

**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: **001-33718**

U.S. STEM CELL, INC.

(Exact name of registrant as specified in its charter)

Florida

(State or other jurisdiction of incorporation or organization)

65-0945967

(I.R.S. Employer Identification No.)

1560 Sawgrass Corporate Pkwy 4th Floor, Sunrise, FL 33323

(Address of principal executive offices) (Zip Code)

(954) 835-1500

(Registrant's telephone number, including area code)

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, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	USRM	OTC

As of November 9, 2022, there were 634,402,623 outstanding shares of the Registrant's common stock, par value \$0.001 per share.

Transitional Small Business Disclosure Format Yes No

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statement

U.S. STEM CELL, INC.
CONDENSED BALANCE SHEETS

	September 30, 2022 <i>(unaudited)</i>	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 30,158	\$ 39,393
Accounts receivable, net of allowance of \$75,000	3,192	1,213
Inventories	702	393
Prepaid expenses and other current assets	137,839	10,000
Total current assets	<u>171,891</u>	<u>50,999</u>
Total assets	<u>\$ 171,891</u>	<u>\$ 50,999</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,568,971	\$ 1,373,413
Accrued expenses	2,410,619	1,951,390
Advances - related parties	1,118,102	951,432
Contract liabilities, current portion	3,000	3,000
Deposits	465,286	465,286
Notes payable - related parties	3,706,700	3,144,200
Notes payable, current portion, net of debt discount of \$10,396 and \$10,052, respectively	2,573,113	2,557,881
Promissory note payable	1,397,762	1,397,762
Convertible notes payable, net of debt discount of \$43,979 and \$0, respectively	384,021	194,411
Total current liabilities	<u>13,627,574</u>	<u>12,038,775</u>
Long-term liabilities:		
Contract liabilities	54,250	56,500
Notes payable, net of debt discount of \$13,756 and \$21,575, respectively	692,186	722,060
Total long-term liabilities	<u>746,436</u>	<u>778,560</u>
Total liabilities	<u>14,374,010</u>	<u>12,817,335</u>
Commitments and contingencies (See Note 11)		
Stockholders' deficit:		
Preferred stock, par value \$0.001; 20,000,000 shares authorized, -0- issued and outstanding	-	-
Common stock, par value \$0.001; 2,000,000,000 shares authorized, 632,275,481 and 503,525,051 shares issued and outstanding, respectively	632,275	503,525
Additional paid-in capital	127,116,272	126,532,063
Accumulated deficit	(141,950,666)	(139,801,924)
Total stockholders' deficit	<u>(14,202,119)</u>	<u>(12,766,336)</u>
Total liabilities and stockholders' deficit	<u>\$ 171,891</u>	<u>\$ 50,999</u>

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

U.S. STEM CELL, INC.
CONDENSED STATEMENTS OF OPERATIONS
(unaudited)

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Revenue:				
Products	\$ 10,661	\$ 52,578	\$ 49,229	\$ 161,308
Services	3,586	4,756	12,846	15,848
Total revenue	<u>14,247</u>	<u>57,334</u>	<u>62,075</u>	<u>177,156</u>
Cost of revenues	<u>5,264</u>	<u>14,200</u>	<u>18,846</u>	<u>43,398</u>
Gross profit	8,983	43,134	43,229	133,758
Operating expenses:				
Selling, general and administrative	405,564	547,977	1,389,490	1,906,962
Total operating expenses	<u>405,564</u>	<u>547,977</u>	<u>1,389,490</u>	<u>1,906,962</u>
Loss from operations	(396,581)	(504,843)	(1,346,261)	(1,773,204)
Other income (expense):				
Gain (loss) on settlement of accounts payable and accrued interest, net	(39)	(5,113)	707	(388,983)
Interest expense	(168,785)	(162,485)	(498,279)	(484,204)
Gain (loss) on debt extinguishment	-	-	(447,494)	-
Total other income (expense)	<u>(168,824)</u>	<u>(167,598)</u>	<u>(945,066)</u>	<u>(873,187)</u>
Net loss before income taxes	(565,405)	(672,441)	(2,291,327)	(2,646,391)
Income taxes (benefit)	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
NET LOSS	<u>\$ (565,405)</u>	<u>\$ (672,441)</u>	<u>\$ (2,291,327)</u>	<u>\$ (2,646,391)</u>
Net loss per common share, basic and diluted	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (0.01)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>609,385,917</u>	<u>455,404,407</u>	<u>577,127,695</u>	<u>450,696,456</u>

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

U.S. STEM CELL, INC.
CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2022
(unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, June 30, 2022 (unaudited)	-	\$ -	598,102,281	\$ 598,102	\$ 126,928,307	\$ (141,385,261)	\$ (13,858,852)
Common shares issued in settlement of accounts payable	-	-	839,866	840	4,199	-	5,039
Common shares issued for services	-	-	25,000,000	25,000	132,000	-	157,000
Common shares issued for cash	-	-	8,333,334	8,333	41,667	-	50,000
Share-based compensation	-	-	-	-	10,099	-	10,099
Net loss	-	-	-	-	-	(565,405)	(565,405)
Balance, September 30, 2022 (unaudited)	-	\$ -	632,275,481	\$ 632,275	\$ 127,116,272	\$ (141,950,666)	\$ (14,202,119)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, December 31, 2021	-	\$ -	503,525,051	\$ 503,525	\$ 126,532,063	\$ (139,801,924)	\$ (12,766,336)
Modified retrospective adoption of ASU 2020-06	-	-	-	-	(384,174)	142,585	(241,589)
Adjusted balance, December 31, 2021	-	-	503,525,051	503,525	126,147,889	(139,659,339)	(13,007,925)

Common shares issued in settlement of accounts payable	-	-	5,395,942	5,396	38,175	-	43,571
Common shares issued in lieu of interest	-	-	1,121,154	1,121	8,745	-	9,866
Common shares issued for services	-	-	45,000,000	45,000	252,000	-	297,000
Common shares and warrants issued to noteholders per addendums to convertible notes payable	-	-	53,400,000	53,400	438,207	-	491,607
Common shares issued as equity kicker for convertible notes payable	-	-	6,750,000	6,750	11,813	-	18,563
Common shares issued upon conversion of convertible notes payable	-	-	3,125,000	3,125	21,875	-	25,000
Common shares issued for cash	-	-	13,958,334	13,958	71,042	-	85,000
Share-based compensation	-	-	-	-	126,526	-	126,526
Net loss	-	-	-	-	-	(2,291,327)	(2,291,327)
Balance, September 30, 2022 (unaudited)	-	\$ -	632,275,481	\$ 632,275	\$ 127,116,272	\$ (141,950,666)	\$ (14,202,119)

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

U.S. STEM CELL, INC.
CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021
(unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, June 30, 2021 (unaudited)	-	\$ -	451,738,971	\$ 451,739	\$ 126,150,449	\$ (138,488,458)	\$ (11,886,270)
Common shares issued in settlement of accounts payable	-	-	674,182	674	9,439	-	10,113
Common shares issued upon conversion of convertible notes	-	-	3,804,348	3,805	31,195	-	35,000
Common shares issued for cash	-	-	5,000,000	5,000	45,000	-	50,000
Share-based compensation	-	-	-	-	121,690	-	121,690
Net loss	-	-	-	-	-	(672,441)	(672,441)
Balance, September 30, 2021 (unaudited)	-	\$ -	461,217,501	\$ 461,218	\$ 126,357,773	\$ (139,160,899)	\$ (12,341,908)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, December 31, 2020	-	\$ -	435,560,794	\$ 435,561	\$ 124,499,655	\$ (136,514,508)	\$ (11,579,292)
Common shares issued in settlement of accounts payable	-	-	5,145,987	5,146	207,146	-	212,292
Common shares issued in lieu of interest	-	-	187,575	187	10,692	-	10,879
Common shares issued for services	-	-	4,000,000	4,000	124,000	-	128,000
Beneficial conversion feature recognized on convertible notes	-	-	-	-	634,250	-	634,250
Common shares issued upon conversion of convertible notes payable	-	-	11,323,145	11,324	399,616	-	410,940
Common shares issued for cash	-	-	5,000,000	5,000	45,000	-	50,000
Share-based compensation	-	-	-	-	437,414	-	437,414
Net loss	-	-	-	-	-	(2,646,391)	(2,646,391)
Balance, September 30, 2021 (unaudited)	-	\$ -	461,217,501	\$ 461,218	\$ 126,357,773	\$ (139,160,899)	\$ (12,341,908)

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

U.S. STEM CELL, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)

	For the Nine Months Ended September 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (2,291,327)	\$ (2,646,391)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bad debt (recoveries)	-	61,797
Interest and amortization of debt discount	492,897	466,948
Loss (gain) on settlement of accounts payable and accrued interest	(707)	388,983
Loss on debt extinguishment	447,494	-
Related party notes payable issued for services rendered	562,500	321,760
Share-based compensation	295,687	565,414
Changes in operating assets and liabilities:		
Accounts receivable	(1,979)	(42,604)
Inventories	(309)	3,476
Prepaid expenses and other current assets	-	(3,730)
Accounts payable	227,073	43,450
Accrued expenses	9,134	1,909
Contract liabilities	(2,250)	(2,250)
Net cash used in operating activities	<u>(261,787)</u>	<u>(841,238)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common shares	85,000	50,000
Proceeds from related party advances	166,670	90,000
Repayments of notes payable	(16,118)	(35,995)
Proceeds from convertible note payable	27,000	749,000
Repayments of convertible note payable	(10,000)	-
Net cash provided by financing activities	<u>252,552</u>	<u>853,005</u>
Net increase (decrease) in cash and cash equivalents	(9,235)	11,767
Cash and cash equivalents, beginning of period	39,393	18,570
Cash and cash equivalents, end of period	<u>\$ 30,158</u>	<u>\$ 30,337</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	\$ 5,382	\$ 17,256
Income taxes paid	\$ -	\$ -
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Modified retrospective adoption of ASU 2020-06	\$ 384,174	\$ -
Common shares issued for prepaid services	\$ 127,839	\$ -
Common shares issued in settlement of accounts payable	\$ 43,571	\$ 212,292
Common shares issued upon conversion of convertible notes and accrued interest	\$ 25,000	\$ 410,940
Common shares issued as equity kicker for convertible notes payable	\$ 18,563	\$ -
Common shares issued in lieu of interest	\$ 9,866	\$ 10,879
Monthly payments on notes payable made on behalf of the Company	\$ 6,000	\$ -
Beneficial conversion feature recognized on convertible note	\$ -	\$ 634,250

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

U.S. STEM CELL, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2022
(unaudited)

NOTE 1 — NATURE OF OPERATIONS

Overview

U.S. Stem Cell, Inc. was incorporated under the laws of the State of Florida in August 1999. The Company is in the cardiovascular sector of the cell technology industry delivering cell therapies and biologics that help address congestive heart failure, lower limb ischemia, chronic heart ischemia, acute myocardial infarctions and other issues. The business includes the development of proprietary cell therapy products as well as revenue generating physician and patient-based regenerative medicine/cell therapy training services, cell collection and cell storage services, the sale of cell collection and treatment kits for humans and animals, and the operation of cell therapy clinics. To date, the Company has not generated significant revenues in that they remain less than their total operating expenses, has incurred expenses, and has sustained losses. Consequently, its operations are subject to all the risks inherent in the establishment of a research and development business enterprise.

Basis of Presentation

The interim unaudited condensed financial statements included herein reflect all material adjustments (consisting of normal recurring adjustments and reclassifications and non-recurring adjustments) which, in the opinion of the Company's management, are ordinary and necessary for a fair presentation of results for the interim periods. Certain information and footnote disclosures required under generally accepted accounting principles in the United States of America ("GAAP") have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). The Company's management believes the disclosures are adequate to make the information presented not misleading.

The condensed balance sheet information as of December 31, 2021 was derived from the Company's annual report on Form 10-K for the fiscal year ended December 31, 2021 ("2021 Annual Report"), filed with the SEC pursuant to Section 13 or 15(d) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), on March 31, 2022 (and amended for Item 9 on July 8, 2022). These interim unaudited condensed financial statements should be read in conjunction with the 2021 Annual Report. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results to be expected for the entire fiscal year or for any other period.

NOTE 2 – GOING CONCERN AND MANAGEMENT'S LIQUIDITY PLANS

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

As shown in the accompanying financial statements, as of September 30, 2022, the Company had cash on hand of \$30,158 and a working capital deficit (current liabilities in excess of current assets) of \$13,455,683. During the nine months ended September 30, 2022, the net loss was \$2,291,327 and net cash used in operating activities was \$261,787. These conditions raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the financial statements.

The Company's primary source of operating funds has been from revenue generated from sales with additional cash proceeds from the sale of common stock and the issuances of promissory notes and other debt. The Company has experienced net losses from operations since inception, but it expects these conditions to improve in the future as it develops its business model. The Company had a stockholders' deficit at September 30, 2022 and requires additional financing to fund future operations.

The Company's existence is dependent upon management's ability to develop profitable operations and to obtain additional funding sources. There can be no assurance that the Company's financing efforts will result in profitable operations or the resolution of the Company's liquidity problems. The accompanying statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

U.S. STEM CELL, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2022
(unaudited)

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include stock-based compensation, debt discounts and the valuation allowance related to deferred tax assets. Actual results may differ from these estimates.

Cash

The Company considers cash to consist of cash on hand and temporary investments having an original maturity of 90 days or less that are readily convertible into cash.

Fair Value Measurements

Accounting Standards Codification subtopic 825-10, Financial Instruments (“ASC 825-10”) requires disclosure of the fair value of certain financial instruments. The carrying value of cash and cash equivalents, accounts payable, accrued liabilities, and short-term borrowings, as reflected in the balance sheets, approximate fair value because of the short-term maturity of these instruments. All other significant financial assets, financial liabilities and equity instruments of the Company are either recognized or disclosed in the financial statements together with other information relevant for making a reasonable assessment of future cash flows, interest rate risk and credit risk. Where practicable the fair values of financial assets and financial liabilities have been determined and disclosed; otherwise only available information pertinent to fair value has been disclosed.

The Company follows Accounting Standards Codification subtopic 820-10, Fair Value Measurements and Disclosures (“ASC 820-10”) and Accounting Standards Codification subtopic 825-10, Financial Instruments (“ASC 825-10”), which permits entities to choose to measure many financial instruments and certain other items at fair value.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are non-interest bearing and are stated at gross invoice amounts less an allowance for doubtful accounts. Credit is extended to customers based on an evaluation of their financial condition, industry reputation, and other judgmental factors considered by the Company’s management. The Company generally does not require collateral or other security interest to support accounts receivable. Based on trends and specific factors, the customer’s credit terms may be modified, including required payment upon delivery.

The Company performs regular on-going credit evaluations of its customers as deemed relevant. As events, trends, and circumstance warrant, the Company’s management estimates the amounts that are more likely than not to be uncollectible. These amounts are recognized as bad debt expense and are reflected within selling, general, administrative and other expenses on the Company’s accompanying statements of operations.

Any charges to the allowance for doubtful accounts on accounts receivable are charged to operations in amounts sufficient to maintain the allowance for uncollectible accounts at a level management believes is adequate to cover any probable losses. Management determines the adequacy of the allowance based on historical write-off percentages and the current status of accounts receivable. Accounts receivable are charged off against the allowance when collectability is determined to be permanently impaired. As of September 30, 2022 and December 31, 2021, the allowance for doubtful accounts was \$75,000.

Inventories

Inventories are stated at the lower of cost or market with cost being determined on a first-in, first-out (FIFO) basis. The Company writes down its inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. During the periods presented, there were no inventory write-downs.

U.S. STEM CELL, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2022
(unaudited)

Investments

The Company follows Accounting Standards Codification subtopic 323-10, Investments-Equity Methods and Joint Ventures (“ASC 323-10”) which requires the accounting for investments where the Company can exert significant influence, but not control of a joint venture or equity investment. The Company accounted for its 49.9% member interest ownership of U.S. Stem Cell Clinic, LLC and its 49% member interest ownership of U.S. Stem Cell Clinic of the Villages utilizing the equity method of accounting (See Note 4).

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606 “Revenue from Contracts with Customers” (“ASC 606”). ASC 606 is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

The Company’s primary sources of revenue are from the sale of test kits and equipment, training services, patient treatments, laboratory services and cell banking.

Revenues for kits and equipment sold are not recorded until kits and equipment are received by the customer. Revenues from in-person trainings are recognized when the training occurs and revenues from on demand online trainings are recognized when the customer purchases the rights to the training course. Any cash received as a deposit for trainings are recorded by the Company as a liability.

Patient treatments and laboratory services revenue are recognized when those services have been completed or satisfied.

Revenues for cell banking are accounted for as multiple performance obligations as described in ASC 606 and addresses accounting for arrangements that may involve the delivery or performance of multiple products, services and/or rights to use assets. Because the Company sells its services separately, on more than a limited basis and at a price within a narrow range, the Company was able to allocate revenue based on stand-alone pricing. The multiple performance obligations include stem cell banking, dose retrieval and yearly storage fees. Revenues for stem cell banking and dose retrieval is recognized at the point of service and revenues for the yearly storage fees is recognized over the term of the banking contract, which is typically one year with annual renewals.

At September 30, 2022 and December 31, 2021, the Company had contract liabilities of \$57,250 and \$59,500, respectively, all of which relates to the Intellectual Property Licensing Agreement.

Research and Development

The Company accounts for research and development costs in accordance with Accounting Standards Codification subtopic 730-10, Research and Development (“ASC 730-10”). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and development costs are expensed when the contracted work has been performed or as milestone results have been achieved as defined under the applicable agreement. Company-sponsored research and development costs related to both present and future products are expensed in the period incurred. The Company did not incur any research and development expenses during the periods presented.

Stock-Based Compensation

Stock-based compensation expense is measured at the grant date fair value of the award and is expensed over the requisite service period. For stock-based awards to employees, non-employees and directors, the Company calculates the fair value of the award on the date of grant using the Black-Scholes option pricing model. Determining the fair value of stock-based awards at the grant date under this model requires judgment, including estimating volatility, employee stock option exercise behaviors and forfeiture rates. The assumptions used in calculating the fair value of stock-based awards represent the Company’s best estimates, but these estimates involve inherent uncertainties and the application of management’s judgment.

U.S. STEM CELL, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2022
(unaudited)

Income Taxes

The Company follows Accounting Standards Codification subtopic 740-10, Income Taxes (“ASC 740-10”) for recording the provision for income taxes. Deferred tax assets and liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability during each period. If available evidence suggests that it is more likely than not that some portion or all of the deferred tax assets will not be realized, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in such valuation allowance are included in the provision for deferred income taxes in the period of change. Deferred income taxes may arise from temporary differences resulting from income and expense items reported for financial accounting and tax purposes in different periods.

Deferred taxes are classified as current or non-current, depending on the classification of assets and liabilities to which they relate. Deferred taxes arising from temporary differences that are not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse and are considered immaterial.

Net Loss per Common Share

The Company computes earnings (loss) per share under Accounting Standards Codification subtopic 260-10, Earnings Per Share (“ASC 260-10”). Net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. Diluted earnings per share, if presented, would include the dilution that would occur upon the exercise or conversion of all potentially dilutive securities into common stock using the “if converted” method.

The computation of basic and diluted income (loss) per share as excludes potentially dilutive securities when their inclusion would be anti-dilutive, or if their exercise prices were greater than the average market price of the common stock during the period.

Potentially dilutive securities excluded from the computation of basic and diluted net loss per share are as follows:

	September 30,	
	2022	2021
Options	110,641,384	110,643,884
Warrants	13,583,127	1,103,127
Convertible notes	36,455,827	33,291,651
Total potentially dilutive shares	<u>160,680,338</u>	<u>145,038,662</u>

Reclassifications

Certain reclassifications have been made to the prior years’ data to conform to the current year presentation. These reclassifications had no effect on reported income (losses).

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, which simplifies the guidance on accounting for convertible debt instruments by removing the separation models for: (1) convertible debt with a cash conversion feature; and (2) convertible instruments with a beneficial conversion feature. As a result, the Company will not separately present in equity an embedded conversion feature in such debt. Instead, we will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. We expect the elimination of these models will reduce reported interest expense and increase reported net income for the Company’s convertible instruments falling under the scope of those models before the adoption of ASU 2020-06. Also, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and the treasury stock method will be no longer available. The Company adopted ASU 2020-06 in the first quarter of 2022 utilizing the modified retrospective method. As a result, the Company adjusted its beginning balance sheet with a decrease in additional paid-in capital of \$384,174, offset by a decrease in debt discount on convertible debt of \$241,589 and an increase in accumulated deficit of \$142,585.

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In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments”, which significantly changes how entities will measure credit losses for most financial assets, including accounts receivable. ASU No. 2016-13 will replace today’s “incurred loss” approach with an “expected loss” model, under which companies will recognize allowances based on expected rather than incurred losses. On November 15, 2019, the FASB delayed the effective date of Topic 326 for certain small public companies and other private companies until fiscal years beginning after December 15, 2022 for SEC filers that are eligible to be smaller reporting companies under the SEC’s definition, as well as private companies and not-for-profit entities. The Company does not expect the new guidance will have a material impact on its financial statements.

There are various other updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to have a material impact on the Company’s financial position, results of operations or cash flows.

NOTE 4 — INVESTMENTS

During March 2021, we divested ourselves of our Member Interest in U.S. Stem Cell Clinic, LLC, while U.S. Stem Cell Clinic of the Villages, LLC is currently dormant.

U.S. Stem Cell Clinic, LLC

The investment in U.S. Stem Cell Clinic, LLC was comprised of a 49.9% (increased from 33.3% on January 29, 2019) member interest ownership and is accounted for using the equity method of accounting. The Company’s income (loss) earned by U.S. Stem Cell Clinic, LLC member interest was \$0 for the three and nine months ended September 30, 2022 and 2021, (inception to date income of \$599,721) and is included in other income (expense) in the accompanying statements of operations. In addition, during the nine months ended September 30, 2022 and 2021, the Company received distributions totaling \$0 from U.S. Stem Cell Clinic, LLC (inception to date of \$663,870). In March 2021, the Company divested its entire interest in U.S. Stem Cell Clinic, LLC (See Note 5, 6 and 11). The carrying value of the investment at September 30, 2022 and December 31, 2021 is \$0.

Revenues earned from sales to U.S. Stem Cell Clinic, LLC for the three and nine months ended September 30, 2022 were \$0, and for the three and nine months ended September 30, 2021 were \$0 and \$2,531 (prior to divestiture), respectively.

An affiliate of one of the Company’s officers is a minority investor in the U.S. Stem Cell Clinic, LLC.

U.S. Stem Cell of the Villages LLC

On January 30, 2018, Greg Knutson, a director of the Company (“Knutson”) and the Company agreed to open and operate a regenerative medicine/cell therapy clinic providing cellular treatments for patients afflicted with neurological, autoimmune, orthopedic and degenerative diseases in Florida. To that end, U.S. Stem Cell Clinic of The Villages LLC (the “Villages”) was formed January 30, 2018. Knutson provided the Company with the sum of Three Hundred Thousand Dollars (\$300,000) (the “Investment”) to be utilized for the formation and initial operation of the Villages. Currently, Knutson holds a 51% member interest in the Villages and the Company holds a 49% member interest. The Company will provide operating assistance as well as management services, the latter to be compensated at fee of five percent (5%) of the Villages gross revenues.

As of December 31, 2018, upon completion of U.S. Stem Cell of the Villages LLC, the Company received \$189,909 from Greg Knutson, the holder of the 51% member interest. Accordingly, this was recognized as additional paid-in capital. Subsequently, the Company contributed \$86,750 as its initial investment in the Villages. The Company’s 49% income (loss) earned by the Villages member interest was \$0 for the three and nine months ended September 30, 2022 and 2021, (inception to date loss of \$23,050) and is included in other income (expense) in the accompanying statements of operations. In addition, during the nine months ended September 30, 2022 and 2021, the Company received distributions totaling \$0 from the Villages. The carrying value of the investment at September 30, 2022 and December 31, 2021 is \$0.

At September 30, 2022 and December 31, 2021, accounts receivable for sales of products and services to the Villages was \$0. Revenues earned from sales to the Villages for the three and nine months ended September 30, 2022 and 2021 was \$0.

During the three and nine months ended September 30, 2022 and 2021, the Company received \$0 in management fees from the Villages.

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As of the date of this filing, U.S. Stem Cell Clinic of the Villages, LLC is currently dormant.

NOTE 5 — ACCRUED EXPENSES

Accrued expenses consisted of the following as of September 30, 2022 and December 31, 2021:

	September 30, 2022	December 31, 2021
Interest and fees payable to the Guarantors of the Company's loan agreement with Seaside Bank	\$ 722,041	\$ 644,670
Accrued interest payable	1,609,446	1,227,588
Vendor accruals and other	79,132	79,132
Total Accrued expenses	<u>\$ 2,410,619</u>	<u>\$ 1,951,390</u>

On February 10, 2021, as part of a settlement agreement, the Company transferred its entire member interest in U.S. Stem Cell, LLC to Dr. Kristen Comella as settlement for \$100,000 of accrued interest owed to Dr. Comella, resulting in a gain on settlement of \$100,000 (See Note 4, Note 6 and Note 11 "Litigation").

NOTE 6 — NOTES PAYABLE

Notes payable were comprised of the following as of September 30, 2022 and December 31, 2021:

	September 30, 2022	December 31, 2021
Seaside Bank note payable	\$ 980,000	\$ 980,000
Dr. Comella note payable*	255,579	255,579
Dr. Comella note payable*	300,000	300,000
Dr. Comella note payable*	300,000	300,000
Dr. Comella note payable*	300,000	300,000
Hunton & Williams note payable	375,000	380,000
Weider note payable	403,622	413,239
Mallard note payable	225,250	232,750
EIDL note payable	150,000	150,000
Total notes payable	3,289,451	3,311,568
Less unamortized debt discount	(24,152)	(31,627)
Total notes payable net of unamortized debt discount	3,265,299	3,279,941
Less current portion	(2,573,113)	(2,557,881)
Long-term portion	<u>\$ 692,186</u>	<u>\$ 722,060</u>

* Dr. Comella is a former member of the Board of Directors and resigned on December 1, 2019. This note was previously included in notes payable - related parties.

Seaside Bank

On October 25, 2010, the Company entered into a Loan Agreement with Seaside National Bank and Trust for a \$980,000 loan at 4.25% per annum interest that was used to refinance the Company's loan with Bank of America. The obligation is guaranteed by certain stockholders of the Company. At the last renewal in 2018, the loan with Seaside National Bank and Trust was converted to a demand note. While the loan no longer has a fixed maturity date, it must be re-documented every four years.

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Dr. Comella, former Chief Science Officer

On September 6, 2016, the Company issued a \$300,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due upon demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$255,579.

On August 7, 2017, the Company issued a \$300,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due one year from date of issuance. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$300,000.

On May 7, 2018, the Company issued a \$300,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due six months from date of issuance. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$300,000.

On July 1, 2019, the Company issued a \$300,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due November 7, 2019. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$300,000.

On February 10, 2021, as part of a settlement agreement, the Company transferred its entire member interest in U.S. Stem Cell, LLC to Dr. Kristen Comella as settlement for \$100,000 of accrued interest owed to Dr. Comella, resulting in a gain on settlement of \$100,000 (See Note 4, Note 5 and Note 11 "Litigation"). At September 30, 2022 and December 31, 2021, accrued interest on the notes was \$209,639 and \$166,424, respectively, and is included in accrued expenses on the accompanying balance sheet.

Dr. Comella has not served as member of the Board of Directors since September 1, 2019.

Hunton & Williams

At December 31, 2016, the Company has two outstanding notes payable with interest at 8% per annum due at maturity. The two notes, \$61,150 and \$323,822, are payable in one balloon payment upon the date the Noteholder provides written demand, however the Company is not obligated to make payments until the Northstar Biotech Group, LLC (or successor) Loan is paid off.

On August 31, 2017, the Company and the noteholder entered into a Note Forbearance, Modification and Repayment Agreement ("Agreement"). The two notes, \$61,150 and \$323,822, were payable in one balloon payment upon the date of a written demand and upon certain triggering events occurring. The sum of unpaid principal and accumulated interest for both notes as of August 31, 2017 of \$747,680 and an accounts payable of \$40,596 result in an aggregate balance due of \$788,276.

The noteholder agreed to accept full payment of their obligation over a four (4) year period in 48 monthly installments on an adjusted debt obligation in aggregate of \$624,000 (reducing the outstanding balance), with such payments staggered in amounts such that the Company will pay \$10,000 monthly the first year, \$12,000 monthly the second year, \$14,000 monthly the third year, and \$16,000 monthly the final year. In addition, the noteholder agreed to suspend accrual interest on the notes commencing September 1, 2017.

The Agreement remains in full force and effect provided the Company continues to make the monthly payments, there is no event of default as defined in the notes and an agreement to a subordination agreement by Northstar Biotech Group, LLC, which has been provided. In May 2019, the Company did not make the required scheduled payment. In September 2019, the noteholder agreed to waive their default rights under the agreement provided a minimum of \$5,000 was paid by the end of 2019 and to reduce the required monthly payment to \$500 per month commencing in January 2020. The Company satisfied the \$5,000 payment requirement by the end of 2019 and commenced making the required \$500 monthly payments in January 2020. The Company last made a \$500 payment in March 2021 and thereby became delinquent until making three \$1,500 payments during the fourth quarter of 2021 (a total of \$6,000 in payments were made during 2021) thereby becoming current as of December 31, 2021.

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The Company imputed an interest rate of 5% and discounted the note accordingly. The imputed debt discount of \$69,700 was amortized to interest expense using the effective interest method. In September 2019, the Company was in default and was negotiating a revised payment structure. Thus, the remaining unamortized debt discount was charged to interest expense at September 30, 2019. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$375,000 and \$380,000, respectively.

Weider

The Company, as one of the parties entered into a Settlement Agreement and General Release (the “Agreement”) dated June 3, 2019 related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year 5.25% unsecured promissory note, dated June 15, 2019, in the principal amount of \$500,000, payable in monthly increments of \$5,000 per month, with a final balloon payment due on June 15, 2024. Accordingly, the Company recognized Pre-litigation expense of \$500,000. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$403,622 and \$413,239, respectively. At September 30, 2022 and December 31, 2021, accrued interest on the note was \$12,062 and \$1,808, respectively, and is included in accrued expenses on the accompanying balance sheet. The Company last made a \$5,000 payment in March 2022 and thereby became delinquent on this note payable.

Mallard

The Company, as one of the parties entered into a Settlement Agreement and General Release (the “Agreement”) dated December 6, 2019 related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year non-interest bearing unsecured promissory note, dated December 6, 2019, in the principal amount of \$250,000, payable in monthly increments of \$750 per month, with a final balloon payment of \$205,000 due on January 1, 2025. The Company imputed an interest rate of 5% and discounted the note accordingly. The imputed debt discount of \$51,063 is being amortized to interest expense using the effective interest method. Accordingly, the Company recognized Pre-litigation expense of \$198,937. During the nine months ended September 30, 2022, U.S. Stem Cell Clinic made eight monthly payments of \$750 (total of \$6,000) on behalf of the Company. For the three and nine months ended September 30, 2022, the Company amortized \$2,548 and \$7,476, respectively; and \$2,435 and \$7,146 during the three and nine months ended September 30, 2021, respectively, of debt discount to interest expense. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$201,098 and \$201,123, net of debt discount of \$24,152 and \$31,627, respectively.

Economic Injury Disaster Loan (EIDL)

On June 20, 2020, the Company executed the standard loan documents for an EIDL from the U.S. Small Business Administration in light of the impact of the COVID-19 pandemic on our business. Pursuant to that certain Loan Authorization and Agreement (the “SBA Loan Agreement”), the principal amount of the EIDL received was \$150,000, with proceeds to be used for working capital purposes. Interest accrues at the rate of 3.75% per annum. Installment payments, including principal and interest, are due monthly beginning June 20, 2021 (twelve months from the date of the SBA Loan Agreement) in the amount of \$731. On March 15, 2021, the initial payment date was extended 12 months to June 20, 2022. On March 15, 2022, the initial payment date was extended 6 months to December 20, 2022. The balance of principal and interest is payable thirty years from the date of the SBA Loan Agreement. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$150,000. At September 30, 2022 and December 31, 2021, accrued interest on the note was \$12,822 and \$8,615, respectively, and is included in accrued expenses on the accompanying balance sheet.

NOTE 7 — PROMISSORY NOTE PAYABLE

On June 1, 2015, the Company issued an amended and restated promissory note of \$1,697,762 in settlement of the \$1,500,000 outstanding subordinated debt, related accrued interest of \$373,469 and accumulated and unpaid guarantor fees of \$624,737.

The note is unsecured and non-interest bearing and required four semi-annual payments of \$75,000 beginning on December 31, 2015 with the remaining unpaid balance due June 1, 2020. On June 1, 2020, the Company defaulted on the promissory note. Upon default, the note became due in full and the Company began accruing interest at the default interest rate of 18%.

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The Company imputed an interest rate of 5% and discounted the promissory note accordingly. The imputed debt discount of \$368,615 was amortized to interest expense using the effective interest method. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$1,397,762. At September 30, 2022 and December 31, 2021, accrued interest on the note was \$586,601 and \$398,420, respectively, and is included in accrued expenses on the accompanying balance sheet.

NOTE 8 — CONVERTIBLE NOTES PAYABLE

The Company adopted ASU 2020-06 in the first quarter of 2022 utilizing the modified retrospective method. As a result, the Company eliminated an aggregate of \$241,589 of debt discount stemming from beneficial conversion features on convertible debt. Accordingly, the Company will not separately present in equity an embedded conversion feature in such debt.

On February 5, 2020, the Company issued an unsecured convertible promissory note in the principal amount of \$35,000 that matured on February 5, 2021 and bears interest at a rate of 5% per annum. The investor has the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price equal to a thirty percent (30%) discount of the average closing price of the Company's common stock on the OTC Markets electronic exchange for the prior thirty (30) trading days prior to conversion, subject to adjustment. Upon the occurrence of an event of default, the investor may accelerate the note pursuant to which the outstanding balance will become, at the noteholder's election, immediately due and payable. As a result of the beneficial conversion feature of the note, debt discount of \$15,000 was recognized with a corresponding increase in additional paid-in capital. As of February 5, 2021, the maturity date, the note was in default. On July 30, 2021, the investor converted the full value of the note into 3,804,348 shares of the Company's common stock, having a fair value of \$50,000, resulting in a loss on conversion of \$15,000. The agreement contains a provision that in the event the conversion right is exercised, then the Holder waives all outstanding interest. Accordingly, all outstanding accrued interest at the time of conversion was reversed. The debt discount was amortized to interest expense using the effective interest method. For the three and nine months ended September 30, 2021, the Company amortized \$0 and \$1,874, respectively, of debt discount to interest expense. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$0. At September 30, 2022 and December 31, 2021, accrued interest on the note was \$0.

From February 17, 2021 through February 26, 2021, the Company issued unsecured convertible promissory notes in the aggregate principal amount of \$619,000 that matured 12 months after the respective issuance date. The notes are non-interest bearing and the investor has the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price of \$0.0266. The agreements contain a provision that in the event the conversion right is exercised, then the Holder waives all outstanding interest. Upon the occurrence of an event of default, the remaining principal and accrued interest become immediately due and payable. As a result of the beneficial conversion feature of the notes, an aggregate of \$521,850 of debt discount was recognized with a corresponding increase in additional paid-in capital. The debt discount was being amortized to interest expense using the effective interest method. On March 23, 2021, one of the holders, a related party, converted a convertible note with a face value of \$200,000, dated February 26, 2021, into 7,518,797 shares of the Company's common stock. Upon conversion, the remaining unamortized debt discount was expensed immediately. In addition, all outstanding accrued interest at the time of conversion was reversed. As the conversion was at a fixed conversion price, no gain or loss was recognized on conversion (See Note 9 and 12). During the three months ended March 31, 2022, the Company entered into addendums with certain holders owning an aggregate of \$294,000 of the convertible notes whereby: [1] for \$214,000 of the convertible notes, the conversion price was changed from \$0.0266 to \$0.008, the maturity date was extended for two years and an aggregate of 53,400,000 common shares and five-year warrants to purchase 12,500,000 common shares at \$0.008 per share were issued, having an aggregate fair value of \$491,607; and [2] for \$80,000 of the convertible notes, the interest rate was changed from 0% to 12% and the maturity date was extended for one year. As a result of the changes in the conversion price and the interest rate, the addendums resulted in an extinguishment of \$294,000 of the old debt in exchange for new debt with the same face value, having aggregate debt discount of \$44,113, and different terms. Accordingly, a loss on debt extinguishment of \$447,494 was recognized in the accompanying statements of operations. On March 11, 2022, one of the holders converted a convertible note with a face value of \$25,000, dated February 26, 2021 (as amended on February 26, 2022), into 3,125,000 shares of the Company's common stock. As the conversion was at a fixed conversion price, no gain or loss was recognized on conversion. During the three and nine months ended September 30, 2022, \$0 and \$10,000, respectively, and for the three and nine months ended September 30, 2021, \$0 of convertible notes were repaid. As of September 30, 2022, \$115,000 of convertible notes payable were in default. For the three and nine months ended September 30, 2022, the Company amortized \$31,771 and \$44,113, respectively, and for the three and nine months ended September 30, 2021, \$28,689 and \$52,230, respectively, of debt discount to interest expense. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the notes was \$355,117 and 419,000, net of debt discount of \$28,883 and \$0 respectively.

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On October 29, 2021, the Company issued an unsecured convertible promissory note in the principal amount of \$17,000 that matures 12 months after the issuance date. The note is non-interest bearing and the investor has the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price of \$0.008. Upon the occurrence of an event of default, the remaining principal and accrued interest become immediately due and payable. As a result of the beneficial conversion feature of the note, \$7,438 of debt discount was recognized with a corresponding increase in additional paid-in capital. The debt discount was being amortized to interest expense using the effective interest method. For the three and nine months ended September 30, 2021, the Company amortized \$0 of debt discount to interest expense. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$17,000.

On February 26, 2022, the Company issued an unsecured convertible promissory note in the principal amount of \$27,000 that matures 24 months after the issuance date and 6,750,000 shares of common stock in exchange for proceeds of \$27,000. The note is non-interest bearing and the investor has the right to convert the outstanding balance of the note at any time into shares of common stock of the Company at a conversion price of \$0.008. The value ascribed to the common shares was \$18,563, which was recognized as debt discount with a corresponding increase in additional paid-in capital. The debt discount is being amortized to interest expense using the effective interest method. For the three and nine months ended September 30, 2022, the Company amortized \$1,623 and \$3,466, respectively, of debt discount to interest expense. As of September 30, 2022, the remaining carrying value of the note was \$11,904, net of debt discount of \$15,096.

NOTE 9 — RELATED PARTY TRANSACTIONS

Advances – Related Parties

As of September 30, 2022 and December 31, 2021, the Company’s officers and directors have provided advances that are unsecured, non-interest bearing and due on demand. During the nine months ended September 30, 2022 and 2021, the Company received aggregate proceeds from advances \$166,670 and \$90,000, respectively. As of September 30, 2022 and December 31, 2021, the Company owed \$1,118,102 and \$951,432, respectively, for related party advances.

Notes Payable – Related Parties

Northstar Biotechnology Group, LLC

On February 29, 2012, a promissory note issued to BlueCrest Master Fund Limited (“BlueCrest”) was assigned to Northstar Biotechnology Group, LLC (“Northstar”), owned partly by certain directors and existing shareholders of the Company at the time, including Dr. William P. Murphy Jr., Dr. Samuel Ahn and Charles Hart. At the date of the assignment, the principal amount of the BlueCrest note was \$544,267 (the “Note”).

On March 30, 2012, the Company and Northstar agreed to extend until May 1, 2012 the initial payment date for any and all required monthly under the Note, such that the first of the four monthly payments required under the Note will be due and payable on May 1, 2012 and all subsequent payments will be due on a monthly basis thereafter commencing on June 1, 2012, and to waive any and all defaults and/or events of default under the Note with respect to such payments. The Company did not make the required payment, and as a result, was in default of the revised agreement. The Company renegotiated the terms of the Note and Northstar agreed to suspend the requirement of principal payments by the Company and allow payment of interest-only in common stock.

On September 21, 2012, the Company issued 5,000 common stock purchase warrants to Northstar that was treated as additional interest expense upon issuance.

On October 1, 2012, the Company and Northstar entered into a limited waiver and forbearance agreement providing a recapitalized new note balance comprised of all sums due Northstar with a maturity date extended perpetually. The Company agreed to issue 5,000,000 shares of Series A Convertible Preferred Stock and 10,000 shares of common stock in exchange for \$210,000 as payment towards outstanding debt, default interest, penalties, professional fees outstanding and due Northstar. In addition, the Company executed a security agreement granting Northstar a lien on all patents, patent applications, trademarks, service marks, copyrights and intellectual property rights of any nature, as well as the results of all clinical trials, know-how for preparing Myoblasts, old and new clinical data, existing approved trials, all right and title to Myoblasts, clinical trial protocols and other property rights.

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In addition, the Company granted Northstar a perpetual license on products as described for resale, relicensing, and commercialization outside the United States. In connection with the granted license, Northstar shall pay the Company a royalty of up to 8% on revenues generated.

Effective October 1, 2012, the interest rate was 12.85% per annum. The parties agreed, as of February 28, 2013, to reduce the interest rate to 7% per annum.

In connection with the consideration paid, Northstar waived, from the effective date through the earlier of termination or expiration of the agreement, satisfaction of the obligations as described in the forbearance agreement.

In 2012, 5,000,000 shares of Series A Convertible Preferred Stock were approved to be issued, which was subsequently increased to 20,000,000 shares of preferred stock as Series A Convertible Preferred Stock. In addition, the Company was obligated to issue additional preferred stock equal in lieu of payment of cash of accrued and unpaid interest on each six-month anniversary of the effective date (October 1, 2012). In lieu of the initial two payments in preferred stock, the parties agreed to modify the voting rights of the subsequently cancelled Series A Convertible Preferred Stock from 20 votes per share on matters to be voted on by the common stockholders to 25 votes per share on matters to be voted on by the common stockholders and all prior and subsequent payments of interest will be in common stock. The Company is required to issue additional shares of its common stock (as amended), in lieu of cash, each six-month anniversary of the effective date for any accrued and unpaid interest.

On September 30, 2013, the Company issued 8,772 shares of its common stock as payment of \$100,000 towards principal.

On December 24, 2013, the Company issued 3,916 shares of its common stock as payment of accrued interest through June 30, 2013 of \$85,447.

On April 2, 2014, the Company issued 275 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$12,635 due April 1, 2014 per the forbearance agreement.

On September 17, 2014, the limited waiver and forbearance agreement entered into on October 1, 2012 to provide that the perpetual license on products as described for resale, relicensing and commercialization outside the United States was amended as such on the condition that Northstar provide certain financing, which financing the Company, in its sole discretion, could decline and retain the license.

On October 3, 2014, the Company issued 515 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$12,705 due October 1, 2014 per the forbearance agreement.

On April 3, 2015, the Company issued 1,363 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$12,635 due April 1, 2015 per the forbearance agreement.

On October 2, 2015, the Company issued 4,156 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$12,705 due October 1, 2015 per the forbearance agreement.

On October 7, 2015, the Company issued 34,522 shares of its common stock in settlement of \$100,000 principal payment towards the outstanding debt.

On April 7, 2016, the Company issued 57,778 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$12,705 due April 1, 2016 per the forbearance agreement.

On October 6, 2016, the Company issued 848,490 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$12,705 due October 1, 2016 per the forbearance agreement.

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On March 1, 2017, Northstar and the Company entered into a settlement agreement (“Settlement Agreement”) related to then pending litigation. Pursuant to the terms and conditions of the Settlement Agreement, Northstar converted its outstanding Series A Convertible preferred stock, into twenty million (20,000,000) shares of common stock according to the original conversion terms. In addition, and separate and apart from the conversion, Northstar received eleven million (11,000,000) shares of the Company’s common stock. Northstar will receive ten percent (10%) of all Company international sales (based on a gross sales basis). There was no effect of the 10% obligation as there were no international sales in 2017 or through 2019. Furthermore, a Northstar designee, Greg Knutson, was appointed as a member of the Board of Directors of the Company and two Company directors, Michael Tomas and Kristin Comella, each exercised their prior Northstar options to each receive a five percent (5%) member interest in Northstar. The parties agreed to a mutual release and Northstar agreed to terminate any UCC lien on the Company assets previously filed for the benefit of Northstar. On March 9, 2017 and April 1, 2017, the Company issued 30,000,000 and 1,000,000 shares of its common stock, respectively, as described above. In connection with the settlement, the Company recorded a loss on litigation settlement of \$316,800.

On April 1, 2017, the Company issued 286,315 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$12,703.

On October 2, 2017, the Company issued 559,187 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$12,705.

On October 19, 2018, the Company issued 164,523 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$9,195.

On April 19, 2019, the Company issued 379,141 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$9,145.

On October 1, 2019, the Company issued 1,692,353 shares of its common stock in lieu of payment in cash of accrued and unpaid interest of \$9,195.

On April 1, 2020, the Company issued 1,445,647 shares of its common stock, having a fair value of \$11,565, in lieu of payment in cash of accrued and unpaid interest of \$9,145, resulting in a loss on settlement of \$2,420.

On October 1, 2020, the Company issued 2,035,820 shares of its common stock, having a fair value of \$10,179, in lieu of payment in cash of accrued and unpaid interest of \$9,195, resulting in a loss on settlement of \$984.

On April 1, 2021, the Company issued 187,575 shares of its common stock, having a fair value of \$10,879, in lieu of payment in cash of accrued and unpaid interest of \$9,145, resulting in a loss on settlement of \$1,734.

On October 1, 2021, the Company issued 743,341 shares of its common stock, having a fair value of \$8,921, in lieu of payment in cash of accrued and unpaid interest of \$9,195, resulting in a gain on settlement of \$274.

On April 5, 2022, the Company issued 1,121,154 shares of its common stock, having a fair value of \$9,866, in lieu of payment in cash of accrued and unpaid interest of \$9,144, resulting in a loss on settlement of \$722.

As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$262,000. At September 30, 2022 and December 31, 2021, accrued interest on the note was \$13,323 and \$8,751, respectively, and is included in accrued expenses on the accompanying balance sheet.

Notes Payable - Mr. Tomas, President and Chief Executive Officer

On August 7, 2017, the Company issued a \$500,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due one year from date of issuance. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$161,786.

On May 7, 2018, the Company issued a \$500,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due six months from date of issuance. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$500,000.

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On July 1, 2019, the Company issued a \$500,000 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due November 7, 2019. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$500,000.

On December 31, 2019, the Company issued a \$178,077 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$178,077.

On March 31, 2020, the Company issued a \$187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$187,500.

On June 30, 2020, the Company issued a \$187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$187,500.

On July 1, 2020, the Company issued a \$500,000 promissory note as payment of an annual bonus awarded. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$500,000.

On September 30, 2020, the Company issued a \$100,962 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$100,962.

On December 31, 2020, the Company issued a \$143,654 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$143,654.

On March 31, 2021, the Company issued a \$90,990 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$90,991.

On June 30, 2021, the Company issued a \$43,269 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$43,269.

On September 30, 2021, the Company issued a \$187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$187,500.

On December 31, 2021, the Company issued a \$100,962 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$100,962.

On March 31, 2022, the Company issued a \$187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022, the remaining carrying value of the note was \$187,500.

On June 30, 2022, the Company issued a \$187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022, the remaining carrying value of the note was \$187,500.

On September 30, 2022, the Company issued a \$187,500 promissory note in exchange for compensation earned. The promissory note bears interest of 5% per annum and is due on demand. As of September 30, 2022, the remaining carrying value of the note was \$187,500.

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At September 30, 2022 and December 31, 2021, accrued interest on the notes was \$727,173 and \$612,323, respectively, and is included in accrued expenses on the accompanying balance sheet.

	September 30, 2022	December 31, 2021
Northstar	\$ 262,000	\$ 262,000
Note payable, Mr. Tomas	161,786	161,786
Note payable, Mr. Tomas	500,000	500,000
Note payable, Mr. Tomas	500,000	500,000
Note payable, Mr. Tomas	178,077	178,077
Note payable, Mr. Tomas	187,500	187,500
Note payable, Mr. Tomas	187,500	187,500
Note payable, Mr. Tomas	500,000	500,000
Note payable, Mr. Tomas	100,962	100,962
Note payable, Mr. Tomas	143,654	143,654
Note payable, Mr. Tomas	90,991	90,991
Note payable, Mr. Tomas	43,269	43,269
Note payable, Mr. Tomas	187,500	187,500
Note payable, Mr. Tomas	100,962	100,962
Note payable, Mr. Tomas	187,500	-
Note payable, Mr. Tomas	187,500	-
Note payable, Mr. Tomas	187,500	-
Total notes payable - related parties	<u>\$ 3,706,700</u>	<u>\$ 3,144,200</u>

NOTE 10 — FAIR VALUE MEASUREMENT

The Company adopted the provisions of ASC 825-10. ASC 825-10 defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of non-performance. ASC 825-10 establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 825-10 establishes three levels of inputs that may be used to measure fair value:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs to the valuation methodology that are significant to the measurement of fair value of assets or liabilities.

All items required to be recorded or measured on a recurring basis are based upon Level 3 inputs.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is disclosed and is determined based on the lowest level input that is significant to the fair value measurement.

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As of September 30, 2022 and December 31, 2021, the Company did not have any items that would be classified as level 1, 2 or 3 disclosures.

As of September 30, 2022 and December 31, 2021, the Company did not have any derivative instruments that were designated as hedges.

NOTE 11 — COMMITMENTS AND CONTINGENCIES

Leases

In October 2019, the Company relocated to a new location within the same city and entered into a month-to-month lease. During the three and nine months ended September 30, 2022 and 2021, lease expense was comprised of the following:

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Operating lease expense	\$ 1,703	\$ 1,322	\$ 4,839	\$ 3,755
Total lease expense	<u>\$ 1,703</u>	<u>\$ 1,322</u>	<u>\$ 4,839</u>	<u>\$ 3,755</u>

Royalty Agreement / Middle East

On November 9, 2016, the Company entered into an Intellectual Property License Agreement whereby the Company granted High Rise Group Company the exclusive right to the Company's intellectual property (as defined) for the licensed use and development in Kuwait and other GCC/Middle East countries for 25 years in exchange for a payment of \$75,000 and a 5% royalty generated under the agreement. The licensing agreement is recorded as contract liabilities and amortized over the term of the agreement. The carrying balance as of September 30, 2022 and December 31, 2021 was \$57,250 and \$59,500, respectively.

The intent is for U.S. Stem Cell Middle East to offer regenerative treatment options to patients, based on U.S. Stem Cell, Inc. products and technologies like MyoCell™. To date, the first clinic in Kuwait City has been completed but has not begun operations as High Rising Group has not yet been able to secure regulatory approvals to operate.

Litigation

On September 17, 2015, a product liability lawsuit was filed in Broward County, specifically Patsy Bade v. Bioheart, Inc. US Stem Cell Clinics LLC, Alejandro Perez, ARNP, and Shareen Greenbaum, M.D., and on November 30, 2015, a product liability lawsuit was filed in Broward County, specifically Elizabeth Noble v. Bioheart, Inc. US Stem Cell Clinics LLC, Alejandro Perez, ARNP, and Shareen Greenbaum, M.D. During the year ended December 31, 2016, both matters settled by the Company's insurance policy with no additional cost to the Company, except for the obligation to pay the insurance company deductible of \$100,000, of which \$11,000 was paid in fiscal 2017. The remaining amount due under this settlement is \$25,810 and \$26,600 as of September 30, 2022 and December 31, 2021, respectively, and is included in accounts payable.

On July 27, 2020, Brenda Leonhardt filed a lawsuit against U.S. Stem Cell, Inc., Mike Tomas, Dr. William P. Murphy, Jr., Richard T. Spencer, III, Mark Borman, Dr. Samuel S. Ahn, Charles Hart, Sheldon T. Anderson, Greg Knutson, and Kristin Comella in Broward County Court, Case No. CACE-10-012095. The lawsuit alleges breach of a settlement agreement, breach of contract with respect to failure to make a balloon payment under a promissory note, and several tort theories such as misrepresentation and fraudulent transfer. The Company denies most of the allegations in the lawsuit and moved to dismiss almost all of the claims. The motions to dismiss was denied. U.S. Stem Cell, Inc. does note that it provided a promissory note to Ms. Leonhardt, which has not been fully satisfied. The stated due date of the promissory note was June 1, 2020 in the amount of \$1,397,762.

The Company, as one of the parties entered into a Settlement Agreement and General Release (the "Agreement") dated June 3, 2019 related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year 5.25% unsecured promissory note, dated June 15, 2019, in the principal amount of \$500,000, payable in monthly increments of \$5,000 per month, with a final balloon payment due on June 15, 2024. Accordingly, the Company recognized Pre-litigation expense of \$500,000. As of September 30, 2022 and December 31, 2021, the remaining carrying value of the note was \$403,621 and \$413,239, respectively. As of September 30, 2022, the Company is delinquent seven payments and, if not cured, would be considered in default of the promissory note underlying the Agreement.

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On February 10, 2021, as part of a settlement agreement, the Company transferred its entire member interest in U.S. Stem Cell Clinic, LLC to Dr. Kristin Comella as settlement for \$100,000 of accrued interest owed to Dr. Comella (See Note 4, 5 and 6).

The Company is subject at times to other legal proceedings and claims, which arise in the ordinary course of its business. Although occasional adverse decisions or settlements may occur, the Company believes that the final disposition of such matters should not have a material adverse effect on its financial position, results of operations or liquidity. There was no outstanding litigation as of September 30, 2022 other than that described above.

Government Claim

On May 9, 2018, the U.S. Department of Justice filed an injunctive action, specifically United States of America v. U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., Kristin C. Comella, and Theodore Gradel. The Complaint alleges, among other matters that the defendants manufacture “stromal vascular fraction” (SVF) products from patient adipose (fat) tissue, which the companies then market as stem cell-based treatments, and which U.S. Stem Cell Clinic, LLC administers to patients, without first obtaining what the government alleges are necessary FDA approvals. Although Theodore Gradel was initially listed as a defendant, he subsequently entered into a consent agreement and is no longer party to this case.

The U.S. and the defendants filed cross motions for summary judgment, each asking for a ruling in its favor. On June 3, 2019, the Court entered an order granting Summary Judgment for the government and denying the defendants’ motion for summary judgment. The order focused on the defendants’ actions in providing and marketing SVF therapy. In an order dated June 4, 2019, the Court granted the defendants’ request to allow it the opportunity to work out the language of the form of injunction with the government, and if unsuccessful, to provide a status report to the Court by June 14, 2019, outlining areas of disagreement. The Court further ordered that the defendants (U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., and Kristin C. Comella) ‘not sell, provide or otherwise engage in any SVF therapy or any other activities to be regulated by the FDA as explained in the Court’s Order on the Parties’ Motions for Summary Judgment.’ On June 25, 2019, the Court entered an Order of Permanent Injunction, generally enjoining the defendants with respect to the SVF Product and requiring other actions. The Company filed an appeal on August 23, 2019 and attended oral argument on January 13, 2021. On June 2, 2021, the Eleventh Circuit Court ruled to affirm the lower court’s judgement. The Company is not able to predict the duration, scope, results, or consequences of the U.S. Department of Justice actions and final rulings and management is assessing its options on a going forward basis. The Company, in having divested certain equipment and other assets and assigning its lease, has and will continue to experience a decrease in revenues as the Company both maintains the remainder of the business and transitions into similar or unrelated business opportunities as determined by management. However, management is not able to predict the duration, scope, results, or consequences of the summary judgment and any transition of the business plan.

After the Court’s issuance of the Order of Permanent Injunction, the Company has received demand letters for compensation from persons who store their SVF Product and/or other tissue product with the tissue bank (several of the persons have requested refunds of the monies paid to the tissue bank and one person has requested a full refund of monies paid to an altogether separate company due to her not receiving the full amount of treatments she requested; such requests for compensation, to date, have not been material) and requests that the Company preserve cells in the Company’s possession. The Company sought guidance from the Court, which entered an order generally staying the requirement to destroy any SVF Product, pending a decision on the Company’s appeal. However, that appeal has now been concluded and the stay order is no longer in place. In the meanwhile, the Company entered into a transaction to generally divest itself from the tissue bank business. The Company no longer stores any SVF product.

NOTE 12 — STOCKHOLDERS’ DEFICIT

Adjustment to Opening Balances Upon Adoption of ASU 2020-06

Upon adoption of ASU 2020-06 during the first quarter of 2022, the Company adjusted its beginning balance sheet with a decrease in additional paid-in capital of \$384,174, offset by a decrease in debt discount on convertible debt of \$241,589 and an increase in accumulated deficit of \$142,585.

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Common Stock

During the nine months ended September 30, 2022, the Company issued an aggregate of 5,395,942 shares of its common stock, having a fair value of \$43,571, in settlement of outstanding accounts payable of \$45,000. In connection with the issuances, the Company incurred a \$1,429 net gain on settlement.

During the nine months ended September 30, 2022, the Company issued an aggregate of 1,121,154 shares of its common stock, having a fair value of \$9,866, in lieu of accrued interest of \$9,144. In connection with the issuances, the Company incurred a \$722 net loss on settlement.

During the nine months ended September 30, 2022, the Company issued an aggregate of 45,000,000 shares of its common stock to consultants, having a fair value of \$297,000, for services to be rendered, which are being amortized to expense over the term of the respective agreements, all of which is 180 days.

During the three months ended March 31, 2022, the Company entered into addendums with certain holders owning an aggregate of \$214,000 of the convertible notes whereby the conversion price was changed from \$0.0266 to \$0.008, the maturity date was extended for two years and an aggregate of 53,400,000 common shares and five-year warrants to purchase 12,500,000 common shares at \$0.008 per share were issued, having an aggregate fair value of \$491,607. As a result of the changes in the conversion price and the interest rate, the addendums resulted in an extinguishment of \$294,000 of the old debt in exchange for new debt with the same face value, having aggregate debt discount of \$44,113, and different terms. Accordingly, a loss on debt extinguishment of \$447,494 was recognized in the accompanying statements of operations.

On February 26, 2022, the Company issued an unsecured convertible promissory note in the principal amount of \$27,000 that matures 24 months after the issuance date and 6,750,000 shares of common stock in exchange for proceeds of \$27,000. The value ascribed to the common shares was \$18,563, which was recognized as debt discount with a corresponding increase in additional paid-in capital. The debt discount of \$18,563 is being amortized to interest expense using the effective interest method.

On March 23, 2022, a convertible note with a face value of \$25,000, having a net book value of \$25,000 at the date of conversion, was converted into 3,125,000 shares of the Company's common stock. As the conversion was at a fixed conversion price, no gain or loss was recognized on conversion (See Note 8).

On September 10, 2021, the Company filing of an Offering Circular on Form 1-A, pursuant to Regulation A (File Number: 024-11617) was qualified by the Securities and Exchange Commission. The Company registered 250,000,000 shares of common stock for maximum proceeds of \$2,500,000 (before deducting the maximum broker discount and costs of the offering). During the nine months ended September 30, 2022, the Company issued an aggregate of 13,958,334 shares of common stock to investors for cash proceeds of \$85,000, net of fees and commission, pursuant to the Offering Circular.

Stock Options

On April 1, 2013, the Board of Directors approved, subject to subsequently received stockholder approval, the establishment of the Bioheart 2013 Omnibus Equity Compensation Plan, or the "2013 Omnibus Plan" (replacing the 1999 Officers and Employees Stock Option Plan, or the Employee Plan, and the 1999 Directors and Consultants Stock Option Plan). The 2013 Omnibus Plan initially reserved up to fifty thousand (50,000) shares of common stock for issuance. On August 4, 2014, the Board of Directors approved to set the reserve to one hundred thousand (100,000) shares of common stock for issuance and to close the 1999 Officers and Employees Stock Option Plan. On February 2, 2015, at the annual meeting of stockholders, the 2013 Omnibus Equity Compensation Plan was approved.

On November 2, 2015, the Company increased the shares reserved under the 2013 Omnibus Plan to five hundred million (500,000,000) shares of common stock for issuance. Effective September 16, 2016, the Company approved an additional twenty five million (25,000,000) shares of common stock to the reserve; effective April 21, 2017, the Company approved an additional twenty five million (25,000,000) shares of common stock to the reserve; effective August 7, 2017, the Company approved an additional thirty million (30,000,000) shares of common stock to the reserve; and effective May 7, 2018, the Company approved an additional one hundred million (100,000,000) shares of common stock to reserve.

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A summary of the stock option activity for the nine months ended September 30, 2022 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, December 31, 2021	110,643,884	\$ 0.0247	6.3	\$ 36,686
Granted	-			
Exercised	-			
Forfeited/Expired	(2,500)	\$ 0.1540		
Outstanding, September 30, 2022	<u>110,641,384</u>	<u>\$ 0.0247</u>	<u>5.5</u>	<u>\$ 40,866</u>
Exercisable, September 30, 2022	<u>104,816,384</u>	<u>\$ 0.0258</u>	<u>5.4</u>	<u>\$ 37,762</u>

Exercise Price	Options Outstanding			Options Exercisable	
	Outstanding Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Exercisable Number of Options	Weighted Average Exercise Price
\$0.004 to \$0.010	41,800,000	\$ 0.0051	6.3	35,975,000	\$ 0.0051
\$0.011 to \$0.020	16,250,000	\$ 0.0196	4.0	16,250,000	\$ 0.0196
\$0.021 to \$0.030	9,510,000	\$ 0.0252	6.1	9,510,000	\$ 0.0252
\$0.0363	22,635,000	\$ 0.0363	4.9	22,635,000	\$ 0.0363
\$0.0536	20,000,000	\$ 0.0536	5.6	20,000,000	\$ 0.0536
\$0.1540	446,384	\$ 0.1540	3.0	446,384	\$ 0.1540
	<u>110,641,384</u>	<u>\$ 0.0247</u>	<u>5.5</u>	<u>104,816,384</u>	<u>\$ 0.0258</u>

The aggregate intrinsic value of outstanding stock options was \$40,866, based on options with an exercise price less than the Company's stock price of \$0.0061 as of September 30, 2022, which would have been received by the option holders had those option holders exercised their options as of that date.

The fair value of all options that vested during the nine months ended September 30, 2022 and 2021 was \$126,526 and \$437,414, respectively. As of September 30, 2022, the Company had \$30,763 of total unrecognized compensation cost related to non-vested awards granted under the 2013 Omnibus Plan, which the Company expects to recognize over a weighted average period of 0.59 years.

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Warrants

A summary of the warrant activity for the nine months ended September 30, 2022 is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, December 31, 2021	1,103,127	\$ 12.41	6.2	\$ -
Granted	12,500,000	0.008		
Exercised	-			
Expired	(20,000)	15.50		
Outstanding, September 30, 2022	<u>13,583,127</u>	<u>\$ 0.99</u>	<u>4.6</u>	<u>\$ -</u>
Exercisable, September 30, 2022	<u>13,581,582</u>	<u>\$ 0.12</u>	<u>4.6</u>	<u>\$ -</u>

Warrants Outstanding				Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Exercisable Number of Warrants	Weighted Average Exercise Price
\$0.008 to \$0.03	13,500,000	\$ 0.01	4.6	13,500,000	\$ 0.01
\$10.00 to \$20.00	61,036	\$ 15.22	1.0	61,036	\$ 15.22
\$20.01 to \$30.00	19,543	\$ 25.06	1.4	19,543	\$ 25.06
\$49.86	1,003	\$ 49.86	1.5	1,003	\$ 49.86
\$7,690.00	1,545	\$ 7,690.00	4.3	-	\$ 7,690.00
	<u>13,583,127</u>	<u>\$ 0.99</u>	<u>4.6</u>	<u>13,581,582</u>	<u>\$ 0.12</u>

The aggregate intrinsic value of the issued and exercisable warrants of \$0 represents the total pretax intrinsic value, based on warrants with an exercise price less than the Company's stock price of \$0.0061 as of September 30, 2022, which would have been received by the warrant holders had those warrants holders exercised their warrants as of that date.

NOTE 13 — CONCENTRATIONS

Concentrations of Credit Risk

The Company's financial instruments that are exposed to a concentration of credit risk are cash and accounts receivable. Generally, the Company's cash and cash equivalents in interest-bearing accounts does not exceed FDIC insurance limits. The financial stability of these institutions is periodically reviewed by senior management.

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Concentrations of Revenues

For the three and nine months ended September 30, 2022 and 2021, the following customers accounted for more than 10% of the Company's net revenues:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Customer 1	26%	-	12%	-
Customer 2	16%	-	11%	-
Customer 3	16%	-	13%	-
Customer 4	12%	-	14%	-
Customer 5	-	59%	-	19%
Customer 6	-	-	11%	-
Customer 7	-	-	-	23%
Totals	<u>70%</u>	<u>59%</u>	<u>61%</u>	<u>42%</u>

Concentrations of Accounts Receivable

As of September 30, 2022 and December 31, 2021, the following customers represented more than 10% of the Company's accounts receivable:

	September 30, 2022	December 31, 2021
Customer 1	96%	98%
Totals	<u>96%</u>	<u>98%</u>

NOTE 14 — SUBSEQUENT EVENTS

On October 1, 2022, the Company issued an aggregate of 1,377,891 shares of common stock for interest.

On October 1, 2022, the Company issued 749,251 common shares in exchange for services rendered.

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

Unless otherwise indicated, references in this Quarterly Report on Form 10-Q to “we,” “us,” and “our” are to the Company, unless the context requires otherwise. The following discussion and analysis by our management of our financial condition and results of operations should be read in conjunction with our unaudited condensed interim financial statements and the accompanying related notes included in this quarterly report and our audited financial statements and related notes and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission.

Cautionary Statement Regarding Forward-Looking Statements

This report may contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act, and we intend that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Any such forward-looking statements would be contained principally in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors.” Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities and the effects of regulation. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “hopes,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would” or similar expressions.

This report may contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act, and we intend that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Any such forward-looking statements would be contained principally in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors.” Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities and the effects of regulation. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “hopes,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would” or similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss many of these risks in greater detail in “Risk Factors.” Risk factors include, but are not limited to, the economic effects of the pandemic and the short and long term economic impact of the pending recession on the marketplace. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management’s beliefs and assumptions only as of the date of this report. You should read this report and the documents that we reference in this report and have filed as exhibits to the report completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Additional information concerning these, and other risks and uncertainties is contained in our filings with the Securities and Exchange Commission, including the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020.

Unless otherwise indicated or the context otherwise requires, all references in this Form 10-Q to “we,” “us,” “our,” “our company,” “U. S. Stem Cell, Inc.” or the “Company” refer to U.S. Stem Cell, Inc. and its subsidiaries.

Our Ability to Continue as a Going Concern

Our independent registered public accounting firm has issued its report dated September 30, 2022, in connection with the audit of our annual financial statements as of December 31, 2021, that included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern and Note 2 to the unaudited financial statements for the period ended September 30, 2022 also describes the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

Our Ability to Continue as a Going Concern

Our independent registered public accounting firm has issued its report dated March 31, 2022, in connection with the audit of our annual financial statements as of December 31, 2021, that included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern and Note 2 to the unaudited financial statements for the period ended September 30, 2022 also describes the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

Overview

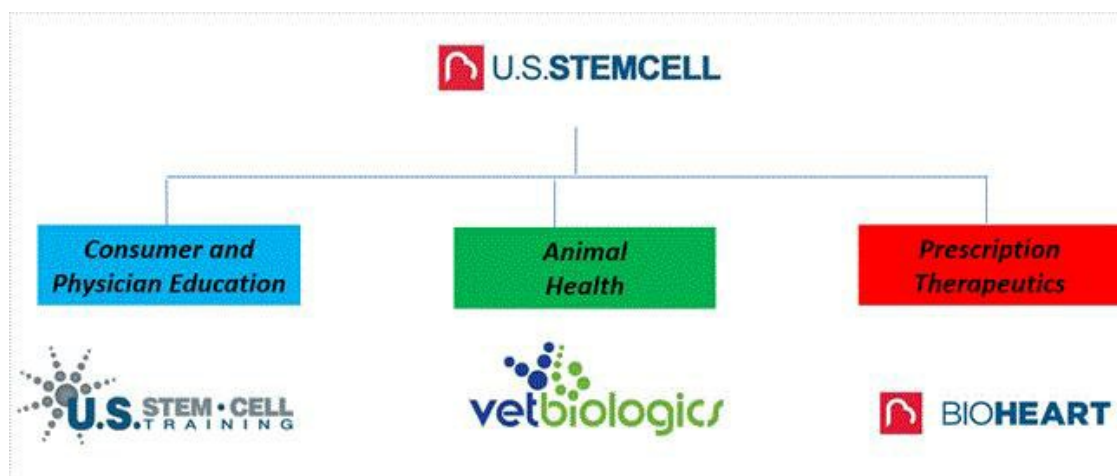
We are an enterprise in the regenerative medicine/cellular therapy industry. Our prior focus was on the discovery, development, and commercialization of cell based therapeutics. Our business included the development of proprietary cell therapy products as well as revenue generating physician and patient based regenerative medicine/cell therapy training services,

US Stem Cell Training, Inc. (“SCT”), an operating division of our company, is a content developer of regenerative medicine/cell therapy informational and training materials for physicians and patients. SCT also provides in-person and online training courses which are delivered through in-person presentations at SCT’s state of the art facilities and globally at university, hospital and physician’s office locations as well as through online webinars. Additionally, SCT provides hands-on clinical application training for physicians and health care professionals interested in providing regenerative medicine / cell therapy procedures.

Vet biologics, (“VBI”), an operating division of our company, is a veterinary regenerative medicine company committed to providing veterinarians with the ability to deliver the highest quality regenerative medicine therapies to dogs, cats and horses. VBI provides veterinarians with extensive regenerative medicine capabilities including the ability to isolate regenerative stem cells from a patient’s own adipose (fat) tissue directly on-site within their own clinic or stall-side.

During fiscal 2019, we had interests in US Stem Cell Clinic, LLC, (“SCC”), Regenerative Wellness Clinic, LLC, and US Stem Cell Clinic of the Villages, LLC as partially owned investments of our company (in which we had a 49.9%, 49.9% and 49% respectively member interests), which were physician run regenerative medicine/cell therapy clinics providing cellular treatments for patients afflicted with neurological, autoimmune, orthopedic and degenerative diseases. During the last quarter of 2019 (and in early 2021 in the case of SCC), we divested ourselves of our Member Interests in SCC and Regenerative Wellness Clinic, LLC, and US Stem Cell Clinic of the Villages, LLC is currently dormant.

Our comprehensive map of products and services:



Our mission is to advance to market novel regenerative medicine and cellular therapy products that substantially benefit humankind. Our business strategy is, to the extent possible, finance our clinical development pipeline through revenue (cash in-flows) generated through the marketing and sales of unique educational and training services, animal health products and personalized cellular therapeutic treatments. Accordingly, we have developed a multifaceted portfolio of revenue generating products and services in our US Stem Cell Training, Vetbiologics, operating divisions that will, if successful, financially support its clinical development programs. Our goal is to maximize shareholder value through the generation of short-term profits that increase cash in-flows and decrease the need for venture financings – a modern biotechnology company development strategy.

Today, our company is a combination of opportunistic business enterprises. What we are establishing is a foundation of value in the products and services we are and plan to sell from US Stem Cell Training and Vetbiologics. Our strategy is to expand the revenues generated from each of these operating divisions and to reinvest the profits we generate into our clinical development pipeline.

On November 9, 2016, we executed a Commercial Agency Agreement with High Rising Group Company (General Trading and Construction) and subsequently, on February 10, 2017, we authorized High Rising Group Company as an independent contractor and Licensee for our company for the territories of Kuwait and the Middle East (expressly excluding prohibited countries pursuant to the Patriot Act and The Iran Threat Reduction and Syria Human Rights Act of 2012). The intent of the agreement is for High Rising Group Company to establish clinics specializing in regenerative medicine, stem cell treatment and therapy, including stem cell bank, training, and all related stem cell machines and equipment. To date, the first clinic in Kuwait City has been completed but has not begun operations as High Rising Group has not yet been able to secure regulatory approvals to operate. With the ongoing construction of the The Sheikha Salwa Sabah Al-Ahmad Center for Stem Cell and Umbilical Cord, a public/private partnership with the government of Kuwait, (see <http://news.kuwaittimes.net/website/stem-cell-center-epitomizes-ppp> which is expressly not incorporated by reference to this filing), management hopes (but cannot guarantee) that private sector stem cell centers, as described above, will get regulatory approval.

We will continue to evaluate and act upon opportunities to increase our top line revenue position and that correspondingly increase cash in-flows. These opportunities include but are not limited to the development and marketing of new products and services, mergers and acquisitions, joint ventures, licensing deals and more.

Further, if the opportunity presents itself whereby we can raise additional capital at a reasonable fair market value, our management will do so. Accordingly, we plan to continue in our efforts to restructure, equitize or eliminate legacy balance sheet issues that are obstacles to market capitalization appreciation and capital fund raising.

Results of Operations Overview

We are a research and development company and our product candidates have not received regulatory approval or generated any material revenues and is not expected generate revenues until commercialization, if ever. We have generated substantial net losses and negative cash flow from operations since inception and anticipate incurring significant net losses and negative cash flows from operations for the foreseeable future as we continue clinical trials, undertake new clinical trials, apply for regulatory approvals, make capital expenditures, add information systems and personnel, make payments pursuant to our license agreements upon our achievement of certain milestones, continue development of additional product candidates using our technology, establish sales and marketing capabilities and incur the additional cost of operating as a public company. In addition, and as a result of the Court Order (see Note 11- Government Claim), we resolved to divest our company of certain equipment and other assets which will substantially reduce our ability to generate revenues until such time as alternative revenue producing materialize as well as assign our lease.

Three Months Ended September 30, 2022 as compared to the Three Months Ended September 30, 2021.

Revenues

We recognized revenues of \$10,661 for the three months ended September 30, 2022. These revenues were generated from the sales of laboratory supplies and equipment, and services. We recognized revenues of \$52,578 for the three months ended September 30, 2021 from the sale of MyoCath catheters, physician training, patient studies and veterinary sales. Due to the Injunction, as described in Note 11- Government Claim in our financial statements, our revenue has been impaired.

Cost of Sales

Cost of sales consists of the costs associated with the production of MyoCath, laboratory supplies necessary for laboratory services, physician course materials. Cost of sales were \$5,264 and \$14,200 in in the three-month periods ended September 30 2022 and 2021, respectively. Associated gross margins were \$8,983 (63.05%) and \$43,134(75.2%) for the three months periods ended September 30 2022 and 2021, respectively.

Marketing, General and Administrative

Our marketing, general and administrative costs were \$405,564 for the three-month period ended September 30, 2022 compared to \$547,977 for the three-month period ended September 30, 2021, a decrease of \$142,413. The decrease in cost due to the decrease in activity.

Our marketing, general and administrative expenses primarily consist of the costs associated with our general management and product and service marketing programs, including, but not limited to, salaries and related expenses for executive, administrative and marketing personnel, rent, insurance, legal and accounting fees, consulting fees, travel and entertainment expenses, conference costs and other clinical marketing and trade program expenses.

(Gain) Loss on settlement of debt

During the three months ended September 30, 2022, we incurred a net loss of \$39 primarily related to accounts payable and debt restructured during the current period as compared to a net aggregate loss of \$5,113 for the same period last year.

Income from equity investment

Our investment of a 49.9% (33.3% in 2018) member interest ownership of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic as well as a 49% interest in U.S. Stem Cell Clinic of the Villages LLC are accounted for using the equity method of accounting. As such, we report our pro rata share of its income or loss for the period. For the three months ended September 30, 2021, our pro rata share of its income (loss) was \$0 as we divested the assets in the first quarter of 2021. For the three months ended September 20, 2020 the pro rata share of income (loss) was \$0. During the last quarter of 2019 (and in early 2021 in the case of SCC), we divested ourselves of our Member Interests in U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC , while and US Stem Cell Clinic of the Villages, LLC is currently dormant.

Interest Expense

Interest expenses during the three months ended September 30, 2022 were \$168,785 compared to \$162,485 for the three months ended September 30, 2021. Interest expenses primarily consists of interest incurred on the principal amount of the Northstar loan, our former Bank of America loan, the Seaside National Bank loan, accrued fees and interest payable to the Guarantors, our capital lease and the amortization of debt discounts and non-cash interest incurred relating to our issued convertible notes payable.

Nine Months Ended September 30, 2022 as compared to the Nine Months Ended September 30, 2021.

Revenues

We recognized revenues of \$49,229 for the nine months ended September 30, 2022. These revenues were generated from the sales of laboratory supplies and equipment, and services. We recognized revenues of \$161,308 for the nine months ended September 30, 2021 from the sale of MyoCath catheters, physician training, sale of product and services and veterinary division. Due to the Injunction, as described in Note 11- Government Claim in our financial statements, our revenue has been impaired.

Cost of Sales

Cost of sales consists of the costs associated with the production of MyoCath, laboratory supplies necessary for laboratory services, physician course materials. Cost of sales were \$18,846 and \$43,398 in in the nine-month periods ended September 30, 2022 and 2021, respectively. Associated gross margins were \$43,229 (63.3%) and \$133,758 (75.5%) for the nine months periods ended September 30, 2022 and 2021 respectively.

Marketing, General and Administrative

Our marketing, general and administrative costs were \$1,389,490 for the nine-month period ended September 30, 2022 compared to \$1,906,962 for the nine-month period ended September 30, 2021, a decrease of \$517,472. The decrease in cost due to the decrease in activity.

Our marketing, general and administrative expenses primarily consist of the costs associated with our general management and product and service marketing programs, including, but not limited to, salaries and related expenses for executive, administrative and marketing personnel, rent, insurance, legal and accounting fees, consulting fees, travel and entertainment expenses, conference costs and other clinical marketing and trade program expenses.

(Gain) Loss on settlement of debt

During the nine months ended September 30, 2022, we incurred a net loss of \$(1,773,204) primarily related to accounts payable and debt restructured during the current period as compared to a net loss of \$(1,346,261) for the same period last year.

Income from equity investment

Our investment of a 49.9% (33.3% in 2018) member interest ownership of U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic as well as a 49% interest in U.S. Stem Cell Clinic of the Villages LLC are accounted for using the equity method of accounting. As such, we report our pro rata share of its income or loss for the period. For the nine months ended September 30, 2021, our pro rata share of its income (loss) was \$0 as we divested the assets in the first quarter of 2021. For the nine month ended September 20, 2020 the pro rata share of income (loss) was \$0. During the last quarter of 2019 (and in early 2021 in the case of SCC), we divested ourselves of our Member Interests in U.S. Stem Cell Clinic, LLC and Regenerative Wellness Clinic, LLC, while and US Stem Cell Clinic of the Villages, LLC is currently dormant.

Interest Expense

Interest expenses during the nine months ended September 30, 2022 were \$498,279 compared to \$484,204 for the nine months ended September 30, 2021. Interest expenses primarily consists of interest incurred on the principal amount of the Northstar loan, our former Bank of America loan, the Seaside National Bank loan, accrued fees and interest payable to the Guarantors, our capital lease and the amortization of debt discounts and non-cash interest incurred relating to our issued convertible notes payable.

Stock-Based Compensation

Stock-based compensation reflects our recognition as an expense of the value of stock options and other equity instruments issued to our employees and non-employees over the vesting period of the options and other equity instruments. We have granted to our employee's options to purchase shares of common stock at exercise prices equal to the fair market value of the underlying shares of common stock at the time of each grant, as determined by our Board of Directors, with input from management.

We follow Accounting Standards Codification subtopic 718-10. Compensation ("ASC 718-10") which requires that all share-based payments to both employee and non-employees be recognized in the income statement based on their fair values.

In awarding our common stock, our Board of Directors considered a number of factors, including, but not limited to:

- our financial position and historical financial performance;
- arm's length sales of our common stock;
- the development status of our product candidates;
- the business risks we face;
- vesting restrictions imposed upon the equity awards; and
- an evaluation and benchmark of our competitors; and
- prospects of a liquidity event.

On April 1, 2013, the Board of Directors approved, subject to subsequently received shareholder approval, the establishment of the Bioheart 2013 Omnibus Equity Compensation Plan, or the “2013 Omnibus Plan”. The 2013 Omnibus Plan initially reserved up to fifty thousand (50,000) shares of common stock for issuance. On August 4, 2014, the Board of Directors approved to set the reserve to one hundred thousand (100,000) shares of common stock for issuance and to close the 1999 Officers and Employees Stock Option Plan. On February 2, 2015, at the annual meeting of shareholders, the majority of shareholders approved the 2013 Omnibus Equity Compensation Plan. On November 2, 2015, the Board of Directors approved the increase of the reserve under the 2013 Omnibus Plan to five hundred million (500,000,000) shares of common stock for issuance, effective September 16, 2016, approved an addition of twenty five million (25,000,000) shares of common stock to the reserve, effective April 21, 2017, approved an addition of twenty five million (25,000,000) shares of common stock to the reserve, effective August 7, 2017, approved an addition of thirty million (30,000,000) shares of common stock to the reserve and effective May 7, 2018, approved an addition of one hundred million (100,000,000) shares of common stock to reserve.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions. While our critical accounting policies are described in Note 1 to our financial statements appearing elsewhere in this report, we believe the following policies are important to understanding and evaluating our reported financial results:

Revenue Recognition

Effective January 1, 2018, the Company recognizes revenue in accordance with Accounting Standards Codification 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific revenue recognition guidance throughout the Industry Topics of the Accounting Standards Codification. The updated guidance states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also provides for additional disclosures with respect to revenues and cash flows arising from contracts with customers.

At the time of each transaction, management assesses whether the fee associated with the transaction is fixed or determinable and whether or not collection is reasonably assured. The assessment of whether the fee is fixed or determinable is based upon the payment terms of the transaction. Collectability is assessed based on a number of factors, including past transaction history with the client and the creditworthiness of the client.

The Company’s primary sources of revenue are from the sale of test kits and equipment, training services, patient treatments, laboratory services and cell banking.

Revenues for product and equipment sold are not recorded until product and equipment are received by the customer. Revenues from in-person trainings are recognized when the training occurs and revenues from on demand online trainings are recognized when the customer purchases the rights to the training course. Any cash received as a deposit for trainings are recorded by the Company as a liability.

Patient treatments and laboratory services revenue are recognized when those services have been completed or satisfied.

Research and Development Activities

We account for research and development costs in accordance with Accounting Standards Codification subtopic 730-10, Research and Development (“ASC 730-10”). Under ASC 730-10, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and development costs are expensed when the contracted work has been performed or as milestone results have been achieved as defined under the applicable agreement. Our company-sponsored research and development costs related to both present and future products are expensed in the period incurred.

Inflation

Our opinion is that inflation has not had, and is not expected to have, a material effect on our operations.

Climate Change

Our opinion is that neither climate change, nor governmental regulations related to climate change, have had, or are expected to have, any material effect on our operations.

Concentrations of Credit Risk

As of September 30, 2022, four customers represented 26%, 16%, 16% and 12%, representing an aggregate of 70% of the Company's accounts receivable. As of December 31, 2021, two customers represented 50% and 44% respectively, representing an aggregate of 94% of the Company's accounts receivable.

Recent Accounting Policies

There are various other updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to have a material impact on our financial position, results of operations or cash flows.

Liquidity and Capital Resources

In the nine months ended September 30, 2022, we incurred negative cash flow from operations of \$261,787 and will continue to finance our considerable operational cash needs with cash generated from financing activities and revenues.

Investing Activities

Net cash provided by investing activities was \$0 for the nine-months ended September 30, 2022 represented proceeds from our equity investment as compared to cash provided by investing activities of \$0 from our equity investments for the same period last year.

Financing Activities

Net cash provided in financing activities was an aggregate of \$252,552 in the nine-month period ended September 30, 2022 as compared to cash provided of \$853,005 in the nine-month period ended in September 30, 2021.

Existing Capital Resources and Future Capital Requirements and Plan of Operations

We have generated substantial net losses and negative cash flow from operations since inception and anticipate incurring significant net losses and negative cash flows from operations for the foreseeable future. Historically, we have relied on proceeds from the sale of our common stock and our incurrence of debt to provide the funds necessary to conduct our research and development activities and to meet our other cash needs.

At September 30, 2022, we had cash and cash equivalents totaling \$30,158. However, our working capital deficit as of such date was \$14,374,010.

Along with diversifying the portfolio of products distributed by our company, including equipment and biologics, it is the intention of our Company to both continue to adhere to the Court Order (see Note 11- Government Claim) as well as re-establish its good standing with the Agency (FDA). These points are not mutually exclusive nor negotiable and we believe that there are still business and patient goodness opportunities while still abiding by all legal requirements. As a result, management shall be continuing with the development of US Stem Cell Training, Inc. , an operating division of our company, that is a content developer of regenerative medicine/cell therapy informational and training materials for physicians and patients and complies with both requirements--as well as Vetbiologics, an operating division of our company, that is a veterinary regenerative medicine company committed to providing veterinarians with the ability to deliver the highest quality regenerative medicine therapies to dogs, cats and horses. In addition, our company is transitioning the current clinics to a more diversified regenerative medicine platform, while complying with recent court rulings. While not providing legal advice, our company may also engage in managing third-party clinics to ensure they too abide by recent regulatory requirements

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required under Regulation S-K for “smaller reporting companies.”

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). The term “internal control over financial reporting” is defined as a process designed by, or under the supervision of, the registrant’s principal executive and principal financial officers, or persons performing similar functions, and effected by the registrant’s board of directors, management and other personnel.

Our management, in reviewing our internal controls and procedures, considered the tenants of the Committee of Sponsoring Organizations (establishing the framework for control environment, risk assessment, information and communication, monitoring activities, and existing control activities for internal control and procedures) such as the requirements 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 and includes those policies and procedures that; pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the registrant; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the registrant are being made only in accordance with authorizations of management and directors of the registrant; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the registrant’s assets that could have a material effect on the financial statements.

Our internal control system is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. In addition, because of changes in conditions, the effectiveness of internal control may vary over time.

We carried out an evaluation, with the participation of our management, including our Chief Executive Officer (“CEO”) who also acts as our Chief Financial Officer (CFO) of the effectiveness our disclosure controls and procedures (as defined under Rule 13a-15(e) under the Exchange Act) as of June 30, 2022. Based upon that evaluation, our CEO/ CFO concluded that our internal control over financial reporting are not effective at the reasonable assurance level due to the following material weaknesses:

1. We do not have sufficient segregation of duties within accounting functions, which is a basic internal control.

Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to have segregation of duties on our assessment of our disclosure controls and procedures and has concluded that the control deficiency that resulted represented a material weakness. The Company expects to remedy this weakness upon Company growth through increased personnel numbers.

To address these material weaknesses, management performed additional analyses and other procedures to ensure that the financial statements included herein fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

Remediation of Material Weaknesses

We intend to remediate the material weaknesses in our disclosure controls and procedures identified above by hiring a full-time CFO with SEC reporting experience in the future and expanding accounting staff when working capital permits and by working with our independent registered public accounting firm to refine our internal procedures. We currently address the limitations through a separately-designated standing Audit Committee established in accordance with Section 3(a) (58) (A) of the Exchange Act. The members of our Audit Committee are Mr. Borman, who serves as Chairperson of the Audit Committee, Dr. Murphy, and Mr. Anderson. Our Board of Directors has determined that Mr. Borman qualifies as a “financial expert” as that term is defined in the rules of the SEC implementing requirements of the Sarbanes-Oxley Act of 2002.

Changes in Internal Controls over Financial Reporting

There have been no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) and 15d-(f) of the Exchange Act) that occurred during our last fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

On September 17, 2015, a product liability lawsuit was filed in Broward County, specifically Patsy Bade v. Bioheart, Inc. US Stem Cell Clinics LLC, Alejandro Perez, ARNP, and Shareen Greenbaum, M.D., and on November 30, 2015, a product liability lawsuit was filed in Broward County, specifically Elizabeth Noble v. Bioheart, Inc. US Stem Cell Clinics LLC, Alejandro Perez, ARNP, and Shareen Greenbaum, M.D. During the year ended December 31, 2016, both matters settled by the Company's insurance policy with no additional cost to the Company, excluding the Company payment of the \$100,000 insurance company deductible of which \$11,000 was paid in fiscal 2017. As a result of the final settlement and determination of insurance coverage, the Company recognized \$100,000 of expense due to litigation for the year ended December 31, 2017. The remaining amount due under this settlement was \$27,350 as of September 30, 2021.

On December 12, 2017, a product liability lawsuit was filed in Broward County, specifically Jeannine Mallard v. U.S. Stem Cell, Inc., US Stem Cell Clinics LLC., Regenestem, LLC., Regenestem Network, LLC., and Kristin C. Comella. The Company will continue to defend it vigorously. On December 6, 2019, the Company was one of the parties to a Settlement Agreement and General Release (the "Agreement") related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year non-interest bearing unsecured promissory note, dated December 6, 2019, in the principal amount of \$250,000, payable in monthly increments of \$750 per month, with a final balloon payment of \$205,000 due on January 1, 2025.

On June 3, 2019, the Company was one of the parties to a Settlement Agreement and General Release (the "Agreement") related to certain medical procedures. Without admitting any liability, and as part of that Agreement, the Company agreed to provide a five-year 5.25% Promissory Note, dated June 15, 2019, in the principal amount of Five Hundred Thousand Dollars (\$500,000), payable in monthly increments of Five Thousand (\$5,000) per month. The remaining amount due under this settlement was \$428,281 as of September 30, 2021.

The Company is subject at times to other legal proceedings and claims, which arise in the ordinary course of its business. Although occasional adverse decisions or settlements may occur, the Company believes that the final disposition of such matters should not have a material adverse effect on its financial position, results of operations or liquidity. There was no outstanding litigation as of September 30, 2021 other than that described above.

Government Claim

On May 9, 2018, the U.S. Department of Justice filed an injunctive action, specifically United States of America v. U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., Kristin C. Comella, and Theodore Gradel. The Complaint alleges, among other matters that the defendants manufacture "stromal vascular fraction" (SVF) products from patient adipose (fat) tissue, which the companies then market as stem cell-based treatments, and which U.S. Stem Cell Clinic, LLC administers to patients, without first obtaining what the government alleges are necessary FDA approvals. Although Theodore Gradel was initially listed as a defendant, he subsequently entered into a consent agreement and is no longer party to this case.

The U.S. and the defendants filed cross motions for summary judgment, each asking for a ruling in its favor. On June 3, 2019, the Court entered an order granting Summary Judgment for the government and denying the defendants' motion for summary judgment. The order focused on the defendants' actions in providing and marketing SVF therapy. In an order dated June 4, 2019, the Court granted the defendants' request to allow it the opportunity to work out the language of the form of injunction with the government, and if unsuccessful, to provide a status report to the Court by June 14, 2019, outlining areas of disagreement. The Court further ordered that the defendants (U.S. Stem Clinic, LLC, U.S. Stem Cell, Inc., and Kristin C. Comella) "not sell, provide or otherwise engage in any SVF therapy or any other activities to be regulated by the FDA as explained in the Court's Order on the Parties' Motions for Summary Judgment." On June 25, 2019, the Court entered an Order of Permanent Injunction, generally enjoining the defendants with respect to the SVF Product and requiring other actions. The Company filed an appeal on August 23, 2019 and attended oral argument on January 13, 2021. On June 2, 2021, the Eleventh Circuit Court ruled to affirm the lower court's judgement. The Company did not challenge the district court's judgment upon any other ground. The Company is not able to predict the duration, scope, results, or consequences of the U.S. Department of Justice actions and final rulings and management is assessing its options on a going forward basis.

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The Company, in divesting certain equipment and other assets and assigning its lease, has and will continue to experience a decrease in revenues as the Company both maintains the remainder of the business and transitions into similar or unrelated business opportunities as determined by management. However, management is not able to predict the duration, scope, results, or consequences of the summary judgment and any transition of the business plan.

After the Court's issuance of the Order of Permanent Injunction, the Company received demand letters for compensation from persons who store their SVF Product and/or other tissue product with the tissue bank (several of the persons have requested refunds of the monies paid to the tissue bank and one person has requested a full refund of monies paid to an altogether separate company due to her not receiving the full amount of treatments she requested; such requests for compensation, to date, have not been material) and requests that the Company preserve cells in the Company's possession. The Company sought guidance from the Court, which entered an order generally staying the requirement to destroy any SVF Product, pending a decision on the Company's appeal. Many of the tissue bank depositors attempted to intervene in the FDA action, and filed an appeal when their intervention was denied. Their appeal was dismissed. It is anticipated that these depositors will present their position on tissue/SVF preservation to the trial court now that the appeal has been decided. As disclosed by the Company previously, the Company entered into a transaction in 2019 in which it divested itself of the operation of the tissue bank. In the meanwhile, the Company entered into a transaction to generally divest itself from the tissue bank business. The Company no longer stores any SVF product.

Item 1A. Risk Factors

Not required under Regulation S-K for "smaller reporting companies."

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

None

Item 3. Defaults Upon Senior Securities

There were no defaults upon senior securities during the period ended September 30, 2022,

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None

Item 6. Exhibits

Exhibit No.	Exhibit Description
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2.1(20)	Asset Sale and Lease Agreement between U.S. Stem Cell, Inc. and GACP Stem Cell Bank LLC., dated March 3, 2017.
2.2(20)	Asset Purchase Agreement between U.S. Stem Cell, Inc. and GACP Stem Cell Bank LLC., dated March 3, 2017.
2.3(20)	Customer Purchase Agreement between U.S. Stem Cell, Inc. and GACP Stem Cell Bank LLC., dated March 3, 2017.
3.1 (1)	Articles of Incorporation
3.2(5)	Amended and Restated Articles of Incorporation
3.3(8)	Articles of Amendment to the Articles of Incorporation
3.4(17)	Articles of Amendment to the Articles of Incorporation
3.5 (7)	Amended and Restated Bylaws
3.6(19)	Amendment to Bylaws
4.1(4)	Loan and Security Agreement, dated as of May 31, 2007 by and between BlueCrest Capital Finance, L.P. and the Registrant
4.2(9)	Amendment to Loan and Security Agreement, between the Company and BlueCrest Venture Finance Master Fund Limited, dated as of April 2, 2009
4.3(9)	Grant of Security Interest (Patents), between the Company and BlueCrest Venture Finance Master Fund Limited, dated as of April 2, 2009
4.4(9)	Security Agreement (Intellectual Property), between the Company and BlueCrest Venture Finance Master Fund Limited, dated as of April 2, 2009
4.5(9)	Subordination Agreement, by Hunton & Williams, LLP in favor of BlueCrest Venture Finance Master Fund Limited, entered into and effective April 2, 2009

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- 4.6(9) [Amended and Restated Promissory Note, dated April 2, 2009, by the Company to BlueCrest Venture Finance Master Fund Limited](#)
- 4.7(9) [Warrant to purchase shares of the Registrant's common stock, dated April 2, 2009, issued to BlueCrest Venture Finance Master Fund Limited](#)
- 4.8(10) [Warrant to purchase shares of the Registrant's common stock, dated April 2, 2009, issued to Rogers Telecommunications Limited](#)
- 4.9(10) [Warrant to purchase shares of the Registrant's common stock, dated April 2, 2009, issued to Hunton & Williams, LLP](#)
- 4.10 (15) [Series A Convertible Preferred Stock](#)
- 10.1(1) [Lease Agreement between the Registrant and Sawgrass Business Plaza, LLC, as amended, dated November 14, 2006.](#)
- 10.2(3) [Loan Guarantee, Payment and Security Agreement, dated as of June 1, 2007, by and between the Registrant, Howard J. Leonhardt and Brenda Leonhardt](#)
- 10.3(3) [Loan Guarantee, Payment and Security Agreement, dated as of June 1, 2007, by and between the Registrant and William P. Murphy Jr., M.D.](#)
- 10.4(3) [Loan Agreement, dated as of June 1, 2007, by and between the Registrant and Bank of America, N.A.](#)
- 10.5(5) [Loan Guarantee, Payment and Security Agreement, dated as of September 12, 2007, by and between the Registrant and Samuel S. Ahn, M.D.](#)
- 10.6(5) [Loan Guarantee, Payment and Security Agreement, dated as of September 12, 2007, by and between the Registrant and Dan Marino](#)
- 10.7(5) [Loan Guarantee, Payment and Security Agreement, dated as of September 19, 2007, by and between the Registrant and Jason Taylor](#)
- 10.8(6) [Loan Guarantee, Payment and Security Agreement, dated as of October 10, 2007, by and between the Registrant and Howard and Brenda Leonhardt](#)
- 10.9(6) [Second Amendment to Loan Guarantee, Payment and Security Agreement, dated as of October 10, 2007, by and between the Registrant and Howard and Brenda Leonhardt](#)
- 10.10(6) [Second Amendment to Loan Guarantee, Payment and Security Agreement, dated as of October 10, 2007, by and between the Registrant and William P. Murphy, Jr., M.D.](#)
- 10.11(11) [Loan Agreement with Seaside National Bank and Trust, dated October 25, 2010.](#)
- 10.12(11) [Promissory Note with Seaside National Bank and Trust, dated October 25, 2010.](#)
- 10.13(11) [Amended and Restated Loan and Security Agreement with BlueCrest Venture Finance Master Fund Limited, dated October 25, 2010.](#)
- 10.14(12) [Unsecured Convertible Promissory Note for \\$25,000, with Magna Group, LLC, dated January 3, 2011.](#)
- 10.15(12) [Promissory Note for \\$139,728.82 with Magna Group, LLC, dated January 3, 2011.](#)
- 10.16(13) [Unsecured Convertible Promissory Note for \\$34,750, with Magna Group, LLC, dated May 16, 2011.](#)
- 10.17(13) [Promissory Note for \\$139,728.82 with Magna Group, LLC, dated May 16, 2011.](#)
- 10.18**(14) [2013 U.S. Stem Cell, Inc. Omnibus Equity Compensation Plan](#)
- 10.19(16) [Senior Convertible Note with Magna Equities II, LLC, dated October 1, 2015](#)
- 10.20(16) [Securities Purchase Agreement, dated as of October 1, 2015, by and between Magna Equities II, LLC and U.S. Stem Cell, Inc.](#)
- 10.21(16) [Registration Rights Agreement, dated as of October 1, 2015, by and between Magna Holdings I, LLC and U.S. Stem Cell, Inc.](#)
- 10.22(18) [Senior Convertible Note Magna Equities II, LLC, dated December 3, 2015](#)
- 10.23(18) [Amended and Restated Senior Convertible Note, dated December 3, 2015.](#)
- 10.24(18) [Securities Purchase Agreement, dated as of December 3, 2015, by and between Magna Equities II, LLC and U.S. Stem Cell, Inc.](#)
- 10.25(18) [Registration Rights Agreement, dated as of December 3, 2015, by and between Magna Holdings I, LLC and U.S. Stem Cell, Inc.](#)
- 10.26(20) [Non-Competition and Non-Solicitation Agreement between U.S. Stem Cell, Inc. and GACP Stem Cell Bank LLC., dated March 3, 2017.](#)
- 10.27(21) [First Amendment to Lease Agreement between the Registrant and Sawgrass Business Plaza, LLC, as amended, dated November 17, 2017.](#)
- 10.28(22) [Second Amendment to Lease Agreement between the Registrant and Sawgrass Business Plaza, LLC, as amended, dated November 17, 2017.](#)
- 10.29(23) [Termination and Release Agreement by and between GACP, the Company, and Michael Tomas and Kristin Comella dated September 24, 2019.](#)

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10.30(23)	Letter Agreement on Stem Cell Processing and Storage by and between the Company and American Cell Technology, LLC, dated September 24, 2019
10.31(24)	Assignment and Assumption of Lease by and between the Company, American Cell Technology, LLC, and Sawgrass Business Plaza, LLC, dated October 24, 2019.
14.1(2)	Code of Business Conduct and Ethics
31.01*	Certification of Chief Executive Officer and Chief Financial Officer (Principal Accounting Officer) pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.01*	Certifications of Chief Executive Officer and Chief Financial Officer (Principal Accounting 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 Calculation Linkbase Document
101 DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101 LAB	Inline XBRL Taxonomy Labels Linkbase Document
101 PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
*	Filed herewith
**	Indicates management contract or compensatory plan.
(1)	Incorporated by reference to the Company's Form S-1 filed with the Securities and Exchange Commission (the "SEC") on February 13, 2007.
(2)	Incorporated by reference to Amendment No. 1 to the Company's Form S-1 filed with the SEC on June 5, 2007.
(3)	Incorporated by reference to Amendment No. 3 to the Company's Form S-1 filed with the SEC on August 9, 2007.
(4)	Incorporated by reference to Amendment No. 4 to the Company's Form S-1 filed with the SEC on September 6, 2007.
(5)	Incorporated by reference to Amendment No. 5 to the Company's Form S-1 filed with the SEC on October 1, 2007.
(6)	Incorporated by reference to Post-effective Amendment No. 1 to the Company's Form S-1 filed with the SEC on October 11, 2007.
(7)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on July 3, 2008.
(8)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 8, 2008.
(9)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 8, 2009.
(10)	Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on April 15, 2009.
(11)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on October 29, 2010.
(12)	Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on January 12, 2011.
(13)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on May 25, 2011.
(14)	Incorporated by reference to the Company Quarterly Report on Form 10-Q filed with the SEC on May 9, 2013.
(15)	Incorporated by reference to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on April 28, 2014.
(16)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on October 2, 2015.
(17)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on November 4, 2015.
(18)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on December 4, 2015.
(19)	Incorporated by reference to the text of the Company Current Report on Form 8-K filed with the SEC on August 3, 2016.
(20)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on March 8, 2017.
(21)	Incorporated by reference to the Company Annual Report on Form 10-K filed with the SEC on April 16, 2018.
(22)	Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 7, 2019.
(23)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on September 27, 2019.
(24)	Incorporated by reference to the Company Current Report on Form 8-K filed with the SEC on October 24, 2019.

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.

Date: November 9, 2022

U.S. Stem Cell, Inc.

By: /s/ Mike Tomas
Mike Tomas
Chief Executive Officer &
President and Principal Financial
and Accounting Officer

Exhibit 31.1

Certification of Chief Executive Officer and Principal Accounting Officer

I, Mike Tomas, certify that:

1. I have reviewed this report on Form 10-Q of U.S. Stem Cell, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such 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 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, 2022

Name: /s/ Mike Tomas
Mike Tomas
President and Chief Executive Officer
Chief Financial Officer and Principal
Accounting Officer

Exhibit 32.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mike Tomas, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge, U.S. Stem Cell, Inc.'s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 9, 2022

Name: /s/ Mike Tomas
Mike Tomas
President and Chief Executive Officer, Chief
Financial Officer and Principal Accounting
Officer