

**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: March 31, 2023

Or

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

For the transition period ended:

QSAM Biosciences, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-41337

(Commission
File Number)

20-1602779

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

9442 Capital of Texas Hwy N, Plaza 1, Suite 500

Austin, TX 78759

(Address of Principal Executive Offices)

(512) 343-4558

(Registrant's Telephone Number, including area code)

(Former name or former address, if changed since last report.)

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value \$0.0001

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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.

(1) Yes No ; (2) Yes No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company:

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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date:

As of May 15, 2023, the registrant had 2,940,799 common shares outstanding.

Documents incorporated by reference: None.

QSAM BIOSCIENCES, INC.

FORM 10-Q
TABLE OF CONTENTS

	<u>Page</u>
<u>PART I – FINANCIAL STATEMENTS</u>	4
<u>ITEM 1. FINANCIAL STATEMENTS</u>	4
<u>Consolidated Balance Sheets as of March 31, 2023 (unaudited) and December 31, 2022</u>	4
<u>Consolidated Statements of Operations for the three months ended March 31, 2023 and 2022 (unaudited)</u>	5
<u>Consolidated Statements of Stockholders' Equity (Deficit) for the three months ended March 31, 2023 and 2022 (unaudited)</u>	6
<u>Consolidated Statements of Cash Flows for the three months ended March 31, 2023 and 2022 (unaudited)</u>	7
<u>Notes to Consolidated Financial Statements (unaudited)</u>	8
<u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF OPERATIONS</u>	19
<u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	25
<u>ITEM 4. CONTROLS AND PROCEDURES</u>	25
<u>PART II – OTHER INFORMATION</u>	26
<u>ITEM 1. LEGAL PROCEEDINGS</u>	26
<u>ITEM 1A. RISK FACTORS</u>	26
<u>ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	28
<u>ITEM 3. DEFAULTS UPON SENIOR SECURITIES</u>	28
<u>ITEM 4. MINE SAFETY DISCLOSURES</u>	28
<u>ITEM 5. OTHER INFORMATION</u>	28
<u>ITEM 6. EXHIBITS</u>	28
<u>SIGNATURES</u>	29

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (“Report”), including this “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, regarding future events and the future results of the Company that are based on current expectations, estimates, forecasts, and projections about the industry in which the Company operates and the beliefs and assumptions of the management of the Company. Words such as “expects,” “anticipates,” “targets,” “goals,” “projects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “may,” “could” and variations of such words, and similar expressions are intended to identify such forward-looking statements. These forward-looking statements are only predictions and are subject to risks, uncertainties and assumptions that are difficult to predict. In particular, as discussed in greater detail below, our financial condition and results could be materially adversely affected by the continued impacts and disruptions caused by the novel coronavirus (COVID-19) global pandemic and governmental responses thereto. Forward-looking statements are based on certain assumptions, discuss future expectations, describe future plans and strategies, contain financial and operating projections or state other forward-looking information. Our ability to predict results or the actual effect of future events, actions, plans or strategies is inherently uncertain. Although we believe that the expectations reflected in our forward-looking statements are based on reasonable assumptions, our actual results and performance could differ materially from those set forth or anticipated in our forward-looking statements. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed elsewhere in this Report, including under “Risk Factors”, and in other reports the Company files with the Securities and Exchange Commission (“SEC”), including the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on March 30, 2023 (under the heading “Risk Factors” and in other parts of that report).

Exchange Act Reporting Requirements

Section 14(a) of the Exchange Act requires all companies with securities registered pursuant to Section 12(g) of the Exchange Act like we are to comply with the rules and regulations of the SEC regarding proxy solicitations, as outlined in Regulation 14A. Matters submitted to shareholders at a special or annual meeting thereof or pursuant to a written consent will require us to provide our shareholders with the information outlined in Schedules 14A (where proxies are solicited) or 14C (where consents in writing to the action have already been received or anticipated to be received) of Regulation 14, as applicable; and preliminary copies of this information must be submitted to the SEC at least 10 days prior to the date that definitive copies of this information are forwarded to our shareholders. We are also required to file annual reports on Form 10-K and quarterly reports on Form 10-Q with the SEC on a regular basis, and will be required to timely disclose certain material events (e.g., changes in corporate control; acquisitions or dispositions of a significant amount of assets other than in the ordinary course of business; and bankruptcy) in a Current Report on Form 8-K. All public filing made with the SEC are available via the SEC’s website on EDGAR at www.sec.gov.

PART I – FINANCIAL INFORMATION**ITEM 1: FINANCIAL STATEMENTS****QSAM BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS**

	March 31, 2023 (Unaudited)	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash	\$ 851,394	\$ 225,276
Prepaid expenses and other current assets	96,242	139,345
Subscription receivable	342,669	-
TOTAL CURRENT ASSETS	1,290,305	364,621
TOTAL ASSETS	\$ 1,290,305	\$ 364,621
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 868,639	\$ 745,011
Accrued payroll and related expenses	79,166	79,166
Accrued Series B preferred stock dividends	341,860	304,653
Convertible notes payable, net of discount	-	443,700
Notes payable - related parties	7,500	7,500
TOTAL CURRENT LIABILITIES	1,297,165	1,580,030
TOTAL LIABILITIES	1,297,165	1,580,030
Redeemable convertible preferred stock - Series A; \$0.0001 par value, 1,500 authorized, 480 shares issued and outstanding (liquidation preference of \$728,400 and \$721,200) as of March 31, 2023 and December 31, 2022, respectively	728,400	721,200
STOCKHOLDERS' DEFICIT		
Preferred stock, Series B, \$0.001 par value; 2,500 shares authorized, 1,509 shares issued and outstanding (liquidation preference of \$1,850,814 and \$1,813,607) as of March 31, 2023 and December 31, 2022	2	2
Preferred stock, Series E-1, \$0.0001 par value; 8,500 shares authorized, 0 shares issued and outstanding as of March 31, 2023 and December 31, 2022	-	-
Common stock, \$0.0001 par value, 300,000,000 shares authorized, 2,894,799 and 2,279,019 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	290	228
Unearned deferred compensation	(35,499)	(187,329)
Additional paid-in capital	36,532,003	33,428,115
Accumulated deficit	(37,232,056)	(35,177,625)
TOTAL STOCKHOLDERS' DEFICIT	(735,260)	(1,936,609)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 1,290,305	\$ 364,621

See notes to the unaudited consolidated financial statements.

QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the three months ended	
	March 31,	
	2023	2022
REVENUES	\$ -	\$ -
OPERATING EXPENSES		
Compensation and related expenses	332,316	756,399
Professional fees	459,134	639,405
General and administrative	68,000	119,468
Research and development expenses	206,544	254,837
Total Operating Expenses	<u>1,065,996</u>	<u>1,770,109</u>
LOSS FROM OPERATIONS	(1,065,996)	(1,770,109)
OTHER INCOME (EXPENSE)		
Financing costs including interest	(43,118)	(18,137)
Inducement interest	(397,928)	-
Total Other Expense, net	<u>(441,046)</u>	<u>(18,137)</u>
Loss from operations before income taxes	(1,507,042)	(1,788,246)
INCOME TAXES	-	-
NET LOSS	<u>(1,507,042)</u>	<u>(1,788,246)</u>
Series A preferred contractual dividends	(7,200)	(7,202)
Series B preferred contractual dividends	(37,207)	(37,206)
Deemed dividends from Series A and B conversion price reduction	(265,080)	-
Deemed dividend on warrant modification	<u>(282,309)</u>	<u>(41,225)</u>
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (2,098,838)</u>	<u>\$ (1,873,879)</u>
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS: BASIC AND DILUTED:	<u>\$ (0.90)</u>	<u>\$ (1.12)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: BASIC AND DILUTED	<u>2,330,690</u>	<u>1,668,677</u>

See notes to the unaudited consolidated financial statements.

QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE THREE MONTHS ENDED MARCH 31, 2023 AND 2022
(UNAUDITED)

	Series B Preferred Stock		Series E-1 Preferred Stock		Common Stock		Deferred Stock-based Compensation	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Par Value	Shares	Par Value	Shares	Par Value				
Balance, December 31, 2021	1,509	\$ 2	-	\$ -	1,652,102	\$ 165	\$ (900,742)	\$ 29,765,585	\$ (29,281,674)	\$ (416,664)
Common stock issued for services, including a director	-	-	-	-	28,750	3	-	254,748	-	254,751
Conversion of debentures	-	-	-	-	5,469	1	-	34,999	-	35,000
Incremental value from warrant modifications	-	-	-	-	-	-	-	41,225	(41,225)	-
Series A, preferred stock contractual dividends	-	-	-	-	-	-	-	(7,202)	-	(7,202)
40:1 Reverse Split Fractional Shares Adjustment	-	-	-	-	266	-	-	-	-	-
Series B, preferred stock contractual dividends	-	-	-	-	-	-	-	(37,206)	-	(37,206)
Accretion of stock-based compensation to employees and directors	-	-	-	-	-	-	213,041	107,312	-	320,353
Net loss period for the three months ended March 31, 2022	-	-	-	-	-	-	-	-	(1,788,246)	(1,788,246)
Balance, March 31, 2022	1,509	2	-	-	1,686,587	169	(687,701)	30,159,461	(31,111,145)	(1,639,214)
Balance, December 31, 2022	1,509	\$ 2	-	\$ -	2,279,019	\$ 228	\$ (187,329)	\$ 33,428,115	\$ (35,177,625)	\$ (1,936,609)
Common stock issued for services	-	-	-	-	16,500	2	115,090	141,477	-	256,569
Incremental value from warrant modifications	-	-	-	-	-	-	-	282,309	(282,309)	-
Deemed dividend from Series A conversion price adjustment	-	-	-	-	-	-	-	96,245	(96,245)	-
Deemed dividend from Series B conversion price adjustment	-	-	-	-	-	-	-	168,835	(168,835)	-
Series A, preferred stock contractual dividends	-	-	-	-	-	-	-	(7,200)	-	(7,200)
Series B, preferred stock contractual dividends	-	-	-	-	-	-	-	(37,207)	-	(37,207)
Accretion of stock-based compensation to employees and directors	-	-	-	-	-	-	36,740	132,593	-	169,333
Issuance of common stock for cash	-	-	-	-	69,834	7	-	314,239	-	314,246
Exercise of warrants for cash to common stock	-	-	-	-	365,001	37	-	1,094,965	-	1,095,001
Conversion of convertible debt to common stock	-	-	-	-	164,446	16	-	519,696	-	519,712
Inducement for conversion of convertible debt	-	-	-	-	-	-	-	397,937	-	397,937
Net loss period for the three months ended March 31, 2023	-	-	-	-	-	-	-	-	(1,507,042)	(1,507,042)
Balance, March 31, 2023	1,509	\$ 2	-	\$ -	2,894,800	\$ 290	\$ (35,499)	\$ 36,532,003	\$ (37,232,056)	\$ (735,260)

See notes to the unaudited consolidated financial statements.

QSAM BIOSCIENCES, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
(UNAUDITED)

	For the three months ended March 31,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (1,507,042)	\$ (1,788,246)
Adjustments to reconcile net loss to net cash used in operations:		
Common stock issued for services	256,569	254,751
Stock-based compensation to employees and directors	169,333	320,353
Amortization of debt discount	36,300	9,075
Inducement expense	397,937	-
Changes in operating assets and liabilities		
Decrease in prepaid expenses and other current assets	43,103	42,006
Increase in accounts payable and accrued expenses	156,522	248,069
Increase in accrued payroll and related expenses	-	251,192
Increase in accrued interest – related parties	6,818	-
Net cash used in operating activities	<u>(440,460)</u>	<u>(662,800)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Deferred offering costs	-	35,000
Proceeds from warrant exercise	812,332	-
Proceeds from sale of common stock and warrants	254,246	-
Net cash provided by financing activities	<u>1,066,578</u>	<u>35,000</u>
NET INCREASE (DECREASE) IN CASH	626,118	(627,800)
CASH - Beginning of period	225,276	1,499,866
CASH - End of period	<u>\$ 851,394</u>	<u>\$ 872,066</u>
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Payment of interest in cash	\$ -	\$ -
Payment of income taxes	\$ -	\$ -
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Accrual of contractual dividends on Series A convertible preferred stock	\$ 7,200	\$ 7,202
Accrual of contractual dividends on Series B convertible preferred stock	\$ 37,207	\$ 37,206
Deemed dividend on warrant modifications	\$ 282,309	\$ 41,225
Incremental value of Series A conversion modifications	\$ 96,245	\$ -
Incremental value of Series B conversion modifications	\$ 168,835	\$ -
Subscription receivable	\$ 342,669	\$ -
Conversion of notes payable to common stock	\$ 519,712	\$ -

See notes to the unaudited consolidated financial statements

QSAM BIOSCIENCES INC.
NOTES TO THE UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND DESCRIPTION OF BUSINESS

QSAM Biosciences Inc. (hereinafter the “Company”, “we”, “our”, “us”), incorporated in Delaware on August 26, 2004, is currently engaged in the business of developing a novel radiopharmaceutical drug candidate for the treatment of bone cancer. This business line commenced in earnest in the fourth fiscal quarter of 2020 as a result of the separation and transfer pursuant to an Omnibus Separation Agreement dated November 6, 2020 (the “Separation Agreement”) of the Company’s prior business in a separate sector (the “Legacy Business”) through an unconsolidated investee entity called Earth Property Holdings LLC, a Delaware limited liability company (“EPH”). Pursuant to the Separation Agreement, the Company transferred to EPH all assets and related liabilities in connection with the Legacy Business in return for a forgiveness of debt. The Company sold its entire equity interest in EPH to a third party in the first quarter of 2021 for \$100,000, and currently holds no ownership in EPH.

In April 2020, the Company established QSAM Therapeutics Inc. (“QSAM”) as a wholly-owned subsidiary incorporated in the state of Texas, and through QSAM, executed a Patent and Technology License Agreement and Trademark Assignment (the “License Agreement”) with IGL Pharma, Inc. (“IGL”). The License Agreement provides QSAM with exclusive, worldwide and sub-licensable rights to all of IGL’s patents, product data and knowhow with respect to Samaium-153 DOTMP aka CycloSam® (the “Technology”), a clinical stage novel radiopharmaceutical meant to treat different types of bone cancer and other diseases.

In connection with the transition to the life sciences sector, the Company changed its name to QSAM Biosciences Inc. on September 4, 2020, and subsequently changed its stock symbol to QSAM, to better reflect its business moving forward.

On March 4, 2022, the Company completed a 40:1 reverse stock split of its common shares. All shares and share prices set forth in this report have been adjusted retroactively to present this reverse stock split as if it had occurred at the beginning of the period presented in these consolidated financial statements.

NOTE 2 – BASIS OF PRESENTATION AND GOING CONCERN

The accompanying unaudited financial statements are prepared in accordance with Rule 8-01 of Regulation S-X of the Securities Exchange Commission (“SEC”). Accordingly, certain information and note disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America (“US GAAP”) have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures included in these unaudited consolidated financial statements are adequate to make the information presented not misleading. The unaudited consolidated financial statements included in this document have been prepared on the same basis as the annual financial statements, and in our opinion reflect all adjustments, which include normal recurring adjustments necessary for a fair presentation in accordance with US GAAP and SEC regulations for interim financial statements. The results for the three months ended March 31, 2023 are not necessarily indicative of the results that the Company will have for any subsequent period or for the calendar year ended December 31, 2023. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements and the notes to those statements for the year ended December 31, 2022 which was filed with the SEC on March 30, 2023.

For the three months ended March 31, 2023, the Company used net cash in operating activities for its operations of \$440,460 and incurred a loss from its operations of \$1,507,042. As of March 31, 2023, the Company's accumulated deficit is \$37,232,056. As of March 31, 2023, the Company has negative working capital of \$6,860 and cash of \$851,394. 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 has supported operations through the issuance of common stock, preferred stock and debt over the last 12 months. This includes a common stock and warrant offering which closed March 31, 2023, of which a total of \$2.85 million was raised, inclusive of \$342,667 in subscriptions receivables existing at the end of the quarter which were received in April 2023.

Management expects expenses to increase in 2023 as our drug technology continues through clinical trials, and as a result, we will need to raise additional capital to support these operations. Management believes that it can do so through equity or debt raises in 2023. If the Company is not successful in raising additional capital, it may need to delay clinical trials, reduce overhead, or in the most extreme scenario, shut down operations.

There is no guarantee whether the Company will be able to generate revenue and/or raise capital sufficient to support its continuing operations. The ability of the Company to continue as a going concern is dependent on management's plans which include implementation of its business model to develop and commercialize its drug candidate, seek strategic partnerships to advance clinical trials and other research endeavors which could provide additional capital to the Company, and continue to raise funds for the Company through equity or debt offerings. There is no assurance, however, that the Company will be successful in raising the needed capital and, if funding is available, that it will be available on terms acceptable to the Company. The unaudited consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The unaudited consolidated financial statements include the accounts of QSAM Biosciences Inc. and its wholly-owned subsidiaries (the "Subsidiaries") QSAM Therapeutics Inc. and Q2Power Corp. (currently inactive). All significant inter-company transactions and balances have been eliminated in consolidation. References herein to the Company include the Company and its Subsidiaries unless the context otherwise requires.

Cash and Cash Equivalents

The Company considers cash, short-term deposits, and other investments with original maturities of no more than ninety days when acquired to be cash and cash equivalents for the purposes of the statement of cash flows. The Company maintains cash balances at one national financial institution and has experienced no losses with respect to amounts on deposit. Any loss incurred or a lack of access to such funds above the FDIC limit could have a significant adverse impact on the Company's financial condition, results of operations and cash flows. The Company held no cash equivalents as of March 31, 2023 and December 31, 2022.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, "Revenue from Contracts with Customers ("ASC 606") and all the related amendments.

The core principle of ASC 606 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than previously required under U.S. GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

The Company had no revenue in 2023 and 2022.

Stock Based Compensation

The Company applies the fair value method of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 718, “*Share Based Payment*”, in accounting for its stock-based compensation with employees and non-employees. This standard states that compensation cost is measured at the grant date based on the fair value of the award and is recognized over the service period, which is usually the vesting period. The Company values stock-based compensation at the market price for the Company’s common stock and other pertinent factors at the grant date.

The Black-Scholes option pricing valuation method is used to determine fair value of stock options consistent with ASC 718, “*Share Based Payment*”. Use of this method requires that the Company make assumptions regarding stock volatility, dividend yields, expected term of the awards and risk-free interest rates.

Research and Development

Research and development costs are expensed as incurred. Research and development costs were \$206,544 for the three months ended March 31, 2023, and are a result of the Company’s clinical trials of its drug Technology. Research and development costs were \$254,837 for the three months ended March 31, 2022, and are also a result of the clinical trials and fees owed under its License Agreement. (see Note 8 – Commitments and Contingencies).

Income Taxes

Income taxes are accounted for under the asset and liability method as stipulated by FASB ASC 740, “*Income Taxes*” (“ASC 740”). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740, the effect on deferred tax assets and liabilities or a change in tax rate is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts to be realized by the use of a valuation allowance. A valuation allowance is applied when in management’s view it is more likely than not (50%) that such deferred tax will not be utilized.

In the event that an uncertain tax position exists in which the Company could incur income taxes, the Company would evaluate whether there is a probability that the uncertain tax position taken would be sustained upon examination by the taxing authorities. Reserves for uncertain tax positions would be recorded if the Company determined it is probable that a position would not be sustained upon examination or if payment would have to be made to a taxing authority and the amount is reasonably estimated. As of March 31, 2023 and December 31, 2022, the Company does not believe it has any uncertain tax positions that would result in the Company having a liability to the taxing authorities. Interest and penalties related to any unrecognized tax benefits is recognized in the unaudited consolidated financial statements as a component of income taxes.

Basic and Diluted Loss Per Share

Net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period plus any potentially dilutive shares related to the issuance of stock options, shares from the issuance of stock warrants, shares issued from the conversion of convertible preferred stock and shares issued for the conversion of convertible debt.

As of March 31, 2023, there were the following potentially dilutive securities that were excluded from diluted net loss per share because their effect would be anti-dilutive (all shares adjusted to reflect a 40:1 reverse stock split effected on March 9, 2022):

Shares from common stock options	177,815
Shares from common stock warrants	50,000
Shares from the conversion of convertible notes and accrued interest	-
Shares from the conversion of Series A Stock inclusive of cumulative dividends	242,800
Shares from the conversion of Series B Preferred Stock inclusive of dividends	301,435
	<u>727,094</u>

As of March 31, 2022, there were the following potentially dilutive securities that were excluded from diluted net loss per share because their effect would be anti-dilutive (all shares adjusted to reflect a 40:1 reverse stock split effected on March 9, 2022):

Shares from common stock options	177,815
Shares from common stock warrants	37,083
Shares from the conversion of convertible notes and accrued interest	77,117
Shares from the conversion of Series A Stock inclusive of cumulative dividends	108,480
Shares from the conversion of Series B Preferred Stock inclusive of dividends	265,555
	<u>666,050</u>

Significant Estimates

U.S. Generally Accepted Accounting Principles (“GAAP”) requires the Company to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited financial statements, the reported amounts of revenues and expenses, cash flows and the related footnote disclosures during the period. On an on-going basis, the Company reviews and evaluates its estimates and assumptions, including, but not limited to, those that relate to the fair value of stock-based compensation, and a valuation allowance on deferred tax assets. Actual results could differ from these estimates.

Recent Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity’s Own Equity (Subtopic 815-40) (“ASU 2020-06”) to simplify accounting for certain financial instruments. ASU 2020-06 eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity’s own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity’s own equity. ASU 2020-06 amends the diluted earnings per share guidance, including the requirement to use the if-converted method for all convertible instruments. ASU 2020-06 is effective January 1, 2022 for public business entities that are not smaller reporting companies and for all other entities, fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The standard should be applied on a full or modified retrospective basis, with early adoption permitted beginning on January 1, 2021. Effective January 1, 2021, the Company adopted ASU 2020-06 and noted no material impact to the consolidated financial statements.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on its unaudited financial statements.

Concentration of Risk

The Company expects cash to be the asset most likely to subject the Company to concentrations of credit risk. The Company's bank deposits may at times exceed federally insured limits. The Company's policy is to maintain its cash with high credit quality financial institutions to limit its risk of loss exposure. The Company's cash balance as of March 31, 2023, is in excess of FDIC limits in the amount of approximately \$601,394.

The Company is subject to a number of risks similar to those of other companies at a clinical-stage for radiopharmaceutical drug candidates, including dependence on key individuals; the need to develop commercially viable therapeutics; competition from other companies, many of which are larger and better capitalized; intellectual property risks; and the need to obtain adequate additional financing to fund the development of its products. The Company currently depends on third-party suppliers for key materials and services used in its research and development manufacturing process, and is subject to certain risks related to the loss of these third-party suppliers or their inability to supply the Company with adequate materials and services. The Company's primary Technology is licensed from one party and is subject to general risks related to contractual relationships and the performance of the parties under the contract.

Fair Value of Financial Instruments

In accordance with Accounting Standards Codification ("ASC") 825, *Financial Instruments*, disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Cash is carried fair value.

Other financial instruments, including accounts payable, accrued liabilities and short-term debt, are carried at cost, which approximates fair value given their short-term nature.

Deferred Offering Cost

Costs incurred prior to an equity offering are capitalized until the offering occurs. Upon the equity offering, all accumulated costs are charged against proceeds. If the Company determines that the equity offering will not occur, the accumulated costs are charged to operations.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company views its operations and manages its business as one segment.

NOTE 4 – RELATED PARTY TRANSACTIONS

The Company has a License Agreement with IGL Pharma, Inc. ("IGL"), an entity in which the Company's Executive Chairman serves as President, holds options to purchase less than a 1% non-controlling equity interest and receives a \$500 per month fee. Effective November 17, 2021, the Company amended the License Agreement with IGL which adjusted milestone payment amounts during the course of the agreement term. Under the License Agreement, the Company incurred research and development related expenses of \$0 and \$9,355 during the three-month period ending March 31, 2023 and March 31, 2022, respectively. As of March 31, 2023 and December 31, 2022, amounts outstanding due IGL for their services amounted to \$7,876 and \$13,900, respectively.

During the year ended December 31, 2020, the Company received \$45,500 of proceeds from short-term notes payable with officers and directors of the Company bearing interest at 10%. As of March 31, 2023 and December 31, 2022, \$7,500 of principal remains outstanding on certain of these short-term notes payable.

NOTE 5 – CONVERTIBLE PROMISSORY NOTES

Convertible Notes Payable

In the fourth quarter of 2021, the Company issued a total of \$605,000 in convertible notes payable, the total principal and accrued interest of which was converted into a total of 186,601 shares of common stock as of March 31, 2023. The convertible notes were to mature on December 31, 2023, and included a 6% simple interest rate per annum payable upon maturity. In addition to the notes payable, each holder received a warrant for the purchase of shares of common stock with a purchase price of \$24.00, which expired in 2022. In accordance with accounting standards, the warrants were valued using a Black Scholes Model and the relative fair value of the warrant was applied against the convertible note for a debt discount of \$72,600.

In the fourth quarter of 2022, two note holders converted \$132,932 of principal and interest on their notes into 22,155 shares of common stock, at a reduced conversion price approved by the Board of \$6.00. In the first quarter of 2023, the remaining holders converted \$519,712 of principal and interest on their notes into 148,621 shares of common stock, at a reduced conversion price approved by the Board of \$3.50, and the two holders who converted in 2022 received an additional 15,825 shares to “make whole” their prior conversion at a higher price. Due to the inducement to the reduced conversion price, the Company recorded \$397,937 of inducement interest expense to other income and expenses. The fair value of the shares issued for the conversion as of March 31, 2023 was \$594,484 based on the stock price of \$4.00 as of March 31, 2023.

During the three-month periods ended March 31, 2023 and 2022, the Company recorded interest expense related to the amortization of the discount of \$36,300 and \$9,075, respectively. As of March 31, 2023 and December 31, 2022, unamortized debt discount was \$0 and \$36,300, respectively.

NOTE 6 – TEMPORARY EQUITY, PREFERRED STOCK, COMMON STOCK, AND WARRANTS

Series A Redeemable Convertible Preferred Stock (“Series A Stock”)

As of March 31, 2023 and December 31, 2022, the Company has 480 shares of Series A Stock issued and outstanding. The Series A Stock has no voting rights until converted to common stock and has a liquidation preference equal to the aggregate purchase price of \$480,000 plus accrued dividends. Pursuant to a modification agreement effective as of March 31, 2023, the two Series A Stockholders have agreed to change the redemption date on their Series A Stock to December 31, 2023 and waive any prior defaults by the Company.

The Series A Stock carries a 6% per annum dividend calculated on the stated value of the stock and is cumulative and payable quarterly beginning July 1, 2016. These dividends are accrued at each reporting period and are added to the redemption value of the stock; however, since the Company has an accumulated deficit, the charge has been recognized in additional paid-in capital. The accrued dividends are \$248,400 and \$241,200 as of March 31, 2023 and December 31, 2022, respectively. As of March 31, 2023 and December 31, 2022, the stated value of the Series A Stock and the accrued dividends was \$728,400 and \$721,200, respectively, which has been presented as mezzanine equity on the consolidated balance sheets, which resides between liabilities and stockholders’ deficit.

The outstanding principal and accrued dividends on the shares of Series A Stock as of March 31, 2023 are convertible into the Company's common stock at \$3.00 (the "Conversion Price"), which was reduced in 2023 pursuant to a price protection provision included in the Series A Stock Certificate of Designation ("Series A Designation"), as the Company offered an inducement to holders of warrants to convert their warrants at such lower conversion price. The Series A Designation requires an adjustment to the Conversion Price if a subsequent equity sale occurs at a price below the conversion rate. The Company recorded a deemed dividend within stockholders' deficit associated with the reduction in Conversion Price from \$3.33 to \$3.00 of \$96,245 based on the incremental value to the Series A Stockholders due to the Conversion Price reduction. This incremental value has also been presented on the consolidated statement of operations as an addition to the net loss available to common stockholders. The incremental value was determined by computing the additional shares the Series A Stockholders would receive based on the Conversion Price reduction multiplied by the estimated fair value of common stock of \$4.00.

The outstanding shares of Series A Stock as of December 31, 2022 were convertible at \$3.33 per share of the Company's common stock, which was reduced in 2022 pursuant to the Series A Designation as the Company sold a common stock and warrant unit in an offering at \$4.50, the fair value of which was determined to be \$3.33. The Company recorded a deemed dividend within stockholders' equity associated with the reduction in Conversion Price from \$6.40 to \$3.33 of \$342,497 based on the incremental value to the Series A Stockholders due to the Conversion Price reduction. This incremental value has also been presented on the consolidated statement of operations as an addition to the net loss available to common stockholders. The incremental value was determined by computing the additional shares the Series A Stockholders would receive based on the Conversion Price reduction multiplied by the estimated fair value of common stock of \$3.33.

Management has determined that the Series A Stock is more akin to a debt security than equity primarily because it contains a mandatory 2-year redemption at the option of the holder (which pursuant to a March 31, 2023 modification signed by both Series A Stockholders, was changed to December 31, 2023), which only occurs if the Series A Stock is not converted to common stock. Therefore, management has presented the Series A Stock outside of permanent equity as mezzanine equity, which resides between liabilities and equity.

Series B Convertible Preferred Stock ("Series B Stock")

In December 2020, the Company filed an amendment to its Articles of Incorporation to authorize the issuance of up to 2,500 shares of Series B Stock, par value \$0.001 per share, pursuant to a Certificate of Designation ("Series B Designation"). The Series B Stock provides the holders a 10% annual paid-in-kind dividend, a liquidation preference equal to the purchase price of the shares (\$1,000 per share) followed by the right to participate with the common stockholders in the instance of a liquidation or other exit event, and provide the holders the right to vote along with the common holders based on the common conversion amount of their holdings. In January 2021, the Company closed a private offering of its Series B Stock for \$1,000 per share, raising a total of \$2,500,000, inclusive of \$156,000 in prior debt conversion and \$23,000 of notes payable with directors converted to shares of Series B Stock and warrants. Between July 27 and August 24, 2021, 15 holders of an aggregate of 991 shares of Series B Stock converted their preferred shares into 163,134 shares of common stock, which included \$53,061 of accrued dividends. As of March 31, 2023 and December 31, 2022, 1,509 shares of Series B Stock were issued and outstanding. The accrued dividends are \$341,860 and \$304,653, as of March 31, 2023 and December 31, 2022, respectively, which are presented on the consolidated balance sheets.

The Series B Stock was originally convertible into common stock at a ratio of \$6.40 per share, subject to anti-dilution protections in the case of certain issuances of securities below that conversion price, and as a result of this price protection, the ratio was reduced in the fourth quarter of 2022 to \$6.19 per share based on the Series B Designation which defines the adjustment to the conversion ratio and incremental shares when the Company issues common stock at a price below the conversion ratio. For the year ended December 31, 2022, the Company recorded a deemed dividend within stockholders' equity associated with the reduction in conversion price from \$6.40 to \$6.19 of \$30,938 based on the incremental value to the Series B Stockholders due to the conversion price reduction. This incremental value has also been presented on the consolidated statement of operations as an addition to the net loss available to common stockholders.

For the three-month period ended March 31, 2023, the anti-dilution protections were triggered as a result of additional common stock issuances and the warrant conversion repricing, and the conversion ratio was reduced to \$5.42. The Company recorded a deemed dividend within stockholders' equity associated with the reduction in conversion price from \$6.19 to \$5.42 of \$168,835 based on the incremental value to the Series B Stockholders due to the conversion price reduction. This incremental value has also been presented on the consolidated statement of operations as an addition to the net loss available to common stockholders.

Series E-1 Preferred Stock (“Series E-1 Stock”)

On December 3, 2020, the Company filed an amendment to its Articles of Incorporation to authorize the issuance of up to 8,500 shares of Series E-1 Stock pursuant to a Certificate of Designation. As discussed below, no shares of Series E-1 Stock are currently outstanding. The shares of Series E-1 Stock were incentive-based, vesting and forfeitable securities that were issued to the Company’s executives and one director. The Series E-1 Stock also provided the holders the right in the aggregate to receive an “earnout” equal to 20% of the total consideration received by the Company in the instance of a sale or sub-license of its core licensed radiopharmaceutical Technology, or sale or merger of the Company, which was to be paid on a priority, senior basis, as well as other conversion and voting rights.

On December 6, 2021, the Company entered into an Exchange Agreement and Plan of Reorganization (the “Exchange Agreement”) with all Series E-1 Stockholders pursuant to which all shares of Series E-1 Stock were exchanged into an aggregate of 720,986 shares of common stock of the Company. The fair value of the Series E-1 Stock was determined to be approximately \$8.65 million at the time of exchange, and was based upon a valuation report provided to the Board by an independent third party expert, and approved for fairness by the independent chairman of the Compensation Committee. The common stock issued in the exchange was based on a value of \$12.00 per share using a 30-day weighted average closing price calculation, and was issued proportionately to each holder based on their individual holdings of Series E-1 Stock. All shares of common stock issued to the shareholders are subject to the same vesting schedules as was originally provided in each shareholder’s Series E-1 Stock issuance agreement, meaning that such shares of common stock are forfeitable if certain conditions of employment are not met by the holders. As of March 31, 2023, all 720,986 common shares are fully vested and there are no remaining common shares that are unvested.

For the three-month periods ending March 31, 2023 and 2022, the Company recognized stock-based compensation to employees and directors totaling \$36,741 and \$213,041, respectively, related to the Series E-1 Stock, which is included in compensation and related expenses on the consolidated statements of operations. As of March 31, 2023, there is no unrecognized compensation remaining.

Common Stock

In 2022, the Company effected a 40:1 reverse stock split and all share numbers herein have been adjusted for that change.

During the three-month periods ended March 31, 2023 and 2022, the Company issued shares of common stock as follows:

	For the three months ended	
	March 31,	
	2023	2022
Conversion of debentures and accrued interest	-	5,469
Exercise of common stock warrants to common stock	365,001	-
Stock based compensation for services performed by one prior director	-	10,000
Conversion of convertible debt to common stock, including “make whole” issuances	164,446	-
Issuance of common stock for cash	69,834	-
Stock based compensation for services	16,500	18,750
Total common shares issued	615,781	34,219

During the three-month period ended March 31, 2023, the Company issued 69,834 shares of common stock for \$314,251 in its common stock and warrant unit offering. Additionally, the Company converted outstanding convertible debt of \$480,000 plus interest totaling \$519,712 into 164,446 shares of common stock at a conversion price of \$3.50. Additionally, the Company received exercises of 365,001 warrants into 381,500 shares of common stock at an exercise price of \$3.00, for a total of \$1,144,501, which included \$49,500 that offset fees owed for services, and which also included \$342,669 in subscription receivables related to conversion notices that were executed prior to March 31, 2023 and funds that were received in April 2023.

During the three-month period ended March 31, 2022, \$35,000 of debentures and accrued interest were converted into 5,469 shares of common stock at a price of \$6.40 per share. Additionally, the Company issued 18,750 shares of common stock for services, and 10,000 shares of common stock for services provided by one director who resigned from the Board in the same period.

Warrants

During the three-month period ended March 31, 2023, the Company issued 69,834 warrants in connection with the common stock and warrant unit offering (the “Common Stock Warrants”), and 50,000 warrants to a service provider totaling \$91,979 in consulting services expense. The Company did not issue any warrants in the same period in 2022.

A summary of warrant activity and related information for the period ending March 31, 2023 is as follows:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	323,543	\$ 6.15	\$ -
Issued	119,832	4.25	-
Exercised	381,500	3.00	-
Expired	11,875	10.00	-
Outstanding as of March 31, 2023	50,000	\$ 6.00	\$ -

The aggregate intrinsic value of the warrants is the difference between the fair market value of the Company’s closing price of its common stock at each reporting date, less the exercise price multiplied by the number of warrants outstanding, which was \$0 at March 31, 2023 and December 31, 2022, respectively.

The following is a summary of the outstanding common stock warrants as of March 31, 2023:

	Number of Warrants	Exercise price per share	Expiration Date
Warrants issued in connection services agreement	50,000	\$ 6.00	January 15, 2025
Total outstanding as of March 31, 2023	50,000		

NOTE 7 – STOCK OPTIONS

In 2016 to compensate officers, directors and other key service providers with equity grants, the Board approved the 2016 Omnibus Equity Incentive Plan (“2016 Plan”), which initially allowed for 4,000 shares of common stock, stock options, stock rights (restricted stock units), or stock appreciation rights to be granted by the Board in its discretion. This authorized amount was increased multiple times by Board resolution, most recently to 200,000 shares on January 13, 2022. As of March 31, 2023, there are 25,000 shares available under the 2016 Plan for future issuance; however, the Board may increase the authorized shares under the 2016 Plan each year to an amount equal to 5% of the total issued and outstanding common shares of the Company or such other amount in its reasonable discretion. The Board has indicated that they intend to increase the authorized shares under the 2016 Plan in 2023.

The Company has not issued any stock options during the three month period ended March 31, 2023.

A summary of stock option activity and related information during the period ended March 31, 2023 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	177,815	\$ 12.57	8.8	\$ -
Granted	-	-	-	-
Outstanding as of March 31, 2023	177,815	\$ 12.57	8.56	\$ -

The Company recorded \$169,333 and \$107,312 of stock-based compensation expense which is included in compensation and related expenses for the period ending March 31, 2023 and March 31, 2022, respectively, on the consolidated statement of operations.

The aggregate intrinsic value of options is the difference between the fair market value of the Company's closing price of its common stock at each reporting date, less the exercise price multiplied by the number of options granted, which was \$0 at March 31, 2023.

As of March 31, 2023, there was unrecognized stock-based compensation of \$505,644 which is expected to be expensed through March 2026 based on the option vesting requirements.

We estimate the fair value of stock-based awards on the date of grant using the Black-Scholes option pricing model using the fair market value of our common stock on the date of grant and a number of other assumptions. These assumptions include estimates regarding the expected term of the awards, estimates of the stock volatility over a duration that approximates the expected term of the awards, estimates of the risk-free rate, and estimates of expected dividend rates.

NOTE 8 – COMMITMENTS AND CONTINGENCIES

Employment Agreements

The employment agreements as amended for the Company's Executive Chairman and CEO each contain termination provisions whereby if they are terminated without cause or following a material change, as defined therein, they will receive salary through the date of termination plus an additional 24 months, bonus that would be earned during the full year when the termination became effective (or a lump sum of 50% of the full target bonus), all stock options shall vest and healthcare benefits will continue for 24 months. The Company's General Counsel's employment agreement, as amended, contains an 18-month severance payment in the instance of a termination without cause or following a material change, as defined therein.

Pursuant to amendments dated November 14, 2022 to the three employment agreements of the Company's Executive Chairman, CEO and General Counsel, as well as an amendment to the employment agreement for the Company's VP Operations (the "2022 Amendments"), each of these four employees have agreed to accept reduced salaries until the Company is successful in raising additional funds. Specifically, when the Company raises at least \$7.5 million in a single offering, each employee's salary will be increased to the full contracted rate; and prior to that time, the reduced salaries will be gradually increased as the Company raises \$2 million and then \$5 million. During this time, the difference between the reduced salaries and the full contracted salaries will not accrue as liabilities for the Company. As of March 31, 2023 and December 31, 2022, the accrued salary for the management team was \$79,166.

Pursuant to the 2022 Amendments, \$758,748 of accrued salaries were settled with shares of common stock with an estimated fair value of \$606,998 and cash payments of \$151,750, of which \$79,166 remains unpaid and has been accrued as of March 31, 2023. The Company issued 168,611 shares of common stock on December 31, 2022 in connection with conversion of management salaries. The salary was converted at a price of \$3.55 per share.

The shares of common stock issued pursuant to the 2022 Amendments are restricted and shall be subject to forfeiture as follows: until such time that the Company successfully closes \$5 million in a single fundraising (the “Trigger Event”), which may be completed in one or more closings over a period of 90 days, the shares of common stock may not be sold, transferred or otherwise disposed of by the holder. Upon the occurrence of the Trigger Event, the shares shall be fully vested. If the Trigger Event does not occur within 36 months of November 2022, the shares of common stock shall be forfeited and returned to the Company. The shares issued with the 2022 Amendments have been presented as issued and outstanding on the statement of stockholders’ deficit as of March 31, 2023.

The employment agreements, as amended, for the Company’s Executive Chairman and CEO each contain a transaction bonus in the instance any of the Company’s assets are sold or sublicensed or if the Company or its subsidiary is acquired, equal to 1.75% of the consideration received by the Company. The employment agreement, as amended, for the Company’s General Counsel and for its VP Operations each contain a similar transaction bonus equal to 0.5% of consideration received by the Company.

Board of Director Agreements

In January 2022, Adriann Sax was appointed as a Director to the Board and awarded an annual retainer of \$30,000 per year with an additional \$7,500 for serving as an Audit Committee member and an additional \$10,000 for serving as the Nominating & Governance Committee Chair. Ms. Sax has agreed to defer compensation for serving as a Director until the completion of the next fundraising round. As such, the Company has accrued the director compensation for Ms. Sax monthly with a total accrued balance of \$59,573 and \$43,542 as of March 31, 2023 and December 31, 2022, respectively.

In February 2022, Charles J. Link, Jr. was appointed as a Director to the Board and awarded an annual retainer of \$30,000 per year with an additional \$7,500 for serving as an Audit Committee member and an additional \$15,000 for serving as the Compensation Committee Chair, and \$3,500 for serving as a member of the Nominating Committee. Dr. Link has agreed to defer compensation for serving as a Director until the completion of the next fundraising round. As such, the Company has accrued the director compensation for Dr. Link monthly with a total accrued balance of \$70,233 and \$51,333 as of March 31, 2023 and December 31, 2022, respectively.

License Agreement

The License Agreement for the Technology, as amended, between the Company’s wholly-owned subsidiary QSAM Therapeutics and IGL is for 20 years or until the expiration of the multiple patents covered under the license and requires multiple milestone-based payments including: up to \$410,000 as CycloSam[®] advances through Phase 3 of clinical trials, and \$2 million upon commercialization. IGL has also received 12,500 shares of the Company’s common stock as additional compensation. Upon commercialization, IGL will receive an on-going royalty equal to 4.5% of Net Sales, as defined in the License Agreement, and 5% of any consideration we receive pursuant to a sublicense, sale of the asset, or sale of the QSAM subsidiary. The Company will also pay for ongoing patent filing and maintenance fees, and has certain requirements to defend the patents against infringement claims.

In connection with the License Agreement, QSAM signed a two-year Consulting and Confidentiality Agreement (the “Consulting Agreement”) with IGL, which provided IGL with payments of \$8,500 per month starting 60 days after signing through April 2022. The Consulting Agreement provided QSAM with additional consulting and advisory services from the Technology’s founders to assist in the clinical development of CycloSam. During the period ending March 31, 2023, the Company paid \$13,961 in expense reimbursements required under the agreement. The drug development costs to IGL which has been reflected as research and development expense on the consolidated statements of operations was \$0 and \$25,500 for the period ending March 31, 2023 and March 31, 2022, respectively.

As of March 31, 2023, \$7,876 of these costs remained outstanding and included in accounts payable and accrued expenses on the consolidated balance sheets.

On July 1, 2022, QSAM signed a new work order under the Master Services Agreement dated August 31, 2020 with IsoTherapeutics Group, Inc. (“ISO”), a company that has common ownership control with IGL. The new work order with ISO is a \$8,500 per month consulting contract to utilize the knowledge and expertise of Drs. Keith Frank and Jim Simon, primary scientists and owners in ISO and IGL, and to provide scientific and manufacturing consulting support with the clinical trials as they progress through each phase. The work order is a 2 year term with a 15 day cancellation notice and the Company is only obligated for fees incurred for services performed to date.

NOTE 9 – SUBSEQUENT EVENTS

In April 2023, the Company received \$342,669 in subscriptions receivable related to warrants exercised in connection with the closing of its common stock and warrant unit offering on March 31, 2023. The Company issued to the holders the 107,556 shares of common stock from the warrant exercises as of March 31, 2023, and are included in total shares outstanding in this report as of that date.

In April 2023, the Company signed two consulting agreements for support in investor relations and other services as follows: a six month agreement with Redstone Communications pursuant to which the Company issued 30,000 shares of restricted common stock; and a six month agreement with Force Family Office pursuant to which the Company issued 16,000 shares of restricted common stock. Under these two agreements, the Company may issue an additional 46,000 shares in total over their respective terms based on certain performance metrics of the parties.

ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF OPERATIONS

FORWARD LOOKING STATEMENTS

This document contains certain forward-looking statements that are subject to various risks and uncertainties. Forward-looking statements are generally identifiable by use of forward-looking terminology such as “may,” “will,” “should,” “potential,” “intend,” “expect,” “outlook,” “seek,” “anticipate,” “estimate,” “approximately,” “believe,” “could,” “project,” “predict,” or other similar words or expressions. Forward-looking statements are based on certain assumptions, discuss future expectations, describe future plans and strategies, contain financial and operating projections or state other forward-looking information. Our ability to predict results or the actual effect of future events, actions, plans or strategies is inherently uncertain. Although we believe that the expectations reflected in our forward-looking statements are based on reasonable assumptions, our actual results and performance could differ materially from those set forth or anticipated in our forward-looking statements. Factors that could have a material adverse effect on our forward-looking statements and upon our business, results of operations, financial condition, funds derived from operations, cash available for dividends, cash flows, liquidity and prospects include, but are not limited to, the factors referenced in this document, including those set forth below, and more fully set forth in the risk factors described in our annual report on Form 10-K for the year ended December 31, 2022 or in this report:

- our lack of an operating history;
- the net losses that we expect to incur as we develop our business;
- obtaining FDA or other regulatory approvals or clearances for our technology;
- implementing and achieving successful outcomes for clinical trials of our products;
- convincing physicians, hospitals and patients of the benefits of our technology and to convert from current standard of care;
- the ability of users of our products (when and as developed) to obtain third-party reimbursement;
- any failure to comply with rigorous FDA and other government regulations; and
- securing, maintaining and defending patent or other intellectual property protections for our technology.

When considering forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this document. Readers are cautioned not to place undue reliance on any of these forward-looking statements, which reflect our views as of the date of this document. The matters summarized below and elsewhere in this document could cause our actual results and performance to differ materially from those set forth or anticipated in forward-looking statements. Accordingly, we cannot guarantee future results or performance. Furthermore, except as required by law, we are under no duty to, and we do not intend to, update any of our forward-looking statements after the date of this document, whether as a result of new information, future events or otherwise.

A. Plan of Operation

We are developing next-generation nuclear medicines for the treatment of cancer and other diseases. Our initial technology is Samarium-153 DOTMP, a/k/a CycloSam[®] (“CycloSam[®]” or the “Technology”), a clinical-stage bone targeting therapeutic radiopharmaceutical. CycloSam[®] features a patented, low specific activity form of Samarium-153, a beta-emitting radioisotope with a short 46-hour half-life, and the chelating agent DOTMP, which selectively targets sites of high bone mineral turnover and reduces off-site migration of the tumor-killing radiation. We believe improvements in formulation and manufacturing from a prior FDA-approved drug (Quadramet[®]) utilizing the same radioisotope has resulted in our drug candidate demonstrating significantly less impurities, lower costs and more frequent availability. Samarium-153 and DOTMP form a highly stable complex, which we believe, when used in multi-dose regimens either as a monotherapy or in combination with other more widely used treatments such as external beam radiation, may demonstrate meaningful disease modifying results in primary and metastatic bone cancer. Ultimately, we may seek to further develop and commercialize CycloSam[®] for one or more market indications or license the Technology to a larger pharmaceutical partner.

In August 2021, the Food & Drug Administration (FDA) cleared our Investigational New Drug (IND) application to commence Phase 1 clinical trials for CycloSam[®] as a treatment for cancer that has metastasized to the bone from the breast, lung prostate, and other organs. We initiated this trial at our first site (Houston, TX) in November 2021, and dosed our first patient in this open-label, dose escalating study in April 2022. As of March 31, 2023, we have dosed a total of three patients, in completion of the first cohort grouping in this study. This phase of our clinical trials is expected to conclude by the end of 2023 or early 2024, subject to timely funding, at which time we expect to seek approval from the FDA to commence Phase 2 efficacy trials of CycloSam[®].

Also in August 2021, the FDA granted Orphan Drug Designation for the use of CycloSam[®] to treat a primary bone cancer called osteosarcoma, a devastating disease that mostly affects children and young adults, and in January 2022, the FDA granted us Rare Pediatric Disease Designation for that indication. Although patients with osteosarcoma or Ewing's sarcoma are eligible to participate in our initial Phase 1 trials, we anticipate filing separate indication-specific protocol(s) to our IND in the future, subject to funding, to commence clinical trials specifically for these primary, pediatric bone cancers. In March 2020, CycloSam[®] was also utilized in a Single Patient Investigational New Drug for Emergency Use at the Cleveland Clinic. We believe the study we conducted at the Cleveland Clinic showed promising safety results in connection with a bone marrow ablation procedure, including patient tolerability at high dosages. To date, CycloSam[®] has completed animal studies in both small and large animals, including treating bone cancer in patient dogs at a university veterinary clinic, and human Phase 1 trials have commenced.

Clinical trials, the drug approval process, and the marketing of drugs are intensively regulated in the United States and in all major foreign countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and related regulations. Drugs are also subject to other federal, state, and local statutes and regulations. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA Institutional Review Board ("IRB") of a clinical hold on trials, the FDA's refusal to approve pending applications or supplements, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

What is CycloSam[®]

CycloSam[®] is a targeted, bone seeking radiopharmaceutical that combines the beta-emitting radioisotope Samarium-153 (153Sm) with a chelating agent, DOTMP (1, 4, 7, 10-tetraazacyclododecane-1, 4, 7, 10-tetramethylenephosphonic acid). Samarium-153 is acquired from a nuclear reactor from a third party and the chelating agent is supplied in the form of kits. Chelating agents are organic compounds capable of linking together metal ions to form complex ring-like structures. This combination forms a stable complex which delivers a radioactive dose to sites of rapid bone mineral turnover such as those that form around bone cancers and tumors. CycloSam[®] has a physical half-life of 46 hours (radiation decreases by half in 46 hours) and emits both medium-energy beta particles that produce the therapeutic effect, and gamma photons that make it possible to take images of the skeleton and locate and characterize the size and nature of tumors. The use of radioisotopes to both diagnose and treat disease is called "theragnostics" and is a rapidly growing area of medical discovery.

License Agreement

Through our wholly-owned subsidiary, QSAM Therapeutics, we entered into an exclusive worldwide patent and technology license agreement (the "License Agreement") with IGL Pharma, Inc. ("IGL") on April 20, 2020 with respect to the innovative work of Jim Simone, PhD and R. Keith Frank, PhD, at IsoTherapeutics on Samarium-153 DOTMP. IGL is an affiliated company with IsoTherapeutics, and the President of IGL also serves as our Executive Chairman.

Our License Agreement with IGL, as amended in November 2021, is for 20 years or until the expiration of the multiple patents covered under the license, and requires multiple milestone-based payments up to \$410,000 as CycloSam[®] advances through multiple stages of clinical trials, and \$2 million upon commercialization. IGL also received 12,500 shares of common stock of the Company. Upon commercialization, IGL will receive an on-going royalty equal to 4.5% of Net Sales, as defined in the License Agreement, and will receive 5% of any consideration we receive pursuant to a sublicense, sale of the asset, or sale of the QSAM subsidiary. We will also pay for ongoing patent filing and maintenance fees, and we have certain requirements to defend the patents against infringement claims. The parties have agreed to mutual indemnification.

Either party may terminate the License Agreement 30 days after notice in the event of an uncured breach, or immediately in the case of bankruptcy or insolvency of the other party. We may terminate for any reason upon 30 days' notice. In the case IGL terminates due to an uncured breach, IGL will repay to us 25% of our direct clinical costs to assume ownership of data and other information gained in that process.

Strategic Plan

We are actively advancing the development of our Technology through clinical trials. We believe that we can complete the current Phase 1 safety trial of approximately 17 patients late this year or early in 2024, if we have adequate funding in a timely manner. Management estimates that an additional \$3 million to \$4 million will be required to complete this phase of our study, which would represent an important near-term milestone that may provide a material value inflection point for the Company.

The next step in our clinical trial program, if cleared by the FDA, is expected to be a study designed to show both safety and efficacy in the treatment of bone tumors utilizing a multi-dose regimen of CycloSam[®]. Significant and compelling data from prior clinical studies suggest that Samarium-153, when used multiple times over a six to nine month period, can have a material beneficial effect on metastatic bone tumors. [*Sinzinger H, Palumbo B, Ozker K. The Vienna protocol and perspectives in radionuclide therapy. The Quarterly Journal of Nuclear Medicine and Molecular Imaging: Official Publication of the Italian Association of Nuclear Medicine (AIMN) [and] the International Association of Radiopharmacology (IAR), [and] Section of the Society of... 2011 Aug;55(4):420-430.*] Replication of certain portions of this study utilizing our new, patented formulation of CycloSam[®] could provide data that allow the Company to seek approval from the FDA to commence pivotal trials, or possibly attract a partnership with a much larger pharmaceutical entity. Management estimates that an additional \$12 million to \$14 million will be required to fully complete this critical phase of our study over the next 24 to 30 months.

Beyond our current focus of studying CycloSam[®] in the treatment of metastatic bone cancer, if funding and resources allow, management will seek to advance other potential indications for our Technology, including the treatment of pediatric osteosarcoma and Ewing's sarcoma, and the use of CycloSam[®] to perform bone marrow ablation procedures prior to stem cell transplants. Advancement of current and future plans for our Technology will require additional funding, which will result in the issuance of more common stock, preferred stock or debt in subsequent raises. There is no guaranty that we will be successful in raising such funding on terms acceptable to our shareholders, if at all, and if we are not successful, we may be required to slow down or cease our clinical trials.

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

COVID-19

In March 2020, the World Health Organization declared COVID-19 a global pandemic and recommended containment and mitigation measures worldwide. Although our operations are not currently affected by the Covid outbreak, Covid previously had a direct impact on the commencement of our clinical trials. Due to Covid infections at one of our vendor labs, team members leading certain startup activities for our project were sent home and work could only be initiated upon their return, causing us to delay a key procedure, which was ultimately completed. General conditions around Covid have also created supply chain delays with certain of our manufacturers and distributors. Lastly, there remains a risk with the rise of Covid cases in the US could delay enrollment of patients into our clinical trials, interrupt treatment, or cause a patient to withdraw due to prolonged effects of infection. To mitigate these risks, we have worked with our vendors and suppliers to designate and train additional staff to support our project, and we have ordered sufficient supplies to support our entire Phase I trial. We are also securing secondary suppliers to ensure supply chain resilience. Additionally, we are working with our clinical trial site to screen more patients in order to have a sufficient volume of qualified patients waiting to enroll.

Results of Operations for the three-month periods ended March 31, 2023 and 2022

For the three-month periods ended March 31, 2023 and 2022, we recorded no revenue from operations.

For the three-month period ended March 31, 2023, we recorded a net loss from operations of \$1,507,042, a decrease of \$281,204 (15.7%) from our net loss from operations of \$1,788,246 for the same period in 2022. Basic and diluted net loss per share was \$0.90 and \$1.12 for the three-month periods ended March 31, 2023 and 2022, respectively. The primary reasons for the decrease in the net loss for 2023 over 2022 were as follows:

(1) FY Q1 2023 decrease in compensation and related expenses of \$424,083 is driven by a decrease in Series E-1 Stock expense of \$213,041, a decrease in accrual of wages of \$241,000 due to reduced salaries for management per their amended employment agreements, offset by an increase in 2023 for Board of Directors Fee.

(2) FY Q1 2023 decrease in General & Administrative costs of \$51,468 is driven primarily by a decrease in SEC filing fees of \$56,640, offset by an increase in dues and subscriptions of \$3,786.

(3) FY Q1 2023 increase in Other Expenses of \$422,909 is driven primarily by inducement expense of \$397,928 for conversion of convertible notes in the 2023 period, and an increase in financing costs including interest of \$24,981.

(4) FY Q1 2023 decrease in Professional Fees of \$180,271 is primarily driven by a decrease in legal fees of \$195,861.

(5) FY Q1 2023 decrease in Research and Development of \$48,293 is driven by a decrease in vendor expenses related to the timing of dosing patients in the clinical trial.

Net Loss Attributable to Common Stockholders

Net loss attributable to common stockholders for the three months ended March 31, 2023 was \$2,098,838 as compared to \$1,873,879 for the three months ended March 31, 2022. The net loss attributed to common stockholders for the three months ended March 31, 2023 and 2022 includes Series A and Series B preferred contractual dividends and deemed dividends. The net loss attributable to common stockholders, basic and diluted, for the three months ended March 31, 2023 was a loss of \$0.90 per share as compared to a loss of \$1.12 per share for the 2022 period.

Financial Condition, Liquidity and Capital Resources

Net cash used in operating activities was \$440,460 for the three months ended March 31, 2023, which reflected our net loss during the period of \$1,507,042, non-cash adjustments of \$789,929, and a net increase in operating assets and a net increase in assets of \$207,555. The non-cash adjustments are comprised of stock-based compensation and inducement expense.

Net cash used in operating activities was \$662,800 for the three months ended March 31, 2022, which reflected our net loss during the period of \$1,788,246, non-cash adjustments of \$646,903, and a net increase in operating assets and a net decrease in liabilities of \$206,443. The non-cash adjustments are comprised of stock-based compensation.

There was no cash provided by or used in investing activities during the three months ended March 31, 2023 and 2022.

Net cash provided by financing activities during the three months ended March 31, 2023 was \$1,066,578 due to the issuance of common stock for cash of \$254,246 and exercise of warrants for cash of \$812,332. Net cash used by financing activities during the three months ended March 31, 2022 was \$35,000 due to deferred offering costs.

As of March 31, 2023, we had cash of \$851,394. Our cash is currently held at large U.S. banks.

Based on our current strategy and operating plan, we will need to raise additional funds in 2023. This process is ongoing and there is substantial doubt about our ability to operate as a going concern. See “Note 2 – Basis of Presentation and Going Concern” in our consolidated financial statements.

As the Company advances its clinical trials, management expects expenses to increase. These expenses include dosing and monitoring of patients who participate in our clinical trials, manufacturing expenses, payment of fees to our CRO and other service providers, and other general overhead expenses including additional public company costs. We anticipate that we have under \$100,000 in commitments to contractors and third-parties, not including employees, that we must pay even if we do not advance the clinical trials. We anticipate that we will be able to continue the clinical trials without material interruption or delay through the third quarter of 2023, but we must raise additional funds through future offerings to maintain this plan. There is no guarantee, however, that we can complete any future offerings on terms suitable to the Company and its shareholders if at all.

We have raised capital through equity and debt fundings over the last two years to advance the development of the Technology. Most recently, on March 31, 2023, we closed a total of \$2.86 million in a common stock and warrant unit offering, which consisted of 381,500 shares of common stock at \$4.50 and 381,500 two-year common stock warrants (the “Warrants”) which were all exercised. The Warrants originally had an exercise price of \$6.00 per share, but on March 31, 2023, our Board approved a reduction of the price to \$3.00 as an inducement to immediate exercise of the Warrants. All Warrant holders exercised at this reduced price, which raised an additional \$1.14 million for the Company, inclusive of \$342,669 in subscription receivables which were received in April 2023.

In the fourth quarter of 2021, we entered into convertible note purchase agreements with eight accredited investors, pursuant to which we issued an aggregate of \$605,000 of 6% annual interest, unsecured convertible notes (the “Notes”). The Notes were due to mature on December 31, 2023 and were originally convertible into shares of common stock of the Company at a conversion price of \$8.00 per share. On March 31, 2023, our Board approved a reduction of the conversion price from \$8.00 to \$3.50 as an inducement to immediate conversion. All outstanding Notes were converted into 164,446 shares of common stock. As of March 31, 2023, we had no Notes outstanding.

As of March 31, 2023, the Company had \$851,394 in cash, \$342,669 in subscription receivables that were received in April 2023, and no debt from convertible notes.

We have limited operations and are not currently generating any revenues from our business operations. Our independent registered public accounting firm has issued a going concern opinion for the year ended December 31, 2022. This means that our auditors believe there is substantial doubt that we can continue as an on-going business for the next 12 months. The unaudited financial statements do not include any adjustments that might result from the outcome of these uncertainties. The ability of the Company to continue as a going concern is dependent on management's plans. The Company has supported operations through the issuance of common stock, preferred stock and debt over the last 12 months. This includes the recent common stock and warrant offering, the Series B Preferred Stock offering in the first quarter of 2021, the exercise of warrants issued in connection with the Series B offering, and also the convertible debt offering conducted in the fourth quarter of 2021 which was recently converted to common stock. Management expects expenses to increase in 2023 as our drug technology advances through clinical trials, and as a result, we will need to raise additional capital to support these operations. There is no assurance, however, that the Company will be successful in raising the needed capital and, if funding is available, that it will be available on terms acceptable to the Company. Management believes that it has cash to support operations into the third quarter of 2023. We currently have accounts payable and accrued expenses that are greater than our cash on hand, and to extend our ability to operate under these conditions, management has deferred a large part of their salaries and we are working with vendors to delay payments until we are able to raise additional capital. Management understands that such efforts cannot be sustained indefinitely. If we are not successful in raising additional capital, we may need to delay clinical trials, reduce overhead, or in the most extreme scenario, shut down operations.

Prior Financings

Series B Financing. In January 2021, the Company closed a Series B Convertible Preferred Stock private placement (the "Series B Offering") and issued a total of 2,500 shares at a price of \$1,000 per share, raising an aggregate amount of \$2.5 million, inclusive of \$156,000 in debt conversion. The Series B Offering, which commenced in 2020, was led by Checkmate Capital Group, LLC, a California based investment firm focused on biotechnology and other technology investments. The Company completed the offering primarily to advance its new business of drug development including funding the Company's clinical trials for its drug candidate CycloSam, as well as for general working capital and overhead. There are currently 1,509 shares of Series B Stock outstanding, and as a result of the current common stock private placement, the conversion price of the Series B Stock has been reset to \$5.42 per share multiplied by the issuance price.

Warrant Conversion. In connection with this Series B Offering closing, we issued in 2021 approximately 150,000 common stock warrants, which were originally exercisable prior to July 8, 2021 at an exercise price of \$14.00 per share, and later modified by our Board to expire on October 15, 2021 and be exercisable at \$10.00 per share. As of October 15, 2021, seven holders of the Series B warrants exercised those warrants and received a total of 46,786 common shares for total consideration to the Company of \$467,858. Also in 2021, our lead investor in the Series B Offering earned a warrant for 11,875 shares exercisable at \$18.00 per share, which warrant was to expire January 15, 2022, but modified in January 2022 to expire January 15, 2023 and be exercisable at \$10.00 per share. These warrants expired in January 2023.

Series A Preferred Stock Financing. The Company raised \$600,000 in a Series A 6% Convertible Preferred Stock (the "Series A Stock") from two separate accredited investors in November 2015 and January 2016, respectively. The Series A Stock bears a 6% dividend per annum, calculable and payable per quarter in cash or additional shares of common stock as determined in the Certificate of Designation. The Series A Stock was originally convertible at \$6.50 per share at the discretion of the holders and contains price protection provisions in the instance that we issue shares at a lower price, subject to certain exemptions. The price has been reset several times since the issuance of the Series A Stock. Most currently, as a result of the current private placement offering and warrant exercise inducement, the conversion price was reset to \$3.00 per share. Series A Stockholders also received other rights and protections including piggy-back registration rights, rights of first refusal to invest in subsequent offerings, security over our assets (secondary to our debt holders), and certain negative covenant guaranties that we will not incur non-ordinary debt, enter into variable pricing security sales, redeem or repurchase stock or make distributions, and other similar warranties. The Series A Stock is redeemable on December 31, 2023, pursuant to a March 31, 2023 modification agreement signed by both Series A Stockholders. The Series A Stock has no voting rights until converted to common stock.

Attempted Underwritten Offering and NASDAQ Uplisting. In December 2021, the Company filed a registration statement on Form S-1 with the SEC to raise up to \$20 million through a common stock offering underwritten by an investment bank based in New York. Concurrently, the Company submitted an application with the NASDAQ Stock Market LLC to list its common shares on that national exchange. Due to market conditions, in May 2022, the Company terminated this offering; however, management plans to pursue a NASDAQ uplisting in the future.

Cash and Working Capital

We have incurred negative cash flows from operations since inception. As of March 31, 2023, we had an accumulated deficit of \$37,232,056 and working capital deficit of \$6,860.

Critical Accounting Policies

Our management's discussion and analysis of financial condition and results of operations is based on 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 and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the revenue and expenses incurred during the reported periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known.

Accrued Research and Development Expenses

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Our expense accruals for contract research, contract manufacturing and other contract services are based on estimates of the fees associated with services provided by the contracting organizations. Payments under some of the contracts we have with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on other information available to us. If we underestimate or overestimate the activity or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Subsequent changes in estimates may result in a material change in our accruals.

Stock-Based Compensation

We recognize stock-based compensation expense for grants of stock option awards, restricted stock units and restricted stock under our Incentive Plan to employees, nonemployees and nonemployee members of our board of directors based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. In addition, in the past we have granted performance-based stock option awards and restricted stock grants, which vest based upon our satisfying certain performance conditions. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, we estimate that these options will vest, which is based on whether we consider the options' performance conditions to be probable of attainment. Our estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods.

We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our common stock price, (ii) the periods of time over which employees and members of the board of directors are expected to hold their options prior to exercise (expected term), (iii) expected dividend yield on the common stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Our financial statements are prepared in conformity with U.S. generally accepted accounting principles (GAAP). Disclosures regarding our Critical Accounting Policies are provided in Note 3 – Summary of Significant Accounting Policies of the footnotes to our consolidated financial statements.

Off-Balance Sheet Arrangements

The Company did not engage in any "off-balance sheet arrangements" (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) as of March 31, 2023.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for smaller reporting companies.

ITEM 4: CONTROLS AND PROCEDURES

In connection with the preparation of this Quarterly Report, management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this Quarterly Report. Disclosure controls and procedures are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Management concluded that, as of March 31, 2023, the Company's disclosure controls and procedure were not effective based on the criteria in *Internal Control – Integrated Framework* issued by the COSO, version 2013 as discussed below.

Management's Quarterly Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). The Company carried out an evaluation under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's internal control over financial reporting. The Company's management used the framework in *Internal Control-Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations (COSO) to perform this evaluation. As a result of this assessment, management identified a material weaknesses in internal control over financial reporting. A material weakness is a control deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The identified material weakness is disclosed below:

- Due to the size of the Company and available resources, there are limited personnel to assist with the accounting and financial reporting function, which results in a lack of segregation of duties.

As a result of the material weakness in internal control over financial reporting described above, management concluded that, as of March 31, 2023, the Company's internal control over financial reporting was not effective based on the criteria in *Internal Control – Integrated Framework* issued by the COSO. Management notes that upon subsequent funding, the Company expects to have the available resources in order to hire additional personnel to expand the finance and accounting department in order to mitigate the material weakness noted above.

This quarterly report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to the rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting in connection with the evaluation required by Rule 13a-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q 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

We are not a party to any pending legal proceeding and, to the knowledge of our management, no federal, state or local governmental agency is presently contemplating any proceeding against us. No director, executive officer, affiliate of ours, or owner of record or beneficially of more than five percent of our common stock is a party adverse to the Company or has a material interest adverse to us in any proceeding.

ITEM 1A: RISK FACTORS

We face risks and uncertainties related to our business, many of which are beyond our control. In particular, risks associated with our business include:

- Drug development is a long and inherently uncertain process with a high risk of failure at every stage of development.
- The future of our business and operations depends on the success of our development and commercialization programs.
- If we do not obtain regulatory approval for our product candidates or if the terms of any approval impose significant restrictions or limitations on use, our business, results of operations and financial condition will be adversely affected.
- Our business is highly dependent on our lead product candidate, CycloSam[®], and a failure to obtain regulatory approval or successfully commercialize our product could adversely affect our financial condition and results of operations.
- We must design and conduct successful clinical trials for our product candidates to obtain regulatory approval. We rely on third parties to conduct our clinical trials, which reduces our control over their timing, conduct and expense and may expose us to conflicts of interest. Clinical trial results may be unfavorable or inconclusive, and often take longer and cost more than expected.
- A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, or coronavirus, may materially and adversely affect our business and our financial results.
- Even if our product candidates obtain regulatory approval, our ability to generate revenue will depend upon public perception of radiopharmaceuticals and will be diminished if our products are not accepted in the marketplace, or if we select pricing strategies for our products that are less competitive than those of our competitors, or fail to obtain acceptable prices or an adequate level of reimbursement for products from third-party payers or government agencies.
- We are subject to extensive and ongoing regulation, which can be costly and time consuming, may interfere with regulatory approval for our product candidates, and can subject us to unanticipated limitations, restrictions, delays and fines.
- Our products may face regulatory, legal or commercial challenges even after regulatory approval.
- We are increasingly dependent on information technology, and potential cyberattacks, security problems, or other disruption and expanding social media vehicles present new risks.
- We have a limited operating history and are operating at a loss, and there is no guaranty that we will become profitable.
- Because our history is limited and we are subject to intense competition, any investment in us would be inherently risky.

- There is substantial doubt as to our ability to continue as a going concern.
- We have limited funds and we will require additional financing.
- Our success will be dependent on our management, and the continued service of key employees.
- We are dependent upon third parties for a variety of functions. These arrangements may not provide us with the benefits we expect.
- Manufacturing resources could limit or adversely affect our ability to commercialize products.
- Failure of any manufacturer of our various product candidates to comply with applicable regulatory requirements could subject us to penalties and have a material adverse effect on supplies of our product candidates.
- If the use of hazardous and biological materials by us or third parties, such as CROs or CMOs, in a manner that causes injury or violates applicable law, we may be liable for damages.
- Unexpected disruptions could seriously harm our future revenue and financial condition and increase our expenditures.
- The validity, enforceability and commercial value of our patents and other intellectual property rights are highly uncertain.
- We depend on intellectual property licensed from third parties and unpatented technology, trade secrets and confidential information. If we lose any of these rights, including by failing to achieve milestone requirements or to satisfy other conditions, our business, results of operations and financial condition could be harmed.
- If we infringe third-party patent or other intellectual property rights, we may need to alter or terminate a product development program.
- We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.
- Liquidity risks associated with our common stock.
- The price of our common stock may fluctuate significantly, which could lead to losses for stockholders.
- The application of the “penny stock” rules could adversely affect the market price of our common stock and increase your transaction costs to sell those shares.
- We do not intend to pay dividends.
- The stock ownership of our management and a few other shareholders represents a significant concentration of stock ownership and control over the Company.
- The Company has Preferred Stock with additional priority rights.
- We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.
- If we fail to comply with the rules and regulations under the Sarbanes-Oxley Act, our operating results, our ability to operate our business and investors’ views of us may be harmed.
- We have historically identified certain material weaknesses in our internal control over financial reporting and if our remediation of such material weaknesses is not effective, or if we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.
- Our financial statements may be materially affected if our estimates prove to be inaccurate as a result of our limited experience in making critical accounting estimates.

These summary risk factors are qualified in their entirety by the Risk Factors provided in the Company's Form 10-K for the year ended December 31, 2022.

ITEM 2: UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

During the quarter ended March 31, 2023, and through the date of this filing, the Company made the following sales of unregistered securities.

Purpose / Holder	Number of Shares	Total Price/Amount
Sale of common stock in private placement (1)	69,834	\$ 314,239
Exercise of warrants issued in private placement (2)	381,500	\$ 1,134,677
Conversion of promissory notes into common stock (3)	164,446	\$ 519,696
Common stock issued under two service agreements (4)	46,000	\$

- (1) Issued to seven accredited investors, who also received 69,833 warrants exercisable for 24-months.
- (2) Nineteen warrant holders exercised their warrants for common stock.
- (3) Eight Convertible Note holders converted all principal and accrued interest on outstanding convertible debt.
- (4) Issued in April 2023 to Redstone Communications (30,000 shares) and Force Family Office (16,000 shares), for investor relations and other similar services.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 3: DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4: MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5: OTHER INFORMATION

- (a) There was no information required to be disclosed in a report on Form 8-K during the period that the Company failed to report.
- (b) None, not applicable.

ITEM 6: EXHIBITS

Exhibit Number	Description
31.1	302 Certification of Douglas Baum, Chief Executive Officer
31.2	302 Certification of Adam King, Chief Financial Officer
32	906 Certification
101	The following financial information from QSAM's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Stockholders Deficit, (iv) the Consolidated Statements of Cash Flows, and (vi) the Notes to Consolidated Financial Statements
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

QSAM BIOSCIENCES INC.

Date: May 15, 2023

By: /s/ Douglas Baum

Chief Executive Officer

Date: May 15, 2023

By: /s/ Adam King

Chief Financial Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
RULE 13a-14(a)/15d-14(a) CERTIFICATIONS**

I, Douglas Baum, certify that:

1. I have reviewed this quarterly report on Form 10-Q of QSAM Biosciences, Inc. for the period ending March 31, 2023;
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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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 controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly 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;
 - 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
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 function):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal controls 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 controls over financial reporting.

Date: *May 15, 2023*

By: /s/ Douglas Baum
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
RULE 13a-14(a)/15d-14(a) CERTIFICATIONS**

I, Adam King, certify that:

1. I have reviewed this quarterly report on Form 10-Q of QSAM Biosciences, Inc. for the period ending March 31, 2023;
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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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 controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly 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;
 - 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
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 function):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal controls 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 controls over financial reporting.

Date: *May 15, 2023*

By: */s/ Adam King*

Chief Financial Officer

**CERTIFICATION OF PRINCIPAL 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**

In connection with the Quarterly Report on Form 10-Q for QSAM Biosciences, Inc., (the “Company”) for the period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), Douglas Baum, Chief Executive Officer and Adam King, Chief Financial Officer, of the Company certify pursuant to 18 U.S.C. section 1350 of the Sarbanes-Oxley Act of 2002 that:

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

Date: *May 15, 2023*

By: */s/ Douglas Baum*
Chief Executive Officer

By: */s/ Adam King*
Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
