of our third-party contractors meet cGMP laws, regulations and guidance. Due to their failure to comply with applicable regulatory requirements, we may face fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. These actions could have a material impact on the availability of products. If we are unable to obtain or maintain contract manufacturing for these product candidates, or to do so on commercially reasonable terms, we may not be able to successfully develop and commercialize our products.

To the extent that we enter into manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner and consistent with regulatory requirements, including those related to quality control and quality assurance. The failure of a third-party manufacturer to perform its obligations as expected could adversely affect our business in a number of ways, including:

- we may not be able to initiate or continue preclinical and clinical trials of products that are under development;

- we may need to repeat pivotal clinical trials;

- we may be delayed in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- we may lose the cooperation of our collaborators;
- our products could be the subject of inspections by regulatory authorities;
- we may be required to cease distribution or recall some or all batches of our products; and
- ultimately, we may not be able to meet commercial demands for our products.

If a third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to seek out one or more other third-party manufacturers to manufacture our preclinical and/or clinical trial materials, which could cause delays in the FDA approval process. Further, should our vaccine candidate be approved for marketing by the FDA, a change in a third-party manufacturer could cause significant delays to meeting the demand of patients. In some cases, the technical skills required to manufacture our product may be unique to the original manufacturer and we may have difficulty transferring such skills to a back-up or alternate manufacturer, or we may be unable to transfer such skills at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also be required to demonstrate that the newly manufactured material is the same or similar to the previously manufactured material, or we may need to repeat clinical trials with the newly manufactured material. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently, which would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our products.

We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.

We plan to rely upon third-party contract research organizations, or CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our licensed ongoing preclinical and clinical programs. We expect to continue to rely on these parties for execution of our preclinical studies and clinical trials, and we control only certain aspects of their activities. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, current Good Clinical Practices or cGCP, and current Good Laboratory Practices, or cGLP, which are a collection of laws and regulations enforced by the FDA or comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of manufacturing facilities, preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products manufactured consistently with cGMP regulations. Failure by us or our third party CRO to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

If any of our relationships with these third-party CROs, medical institutions, clinical investigators or contract laboratories terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties, or comply with cGCP laws, regulations and guidance, or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We may fail to retain qualified personnel.

We have substantially reduced the number of our employees in order to reduce our costs. Accordingly, retaining our remaining personnel in the future will be critical to our success. If we fail to retain and motivate these highly skilled personnel, we may be unable to continue our operating activities, and this could have a material adverse effect on our business, financial condition, results of operations and future prospects.

We rely on the key executive officer of the management team.

We are dependent on our management team to execute against our business plan. Failure could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

Expenses incurred with respect to monitoring, protecting, and defending our intellectual property rights could adversely affect our business.

Competitors and others may infringe on our intellectual property rights, or may allege that we have infringed on theirs. Monitoring infringement and misappropriation of intellectual property can be difficult and expensive, and we may not be able to detect infringement or misappropriation of our proprietary rights.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

Some or all of our patent applications may not result in the issue of patents, or the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors, if any, may be challenged and subsequently narrowed, invalidated, found unenforceable or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position. Patentability, invalidity, freedom-to-operate or other opinions may be required to determine the scope and validity of third-party proprietary rights. If we choose to go to court to stop a third party from using the inventions protected by our patent, that third party would have the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and we may not have the required resources to pursue such litigation or to protect our patent rights. In addition, there is a risk that the court will decide that our patents are not valid or that we cannot stop the other party from using their inventions. There is also the risk that, even if the validity of these patents is upheld, the court will find that the third party's activities do not infringe our rights in these patents.

Furthermore, a third party may claim that we are infringing the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products or product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party's treble damages or attorneys' fees for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the claims of the relevant patent and/or that the third-party patent claims are invalid, and we may not be able to do this. Proving invalidity in the United Sates is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any claims against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. To date, none of our employees have been subject to such claims.

****The use of our PIFA products could result in serious injuries, product liability claims, regulatory enforcement action, and/or recalls or market withdrawals, any of which would likely subject us to substantial costs and reputational harm and have a material adverse effect on our business.***

In July 2020, we ceased the production and sale of our rapid, point-of-care screening and testing products. We will continue to provide support for these testing products that remain in the market through their respective product expiration dates. We believe that the users of our PIFA products are likely to be particularly sensitive to test defects and errors, as the conditions that the PIFA products are designed to identify may cause limb- and life-threatening complications if not accurately diagnosed in a timely manner. As a result, the failure of our tests or services to perform as expected could subject us to legal claims arising from any defects or errors.

The use of our PIFA products and our other products could lead to product liability (and other similar) claims against us if someone were to allege that one of our tests failed to perform as it was designed or as claimed in our promotional materials, was performed pursuant to incorrect or inadequate laboratory procedures, if we delivered incorrect or incomplete test results, or if someone were to misinterpret test results. In addition, we may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide, or for failure to provide such information, in connection with the results generated by our products. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Our PIFA products are not 100% accurate and may generate erroneous results that could cause patient harm. For example, PIFA could provide a so-called "false negative" result upon which a patient or physician may rely to make a conclusion about how to proceed with the patient's treatment. If the false negative causes, or exacerbates, a patient injury or condition, the patient (and/or the patient's family) may file a lawsuit against us based on product liability.

Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates, cause our insurance coverage to be terminated or prevent us from securing insurance coverage in the future.

Further, under the FDA's MDR regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

We may be at risk that our former employees may wrongfully use or disclose our trade secrets.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee, former employee, consultant, former consultant or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We are currently subject to a number of securities litigations and we may be subject to similar or other litigation in the future.

We are currently subject to a number of litigations as described in the "Legal Proceedings" section. In connection with certain of these litigations, we have entered into settlements of claims for significant monetary damages. We may also be subject to judgements or enter into additional settlements of claims for significant monetary damages for the securities litigations that we have yet to enter into settlement agreements. Defending against the current litigations is or can be time-consuming, expensive and cause diversion of our management's attention.

With respect to any litigation, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer in contesting and concluding such lawsuit. Substantial litigation costs, including the substantial self-insured retention that we are required to satisfy before any insurance applies to a claim, unreimbursed legal fees or an adverse result in any litigation may adversely impact our business, operating results or financial condition. We believe that our directors' and officers' liability insurance will cover our potential liability with respect to the securities class-action lawsuit; however, the insurer has reserved its rights to contest the applicability of the insurance to such claims and the limits of the insurance may be insufficient to cover our eventual liability.

If we market products or interact with health care practitioners in a manner that violates healthcare fraud or abuse laws, we may be subject to civil or criminal penalties, including exclusion from participation in government healthcare programs.

If we receive payments directly from or bill directly to Medicare, Medicaid or other national or third-party payers for our products, U.S. federal and state healthcare laws and regulations pertaining to fraud or abuse will be applicable to our business. We are subject to healthcare fraud and abuse regulation by the U.S. federal government and the states in which we conduct our business.

The laws that may affect our ability to operate include the federal healthcare program anti-kickback statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce, or in return for, the purchase, lease or order, or arrangement for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute applies to arrangements between pharmaceutical manufacturers and prescribers, purchasers and formulary managers. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product, reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates, engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses and submitting inflated best price information to the Medicaid Drug Rebate Program.

The Health Insurance Portability and Accountability Act of 1996 also created prohibitions against healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. The false statements statute immediately noted above prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, there has been a trend of increased federal and state regulation of payments made to physicians. The ACA, through the Physician Payment Sunshine Act of 2010, imposed new requirements on manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members. Manufacturers are required to report such data to the government by the 90th calendar day of each year.

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals, as amended. Moreover, certain states mandate the tracking and reporting of gifts, compensation and other remuneration paid by us to physicians and other healthcare providers.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, cause reputational harm and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable U.S. federal and state laws may prove costly.

Our internal computer systems, or those of our third-party vendors, collaborators, or other contractors may be subject to various federal and state confidentiality and privacy laws in the United States and abroad and could sustain system failures, security breaches, or other disruptions, any of which could have a material adverse effect on our business.

Numerous international, national, federal, provincial and state laws, including state privacy laws (such as the California Consumer Privacy Act, or "CCPA"), state security breach notification and information security laws, and federal and state consumer protection laws govern the collection, use, and disclosure of personal information. In addition, most healthcare providers who may, in future, prescribe and dispense our products in the United States and research institutions in the United States with whom we may collaborate in the future are "covered entities" subject to privacy and security requirements under HIPAA. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. We could be subject to a wide range of penalties and sanctions under HIPAA, including criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a covered entity in a manner that is not authorized or permitted by HIPAA. Failure to comply with applicable HIPAA requirements or other current and future privacy laws and regulations could result in governmental enforcement actions (including the imposition of significant penalties), criminal and civil liability, and/or adverse publicity that negatively affects our business.

Moreover, we rely on our internal and third-party provided information technology systems and applications to support our operations and to maintain and process company information including personal information, confidential business information and proprietary information. If these information technology systems are subject to cybersecurity attacks, or are otherwise compromised, due to cyberattacks, human error or malfeasance, system errors or otherwise, it may adversely impact our business, disrupt our operations, or lead to the loss, theft, destruction, corruption, or compromise of our information or that of our collaborators, study subjects, or other third-party contractors, as applicable. Such information technology or security events could also lead to legal liability, regulatory investigations or enforcement actions, loss of business, negative media coverage, and reputational damage. While we seek to protect our information technology systems from these types of incidents, the healthcare sector continues to see a high frequency of cyberattacks and increasingly sophisticated threat actors, and our systems and the information maintained within those systems remain potentially vulnerable to data security incidents.

Any of the above-described cyber or other security-related incidents may trigger notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under foreign, federal, provincial and state laws that protect the privacy and security of personal information. Our proprietary and confidential information may also be accessed. Any one of these events could cause our business to be materially harmed and our results of operations may be adversely impacted. Finally, as cyber threats continue to evolve, and privacy and cybersecurity laws and regulations continue to develop, we may need to invest additional resources to implement new compliance measures, strengthen our information security posture, or respond to cyber threats and incidents.

We are subject to various internal control reporting requirements under the Sarbanes-Oxley Act. We can provide no assurance that we will at all times in the future be able to report that our internal controls over financial reporting are effective.

As a public company, we are required to comply with Section 404 of the U.S.*Sarbanes-Oxley Act of 2002* ("Section 404"). In any given year, we cannot be certain as to the time of completion of our internal control evaluation, testing and remediation actions or of their impact on our operations. Upon completion of this process, we may identify control deficiencies of varying degrees of severity under applicable SEC and Public Company Accounting Oversight Board (U.S.) rules and regulations. Our management, including our chief executive officer and principal financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, as a public company, we are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal controls that, or that are reasonably likely to, materially affect internal controls over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual consolidated financial statements will not be prevented or detected on a timely basis. If we fail to comply with the requirements of Section 404 or if we report a material weakness, we might be subject to regulatory sanction and investors may lose confidence in our consolidated financial statements, which may be inaccurate if we fail to remedy such material weakness.

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010, as well as rules implemented by the SEC and the Nasdaq Stock Market, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, compliance with these rules and regulations has increased our legal, accounting and financial compliance costs and has made some activities more time-consuming and costly. It is also more expensive for us to obtain director and officer liability insurance.

RISKS RELATED TO OUR PURSUIT OF STRATEGIC ALTERNATIVES

****We may opportunistically review strategic transactions and there can be no assurance that that any such strategic transaction we may purse will result in additional value for our stockholders. As a result, the makeup of our lines of business may change.***

We may from time to time assess alternate ways to generate value for shareholders, including reviewing opportunities that may lead to acquisitions, dispositions, business combinations or other strategic transactions. Strategies we may employ include seeking new or expanding existing specialty market niches, expanding our presence, acquiring businesses complementary to existing strengths and continually evaluating the performance and strategic fit of our existing business units. As a result, the makeup of our lines of business is subject to change. For example, as previously disclosed, in light of the unfavorable factors persistent in our rapid, point-of-care screening and testing product business and the progress we have made in our partnership with Premas, we conducted a strategic review of the screening and testing products business. Following such review, in early July 2020, we ceased the production and sale of our rapid, point-of-care screening and testing products. In connection with the discontinuation of our existing product line, we decided to close Thorofare Facility, which lease will terminate on December 13, 2020. We do not plan to disclose or comment on developments regarding the strategic review process until it is complete or further disclosure is deemed appropriate. However, there can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

To the extent we engage in other strategic transactions, the process may be time consuming and disruptive to our business operations and, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with evaluating and negotiating potential strategic alternatives. Furthermore, our ability to effectively integrate any future acquisitions will depend on, among other things, the adequacy of our implementation plans, the ability of our management to oversee and operate effectively the combined operations and our ability to achieve desired operational efficiencies. If we are unable to successfully integrate the operations of any businesses that we may acquire in the future, our business, financial position, results of operations or cash flows could be adversely affected. There can be no assurance that any potential transaction, if consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock.

If we are unable to make acquisitions and investments, or successfully integrate them into our business, our business could be harmed.

As part of our business strategy, we may acquire other companies or businesses. However, we may not be able to find suitable acquisition candidates, and we may not be able to complete acquisitions on favorable terms, if at all. Acquisitions involve numerous risks, any of which could harm our business and negatively affect our operating results, including:

- difficulties in integrating the technologies, operations, existing contracts and personnel of an acquired company;
- difficulties in supporting and transitioning clients and suppliers, if any, of an acquired company;
- diversion of financial and management resources from existing operations or alternative acquisition opportunities;
- failure to realize the anticipated benefits or synergies of a transaction;
- failure to identify all of the problems, liabilities or other shortcomings or challenges of an acquired company or technology, including issues related to intellectual property, regulatory compliance practices, revenue recognition or other accounting practices, or employee or client issues;
- risks of entering new markets in which we have limited or no experience;
- potential loss of key employees, clients, vendors and suppliers from either our current business or an acquired company's business;
- inability to generate sufficient revenue to offset acquisition costs;
- additional costs or equity dilution associated with funding the acquisition; and
- possible write-offs or impairment charges relating to acquired businesses.

If we acquire a new business or retain individuals with expertise in a new industry to pursue a strategic alternative, we will have a limited operating history in such new industry and may not succeed.

We may from time to time assess alternative ways to generate value for shareholders, including reviewing opportunities in a new industry. If we acquire a new business or retain individuals with expertise in a new industry to pursue a strategic alternative, we will have a limited operating history within such new industry and may not succeed. We will be subject to all risks inherent in a developing business enterprise. The likelihood of our continued viability must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with manufacturing specialty products and the competitive and regulatory environment in which we operate. Furthermore, unanticipated expenses, problems, and technical difficulties may occur and they may result in material delays in the operation of our business, in particular with respect to our new products. We may not be able to successfully address these risks and uncertainties or successfully implement our operating strategies. If we fail to do so, such failure could materially harm our business to the point of having to cease operations and could impair the value of our common stock to the point investors may lose their entire investment.

RISKS RELATED TO OUR COMMON STOCK AND OUR COMPANY GENERALLY

The market price for our common stock may be volatile, and your investment in our common stock could decline in value.

The stock market in general has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology and specialty pharmaceutical companies, particularly companies like ours without product revenues and earnings, have been highly volatile and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or disapproval of our product candidates or other product-related actions;
- developments involving our discovery efforts and clinical studies;
- developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees;
- announcements concerning our competitors, or the biotechnology, pharmaceutical or drug delivery industry in general;
- public concerns as to the safety or efficacy of our products or our competitors' products;
- changes in government regulation of the pharmaceutical or medical industry;
- changes in the reimbursement policies of third party insurance companies or government agencies;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- developments involving corporate collaborators, if any;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

Moreover, on March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic, and the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent weeks. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock.

In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business, operating results and financial condition.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock. The delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on NASDAQ. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital and a minimum price per share. We cannot assure you that we will continue to meet the continued listing requirements in the future.

If NASDAQ delists our common stock from trading on its exchange, due to failure to meet its continued listing requirements, and we are not able to list our common stock on another national securities exchange, we expect our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity for our common stock;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current market price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible or exercisable into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

We do not anticipate paying dividends on our common stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our Board of Directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our Board of Directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales by our stockholders of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

We may issue additional series of preferred stock that rank senior or equally to the Series C Preferred Stock as to dividend payments and liquidation preference.

Neither our certificate of incorporation nor the Certificate of Designation for the Series C Preferred Stock prohibits us from issuing additional series of preferred stock that would rank senior or equally to the Series C Preferred Stock as to dividend payments and liquidation preference. Our certificate of incorporation provides that we have the authority to issue up to 50,000,000 shares of preferred stock, no shares of which are outstanding prior to this offering. The issuances of other series of preferred stock could have the effect of reducing the amounts available to the Series C Preferred Stock in the event of our liquidation, winding-up or dissolution. It may also reduce cash dividend payments on the Series C Preferred Stock if we do not have sufficient funds to pay dividends on all Series C Preferred Stock outstanding and outstanding parity preferred stock.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

There were no unregistered sales of the Company's equity securities during the six months ended June 30, 2020, other than those previously reported in a Current Report on Form 8-K .

Item 3. Defaults Upon Senior Securities

There has been no default in the payment of principal, interest, sinking or purchase fund installment, or any other material default, with respect to any indebtedness of the Company.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

3.1	Amended & Restated Certificate of Incorporation dated March 7, 2002 (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.2*	Certificate of Amendment to Certificate of Incorporation dated May 31, 2005.
3.3*	Certificate of Amendment to Certificate of Incorporation dated December 20, 2006.
3.4	Certificate of Amendment to Certificate of Incorporation dated June 2, 2008 (incorporated herein by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.5	Certificate of Amendment to Certificate of Incorporation dated January 22, 2013 (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.6	Certificate of Amendment to Certificate of Incorporation dated November 7, 2018 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 9, 2018).
3.7	Certificate of Amendment to Certificate of Incorporation dated November 15, 2019 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 29, 2019).
3.8	Certificate of Amendment to Certificate of Incorporation dated November 22, 2019 (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 29, 2019).
3.9	Certificate of Amendment to the Certificate of Incorporation dated January 3, 2020 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2020).
3.10	Certificate of Designation of Series A Preferred Stock dated September 21, 2012. (incorporated herein by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.11	Certificate of Designation of Series B Convertible Preferred Stock dated December 19, 2017 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 26, 2017).
3.12	Certificate of Designation of Series C Convertible Preferred Stock dated December 9, 2019 (incorporated herein by reference to Exhibit 3.10 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 25, 2020).
3.13	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
3.14	Amended and Restated Bylaws of Akers Biosciences, Inc. dated July 21, 2020 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 27, 2020).
4.1	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2020).
4.2	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2020).
4.3	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 13, 2020).

10.1	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2020).
10.2	Amendment No. 1 to the Membership Interest Purchase Agreement, dated May 14, 2020 (incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-K filed with the Securities and Exchange Commission on May 15, 2020).
10.3	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 15, 2020).
10.4 +	CFO Consulting Agreement, dated as of July 21, 2020, between Akers Biosciences, Inc. and Brio Financial Group (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 22, 2020).
10.5	Settlement Agreement and General, Release, dated as of August 3, 2020, by and among Akers Biosciences, Inc. and ChubeWorkx Guernsey Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 10, 2020).
10.6	Leak-Out and Support Agreement, dated as of August 3, 2020, by and among Akers Biosciences, Inc. and ChubeWorkx Guernsey Limited (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 10, 2020).
10.7	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 13, 2020).
31.1*	Certification by the Principal Financial Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rule 13a-14(a) or Rule 15d-14(a)).
31.2*	Certification by the Principal Executive Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rule 13a-14(a) or Rule 15d-14(a)).
32.1*	Certification by the 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
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

* Filed herewith

+ Indicates a management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AKERS BIOSCIENCES, INC.

Date: August 14, 2020

By: */s/ Christopher C. Schreiber*
Name: Christopher C. Schreiber
Title: Executive Chairman of the Board of Directors and Director
(Principal Executive Officer)

Date: August 14, 2020

By: */s/ Howard R. Yeaton*
Name: Howard R. Yeaton
Title: Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT A

CERTIFICATE OF AMENDMENT

AMENDMENT TO ARTICLE FOURTH OF THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

ARTICLE FOURTH of the Amended and Restated Certificate of Incorporation of Akers Biosciences, Inc. is hereby amended and restated to read in its entirety as follows:

"FOURTH Capitalization. The total number of shares of stock which the Corporation shall have the authority to issue is ninety-five million (95,000,000) shares, of which eighty million (80,000,000) shares shall be common stock, without par value ("Common Stock"), and fifteen million (15,000,000) shares shall be preferred stock, without par value ("Preferred Stock"). Each fractional share of Common Stock outstanding on the date hereof shall be combined into and reconstituted as one (1) share of Common Stock. No fractional shares shall be issued upon such combination and reconstitution. If a fractional interest in a share of Common Stock would, except for the provisions of the preceding sentence, be deliverable upon such combination ad reconstitution, in lieu of fractional shares, the Corporation shall pay an amount in cash equal to the fair market value of such fractional interest, as determined by the Corporation's Board of Directors, to each holder of shares of Common Stock to whom such fractional interest would have been deliverable."

EXHIBIT A

CERTIFICATE OF AMENDMENT

AMENDMENT TO SECTION 7.1 AND 7.3 OF ARTICLE SEVENTH AND ARTICLE EIGHTH OF THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

Section 7.1 and Section 7.3 of ARTICLE SEVENTH and ARTICLE EIGHTH of the Amended and Restated Certificate of Incorporation of Akers Biosciences, Inc. is hereby amended and restated to read in its entirety as follows:

"7.1 Number. The business and affairs of the Corporation shall be under the direction of the Board of Directors. The number of directors shall be fixed from time to time by the Board of Directors pursuant to the By-Laws of the Corporation, but in any event shall be not less than two (2) nor more than eleven (11) directors. The directors shall be divided into three classes designated Class I, Class II and Class III. Each class shall consist, as nearly as possible, of one-third of the total number of directors constituting the entire Board of Directors. Class I directors shall be originally elected for a term expiring at the first succeeding annual meeting of stockholders, Class II directors shall be originally elected for a term expiring at the second succeeding annual meeting of stockholders, and Class III directors shall be originally elected for a term expiring at the third succeeding annual meeting of stockholders. At each succeeding annual meeting of stockholders beginning in 2007, successors to the class of directors whose term expires at that annual meeting shall be elected for a term expiring at the third succeeding annual meeting of stockholders. If the number of directors is changed, any increase or decrease shall be apportioned among the classes so as to maintain the number of directors in each class as nearly equal as possible, and any additional director of any class elected to fill a newly created directorship resulting from an increase in such class shall hold office for a term that shall coincide with the remaining term of that class, but in no case shall a decrease in the number of directors remove or shorten the term of any incumbent director. A director shall hold office until the annual meeting for the year in which his term expires and until his successor shall be elected and shall qualify, subject, however, to prior death, resignation, retirement, disqualification or removal from office.

7.3 Vacancies. Subject to the rights of the holders of any series of Preferred Stock, newly created directorships resulting from any increase in the authorized number of directors or any vacancies on the Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause may be filled only by a majority vote of the directors then in office, though less than a quorum, and shall not be filled by the shareholders unless there are no directors remaining on the Board of Directors. Any director so chosen (a "vacancy

director") shall be a director of the same class as the director whose vacancy he or she fills or, if the vacancy resulted from an increase in the authorized number of directors, the vacancy director shall be a director of the class as determined by the Board of Directors pursuant to Section 7.1 above. Such vacancy director shall hold office until the annual meeting of shareholders at which the directors in such vacancy director's class are up for reelection, and until his or her successor shall have been elected and qualified. The shareholders shall thereupon elect a director to fill the vacancy having been temporarily filled by the vacancy director, which individual may include the incumbent vacancy director. The director so elected shall be a director of the same class as the vacancy director and shall serve until the annual meeting of shareholders at which the term of office of such class expires and until such director's successor shall have been duly elected and qualified.

EIGHTH Shareholder Action. Any action required or permitted to be taken by shareholders pursuant to this Amended and Restated Certificate or under applicable law may be effected only at a duly called annual or special meeting of shareholders and with a vote thereat. The holder of shares entitled to cast forty percent (40%) of the votes at a meeting of shareholders shall constitute a quorum at such meeting. Except as otherwise required by law and subject to the rights of the holders of any series of Preferred Stock, annual and special meetings of shareholders of the corporation may be called only by the President, the Chief Executive Officer, or the Board of Directors pursuant to a resolution approved by a majority of the members of the Board of Directors. Subject to applicable law and the rights of holders of any series of Preferred Stock, shareholders are not permitted to call an annual or special meeting of shareholders or to require that the Board of Directors call an annual or special meeting of shareholders."

Exhibit 31.1

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

I, Christopher C. Schreiber, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Akers Biosciences, Inc.;

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 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. I am 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 13-a-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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal 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 financial statements for external purposes in accordance 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. 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.

Date: August 14, 2020

By: */s/ Christopher C. Schreiber*
Christopher C. Schreiber
Executive Chairman of the Board of Directors and Director (Principal Executive Officer)

Exhibit 31.2

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

I, Howard Yeaton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akers Biosciences, Inc.;

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 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. I am 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 13-a-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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal 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 financial statements for external purposes in accordance 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. 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.

Date: August 14, 2020

By: */s/ Howard Yeaton*
Howard Yeaton
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Quarterly Report of Akers Biosciences, Inc. (the "Company"), on Form 10-Q for the period ended June 30, 2020, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: August 14, 2020

By: */s/ Christopher C. Schreiber*
Christopher C. Schreiber
Executive Chairman of the Board of Directors and Director
(Principal Executive Officer)
Akers Biosciences, Inc.

Date: August 14, 2020

By: */s/ Howard Yeaton*
Howard Yeaton
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)
Akers Biosciences, Inc.