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

FORM 10-Q

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

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

OR

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

For the transition period from _____ to _____

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 November 16, 2020, there were 8,859,868 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
September 30, 2020 and December 31, 2019

	As of	
	September 30, 2020 (unaudited)	**December 31, 2019 (audited)**
ASSETS		
Current Assets		
Cash	$ 16,189,651	$ 517,444
Marketable Securities	6,929,356	9,164,273
Prepaid expenses	446,507	340,971
Current assets of discontinued operations	-	288,126
Total Current Assets	23,565,514	10,310,814
Non-Current Assets		
Restricted Cash	115,094	115,094
Property, Plant and Equipment, net	3,738	10,554
Right-of-Use Asset	40,469	-
Other Assets	-	2,722
Non-current assets of discontinued operations	-	445,751
Total Non-Current Assets	159,301	574,121
Total Assets	$ 23,724,815	$ 10,884,935
LIABILITIES		
Current Liabilities		
Trade and Other Payables	$ 1,057,469	$ 901,207
Right-of-Use Liability	40,506	-
Current liabilities of discontinued operations	1,457,671	628,558
Total Current Liabilities	2,555,646	1,529,765
Non-Current Liabilities		
Right-of-Use Liability, net of current	-	-
Total Non-Current Liabilities	-	-
Total Liabilities	$ 2,555,646	$ 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 September 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, 72,992 and 0 shares issued and outstanding as of September 30, 2020 and December 31, 2019	144,524	-
Series E Junior Participating Preferred Stock, 100,000 shares designated, no par value and a stated value of $0.001 per share, 0 shares issued and outstanding as of September 30, 2020 and December 31, 2019	-	-
Common stock, No par value, 100,000,000 shares authorized 8,859,868 and 1,738,837 issued and outstanding as of September 30, 2020 and December 31, 2019	154,901,639	128,920,414
Accumulated Other Comprehensive Income (Loss)	-	17,886
Accumulated Deficit	(133,876,994)	(119,583,130)
Total Shareholders' Equity	21,169,169	9,355,170
Total Liabilities and Shareholders' Equity	$ 23,724,815	$ 10,884,935

See accompanying notes to the condensed consolidated financial statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Product Revenue	$ -	$ -	$ -	$ -
Product Cost of Sales	-	-	-	-
Gross Income	-	-	-	-
Research and Development Expenses	1,741,269	-	6,140,487	-
Administrative Expenses	1,223,354	843,144	2,983,443	2,687,681
Sales and Marketing Expenses	6,250	6,163	16,667	18,750
Litigation Settlement Expenses	-	-	-	75,000
Loss from Operations	(2,970,873)	(849,307)	(9,140,597)	(2,781,431)
Other (Income) Expenses				
Foreign Currency Transaction (Gain) Loss	-	(32)	(93)	4,846
(Gain)/Loss on Investments	-	(6,416)	36,714	(2,155)
Gain on FMV of Equity Investments	(31,465)	-	(31,465)	-
Interest and Dividend Income	(23,368)	(22,015)	(99,116)	(81,017)
Total Other Income	(54,833)	(28,463)	(93,960)	(78,326)
Loss from Continuing Operations Before Income Tax	(2,916,040)	(820,844)	(9,046,637)	(2,703,105)
Income Tax Benefit	-	-	-	-
Net Loss from Continuing Operations	(2,916,040)	(820,844)	(9,046,637)	(2,703,105)
(Loss)/Income from Discontinued Operations Before Income Tax	(4,211,157)	(16,182)	(5,247,227)	154,230
Income Tax	-	-	-	-
Net (Loss)/Income from Discontinued Operations	(4,211,157)	(16,182)	(5,247,227)	154,230
Net Loss	(7,127,197)	(837,026)	(14,293,864)	(2,548,875)
Other Comprehensive Income (Loss)				
Net Unrealized Gain (Loss) on Marketable Securities	-	(1,805)	-	45,597
Total Other Comprehensive Income (Loss)	-	(1,805)	-	45,597
Comprehensive Loss	$ (7,127,197)	$ (838,831)	$ (14,293,864)	$ (2,503,278)
Basic and Diluted loss per common share from continuing operations	$ (0.38)	$ (1.51)	$ (1.79)	$ (4.99)
Basic and Diluted (loss) earnings per common share from discontinued operations	$ (0.55)	$ (0.03)	$ (1.04)	$ 0.28
Basic and Diluted loss per common share	$ (0.93)	$ (1.54)	$ (2.83)	$ (4.71)
Weighted average basic common shares outstanding	7,626,780	541,859	5,044,737	541,289

See accompanying notes to the condensed consolidated financial statements

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statement of Changes in Shareholders Equity
For the Nine Months Ended September 30, 2020 and 2019

	Series D Convertible Preferred Stock		Common Stock			Accumulated Other Comprehensive	
	Shares	Series D	Shares	Common Stock	Accumulated Deficit	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
Issuance of restricted stock units for services	-	-	-	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
Issuance of restricted stock units for services	-	-	-	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
Net loss	-	-	-	-	(837,026)	-	(837,026)
Issuance of stock grants to key employees	-	-	312	3,111	-	-	3,111
Issuance of restricted stock units for services	-	-	-	119,781	-	-	119,781
Net unrealized gain on marketable securities	-	-	-	-		(1,805)	(1,805)
Balance at September 30, 2019 (unaudited)	-	$ -	542,014	$ 121,822,267	$ (118,243,756)	$ 19,684	$ 3,598,195

	Series D Convertible Preferred Stock		Common Stock			Accumulated Other Comprehensive	
	Shares	Series D	Shares	Common Stock	Accumulated Deficit	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
Stock-based compensation - restricted stock units	-	-	-	1,302	-	-	1,302
Stock-based compensation - acquisition of license for preferred series 'D' stock	211,353	418,479	-	-	-	-	418,479
Stock-based compensation - acquisition of license for common stock	-	-	411,403	814,578	-	-	814,578
Stock-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
Exercise 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
Net loss	-	-	-	-	(7,127,197)	-	(7,127,197)
Exercise of Series C Convertible Preferred Warrants for common stock	-	-	891,500	3,566,000	-	-	3,566,000
Exercise of Series D Convertible Preferred Shares for common stock	(135,585)	(268,458)	135,585	268,458	-	-	-
Registered direct offering of common stock net of offering costs of $689,874	-	-	1,207,744	6,158,034	-	-	6,158,034
Share-based compensation - shares issued for litigation settlements			500,000	2,510,000			2,510,000
Stock-based compensation - restricted stock units	-	-	-	69,031			69,031
Reclassification of unrealized loss on marketable securities	-	-	-	-	-	21,153	21,153
Balance at September 30, 2020 (unaudited)	72,992	$ 144,524	8,859,868	$ 154,901,639	$ (133,876,994)	$ -	$ 21,169,169

See accompanying notes to the condensed consolidated financial statements

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2020 and 2019
(unaudited)

	For the Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss from ongoing operations	$ (9,046,637)	$ (2,703,105)
Net income/(loss) from discontinued operations	(5,247,227)	154,230
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss/(gain) on sale of securities	36,714	(2,155)
Gain on fair market value of equity investments	(31,465)	-
Accrued loss on marketable securities	1,749	6,289
Depreciation and amortization	28,757	54,522
Loss on disposal of fixed assets	18,680	-
Impairment of Prepaid Royalties	291,442	
Impairment of intangible assets	152,822	-
Inventory adjustment for net realizable value	197,723	-
Reserve for obsolete inventory	-	126,422
Reserve for doubtful other receivables	-	105,325
Share based compensation to an employee - restricted stock	-	25,555
Share based compensation to directors - restricted stock units	70,333	242,165
Share based compensation - shares issued to vendors	7,318	-
Share based compensation - shares issued to Chubeworkx	2,510,000	
Share based compensation - shares issued for Cystron	1,233,057	-
Change in assets and liabilities		
Decrease/(increase) in trade receivables	67,122	(59,899)
Decrease in deposits and other receivables	-	9,347
Decrease in inventories	1,262	46,786
(Increase)/decrease in prepaid expenses	(98,410)	18,147
Decrease in other assets	2,722	4,330
Increase/(decrease) in trade and other payables	961,134	(600,537)
Increase in right-of-use liabilities	37	-
Net cash used by operating activities	(8,842,867)	(2,572,578)
Cash flows from investing activities:		
Short-term note receivable	-	(100,000)
Purchases of marketable securities	(100,865)	(87,305)
Proceeds from sale of marketable securities	2,310,898	2,556,516
Net cash provided by investing activities	2,210,033	2,369,211
Cash flows from financing activities		
Net proceeds from issuance of common stock	14,564,961	-
Net proceeds from the exercise of Series C Convertible Preferred warrants for the purchase of common stock	7,740,000	-
Net proceeds from the exercise of prepaid equity forward contracts for the purchase of common stock	80	-
Net cash provided by financing activities	22,305,041	-
Net increase/(decrease) in cash and restricted cash	15,672,207	(203,367)
Cash and restricted cash at beginning of period	632,538	681,755
Cash and restricted cash at end of period	$ 16,304,745	$ 478,388
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	$ -	$ 45,597
Operating lease right-of-use asset obtained in exchange for lease obligation	$ (79,942)	$ -
Exercise of Series D Convertible Preferred Stock for Common Stock	$ 273,955	$ -

See accompanying notes to the 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 ("Cystron"), 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").

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 and Note 6 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 September 30, 2020 and its results of operations and cash flows for the three and nine months ended September 30, 2020 and 2019. The results of operations for the three and nine months ended September 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 September 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 September 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 September 30, 2020	$ 6,929,356	$ -	$ -
Fixed Income Bonds at December 31, 2019	$ 9,164,273	$ -	$ -

Marketable securities are classified as available for sale and are valued at fair market value. Maturities of the securities are less than one year.

As of September 30, 2020, the Company held certain fixed income investments which, under FASB ASC 321-10, were considered equity investments. As such, the change in fair value in the three months ended September 30, 2020 and the accumulated other comprehensive income (loss) of $21,153 at June 30, 2020 were included in the net loss.

Gains and losses resulting from the sales of marketable securities were gains of $0 and $6,416 for the three months ended September 30, 2020 and 2019, respectively and were (losses) and gains of ($36,714) and $2,155 for the nine months ended September 30, 2020 and 2019, respectively

Proceeds from the sales of marketable securities in the three and nine months ended September 30, 2020 were $3,436 and $2,310,898, respectively and were $1,201,870 and $2,556,516 for the three and nine months ended September 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.

(i) Prepaid Expenses

Prepaid expenses represent 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.

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.

(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 $1,045 and $6,815 for the three and nine months ended September 30, 2020, respectively and $6,455 and $19,366 for the three and nine months ended September 30, 2019, respectively.

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 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

In June 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	September 30, 2020	January 1, 2020	December 31, 2019
Operating Lease			
Right-of-use asset	$ 40,469	$ 306,706	$ -
Liability, current	40,506	143,018	-
Liability, net of current	$ -	$ 163,688	-

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

	Three months ended September 30, 2020	Nine months ended September 30, 2020
Lease cost		
Operating lease	$ 41,148	$ 124,222

Other information related to leases is presented below:

Other information	As of September 30, 2020
Operating cash used by operating leases	$ 124,184
Weighted-average remaining lease term – operating leases (in months)	3
Weighted-average discount rate – operating leases	10.00%

As of September 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 nine months ended September 30, 2020)	$ 41,146
Total future minimum lease payments, undiscounted	$ 41,146
Less: Imputed interest	(640)
Present value of future minimum lease payments	$ 40,506

Note 2 - Significant Accounting Policies, continued

(n) 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.

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.

Note 2 - Significant Accounting Policies, continued

(o) 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.

(p) 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

(q) 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 September 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 nine months ended September 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 nine months ended September 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.

(r) Shipping and Handling Fees and Costs

The Company charges actual shipping costs plus a handling fee to customers. 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.

Note 2 - Significant Accounting Policies, continued

(s) 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.

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

As the Company reported a net loss from continuing operations for the three and nine months ended September 30, 2020 common stock equivalents were anti-dilutive.

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

	For the Nine Months Ended September 30,	
	2020	2019
Stock Options	-	40
Unvested RSUs	789,360	15,603
Warrants to purchase common stock	514,516	88,015
Series D Preferred Convertible Stock	72,992	-
Warrants to purchase Series C Preferred stock	55,000	-
Total potentially dilutive shares	1,431,868	103,658

(t) Reclassifications

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

(u) Discontinued Operations

In accordance with FASB ASC 205, results of operations of a component of an entity that has either been disposed of or is held for sale is to be reported as discontinued operations in the condensed consolidated financial statements if the disposition or sale represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. See Note 6 herein.

Note 2 - Significant Accounting Policies, continued

(v) 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 September 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 transactions 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.

The Company determined that the discontinuation of the production and distribution of the Company's screening and testing products constituted a strategic shift in the Company's business and as a result the elimination of the product lines should be presented as discontinued operations under FASB ASC 205-20 Presentation of Financial Statements, Discontinued Operations.

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 in the three months ended March 31,2020 and nine months ended September 30,2020. 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.

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 (the "August Payment") to the Sellers upon the consummation of the registered direct equity offerings that closed on May 18, 2020 and August 13, 2020, respectively. These funds (including funds of $299,074 representing Premas' portion of the cash purchase price and $83,334 representing Premas' portion of the April Payment temporarily returned to the Company in April 2020) due the sellers under the MIPA, as amended, were disbursed on September 25, 2020. For the three and nine month periods ended September 30, 2020, $684,790 and $1,827,290 are included in research and development expense within the Condensed Consolidated Statements of Operations and Comprehensive Loss for the April Payment, May Payment and August Payment.

On October 13, 2020, Premas returned $908,117 representing Premas' portion of the initial cash component for the purchase of Cystron and Premas' portion of the April Payment, May Payment and August Payment under the MIPA, as amended. These funds were returned temporarily for Premas to meet certain regulatory requirements in India.

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 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.

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 on July 7, 2020, Premas was paid $1,000,000 on August 4, 2020. Accordingly, for the three and nine months ended September 30, 2020, research and development expenses of $1,000,000 and $2,000,000 were recorded in the condensed consolidated statements of operations and comprehensive loss.

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 nine months ended September 30, 2020, the Company recorded $10,651 and $20,925 as a charge to research and development expense within the Condensed Consolidated Statements of Operations and Comprehensive Loss.

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.

Subject to the Beneficial Ownership Limitation, 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 nine months ended September 30, 2020, 135,585 and 138,361 shares of Preferred Stock were converted to 135,585 and 138,361 common shares, respectively. As of September 30, 2020, 72,992 shares of Series D Preferred Stock were issued and outstanding.

Restricted Stock Unit Award Agreement

On September 11, 2020, the Company entered into Restricted Stock Unit Award Agreements (the "Agreements") with the Company's four directors. Pursuant to the Agreements, Christopher C. Schreiber, who is also the Company's Executive Chairman and President, was granted 263,500 Restricted Stock Units ("RSUs"), Joshua Silverman was granted 219,000 RSUs, William White was granted 219,000 RSUs, and Robert Schroeder was granted 87,860 RSUs (each, a "Grant," and, collectively, the "Grants") under the Company's 2018 Equity Incentive Plan, as amended (the "2018 Plan").

Fifty percent (50%) of the RSUs in each Grant will vest on the first anniversary of the date of Grant, and the remaining fifty percent (50%) will vest on the second anniversary of the date of Grant; provided that the RSUs shall vest immediately upon the occurrence of (i) a change in control, provided that the director is employed by or providing services to the Company and its affiliates on the closing date of such change in control, (ii) the director's termination of employment or service from the Company and its affiliates by reason of the director's death or disability, or (iii) the director's termination of employment or service by the Company without cause.

Rights Agreement

The Company's board of directors (the "Board") declared a dividend of one preferred share purchase right (a "Right") for each of the Company's issued and outstanding shares of common stock. The dividend is payable to the stockholders of record on September 21, 2020 (the "Record Date"). Each Right entitles the registered holder, subject to the terms of the Rights Agreement (as defined below), to purchase from the Company one one-thousandth of a share of the Company's Series E Junior Participating Preferred Stock, no par value with a stated value of $0.001 (the "Preferred Stock") at $15.00 (the "Purchase Price"), subject to certain adjustments. The description and terms of the Rights are set forth in the Rights Agreement dated as of September 9, 2020 (the "Rights Agreement") between the Company and VStock Transfer, LLC, as Rights Agent (the "Rights Agent").

The Rights will not be exercisable until the earlier to occur of (i) the tenth business day following a public announcement or filing that a person has, or affiliates or associates of such person have, become an "Acquiring Person," which is defined as a person, or affiliates or associates of such person, who, at any time after the date of the Rights Agreement, has acquired, or obtained the right to acquire, Beneficial Ownership of 10% or more of the Company's outstanding shares of common stock, subject to certain exceptions, or (ii) the tenth business day (or such later date as may be determined by action of the Board prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person becoming an Acquiring Person (the earlier of such dates being called the "Distribution Date"). Beneficial Ownership, as defined in the Rights Agreement, includes certain interests in securities created by derivatives contracts, which are beneficially owned, directly or indirectly, by a counterparty (or any of such counterparty's affiliates or associates) under any derivatives contract to which such person or any of such person's affiliates or associates is a receiving party (as such terms are defined in Rights Agreement), subject to certain limitations.

Until the Distribution Date, (i) the Rights will be evidenced by the common stock certificates (or, for uncertificated shares of common stock, by the book-entry account that evidences record ownership of such shares) and will be transferred with, and only with, such Common Stock, and (ii) new common stock certificates issued after the Record Date will contain a legend incorporating the Rights Agreement by reference (for book entry common stock, this legend will be contained in the notations in book entry accounts). Until the earlier of the Distribution Date and the Expiration Date (defined below), the transfer of any shares of common stock outstanding on the Record Date will also constitute the transfer of the Rights associated with such shares of common stock. As soon as practicable after the Distribution Date, the Rights Agent will send by first-class, insured, postage prepaid mail, to each record holder of the common stock as of the close of business on Distribution Date separate rights certificates evidencing the Rights ("Right Certificates"), and such Right Certificates alone will evidence the Rights. The Company may choose book entry in lieu of physical certificates, in which case, references to "Rights Certificates" shall be deemed to mean the uncertificated book entry representing the Rights.

The Rights, which are not exercisable until the Distribution Date, expire upon the earliest to occur of (i) the close of business on September 8, 2021; (ii) the time at which the Rights are redeemed or exchanged pursuant to the Rights Agreement; and (iii) the time at which the Rights are terminated upon the closing of any merger or other acquisition transaction involving the Company pursuant to a merger or other acquisition agreement that has been approved by the Board prior to any person becoming an Acquiring Person (the earliest of (i), (ii), and (iii) is referred to as the "Expiration Date").

Each share of Preferred Stock will be entitled to a preferential per share dividend rate equal to the greater of (i) $0.001 and (ii) the sum of (1) 1,000 times the aggregate per share amount of all cash dividends, plus (2) 1,000 times the aggregate per share amount (payable in kind) of all non-cash dividends or other distributions other than certain dividends or subdivisions of the outstanding shares of common stock. Each Preferred Stock will entitle the holder thereof to a number of votes equal to 1,000 on all matters submitted to a vote of the stockholders of the Company. In the event of any merger, consolidation or other transaction in which shares of common stock are exchanged, each Preferred Stock will be entitled to receive 1,000 times the amount received per one share of common stock. Pursuant to the Rights Agreement, the preferential rates noted above may be adjusted in the event that the Company (i) pays dividends in common stock, (ii) subdivides the outstanding common stock or (iii) combines outstanding Common Stock into a smaller number of shares.

The Purchase Price payable, and the number of shares of Preferred Stock or other securities or property issuable, upon exercise of the Rights are subject to adjustment from time to time to prevent dilution (i) in the event of a stock dividend, or a subdivision, combination or reclassification of the Preferred Stock, (ii) if the holders of Preferred Stock are granted certain rights, options or warrants to subscribe for the applicable Preferred Stock or securities convertible into the applicable Preferred Stock at less than the current market price of the applicable Preferred Stock, or (iii) upon the distribution to holders of Preferred Stock of evidences of indebtedness, cash (excluding regular quarterly cash dividends), assets (other than dividends payable in Preferred Stock) or subscription rights or warrants (other than those referred to in (ii) immediately above). The number of outstanding Rights and the number of one one-thousandths of a Preferred Stock issuable upon exercise of each Right are also subject to adjustment in the event of a stock split, reverse stock split, stock dividends and other similar transactions.

With some exceptions, no adjustment in the purchase price relating to a Right will be required until cumulative adjustments amount to at least one percent (1%) of the purchase price relating to the Right. No fractional shares of Preferred Stock are required to be issued (other than fractions which are integral multiples of one one-thousandth of a share of Preferred Stock) and, in lieu of the issuance of fractional shares, the Company may make an adjustment in cash based on the market price of the Preferred Stock on the trading date immediately prior to the date of exercise.

In the event that a person or group of affiliated or associated persons becomes an Acquiring Person, each holder of a Right will thereafter have the right to receive, upon exercise, common stock (or, in certain circumstances, other securities, cash or other assets of the Company) having a value equal to two (2) times the exercise price of the Right. Notwithstanding any of the foregoing, following the occurrence of a person becoming an Acquiring Person, all Rights that are, or (under certain circumstances specified in the Rights Agreement) were, Beneficially Owned by any Acquiring Person (or by certain related parties) will be null and void and any holder of such Rights (including any purported transferee or subsequent holder) will be unable to exercise or transfer any such Rights. However, Rights are not exercisable following the occurrence of a person becoming an Acquiring Person until the Distribution Date.

In the event that, after a person or a group of affiliated or associated persons has become an Acquiring Person, the Company is acquired in a merger or other business combination transaction, or 50% or more of the Company's assets or earning power are sold, proper provision will be made so that each holder of a Right will thereafter have the right to receive, upon the exercise of a Right that number of shares of common stock of the person with whom the Company has engaged in the foregoing transaction (or its parent) that at the time of such transaction have a market value of two (2) times the exercise price of the Right.

At any time before any person or group of affiliated or associated persons becomes an Acquiring Person, the Board may redeem the Rights in whole, but not in part, at a price of $0.001 per Right (subject to certain adjustments) (the "Redemption Price"). The redemption of the Rights may be made effective at such time, on such basis and with such conditions as the Board in its sole discretion may establish. Immediately upon the action of the Board electing to redeem or exchange the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the Redemption Price.

The Board may, at its option, at any time after the first occurrence of a Flip-in Event (as defined in the Rights Agreement), exchange all or part of the then outstanding and exercisable Rights for shares of common stock at an exchange ratio of one share of common stock per Right, appropriately adjusted to reflect any stock split, stock dividend or similar transaction occurring after the effective date. However, the Board shall not effect such an exchange at any time after any person, together with all affiliates and associates of such person, becomes a beneficial owner of 50% or more of the outstanding shares of common stock. Immediately upon the action of the Board to exchange the Rights, the Rights will terminate and the only right of the holders of Rights will be to receive the number of shares of Common equal to the number of Rights held by such holder multiplied by the exchange ratio.

Until a Right is exercised or exchanged, the holder thereof, as such, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

The Board may amend or supplement the Rights Agreement without the approval of any holders of Rights at any time so long as the Rights are redeemable. At any time the Rights are no longer redeemable, no such supplement or amendment may (i) adversely affect the interests of the holders of Rights (other than an Acquiring Person or an affiliate or associate of an Acquiring Person), (ii) cause the Rights Agreement to become amendable other than in accordance with Section 27 of the Rights Agreement, or (iii) cause the Rights again to become redeemable.

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

Liquidity

As of September 30, 2020, the Company's cash on hand was $16,304,745 (which included restricted cash of $115,094), and marketable securities were $6,929,356. The Company has incurred net losses of $14,293,864 for the nine months ended September 30, 2020. As of September 30, 2020, the Company had working capital of $21,009,868 and stockholder's equity of $21,169,169. During the nine months ended September 30, 2020, cash flows used in operating activities were $8,842,867, consisting primarily of a net loss of $14,293,864, which includes, principally, research and development costs in connection with the purchase of a license and milestone license fees of $6,060,348. 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, pursuant to the terms of the 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 July 21, 2020 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.

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 $6,847,908 and $6,158,034, 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

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 Candidate, 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 in connection with the Merger. 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.

Note 5 - Trade and Other Payables

Trade and other payables consist of the following:

	September 30, 2020	December 31, 2019
Accounts Payable – Trade	$ 820,012	$ 608,630
Accrued Expenses	237,457	232,827
Deferred Compensation	-	59,750
	$ 1,057,469	$ 901,207

See also Note 9 for related party information.

Note 6 – Discontinued Operations

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 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 assets and liabilities of the discontinued operations have been reflected in the condensed consolidated balance sheet as of September 30, 2020 and consist of the following:

	As of September 30, 2020
Current Assets:	$ -
Non-Current Assets	-
Total Assets	$ -
Current Liabilities:	
Trade and Other Payables of Discontinued Operations	$ 1,457,671
Total Current Liabilities	1,457,671
Non-Current Liabilities	-
Total Liabilities	$ 1,457,671
Shareholder Equity	$ -
Total Liabilities and Shareholder Equity	$ 1,457,671

The results from the discontinued operations have been reflected in the condensed consolidated statements of operations for the three and nine months ended September 30, 2020 and consist of the following:

	For the Three Months Ended September 30, 2020	For the Nine Months Ended September 30, 2020
Product Revenue	$ -	$ 361,627
Product Cost of Sales	109,983	660,023
Gross Loss	(109,983)	(298,396)
Administrative Expenses	62,550	196,901
Sales and Marketing Expenses	29,300	40,586
Regulatory and Compliance Expenses	59,910	199,668
Litigation Settlement Expenses	3,949,414	4,031,131
Amortization of Non-Current Assets	-	17,601
Impairment of Prepaid Royalties	-	291,442
Impairment of Production Equipment	-	18,680
Impairment of Intangible Assets	-	152,822
Loss from Discontinued Operations	$ (4,211,157)	$ (5,247,227)

As a result of the discontinued operations, the previously presented 2019 financial statements have been revised to present the consolidated financial statements of the continuing operations separate from the discontinued operations. The effects on the consolidated balance sheet as of December 31, 2019 were as follows:

	December 31, 2019		
	As previously Reported	Adjustment	As Revised
ASSETS			
Current Assets			
Cash	$ 517,444	$ -	$ 517,444
Marketable Securities	9,164,273	-	9,164,273
Accounts Receivable, net	42,881	42,881	-
Deposits and Other Receivables	-	-	-
Inventories, net	198,985	198,985	-
Prepaid Expenses	387,231	46,260	340,971
Current Assets – discontinued operations	-	(288,126)	288,126
Total Current Assets	10,310,814	-	10,310,814
Non-Current Assets			
Prepaid Expenses, net of current	252,308	252,308	-
Restricted Cash	115,094	-	115,094
Plant, Property and Equipment, net	33,574	23,020	10,554
Intangible assets, net	170,423	170,423	-
Other assets	2,722	-	2,722
Non-current Assets – discontinued operations		(445,751)	445,751
Total Non-Current Assets	574,121	-	574,121
Total Assets	$ 10,884,935	$ -	$ 10,884,935
LIABILITIES			
Current Liabilities			
Trade and Other Payables	1,529,765	628,558	901,207
Current Liabilities – discontinued operations	-	(628,558)	628,558
Total Current Liabilities	1,529,765	-	1,529,765
Total Liabilities	1,529,765	-	1.529.765
Commitments and Contingencies			
SHAREHOLDERS' EQUITY			
Preferred Stock, No par value, 50,000,000 total preferred shares authorized	-	-	-
Common stock, No par value, 100,000,000 shares authorized 1,738,837 issued and outstanding as of December 31, 2019	128,920,414	-	128,920,414
Accumulated Other Comprehensive Income (Loss)	17,886	-	17,886
Accumulated Deficit	(119,583,130)	-	(119,583,130)
Total Shareholders' Equity	9,355,170	-	9,355,170
Total Liabilities and Shareholders' Equity	$ 10,884,935	$ -	$ 10,884,935

The effects on the condensed consolidated statement of operations and comprehensive income (loss) for the three and nine months ended September 30, 2019 were as follows:

	For the Three Months Ended September 30, 2019			For the Nine Months Ended September 30, 2019		
	As Previously Reported	Adjusted	As Revised	As Previously Reported	Adjusted	As Revised
Product Revenue	$ 420,812	$ 420,812	$ -	$ 1,497,448	$ 1,497,448	$ -
Product Cost of Sales	(285,510)	(285,510)	-	(751,311)	(751,311)	-
Gross Income	135,302	135,302	-	746,137	746,137	-
Research and Development Expenses	-	-	-	-	-	-
Administrative Expenses	895,026	51,882	843,144	2,859,288	171,607	2,687,681
Sales and Marketing Expenses	38,262	32,099	6,163	202,242	183,492	18,750
Compliance and Regulatory Expenses	57,502	57,502	-	206,802	206,802	-
Litigation Settlement Expenses	-	-	-	75,000	-	75,000
Amortization of Non-Current Assets	10,001	10,001	-	30,006	30,006	-
Impairment of Intangible Assets	-	-	-	-	-	-
(Loss) income from Operations	(865,489)	(16,182)	(849,307)	(2,627,201)	154,230	(2,781,431)
Other (Income) Expense						
Foreign Currency Transaction (Gain) Loss	(32)	-	(32)	4,846	-	4,846
Gain on Investments	(6,416)	-	(6,416)	(2,155)	-	(2,155)
Interest and Dividend Income	(22,015)	-	(22,015)	(81,017)	-	(81,017)
Total Other Income	(28,463)	(16,182)	(28,463)	(78,326)	154,230	(78,326)
Loss from Continuing Operations	(837,026)	-	(820,844)	(2,548,875)	-	(2,703,105)
Income/(Loss) from Discontinued Operations	-	16,182	(16,182)	-	(154,230)	154,230
Loss Before Income Taxes	(837,026)	-	(837,026)	(2,548,875)	-	(2,548,875)
Income Tax Benefit	-	-	-	-	-	-
Net Loss	(837,026)	-	(837,026)	(2,548,875)	-	(2,548,875)
Other Comprehensive (Loss) Income						
Net Unrealized Gain (Loss) on Marketable Securities	(1,805)	-	(1,805)	45,597	-	45,597
Total Other Comprehensive (Loss) Income	(1,805)	-	(1,805)	45,597	-	45,597
Comprehensive Loss	$ (838,831)	$ -	$ (838,831)	$ (2,503,278)	-	$ (2,503,278)

The depreciation, amortization and significant operating noncash items of the discontinued operations were as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Depreciation and amortization	$ -	$ 13,087	$ 21,941	$ 35,156
Impairment of Prepaid Royalties	-	-	291,442	-
Impairment of intangible assets	-	-	152,822	-
Inventory adjustment for net realizable value	-	-	197,723	-
Reserve for obsolete inventory	-	79,413	-	126,422
Share based compensation - shares issued to Chubeworkx	2,510,000	-	2,510,000	-
	$ 2,510,000	$ 92,500	$ 3,173,928	$ 161,578

Note 7 - 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 September 30, 2020, grants of restricted stock and options to purchase 2,813 shares of common stock have been issued pursuant to the 2013 Plan, and 1,510 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 September 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 Plan. The 2018 Plan initially provided for the issuance of up to 78,125 shares of the Company's common stock. On August 27, 2020, the stockholders approved an amendment to the 2018 Plan increasing the number of shares available for issuance by an additional 1,042,000 shares to a total of 1,120,125 shares of the Company's common stock. As of September 30, 2020, grants of RSUs to purchase 804,963 shares of common stock have been issued pursuant to the 2018 Plan, and 315,162 shares of common stock remain available for issuance.

Note 7 - Share-based Payments, continued

Stock Options

The following table summarizes the option activities for the nine months ended September 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	(40)	236.16	151.68	0.24	-
Canceled/Expired	-	-	-	-	-
Balance at September 30, 2020	-	$ -	$ -	-	$ -
Exercisable As of September 30, 2020	-	$ -	$ -	-	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $2.25 for the Company's common stock on September 30, 2020. As the closing stock price on September 30, 2020 is lower than the exercise price, there is no intrinsic value to disclose.

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

Note 7 - Share-based Payments, continued

Restricted Stock Units

On March 29, 2019, the Compensation Committee of the Board approved the grant of 5,201 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 December 31, 2020.

On September 11, 2020, the Compensation Committee of the Board approved grant totaling 789,360 Restricted Stock Units ("RSUs") to the four directors. Each RSU had a grant date fair value of $2.24 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 50% vest on September 11, 2021 and 50% vest on September 11, 2022.

At September 30, 2020, the unamortized value of the RSUs was $1,699,135. A summary of activity related to RSUs for the nine months ended September 30, 2020 is presented below:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at December 31, 2019	15,603	$ 23.28
Granted	789,360	2.24
Exercised	-	-
Vested	(15,603)	23.28
Forfeited	-	-
Canceled/Expired	-	-
Balance at September 30, 2020	789,360	$ 2.24

The Company incurred RSU expense of $69,031 and $119,780 during the three months ended September 30, 2020 and 2019, respectively and $70,333 and $242,165 during the nine months ended September 30, 2020 and 2019, respectively.

Note 7 - Share-based Payments, continued

Common Stock Warrants

The table below summarizes the warrant activity for the nine month period ended September 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	267,301	6.09	4.69
Exercised	-	-	-
Forfeited	-	-	-
Canceled/Expired	-	-	-
Balance at September 30, 2020	514,516	$ 17.48	4.15
Exercisable As of September 30, 2020	514,516	$ 17.48	4.15

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 nine month period ended September 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 September 30, 2020	-	$ -	-
Exercisable As of September 30, 2020	-	$ -	-

All pre-funded warrants were vested on the date of grant and are exercisable at any time. During the nine months ended September 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 7 - Share-based Payments, continued

Warrants for the purchase of Series C Convertible Preferred Stock

The table below summarizes the activity during the nine month period ended September 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	(1,935,000)	4.00	4.19
Forfeited	-	-	-
Canceled/Expired	-	-	-
Balance at September 30, 2020	55,000	$ 4.00	4.19
Exercisable As of September 30, 2020	55,000	$ 4.00	4.19

All warrants to purchase Series C Convertible Preferred Stock were vested on the date of grant. During the nine months ended September 30, 2020, 1,935,000 warrants to purchase 1,935,000 shares 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 1,935,000 shares of common stock at an exercise price of $4.00 per share, yielding net proceeds of $7,740,000 (See Note 3).

Note 8 – Commitments and Contingencies

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, (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 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") with a fair market value of $2,510,000. Accordingly, for the three and nine months ended September 30, 2020, litigation settlement expense of $2,810,000 was recorded in the condensed consolidated statements of operations and comprehensive loss.

The Company granted ChubeWorkx registration rights with respect to the Shares. The Company filed a registration statement on Form S-3 with the Securities and Exchange Commission on August 18, 2020, which was declared effected on September 8, 2020, for the resale of such Shares.

As of the September 8, 2020 (the "Release Date"), the Company delivered and completed the full transfer to ChubeWorkx of the Shares in accordance with the SAGR, and, therefore, 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 were 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 was terminated, and ChubeWorkx will automatically and irrevocably released all security interests and liens created under the Security Agreement or otherwise as security for the Company obligations under the Prior Agreements.

Litigation

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 disputed 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. In anticipation of the case being settled, on October 20, 2020, the Court administratively closed the case. On November 13, 2020, the parties entered into a settlement agreement without either party admitting liability, effective as of November 3, 2020. The settlement agreement requires the Company to make a lump sum payment of $1,350,000 to Novotek within 60 days. The settlement expense is included in Loss from Discontinued Operations on the Condensed Consolidated Statement of Operations and Comprehensive Loss for the three and nine months ended September 30, 2020 and the Company's obligation is included in Current Liabilities – Discontinued Operations on the Condensed Consolidated Balance Sheet as of September 30, 2020.

Note 9 – 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 served as the Company's Interim Chief Financial Officer. Pursuant to a mutual understanding between the Company and Mr. Yeaton, Mr. Yeaton's employment as Interim Chief Financial Officer ceased as of August 19, 2020. During his service as the Company's Interim Chief Financial Officer Mr. Yeaton was the managing principal of Financial Consulting Strategies ("FCS"), and the Company had an ongoing relationship with FCS with FCS continuing to provide accounting services to the Company, as of September 30, 2020. As of September 30, 2020 FCS was considered to be a related party. During the three months ended September 30, 2020 and 2019, the Company incurred costs of $4,650 and $15,382, respectively and during the nine months ended September 30, 2020 and 2019, the Company incurred costs of $13,900 and $38,888, respectively with FCS in connection with these services. As of September 30, 2020, and December 31, 2019 the Company had an obligation to FCS in the amounts of $4,650 and $18,323, respectively, for these services which is included in trade and other payables in the Condensed Consolidated Balance Sheet.

During the nine months ended September 30, 2020 and 2019, pursuant to his October 2018 employment agreement, the Company issued 0 andl ,407 shares of common stock under the 2017 Plan to Mr. Yeaton, with a fair value on the date of grant, of $0 and $23,129, respectively.

As of September 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 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 September 30, 2020 and 2019 of $4,277 and $5,860, respectively and $27,201 and $22,748 during the nine months ended September 30, 2020 and 2019, respectively.

Note 11 – Subsequent Events.

Agreement and Plan of Merger and Reorganization

On November 11, 2020, the Company, XYZ Merger Sub Inc., a Florida corporation and a wholly-owned subsidiary of the Company ("*Merger Sub*"), and MYMD Pharmaceuticals, Inc., a privately-held Florida corporation ("*MYMD*"), entered into an Agreement and Plan of Merger and Reorganization (the "*Merger Agreement*"), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into MYMD, with MYMD being the surviving corporation and becoming a wholly-owned subsidiary of the Company (the "*Merger*"). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended. In addition, in connection with the execution of the Merger Agreement, Akers agreed to advance a bridge loan of up to $3,000,000 to MYMD pursuant to a Secured Promissory Note.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the "*Effective Time*"), (i) each outstanding share of common stock of MYMD ("*MYMD common stock*"), will be converted into the right to receive the number of shares of the common stock of Akers (the "*Akers common stock*") equal to the exchange ratio described below; and (ii) each outstanding stock option of MYMD (collectively, "*MYMD options*") that has not previously been exercised prior to the Effective Time, whether or not vested, will be assumed by the Company subject to certain terms contained in the Merger Agreement (including, but not limited to, the amendment of such stock option to extend the term of such stock option for a period expiring on the second-year anniversary of the Effective Time). In connection with the Merger, each holder of options is required to enter into a Lock-Up Agreement/Leak-Out Agreement with respect to the shares of Akers common stock issued upon the exercise of such option. Also, not later than 30 days after the second-year anniversary of the Effective Date, the Company will pay stockholders of MYMD on a pro rata basis an amount in cash equal to the aggregate cash proceeds received by Akers from the exercise of any MYMD options assumed by the Company prior to the second-year anniversary of the Effective Time; provided, however, the amount of such payment will not exceed the maximum amount of cash consideration that may be received by stockholders of MYMD without affecting the intended tax consequences of the Merger.

Additionally, under the terms of the Merger Agreement, the Company has agreed to pay contingent consideration to MYMD stockholders in the form of milestone payments payable in shares of Akers common stock (collectively, the "*Milestone Payments*"). The Milestone Payments are payable in the dollar amounts set forth in the chart below upon the achievement of the milestone events set forth opposite such dollar amount during the 36-month period immediately following the Effective Date (the "*Milestone Period*") as follows:

Milestone Event	Milestone Payment
Market capitalization of Akers for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period is equal to or greater than $500 million (the "*First Milestone Event*").	$20 million.
For every $250 million incremental increase in market capitalization of Akers after the First Milestone Event to the extent such incremental increase occurs for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period, up to a $1 billion market capitalization of Akers.	$10 million per each incremental increase (it being understood, however, that, if such incremental increase results in market capitalization equal to $1 billion , such $20 million payment in respect of such incremental increase shall be payable without duplication of any amount payable in respect of a Second Milestone Event).
Market Capitalization of Akers for at least 10 trading days during any 20 consecutive trading day period is equal to or greater than $1 billion (the "*Second Milestone Event*").	$25 million.
For every $1 billion incremental increase in market capitalization of Akers after the Second Milestone Event to the extent such incremental increase occurs for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period.	$25 million per each incremental increase.

Each milestone payment will be payable in shares of common stock of Akers (the "Milestone Shares"), with the number of Milestone Shares to be issued determined by dividing the applicable Milestone Payment amount by the volume-weighted average price of a share of Akers' common stock during the 10 trading days immediately preceding the achievement of the milestone event; provided, however, that in no event shall the price of a share of Akers common stock used to determine the number of Milestone Shares to be issued be deemed to be less than $5.00 per share (as adjusted for stock splits, stock dividends, reverse stock splits, and the like occurring after the Closing Date).

Notwithstanding the above, the number of Milestone Shares payable by Akers shall not exceed the number of shares of Akers common stock to be issued to MyMD stockholders at the Effective Time in connection with the Merger (as described in the following paragraph).

Under the exchange ratio formula in the Merger Agreement, upon the closing of the Merger, the former MYMD securityholders are expected to own approximately 80% of the aggregate number of shares of Akers common stock issued and outstanding immediately following the consummation of the Merger (the "*Post-Closing Shares*"), and the stockholders of the Company as of immediately prior to the Merger are expected to own approximately 20% of the aggregate number of Post-Closing Shares.

Immediately prior to the Effective Time, the name of the Company will be changed from "Akers Biosciences, Inc." to "MyMD Pharmaceuticals, Inc." At the Effective Time, the Merger Agreement contemplates that the board of directors of the Company will consist of seven directors, with (i) Akers having the right to designate up to four members and (ii) MYMD having the right to designate up to three members. The officers of the Company immediately after the Effective Time will be elected by the board of directors of Akers.

The Merger Agreement contains customary representations, warranties and covenants made by the Company and MYMD, including covenants relating to obtaining the requisite approvals of the stockholders of the Company and MYMD, indemnification of directors and officers, and the Company's and MYMD's conduct of their respective businesses between the date of signing the Merger Agreement and the closing of the Merger. Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of Akers and MYMD.

The Merger Agreement contains certain termination rights for both the Company and MYMD, including, among other things, (a) Akers may, upon written notice, extend the originally scheduled End Date (defined in the Merger Agreement as April 15, 2021) to May 15, 2021 (the "*Extended Date*") so long as (i) Akers and Merger Sub are not then in material breach of any provision of the Merger Agreement and (ii) within three calendar days of the written request by MYMD, Akers makes an additional loan to MYMD of up to $600,000, which will have the same terms and conditions of the Note (as defined below and such additional note "*Second Note*") and (b) Akers may, upon written notice, extend the Extended Date to June 30, 2021, so long as (i) Akers and Merger Sub are not then in material breach of any provision of the Merger Agreement, (ii) on the effective date of such extension, the loan amount evidenced by the Note and the Second Note may, at the sole option of MYMD upon written notice to Akers, be converted into shares of MYMD common stock at a conversion price of $2.00 per share, subject to certain adjustments and (iii) Akers will, at MYMD's request, either (at the option of MYMD); (A) subscribe for 300,000 shares of MYMD common stock at a subscription price of $2.00 per share, subject to certain adjustments as set forth in the Merger Agreement, or (B) makes an additional loan to MYMD of up to $600,000, which will have the same terms and conditions of the Note (the "*Third Note*," and all amounts outstanding under the Note, the Second Note and the Third Note, the "*Loan Amount*"). In addition, if Akers terminates the Merger Agreement under certain circumstances specified therein, the Loan Amount, if any, at the sole discretion of MYMD, will be convertible into shares of common stock of MYMD at a conversion price of $2.00 per share upon delivery of written notice by MYMD to Akers within 30 calendar days after the effective date of termination of the Merger Agreement.

The Merger Agreement also contemplates that the Company will seek approval from its stockholders to effect a reverse stock split, if applicable, at a reverse stock split ratio mutually agreed to by the Company and MYMD and within the range approved by the Company's stockholders immediately prior to the Effective Time, which range shall be sufficient to cause the price of Akers common stock on the Nasdaq Capital Market following such reverse stock split and the Effective Time to be no less than $5.00 per share. In addition, under the Merger Agreement, Akers may, in its discretion, consummate a spin-off of all or a part of its pre-closing assets and liabilities (the "*Spin-Off*").

In connection with the Merger, the Company will seek the approval of its stockholders of (a) the transactions contemplated in the Merger Agreement, including the issuance of Akers common stock pursuant to the Merger and (b) the amendment of its certificate of incorporation, including for purposes of (i) effectuating a reverse split of Akers common stock at a ratio to be determined by a split ratio to be mutually agreed to by Akers and MYMD within the range approved by the Company's stockholders immediately prior to the Effective Time and on certain terms as specifically described herein, (ii) change Akers' name to "MyMD Pharmaceuticals, Inc.," and (c) to the extent necessary, the Spin-Off.

In accordance with the terms of the Merger Agreement, (i) the officers and directors of Akers have each entered into a voting agreement with MYMD (the "*Akers Voting Agreements*"), and (ii) the officers, directors and certain affiliated stockholders of MYMD have each entered into a voting agreement with Akers (the "*MYMD Voting Agreements*," together with the Akers Voting Agreements, the "*Voting Agreements*"). The Voting Agreements place certain restrictions on the transfer of the shares of Akers and MYMD held by the respective signatories thereto and include covenants as to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any actions that could adversely affect the consummation of the Merger.

Concurrently with the execution of the Merger Agreement or prior to the Closing, the officers and directors of Akers, and the officers, directors and certain stockholders of MYMD, each entered into lock-up/leak-out agreements (the "*Lock-Up/Leak-Out Agreements*") pursuant to which they have agreed, among other things, not to sell or dispose of (subject to certain exceptions specified therein) any shares of Akers common stock which are or will be beneficially owned by them at the Effective Time or which are acquired thereafter, with such shares being released from such restrictions 180 days after the Effective Time. After the expiration of such initial 180-day period, such stockholders will be subject to a 180-day leak-out period during which they may not sell shares in excess of the amount permitted by the Rule 144 volume limitations (even if such stockholder is not currently subject to such provisions of Rule 144), which leak- out period shall be extended for an additional 180 days for any shares of Akers common stock issued upon the exercise of existing options or warrants.

Secured Promissory Note

As set forth above, in connection with the execution of the Merger Agreement, Akers will advance a bridge loan to MYMD in an amount of up to $3,000,000 pursuant to a Secured Promissory Note (the "*Note*"). Advances under the Note will be made in accordance with MYMD's cash needs pursuant to a pre-agreed operating budget for MYMD. The Note accrues interest on the outstanding principal amount at the rate of 5% per annum and matures on the earliest of (i) April 15, 2022, (ii) upon demand of Akers in the event the Merger is consummated, or (iii) the date on which MYMD's obligations under the Note are accelerated in accordance with the terms of the Note. As set forth above, in the event the Merger Agreement is terminated by MYMD upon a change in Akers' board of directors' recommendations to the Akers stockholders in connection with the Merger Agreement and certain other circumstances specified in the Merger Agreement, the principal amount of the Note, and all accrued and unpaid interest thereon, shall be converted into shares of MYMD common stock at a conversion price of $2.00 per share. MYMD may prepay the Note in whole or in part at any time or from time to time at its sole discretion. Under the terms of the Note, if, at any time after the termination or expiration of the Merger Agreement, MYMD (i) incurs any debt other than Permitted Debt (as defined in the Note), (ii) issues any equity interests, or (iii) consummates any Asset Sale or Recovery Event (each as defined in the Note) then, in each case, no later than two business days after MYMD receives the net cash proceeds of such incurrence, issuance or other action, then MYMD shall be required to prepay an amount under the Note equal to the net cash proceeds received, up to the total amount of the advances made under the Note at such time, including all accrued and unpaid interest thereon, of the Note. The payment and performance of all obligations under the Note are secured by a first priority security interest in all of MYMD's right, title and interest in and to its assets as collateral.

Securities Purchase Agreement

Concurrently with the Merger Agreement, on November 11, 2020, the Company entered into a Securities Purchase Agreement (the "*Purchase Agreement*") with certain institutional and accredited investors (the "*Purchasers*"), pursuant to which the Company agreed to issue and sell to the Purchasers in a private placement (the "*Private Placement*") (i) an aggregate of 9,765,933 shares of Akers common stock, at an offering price of $1.85 per share or, at the election of each investor, pre-funded warrants ("*Pre-Funded Warrants*"), and (ii) for each share of Akers common stock (or for each Pre-Funded Warrant, as applicable) purchased in the Private Placement, a common warrant (the "*Investor Warrants*" and together with the Pre-Funded Warrants, the "*Warrants*") to purchase one share of Akers common stock, for gross proceeds of approximately $18.1 million before the deduction of placement agent fees and expenses and estimated offering expenses.

In the Private Placement, the Company will issue up to an aggregate of 9,765,933 shares of Akers common stock (the "*Shares*") and Pre-Funded Warrants. The Pre-Funded Warrants will be immediately exercisable, will have an exercise price of $0.01 and may be exercised at any time after their original issuance until such Pre-funded Warrants are exercised in full. The Investor Warrants are exercisable immediately upon issuance and terminate five and a half years following issuance. The Investor Warrants have an exercise price of $2.06 per share and represent the right to purchase an aggregate of up to 9,765,933 shares of Akers common stock. A holder of a Warrant will not have the right to exercise any portion of its Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or 9.99% at the election of the holder prior to the date of issuance) of the number of shares of Akers common stock issued and outstanding immediately after giving effect to such exercise (the "*Beneficial Ownership Limitation*"); provided, however, that upon 61 days' prior notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, but in no event shall the Beneficial Ownership Limitation exceed 9.99%.

In the Purchase Agreement, the Company has agreed not to (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of, any shares of the Company's common stock or any securities convertible into or exercisable or exchangeable for shares of the Company's common stock at an effective price less than the exercise price of the Investor Warrants or (ii) file any registration statement or any amendment or supplement thereto, other than as contemplated under the Purchase Agreement, for a period of 90 days following the later of (x) the date the Registration Statement (as defined below) is declared effective by the SEC and (y) the record date for the Company's stockholder meeting called to approve the Merger. In addition, the Company agreed not to effect or enter into an agreement to effect any issuance of the Company's common stock or common stock equivalents involving a variable rate transaction (as defined in the Purchase Agreement) from the date of the Purchase Agreement until such time as no Purchaser holds any of the Investor Warrants, subject to certain exceptions (including the issuance of any of the Company's common stock pursuant to the Merger Agreement).

The Purchase Agreement provides that (i) within 10 days following the date that the Company first files a proxy statement with the SEC in connection with the Merger (including by means of a registration statement on Form S-4), the Company shall file a registration statement (the "*Registration Statement*") under the Securities Act of 1933, as amended (the "*Securities Act*") for the resale of all of the Shares and the shares of the Company's common stock issuable upon exercise of the Warrants (the "*Warrant Shares*") by the Purchasers and (ii) the Company shall use commercially reasonable efforts to cause such Registration Statement to be declared effective within 60 days of the filing thereof (or 90 days in the event of a full review); provided, however, that the Company shall not be required to register any Shares or Warrant Shares that are eligible for resale pursuant to Rule 144 under the Securities Act (assuming cashless exercise of the Warrants).

The closing of the Private Placement is subject to the satisfaction of customary closing conditions set forth in the Purchase Agreementand is expected to occur on or around November 16, 2020.

On October 31, 2020, the Company entered into an engagement letter (the "*Engagement Letter*") with Katalyst Securities LLC (the "*Placement Agent*"), pursuant to which the Placement Agent agreed to serve as the non-exclusive placement agent for the Company, on a reasonable best efforts basis, in connection with the Private Placement. The Company has agreed to pay the Placement Agent an aggregate cash fee equal to 6.5% of the gross proceeds received in the Private Placement and reimburse the Placement Agent's expenses in the Private Placement up to $25,000. In addition, the Company has agreed to grant to the Placement Agent warrants to purchase up to 390,368 shares of the Company's common stock at an exercise price of $1.85 (the "*Placement Agent Warrants*"). The 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 closing of the Merger.

The gross proceeds to the Company from the Private Placement, before deducting the Placement Agent's fees and expenses and estimated offering expenses, and excluding the proceeds, if any, from the exercise of the Warrants, are expected to be approximately $18.1 million. The Company currently intends to use the proceeds from the Private Placement in order to satisfy the closing conditions set forth in the Merger Agreement that requires the Company to have at least $25 million on the closing date of the Merger, and for general working capital purposes. In addition, the Company will pay approximately $1.8 million of the proceeds from the Private Placement to the former members of Cystron pursuant to the MIPA.

The Shares, the Pre-Funded Warrants, the Investor Warrants, the Placement Agent Warrants and the shares of Akers common stock issuable upon the exercise of such warrants are not being registered under the Securities Act, are not being offered pursuant to the Registration Statement, and are being offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

To induce the Purchasers to enter into the Purchase Agreement, on November 11, 2020, the Company entered into a Lock-Up and Support Agreement (the "*Support Agreement*") with certain of its stockholders named therein, pursuant to which, from the date of the Support Agreement until May 31, 2021, such stockholders agreed to vote their respective shares of Akers common stock in favor of each matter proposed and recommended for approval by the Company's board of directors or management at every stockholders' meeting.

Executive Chairman Cash Bonus

On November 11, 2020, the Board approved a special cash bonus of $150,000 to Christopher C. Schreiber, the Company's Executive Chairman and President for his service in year-to-date 2020.

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 Securities and Exchange Commission (the "SEC" and such reports, 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:

- the occurrence of any event, change or other circumstances that could give rise to the termination of an agreement and plan of merger and reorganization (the "Merger Agreement"), dated November 11, 2020, by and among us, XYZ Merger Sub Inc. ("Merger Sub"), and MYMD Pharmaceuticals ("MYMD");
- our stockholders failing to approve the share issuances for the merger with MYMD (the "Merger") contemplated by the Merger Agreement;
- an increase in the amount of costs, fees, expenses, and other charges related to the Merger Agreement;
- risks arising from the diversion of management's attention from our ongoing business operations due to the Merger;
- risks associated with our ability to identify and realize business opportunities following the Merger;
- our ability to complete the private placement pursuant to that certain securities purchase agreement, dated November 11, 2020, by and among us and certain institutional and accredited investors (the "Purchase Agreement");

- 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 or at all;
- 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 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;
- risks of mergers and acquisitions including the time and cost of implementing transactions and the potential failure to achieve expected gains, revenue growth or expense savings; and
- the impact of the recent COVID-19 pandemic 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.

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 November 10, 2020, approximately 49.7 million cases were reported globally and 1.2 million 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 3,900 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 U.S. Food and Drug Administration ("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 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. On August 27, 2020, we announced with Premas positive proof of concept results from the animal studies conducted during a four-week test of the COVID-19 Vaccine Candidate in mice. The test had two primary endpoints, safety and immune responses, both of which were met. The study consisted of 50 mice, divided into 10 cohorts dosed with 5, 10 and 20 micrograms of the COVID-19 Vaccine Candidate. The COVID-19 Vaccine Candidate was generally well tolerated and safe at all doses, with no adverse events reported. The COVID-19 Vaccine Candidate was safe even at higher doses and generated a robust immune response against the three SARS-Cov2 antigens, S, E, and M. The COVID-19 Vaccine Candidate elicited neutralizing antibody titers levels in all the dose cohorts starting from 5 microgram to 20 microgram dose regimens. After three doses in mice, all the groups' cohorts showed binding antibody levels similar to convalescent patients' levels. 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 our board of directors 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 COVID-19 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 continuation of the COVID-19 pandemic 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

Agreement and Plan of Merger and Reorganization

On November 11, 2020, the Company, XYZ Merger Sub Inc., a Florida corporation and a wholly-owned subsidiary of the Company ("*Merger Sub*"), and MYMD Pharmaceuticals, Inc., a privately-held Florida corporation ("*MYMD*"), entered into an Agreement and Plan of Merger and Reorganization (the "*Merger Agreement*"), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into MYMD, with MYMD being the surviving corporation and becoming a wholly-owned subsidiary of the Company (the "*Merger*"). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended. In addition, in connection with the execution of the Merger Agreement, Akers agreed to advance a bridge loan of up to $3,000,000 to MYMD pursuant to a Secured Promissory Note.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the "*Effective Time*"), (i) each outstanding share of common stock of MYMD ("*MYMD common stock*"), will be converted into the right to receive the number of shares of the common stock of Akers (the "*Akers common stock*") equal to the exchange ratio described below; and (ii) each outstanding stock option of MYMD (collectively, "*MYMD options*") that has not previously been exercised prior to the Effective Time, whether or not vested, will be assumed by the Company subject to certain terms contained in the Merger Agreement (including, but not limited to, the amendment of such stock option to extend the term of such stock option for a period expiring on the second-year anniversary of the Effective Time). In connection with the Merger, each holder of options is required to enter into a Lock-Up Agreement/Leak-Out Agreement with respect to the shares of Akers common stock issued upon the exercise of such option. Also, not later than 30 days after the second-year anniversary of the Effective Date, the Company will pay stockholders of MYMD on a pro rata basis an amount in cash equal to the aggregate cash proceeds received by Akers from the exercise of any MYMD options assumed by the Company prior to the second-year anniversary of the Effective Time; provided, however, the amount of such payment will not exceed the maximum amount of cash consideration that may be received by stockholders of MYMD without affecting the intended tax consequences of the Merger.

Additionally, under the terms of the Merger Agreement, the Company has agreed to pay contingent consideration to MYMD stockholders in the form of milestone payments payable in shares of Akers common stock (collectively, the "*Milestone Payments*"). The Milestone Payments are payable in the dollar amounts set forth in the chart below upon the achievement of the milestone events set forth opposite such dollar amount during the 36-month period immediately following the Effective Date (the "*Milestone Period*") as follows:

Milestone Event	Milestone Payment
Market capitalization of Akers for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period is equal to or greater than $500 million (the "*First Milestone Event*").	$20 million.
For every $250 million incremental increase in market capitalization of Akers after the First Milestone Event to the extent such incremental increase occurs for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period, up to a $1 billion market capitalization of Akers.	$10 million per each incremental increase (it being understood, however, that, if such incremental increase results in market capitalization equal to $1 billion , such $20 million payment in respect of such incremental increase shall be payable without duplication of any amount payable in respect of a Second Milestone Event).
Market Capitalization of Akers for at least 10 trading days during any 20 consecutive trading day period is equal to or greater than $1 billion (the "*Second Milestone Event*").	$25 million.
For every $1 billion incremental increase in market capitalization of Akers after the Second Milestone Event to the extent such incremental increase occurs for at least 10 trading days during any 20 consecutive trading day period during the Milestone Period.	$25 million per each incremental increase.

Each milestone payment will be payable in shares of common stock of Akers (the "Milestone Shares"), with the number of Milestone Shares to be issued determined by dividing the applicable Milestone Payment amount by the volume-weighted average price of a share of Akers' common stock during the 10 trading days immediately preceding the achievement of the milestone event; provided, however, that in no event shall the price of a share of Akers common stock used to determine the number of Milestone Shares to be issued be deemed to be less than $5.00 per share (as adjusted for stock splits, stock dividends, reverse stock splits, and the like occurring after the Closing Date).

Notwithstanding the above, the number of Milestone Shares payable by Akers shall not exceed the number of shares of Akers common stock to be issued to MyMD stockholders at the Effective Time in connection with the Merger (as described in the following paragraph).

Under the exchange ratio formula in the Merger Agreement, upon the closing of the Merger, the former MYMD securityholders are expected to own approximately 80% of the aggregate number of shares of Akers common stock issued and outstanding immediately following the consummation of the Merger (the "*Post-Closing Shares*"), and the stockholders of the Company as of immediately prior to the Merger are expected to own approximately 20% of the aggregate number of Post-Closing Shares.

Immediately prior to the Effective Time, the name of the Company will be changed from "Akers Biosciences, Inc." to "MyMD Pharmaceuticals, Inc." At the Effective Time, the Merger Agreement contemplates that the board of directors of the Company (the "*Board*") will consist of seven directors, with (i) Akers having the right to designate up to four members and (ii) MYMD having the right to designate up to three members. The officers of the Company immediately after the Effective Time will be elected by the Board.

The Merger Agreement contains customary representations, warranties and covenants made by the Company and MYMD, including covenants relating to obtaining the requisite approvals of the stockholders of the Company and MYMD, indemnification of directors and officers, and the Company's and MYMD's conduct of their respective businesses between the date of signing the Merger Agreement and the closing of the Merger. Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of Akers and MYMD.

The Merger Agreement contains certain termination rights for both the Company and MYMD, including, among other things, (a) Akers may, upon written notice, extend the originally scheduled End Date (defined in the Merger Agreement as April 15, 2021) to May 15, 2021 (the "*Extended Date*") so long as (i) Akers and Merger Sub are not then in material breach of any provision of the Merger Agreement and (ii) within three calendar days of the written request by MYMD, Akers makes an additional loan to MYMD of up to $600,000, which will have the same terms and conditions of the Note (as defined below and such additional note "*Second Note*") and (b) Akers may, upon written notice, extend the Extended Date to June 30, 2021, so long as (i) Akers and Merger Sub are not then in material breach of any provision of the Merger Agreement, (ii) on the effective date of such extension, the loan amount evidenced by the Note and the Second Note may, at the sole option of MYMD upon written notice to Akers, be converted into shares of MYMD common stock at a conversion price of $2.00 per share, subject to certain adjustments and (iii) Akers will, at MYMD's request, either (at the option of MYMD); (A) subscribe for 300,000 shares of MYMD common stock at a subscription price of $2.00 per share, subject to certain adjustments as set forth in the Merger Agreement, or (B) makes an additional loan to MYMD of up to $600,000, which will have the same terms and conditions of the Note (the "*Third Note*," and all amounts outstanding under the Note, the Second Note and the Third Note, the "*Loan Amount*"). In addition, if Akers terminates the Merger Agreement under certain circumstances specified therein, the Loan Amount, if any, at the sole discretion of MYMD, will be convertible into shares of common stock of MYMD at a conversion price of $2.00 per share upon delivery of written notice by MYMD to Akers within 30 calendar days after the effective date of termination of the Merger Agreement.

The Merger Agreement also contemplates that the Company will seek approval from its stockholders to effect a reverse stock split, if applicable, at a reverse stock split ratio mutually agreed to by the Company and MYMD and within the range approved by the Company's stockholders immediately prior to the Effective Time, which range shall be sufficient to cause the price of Akers common stock on the Nasdaq Capital Market following such reverse stock split and the Effective Time to be no less than $5.00 per share. In addition, under the Merger Agreement, Akers may, in its discretion, consummate a spin-off of all or a part of its pre-closing assets and liabilities, all as more specifically described therein (the "*Spin-Off*").

In connection with the Merger, the Company will seek the approval of its stockholders of (a) the transactions contemplated in the Merger Agreement, including the issuance of Akers common stock pursuant to the Merger and (b) the amendment of its certificate of incorporation, including for purposes of (i) effectuating a reverse split of Akers common stock at a ratio to be determined by a split ratio to be mutually agreed to by Akers and MYMD within the range approved by the Company's stockholders immediately prior to the Effective Time and on certain terms as specifically described herein, (ii) change Akers' name to "MyMD Pharmaceuticals, Inc.," and (c) to the extent necessary, the Spin-Off.

In accordance with the terms of the Merger Agreement, (i) the officers and directors of Akers have each entered into a voting agreement with MYMD (the "*Akers Voting Agreements*"), and (ii) the officers, directors and certain affiliated stockholders of MYMD have each entered into a voting agreement with Akers (the "*MYMD Voting Agreements*," together with the Akers Voting Agreements, the " *Voting Agreements*"). The Voting Agreements place certain restrictions on the transfer of the shares of Akers and MYMD held by the respective signatories thereto and include covenants as to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any actions that could adversely affect the consummation of the Merger.

Concurrently with the execution of the Merger Agreement or prior to the Closing, the officers and directors of Akers, and the officers, directors and certain stockholders of MYMD, each entered into lock-up/leak-out agreements (the "*Lock-Up/Leak-Out Agreements*") pursuant to which they have agreed, among other things, not to sell or dispose of (subject to certain exceptions specified therein) any shares of Akers common stock which are or will be beneficially owned by them at the Effective Time or which are acquired thereafter, with such shares being released from such restrictions 180 days after the Effective Time. After the expiration of such initial 180-day period, such stockholders will be subject to a 180-day leak-out period during which they may not sell shares in excess of the amount permitted by the Rule 144 volume limitations (even if such stockholder is not currently subject to such provisions of Rule 144), which leak- out period shall be extended for an additional 180 days for any shares of Akers common stock issued upon the exercise of existing options or warrants.

Secured Promissory Note

As set forth above, in connection with the execution of the Merger Agreement, Akers agreed to advance a bridge loan to MYMD in an amount of up to $3,000,000 pursuant to a Secured Promissory Note (the "*Note*"). Advances under the Note will be made in accordance with MYMD's cash needs pursuant to a pre-agreed operating budget for MYMD. The Note accrues interest on the outstanding principal amount at the rate of 5% per annum and matures on the earliest of (i) April 15, 2022, (ii) upon demand of Akers in the event the Merger is consummated, or (iii) the date on which MYMD's obligations under the Note are accelerated in accordance with the terms of the Note. As set forth above, in the event the Merger Agreement is terminated by MYMD upon a change in Akers' board of directors' recommendations to the Akers stockholders in connection with the Merger Agreement and certain other circumstances specified in the Merger Agreement, the principal amount of the Note, and all accrued and unpaid interest thereon, shall be converted into shares of MYMD common stock at a conversion price of $2.00 per share. MYMD may prepay the Note in whole or in part at any time or from time to time at its sole discretion. Under the terms of the Note, if, at any time after the termination or expiration of the Merger Agreement, MYMD (i) incurs any debt other than Permitted Debt (as defined in the Note), (ii) issues any equity interests, or (iii) consummates any Asset Sale or Recovery Event (each as defined in the Note) then, in each case, no later than two business days after MYMD receives the net cash proceeds of such incurrence, issuance or other action, then MYMD shall be required to prepay an amount under the Note equal to the net cash proceeds received, up to the total amount of the advances made under the Note at such time, including all accrued and unpaid interest thereon, of the Note. The payment and performance of all obligations under the Note are secured by a first priority security interest in all of MYMD's right, title and interest in and to its assets as collateral.

Securities Purchase Agreement

Concurrently with the Merger Agreement, on November 11, 2020, the Company entered into a Securities Purchase Agreement (the "*Purchase Agreement*") with certain institutional and accredited investors (the "*Purchasers*"), pursuant to which the Company agreed to issue and sell to the Purchasers in a private placement (the "*Private Placement*") (i) an aggregate of 9,765,933 shares of Akers common stock, at an offering price of $1.85 per share or, at the election of each investor, pre-funded warrants (*Pre-Funded Warrants*"), and (ii) for each share of Akers common stock (or for each Pre-Funded Warrant, as applicable) purchased in the Private Placement, a common warrant (the "*Investor Warrants*" and together with the Pre-Funded Warrants, the "*Warrants*") to purchase one share of Akers common stock, for gross proceeds of approximately $18.1 million before the deduction of placement agent fees and expenses and estimated offering expenses.

In the Private Placement, the Company will issue up to an aggregate of 9,765,933 shares of Akers common stock (the "*Shares*") and Pre-Funded Warrants. The Pre-Funded Warrants will be immediately exercisable, will have an exercise price of $0.01 and may be exercised at any time after their original issuance until such Pre-funded Warrants are exercised in full. The Investor Warrants are exercisable immediately upon issuance and terminate five and a half years following issuance. The Investor Warrants have an exercise price of $2.06 per share and represent the right to purchase an aggregate of up to 9,765,933 shares of Akers common stock. A holder of a Warrant will not have the right to exercise any portion of its Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or 9.99% at the election of the holder prior to the date of issuance) of the number of shares of Akers common stock issued and outstanding immediately after giving effect to such exercise (the "*Beneficial Ownership Limitation*"); provided, however, that upon 61 days' prior notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, but in no event shall the Beneficial Ownership Limitation exceed 9.99%.

In the Purchase Agreement, the Company has agreed not to (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of, any shares of the Company's common stock or any securities convertible into or exercisable or exchangeable for shares of the Company's common stock at an effective price less than the exercise price of the Investor Warrants or (ii) file any registration statement or any amendment or supplement thereto, other than as contemplated under the Purchase Agreement, for a period of 90 days following the later of (x) the date the Registration Statement (as defined below) is declared effective by the SEC and (y) the record date for the Company's stockholder meeting called to approve the Merger. In addition, the Company agreed not to effect or enter into an agreement to effect any issuance of the Company's common stock or common stock equivalents involving a variable rate transaction (as defined in the Purchase Agreement) from the date of the Purchase Agreement until such time as no Purchaser holds any of the Investor Warrants, subject to certain exceptions (including the issuance of any of the Company's common stock pursuant to the Merger Agreement).

The Purchase Agreement provides that (i) within 10 days following the date that the Company first files a proxy statement with the SEC in connection with the Merger (including by means of a registration statement on Form S-4), the Company shall file a registration statement (the "*Registration Statement*") under the Securities Act of 1933, as amended (the "*Securities Act*") for the resale of all of the Shares and the shares of the Company's common stock issuable upon exercise of the Warrants (the "*Warrant Shares*") by the Purchasers and (ii) the Company shall use commercially reasonable efforts to cause such Registration Statement to be declared effective within 60 days of the filing thereof (or 90 days in the event of a full review); provided, however, that the Company shall not be required to register any Shares or Warrant Shares that are eligible for resale pursuant to Rule 144 under the Securities Act (assuming cashless exercise of the Warrants).

The closing of the Private Placement is subject to the satisfaction of customary closing conditions set forth in the Purchase Agreement and is expected to occur on or around November 16, 2020.

On October 31, 2020, the Company entered into an engagement letter (the "*Engagement Letter*") with Katalyst Securities LLC (the "*Placement Agent*"), pursuant to which the Placement Agent agreed to serve as the non-exclusive placement agent for the Company, on a reasonable best efforts basis, in connection with the Private Placement. The Company has agreed to pay the Placement Agent an aggregate cash fee equal to 6.5% of the gross proceeds received in the Private Placement and reimburse the Placement Agent's expenses in the Private Placement up to $25,000. In addition, the Company has agreed to grant to the Placement Agent warrants to purchase up to 390,368 shares of the Company's common stock at an exercise price of $1.85 (the "*Placement Agent Warrants*"). The 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 closing of the Merger.

The gross proceeds to the Company from the Private Placement, before deducting the Placement Agent's fees and expenses and estimated offering expenses, and excluding the proceeds, if any, from the exercise of the Warrants, are expected to be approximately $18.1 million. The Company currently intends to use the proceeds from the Private Placement in order to satisfy the closing conditions set forth in the Merger Agreement that requires the Company to have at least $25 million on the closing date of the Merger, and for general working capital purposes. In addition, the Company will pay approximately $1.8 million of the proceeds from the Private Placement to the former members of Cystron pursuant to the MIPA.

The Shares, the Pre-Funded Warrants, the Investor Warrants, the Placement Agent Warrants and the shares of Akers common stock issuable upon the exercise of such warrants are not being registered under the Securities Act, are not being offered pursuant to the Registration Statement, and are being offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

To induce the Purchasers to enter into the Purchase Agreement, on November 11, 2020, the Company entered into a Lock-Up and Support Agreement (the "*Support Agreement*") with certain of its stockholders named therein, pursuant to which, from the date of the Support Agreement until May 31, 2021, such stockholders agreed to vote their respective shares of Akers common stock in favor of each matter proposed and recommended for approval by the Company's board of directors or management at every stockholders' meeting.

Executive Chairman Cash Bonus

On November 11, 2020, the Board approved a special cash bonus of $150,000 to Christopher C. Schreiber, the Company's Executive Chairman and President for his service in year-to-date 2020.

Rights Agreement

The Board declared a dividend of one preferred share purchase right (a "Right") for each of our issued and outstanding shares of common stock, no par value per share. The dividend is payable to the stockholders of record on September 21, 2020 (the "Record Date"). Each Right entitles the registered holder, subject to the terms of the Rights Agreement (as defined below), to purchase from us one one-thousandth of a share of our Series E Junior Participating Preferred Stock, no par value with a stated value of $0.001 (the "Preferred Stock") at $15.00 (the "Purchase Price"), subject to certain adjustments. The description and terms of the Rights are set forth in the Rights Agreement dated as of September 9, 2020 (the "Rights Agreement") between us and VStock Transfer, LLC, as Rights Agent (the "Rights Agent").

The Rights will not be exercisable until the earlier to occur of (i) the tenth business day following a public announcement or filing that a person has, or affiliates or associates of such person have, become an "Acquiring Person," which is defined as a person, or affiliates or associates of such person, who, at any time after the date of the Rights Agreement, has acquired, or obtained the right to acquire, Beneficial Ownership of 10% or more of our outstanding shares of common stock, subject to certain exceptions, or (ii) the tenth business day (or such later date as may be determined by action of the Board prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person becoming an Acquiring Person (the earlier of such dates being called the "Distribution Date"). Beneficial Ownership, as defined in the Rights Agreement, includes certain interests in securities created by derivatives contracts, which are beneficially owned, directly or indirectly, by a counterparty (or any of such counterparty's affiliates or associates) under any derivatives contract to which such person or any of such person's affiliates or associates is a receiving party (as such terms are defined in Rights Agreement), subject to certain limitations.

Until the Distribution Date, (i) the Rights will be evidenced by the common stock certificates (or, for uncertificated shares of common stock, by the book-entry account that evidences record ownership of such shares) and will be transferred with, and only with, such common stock, and (ii) new common stock certificates issued after the Record Date will contain a legend incorporating the Rights Agreement by reference (for book entry common stock, this legend will be contained in the notations in book entry accounts). Until the earlier of the Distribution Date and the Expiration Date (defined below), the transfer of any shares of common stock outstanding on the Record Date will also constitute the transfer of the Rights associated with such shares of common stock. As soon as practicable after the Distribution Date, the Rights Agent will send by first-class, insured, postage prepaid mail, to each record holder of the common stock as of the close of business on Distribution Date separate rights certificates evidencing the Rights ("Right Certificates"), and such Right Certificates alone will evidence the Rights. We may choose book entry in lieu of physical certificates, in which case, references to "Rights Certificates" shall be deemed to mean the uncertificated book entry representing the Rights.

The Rights, which are not exercisable until the Distribution Date, expire upon the earliest to occur of (i) the close of business on September 8, 2021; (ii) the time at which the Rights are redeemed or exchanged pursuant to the Rights Agreement; and (iii) the time at which the Rights are terminated upon the closing of any merger or other acquisition transaction involving us pursuant to a merger or other acquisition agreement that has been approved by the Board prior to any person becoming an Acquiring Person (the earliest of (i), (ii), and (iii) is referred to as the "Expiration Date").

Each share of Preferred Stock will be entitled to a preferential per share dividend rate equal to the greater of (i) $0.001 and (ii) the sum of (1) 1,000 times the aggregate per share amount of all cash dividends, plus (2) 1,000 times the aggregate per share amount (payable in kind) of all non-cash dividends or other distributions other than certain dividends or subdivisions of the outstanding shares of common stock. Each Preferred Stock will entitle the holder thereof to a number of votes equal to 1,000 on all matters submitted to a vote of our stockholders. In the event of any merger, consolidation or other transaction in which shares of common stock are exchanged, each Preferred Stock will be entitled to receive 1,000 times the amount received per one share of common stock. Pursuant to the Rights Agreement, the preferential rates noted above may be adjusted in the event that we (i) pays dividends in common stock, (ii) subdivides the outstanding common stock or (iii) combines outstanding common stock into a smaller number of shares.

The Purchase Price payable, and the number of shares of Preferred Stock or other securities or property issuable, upon exercise of the Rights are subject to adjustment from time to time to prevent dilution (i) in the event of a stock dividend, or a subdivision, combination or reclassification of the Preferred Stock, (ii) if the holders of Preferred Stock are granted certain rights, options or warrants to subscribe for the applicable Preferred Stock or securities convertible into the applicable Preferred Stock at less than the current market price of the applicable Preferred Stock, or (iii) upon the distribution to holders of Preferred Stock of evidences of indebtedness, cash (excluding regular quarterly cash dividends), assets (other than dividends payable in Preferred Stock) or subscription rights or warrants (other than those referred to in (ii) immediately above). The number of outstanding Rights and the number of one one-thousandths of a Preferred Stock issuable upon exercise of each Right are also subject to adjustment in the event of a stock split, reverse stock split, stock dividends and other similar transactions.

With some exceptions, no adjustment in the purchase price relating to a Right will be required until cumulative adjustments amount to at least one percent (1%) of the purchase price relating to the Right. No fractional shares of Preferred Stock are required to be issued (other than fractions which are integral multiples of one one-thousandth of a share of Preferred Stock) and, in lieu of the issuance of fractional shares, we may make an adjustment in cash based on the market price of the Preferred Stock on the trading date immediately prior to the date of exercise.

In the event that a person or group of affiliated or associated persons becomes an Acquiring Person, each holder of a Right will thereafter have the right to receive, upon exercise, common stock (or, in certain circumstances, other securities, cash or other assets) having a value equal to two (2) times the exercise price of the Right. Notwithstanding any of the foregoing, following the occurrence of a person becoming an Acquiring Person, all Rights that are, or (under certain circumstances specified in the Rights Agreement) were, Beneficially Owned by any Acquiring Person (or by certain related parties) will be null and void and any holder of such Rights (including any purported transferee or subsequent holder) will be unable to exercise or transfer any such Rights. However, Rights are not exercisable following the occurrence of a person becoming an Acquiring Person until the Distribution Date.

In the event that, after a person or a group of affiliated or associated persons has become an Acquiring Person, we are acquired in a merger or other business combination transaction, or 50% or more of our assets or earning power are sold, proper provision will be made so that each holder of a Right will thereafter have the right to receive, upon the exercise of a Right that number of shares of common stock of the person with whom we have engaged in the foregoing transaction (or its parent) that at the time of such transaction have a market value of two (2) times the exercise price of the Right.

At any time before any person or group of affiliated or associated persons becomes an Acquiring Person, the Board may redeem the Rights in whole, but not in part, at a price of $0.001 per Right (subject to certain adjustments) (the “Redemption Price”). The redemption of the Rights may be made effective at such time, on such basis and with such conditions as the Board in its sole discretion may establish. Immediately upon the action of the Board electing to redeem or exchange the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the Redemption Price.

The Board may, at its option, at any time after the first occurrence of a Flip-in Event (as defined in the Rights Agreement), exchange all or part of the then outstanding and exercisable Rights for shares of common stock at an exchange ratio of one share of common stock per Right, appropriately adjusted to reflect any stock split, stock dividend or similar transaction occurring after the effective date. However, the Board shall not effect such an exchange at any time after any person, together with all affiliates and associates of such person, becomes a beneficial owner of 50% or more of the outstanding shares of common stock. Immediately upon the action of the Board to exchange the Rights, the Rights will terminate and the only right of the holders of Rights will be to receive the number of shares of Common equal to the number of Rights held by such holder multiplied by the exchange ratio.

Until a Right is exercised or exchanged, the holder thereof, as such, will have no rights as our stockholder, including, without limitation, the right to vote or to receive dividends.

The Board may amend or supplement the Rights Agreement without the approval of any holders of Rights at any time so long as the Rights are redeemable. At any time, the Rights are no longer redeemable, no such supplement or amendment may (i) adversely affect the interests of the holders of Rights (other than an Acquiring Person or an affiliate or associate of an Acquiring Person), (ii) cause the Rights Agreement to become amendable other than in accordance with Section 27 of the Rights Agreement, or (iii) cause the Rights again to become redeemable.

RESULTS OF OPERATIONS

As discussed in Note 3 and Note 6 of the Notes to the condensed Consolidated Financial Statements, the results of operations presented below exclude our screening and testing products business due to its classification as discontinued operations.

Summary of Statements of Operations for the Three Months Ended September 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.

Revenue

We had no revenue from continuing operations during the three months ended September 30, 2020 and September 30, 2019.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2020 totaled $1,741,269, which was a 100% increase as compared to $0 for the three months ended September 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 September 30, 2020 and 2019 as well as the percentage of change year-over-year:

	For the Three Months Ended September 30,		
Description	2020	2019	Percent Change
Professional Service Costs	$ 56,479	$ -	100%
Vaccine License and Development Costs	1,684,790	-	100%
Total Research and Development Expenses	$ 1,741,269	$ -	100%

Professional services costs are associated with the Cystron Medical Advisory Board established by the Board on April 10, 2020 and fees associated with the evaluation of the milestone achievements under that certain license agreement, dated March 29, 2020 (the "License Agreement").

Pursuant to the terms of the MIPA, upon the closing of our registered direct equity offering on August 13, 2020, we paid the Sellers $684,790. Pursuant to the License Agreement, during the three months ended September 30, 2020, we incurred development costs of $1,000,000 upon Premas having achieved certain development milestones.

Administrative Expenses

Administrative expenses for the three months ended September 30, 2020, totaled $1,223,354, which was a 45% increase as compared to $843,144 for the three months ended September 30, 2019.

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

	For the Three Months Ended September 30,		
Description	2020	2019	Percent Change
Personnel Costs	$ 245,077	$ 159,932	53%
Professional Service Costs	501,900	176,570	184%
Stock Market & Investor Relations Costs	92,589	5,906	1,468%
Other Administrative Costs	383,788	500,736	-23%
Total Administrative Expense	$ 1,223,354	$ 843,144	45%

Personnel costs increased 53% for the three months ended September 30, 2020 as compared to the same period of 2019 due to the addition of an executive staff member.

Professional service costs increased 184% for the three months ended September 30, 2020 as compared to the same period of 2019, principally due to increased accounting & audit, general consulting and legal fees.

Stock market and investor relations costs increased 1,468% for the three months ended September 30, 2020. The increase in these costs was principally associated with our annual shareholders meeting.

Other administrative costs decreased by 23%, primarily due to a decrease in bad debt expense.

Sales and Marketing Expenses

Sales and marketing expenses for the three months ended September 30, 2020 totaled $6,250 which was a 1% decrease compared to $6,163 for the three months ended September 30, 2019.

Other Income and Expense

Other income, net of expenses, for the three months ended September 30, 2020, totaled $54,833. Other income, net of expense, for the three months ended September 30, 2019 totaled $28,463.

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

	For the Three Months Ended September 30,		
Description	2020	2019	Percent Change
Currency Translation Gains	$ 0	$ (32)	-100%
Realized Gains on Investments	0	(6,416)	-100%
Equity Investments Gains	(31,465)	0	100%
Interest and Dividend Income	(23,368)	(22,015)	6%
Total Other Income, Net of Expenses	$ (54,833)	$ (28,463)	93%

Realized gains on investments decreased by 100% for the three months ended September 30, 2020 as compared to the same period in 2019. The decrease is principally due to the impact of the COVID-19 pandemic on the financial markets.

Equity investment gains increased by 100% for the three months ended September 30, 2020 as compared to the same period in 2019. The increase was due to an increase in the fair market value of the equity investments.

Interest and dividend income increased to $23,368 for the three months ended September 30, 2020 compared to $22,015 for the three months ended September 30, 2019. The increase was principally due to the increase in funds available for investment.

Summary of Statements of Operations for the Nine Months ended September 30, 2020 and 2019

Revenue

We had no revenue from continuing operations during the nine months ended September 30, 2020 and September 30, 2019.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2020 totaled $6,140,487 which was a 100% increase as compared to $0 for the nine months ended September 30, 2019.

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

	For the Nine Months Ended September 30,		
Description	2020	2019	Percent Change
Professional Service Costs	$ 80,139	$ -	100%
Vaccine License and Development Costs	6,060,348	-	100%
Total Research and Development Expenses	$ 6,140,487	$ -	100%

Professional services costs are associated with the Cystron Medical Advisory Board established by the Board on April 10, 2020, fees associated with the evaluation of the milestone achievements under the License Agreement and general consulting services.

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, May 18, 2020 and August 13, 2020, we incurred obligations to pay the Sellers $250,000, $892,500 and $684,791 respectively. Pursuant to the License Agreement, during the nine months ended September 30, 2020, we incurred development costs of $2,000,000 upon Premas having achieved certain development milestones.

Administrative Expenses

Administrative expenses for the nine months ended September 30, 2020, totaled $2,983,443, which was a 11% increase as compared to $2,687,681 for the nine months ended September 30, 2019.

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

	For the Nine Months Ended September 30,		
Description	2020	2019	Percent Change
Personnel Costs	$ 782,660	$ 509,537	54%
Professional Service Costs	1,047,956	680,824	54%
Stock Market & Investor Relations Costs	178,289	283,867	-37%
Other Administrative Costs	974,538	1,213,453	-20%
Total Administrative Expense	$ 2,983,443	$ 2,687,681	11%

Personnel costs increased 54% for the nine months ended September 30, 2020 as compared to the same period of 2019 due to the addition of an executive staff member.

Professional service costs increased 54% for the nine months ended September 30, 2020 as compared to the same period of 2019, principally due to increased accounting & audit, general consulting and legal fees.

Stock market and investor costs decreased 37% for the nine months ended September 30, 2020. The decrease in these costs was principally associated with our 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 costs decreased by 20%, principally attributable to decreased bad debts expense, stock-based compensation and the elimination of the facility management department and were offset by increases in business insurance expenses.

Sales and Marketing Expenses

Sales and marketing expenses for the nine months ended September 30, 2020 totaled $16,667 which was an 11% decrease compared to $18,750 for the nine months ended September 30, 2019.

Sales and marketing expenses are made up of the hosting and maintenance expenses for the Company’s website.

Litigation Settlement Expenses

Litigation settlement expenses from continuing operations for the nine months ended September 30, 2020 decreased 100% as compared to $75,000 for the nine months ended September 30, 2019. Litigation expenses incurred from discontinued operations for the nine months ended September 30, 2020 were $4,031,131(see Note 6).

Other Income and Expense

Other income, net of expenses, for the nine months ended September 30, 2020, totaled $93,960. Other income, net of expense, for the nine months ended September 30, 2019 totaled $78,326.

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

Description	For the Nine Months Ended September 30, 2020	2019	Percent Change
Currency Translation (Gains)/Losses	$ (93)	$ 4,846	102%
Realized Losses/(Gains) on Investments	36,714	(2,155)	-1,804%
Equity Investments Gains	(31,465)	0	100%
Interest and Dividend Income	(99,116)	(81,017)	22%
Total Other Income, Net of Expenses	$ (93,960)	$ (78,326)	20%

Realized losses/gains on investments decreased by 1,804% for the nine months ended September 30, 2020 as compared to the same period in 2019. The decrease was principally due to the impact of the COVID-19 pandemic on the financial markets.

Equity investment gains increased by 100% for the nine months ended September 30, 2020 as compared to the same period in 2019. The increase was due to an increase in the fair market value of the equity investments.

Interest and dividend income increased to $99,116 for the nine months ended September 30, 2020 compared to $81,017 for the nine months ended September 30, 2019. The increase was principally due to the increase in funds available for investment.

Liquidity and Capital Resources

As of September 30, 2020, our cash on hand was $16,304,745 (which included restricted cash of $115,094), and marketable securities were $6,929,356. We have incurred net losses of $14,293,864 for the nine months ended September 30, 2020. As of September 30, 2020, we had working capital of $21,009,868 and stockholder's equity of $21,169,169. During the nine months ended September 30, 2020, cash flows used in operating activities were $8,842,867, consisting primarily of a net loss of $14,293,864, which includes, principally, research and development expenses in connection with the purchase of a license and milestone license fees of $6,060,348. Since its inception, we have met our liquidity requirements principally through the sale of its common stock in public offerings 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 July 21, 2020 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.

On August 13, 2020, pursuant to a Securities Purchase Agreement with certain institutional and accredited investors, we 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 $6,847,908 and $6,158,034, 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.

On September 25, 2020, we disbursed $1,959,697 to the Sellers of our obligations under the MIPA for the May Offering ($892,500) and August Offering ($684,790). The payment also included Premas' portion of the initial payment ($299,074) and the April Offering ($83,333) which had previously been returned temporarily to the Company for Premas to meet certain regulatory requirements in India.

On November 11, 2020, we entered into the Purchase Agreement, pursuant to which we agreed to issue and sell to the Purchasers in a private placement up to an aggregate of 9,765,933 shares of Akers common stock (or, at the election of each investor, Pre-Funded Warrants) and the Investor Warrants to purchase an aggregate of up to 9,765,933 shares of Akers common stock at an exercise price of $2.06 per share, at an offering price of $1.85 per share and the accompanying Investor Warrant, for gross proceeds of approximately $18.1 million before the deduction of placement agent fees and expenses and estimated offering expenses. In connection with the Private Placement, we agreed to pay the Placement Agent an aggregate cash fee equal to 6.5% of the gross proceeds received in the Private Placement and reimburse the Placement Agent's expenses in the Private Placement up to $25,000. In addition, we agreed to grant to the Placement Agent Warrants to purchase up to 390,368 shares of our common stock at an exercise price of $1.85. The closing of the Private Placement is subject to the satisfaction of customary closing conditions set forth in the Purchase Agreement and is expected to occur on or around November 16, 2020. The Company will pay approximately $1.8 million of the proceeds from the Private Placement to the former members of Cystron pursuant to the MIPA.

In connection with the execution of the Merger Agreement, we agreed to advance a bridge loan to MYMD in an amount of up to $3,000,000 pursuant to the Note. Advances under the Note will be made in accordance with MYMD's cash needs pursuant to a pre-agreed operating budget for MYMD.

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 Candidate, we anticipate that we will need to raise significant additional funds in order to continue the development of our COVID-19 Vaccine Candidate during the next 12-months. In addition, we could also have increased capital needs in connection with the Merger. 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 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, the resurgent of COVID-19 cases, and any additional preventative and protective actions that regulators, or our 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. Moreover, the closing of the Private Placement is subject to the satisfaction of closing conditions and may not be completed.

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 $8,842,867 during the nine months ended September 30, 2020. Net cash used consisted principally of the net loss of $14,293,864, offset by a non-cash adjustment principally consisting of the fair value of shares issued for the purchase of a license for $1,233,057 and for the amended settlement with ChubeWorkx Guernsey Limited of $2,510,000 and an increase in trade and other payables of $961,134.

Our net cash consumed by operating activities totaled $2,572,578 during the nine months ended September 30, 2019. Cash was consumed by the loss of $3,092,444 reduced by non-cash adjustments principally consisting of $100,000 for the allowance of doubtful accounts and other receivables and $267,720 for share based compensation. For the nine months ended September 30, 2019, within changes of assets and liabilities, cash consumed consisted of a decrease a decrease in trade and other payables of $475,687.

Investing Activities

Our net cash provided by investing totaled $2,210,033, as compared to $2,369,211 during the nine months ended September 30, 2020 and 2019, respectively. Net cash provided by investing activities for the nine months ended September 30, 2020 consisted of proceeds from the sale of marketable securities of $2,310,898, offset by $100,865 for the purchase of marketable securities. During the nine months ended September 30, 2019, investing activities consisted of proceeds from the sale of marketable securities of $2,556,516, offset by $87,305 for the purchase of marketable securities $100,000 for the issuance of a short-term note receivable.

Financing Activities

Our net cash provided by financing activities during the nine months ended September 30, 2020 was $22,305,041, as compared to $0 during the nine months ended September 30, 2019. Net cash provided during the nine months ended September 30, 2020 reflected the net proceeds from the April Offering, May Offering and August Offering of $14,564,961, the net proceeds from the exercise of Series C Convertible Preferred Warrants of $7,740,000, 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 Securities Exchange Act of 1934, as amended (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 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 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 September 30, 2020. Based on this evaluation, our Executive Chairman and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2020.

(b) Changes in Internal Control over Financial Reporting

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

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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. In anticipation of the case being settled, on October 20, 2020, the Court administratively closed the case. On November 13, 2020, the parties entered into a settlement agreement without either party admitting liability, effective as of November 3, 2020. The settlement agreement requires the Company to make a lump sum payment of $1,350,000 to Novotek within 60 days. The settlement expense is included in Loss from Discontinued Operations on the Condensed Consolidated Statement of Operations and Comprehensive Loss for the three and nine months ended September 30, 2020 and the Company's obligation is included in Current Liabilities – Discontinued Operations on the Condensed Consolidated Balance Sheet as of September 30, 2020.

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.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission before making investment decisions regarding our common stock.

- We may be unable to successfully consummate the Merger with MYMD in a timely manner or achieve the anticipated benefits of the Merger, and the issuance of shares of our common stock in connection with the Merger will substantially dilute the voting power of our current stockholders and/or may adversely affect the price of our common stock.
- We may fail to realize the anticipated benefits and costs of the transactions related to our acquisition of Cystron and those benefits may take longer to realize than expected.
- We have a history of operating losses and we cannot guarantee that we can ever achieve sustained profitability.
- 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.
- We operate in a highly competitive industry.
- Our business may be materially adversely affected by the COVID-19 pandemic.
- Our success is dependent on the successful clinical development, regulatory approval and commercialization of the COVID-19 Vaccine, which will require significant time and resources.
- We expect to require additional capital in the future in order to develop our vaccine candidate. If we do not obtain any such additional financing, it may be difficult to effectively realize our long-term strategic goals and objectives.
- 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.

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, as amended on October 21, 2020.

RISKS RELATED TO OUR MERGER WITH MYMD

The issuance of shares of our common stock to MYMD stockholders in the Merger will substantially dilute the voting power of our current stockholders. Having a minority share position will reduce the influence that current stockholders have on our management.

Pursuant to the terms of the Merger Agreement, at the Effective Time of the Merger, the former MYMD security holders are expected to own approximately 80% of the aggregate number of shares of the Post-Closing Shares, and our stockholders as of immediately prior to the Merger are expected to own approximately 20% of the aggregate number of Post-Closing Shares. Accordingly, the issuance of the shares of our common stock to MYMD equity holders in the Merger will significantly reduce the ownership stake and relative voting power of each share of our common stock held by our current stockholders. Consequently, following the Merger, the ability of our current stockholders to influence our management and the composition of the Board will be substantially reduced.

Moreover, under the terms of the Merger Agreement, we agreed to pay milestone payments payable in shares of Akers common stock to MYMD stockholders upon the achievement of certain market capitalization milestone events during the 3-year period following the closing date of the Merger, up to the number of shares of Akers common stock issuable to the MYMD stockholders upon the closing of the Merger. In the event that such milestones are achieved and milestone shares are paid, our stockholders will experience further dilution.

There is no assurance when or if the Merger will be completed. Any delay in completing the Merger may substantially reduce the benefits that we and MYMD expect to obtain from the Merger.

Completion of the Merger is subject to the satisfaction or waiver of a number of conditions as set forth in the Merger Agreement. There can be no assurance that we and MYMD will be able to satisfy the closing conditions or that closing conditions beyond our or MYMD's control will be satisfied or waived. If the Merger is not completed within the expected timeframe, such delay may materially and adversely affect the potential benefits that we and MYMD expect to achieve as a result of the Merger and could result in additional transaction costs or other effects associated with uncertainty about the Merger. In addition, pursuant to the Merger Agreement, we may extend the originally scheduled End Date (defined in the Merger Agreement as April 15, 2021) to a later date, but we will have to make additional loans to MYMD or purchase MYMD common stock for such extensions.

We and MYMD can agree at any time to terminate the Merger Agreement, even if our stockholders and/or MYMD's securityholders have already adopted the Merger Agreement and thereby approved the Merger and the other transactions contemplated by the Merger Agreement. We and MYMD can also terminate the Merger Agreement under other specified circumstances.

The issuance, or expected issuance, of our common stock in connection with the Merger could decrease the market price of our common stock.

In connection with the Merger and as part of the merger consideration, we expect to issue shares of our common stock to MYMD equity holders. The anticipated issuance of our common stock in the Merger may result in fluctuations in the market price of our common stock, including a stock price decrease. In addition, issuance of the Milestone Shares, if any applicable milestone is achieved, and the perception in the market that the holders of a large number of shares of common stock may intend to sell shares could reduce the market price of our common stock.

Failure to complete the Merger could negatively affect the value of our common stock and the future business and financial results.

If the Merger is not completed, our ongoing businesses could be adversely affected and we will be subject to a variety of risks associated with the failure to complete the Merger, including without limitation the following:

- diversion of management focus and resources from operational matters and other strategic opportunities while working to implement the Merger;
- reputational harm due to the adverse perception of any failure to successfully complete the Merger; and
- having to pay certain costs relating to the Merger, such as legal, accounting, financial advisory, filing and printing fees.

If the Merger is not completed, these risks could materially affect the market price of our common stock and our business and financial results and may result in the cessation of our operations.

MYMD is a clinical development stage pharmaceutical company and has never been profitable. MYMD expects to incur additional losses in the future and may never be profitable.

MYMD is a clinical development stage pharmaceutical company. MYMD has not commercialized any product candidates or recognized any revenues from product sales. All of MYMD's product candidates are still in the preclinical or clinical development stage, and none has been approved for marketing or is being marketed or commercialized. MYMD's product candidates will require significant additional development, clinical studies, regulatory clearances and additional investment before they can be commercialized. MYMD cannot be certain when or if any of its product candidates will obtain the required regulatory approval.

MYMD has never been profitable or generated positive cash flow from operation. MYMD may incur significant additional losses as it continues to focus its resources on prioritizing, selecting and advancing its product candidates. MYMD's ability to generate revenue and achieve profitability depends mainly upon its ability, alone or with others, to successfully develop its product candidates, obtain the required regulatory approvals in various territories and commercialize its product candidates. MYMD may be unable to achieve any or all of these goals with regard to its product candidates. As a result, MYMD may never be profitable or achieve significant and/or sustained revenues.

The intended benefits of the Merger may not be realized.

The Merger poses risks for our ongoing operations, including, among others:

- that senior management's attention may be diverted from the management of our current operations and development of the COVID-19 Vaccine Candidate;
- costs and expenses associated with any undisclosed or potential liabilities;
- unforeseen difficulties may arise in integrating MYMD and Akers business in the combined organization.

As a result of the foregoing, the combined organization may be unable to realize the full strategic and financial benefits currently anticipated from the Merger, and we cannot assure you that the Merger will be accretive to us in the near term or at all. Furthermore, if we fail to realize the intended benefits of the Merger, the market price of our common stock could decline to the extent that the market price reflects those benefits. Our stockholders will have experienced substantial dilution of their ownership interests in the Company without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

If the Merger is completed, MYMD executive officers and MYMD appointees to the Board will have the ability to significantly influence the combined company's management and business affairs, as well as matters submitted to the combined company's board of directors or stockholders for approval, especially if they decide to act together with the current MYMD stockholders.

Upon completion of the Merger, the current MYMD stockholders will own approximately 80% of the combined company on a fully diluted basis (excluding the effect of warrants issued in the Private Placement). If the Merger is completed, the combined company is expected to be led by MYMD executive officers. Furthermore, three directors of the combined company's anticipated Board consisting of seven members will be appointed by MYMD pursuant to the terms of the Merger Agreement. As a result, such persons, if they choose to act together, will have the ability to significantly influence the combined company's management and business affairs, as well as matters submitted to the combined company's board of directors or stockholders for approval.

RISKS RELATED TO OUR ACQUISITION OF CYSTRON

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 acquired 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 our 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. Moreover, we have the right to terminate the License Agreement on a country by country basis for any reason or for no reason at any time upon sixty (60) days' prior written notice to Premas, and may decide to cease development of the COVID-19 Vaccine Candidate and terminate the License Agreement, The failure to produce the COVID-19 Vaccine Candidate or termination of the License Agreement could adversely affect our business, financial condition and results of operations. In addition, we have incurred and 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 have been paid or 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. We had a net loss of $14,293,864 during the nine months ended September 30, 2020. Our accumulated deficit at September 30, 2020 was $133,876,994. 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 are focusing on the development of the COVID-19 Vaccine Candidate in partnership with Premas and expect to incur additional operating losses for the foreseeable future. As part of our efforts to increase shareholder value, on November 11, 2020, we entered into the Merger Agreement with MYMD, pursuant to which Merger Sub will merge with and into MYMD, with MYM becoming our wholly owned subsidiary. For risks related to the Merger, please see risk factors set forth under the heading "—Risks Related to the Merger with MYMD" herein. 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 the consummation of the Merger.

****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 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 3,900 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. For example, Pfizer announced in November 2020 that its vaccine candidate against SARS-CoV-2 has demonstrated evidence of efficacy against COVID-19 based on the first interim efficacy analysis of a Phase 3 clinical study. 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.

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.

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.

RISKS RELATED TO OUR PRODUCT DEVELOPMENT

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 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, 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.

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.

RISKS RELATED TO OUR CAPITAL REQUIREMENTS AND FINANCINGS

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

Our current cash resources will not be sufficient to fund the development of the 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 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 in connection with the Merger or other acquisitions. 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.

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, 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, including in the Private Placement, 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. Pursuant to the Purchase Agreement, we agreed to sell in the Private Placement an aggregate of 9,765,933 Shares and the Investor Warrants to purchase an aggregate of up to 9,765,933 shares of Akers common stock, at an offering price of $1.85 per Share and the accompanying Investor Warrant. Our current stockholders may experience dilution due to the Private Placement. 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 cash 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. Pursuant to the Purchase Agreement, we are required to file a Registration Statement for the resale of 9,765,933 Shares and 9,765,933 shares of Akers common stock issuable upon exercise of the Warrants shortly after we file a proxy statement with the SEC in connection with the Merger. Following their registration and resale under the Registration Statement, such shares would become freely tradable. Sales by our stockholders of a substantial number or resales by the Purchasers of the Shares or Warrant Shares pursuant to the Registration Statement, or the perception in the market that the holders of a large number of shares of common stock may or intend to sell their shares, could reduce the market price of our common stock and make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire.

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.

****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. Furthermore, on November 11, 2020, we entered into the Merger Agreement with MYMD. For risks related to the Merger, please see risks set forth under the heading "Risks Related to the Merger with MYMD" herein. However, there can be no assurance that our pursuit of such 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 or mergers will depend on, among other things, our ability to integrate businesses, 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.

GENERIC RISK FACTORS

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.

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 may be at risk of securities class action litigation.***

We have been subject to a number of litigations, and we have entered into settlements of claims for significant monetary damages in connection with such litigations. We may also be subject to judgements or enter into additional settlements of claims for significant monetary damages. Defending against such 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.

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.

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

There were no unregistered sales of the Company's equity securities during the nine months ended September 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.

On November 11, 2020, the board of directors approved a special cash bonus of $150,000 to Christopher C. Schreiber, the Company's Executive Chairman and President for his service in year-to-date 2020.

Item 6. Exhibits.

2.1§	Agreement and Plan of Merger and Reorganization, dated November 11, 2020, by and among Akers Biosciences, Inc., XYZ Merger Sub Inc., and MYMD Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020)
2.2	Form of Voting Agreement, by and between Akers Biosciences, Inc. and the directors, officers and certain specified stockholders of MyMD Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020)
2.3	Form of Voting Agreement, by and between MYMD Pharmaceuticals, Inc. and the directors, officers and certain stockholders of Akers Biosciences, Inc. (incorporated herein by reference to Exhibit 2.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2019)
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 (incorporated herein by reference to Exhibit 3.2 to the Company's Amendment to Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on October 21, 2020).
3.3	Certificate of Amendment to Certificate of Incorporation dated December 20, 2006 (incorporated herein by reference to Exhibit 3.3 to the Company's Amendment to Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on October 21, 2020).
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 October 12, 2020 (incorporated herein by reference to Exhibit 3.13 to the Company's Amendment to Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on October 21, 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	Certificate of Designations of Series E Junior Participating 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 September 9, 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 August 13, 2020).
4.2	Rights Agreement dated as of September 9, 2020 between Akers Biosciences, Inc. and VStock Transfer, LLC as Rights Agent (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 September 9, 2020).
4.3	Form of Pre-Funded Warrant. of Akers Biosciences, Inc. (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 November 12, 2020)
4.4	Form of Investor Warrant. of Akers Biosciences, Inc. (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2020)

10.1 +	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).
10.2	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).
10.3	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).
10.4	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).
10.5+	Akers Biosciences, Inc. 2018 Plan Amendment (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 28, 2020).
10.6	Form of Lock-Up/Leak-Out 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 November 12, 2019)
10.7	The Secured Promissory Note, dated November 11, 2020, by and between Akers Biosciences, Inc. and MYMD Pharmaceuticals, Inc. (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 November 12, 2019)
10.8	Form of Securities Purchase Agreement, dated November 11, 2020, by and between Akers Biosciences, Inc. and purchasers named therein (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2019)
10.9	Form of Lock-Up and Support Agreement, dated November 11, 2020, by and between Akers Biosciences, Inc. and its stockholders named therein (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2019)
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.

§ The schedules and exhibits to the Agreement and Plan of Merger and Reorganization have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

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: November 16, 2020

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

Date: November 16, 2020

By: */s/ Stuart Benson*
Name: Stuart Benson
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

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: November 16, 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, Stuart Benson, 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: November 16, 2020

By: */s/ Stuart Benson*
Stuart Benson
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 September 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: November 16, 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: November 16, 2020

By: */s/ Stuart Benson*
Stuart Benson
Chief Financial Officer
(Principal Financial and Accounting Officer)
Akers Biosciences, Inc.