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

FORM 10-Q

QUARTERLY REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2020

Commission File No. 001-32404

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

DELAWARE	**06-1529524**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

1960 S. 4250 West, Salt Lake City, UT 84104
(Address of principal executive offices)

Registrant's Telephone Number, Including Area Code: **(800)** 560-3983

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $0.001	PTE	Nasdaq Capital Market 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 preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition 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	☐	Smaller reporting company	☒
		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 ☒

As of November 5, 2020, there were 39,241,323 shares of the Registrant's common stock outstanding.

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PART I - FINANCIAL INFORMATION
Item 1. Financial Statements:

POLARITYTE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands, except share and per share amounts)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 23,186	$ 10,218
Short-term investments	–	19,022
Accounts receivable, net	3,379	1,731
Inventory	907	252
Prepaid expenses and other current assets	1,596	1,264
Total current assets	29,068	32,487
Property and equipment, net	11,970	14,911
Operating lease right-of-use assets	3,110	4,590
Intangible assets, net	589	731
Goodwill	278	278
Other assets	472	602
TOTAL ASSETS	$ 45,487	$ 53,599
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 4,818	$ 7,095
Other current liabilities	2,311	2,338
Current portion of long-term notes payable	1,887	528
Deferred revenue	25	98
Total current liabilities	9,041	10,059
Common stock warrant liability	7,233	–
Operating lease liabilities	1,817	2,994
Other long-term liabilities	872	1,630
Long-term notes payable	1,964	–
Total liabilities	20,927	14,683
Commitments and Contingencies (Note 14)		
STOCKHOLDERS' EQUITY		
Preferred stock - 25,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2020 and December 31, 2019	–	–
Common stock – $.001 par value; 250,000,000 shares authorized; 38,912,005 and 27,374,653 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	39	27
Additional paid-in capital	492,676	474,174
Accumulated other comprehensive income	–	72
Accumulated deficit	(468,155)	(435,357)
Total stockholders' equity	24,560	38,916
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 45,487	$ 53,599

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

POLARITYTE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands, except share and per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Net revenues				
Products	$ 1,156	$ 839	$ 2,528	$ 1,640
Services	2,181	556	4,008	2,546
Total net revenues	3,337	1,395	6,536	4,186
Cost of sales				
Products	210	315	825	930
Services	1,142	330	1,925	1,087
Total cost of sales	1,352	645	2,750	2,017
Gross profit	1,985	750	3,786	2,169
Operating costs and expenses				
Research and development	2,698	2,956	9,235	13,072
General and administrative	6,264	16,044	22,080	48,299
Sales and marketing	1,606	4,988	7,324	12,922
Restructuring and other charges	–	–	2,536	–
Total operating costs and expenses	10,568	23,988	41,175	74,293
Operating loss	(8,583)	(23,238)	(37,389)	(72,124)
Other income (expenses)				
Change in fair value of common stock warrant liability	1,503	–	4,444	–
Interest (expense) income, net	(58)	27	(135)	126
Other income, net	57	228	282	650
Net loss	$ (7,081)	$ (22,983)	$ (32,798)	$ (71,348)
Net loss per share, basic and diluted	$ (0.18)	$ (0.87)	$ (0.89)	$ (2.94)
Weighted average shares outstanding, basic and diluted	38,761,141	26,405,307	36,743,864	24,273,774

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

POLARITYTE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited, in thousands)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Net loss	$ (7,081)	$ (22,983)	$ (32,798)	$ (71,348)
Other comprehensive income/(loss):				
Unrealized gain on available-for-sale securities	–	113	11	425
Reclassification of realized gains included in net loss	–	(129)	(83)	(398)
Comprehensive loss	$ (7,081)	$ (22,999)	$ (32,870)	$ (71,321)

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

POLARITYTE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited, in thousands, except share and per share amounts)

	For the Three and Nine Months Ended September 30, 2020					
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income	Deficit	Equity
Balance – December 31, 2019	27,374,653	$ 27	$ 474,174	$ 72	$ (435,357)	$ 38,916
Issuance of common stock, net of issuance costs of $1.3 million	10,854,710	11	12,588	–	–	12,599
Stock-based compensation expense	–	–	3,221	–	–	3,221
Stock option exercises	10,000	–	31	–	–	31
Vesting of restricted stock units	158,513	–	–	–	–	–
Shares withheld for tax withholding	(4,587)	–	(5)	–	–	(5)
Other comprehensive loss	–	–	–	(69)	–	(69)
Net loss	–	–	–	–	(13,040)	(13,040)
Balance – March 31, 2020	38,393,289	38	490,009	3	(448,397)	41,653
Stock-based compensation expense	–	–	563	–	–	563
Purchase of ESPP shares	38,293	–	40	–	–	40
Vesting of restricted stock units	119,132	–	–	–	–	–
Shares withheld for tax withholding	(6,918)	–	(9)	–	–	(9)
Forfeiture of restricted stock awards	(46,886)	–	–	–	–	–
Other comprehensive loss	–	–	–	(3)	–	(3)
Net loss	–	–	–	–	(12,677)	(12,677)
Balance – June 30, 2020	38,496,910	38	490,603	–	(461,074)	29,567
Stock-based compensation expense	–	–	2,179	–	–	2,179
Stock option exercises	208	–	–	–	–	–
Vesting of restricted stock units	485,614	1	(1)	–	–	–
Shares withheld for tax withholding	(70,727)	–	(105)	–	–	(105)
Net loss	–	–	–	–	(7,081)	(7,081)
Balance – September 30, 2020	38,912,005	$ 39	$ 492,676	$ –	$ (468,155)	$ 24,560

	For the Three and Nine Months Ended September 30, 2019					
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income	Deficit	Equity
Balance – December 31, 2018	21,447,088	$ 21	$ 414,840	$ 36	$ (342,864)	$ 72,033
Stock-based compensation expense	–	–	10,327	–	–	10,327
Stock option exercises	283,250	1	528	–	–	529
Vesting of restricted stock units	100,912	–	–	–	–	–
Shares withheld for tax withholding	(82,011)	–	(740)	–	–	(740)
Other comprehensive income	–	–	–	17	–	17
Net loss	–	–	–	–	(25,573)	(25,573)
Balance – March 31, 2019	21,749,239	22	424,955	53	(368,437)	56,593
Proceeds received from issuance of common stock, net of issuance costs of $1,146	3,418,918	3	27,945	–	–	27,948
Stock-based compensation expense	–	–	8,618	–	–	8,618
Stock option exercises	9,167	–	–	–	–	–
Purchase of ESPP shares	7,260	–	35	–	–	35
Vesting of restricted stock units	51,440	–	–	–	–	–
Shares withheld for tax withholding	(17,418)	–	(62)	–	–	(62)
Other comprehensive income	–	–	–	26	–	26
Net loss	–	–	–	–	(22,792)	(22,792)
Balance – June 30, 2019	25,218,606	25	461,491	79	(391,229)	70,366
Stock-based compensation expense	–	–	5,025	–	–	5,025
Issuance of restricted stock awards	1,590,710	2	(2)	–	–	–
Vesting of restricted stock units	123,448	–	–	–	–	–
Other comprehensive loss	–	–	–	(16)	–	(16)
Net loss					(22,983)	(22,983)
Balance – September 30, 2019	26,932,764	$ 27	$ 466,514	$ 63	$ (414,212)	$ 52,392

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

POLARITYTE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	For the Nine Months Ended September 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (32,798)	$ (71,348)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation expense	5,963	23,932
Depreciation and amortization	2,337	2,243
Amortization of intangible assets	142	146
Amortization of debt discount	17	40
Change in fair value of common stock warrant liability	(4,444)	–
Change in fair value of contingent consideration	–	(48)
Loss on abandonment and disposal of property and equipment	1,566	265
Other non-cash adjustments	(21)	3
Changes in operating assets and liabilities:		
Accounts receivable	(1,648)	(881)
Inventory	(655)	(10)
Prepaid expenses and other current assets	(332)	126
Operating lease right-of-use assets	1,348	1,214
Other assets	130	25
Accounts payable and accrued expenses	(2,349)	4,095
Other current liabilities	–	155
Deferred revenue	(73)	(36)
Operating lease liabilities	(1,353)	(1,142)
Other long-term liabilities	–	571
Net cash used in operating activities	(32,170)	(40,650)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(1,225)	(2,386)
Purchase of available-for-sale securities	(14,144)	(29,002)
Proceeds from maturities of available-for-sale securities	16,945	14,636
Proceeds from sale of available-for-sale securities	16,171	1,877
Net cash provided by (used in) investing activities	17,747	(14,875)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from the sale of common stock and warrants	24,276	27,948
Proceeds from stock options exercised	31	529
Proceeds from ESPP purchase	40	35
Cash paid for tax withholdings related to net share settlement	(114)	(679)
Payment of contingent consideration liability	–	(109)
Principal payments on financing leases	(376)	(336)
Proceeds from term note payable and financing arrangements	4,630	–
Principal payments on term note payable and financing arrangements	(1,096)	(263)
Net cash provided by financing activities	27,391	27,125
Net increase (decrease) in cash and cash equivalents	12,968	(28,400)
Cash and cash equivalents - beginning of period	10,218	55,673
Cash and cash equivalents - end of period	$ 23,186	$ 27,273
Non-cash investing and financing activities:		
Unpaid liability for acquisition of property and equipment	$ 10	$ 249
Reclassification of stock-based compensation expense that was previously classified as a liability to paid-in capital	**$** –	$ 38
Unpaid tax liability related to net share settlement	$ 5	**$** –
Allocation of proceeds from sale of common stock and warrants to warrant liability	$ 11,677	**$** –
Property and equipment acquired through finance lease	**$** –	$ 2,341
Property and equipment acquired through financing arrangement	**$** –	$ 58

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

1. PRINCIPAL BUSINESS ACTIVITY AND BASIS OF PRESENTATION

PolarityTE, Inc. (together with its subsidiaries, the "Company") is a biotechnology company developing and commercializing regenerative tissue products and biomaterials.

The accompanying interim condensed consolidated financial statements of the Company are unaudited, but in the opinion of management, reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the results for the interim periods presented. Accordingly, they do not include all information and notes required by generally accepted accounting principles for complete financial statements. The results of operations for interim periods are not necessarily indicative of results to be expected for the entire fiscal year. The balance sheet at December 31, 2019 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America (U.S. GAAP) for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2019 filed with the Securities and Exchange Commission on Form 10-K on March 12, 2020.

2. LIQUIDITY AND NEED FOR ADDITIONAL CAPITAL

The Company has experienced recurring losses and cash outflows from operating activities. As of September 30, 2020, the Company had an accumulated deficit of $468.2 million. As of September 30, 2020, the Company had cash and cash equivalents of $23.2 million. The Company has been funded historically through sales of equity and debt.

On April 10, 2019, the Company completed an underwritten offering providing for the issuance and sale of3,418,918 shares of the Company's common stock, par value $0.001 per share, at an offering price of $8.51 per share, for net proceeds of approximately $27.9 million, after deducting offering expenses payable by the Company.

On December 5, 2019, the Company entered into an Equity Purchase Agreement (the "Purchase Agreement"), with Keystone Capital Partners, LLC ("Keystone"), pursuant to which Keystone has agreed to purchase from the Company up to $25.0 million of shares of its common stock, subject to certain limitations including a minimum stock price of $2.00, at the direction of the Company from time to time during the36-month term of the Purchase Agreement. Concurrently, the Company entered into a Registration Rights Agreement with Keystone, pursuant to which it agreed to register the sales of its common stock pursuant to the Purchase Agreement under the Company's existing shelf registration statement on Form S-3 or a new registration statement. On December 19, 2019, the Company sold 54,090 shares under the Purchase Agreement at a purchase price of $2.31 per share, for total proceeds of $0.1 million. During the three months ended March 31, 2020, the Company completed four additional sales of common stock to Keystone under the Purchase Agreement for a total of 216,412 shares generating total gross proceeds of $0.6 million.

On February 14, 2020, the Company completed an underwritten offering of10,638,298 shares of its common stock and warrants to purchase10,638,298 shares of common stock. Each common share and warrant were sold together for a combined public purchase price of $2.35 before underwriting discount and commission. The exercise price of each warrant is $2.80 per share, the warrants were exercisable immediately, and they will expire February 12, 2027. The net proceeds to the Company from the offering were $22.5 million, after offering expenses payable by the Company. In connection with this agreement, the Company agreed not to sell any additional shares under the Keystone Purchase Agreement for a period of 90 days after the closing date of the offering.

The Company entered into a promissory note for $3.6 million under the Paycheck Protection Program on April 12, 2020. Additional details are available in note 12.

In the second quarter of 2020 the Company took steps to reduce cash burn by reducing payroll expense, adopting a salary and wage reduction, and reducing discretionary spending across the organization to minimal levels.

The Company does not expect existing cash as of September 30, 2020 to be sufficient to fund the Company's operations for at least twelve months from the date of filing. The Company will seek additional capital through equity offerings or debt financing. However, such financing may not be available in the future on favorable terms, if at all. If adequate financing is not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its product development programs, or be unable to continue operations over a longer term. These financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and settle its liabilities in the normal course of business. The Company has incurred recurring losses and negative cash flows, has not yet generated material revenue from operations, and will require additional funds to maintain its operations. These factors raise substantial doubt regarding the Company's ability to continue as a going concern within one year after these condensed consolidated financial statements are issued. No adjustments have been made to these consolidated financial statements as a result of these uncertainties.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation. The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Significant intercompany accounts and transactions have been eliminated in consolidation.

Use of estimates. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities or the disclosure of gain or loss contingencies at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Among the more significant estimates included in these financial statements is the extent of progress toward completion of contracts, stock-based compensation, valuation of common stock warrant liability, and the valuation allowances for deferred tax benefits. Actual results could differ from those estimates.

Cash and cash equivalents. Cash equivalents consist of highly liquid investments with original maturities of three months or less from the date of purchase.

Leases. The Company determines if an arrangement is a lease at inception. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Finance leases are reported in the condensed consolidated balance sheet in property and equipment and other current and long-term liabilities. The short-term portion of operating lease obligations are included in other current liabilities. The classification of the Company's leases as operating or finance leases along with the initial measurement and recognition of the associated ROU assets and lease liabilities is performed at the lease commencement date. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The ROU asset is based on the measurement of the lease liability and also includes any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. The lease terms may include options to extend or terminate the lease when it is reasonably certain the Company will exercise any such options. Rent expense for the Company's operating leases is recognized on a straight-line basis over the lease term. Amortization expense for the ROU asset associated with its finance leases is recognized on a straight-line basis over the term of the lease and interest expense associated with its finance leases is recognized on the balance of the lease liability using the effective interest method based on the estimated incremental borrowing rate.

The Company has lease agreements with lease and non-lease components. As allowed under ASC 842, the Company has elected not to separate lease and non-lease components for any leases involving real estate and office equipment classes of assets and, as a result, accounts for the lease and non-lease components as a single lease component. The Company has also elected not to apply the recognition requirement of ASC 842 to leases with a term of 12 months or less for all classes of assets.

Revenue Recognition. Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company records product revenues primarily from the sale of its regenerative tissue products. The Company sells its products to healthcare providers (customers), primarily through direct sales representatives. Product revenues consist of a single performance obligation that the Company satisfies at a point in time. In general, the Company recognizes product revenue upon delivery to the customer.

The Company records service revenues from the sale of its preclinical research services and contract services. Preclinical research services include delivery of preclinical studies and other research services to unrelated third parties. These customer contracts generally consist of a single performance obligation that the Company satisfies over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. The Company believes that this method provides an appropriate measure of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires the Company to make reasonable estimates of the extent of progress toward completion of the contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. Generally, a portion of the payment is due upfront and the remainder upon completion of the contract, with most contracts completing in less than a year. Contract services include research and laboratory testing services to unrelated third parties on a contract basis. These customer contracts generally consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes revenue upon delivery of testing results to the customer.

For the three months ended September 30, 2020 revenue from two hospital systems accounted for 55% of total revenue in the regenerative medicine product segment. For the nine months ended September 30, 2020 revenue from one hospital system accounted for 33% of total revenue in the regenerative medicine product segment. As of September 30, 2020, accounts receivable from the two hospital systems represented 10% of total accounts receivable.

For the three months ended September 30, 2020 revenue from 32 facilities controlled by a single company accounted for 94% of COVID-19 testing revenues. For the nine months ended September 30, 2020 revenue from 32 facilities controlled by a single company accounted for 96% of COVID-19 testing revenues. As of September 30, 2020, accounts receivable from the 32 facilities represented 40% of total accounts receivable.

Research and Development Expenses. Costs incurred for research and development are expensed as incurred. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities pursuant to executory contractual arrangements with third party research organizations are deferred and recognized as an expense as the related goods are delivered or the related services are performed.

Accruals for Research and Development Expenses and Clinical Trials. As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment terms that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the timing of various aspects of the expenses. The Company determines accrual estimates by taking into account discussion with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period.

Common Stock Warrant Liability. The Company accounts for common stock warrants issued as freestanding instruments in accordance with applicable accounting guidance as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. The Company's warrants under certain change of control situations, could require settlement in cash, which require the warrants to be recorded as liabilities. Warrants classified as liabilities are remeasured each period until settled or until classified as equity.

Stock-Based Compensation. The Company measures all stock-based compensation to employees and non-employees using a fair value method and records such expense in general and administrative, research and development, and sales and marketing expenses. For stock options with graded vesting, the Company recognizes compensation expense over the service period for each separately vesting tranche of the award as though the award were in substance, multiple awards based on the fair value on the date of grant.

The fair value of options issued is estimated at the date of grant using a Black-Scholes option-pricing model. The risk-free rate is derived from the U.S. Treasury yield curve in effect at the time of the grant. The volatility factor is determined based on the Company's historical stock prices. Forfeitures are recognized as they occur.

The fair value of restricted stock grants is measured based on the fair market value of the Company's common stock on the date of grant and amortized over the vesting period of, generally, six months to three years.

Loss Per Share. Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive. Further, any gain on the warrant liability may be considered dilutive when the average market price of the common stock during the period exceeds the exercise price of the warrant.

Impairment of Long-Lived Assets. The Company reviews long-lived assets, including property and equipment, intangible assets, and goodwill for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326)*, which requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost. This standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates* , which defers the effective date of Topic 326. As a smaller reporting company, Topic 326 will now be effective for the Company beginning January 1, 2023. As such, the Company plans to adopt this ASU beginning January 1, 2023. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement.* The ASU modifies the disclosure requirements for fair value measurements by removing, modifying or adding certain disclosures. The standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. The Company adopted this standard on January 1, 2020. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The ASU aligns the requirements of capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. Adoption of the ASU is either retrospective or prospective. The Company adopted this standard prospectively on January 1, 2020. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

4. FAIR VALUE

In accordance with *ASC 820, Fair Value Measurements and Disclosures*, financial instruments were measured at fair value using a three-level hierarchy which maximizes use of observable inputs and minimizes use of unobservable inputs:

- Level 1: Observable inputs such as quoted prices in active markets for identical instruments.
- Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the market.
- Level 3: Significant unobservable inputs supported by little or no market activity. Financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, for which determination of fair value requires significant judgment or estimation.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. There were no transfers within the hierarchy for any of the periods presented.

During the nine months ended September 30, 2020, the Company transferred all available-for-sale securities to cash accounts.

The following table sets forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy (in thousands):

	September 30, 2020			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liability	$ –	$ –	$ 7,233	$ 7,233
Total	$ –	$ –	$ 7,233	$ 7,233

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 2,019	$ –	$ –	$ 2,019
Commercial paper	–	11,064	–	11,064
Corporate debt securities	–	8,982	–	8,982
U.S. government debt securities	–	3,770	–	3,770
Total	$ 2,019	$ 23,816	$ –	$ 25,835
Liabilities:				
Contingent consideration	$ –	$ –	$ 31	$ 31
Total	$ –	$ –	$ 31	$ 31

The fair value of the common stock warrant liability is estimated using a Monte Carlo simulation model, which uses certain assumptions related to risk-free interest rates, expected volatility, and expected term. The fair value of the warrant liability was $11.7 million upon the issuance date of February 14, 2020 and $7.2 million as of September 30, 2020.

The following assumptions were used in estimating the fair value of the warrant liability as of September 30, 2020 and upon the issuance date of February 14, 2020:

	September 30, 2020	February 14, 2020
Stock price	$ 1.04	$ 1.69
Exercise price	$ 2.80	$ 2.80
Risk-free rate	0.41%	1.51%
Volatility	99.6%	93.40%
Term	6.37	6.99

The contingent consideration related to the IBEX acquisition of $31,000 outstanding at December 31, 2019, was paid during the nine months ended September 30, 2020. As of September 30, 2020, the obligation related to the contingent consideration was fully satisfied.

5. CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

During the nine months ended September 30, 2020, the Company transferred all available-for-sale securities to cash accounts.

Cash equivalents and short-term investments consisted of the following as of December 31, 2019 (in thousands):

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
Cash equivalents:				
Money market funds	$ 2,019	$ –	$ –	$ 2,019
Commercial paper	1,020	4	–	1,024
U.S. government debt securities	3,761	9	–	3,770
Total cash equivalents (1)	6,800	13	–	6,813
Short-term investments:				
Commercial paper	9,986	54	–	10,040
Corporate debt securities	8,977	5	–	8,982
Total short-term investments	18,963	59	–	19,022
Total	$ 25,763	$ 72	$ –	$ 25,835

(1) Included in cash and cash equivalents in the Company's consolidated balance sheet as of December 31, 2019 in addition to $3.4 million of cash.

For the nine months ended September 30, 2020 and 2019, the Company recognized net realized gains on available-for-sale securities of $0.1 million and $0.4 million, respectively.

6. PROPERTY AND EQUIPMENT, NET

The following table presents the components of property and equipment, net (in thousands):

	September 30, 2020	December 31, 2019
Machinery and equipment	$ 12,215	$ 12,083
Land and buildings	2,000	2,000
Computers and software	1,240	1,189
Leasehold improvements	3,057	2,282
Construction in progress	169	1,606
Furniture and equipment	233	470
Total property and equipment, gross	18,914	19,630
Accumulated depreciation and amortization	(6,944)	(4,719)
Total property and equipment, net	$ 11,970	$ 14,911

Depreciation and amortization expense for property and equipment, including assets acquired under financing leases was as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
General and administrative expense	$ 402	$ 407	$ 1,202	$ 1,171
Research and development expense	386	390	1,135	1,072
Total depreciation and amortization expense	$ 788	$ 797	$ 2,337	$ 2,243

7. LEASES

The Company leases facilities and certain equipment under noncancelable leases that expire at various dates through November 2024. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases may include options to extend or terminate the lease at the election of the Company. These optional periods have not been considered in the determination of the right-of-use-assets or lease liabilities associated with these leases as the Company did not consider it reasonably certain it would exercise the options. In May 2020, the Company reduced space under one of its facility leases, which resulted in a remeasurement of the operating lease liability. See Note 15 for further discussion of the modification.

As of September 30, 2020, the maturities of our operating and finance lease liabilities were as follows (in thousands):

	Operating leases	Finance leases
2020 (excluding the nine months ended September 30, 2020)	$ 416	$ 166
2021	1,646	656
2022	1,345	405
2023	132	336
2024	86	42
Total lease payments	3,625	1,605
Less imputed interest	(369)	(206)
Total lease liabilities	$ 3,256	$ 1,399

Supplemental balance sheet information related to leases was as follows (in thousands):

Finance leases

	September 30, 2020	December 31, 2019
Finance lease right-of-use assets included within property and equipment, net	$ 1,466	$ 2,177
Current finance lease liabilities included within other current liabilities	$ 544	$ 508
Non-current finance lease liabilities included within other long-term liabilities	855	1,267
Total finance lease liabilities	$ 1,399	$ 1,775

Operating leases

	September 30, 2020	December 31, 2019
Current operating lease liabilities included within other current liabilities	$ 1,439	$ 1,746
Operating lease liabilities – non current	1,817	2,994
Total operating lease liabilities	$ 3,256	$ 4,740

The components of lease expense were as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease costs included within operating costs and expenses	$ 531	$ 556	$ 1,635	$ 1,617
Finance lease costs:				
Amortization of right-of-use assets	$ 175	$ 171	$ 524	$ 479
Interest on lease liabilities	36	42	118	109
Total	$ 211	$ 213	$ 642	$ 588

Supplemental cash flow information related to leases was as follows (in thousands):

	For the Nine Months Ended September 30,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash out flows from operating leases	$ 1,640	$ 1,550
Operating cash out flows from finance leases	$ 118	$ 109
Financing cash out flows from finance leases	$ 376	$ 336
Lease liabilities arising from obtaining right-of-use assets:		
Finance leases	$ –	$ 1,828
Lease payments made in prior period reclassified to property and equipment	$ –	$ 535
Remeasurement of finance lease liability due to lease modification	$ –	$ (22)
Operating leases	$ –	$ 936
Remeasurement of operating lease liability due to lease modification	$ 131	$ –

As of September 30, 2020 and December 31, 2019, the weighted average remaining lease term for operating leases was 2.3 and 2.8 years, respectively, and the weighted average discount rate used for operating leases was 9.79% and 9.83%, respectively. As of September 30, 2020 and December 31, 2019, the weighted average remaining lease term for finance leases was 2.8 and 3.5 years, respectively, and the weighted average discount rate used for finance leases was 9.77% for both periods.

8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

The following table presents the major components of accounts payable and accrued expenses (in thousands):

	September 30, 2020	December 31, 2019
Accounts payable	$ 1,384	$ 1,689
Salaries and other compensation	1,362	1,462
Legal and accounting	317	1,404
Accrued severance	571	1,053
Benefit plan accrual	588	557
Other	596	930
Total accounts payable and accrued expenses	$ 4,818	$ 7,095

Other current liabilities are comprised of the current portion of operating lease liabilities and finance lease liabilities, and short-term debt. The short-term debt had a balance of $0.3 million as of September 30, 2020, while the other components are disclosed in Note 7 above. The short-term debt balance is related to two financing arrangements entered into during the nine months ended September 30, 2020 to fund an insurance contract. Under the financing arrangements, the Company borrowed $0.8 million and $0.2 million. The amounts will be repaid in nine equal monthly installments, with an interest rate of 4.25% and 6.35%, respectively.

9. STOCK-BASED COMPENSATION

2020, 2019 and 2017 Equity Incentive Plans

2020 Plan

On October 25, 2019, the Company's Board of Directors (the "Board") approved the Company's 2020 Stock Option and Incentive Plan (the "2020 Plan"). The 2020 Plan became effective on December 19, 2019, the date approved by the stockholders. The 2020 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, unrestricted stock awards, dividend equivalent rights, and cash-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2020 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 3,000,000 shares of common stock are issuable pursuant to awards under the 2020 Plan. No grants of awards may be made under the 2020 Plan after the later of December 19, 2029, or the tenth anniversary of the latest material amendment of the 2020 Plan and no grants of incentive stock options may be made after October 25, 2029. As of September 30, 2020, the Company had 70,190 shares available for future issuances under the 2020 Plan.

2019 Plan

On October 5, 2018, the Company's Board approved the Company's 2019 Equity Incentive Plan (the "2019 Plan"). The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other types of stock-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2019 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 3,000,000 shares of common stock are issuable pursuant to awards under the 2019 Plan. Unless earlier terminated by the Board, the 2019 Plan shall terminate at the close of business on October 5, 2028. As of September 30, 2020, the Company had 287,615 shares available for future issuances under the 2019 Plan.

2017 Plan

On December 1, 2016, the Company's Board approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). The purpose of the 2017 Plan is to promote the success of the Company and to increase stockholder value by providing an additional means through the grant of awards to attract, motivate, retain and reward selected employees, consultants and other eligible persons. The 2017 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other types of stock-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2017 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 7,300,000 shares of common stock are issuable pursuant to awards under the 2017 Plan. Unless earlier terminated by the Board, the 2017 Plan shall terminate at the close of business on December 1, 2026. As of September 30, 2020, the Company had 1,013,450 shares available for future issuances under the 2017 Plan.

A summary of the Company's employee and non-employee stock option activity for the nine months ended September 30, 2020 is presented below:

	Number of Shares	Weighted-Average Exercise Price
Outstanding – December 31, 2019	4,529,988	$ 15.26
Granted	1,882,888	$ 1.23
Exercised	(10,208)	$ 3.08
Forfeited	(1,363,754)	$ 16.30
Outstanding – September 30, 2020	5,038,914	$ 9.75
Options exercisable, September 30, 2020	3,447,648	$ 12.69

Employee Stock Purchase Plan (ESPP)

In May 2018, the Company adopted the Employee Stock Purchase Plan ("ESPP"). The Company has initially reserved500,000 shares of common stock for purchase under the ESPP. The initial offering period began January 1, 2019 and ended on June 30, 2019 with the first purchase date. Subsequent offering periods will automatically commence on each January 1 and July 1 and will have a duration of six months ending with a purchase date June 30 and December 31 of each year. On each purchase date, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date.

Restricted Stock

A summary of the Company's employee and non-employee restricted-stock activity is presented below:

	Number of Shares
Unvested - December 31, 2019	1,843,001
Granted	3,628,204
Vested (1)	(1,501,072)
Forfeited	(95,188)
Unvested – September 30, 2020	3,874,945

(1) The number of vested restricted stock units and awards includes shares that were withheld on behalf of employees to satisfy the minimum statutory tax withholding requirements.

Stock-Based Compensation Expense

The stock-based compensation expense related to stock options, restricted stock awards, and the employee stock purchase plan was as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
General and administrative expense	$ 1,655	$ 4,822	$ 4,875	$ 20,751
Research and development expense	388	(164)	755	2,401
Sales and marketing expense	136	367	333	780
Total stock-based compensation expense	$ 2,179	$ 5,025	$ 5,963	$ 23,932

10. COMMON STOCK WARRANTS

On February 14, 2020, the Company completed an underwritten offering of10,638,298 shares of its common stock and warrants to purchase10,638,298 shares of common stock. Each common share and warrant were sold together for a combined public purchase price of $2.35 before underwriting discount and commission. The exercise price of each warrant is $2.80 per share, the warrants were exercisable immediately, and they will expireFebruary 12, 2027. As the warrants could require cash settlement in certain scenarios, the warrants were classified as a liability and are recorded at an estimated fair value using a Monte Carlo simulation model. The total proceeds from the offering were allocated first to the warrant liability based on the estimated fair value with the residual allocated to the common shares. As of September 30, 2020, none of the warrants had been exercised.

The change in fair value of the common stock warrant liability is presented in the following table and is reported as a change in fair value of common stock warrant liability in the statements of operations (in thousands):

	September 30, 2020
Beginning balance	$ –
Initial value of common stock warrant liability	11,677
Change in fair value of common stock warrant liability	(4,444)
Ending balance	$ 7,233

11. LOSS PER SHARE

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	As of September 30,	
	2020	2019
Stock options	5,038,914	6,357,029
Restricted stock	3,874,945	2,027,100
Common stock warrants	10,638,298	15,235

12. DEBT

On April 12, 2020, our subsidiary PolarityTE MD, Inc. (the "Borrower") entered into a promissory note evidencing an unsecured loan in the amount of **$**,576,145 made to it under the Paycheck Protection Program (the "Loan"). The Paycheck Protection Program (or "PPP") was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration. The Loan to the Borrower was made through KeyBank, N.A., a national banking association (the "Lender"). The interest rate on the Loan is 1.00%. Beginning seven months from the date of the Loan the Borrower is required to make24 monthly payments of principal and interest in the amount of $150,563. The promissory note evidencing the Loan contains customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the SBA or Lender, or breaching the terms of the Loan documents. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Borrower, or filing suit and obtaining judgment against the Borrower. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of a loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. No assurance is provided that the Company will obtain forgiveness of the Loan in whole or in part.

13. RESTRUCTURING

In the second quarter of 2020, management approved several actions as part of a restructuring plan designed to improve operational efficiency and financial results. Management approved a reduction in force, which affected 40 of the 126 employees in the regenerative medicine business segment, or approximately 31.7% of that workforce. The Company did not make any change in the workforce of its contract services segment. The Company recognized $0.6 million of expense related to employee severance and benefit arrangements for the second quarter restructuring. The Company also recognized $0.4 million of other employee severance expense during the first quarter of 2020. Total severance expense recorded during the nine months ended September 30, 2020 was $1.0 million. It is expected that the full amount of severance will be paid by the end of 2020. Management also recorded $1.5 million of asset abandonments within the Company's regenerative medicine business segment.

14. COMMITMENTS AND CONTINGENCIES

Contingencies

On June 26, 2018, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Jose Moreno against the Company and two directors of the Company, Case No. 2:18-cv-00510-JNP (the "Moreno Complaint"). On July 6, 2018, a similar complaint was filed in the same court against the same defendants by Yedid Lawi, Case No. 2:18-cv-00541-PMW (the "Lawi Complaint"). Both the Moreno Complaint and Lawi Complaint allege that the defendants made statements or disseminated information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10 and 20(a) of the Exchange Act and Rule 10b-5 adopted thereunder. Specifically, both complaints allege that the defendants misrepresented the status of one of the Company's patent applications while touting the unique nature of the Company's technology and its effectiveness. Plaintiffs are seeking damages suffered by them and the class consisting of the persons who acquired the publicly-traded securities of the Company between March 31, 2017, and June 22, 2018. Plaintiffs have filed motions to consolidate and for appointment as lead plaintiff. On November 28, 2018, the Court consolidated the *Moreno* and *Lawi* cases under the caption *In re PolarityTE, Inc. Securities Litigation* (the "Consolidated Securities Litigation"), and requested the appointment of the plaintiff in *Lawi* as the lead plaintiff. On January 16, 2019, the Court granted the motion of Yedid Lawi for appointment as lead plaintiff, and on February 1, 2019, the Court granted the lead plaintiff's motion for approval of lead counsel and liaison counsel. The Court also ordered that the lead plaintiff file and serve a consolidated complaint no later than 60 days after February 1, 2019. The lead plaintiff filed a consolidated complaint on April 2, 2019, and asserted essentially the same violations of Federal securities laws recited in the original complaints. The Company filed a motion to dismiss the consolidated complaint on June 3, 2019. Plaintiffs' opposition to the Company's motion to dismiss was filed on August 2, 2019, and the Company filed a reply to the opposition on September 13, 2019. A hearing on the Company's motion to dismiss was held on November 19, 2019; no order has been issued to date. At this early stage of the proceedings the Company is unable to make any prediction regarding the outcome of the litigation.

In November 2018, a shareholder derivative lawsuit was filed in the United States District Court, District of Utah, with the caption *Monther v. Lough, et al.*, case no. 2:18-cv-00791-TC, alleging violations of the Exchange Act, breach of fiduciary duty, and unjust enrichment on the part of certain officers and directors based on the facts and circumstances recited in the Consolidated Securities Litigation. On November 26, 2018, the court issued an order staying all proceedings until after the disposition of motions to dismiss the Consolidated Securities Litigation.

Other Matters

In the ordinary course of business, the Company may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment, regulatory compliance, and other matters. Except as noted above, as of September 30, 2020, the Company was not party to any legal or arbitration proceedings that may have material effects on its financial position or results of operations. No governmental proceedings are pending or, to the Company's knowledge, contemplated against the Company. The Company is not a party to any material proceedings in which any director, member of senior management or affiliate of the Company is either a party adverse to the Company or its subsidiaries or has a material interest adverse to the Company or its subsidiaries.

Commitments

The Company has entered into employment agreements with key executives and adopted a change in control plan that contain severance terms and change of control provisions.

On September 2, 2020, Arches Research, Inc., a subsidiary of PolarityTE, Inc. ("Arches") entered into two agreements with Co-Diagnostics, Inc. ("Co-Diagnostics"). The COVID-19 Laboratory Services Agreement between the parties provides that Arches will perform specimen testing services for customers referred by Co-Diagnostics to Arches. Co-Diagnostics will arrange all logistics for delivering specimens to Arches for COVID-19 testing for those customers of Co-Diagnostics electing to use the service. Arches bills Co-Diagnostics for the testing services and Co-Diagnostics manages all customer billing. The Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches and Co-Diagnostics provides that Co-Diagnostics will make available to Arches the Oktopure high throughput extraction machine that Arches will use to perform COVID-19 testing. The term of the agreement is 12 months, requires Arches to use Co-Diagnostics tests exclusively in the machine, and establishes for Arches a minimum monthly purchase obligation, valued at approximately $1.1 million annually for Co-Diagnostics tests and related consumables used in the testing process.

15. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

On August 21, 2019, the Company and Dr. Denver Lough, a principal shareholder and former officer and director, signed a settlement terms agreement that provides, in part, that the Company pay to Dr. Lough $1,500,000 in cash on October 1, 2019 and an additional $1,500,000 in cash in equal monthly installments beginning November 1, 2019 and ending April 1, 2021. In addition, the Company agreed to award to Dr. Lough 200,000 restricted stock units that vest in 18 equal monthly installments beginning October 1, 2019. The fair value of the restricted stock units was $0.8 million. The Company expensed the cash portion and equity portion of these awards upon Dr. Lough's termination. As of September 30, 2020, the Company has recorded a liability of $0.6 million related to future cash payments under the agreement.

In October 2018, the Company entered into an office lease covering approximately7,250 square feet of rental space in the building located at 40 West 57th Street in New York City. The lease is for a term of three years. The annual lease rate is $60 per square foot. Initially the Company occupied and paid for only 3,275 square feet of space, and the Company is not obligated under the lease to pay for the remaining 3,975 square feet covered by the lease unless we elect to occupy that additional space. The Company believes the terms of the lease are very favorable to us, and the Company obtained these favorable terms through the assistance of Peter A. Cohen, a director, which he provided so that the company he owns, Peter A. Cohen, LLC ("Cohen LLC"), could sublease a portion of the office space.

During 2019, the Company increased the space from 3,275 square feet to6,232 square feet. In May 2020, the Company reduced the space from 6,232 to 4,554. The Company is using 1,099 square feet, and Cohen LLC is using approximately 3,455 square feet as of September 30, 2020. The monthly lease payment for 4,554 square feet is $22,771. Of this amount $17,277 is charged pro rata to Cohen LLC based on square footage occupied. Additional lease charges for operating expenses and taxes are also charged under the sublease based on the ratio of rent paid by the Company and Cohen LLC to total rent. If the space becomes fully occupied, the Company will reduce the overall annual lease rate for the Cohen LLC space to $58.60 per square foot. The Company recognized sublease income related to this agreement of $52,000 and $69,000 for the three months ended September 30, 2020 and 2019, respectively, and $184,000 and $195,000 for the nine months ended September 30, 2020 and 2019, respectively. The sublease income is included in other income, net in the statements of operations. As of September 30, 2020 and December 31, 2019, there were no amounts due from the related party under this agreement.

16. SEGMENT REPORTING

Reportable segments are presented in a manner consistent with the internal reporting provided to the chief operating decision maker (CODM). In April 2020, the Company designated its Chief Executive Officer (CEO) to be its Chief Operating Decision Maker (CODM) and dissolved the function of the Office of the Chief Executive consisting of the President, Chief Operating Officer, and Chief Financial Officer, which previously acted as its CODM.

The CODM allocates resources to and assesses the performance of each segment using information about its revenue and operating income (loss). These measures are presented in the following tables (in thousands). Asset information by segment is not presented, as this measure is not used by the CODM to assess the segment's performance.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Net revenues by segment:				
Regenerative medicine	$ 1,156	$ 839	$ 2,528	$ 1,640
Contract services	2,181	556	4,008	2,546
Total net revenues	$ 3,337	$ 1,395	$ 6,536	$ 4,186
Net income (loss) by segment:				
Regenerative medicine	$ (7,246)	$ (22,466)	$ (32,516)	$ (70,247)
Contract services	165	(517)	(282)	(1,101)
Total net loss	$ (7,081)	$ (22,983)	$ (32,798)	$ (71,348)

17. SUBSEQUENT EVENTS

On October 15, 2020, the Borrower applied to the Lender for forgiveness of the PPP loan described under Note 12 in its entirety based on the Borrower's use of the PPP loan for payroll costs, rent, and utilities. On October 26, 2020, the Borrower was advised that the Lender approved the application and that the Lender was submitting the application to the SBA for a final decision. The SBA may take up to 90 days to make a decision on the Borrower's forgiveness application. The Company classified the principal balance of the PPP loan within "Current portion of long-term notes payable" and "Long-term notes payable" on the consolidated balance sheet as of September 30, 2020. If the Borrower's application for forgiveness of the PPP loan is not approved or approved only in part, it will be obligated to repay the unforgiven portion of the loan after the SBA makes its decision on the application for forgiveness.

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

The discussion and analysis below includes certain forward-looking statements that are subject to risks, uncertainties and other factors, as described in "Risk Factors" in our Annual Report on Form 10-K and this report, that could cause our actual growth, results of operations, performance, financial position and business prospects and opportunities for this fiscal year and periods that follow to differ materially from those expressed in or implied by those forward-looking statements. Readers are cautioned that forward-looking statements contained in this Quarterly Report on Form 10-Q should be read in conjunction with our disclosure under the heading "Disclosure Regarding Forward-Looking Statements" below.

Overview

We are a commercial-stage biotechnology and regenerative biomaterials company focused on transforming the lives of patients by discovering, designing and developing regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering and material sciences. Historically, we have operated two segments: the regenerative medicine product segment and the contract services segment.

Segment Reporting

Regenerative Medicine Product Segment

The regenerative medicine product segment is engaged in the development of SkinTE, our first commercial product, and also the development of SkinTE POC (point-of-care device for on-site SkinTE processing and deployment), Skin TE Cryo (cryopreservation of SkinTE for multiple deployments on a single patient), and PTE 11000 (allogeneic, biologically active dressing for use in wound care).

SkinTE was registered and listed with the United States Food and Drug Administration (FDA) in August 2017 based on our determination that SkinTE is appropriately regulated solely under Section 361 of the Public Health Service Act and Part 1271 of Title 21 of the Code of Federal Regulations (i.e., as a so-called "361 HCT/P") and that, as a result, no premarket review or approval by the FDA is required. We proceeded to develop sales and manufacturing capabilities for SkinTE and focused on advancing commercialization of SkinTE.

Following informal, voluntary discussions between us and the FDA we were advised by the FDA in April 2020 that its preliminary assessment is that SkinTE does not meet the requirements to be regulated as a 361 HCT/P. Rather, FDA's view is that SkinTE is a biological product that should be regulated under Section 351 of the Public Health Service Act. We re-evaluated our regulatory approach and determined it is prudent to submit an investigational new drug application (IND), and thereafter a biologics license application (BLA) for SkinTE, and to adjust the focus of our commercial effort for SkinTE based on the following factors:

- license exclusivity for 12 years that arises under a BLA could enhance the value of SkinTE;
- clinical testing in the BLA process could accelerate commercial acceptance of SkinTE;
- the possibility the FDA could restrict our commercial sale of SkinTE in the future; and
- the contraction of the commercial opportunity for SkinTE in March and April 2020 because healthcare providers were dedicating resources to the care and treatment of COVID-19 patients and the acute and traumatic care needs of the general population and, as a result, were putting a hold on elective procedures in many regions across the country.

In August 2020 we submitted a Type B Pre-IND meeting request to FDA regarding an indication for SkinTE to treat diabetic foot ulcers (DFUs), and we received written responses to our meeting request and questions in October 2020. FDA's responses included, among other things, feedback and recommendations on SkinTE manufacturing, preclinical studies, and clinical data submitted in the Company's briefing package, and guidance on additional information for the Company to include in its IND submission. Consistent with published FDA guidance documents, including "Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," the Agency stated that for a condition like DFUs, it would generally expect at least two adequate and well-controlled studies to provide substantial evidence of effectiveness and evidence of safety to support a future marketing application. The Agency noted that our ongoing randomized controlled trial (RCT) in DFUs has elements of an adequate and well-controlled study, but stated that it would not accept our ongoing post-marketing RCT in DFUs as one of the two adequate and well-controlled studies to support a future marketing application.

With this FDA feedback we are re-evaluating our development plan for SkinTE. We believe much of the chemistry, manufacturing and controls (CMC) work, as well as non-clinical work, we will do for the DFU indication can be leveraged for multiple indications. Based on our experience with the deployment of SkinTE, we believe SkinTE can be successful in closing complex wounds such as DFU Wagner grade 2 through 4, grade 3 & 4 pressure injuries, and acute wounds. Our present intention is to focus our efforts on these wound types, where we believe there are significant unmet needs, and pursue these indications in our IND submission for approval either in parallel or a tight sequential process.

In the coming months we will pursue the preparation of an IND filing with FDA, which we believe we will be able to file in the second half of 2021. This effort will include, among other things, the completion of CMC and pre-clinical work to satisfy FDA requirements, interaction with FDA on additional indications, trials design, preparation and submission of the IND, and planning for clinical trial enrollment to begin as soon as we have an open IND.

Contract Services Segment

The contract services segment operates a preclinical research and veterinary sciences business through our subsidiary, Ibex Preclinical Research, Inc. We also offer research and laboratory testing services to unrelated third parties on a contract basis through our subsidiary, Arches Research, Inc. ("Arches").

There was a substantial surge in COVID-19 testing throughout the United States as a result of the COVID-19 pandemic, which began in the spring of 2020. In the course of its operations, Arches maintains equipment and staff capable of performing molecular polymerase chain reaction testing for COVID-19, which made it possible for Arches to begin providing COVID-19 testing services on May 27, 2020. We believe that COVID-19 testing offers an opportunity to use existing resources to generate additional revenue in the contract services segment and thereby help defray our operating expenses. We have pursued this opportunity during the third quarter of 2020 and expect to continue to do so as long as we believe COVD-19 testing services are beneficial to supporting our operations.

Revenue Recognition

In the regenerative medicine products segment, we record product revenues primarily from the sale of our regenerative tissue products. We sell our products to healthcare providers, primarily through direct sales representatives. Product revenues consist of a single performance obligation that we satisfy at a point in time. In general, we recognize product revenue upon delivery to the customer. In the contract services segment, we earn service revenues from the provision of contract research services, which includes delivery of preclinical studies and other research services to unrelated third parties. Service revenues generally consist of a single performance obligation that we satisfy over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. Contract services also includes research and laboratory testing services to unrelated third parties on a contract basis. These customer contracts generally consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes revenue upon delivery of testing results to the customer.

Research and Development Expenses

Research and development expenses primarily represent employee related costs, including stock compensation for research and development executives and staff, lab and office expenses, clinical trial costs, and other overhead charges.

General and Administrative Expenses

General and administrative expenses primarily represent employee related costs, including stock compensation for corporate executives and support staff, general office expenses, professional fees and various other overhead charges. Professional fees, including legal and accounting expenses, typically represent one of the largest components of our general and administrative expenses. These fees are partially attributable to our required activities as a publicly traded company, such as SEC filings, and corporate and business development initiatives.

Sales and Marketing Expenses

Sales and marketing expenses primarily represent employee related costs, including stock compensation for sales and marketing executives and staff, marketing and advertising expenses, trade shows and other promotional costs, and other related charges.

Results of Operations

Comparison of the three months ended September 30, 2020 compared to the three months ended September 30, 2019.

(in thousands)	For the Three Months Ended		Increase (Decrease)	
	September 30, 2020	September 30, 2019	Amount	%
	(Unaudited)			
Net revenues				
Products	$ 1,156	$ 839	$ 317	38%
Services	2,181	556	1,625	292%
Total net revenues	3,337	1,395	1,942	139%
Cost of sales				
Products	210	315	(105)	(33)%
Services	1,142	330	812	246%
Total cost of sales	1,352	645	707	110%
Gross profit	1,985	750	1,235	165%
Operating costs and expenses				
Research and development	2,698	2,956	(258)	(9)%
General and administrative	6,264	16,044	(9,780)	(61)%
Sales and marketing	1,606	4,988	(3,382)	(68)%
Total operating costs and expenses	10,568	23,988	(13,420)	(56)%
Operating loss	(8,583)	(23,238)	14,655	(63)%
Other income (expense)				
Change in fair value of common stock warrant liability	1,503	–	1,503	*
Interest income (expense), net	(58)	27	(85)	(315)%
Other income, net	57	228	(171)	(75)%
Net loss	$ (7,081)	$ (22,983)	$ 15,902	(69)%

Net Revenues

For the three-month period ended September 30, 2020, we recorded net revenues of $3.337 million, which represents an increase of $1.942 million or 139% from the $1.395 million of net revenues recorded for the three months ended September 30, 2019. The increase in net revenues was due to an increase in revenue in both our regenerative medicine product segment and the contract services segment.

Regenerative Medicine Product Segment

For the three-month period ended September 30, 2020, net revenues from the regenerative medicine product segment are $1.156 million, which represents an increase of $0.317 million or 38% from the $0.839 million of net revenues recorded for the three months ended September 30, 2019. This change is attributable to an increase of 51% in the number of paid cases from 81 in the third quarter of 2019 to 122 in the third quarter of 2020, and to a lesser extent the higher average revenue per paid case we experienced in the third quarter of 2020. Of SkinTE revenues for the third quarter, $0.639 million, or 55%, of net revenues was generated by two hospital systems, and one of these hospital systems alone was the source of 44% of the net revenues.

As noted above, we plan to submit to FDA an IND and BLA for SkinTE. We are in the process of preparing our IND submission and FDA has not asked us to stop marketing SkinTE pending submission or approval of a BLA. FDA announced in revised final guidance issued in July 2020 that it would generally observe its practice of enforcement discretion established in prior guidance unless there are reported or potential significant safety concerns until May 31, 2021. It is not customary for the FDA to allow wide-spread commercial sales of a product subject to a pending BLA, but we plan to discuss with FDA the possibility of continued marketing of SkinTE as a 361 HCT/P on a limited basis at a future meeting.

At the same time as the regulatory development described above, we were experiencing the effects of the COVID-19 pandemic. Throughout the country, healthcare assets in terms of facilities and providers were dedicated in March, April, and May to the care and treatment of COVID-19 patients while still trying to meet the acute and traumatic care needs of the general population. The substantial rise in COVID-19 cases since the spring of 2020 indicates that the dedication of resources to the treatment of COVID-19 will continue for the immediate future. Consequently, medical care and procedures that are considered "elective" have been put on hold in many regions across the country. We experienced the effect of the COVID-19 pandemic in our commercial operations in March 2020, when there was a drop in paid cases in that month followed by cancellation or postponement of SkinTE procedures scheduled for April 2020. This negative impact was most evident in chronic wounds without amputation risk and we expect this impact to continue in subsequent periods as long as the pandemic continues to surge.

We do not know, and cannot predict, whether FDA will allow us to continue selling SkinTE while our BLA is pending. Accordingly, management determined it was prudent under the circumstances discussed above to focus our commercialization effort on the territories where we have current and repeat users of SkinTE. As a result, in May 2020 we eliminated 40 positions in the regenerative medicine product segment, including 24 positions engaged in performing sales and marketing functions.

Contract Services Segment

For the three-month period ended September 30, 2020, net revenues from the contract services segment are $2.181 million, which represents an increase of $1.625 million or 292% from the $0.556 million of net revenues recorded for the three months ended September 30, 2019. This change is primarily attributable to the revenues generated by the new COVID-19 testing services offered by Arches. COVID-19 testing service contributed $1.751 million to net revenues in the third quarter of 2020 and the remainder was generated by our historical clinical service offerings. Net revenues from our historical clinical service offerings decreased from $0.556 million for the three months ended September 30, 2019 to $0.430 million for the three months ended September 30, 2020.

As noted above we began COVID-19 testing at the end of May 2020. At September 30, 2020, we had testing agreements with 29 nursing homes and three pharmacies in the northeast, controlled by a single company, 29 of which are located in the state of New York. These 32 facilities accounted for $1.651 million, or 94%, of COVID-19 testing revenues in the third quarter ended September 30, 2020, most of which was generated in New York. On May 10, 2020, the Governor of the State of New York issued an order requiring COVID-19 testing of all employees working in nursing homes within the state weekly, which has been renewed on a monthly basis. Previously the New York Governor issued an order, Executive Order 202.10 (the "Executive Order') that, among other things, suspended the requirement that a laboratory outside New York obtain a clinical laboratory permit from New York State if the laboratory holds a CLIA certificate and is engaged to test for COVID-19 in specimens collected from persons in New York State. The Executive Order had a limited duration until April 22, 2020 but has been extended monthly and now expires December 3, 2020. We have not received any indication from the State of New York that the Executive Order will not be renewed in December 2020. Furthermore, our testing service agreements for the 32 facilities controlled by a single company in the northeast are on a month-to-month basis.

On September 2, 2020, Arches entered into two agreements with Co-Diagnostics, Inc. ("Co-Diagnostics"). The COVID-19 Laboratory Services Agreement between the parties provides that Arches will perform specimen testing services for customers referred by Co-Diagnostics to Arches. Co-Diagnostics will arrange all logistics for delivering specimens to Arches for COVID-19 testing for those customers of Co-Diagnostics electing to use the service. Arches bills Co-Diagnostics for the testing services and Co-Diagnostics manages all customer billing. The Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches and Co-Diagnostics provides that Co-Diagnostics will make available to Arches the Oktopure high throughput extraction machine that Arches will use to perform COVID-19 testing. The term of the agreement is 12 months, requires Arches to use Co-Diagnostics tests exclusively in the machine, and establishes for Arches a minimum monthly purchase obligation, valued at approximately $1.1 million annually for Co-Diagnostics tests and related consumables used in the testing process.

Gross Profit

Cost of sales for the product segment as a percentage of product revenues was 18% in the third quarter of 2020 compared to 38% for the third quarter of 2019. Built in production capacity results in a lower incremental cost per unit as product sales increase. There was a reduction in staff during 2020 that reduced fixed overhead costs increasing gross profit. Cost of sales for the services segment as a percentage of service revenues was 59% in the third quarter of 2019 compared to 52% for the third quarter of 2020, which we primarily attribute to cost variations in the services provided by our historical clinical service business and by Arches including the new COVID-19 testing in the third quarter of 2020, which was not being performed in 2019. As a result of the changes in net revenues and cost of sales in both segments, the combined effect is that gross profit increased as a percentage higher than net revenues period over period from $0.750 million for the three-month period ended September 30, 2019 to $1.985 million for the three-month period ended September 30, 2020, or an increase in gross profit of 165%.

Research and Development

For the three-month period ended September 30, 2020, we recorded research and development expenses totaling $2.698 million, which represents a decrease of $0.258 million, or 9%, from $2.956 million of research and development expenses for the three months ended September 30, 2019. There was a reduction in staff in research and development that reduced compensation and benefits costs by $0.443 million, which was offset by an increase in the portion of allocated operating costs assigned to research and development.

General and Administrative Expenses

General and administrative expenses totaled $6.264 million for the three-month period ended September 30, 2020, which represents a decrease of $9.780 million as compared to $16.044 million of general and administrative expenses incurred during the three months ended September 30, 2019. The primary drivers for this decrease are a $3.167 million reduction in stock-based compensation expense, due to restricted stock and option forfeitures related to the reductions in force taken during 2020, a $2.888 million decrease in severance expense, a $1.684 million reduction in legal, accounting, and consulting fees, and a $2.414 million reduction in compensation-related expenses in the third quarter of 2020 compared to the third quarter of 2019.

Sales and Marketing

Sales and marketing expenses totaled $1.606 million for the three-month period ended September 30, 2020, which represents a decrease of $3.382 million, as compared to $4.988 million of sales and marketing expenses incurred during the three months ended September 30, 2019. There was a reduction in staff that reduced compensation and benefits costs by $0.807 million and stock-based compensation expense of $0.231 million in the third quarter of 2020 compared to the third quarter of 2019. Furthermore, we recognized a reduction of marketing and consultant spending of $1.452 million and travel expense of $0.232 million, and allocated a lower portion of operating costs to sales and marketing in the third quarter of 2020 compared to the third quarter of 2019. The contract service segment does not have a meaningful sales and marketing component to its business.

Comparison of the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019.

(in thousands)	For the Nine Months Ended		Increase (Decrease)	
	September 30, 2020	September 30, 2019	Amount	%
	(Unaudited)			
Net revenues				
Products	$ 2,528	$ 1,640	$ 888	54%
Services	4,008	2,546	1,462	57%
Total net revenues	6,536	4,186	2,350	56%
Cost of sales				
Products	825	930	(105)	(11)%
Services	1,925	1,087	838	77%
Total cost of sales	2,750	2,017	733	36%
Gross profit	3,786	2,169	1,617	75%
Operating costs and expenses				
Research and development	9,235	13,072	(3,837)	(29)%
General and administrative	22,080	48,299	(26,219)	(54)%
Sales and marketing	7,324	12,922	(5,598)	(43)%
Restructuring and other charges	2,536	–	2,536	*
Total operating costs and expenses	41,175	74,293	(33,118)	(45)%
Operating loss	(37,389)	(72,124)	34,735	(48)%
Other income (expense)				
Change in fair value of common stock warrant liability	4,444	–	4,444	*
Interest income, net	(135)	126	(261)	(207)%
Other income, net	282	650	(368)	(57)%
Net loss	$ (32,798)	$ (71,348)	$ 38,550	(54)%

Net Revenues

For the nine-month period ended September 30, 2020, we recorded net revenues of $6.536 million, which represents an increase of $2.350 million or 56% from the $4.186 million of net revenues recorded for the nine months ended September 30, 2019.

Regenerative Medicine Product Segment

Net revenues for SkinTE in the nine-month period ended September 30, 2020 increased by 54% over the comparable period in 2019 to $2.528 million for the nine months ended September 30, 2020, compared to $1.640 million for the nine months ended September 30, 2019. This change is attributable to an increase of 74% in the number of paid SkinTE cases from 168 in the first nine months of 2019 to 291 for the first nine months of 2020, and the higher average revenue per paid case we experienced in the second and third quarters of 2020. Of SkinTE revenues for the nine months ended September 30, 2020, $0.836 million, or 33%, of net revenues was generated by one hospital system.

As noted above, we plan to submit to FDA an IND and BLA for SkinTE. We are in the process of preparing our IND submission and FDA has not asked us to stop marketing SkinTE pending submission or approval of a BLA. FDA announced in revised final guidance issued in July 2020 that it would generally observe its practice of enforcement discretion established in prior guidance unless there are reported or potential significant safety concerns until May 31, 2021. It is not customary for the FDA to allow wide-spread commercial sales of a product subject to a pending BLA, but we plan to discuss with FDA the possibility of continued marketing of SkinTE as a 361 HCT/P on a limited basis at a future meeting.

At the same time as the regulatory development described above, we were experiencing the effects of the COVID-19 pandemic. Throughout the country, healthcare assets in terms of facilities and providers were dedicated in March, April, and May to the care and treatment of COVID-19 patients while still trying to meet the acute and traumatic care needs of the general population. The substantial rise in COVID-19 cases since the spring of 2020 indicates that the dedication of resources to the treatment of COVID-19 will continue for the immediate future. Consequently, medical care and procedures that are considered "elective" have been put on hold in many regions across the country. We experienced the effect of the COVID-19 pandemic in our commercial operations in March 2020, when there was a drop in paid cases in that month followed by cancellation or postponement of SkinTE procedures scheduled for April 2020. This negative impact was most evident in chronic wounds without amputation risk and we expect this impact to continue in subsequent periods as long as the pandemic continues to surge.

We do not know, and cannot predict, whether FDA will allow us to continue selling SkinTE while our BLA is pending. Accordingly, management determined it was prudent under the circumstances discussed above to focus our commercialization effort on the territories where we have current and repeat users of SkinTE. As a result, in May 2020 we eliminated 40 positions in the regenerative medicine product segment, including 24 positions engaged in performing sales and marketing functions.

Contract Services Segment

Net revenues for contract services segment in the nine months ended September 30, 2020 are $4.008 million compared to $2.546 million for the nine months ended September 30, 2019, which is an increase of 57% for the first nine months of 2020 over the comparable period in 2019. This change is attributable to net revenues generated by the new COVID-19 testing services offered by Arches. COVID-19 testing service contributed $2.462 million to net revenues for the contract services segment in the first nine months of 2020 and the remainder was generated by our historical clinical service offerings. Net revenues from our historical clinical service offerings decreased from $2.546 million for the nine months ended September 30, 2019 to $1.546 million for the nine months ended September 30, 2020. As noted above we began COVID-19 testing at the end of May 2020. At September 30, 2020, we had testing agreements with 29 nursing homes and three pharmacies in the northeast, controlled by a single company, 29 of which are located in the state of New York. These 32 facilities accounted for accounted for $2.362 million, or 96%, of COVID-19 testing revenues for the nine-month ended September 30, 2020, most of which was generated in New York.

Gross Profit

Cost of sales for the product segment as a percentage of product revenues was 57% in the first nine months of 2019 compared to 33% for the first nine months of 2020. Built in production capacity resulted in a lower incremental cost per unit as product sales increased in 2020. There was also a reduction in staff during 2020 that reduced fixed overhead costs increasing gross profit. Cost of sales for the services segment as a percentage of service revenues was 43% in the first nine months of 2019 compared to 48% for the first nine months of 2020, which we primarily attribute to the higher cost of sales for the COVID-19 testing service in the first nine months of 2020, which was not being performed in 2019. As a result of the changes in net revenues and cost of sales in both segments, the combined effect is that gross profit increased as a percentage higher than net revenues period over period from $2.169 million for the nine-month period ended September 30, 2019 to $3.786 million for the nine-month period ended September 30, 2020, or an increase in gross profit of 75%.

Research and Development

For the nine-month period ended September 30, 2020, we recorded research and development expenses totaling $9.235 million, which represents a decrease of $3.837 million, or 29%, from $13.072 million of research and development expenses for the nine months ended September 30, 2019. There was a reduction in staff in research and development that reduced compensation and benefits costs by $1.427 million and stock-based compensation expense decreased $1.646 million.

General and Administrative Expenses

General and administrative expenses totaled $22.080 million for the nine-month period ended September 30, 2020, which represents a decrease of $26.219 million as compared to $48.299 million of general and administrative expenses incurred during the nine months ended September 30, 2019. The primary driver for this decrease is a $15.876 million reduction in stock-based compensation expense due to restricted stock and option forfeitures in addition to lower stock price and option values in the first nine months of 2020 compared to the first nine months of 2019.In addition, there was a decrease of $2.631 million in legal and consulting expense, a reduction of $2.422 million in compensation and benefit expense, severance expense decreased by $2.386 million, and a reduction in travel expense of $0.848 million in the first nine months of 2020 compared to the first nine months of 2019.

Sales and Marketing

Sales and marketing expenses totaled $7.324 million for the nine-month period ended September 30, 2020, compared to $12.922 million of sales and marketing expenses incurred during the nine months ended September 30, 2019. There was a reduction in staff that reduced compensation and benefit costs by $1.540 million and stock-based compensation expense of $0.447 million for the first nine months of 2020 compared to the same period in 2019. In addition, we recognized a reduction of marketing and consultant spending of $3.169 million and travel expense of $0.843 million, offset by an increase in severance expense of $0.447 million in the first nine months of 2020 compared to the same period in 2019. The contract service segment does not have a meaningful sales and marketing component to its business.

Restructuring and Other Charges

Restructuring and other charges totaled $2.536 million for the nine-month period ended September 30, 2020. There were no restructuring and other charges for the nine-month period ended September 30, 2019. Management approved several actions designed to improve operational efficiency and financial results including a reduction in force taken during the first nine months of 2020 that increased severance expense by $1.007 million. Management also recorded $1.566 million of asset abandonments within the Company's regenerative medicine business segment during the nine-month period ended September 30, 2020.

Liquidity and Capital Resources

As of September 30, 2020, our cash and cash equivalents totaled $23.186 million and our working capital was $20.027 million, compared to cash and cash equivalents and short-term investments of $29.240 million and our working capital of $22.428 million at December 31, 2019. Our accumulated deficit at September 30, 2020, was $468.155 million.

On April 12, 2020, our subsidiary PolarityTE MD, Inc. (the "Borrower") entered into a promissory note evidencing an unsecured loan in the amount of $3,576,145 made to us under the Paycheck Protection Program (the "Loan"). The Paycheck Protection Program (or "PPP") was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration. The Loan to the Borrower was made through KeyBank, N.A., a national banking association (the "Lender"). The interest rate on the Loan is 1.00%. Beginning seven months from the date of the Loan the Borrower is required to make 24 monthly payments of principal and interest in the amount of $150,563. The promissory note evidencing the Loan contains customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the SBA or Lender, or breaching the terms of the Loan documents. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Borrower, or filing suit and obtaining judgment against the Borrower. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of a loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. No assurance is provided that the Borrower will obtain forgiveness of the Loan in whole or in part. On October 15, 2020, the Borrower applied to the Lender for forgiveness of the PPP loan described under Note 12 in its entirety based on the Borrower's use of the PPP loan for payroll costs, rent, and utilities. On October 26, 2020, the Borrower was advised that the Lender approved the application and that the Lender was submitting the application to the SBA for a final decision. The SBA may take up to 90 days to make a decision on the Borrower's forgiveness application. If the Borrower's application for forgiveness of the PPP loan is not approved or approved only in part, it will be obligated to repay the unforgiven portion of the loan after the SBA makes its decision on the application for forgiveness.

On February 14, 2020, we completed an underwritten offering of 10,638,298 shares of our common stock and warrants to purchase 10,638,298 shares of common stock. Each common share and warrant were sold together for a combined public purchase price of $2.35 before underwriting discount and commission. Each warrant has an exercise price of $2.80 per share, was exercisable immediately, and will expire February 12, 2027. The net proceeds to the Company from the offering were $22.5 million, after offering expenses payable by the Company. In connection with this offering, the Company agreed not to sell any additional shares under the Keystone Purchase Agreement described below for a period of 90 days after the closing date of the offering.

We are party to an Equity Purchase Agreement dated as of December 5, 2019 (the "Purchase Agreement"), with Keystone Capital Partners, LLC ("Keystone"), pursuant to which Keystone has agreed to purchase from us up to $25.0 million of shares of our common stock, subject to certain limitations including a minimum purchase price of $2.00 per share, at our direction from time to time during the 36-month term of the Purchase Agreement. Concurrently, we entered into a Registration Rights Agreement with Keystone, pursuant to which we agreed to register the sales of our common stock pursuant to the Purchase Agreement under our existing shelf registration statement on Form S-3 or a new registration statement. During the period from the date of the Purchase Agreement to the date of this filing, we have sold 270,502 shares of our common stock under the Purchase Agreement generating total gross proceeds of $725,000 and have up to $24,275,000 available for future sale under the Purchase Agreement. In connection with the underwritten offering described in the preceding paragraph, we agreed not to sell any additional shares under the Purchase Agreement for a period of 90 days after the closing date of the offering.

As of the date of issuance of these unaudited interim condensed financial statements, the Company expects that its cash and cash equivalents of $23.186 million as of September 30, 2020, will not be sufficient to fund its current business plan including related operating expenses and capital expenditure requirements into the second quarter of 2021. Accordingly, there is substantial doubt about the Company's ability to continue as a going concern as the Company does not believe that its cash and cash equivalents will be sufficient to fund such business plan for at least twelve months from the date of issuance of these interim financial statements. The Company plans to address this condition by raising additional capital to finance its operations. Although the Company has been successful in raising capital in the past, financing may not be available on terms favorable to us, if at all, so there is no assurance that it will be successful in obtaining additional financing. Therefore, it is not considered probable, as defined in applicable accounting standards, that the Company's plans to raise additional capital will alleviate the substantial doubt regarding its ability to continue as a going concern.

For the foreseeable future we will continue to pursue fundraising opportunities when available. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our product development programs or be unable to continue operations over a longer term. We plan to meet our future capital requirements primarily through issuances of equity securities, debt financing, or strategic partnership arrangements. Failure to generate revenue or raise additional capital would adversely affect our ability to achieve our intended business objectives

Our actual capital requirements will depend on many factors, including the cost and timing of pursuing a biologics license application for SkinTE we intend to file with FDA, the cost and timing of pre-clinical and clinical trials, the cost of establishing and maintaining our facilities in compliance with cGMP regulations, and the cost and timing of advancing our product development initiatives related to SkinTE. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The foregoing factors, along with the other factors described in the section, Item 1A, "Risk Factors" in Part II of this Report on Form 10-Q will impact our future capital requirements and the adequacy of our available funds. If we are required to raise additional funds, any additional equity financing may be highly dilutive, or otherwise disadvantageous, to existing stockholders, and debt financing, if available, may involve restrictive covenants. If we elect to pursue collaborative arrangements, the terms of such arrangements may require us to relinquish rights to certain of our technologies, products, or marketing territories. Our failure to raise additional capital when needed, and on acceptable terms, would require us to reduce our operating expenses and would limit our ability to develop our product candidates and to continue operations, any of which would have a material adverse effect on our business, financial condition, and results of operation.

The following table sets forth the primary sources and uses of cash for each period indicated:

(in thousands)	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Net cash provided by (used in)		
Operating activities	$ (32,170)	$ (40,650)
Investing activities	17,747	(14,875)
Financing activities	27,391	27,125
Net increase/(decrease) in cash and cash equivalents	$ 12,968	$ (28,400)

Cash used in operating activities

During the nine-month period ended September 30, 2020, net cash used in operating activities was $32.170 million, which included $1.16 million of issuance fees related to the February equity raise. The cash used in operating activities was due to a net loss of $32.798 million plus $4.444 million due to remeasurement of the warrant liability arising from the underwritten offering of common stock and warrants in February 2020, which was offset by the non-cash expenses of $5.963 million for stock-based compensation expense.

During the nine-month period ended September 30, 2019, net cash used in operating activities was $40.650 million, which was due to a net loss of $71.348 million offset primarily by the non-cash expenses of $23.932 million for stock-based compensation expense.

Cash provided by (used in) investing activities

During the nine-month period ended September 30, 2020, net cash provided by investing activities was $17.747 million, which was due primarily to proceeds from the sale and maturities of available for sale securities.

During the nine-month period ended September 30, 2019, net cash used in investing activities was $14.875 million, which was due primarily due to purchases of available for sale securities.

Cash provided by financing activities

During the nine-month period ended September 30, 2020, net cash provided by financing activities was $27.391 million due to proceeds from financing arrangements and net proceeds received from the sale of common stock and warrants.

During the nine-month period ended September 30, 2019, net cash provided by financing activities was $27.125 million primarily due to proceeds received from the sale of common stock.

Critical Accounting Policies and Estimates

For a description of our significant accounting policies, see note 3 to our condensed consolidated financial statements.

Our discussion and analysis of the financial condition and results of operations is based upon our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities or the disclosure of gain or loss contingencies at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Among the more significant estimates included in these financial statements is the extent of progress toward completion of contracts, stock-based compensation, the valuation allowances for deferred tax benefits, and the valuation of tangible and intangible assets included in acquisitions. Actual results could differ from those estimates.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company records product revenues primarily from the sale of its regenerative tissue products. The Company sells its products to healthcare providers, primarily through direct sales representatives. Product revenues consists of a single performance obligation that the Company satisfies at a point in time. In general, the Company recognizes product revenue upon delivery to the customer.

The Company records service revenues from the sale of its preclinical research services and contract services. Preclinical research services includes delivery of preclinical studies and other research services to unrelated third parties. Service revenues generally consist of a single performance obligation that the Company satisfies over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. The Company believes that this method provides a faithful depiction of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires the Company to make reasonable estimates of the extent of progress toward completion of the contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. Generally, a portion of the payment is due upfront and the remainder upon completion of the contract, with most contracts completing in less than a year. Contract services includes research and laboratory testing services to unrelated third parties on a contract basis. These customer contracts generally consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes revenue upon delivery of testing results to the customer.

Costs to obtain the contract are incurred for products revenues as they are shipped and are expensed as incurred.

Stock-Based Compensation

The Company measures all stock-based compensation using a fair value method and records such expense in research and development, general and administrative, and sales and marketing expenses. Compensation expense for stock options with graded vesting is recognized over the service period for each separately vesting tranche of the award as though the award were in substance, multiple awards.

The fair value for options issued is estimated at the date of grant using a Black-Scholes option-pricing model. The risk-free rate is derived from the U.S. Treasury yield curve in effect at the time of the grant. The volatility factor is determined based on the Company's historical stock prices. Forfeitures are recognized as they occur.

The fair value of restricted stock grants is measured based on the fair market value of the Company's common stock on the date of grant and amortized over the vesting period of, generally, six months to three years.

Accruals for Research and Development Expenses and Clinical Trials

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment terms that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the timing of various aspects of the expenses. The Company determines accrual estimates by taking into account discussion with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, intangible assets and goodwill for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows.

Common Stock and Warrant Transactions

The Company issued units consisting of common stock and warrants and subsequently remeasured those warrants at fair value. Determining the fair value of the securities in these transactions requires significant judgment, including adjustments to quoted share prices and expected stock volatility. Such estimates may significantly impact our results of operations and losses applicable to common stockholders.

Disclosure Regarding Forward-Looking Statements

Statements that are not historical facts contained in or incorporated by reference into this Quarterly Report on Form 10-Q are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements involve risks and uncertainties that could cause actual results to differ from projected results. The words "anticipate," "goal," "seek," "project," "strategy," "future," "likely," "may," "should," "will," "believe," "estimate," "expect," "plan," "intend" and similar expressions and references to future periods, as they relate to us, are intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are subject to certain risks, uncertainties and assumptions. We cannot assure you that any of our expectations will be realized. Forward-looking statements include, among others, statements we make regarding:

- the timing or success of obtaining regulatory licenses or approvals for marketing our products;
- the initiation, timing, progress, and results of our research and development programs;
- the initiation, timing, progress, and results of our pre-clinical or clinical trials;
- the timing for the healthcare industry to resume performing elective procedures that may impact the timing and cost of clinical trials;
- the impact of new accounting pronouncements;
- size and growth of our target markets;
- sufficiency of our working capital to fund our operations over the next 12 months;
- infrastructure required to support operations in future periods, including the expected costs thereof;
- estimates associated with revenue recognition, asset impairments, and cash flows;
- variance in our estimates of future operating costs;

- future vesting and forfeitures of compensatory equity awards;
- the effectiveness of our disclosure controls and our internal control over financial reporting; and
- our plans to remediate material weaknesses in our internal control over financial reporting.

Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, without limitation:

- the ability to comply with regulations applicable to the manufacture, marketing, sale and distribution of our products;
- the ability to gain adoption by healthcare providers of our products for patient care;
- the ability to manufacture product to meet demand;
- the acceptance and level of reimbursement to healthcare providers for application of our products by public and private payors;
- the scope of protection we can establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and industry;
- the development of new therapies or new discoveries that render our products obsolete;
- outbreaks of disease, including the COVID-19 pandemic, and related stay-at-home orders, quarantine policies and restrictions on travel, trade and business operations;
- political and economic instability, whether resulting from natural disasters, wars, terrorism, pandemics or other sources;
- decisions made by healthcare providers regarding elective procedures and use of facilities and resources when there is a major outbreak of life-threatening infectious disease, such as COVID-19;
- the ability to pursue sales activity in the healthcare industry when there is a major outbreak of life-threatening infectious disease, such as COVID-19;
- the ability to manufacture and deliver our products if employees are quarantined due to the impact of the COVID-19;
- the ability to find and retain skilled personnel;
- the need for, and ability to obtain, additional financing in the future;
- general economic conditions;
- inaccuracies in estimates of our expenses, future revenues, and capital requirements;
- future accounting pronouncements;
- unauthorized access to confidential information and data on our information technology systems and security and data breaches; and
- factors described under “Risk Factors” in our 2019 Annual Report on Form 10-K and under Item 1A of this Quarterly Report on Form 10-Q.

We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are expressly qualified by these cautionary statements.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Not applicable.

Item 4. Controls and Procedures

Our management, with the participation of our principal executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on the evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2020, our principal executive and financial officers concluded that, as of such date, our disclosure controls and procedures were effective. There were no changes in our internal control over financial reporting during the three-month period ended September 30, 2020.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

You should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020, which could materially affect our business, financial position, or future results of operations. The risks described in that Annual Report and Quarterly Reports are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial position, or future results of operations. The risk factor set forth below updates, and should be read together with, the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020.

Risks Related to Our Business

Changes in our relationships with any of our significant customers, including the loss or reduction in business from one or more of them, could have a material adverse effect on us.

Since the beginning of 2020 several factors have contributed to the concentration of net revenues among several customers in both the regenerative medicine product segment and the contract services segment.

Due to the shift in our regulatory approach with FDA we determined it was prudent to focus our commercialization effort on the territories where we have current and repeat users of SkinTE and reduce the number of employees performing sales and marketing functions. For the three months ended September 30, 2020, 55%, of net revenues from the regenerative medicine product segment was generated by two hospital systems, one of which was the source of 44% of the net revenues, and for the nine months ended September 30, 2020, 33% of net revenues was generated by one hospital system, which is the same system that was the major contributor in the three-month period ended September 30, 2020.

At September 30, 2020, we had testing agreements with 29 nursing homes and three pharmacies in the northeast, controlled by a single company, 29 of which are located in the state of New York. These 32 facilities accounted for 94% of COVID-19 testing revenues in the third quarter ended September 30, 2020, and 96% of COVID-19 testing revenues for the nine-month period then ended, most of which was generated in New York. Accordingly, most of this business is dependent on monthly renewal by the state of New York of an order suspending the regulatory requirement that a laboratory outside New York obtain a clinical laboratory permit before providing laboratory testing services in the state, New York State regulations mandating testing for nursing home employees, and our ability to compete with other laboratories that may offer similar services in the state of New York.

There is no agreement or arrangement that prevents our significant customers from reducing or ending purchases of our product or services at any time. Purchases in the regenerative medicine product segment by significant customers depends on the demand for SkinTE for patient care, which is not predictable, and our ability to continue offer SkinTE while our BLA is pending. Our COVID-19 testing business in New York facilities is dependent on New York State orders and regulations, which are subject to change at any time, and our ability to compete for the business on the basis of price and service. If the demand by one or more of our significant customers for our product or services significantly decreased or all or a portion of our business dealings or relationships with one or more significant customers were to terminate or be canceled, it could materially adversely affect us and our ability to defray operating expenses with net revenues generated by those customers, thereby increasing our need and dependence on financing activities to fund operations.

Item 6. Exhibits

Except as otherwise noted, the following exhibits are included in this filing:

10.1	COVID-19 Laboratory Services Agreement between Arches Research, Inc., and Co-Diagnostics, Inc., dated September 2, 2020 (service pricing information is redacted from the exhibit)
10.2	Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches Research, Inc., and Co-Diagnostics, Inc., dated September 2, 2020 (product pricing information is redacted from the exhibit)
31.1	Certification Pursuant to Rule 13a-14(a)
31.2	Certification Pursuant to Rule 13a-14(a)
32.1	Certification Pursuant to Rule 13a-14(b) and Section 1350, Chapter 63 of Title 18, United States Code
101.INS	XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Label Linkbase Document
101.PRE	XBRL Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

Pursuant to the requirements 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.

POLARITYTE, INC.

Date: November 9, 2020

/s/ David Seaburg

David Seaburg
Chief Executive Officer
Duly Authorized Officer

Date: November 9, 2020

/s/ Jacob Patterson

Jacob Patterson
Interim Chief Financial Officer
Chief Accounting Officer

Exhibit 10.1

Service pricing information in Section 3 of this agreement has been redacted based on the registrant's determination the information is not material and would likely cause competitive harm.

COVID-19 LABORATORY SERVICES AGREEMENT

This Covid-19 Laboratory Services Agreement ("Agreement") is made between Co-Diagnostics, Inc., a Utah corporation having its principal place of business at 2401 South Foothill Drive, Suite D, Salt Lake City, UT 84109 (hereinafter "Client"), and Arches Research, Inc., a Nevada corporation having its principal place of business at 1960 S 4250 W, Salt Lake City, UT 84104 (hereinafter "Arches") (each referred to individually as a "Party" and collectively as the "Parties"). When signed by both Parties, this Agreement will set forth the terms and conditions under which Arches agrees to provide certain services to Client as set forth herein.

Recitals:

WHEREAS, Client is a medical diagnostic products and services company engaged, in part, in the business of marketing test kits ("Kits") for SARS-CoV-2 ("CoV-2");

WHEREAS, Client is pursuing a logistics business pursuant to which Client will manage all aspects of delivering Kits to end users of the Kits ("Customers"), collecting Kits from Customers after specimens are collected, and delivering Kits to a pre-selected testing laboratory (the "Logistics Business");

WHEREAS, Arches is a provider of laboratory testing services and is registered under the Clinical Laboratory Improvement Amendments (CLIA), CLIA Certificate No.: 46D2182352;

WHEREAS, Arches performs testing for the detection of CoV-2 in specimens collected from individuals; and

WHEREAS, Client desires to engage Arches as a provider of laboratory testing services for the Logistics Business and Arches desires to provide such services, and to that end the Parties wish to enter into this Agreement to provide the terms and conditions upon which Client engages Arches to perform validated tests to detect coronavirus RNA following applicable CLIA and FDA standards (the "Services").

NOW, THEREFORE, in consideration of the promises and the mutual covenants and agreements contained herein, the Parties hereby agree as follows:

1. PERFORMANCE DUTIES OF ARCHES.

Arches shall:

A. Perform validated tests to detect CoV-2 RNA (the "Services") following applicable CLIA standards and standards set by the U.S. Food and Drug Administration ("FDA"). The Parties explicitly acknowledge that the duty of Arches to provide Services is subject to the availability of governmental Emergency Use Authorizations and other emergency regulatory flexibility.

B. Process CoV-2 tests on Customer specimens received using commercially reasonable efforts; provided, however, that in no event shall Arches be obligated to process more than 500 tests during the period ending November 30, 2020, and 1,000 tests thereafter on Customer specimens, in the aggregate, during any 24-hour period beginning at 12:00 a.m. Mountain Time, on the weekdays Monday through Friday, excluding U.S. national holidays, Christmas Eve, and New Year's Eve (the "Test Cap").

C. Retain processed specimens for a period of at least 24 hours, or until laboratory test results are provided to the Customer providing the specimens.

D. Dispose of specimens and waste associated with the Services in compliance with law and Arches' safety policies.

E. Establish and maintain a system for communicating directly with Customers (the "Customer Portal") to (i) collect information reasonably required to perform Services for the Customers, (ii) obtain the Customers' orders for Services issued, in each case, by an authorized healthcare professional, (iii) deliver reports on specimen test results to Customers, and (iv) exchange any other information or documents pertaining to the performance of Services for Customers. Arches has no obligation to perform Services for any Customer that does not provide the information and documents reasonably required by Arches, including an order for Services issued by an authorized healthcare professional.

F. Respond to Customer communications sent to Arches through the Customer Portal no later than 5:00, p.m., Mountain Time, on the day following the day the communication from the Customer is received by Arches and such day following the communication is any of Monday through Saturday (excluding U.S. national holidays, Christmas Eve, and New Year's Eve).

G. Deliver a report on specimen test results to each Customer within 72 hours of Arches' receipt of the specimen.

H. Report data for all testing completed, for each individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department based on the individual's residence in accordance with federal, state, and local law.

2. PERFORMANCE DUTIES OF CLIENT.

Client shall:

A. Manage all aspects of its Logistics Business except for the Services provided by Arches to Customers hereunder, including but not limited to providing at Client's sole cost all Kits required by Customers, and arranging at Client's sole cost all shipping and delivery of Kits to Customers and shipping and delivery of specimens collected with the Kits from Customers to Arches. Customer Kits shall be delivered to Arches' facility at 1960 S 4250 W, Salt Lake City, UT 84104. Delivery hours are between 7:00 a.m. and 5:00 p.m., Mountain Time, Monday through Saturday, excluding U.S. national holidays.

B. Provide to Arches a work order for each Customer of the Logistics Business in the form attached hereto as Exhibit A ("Work Order"), that lists the name and address of the Customer of the Logistics Business, an estimate of the number of Kits the Customer will order from Client, the estimated date of delivery of Kits by Client to the Customer, and the contact information for Customer, including name, title, phone number, and email address. At the time each Work Order is issued by Client to Arches, Client will send to the Customer (with a copy to Arches) an email with instructions for accessing the Customer Portal. The foregoing notwithstanding, Arches may reject or terminate any Work Order in its sole discretion with no further duty to provide Services and no liability to Client or Customer if Customer does not provide to Arches the information, order for Services issued by an authorized healthcare professional, or other documents required of Customer through the Customer Portal.

C. Bill Customers for the use of the Logistics Business. Client has the sole right to bill for specimen testing provided in connection with the Logistics Business, and Arches has no right to bill or collect any amount from Customers for the Services. Client has sole responsibility and risk with respect to the collection of billings to Customers, and the obligation of Client to make payment to Arches for the Services provided to Customers pursuant to this Agreement is not contingent upon, or in any way related to, whether Client bills Customers or collects on its bills to Customers.

D. Use commercially reasonable efforts to manage the timing and flow of Work Orders from Client to Arches so that the number of Customer CoV-2 tests requested from time to time does not exceed the Test Cap.

E. Not pay commissions earned through this Agreement to any referring healthcare provider or make any payments prohibited by law.

3. PAYMENT OF FEES

Client will pay Arches for testing at the rate of $[ ] per test if 500 tests or fewer are processed on a single day between the hours of 12:00 a.m. and 11:59 p.m. Mountain Time. Client will pay Arches for testing at the rate of $[ ] per test if more than 500 tests are processed on a single day between the hours of 12:00 a.m. and 11:59 p.m. Mountain Time. If Client requests results within 24 hours of Arches' receipt of the specimen, an additional $[ ] per test STAT fee will be added to the per test rate. Arches will invoice Client on or around the first day[t] of each month for the Services performed and Client shall pay each invoice within 15 days of receipt of the invoice. If any portion of an invoice is disputed, then Client shall pay the undisputed amounts as set forth in the preceding sentence and the Parties shall use good faith efforts to reconcile the disputed amount as soon as practicable. Client shall pay Arches interest in an amount equal to one percent per month (or the maximum lesser amount permitted by law) of all undisputed amounts owing hereunder and not paid within 30 days of the date of the invoice.

4. CONFIDENTIALITY

As used in this Agreement, the term "Confidential Information" means any and all proprietary nonpublic information, knowledge, data, and all other content and materials belonging to either Party hereto and disclosed or provided to the other Party either directly or indirectly in any manner whatsoever, including, without limitation, in writing, orally, electronically, in all types of hard drives, disks, diskettes, computer memory or storage, or other media, or by drawings or inspection of physical items, and whether or not modified or merged into other materials. Confidential Information disclosed under this Agreement shall be used by the receiving Party and its employees only for purposes of performing the receiving Party's obligations hereunder. Each Party agrees that it will not reveal, publish or otherwise disclose the Confidential Information of the other Party to any third party without the prior written consent of the disclosing Party. Each Party agrees that it will not disclose the terms of this Agreement to any third party without the written consent of the other Party, which shall not unreasonably be withheld. These obligations of confidentiality and nondisclosure shall remain in effect for a period of one year after the completion or termination of this Agreement. The foregoing obligations shall not apply to Confidential Information to the extent that it: (a) is or becomes generally available to the public other than as a result of a disclosure by the receiving Party; (b) becomes available to the receiving Party on a non-confidential basis from a source which is not prohibited from disclosing such information; (c) was developed independently of any disclosure by the disclosing Party or was known to the receiving Party prior to its receipt from the disclosing Party, as shown by contemporaneous written evidence; or, (d) is required by law or regulation to be disclosed.

5. INDEPENDENT CONTRACTOR RELATIONSHIP.

For the purposes of this Agreement, the Parties hereto are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint venturers. Neither Party shall have the power or right to bind or obligate the other Party, and neither Party shall hold itself out as having such authority.

6. COMPLIANCE WITH LAWS AND POLICIES.

A. Both Parties shall be responsible for complying with any and all applicable laws, regulations, obligations and guidelines in relation to the Services, including those established under or by CLIA, FDA, and of all other regulatory agencies having jurisdiction over the Logistics Business and Services.

B. Medicare payment for a clinical diagnostic laboratory test may be made only to the person or entity that performs or supervises the performance of the test, subject to certain exceptions. 42 U.S.C. § 1395l(h). One of these exceptions permits Medicare payment to be made in the case of a test performed at the request of a laboratory (a "referring laboratory") by another laboratory (a "reference laboratory") if certain conditions are satisfied, but only if the reference laboratory is a Medicare-enrolled laboratory. Client acknowledges that Arches is not a Medicare-enrolled laboratory and, therefore, Medicare payment may not be made for the Services. Client further acknowledges that it has provided written notification to any of its contracted providers who may bill third-party payors for the Logistics Business (including the Services) that Arches is not a Medicare-enrolled laboratory and that Medicare payment may not be made for the Services.

C. Client shall comply with applicable third-party payor rules and policies with regard to reimbursement for the Services. In addition, Client shall seek representations from its contracted providers who may bill third-party payers for the Services that they will also comply with applicable third-party payor rules and policies with regard to reimbursement for the Services.

D. Client shall comply with applicable federal and state anti-markup payment limitations with regard to reimbursement for the Services. In addition, Client shall seek representations from its contracted providers who may bill third-party payors for the Services that they will also comply with applicable federal and state anti-markup payment limitations with regard to reimbursement for the Services.

E. Neither Party, nor its principals, is a Sanctioned Person or Entity. For purposes of this Agreement, the term "Sanctioned Person or Entity" means a person or entity that: (i) has been, or currently is, excluded pursuant to 42 U.S.C. §1320a-7 or similar state exclusion authority, suspended, debarred, or otherwise ineligible to participate in any federal health care program as that term is defined in 42 U.S.C. §1320a-7b(l) or comparable state programs; (ii) has been convicted of a criminal offense related to the provision of health care items or services or any other offense that may lead to exclusion under 42 U.S.C. §1320a-7 or investigation or otherwise aware of any circumstances (including the receipt of any notice, warning or reprimand) which may result in being excluded from participation in any federal or state health care program. If any change in circumstance occurs to make the foregoing statement inaccurate, one Party must notify the other Party in writing immediately and the other Party shall have the right to immediately terminate this Agreement.

7. INDEMNIFICATION.

A. Client shall indemnify, defend and hold harmless Arches and its parent, subsidiaries, affiliates, co-venturers, representatives, and contractors along with their respective directors, officers, shareholders, employees, subcontractors and agents from and against any and all claims, demands, actions, causes of actions, losses, damages, costs, expenses and other liabilities, and expenses, costs of litigation and attorneys' fees (collectively, the "Liabilities") related to, resulting from, or arising out of (a) any breach by Client of any of its obligations under this Agreement, or (b) the negligence of Client. Arches shall indemnify, defend and hold harmless Client from and against any and all Liabilities to the extent resulting from or arising out of (a) any breach by Arches of its obligations under this Agreement or (b) the negligence of Arches.

B. I f either Party intends to claim indemnification under Section 9.A, the Party seeking indemnification ("Claiming Party") shall promptly notify the other Party ("Indemnifying Party") in writing of any Liabilities in respect of which the Claiming Party intends to claim such indemnification. Claiming Party shall permit Indemnifying Party, at its discretion, to settle any such Liabilities and agrees to the complete control of such defense or settlement by Indemnifying Party. Claiming Party shall cooperate fully with Indemnifying Party and its legal representatives in the investigation and defense of any of the Liabilities covered by this indemnification. Claiming Party shall have the right, but not the obligation, to be represented by counsel of its own selection and expense. Claiming Party shall not negotiate, compromise or settle any claim, action, suit or judgment without Indemnifying Party's prior written consent.

C. NEITHER PARTY WILL BE LIABLE FOR LOSS OF USE, LOSS OF PROFITS OR OTHER COLLATERAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES. ARCHES' TOTAL LIABILITY ARISING UNDER THIS AGREEMENT SHALL BE LIMITED TO THE TOTAL AMOUNT OF COMPENSATION PAID BY CLIENT TO ARCHES HEREUNDER DURING THE 12 MONTHS IMMEDIATELY PRECEDING ANY CLAIM, ACTION OR SUIT CREATING THE LIABILITY.

D. Each Party acknowledges that the mutual promises contained in this Section 9 reflect the allocation of risk set forth in this Agreement, that each Party would not enter into this Agreement without these limitations on liability, and such limitations shall remain in full effect even if any of the remedies provided in this Agreement are deemed by a court of competent jurisdiction to have failed of their essential purpose.

8. TERMINATION.

Either Party may terminate this Agreement without cause at any time during the term of the Agreement on sixty (60) days' prior written notice to the other Party. Either Party may terminate this Agreement for material breach upon thirty (30) days' written notice specifying the nature of the breach, if such breach has not been substantially cured within the thirty (30) day period. During the 30-day cure period for termination due to breach, each Party will continue to perform its obligations under the Agreement. If the termination notice is not due to a breach, or if the cure period has expired without a substantial cure of the breach, then the Parties shall promptly meet to prepare a close-out schedule, and Arches shall cease performing all work not necessary for the orderly close-out of the Services or required by applicable laws or regulations. If Arches determines, in its sole discretion, that its continued performance of the Services would constitute a potential or actual violation of regulatory or scientific standards of integrity or violate complaince with applicable laws or regulations, then Arches may terminate the Services by giving written notice stating the effective date (which may be less than thirty days from the notice date) of such termination. Either Party may terminate this Agreement immediately upon provision of written notice if the other Party becomes insolvent or files for bankruptcy. This Agreement shall be deemed to be terminated upon the occurrence of any of the following: (i) the suspension, revocation or cancellation of Arches' CLIA registration; or (ii) the imposition of any restrictions or limitations by any governmental authority having jurisdiction over either Arches or the Client to such an extent that either Party cannot provide the Services or obligations contemplated by this Agreement, specifically the end of Emergency Use Authorizations or other Covid-19 regulatory flexibility.

9. RELATIONSHIP WITH AFFILIATES.

Client agrees that Arches may use the services of its corporate affiliates to fulfill Arches' obligations under this Agreement. Any affiliate so used shall be subject to all of the terms and conditions applicable to Arches under this Agreement, and entitled to all rights and protections afforded Arches under this Agreement. Arches agrees that Client's affiliates may use the services of Arches (and its affiliates) under this Agreement. In such event, such Client's affiliates shall be bound by all the terms and conditions of this Agreement and entitled to all rights and protections afforded Client under this Agreement. The term "affiliate" shall mean all entities controlling, controlled by or under common control with Client or Arches. The term "control" shall mean the ability to vote fifty percent (50%) or more of the voting securities of any entity or otherwise having the ability to influence and direct the polices and direction of an entity.

10. FORCE MAJEURE.

In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, Acts of God, inclement weather or other reason or cause beyond that Party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay. Both Parties recognize that this Agreement is to help address the Covid-19 pandemic and will excuse late or non-performance related to Covid-19.

11. NOTICES AND DELIVERIES.

Any notice required or permitted to be given hereunder by either Party hereunder shall be in writing and shall be deemed given on the date received if delivered personally or by a reputable overnight delivery service, or three (3) days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following address identified below, as follows:

If to Arches:
Arches Research, Inc.
1960 S 4250 W
Salt Lake City, UT 84104
With a Copy to:
contracts@archesresearch.com

If to Client:
Co-Diagnostics, Inc.
2401 South Foothill Drive, Suite D
Salt Lake City, UT 84109

12. BINDING AGREEMENT AND ASSIGNMENT.

This Agreement shall be binding upon and inure to the benefit of Client and Arches and their respective successors and permitted assigns. Except as stated above in Section 11 regarding Affiliates, neither Party may assign any of its rights or obligations under this Agreement to any party without the express, written consent of the other Party.

13. CHOICE OF LAW, WAIVER AND ENFORCEABILITY.

This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of the State of Utah, exclusive of its conflicts of law provisions. The failure to enforce any right or provision herein shall not constitute a waiver of that right or provision. Any waiver of a breach of a provision shall not constitute a waiver of any subsequent breach of that provision. If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with applicable laws, it is the intent of the Parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

14. REAGENT RENTAL AGREEMENT.

Client and Arches are parties to the Rental Agreement for LGC Oktopure Extraction Machine of even date herewith (the "Rental Agreement"). In the event the Rental Agreement is terminated for any reason and not replaced with a new agreement of like tenor, Arches shall not be deemed to be in breach of, or have any liability for, any delay in performing the Services described in Sections 1.B or 1.G of this Agreement. In the event this Agreement is terminated for any reason, Arches may, at its election, terminate the Rental Agreement without further obligation to Client under the Rental Agreement by written notice given by Arches to Client within 60 days following the date this Agreement terminates, and termination of the Rental Agreement will be effective as of the date specified in the notice given by Arches to Client.

15. SURVIVAL.

The rights and obligations of Client and Arches, which by intent or meaning have validity beyond such termination (including, but not limited to, rights with respect to inventions, confidentiality, discoveries and improvements, indemnification and liability limitations) shall survive the termination of this Agreement.

16. ENTIRE AGREEMENT, HEADINGS AND MODIFICATION.

This Agreement, together with any attachment(s) contains the entire understandings of the Parties with respect to the subject matter herein, and supersedes all previous agreements (oral and written), negotiations and discussions. The descriptive headings of the sections of this Agreement are inserted for convenience only and shall not control or affect the meaning or construction of any provision hereof. Any modifications to the provisions herein must be in writing and signed by the Parties.

Signature Page Follows

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

Arches Research, Inc.		**Co-Diagnostics, Inc.**	
Name:	Richard Hague	Name:	Reed Benson
Title:	COO	Title:	CFO
Signature:	*/s/ Richard Hague*	Signature:	*/s/ Reed Benson*
Date:	September 2, 2020	Date:	September 2, 2020

Exhibit A
Work Order No. [ ]
Arches Project Code: [ ]

This Work Order is issued under the COVID-19 Laboratory Services Agreement dated September 2, 2020, between Co-Diagnostics, Inc. ("Client") and Arches Research, Inc. ("Arches"), as the same may be amended from time to time (the "Agreement"). To the extent there is any conflict between any terms and conditions of this Work Order and the Agreement, the terms and conditions of the Agreement shall control. Conflicting or differing terms set forth in this Work Order shall be of no force or effect. Capitalized terms used herein shall have the same meaning ascribed thereto in the Agreement.

Effective Date of Work Order:
Type of Testing: [ ] One Time Testing
[ ] Ongoing Testing

Estimated Number of Tests per Week*:
State of Origin of Specimens to be Tested:

Customer Name:
Customer Address:

Customer Contact:
Name
Phone Number
Email Address

Remarks:

Authorized Client Representative:
Print Name
Signature

*Client is billed under the Agreement for the total number of Kits tested by Arches for the Customer and not on the basis of any estimate

Pricing information in Exhibit B to this agreement has been redacted based on the registrant's determination the information is not material and would likely cause competitive harm.

Rental Agreement for LGC Genomics Oktopure Extraction Machine

Agreement made on this 2nd day of September, 2020, between Co-Diagnostics, Inc., a Utah corporation (herein after called "CoDx") with offices at 2401 S. Foothill Dr., Suite D, Salt Lake City, Utah 84109 and Arches Research, Inc., a Utah corporation ("Arches"), with a lab located at 1960 S. 4250 W. Salt Lake City, Utah 84104.

WHEREAS, CoDx sells testing reagents for use with hardware to provide real-time polymerase chain reaction testing ("PCR") for COVID-19 and various diseases and Arches conducts testing services including PCR based tests; and,

WHEREAS, from time to time businesses, governmental agencies, schools and other entities contact CoDx regarding testing services and CoDx desires to engage Arches pursuant to the COVID-19 Laboratory Services Agreement of even date herewith ("Services Agreement") to provide testing services for customers which desire such services; and,

WHEREAS, Arches desires to increase its capacity to test for COVID using CoDx Logix Smart COVID-19 tests, but needs to have a high throughput extraction machine and CoDx has agreed to provide such a machine to facilitate the purchase of more of its tests on the following terms and conditions.

Terms and Conditions

1. **Appointment & Acceptance** – CoDx agrees to purchase and place a LGC Genomics manufactured high throughput extraction machine ("Oktopure") at the Arches lab. Arches agrees to use the Oktopure to increase the number of COVID tests it can perform. The details of Oktopure is described more completely in **Exhibit A**.

2. **Term of Agreement** – The term of this agreement is 12 months. Following the end of the Term, the agreement may be extended for a specific period of time subject to the written mutual agreement and understanding of both parties or until terminated by either party in writing upon 30 days prior notice.

3. **Minimum Exclusive Purchase** – Arches agrees that it will only use reagents supplied by CoDx in performing PCR tests for its customers in testing for COVID. Arches agrees to purchase a minimum of 10,000 tests per calendar month from CoDx. In addition, Arches will purchase all of the consumables required for operation of the Oktopure from CoDx and listed on Exhibit B. The purchase of reagents and extraction consumables will be at mutually agreed purchase prices as shown in Exhibit B. Tests acquired to perform services under the Services Agreement will count towards the 10,000 tests per month required under this Agreement.

4 . Oktopure. (a) Due Care of Oktopure. Arches warrants and represents that the Oktopure shall be used only in the manner intended and Arches will exercise reasonable care to prevent loss or damage to the Oktopure and not permit the Oktopure or any part thereof to be used by anyone other than employees of Arches or its affiliates; (b) Ownership. The Oktopure is, and shall at all times remain, the sole and exclusive property of CoDx, and Arches shall have no right, title or interest therein except as expressly set forth in these terms and conditions; (c) Assignment or Transfer prohibited. Arches agrees that the Oktopure is not for resale. Resale or attempted resale of the Oktopure shall result in the immediate termination of this Agreement; and (d) Return of Oktopure. Arches agrees to return the Oktopure listed in Exhibit A at its cost within 10 days of the expiration or termination of this agreement in good working order, reasonable wear and tear accepted. If the Oktopure is lost or damaged, Arches shall be liable for the cost of repair or if lost for the full depreciated cost of the Oktopure.

5. Price – Test Reagents and extraction consumables will be supplied throughout the duration of this Agreement as mentioned in Exhibit B. The prices are subject to change by mutual agreement of the parties based on market fluctuations but shall not increase earlier than six months from the date hereof.

6 . **Ordering, Delivery, Credit Policy and Terms of Payment** – Orders are to be placed by Arches via Purchase Order to CoDx 30 days in advance of the anticipated delivery date. Payment terms will be Net **30 days** from date of invoice. In the event the invoice is paid in full in 15 days a cash discount of 2% of the invoice price will allowed. 18% per annum interest rate shall be automatically applied to all outstanding balances not paid on or before the due date from the due date to the date paid in full.

7 . **Reagent Usage** – Arches agrees to share results of reagent usage with CoDx; provided that this obligation is limited by the limits and restrictions imposed under applicable privacy and health information laws. CoDx shall not be held accountable for Reagents contaminated after receipt by Arches, and the Reagent Usage clause shall not be affected by any such contamination. Arches will be responsible to maintain the inventory after receiving the test reagent as recommended by CoDx.

8 . **CoDx Oktopure Warranty** – CoDx will be responsible for the repair or replacement of malfunctioning Oktopure without charge during the term as long as Arches Oktopure has not damaged the Oktopure through improper use or care. CoDx makes no other warranties, express or implied, or of merchantability or fitness for use, for the Oktopure. CoDx will not be responsible for any consequential or incidental damages resulting from the use, or improper functioning of the Oktopure. Such damages, for which CoDx will not be responsible include, but are not limited to, loss of revenue or profit, down time costs, loss of use of the Oktopure, contamination of Oktopure resulting from improper or insufficient decontamination measures, cost of any substitute Oktopure or services or claims of Arches's customers for such damages.

9 . **Trademarks, Trade Names, and Trade Dress** – All sales and rentals are made with the understanding that the CoDx trademarks, Trade Names, Trade Dress, and original packaging will not be misused.

10. **Governing Law** – The Agreement is governed by the laws of the State of Utah without regard to any applicable conflicts or choice of law provisions. The exclusive venue for any judicial action or proceeding arising out of this Agreement shall be the state or federal courts located in Salt Lake City, Utah. The parties hereby consent to the jurisdiction of said courts and waive any objection that venue in such courts is inconvenient. The prevailing party in any judicial action or proceeding arising out of this Agreement shall be entitled to recover from the non-prevailing party, in addition to any other rights and remedies hereunder, at law or in equity, its reasonable costs, fees, and expenses, including reasonable attorneys fees and court costs.

11. **Termination of Agreement** – CoDx reserves the right to terminate this agreement if any one of the conditions stated in this agreement is not met by Arches including, but not limited to, the minimum monthly purchase requirement or failure to make timely payments on reagents or extraction consumables ordered by Arches.

12. **Notice** – Any notice required to be given hereunder shall be given in writing, by personal delivery, or by certified or registered mail, return receipt requested, sent to the party at its address set forth on the signature page hereto, or such other address as may be specified by notice given in accordance herewith. Notice shall be deemed given upon receipt by the party to which it is sent or refusal to accept delivery.

13. **Entire Agreement** - This document is the entire agreement between the parties with respect to the subject matter hereof.

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

Arches Research, Inc.		**Co-Diagnostics, Inc.**	
Name:	Richard Hague	Name:	Reed Benson
Title:	COO	Title:	CFO
Signature:	*/s/ Richard Hague*	Signature:	*/s/ Reed Benson*
Date:	September 2, 2020	Date:	September 2, 2020

Exhibit A

Details of Oktopure:
Serial Numbers: 09-00191

Instruction for use will provided.

CoDx will be responsible for the Installation and Qualification of the machine and providing necessary documentation support.

Installation report will be signed by both the parties upon successful installation and qualification.

Required training will be provided by CoDx to the operating personnel and also will be responsible for trouble-shooting in the case of any time during the contract period.

Exhibit B

Test Reagents	Price
A Logix Smart COVID-19 test	$[ ] per reaction *
B sbeadex RNA extraction (LGC)	$[ ] per reaction
C	
D	
E	

Sales taxes will be charged on sales of all reagents and extraction consumables.
Prices subject to change upon 30 days prior written notice.

***Volume purchase at one time will receive price break for Logix Smart COVID-19 Test.**

250 Reaction Size Kit:
40-99 kits (10,000-24,750 reaction) = $[ ]
100-199 kits (25,000-49,750 reactions) = $[ ]
200- 399 kits (50,000-99,750 reactions) = $[ ]
400 or more kits (100,000 or more reactions) = $[ ]

5000 Reaction Size Kit:
2-4 kits (10,000-20,000 reactions) = $[ ]
5-9 kits (25,000-45,000 reactions) = $[ ]
10-19 kits (50,000-95,000 reactions) =$[ ]
20-49 kits (100,000-245,000 reactions) = $[ ]
50 or more kits (250,000 or more reactions) = $[ ]

EXHIBIT 31.1

CERTIFICATION

I, David Seaburg, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PolarityTE, 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. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15(d)-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. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 9, 2020

/s/ David Seaburg
David Seaburg
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Jacob Patterson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PolarityTE, 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. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15(d)-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. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 9, 2020

/s/ Jacob Patterson
Jacob Patterson
Interim Chief Financial Officer

EXHIBIT 32.1

Certification Pursuant to Rule 13a-14(b) and Section 1350, Chapter 63 of Title 18, United States Code

Pursuant to Section 1350, Chapter 63 of Title 18, United States Code, the undersigned officers of PolarityTE, Inc. (the "Company"), do hereby certify, to such officers' knowledge, that:

The Quarterly Report on Form 10-Q for the period ending September 30, 2020 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2020

/s/ David Seaburg
David Seaburg
Chief Executive Officer

/s/ Jacob Patterson
Jacob Patterson
Interim Chief Financial Officer