

**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, 2022**

OR

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

For the transition period from _____ to _____

Commission file number: **000-56257**

ACCUSTEM SCIENCES, INC.

(Exact name of registrant as specified in Its Charter)

Delaware
(State of other jurisdiction of
incorporation or organization)

87-3774438
(I.R.S. Employer
Identification No.)

5 Penn Plaza, 19th Floor, #1954 New York, NY
(Address of principal executive offices)

10001
(Zip Code)

Registrant's telephone number, including area code: **00 44 2074952379**

Securities registered pursuant to Section 12(b) of the Act: **None**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ACUT	OTCQB Venture Marketplace ("OTCQB")

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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b 2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 8, 2022, there were 11,346,535 shares of Common Stock, \$0.001 par value outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

ACCUSTEM SCIENCES INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	(Unaudited) September 30, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash	\$ 1,331,960	\$ -
Related party receivable	-	1,353,373
Prepaid expenses	282,113	-
Total Current Assets	\$ 1,614,073	\$ 1,353,373
Equipment, net	8,585	-
TOTAL ASSETS	\$ 1,622,658	\$ 1,353,373
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 154,889	\$ 388,681
Related party payable	108,806	190,838
Accrued expenses	349,183	123,181
Note Payable	212,056	-
Total Current Liabilities	824,934	702,700
TOTAL LIABILITIES	824,934	702,700
Stockholders' Equity		
Preferred stock \$.001 par value; 10,000,000 shares authorized; none issued and outstanding	\$ -	\$ -
Common stock \$.001 par value; 150,000,000 shares authorized; 11,346,535 and 9,999,132 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	11,346	9,999
Additional paid-in capital	4,279,125	1,503,434
Related party subscription receivable	-	(204,879)
Accumulated other comprehensive loss	-	66,981
Accumulated deficit	(3,492,747)	(724,862)
TOTAL STOCKHOLDERS' EQUITY	797,724	650,673
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 1,622,658	\$ 1,353,373

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

ACCUSTEM SCIENCES INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended September 30		Nine Months Ended September 30	
	2022	2021	2022	2021
OPERATING EXPENSES				
Research and development expenses	\$ 58,270	\$ 14,125	\$ 133,809	\$ 46,869
General and administrative expenses	840,855	48,597	2,634,076	80,263
Total operating expenses	899,125	62,722	2,767,885	127,132
LOSS FROM OPERATIONS	(899,125)	(62,722)	(2,767,885)	(127,132)
LOSS, BEFORE TAX	(899,125)	(62,722)	(2,767,885)	(127,132)
Income tax benefit (expense)	-	-	-	-
NET LOSS	\$ (899,125)	\$ (62,722)	\$ (2,767,885)	\$ (127,132)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.08)	\$ (0.01)	\$ (0.25)	\$ (0.01)
Weighted average common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	11,337,668	9,999,132	10,904,423	9,999,132
NET LOSS	\$ (899,125)	\$ (62,722)	\$ (2,767,885)	\$ (127,132)
Translation adjustments	-	(33,433)	-	(16,347)
COMPREHENSIVE LOSS	\$ (899,125)	\$ (96,155)	\$ (2,767,885)	\$ (143,479)

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

ACCUSTEM SCIENCES INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(UNAUDITED)

For Three Months Ended September 30, 2022

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Related Party Subscription Receivable</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Accumulated Deficit</u>	<u>Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Amount</u>					
Balance at June 30, 2022	11,337,571	\$ 11,337	\$4,232,851	-	-	\$ (2,593,622)	\$ 1,650,566
Share-based compensation	-	-	38,001	-	-	-	38,001
Exercise of common stock options	8,964	9	8,273	-	-	-	8,282
Net loss	-	-	-	-	-	(899,125)	(899,125)
Balance at September 30, 2022	<u>11,346,535</u>	<u>\$ 11,346</u>	<u>\$4,279,125</u>	<u>-</u>	<u>-</u>	<u>\$ (3,492,747)</u>	<u>\$ 797,724</u>

For Three Months Ended September 30, 2021

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Related Party Subscription Receivable</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Accumulated Deficit</u>	<u>Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Amount</u>					
Balance at June 30, 2021	9,999,132	\$ 9,999	\$1,482,174	\$ (208,928)	\$ 95,260	\$ (118,658)	\$ 1,260,207
Share-based compensation	-	-	21,260	-	-	-	21,260
Foreign currency translation adjustment	-	-	(1,004)	5,078	(33,433)	-	(29,359)
Net loss	-	-	-	-	-	(62,722)	(62,722)
Balance at September 30, 2021	<u>9,999,132</u>	<u>\$ 9,999</u>	<u>\$1,502,430</u>	<u>\$ (203,850)</u>	<u>\$ 62,187</u>	<u>\$ (181,380)</u>	<u>\$ 1,189,386</u>

For Nine Months Ended September 30, 2022

	Common Stock		Additional Paid-in Capital	Related Party Subscription Receivable	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
	Number of Shares	Amount					
Balance at December 31, 2021	9,999,132	\$ 9,999	\$1,503,434	\$ (204,879)	\$ 66,981	\$ (724,862)	\$ 650,673
Share-based compensation	-	-	92,629	-	-	-	92,629
Issuance of common stock	1,337,970	1,338	2,674,602	-	-	-	2,675,940
Receipt of subscription receivable	-	-	-	204,879	-	-	204,879
Exercise of common stock options	9,433	9	8,460	-	-	-	8,469
Foreign currency translation adjustment	-	-	-	-	(66,981)	-	(66,981)
Net loss	-	-	-	-	-	(2,767,885)	(2,767,885)
Balance at September 30, 2022	<u>11,346,535</u>	<u>\$ 11,346</u>	<u>\$4,279,125</u>	<u>-</u>	<u>-</u>	<u>\$ (3,492,747)</u>	<u>\$ 797,724</u>

For Nine Months Ended September 30, 2021

	Common Stock		Additional Paid-in Capital	Related Party Subscription Receivable	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
	Number of Shares	Amount					
Balance at December 31, 2020	9,999,132	\$ 9,999	\$1,482,174	\$ (206,663)	\$ 78,534	\$ (54,248)	\$ 1,309,796
Share-based compensation	-	-	21,260	-	-	-	21,260
Foreign currency translation adjustment	-	-	(1,004)	2,813	(16,347)	-	(14,538)
Net loss	-	-	-	-	-	(127,132)	(127,132)
Balance at September 30, 2021	<u>9,999,132</u>	<u>\$ 9,999</u>	<u>\$1,502,430</u>	<u>\$ (203,850)</u>	<u>\$ 62,187</u>	<u>\$ (181,380)</u>	<u>\$ 1,189,386</u>

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

ACCUSTEM SCIENCES INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Nine Months Ended September 30	
	2022	2021
Operating Activities		
Net loss	(2,767,885)	(127,132)
<i>Adjustments to reconcile net income to net cash provided by operating activities</i>		
Foreign currency translation	(66,981)	(14,538)
Depreciation	2,414	-
Share-based compensation	92,629	21,260
<i>Change in operating assets and liabilities:</i>		
Related party receivable	1,353,373	18,586
Prepaid expenses	157,009	-
Accounts payable	(233,791)	41,414
Related party payable	(82,033)	60,983
Accrued expenses	229,940	(573)
Net cash used in operating activities	(1,315,325)	-
Investing Activities		
Purchases of equipment	(10,999)	-
Net cash used in investing activities	(10,999)	-
Financing Activities		
Proceeds from receipt of subscription receivable	204,879	-
Proceeds from issuance of common stock	2,675,940	-
Proceeds from exercise of options	8,469	-
Payments on note payable	(231,004)	-
Net cash provided by financing activities	2,658,284	-
Increase in cash	1,331,960	-
Cash, beginning of year	-	-
Cash, end of year	1,331,960	-
Supplemental disclosure of noncash investing and financing activities		
Issuance of Note Payable for payment of prepaid expense	439,122	-
Supplemental cash flow information		
Cash paid for interest	5,726	-

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

ACCUSTEM SCIENCES INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. NATURE OF BUSINESS

AccuStem Sciences, Inc. is an early-stage life sciences company committed to developing and commercializing novel products for the treatment and management of many cancers. The principal activities of the Company are that of a genomics-based personalized medicine business, particularly focused on breast and lung cancer patients.

Impact of the COVID-19 Pandemic

In early 2020, an outbreak of the novel strain of coronavirus (COVID-19) emerged globally. As a result, there have been mandates from federal, state and local authorities resulting in an overall decline in economic activity. There have been no material impacts from COVID-19 on the Company's operations for the nine months ended September 30, 2022 and 2021. However, it is possible that the pandemic will continue to significantly impact economies worldwide, which could result in adverse effects on the Company's operations. The extent of the impact of COVID-19 on operations, liquidity, financial condition, and results of operations remain uncertain at this time.

Liquidity and Going Concern

The condensed consolidated financial statements have been prepared on the going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business.

The Company has financed its activities principally from support from a related party. The Company has incurred a net loss in every fiscal period since inception. For the nine months ended September 30, 2022, the Company incurred a net loss of \$2,767,885. The Company has an accumulated deficit of \$3,492,747 as of September 30, 2022. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, further development of its technology and products, and expenses related to the commercialization of its products.

Management believes that the Company does not have sufficient cash and current assets to support its operations through at least 12 months from the issuance date of these condensed consolidated financial statements, and will require significant additional cash resources to continue its planned research and development activities.

The Company will need additional funds for promoting new products and working capital required to support research and development activities and generate sales from its products. There can be no assurance, however, that such financing will be available when needed, if at all, or on favorable terms and conditions. The precise amount and timing of the funding needs cannot be determined accurately at this time, and will depend on a number of factors, including the quality of product development efforts, management of working capital, and the continuation of normal payment terms and conditions for purchase of services.

In order to address its capital needs, including its planned research and development activities and other expenditures, the Company is actively pursuing additional equity financing in the form of a private investment and public equity. The Company has been in ongoing discussions with institutional investors and other parties with respect to such possible offerings. Adequate financing opportunities might not be available to the Company, when and if needed, on acceptable terms or at all. If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms or if the Company fails to consummate the private placement or a public offering, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs and product portfolio expansion, which could adversely affect its operating results or business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding in terms acceptable to the Company to fund continuing operations, if at all. After considering the uncertainties, management determined it is appropriate to continue to adopt the going concern basis in preparing the condensed consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these condensed consolidated financial statements are set out below.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“U.S. GAAP”) and applicable rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) regarding interim financial reporting. Certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. Therefore, these condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on April 18, 2022. Unless otherwise indicated, all references to “\$” are to U.S. dollars, and all references to “£” or “GBP” are to Great Britain Pounds. The Company’s reporting currency is U.S. dollars.

Basis of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary after elimination of intercompany transactions and balances.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management of the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

Comprehensive Loss

Comprehensive loss of all periods presented is comprised primarily of net loss and foreign currency translation adjustments.

Risk and Uncertainties

The Company is subject to a number of risks similar to those of other companies of similar size in its industry, including but not limited to, the success of its exploration to research and development activities, need for additional capital (or financing) to fund operating losses, competition from substitute products and services from larger companies, protection of proprietary technology, patent litigation, dependence on key individuals, and risks associated with changes in information technology.

Cash

The Company considers all highly liquid investments purchased with an original maturity date of three months or less at the date of purchase and money market accounts to be cash equivalents. At September 30, 2022 and December 31, 2021, the Company had no cash equivalents and all cash amounts consisted of cash on deposit.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant contribution of credit risk consist of cash. Periodically, the Company maintains deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses in these deposits.

Equipment, net

Equipment is stated at cost, less accumulated depreciation. The Company depreciates its equipment for financial reporting purposes using the straight-line method over the estimated useful lives of the assets. The Equipment consists of computer equipment, which has a useful life of 3 years. Maintenance and repairs are expensed when incurred. Additions and improvements that extend the economic useful life of the asset are capitalized and depreciated over the remaining useful lives of the assets. The cost and accumulated depreciation of assets sold or retired are removed from the respective accounts, and any resulting gain or loss is reflected in current earnings.

Share-based Compensation

The Company may award stock options, performance-based options and other equity-based instruments to its employees, directors and consultants. Compensation cost related to equity-based instruments is based on the fair value of the instrument on the grant date, and is recognized over the requisite service period on a straight-line basis over the vesting period except for performance-based options. Performance-based stock options vest based on the achievement of performance targets. Compensation costs associated with performance-based option awards are recognized over the requisite service period based on probability of achievement. Performance-based stock options require management to make assumptions regarding the likelihood of achieving performance targets.

The Company estimates the fair value of service based and performance-based stock option awards, including modifications of stock option awards, using the Black-Scholes option pricing model. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield.

Recent Accounting Standards

Adopted Accounting Standards

None

Standards not yet adopted

None

3. ACQUISITION OF STEMPRINTER SCIENCES LIMITED AND EQUITY RAISE

The consolidated position of the Company is a result of the demerger of StemPrintER Sciences Limited (“StemPrintER”) from Tiziana Life Sciences plc (“Tiziana”) on October 30, 2020.

On October 5, 2020, AccuStem Sciences Limited (“Limited”) entered into an agreement with Tiziana to acquire its subsidiary StemPrintER, including the ownership rights and intellectual property relating to the StemPrintER project, the SPARE project and cash receivable of \$1,353,373 (which was collected in January 2022). In exchange for the transfer of ownership, Limited issued a total of 9,520,069 ordinary shares of \$0.001 par value to Tiziana shareholders on a one for one basis based on the Tiziana ownership at October 30, 2020. On October 30, 2021, a supplemental demerger agreement was executed and 479,063 of ordinary shares of \$0.001 par value issued for consideration of \$204,879 in relation to the associated option and warrant holders of Tiziana. The Company considered ASC 805 - *Business Combinations* and ASC 730 - *Research and Development* in determining how to account for the transaction. As the transaction was between entities that were ultimately controlled by the same parties, the acquisition has been treated as a common control combination under ASC 805-50 - *Business Combinations*, therefore the carrying value of contributed assets remained unchanged and were recorded at historical costs.

The transfer of all the ownership rights and intellectual property was treated as an asset transfer. The treatment as a separate asset acquisition at this stage reflected the fact that, immediately prior to transfer, Tiziana carried out only limited maintenance type activity on the StemPrintER project and the concentration of fair value was in the StemPrintER intellectual property asset.

In March 2022, per the terms of the supplemental agreement to the demerger agreement, Tiziana invested \$2,765,940 (£2,000,000 GBP) in exchange for an additional 1,337,970 common shares of the Company. No offering costs were recorded with the additional contribution.

4. NOTE PAYABLE

On May 20, 2022, the Company entered into a one-year Directors and Officers Liability Insurance agreement for \$439,122. Under the terms of the agreement, the Company made a down payment of \$88,000, with the remaining balance financed over the remaining term at an annual percentage rate of 3.95%. Beginning June 2022, the Company will make 10 monthly payments of \$35,751, with the last payment expected to be made in March 2023. At the end of September 30, 2022, the outstanding balance on the note payable was \$212,056.

5. EQUIPMENT

Equipment consists of the following:

	September 30, 2022	December 31, 2022
Computer equipment	\$ 10,999	-
Less: Accumulated depreciation	2,414	-
Equipment, net	<u>\$ 8,585</u>	<u>-</u>

Depreciation expense was approximately \$907 and \$0, respectively, for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, respectively, depreciation expense was approximately \$2,414 and \$0, respectively.

Depreciation expense is included within General and Administrative expenses in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

6. LICENSE

On June 24, 2014, Tiziana entered into an exclusive license agreement with IEO/University of Milan, pursuant to which it obtained a worldwide, royalty-bearing, exclusive license under certain patents and a worldwide, royalty-bearing, non-exclusive license under certain know-how, respectively, of IEO/University of Milan to develop and commercialize licensed products in connection with a multi-gene prognostic tool. This license was assigned to the Company pursuant to the terms of the acquisition of StemprintER as noted in Note 3.

The license provides for full control and authority over the research, development and commercialization of licensed products and are required to use commercially reasonable efforts in connection with the development and commercialization of the licensed products.

For the term of the license, the following milestone payments are required to be made (converted from EUROS to USD using exchange rate of €1:\$1.10815)

- €50,000 (\$55,408) within 30 days of completion of development of a commercial test;
- €100,000 (\$110,815) within 30 days of the first commercial sale of a licensed product; and
- €150,000 (\$166,223) within 30 days of first regulatory approval in the U.S. or any other major market.

Tiziana was also required, as licensee prior to the assignment to us of the License, to fund €50,000 (\$55,408) per year for sponsored research for up to four years from the effective date of the license (2014-2018), subject to certain conditions. The license also requires payment for all ongoing patent prosecution and maintenance costs and for the royalty term (until the expiration of the last claim in an issued, unexpired patent within the licensed patents or a claim that has not been pending more than four years which covers the sale of such licensed product or service in such country) a royalty of 1.5% on net sales of licensed products and services (and a 15% royalty of sub-license revenues for each country for the term of the license). The license agreement may be terminated at any time on 30 days' notice and either party may terminate the license by written notice for a material payment breach or any other material breach, subject to 45-day and 120-day periods, respectively. Absent early termination, the license will remain in effect, on a product by product and country by country basis, until the date on which the patents and patent applications expire. The license may also be terminated in the case of insolvency.

For the three and nine months ended September 30, 2022 and 2021, the Company did not recognize any expense related to this license agreement.

7. LOSS PER SHARE

Basic and diluted net loss per common share were the same since the inclusion of common shares issuable pursuant to the exercise of options in the calculation of diluted net loss per common shares would have been antidilutive.

For the three and nine months ended September 30, 2022 and 2021, loss per share of the Company are as follows:

	Three Months Ended September 30		Nine Months Ended September 30	
	2022	2021	2022	2021
Numerator:				
Net Loss	\$ (899,125)	\$ (62,722)	\$ (2,767,885)	\$ (127,132)
Net loss per share attributable to common stockholders	\$ (899,125)	\$ (62,722)	\$ (2,767,885)	\$ (127,132)
Denominator:				
Weighted average common shares outstanding, basic and diluted	11,337,668	9,999,132	10,904,423	9,999,132
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.08)	\$ (0.01)	\$ (0.25)	\$ (0.01)

The Company's potentially dilutive securities, which include stock options and warrants, have been excluded from the computation of diluted net loss per common share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders is the same.

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders for the three months and nine months ended September 30, 2022 and 2021 because including them would have had an anti-dilutive effect.

	<u>Three Months Ended September 30</u>		<u>Nine Months Ended September 30</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Shares issuable upon exercise of stock options	207,825	100,005	207,825	100,005
Total	207,825	100,005	207,825	100,005

8. SHARE-BASED COMPENSATION

In August 2021, Limited adopted the 2021 Omnibus Equity Incentive Plan (the “Incentive Plan”). The Incentive Plan provides that the Company may grant Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, and Other Share-Based Awards to selected employees, directors, and independent contractors of the Company.

Each Award shall be exercisable at such time or times and subject to such terms and conditions set forth in the Incentive Plan, as shall be determined by the administrator in the applicable award agreement. Total shares authorized by the plan was 2,500,000. Awards under the Incentive Plan are exercisable for up to 10 years from the date of issuance. There are 1,092,756 remaining available shares to be issued under the Incentive Plan at September 30, 2022. The number of shares of Common Stock that are reserved and available for issuance under the Incentive Plan shall be subject to an annual increase on the first day of each calendar year beginning with the first January 1 following the effective date and ending with the last January 1 during the initial ten-year term of the Plan as defined in Section 4(a) of the Incentive Plan.

Options

On December 1, 2021 (the “Effective Date”), Limited completed the Company’s redomiciliation from the United Kingdom to Delaware (see Note 1). As of the Effective Date, the option instruments to purchase Limited Ordinary Shares granted by Limited (the “Old Options”) were exchanged automatically in consideration of the grant of new options by New AccuStem which, in the opinion of the board of directors of Limited, are equivalent to the Old Options, but relate to the New AccuStem Common Stock. As of the Effective Date, New AccuStem assumed Limited’s obligations under its 2021 Incentive Plan and other arrangements under which incentives in relation to Limited Ordinary Shares were agreed with before the effective date of the redomiciliation and the Company replaced all equity awards granted under the Limited Plan with equivalent equity awards for New AccuStem Common Stock. Also, as of the Effective Date, New AccuStem’s 2021 Equity Incentive Plan (the “2021 Plan”), became effective. Any employee, director or consultant of New AccuStem or any of its subsidiary is eligible to participate in the 2021 Plan.

As a result of the redomiciliation an aggregate of 100,005 options were issued during December 2021 in consideration for the share exchange. The issued options had an exercise price of \$0.42 per share and all expire on the ten-year anniversary of the grant date. These options were fully vested on the grant date.

In addition, the Company issued 1,307,239 options during the first quarter of 2022 for employees, directors and non-employees under the Incentive Plan.

The options granted have an exercise price ranging from \$1.06 to \$2.13 and expire on the ten-year anniversary of the grant date.

There were no options granted or modified for the three months ended September 30, 2022. The Company granted 100,005 options for the three months ended September 30, 2021.

For the nine months ended September 30, 2022, stock option activity for time-based options of the Company are as follows:

	Number of Time-Based Share Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	100,005	\$ 0.42	9.72	\$ —
Issued	363,239	2.07	9.43	
Exercised	(9,433)	0.90	—	
Expired/Forfeited	—	—	—	
Outstanding at September 30, 2022	<u>453,811</u>	<u>\$ 1.70</u>	<u>9.30</u>	<u>\$ 16,672</u>
Vested and exercisable September 30, 2022	<u>207,825</u>	<u>\$ 1.20</u>	<u>9.14</u>	<u>\$ 16,672</u>

For the nine months ended September 30, 2022, stock option activity for performance-based options of the Company are as follows:

	Number of Performance- Based Share Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	—	\$ —	—	\$ —
Issued	944,000	1.45	9.36	
Exercised	—	—	—	
Expired/Forfeited	—	—	—	
Outstanding at September 30, 2022	<u>944,000</u>	<u>\$ 1.45</u>	<u>9.36</u>	<u>\$ —</u>
Vested and exercisable September 30, 2022	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>

The aggregate intrinsic value is calculated as the difference between the estimated fair value of the underlying common stock as of September 30, 2022 and the option exercise price.

Total share-based compensation was approximately \$38,001 and \$21,260, respectively, for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, respectively, share-based compensation was approximately \$92,629 and \$21,260, respectively.

Total share-based compensation expense is included in General and Administrative expenses on the Condensed Consolidated Statement of Operations and Other Comprehensive Income.

The weighted average grant date fair value for stock options granted during the nine-months ended September 30, 2022 is \$0.76. The performance-based and time-based stock options are equity-classified. There were no stock option granted during the three months ended September 30, 2022.

The Company uses the Black-Scholes option pricing model to estimate the fair value of the option awards. The table below summarizes the resulting weighted average inputs used to calculate the estimated fair value of options awarded for the nine months ended September 30, 2022.

	For the Nine Months Ended September 30, 2022
Risk-free interest rate	1.54 - 2.34%
Expected dividend yield	—%
Expected term	5.00 - 8.50 years
Expected volatility	57.2 - 65.7%

The risk-free interest rate assumption is determined using the yield currently available on U.S. Treasury zero-coupon issues with a remaining term commensurate with the expected term of the award. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Management has estimated expected volatility based on similar public companies. Expected life of the option represents the period of time options are expected to be outstanding. The estimate for dividend yield is 0% because the Company has not historically paid, and does not intend to pay, a dividend on common stock in the foreseeable future.

As of September 30, 2022, there was \$904,780 unrecognized compensation expense related to options. \$211,442 of this cost is subject to time-based conditions, and is to be recognized over a period of approximately 3.3 years. The remaining \$693,338 of unrecognized compensation expense relates to performance-based conditions for unvested options. These costs are expected to be recognized over the required service period once the performance condition has occurred or becomes probable. Compensation costs related to the performance stock options are evaluated at each reporting period and subsequently adjusted for changes in the expected outcomes of the performance conditions.

Warrants

In March 2022, the Company issued 350,000 common stock warrants to a non-employee under the Incentive Plan. The common stock warrants are subject to vesting and, grantees become fully vested and exercisable when certain performance requirements are met.

The common stock warrants granted have an exercise price of \$1.06. The common stock warrants expire on the ten-year anniversary of the grant date. There were no warrants issued during the three months ended September 30, 2022 and 2021.

A summary of the Company's warrants to purchase common stock activity is as follows:

	Number of shares	Weighted Average Exercise Price	Weighted average remaining contractual life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	—	\$ —	—	\$ —
Issued	350,000	1.06	9.32	
Exercised	—	—	—	
Expired/Forfeited	—	—	—	
Outstanding at September 30, 2022	<u>350,000</u>	<u>\$ 1.06</u>	<u>9.32</u>	<u>\$ —</u>
Vested and exercisable September 30, 2022	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>

The grant date fair value for these warrants of \$0.66 per warrant for a total fair value of \$232,490. The table below summarizes the resulting weighted average inputs used to calculate the estimated fair value of the common stock warrants options awarded for the nine months ended September 30, 2022.

	Nine Months Ended September 30, 2022
Risk-free interest rate	1.75%
Expected dividend yield	—%
Expected term	8.50 years
Expected volatility	63.9%

There was no share-based compensation expense recognized during the three and nine months ended September 30, 2022 and 2021 for warrants.

As of September 30, 2022, there was \$232,490 of total performance-based unrecognized compensation costs related to unvested common stock warrants. These costs are expected to be recognized once the performance condition has occurred or becomes probable.

9. RELATED PARTY TRANSACTIONS

Tiziana is a related party as it is under common control. The Company and Tiziana share some directors, an officer and significant shareholders. The Company has also been formed due to an acquisition of a subsidiary company from Tiziana. As of September 30, 2022, Tiziana owns approximately 11.8% of the Company.

As of September 30, 2022 and December 31, 2021, \$0 and \$1,558,252 respectively, was due from Tiziana in relation to the demerger and supplemental demerger of Limited and StemPrintER, which consists of the related party receivable and related party subscription receivable on the condensed consolidated balance sheet.

Effective with the demerger agreement, the Company entered into a shared services agreement, where the Company outsources certain limited management and administrative services. The Company notes that the fees consist of payroll costs associated with time spent providing services for the Company and are based on actual time spent and the allocated payroll costs. In addition, the Company is charged at cost, for utilization of certain office space. There was no mark-up associated with fees charged for these services. For the three months ended September 30, 2022 and 2021, the Company has incurred approximately \$4,708 and \$2,986, respectively. Total cost for the nine months ended September 30, 2022 and 2021 were \$31,154 and \$9,166, respectively.

As of September 30, 2022 and December 31, 2021, \$59,306 and \$190,838 respectively, was also due to Tiziana, as Tiziana had paid for expenses on behalf of the Company.

In January 2022, the Company and Gabriele Cerrone, who is the Chairman of the Board of Directors and the largest shareholder, entered into an agreement in which he will provide consulting services to the Company for a monthly fee of \$5,500. As of September 30, 2022, \$49,500 was due to Gabriele Cerrone.

10. INCOME TAXES

For all periods presented, the pretax losses incurred by the Company received no corresponding tax benefit because the Company concluded that it is more likely than not that the Company will be unable to realize the value of any resulting deferred tax assets. The Company will continue to assess its position in future periods to determine if it is appropriate to reduce a portion of its valuation allowance in the future. On March 27, 2020, Congress enacted the CARES Act to provide certain relief as a result of the COVID-19 pandemic. The CARES Act, among other things, includes provisions relating to net operating loss carryback periods, alternative minimum tax credit refunds, and modification to the net interest deduction limitations. The CARES Act did not have a material impact on the Company's consolidated financial statements for the nine months ended September 30, 2022. The Company continues to monitor any effects on its financial statements that may result from the CARES Act.

The Company has no open tax audits with any taxing authority as of September 30, 2022.

11. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

The Company is involved from time to time in various claims, proceedings, and litigation. The Company establishes reserves for specific legal proceedings when it determines that the likelihood of an unfavorable outcome is probable, and the amount of loss can be reasonably estimated. Management has not identified any legal matters where it believes an unfavorable outcome is reasonably possible and/or for which an estimate of possible losses can be made.

Item 2: Management’s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of our financial condition and results of operations in conjunction with the condensed consolidated financial statements and the related notes included elsewhere in this Form 10-Q and with our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on April 18, 2022. In addition to our historical condensed consolidated financial information, the following contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Form 10-Q.

Forward-Looking Statements

This Quarterly Report on Form 10-Q (this “Form 10-Q”) contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the “safe harbor” created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as “believe,” “expect,” “may,” “will,” “should,” “would,” “could,” “seek,” “intend,” “plan,” “goal,” “project,” “estimate,” “anticipate,” “strategy,” “future,” “likely” or the negative thereof or other variations thereon or other comparable terminology. All statements other than statements of historical facts included in this Form 10-Q regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements we make regarding: expectations for revenues, cash flows and financial performance and the anticipated results of our ongoing development and business strategies.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, but are not limited to, the following:

- the success, cost and timing of our clinical development of our products, including the progress of, and results from, our discovery programs and clinical trials of StemPrintER.
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our ability to compete with companies currently marketing or engaged in the development of diagnostic tests for indications that our product candidates are designed to target;
- our plans to pursue research and development of other future product candidates;
- the potential advantages of our product candidates and those being developed;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- the success of our collaborations and partnerships with third parties;
- our estimates regarding the potential market opportunity for our product candidates;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- our intellectual property position;
- our expectations related to the use of capital;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and future clinical trials;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations; and
- our competitive position.

The forward-looking statements are based upon management’s beliefs and assumptions and are made as of the date of this report. We undertake no obligation to publicly update or revise any forward-looking statements included in this report. You should not place undue reliance on these forward-looking statements.

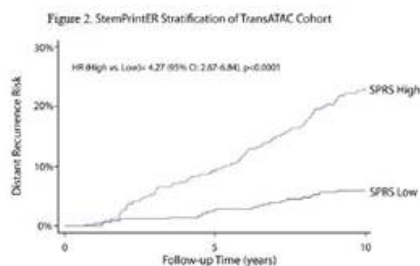
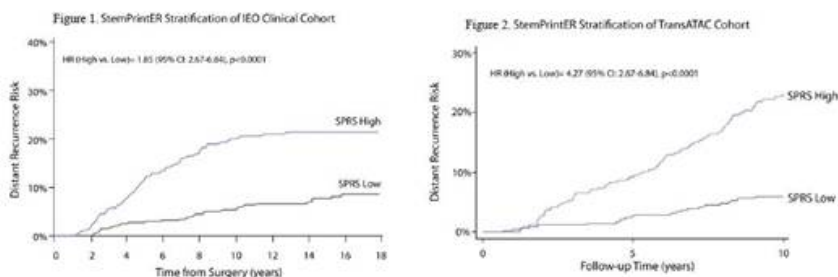
This report also contains or may contain estimates, projections and other information concerning our industry and our business, including data regarding the estimated size of our markets and their projected growth rates. Information that is based on estimates, forecasts, projections, or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, studies and similar data prepared by third parties, industry and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

Unless otherwise stated or the context otherwise requires, the terms “AccuStem” “we,” “us,” “our” and the “Company” refer collectively to AccuStem and, where appropriate, its subsidiaries.

Overview

We are a clinical stage diagnostics company dedicated to improving quality of life and outcomes for the more than 18 million people worldwide who are diagnosed with cancer each year. Our plan is to develop and commercialize a suite of novel genomic tests that support decision making along the entire continuum of oncology care. Our focus will be the commercialization of our proprietary genomic test, StemPrintER, for patients with early-stage breast cancer, and we estimate this market opportunity represents more than \$1.3 billion in annual revenue.

Our primary product candidate is StemPrintER, a 20-gene prognostic assay intended to predict the risk of distant recurrence (“DR”) in luminal (ER+/HER2-negative) breast cancer patients. The assay was developed to measure the “stemness” of tumors, or how much a tumor behaves like stem cells which could indicate how likely a cancer is to recur or be resistant to standard treatments, ultimately impacting how patients are managed by their multi-disciplinary care team. StemPrintER has been validated in several clinical cohorts and studies, the largest of which are a consecutive series of approximately 2,400 patients from the European Institute of Oncology (“IEO”) and approximately 800 patients from the TransATAC study. In the IEO cohort, StemPrintER High Risk patients (“SPRS High”) were 1.85 times more likely to have a distant recurrence compared to Low Risk (“SPRS Low”) patients (Figure 1) and in the TransATAC cohort, SPRS High patients were 4.27 times more likely to experience a distant recurrence compared to SPRS Low Risk patients (Figure 2). Together, these data confirm that StemPrintER is highly prognostic for outcomes in patients with breast cancer and indicate the potential utility of the test in the oncology clinic.



*SPRS- StemPrintER Recurrence Score; SPRS High- StemPrintER High Risk; SPRS Low- StemPrintER Low Risk

Beyond our initial plans for StemPrintER, we believe there is significant opportunity to expand our product portfolio. First, given the broad applicability of tumor “stemness”, which has been evaluated in a multitude of different cancers, we believe the StemPrint platform will have meaningful clinical utility beyond breast cancer. As such, we will seek to validate and commercialize StemPrint for a variety of different tumor types. Each tumor type, where applicable, would also include ancillary testing to boost our value proposition to physicians and their patients. In addition, we plan to offer ancillary commodity testing (e.g., hereditary genetic testing, somatic mutation testing) that augments our proprietary assays and provides additional information and value to patients and physicians throughout the patient care continuum.

We plan to launch StemPrintER once we have achieved several key milestones. First, we plan to identify or build a laboratory that will be responsible for processing, testing and reporting StemPrintER results for all commercial samples. Further, we plan to transfer the StemPrintER assay from the laboratories in which they were developed to our commercial laboratory. Finally, upon establishing testing capabilities in our commercial laboratory, we will seek to obtain U.S. Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) certification so that we are able to report results for clinical use and to seek reimbursement from the Centers for Medicare and Medicaid Services. We anticipate that it will take at least 18 months to complete these milestones. Once those tasks are complete, we plan to initially launch StemPrintER in the US and then expand to other markets as we evaluate clinical need and revenue opportunity.



Impact of the COVID-19 Pandemic

In early 2020, an outbreak of the novel strain of coronavirus (COVID-19) emerged globally. As a result, there have been mandates from federal, state and local authorities resulting in an overall decline in economic activity. There have been no material impacts from COVID-19 on our operations for the periods through September 30, 2022. However, it is possible that the pandemic will continue to significantly impact economies worldwide, which could result in adverse effects on our operations. The extent of the impact of COVID-19 on operations, liquidity, financial condition, and results of operations remain uncertain at this time.

Financial Operations Overview

We have no products approved for commercial sale and have not generated revenue to date. We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of \$899,125 and \$62,722 for the three months ended September 30, 2022 and 2021, respectively. We incurred net losses of \$2,767,855 and \$127,132 for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of \$3,492,747. Substantially all of our net losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

Segment Information

As of September 30, 2022, we viewed our operations and managed our business as one operating segment consistent with how our chief operating decision maker, our Chief Executive Officer, makes decisions regarding resource allocation and assessing performance. As of September 30, 2022, substantially all of our assets were located in the United States. Our headquarters and operations are located in New York, NY and London, UK.

Results of Operations

The following discussion and analysis of our results of operations includes a comparison of the three and nine months ended September 30, 2022 to the three and nine months ended September 30, 2021:

	Three Months Ended September 30				Nine Months Ended September 30			
	2022	2021	\$ Change	% Change	2022	2021	\$ Change	% Change
Research and development expenses	\$ 58,270	\$ 14,125	\$ 44,145	313%	\$ 133,809	\$ 46,869	\$ 86,940	185%
General and administrative expenses	840,855	48,597	792,258	1630%	2,634,076	80,263	2,553,813	3182%
Loss from operations	899,125	62,722	836,403	1334%	2,767,885	127,132	2,640,753	2077%
Loss, before income tax	(899,125)	(62,722)	(836,403)	1334%	(2,767,885)	(127,132)	(2,640,753)	2077%
Income tax benefit (expense)	-	-	-	0%	-	-	-	0%
Net Loss	<u>\$(899,125)</u>	<u>\$(62,722)</u>	<u>\$(836,403)</u>	<u>1334%</u>	<u>\$(2,767,885)</u>	<u>\$(127,132)</u>	<u>\$(2,640,753)</u>	<u>2077%</u>

Research and development

Research and development expenses for the three and nine months ended September 30, 2022 increased to \$58,270 and \$133,809, respectively, compared to \$14,125 and \$46,869, respectively, for the three and nine months ended September 30, 2021 primarily due to increase in patent related expenses, and laboratory work and consulting.

General and administrative

General and administrative expenses for the three and nine months ended September 30, 2022 increased to \$840,855 and \$2,634,076, respectively, compared to \$48,597 and \$80,263, respectively, for the three and nine months ended September 30, 2021 primarily due to increase an increase of payroll related costs as a result of the new management team structure, as well as costs related to legal fees and other compliance expenses.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue and have incurred significant operating losses. Our potential products are at various phases of development. We do not expect to generate significant revenue from product sales for several years, if at all. Pursuant to the demerger, Tiziana transferred \$1,353,373 (£1,000,000) in cash in January 2022 to us. In addition, subject to the terms of the supplemental demerger agreement, Tiziana invested \$2,675,940 (£2,000,000) in cash in March 2022 for additional shares of the Company. Our cash flows may fluctuate and are difficult to forecast and will depend on many factors. As of September 30, 2022, our cash balance is \$1,331,960, which is adequate for our current planned level of operations, through at least December 2022.

Cash Flows

The following table summarizes our cash flows:

	Nine Months Ended September 30,	
	2022	2021
Cash flows used in operating activities	\$ (1,315,325)	\$ —
Cash flows used in investing activities	(10,999)	—
Cash flows from financing activities	2,658,284	—
Net increase in cash and cash equivalents	1,331,960	—
Cash and cash equivalents at beginning of period	—	—
Cash and cash equivalents at end of period	\$ 1,331,960	\$ —

We did not generate any cash flows through September 30, 2021 as cash was funded by a related party.

Operating Activities

There was an increase in cash flows from operating activities during the nine months ended September 30, 2022 due to the collection of a receivable from a related party. There were no cash flows from operating activities during the nine months ended September 30, 2021.

Investing Activities

The cash flow used in investing activities increased during the nine months ended September 30, 2022 due to the purchase of computer equipment. There were no cash flows from investing activities during the nine months ended September 30, 2021.

Financing Activities

We generated cash flows from financing activities during the nine months ended September 30, 2022 due to proceeds from the issuance of common stock to Tiziana, as mentioned in the “Sources of Liquidity” section above. There was no net cash received in financing investing activities for the nine months ended September 30, 2021.

Market Capital Expenditure Commitments

We have no material commitment for capital expenditures.

Funding Requirements

We expect that our expenses will increase and operating losses will be generated, and we have \$3,492,747 of accumulated deficit as at September 30, 2022. Based on our current plans, we believe our existing cash and cash equivalents will be sufficient to fund our operations and capital expenditure requirements until December 2022. We expect to incur substantial additional expenditures in the near term to support our acceleration of activities. We expect to incur net losses for the foreseeable future. Our ability to fund our product development and clinical operations as well as commercialization of our product candidates, will depend on the amount and timing of cash received from planned financings. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our product candidates;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the emergence of competing technologies and products and other adverse marketing developments;
- the effect on our product development activities of actions taken by the FDA, EMA or other regulatory authorities;
- our degree of success in commercializing our product candidates, if and when approved; and
- the number and types of future products we develop and commercialize.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity financings, debt financings, collaborations with other companies or other strategic transactions. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Critical Accounting Policies

There have been no significant changes to our critical accounting policies and estimates from the information provided in Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in our Form 10-K for the year ended December 31, 2021.

Off-Balance Sheet Arrangements

We have no other off-balance sheet arrangements that have had, or are reasonably likely to have, a material current or future effect on our consolidated financial statements or changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

For information on recent accounting pronouncements, see our condensed consolidated financial statements - Note 2 and the related notes found elsewhere in this quarterly report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no significant changes to our quantitative and qualitative disclosures about market risk as discussed in Part II, Item 7A “Quantitative and Qualitative Disclosures About Market Risk,” included our Form 10-K for the year ended December 31, 2021.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our “disclosure controls and procedures” (as defined in Exchange Act Rules 13a-15I and 15d-15(e)) as of September 30, 2022, the end of the period covered by this Quarterly Report on Form 10-Q. The term “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is accumulated and communicated to a company’s management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our management, with the participation of our principal executive officer and principal financial officer has concluded that, based on such evaluation, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were not effective due to the material weakness described below.

Material Weaknesses in Internal Controls Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Management has determined that we did not maintain effective internal control over financial reporting as of the period ended September 30, 2022 due to a lack of accounting resources resulting in inadequate monitoring controls and other oversight procedures. Our management has determined that our disclosure controls and procedures and internal controls were ineffective due to weaknesses in our financial closing process, inadequate segregation of duties over authorization, review and recording of transactions, lack of accounting resources, as well as the financial reporting of such transactions.

Management's Plan to Remediate the Material Weakness

Management intends to remediate this item in the following manner:

- i. Recruit appropriately skilled accounting resources (the "Remediation Plan")

Accordingly, management has determined that these control deficiencies constitute a material weakness. Management has begun implementing the Remediation Plan described herein and intends to continue working on it through the year ended December 31, 2022.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Form 10-K for the year ended December 31, 2021

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

None

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

31.1 [Certification by Chief Executive Officer pursuant to Rule 13a-14\(a\) and Rule 15d-14\(a\) of the Securities Exchange Act](#)

31.2 [Certification by Chief Financial Officer pursuant to Rule 13a-14\(a\) and Rule 15d-14\(a\) of the Securities Exchange Act](#)

32.1 [Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)

32.2 [Certification by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)

101.INS* Inline XBRL Instance Document

101.SCH* Inline XBRL Taxonomy Extension Schema Document

101.CAL* Inline XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF* Inline XBRL Taxonomy Extension Definition Linkbase Document

101.LAB* Inline XBRL Taxonomy Extension Label Linkbase Document

101.PRE* Inline XBRL Taxonomy Extension Presentation Linkbase Document

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on November 8, 2022.

ACCUSTEM SCIENCES, INC.

/s/ Keeren Shah

Keeren Shah
Chief Financial Officer

/s/ Wendy Blosser

Wendy Blosser
Chief Executive Officer and Director

Exhibit 31.1**CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER, PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER**

I, Wendy Blosser, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AccuStem Sciences 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 Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, 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.

Dated: November 8, 2022

/s/ Wendy Blosser

Name: Wendy Blosser

Title: Chief Executive Officer

Exhibit 31.2**CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER, PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER**

I, Keeren Shah, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AccuStem Sciences 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 Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, 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.

Dated: November 8, 2022

/s/ Keeren Shah

Name: Keeren Shah

Title: Chief Financial Officer

Exhibit 32.1

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of AccuStem Sciences Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Wendy Blosser, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: November 8, 2022

/s/ Wendy Blosser

Name: Wendy Blosser

Title: Chief Executive Officer

Exhibit 32.2

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of AccuStem Sciences Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keeren Shah, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: November 8, 2022

/s/ Keeren Shah

Name: Keeren Shah

Title: Chief Financial Officer
