

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (date of earliest event reported): November 15, 2022

QSAM BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-55148
(Commission File
Number)

20-1602779
(IRS Employer
Identification Number)

9442 Capital of Texas Hwy N, Plaza 1, Suite 500
(Address of principal executive offices)

78759
(Zip Code)

Registrant's telephone number, including area code

(512) 343-4558

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
N/A	N/A	N/A

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On November 15, 2022, QSAM Biosciences Inc. issued a press release regarding its results of operations and financial condition for the quarter ended September 30, 2022. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit Number	Description
99.1	Press Release dated November 15, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 15, 2022

QSAM Biosciences, Inc.

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



QSAM Biosciences Reports Third Quarter 2022 Financial Results and Provides Corporate Update

Further Progress Demonstrated in Clinical Program Evaluating CycloSam® Radiopharmaceutical Drug Candidate for Treatment of Metastatic Bone Cancer

AUSTIN, Texas, November 15, 2022 – QSAM Biosciences Inc. (OTCQB: QSAM), a company developing next-generation therapeutic radiopharmaceuticals, including Samarium-153-DOTMP (CycloSam®), for the treatment of bone cancer and related diseases, today announces financial results for the third quarter ended September 30, 2022, as filed with the SEC on November 14, 2022 in the Company’s Form 10-Q, and provides a corporate update.

Recent Corporate Highlights:

- Second patient dosed in Phase 1 clinical trial; data continues to demonstrate preliminary positive results. Completion of the initial cohort grouping of patients is expected in the fourth calendar quarter.
- Rutgers Cancer Institute of New Jersey (RCINJ) has been added as a clinical trial site to begin enrolling patients; expected to help accelerate pace of study and add key expertise.
- Approximately \$1 million was raised in a common stock / warrant private placement during third quarter.

“Initial, preliminary data from our second patient dosed with CycloSam® continues to show positive signals in terms of safety and efficacy. While it is too early for formal conclusions to be made of these results, CycloSam generally performed how we expected it to perform, even given the lowest dosage in our dose-escalating study. This is all very encouraging,” stated Douglas R. Baum, CEO and co-founder of the Company.

“We expect the pace of our clinical trials to accelerate in the fourth quarter of 2022 and into 2023. This is partly due to the onboarding as a trial site the highly-regarded Rutgers Cancer Institute of New Jersey, which is a National Cancer Institute (NCI) – designated Comprehensive Cancer Center that treats a significant population of patients who could potentially qualify for our study. We have also been able to raise equity funding on favorable terms from supportive investors who share our long-term vision for QSAM. Our team continues to work towards creating shareholder value in conjunction with our most important mission to help adult and pediatric patients suffering from bone cancer,” added Baum.

Summary Financial Results for the Quarter Ended September 30, 2022: (All numbers except shares are approximated)

For the three months ended September 30, 2022, we recorded a net loss of \$1.23 million, an increase of \$0.18 million from our net loss of \$1.05 million for the same period in 2021. Our operating expenses were \$1.21 million for the third quarter of 2022 as compared to \$1.20 million in the 2021 period. The slight increase in operating expenses was largely due to an increase in compensation and related expenses of \$0.23 million, an increase in research and development expenses of \$0.08 million, and an increase in general and administrative expenses of \$0.07 million, offset by a decrease in professional fees of \$0.36 million in the three months ended September 30, 2022.

Net loss attributable to common stockholders for the third quarter of 2022 was \$1.28 million as compared to \$1.92 million for the 2021 period. The net loss attributed to common stockholders 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 September 30, 2022 was a loss of \$0.75 per share as compared to a loss of \$2.45 per share for the 2021 period.

As of September 30, 2022, we had cash on hand of \$899,290, primarily from the closing of the first tranche of a common stock and warrant private placement.

As of November 10, 2022, the Company had 1,922,142 common shares outstanding, which includes the issuance of 205,556 shares in the quarter in connection with a private placement and 30,000 shares for a services contract. At the end of the second quarter of 2022 there were approximately 705,419 shares of common stock that could be issued upon the conversion of preferred stock, warrants and convertible debt, excluding employee stock options.

The following tables summarize our results of operations for the periods indicated, and are qualified in their entirety by the Company’s Form 10-Q for the period ended September 30, 2022, filed with the SEC on November 14, 2022, including the financial footnotes contained therein:

QSAM BIOSCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash	\$ 899,290	\$ 1,499,866
Prepaid expenses and other current assets	66,159	135,014
Deferred offering costs	-	35,000
TOTAL CURRENT ASSETS	965,449	1,669,880
TOTAL ASSETS	\$ 965,449	\$ 1,669,880

LIABILITIES AND STOCKHOLDERS' DEFICIT**CURRENT LIABILITIES**

Accounts payable and accrued expenses	\$	1,020,650	\$	569,321
Accrued payroll and related expenses		810,454		95,400
Accrued Series B preferred stock dividends		266,619		153,343
Convertible notes payable, net of discount		559,625		532,400
Notes payable - related parties		7,500		7,500
Debentures		-		35,000
TOTAL CURRENT LIABILITIES		2,664,848		1,392,964
TOTAL LIABILITIES		2,664,848		1,392,964

Redeemable convertible preferred stock - Series A; \$0.0001 par value, 1,500 designated Series A, and 480 shares issued and outstanding (liquidation preference of \$714,000 and \$693,580) as of September 30, 2022 and December 31, 2021

	714,000	693,580
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STOCKHOLDERS' DEFICIT

Preferred stock, Series B, \$0.001 par value; 2,500 shares authorized, 1,509 shares issued and outstanding (liquidation preference of \$1,737,585 and \$1,662,757) as of September 30, 2022 and December 31, 2021		2		2
Preferred stock, Series E-1, \$0.0001 par value; 8,500 shares authorized, 0 shares issued and outstanding as of September 30, 2022 and December 31, 2021		-		-
Common stock, \$0.0001 par value, 300,000,000 shares authorized, 1,922,142 and 1,652,102 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively		193		165
Unearned deferred compensation		(348,548)		(900,742)
Additional paid-in capital		31,563,286		29,765,585
Accumulated deficit		(33,628,332)		(29,281,674)
TOTAL STOCKHOLDERS' DEFICIT		(2,413,399)		(416,664)

TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT

\$	965,449	\$	1,669,880
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QSAM BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2022	2021	2022	2021
REVENUES	\$ -	\$ -	\$ -	\$ -
OPERATING EXPENSES				
Payroll and related expenses	773,387	540,450	2,321,508	5,555,471
Professional fees	108,841	473,017	966,251	1,427,703
General and administrative	86,916	18,839	255,687	64,887
Research and development expenses	245,853	164,378	704,902	385,785
Total Operating Expenses	1,214,997	1,196,684	4,248,348	7,433,846
LOSS FROM OPERATIONS	(1,214,997)	(1,196,684)	(4,248,348)	(7,433,846)
OTHER INCOME (EXPENSE)				
Financing costs including interest	(18,744)	(450)	(57,084)	(38,978)
Gain on sale of equity method investment	-	-	-	100,000
Loss on debentures and accrued expenses converted to common stock	-	-	-	(390,068)
Gain on forgiveness of debt from Paycheck Protection Program	-	142,942	-	142,942
Loss on conversion of bridge notes and accrued interest	-	-	-	(744,505)
Total Other Expense, net	(18,744)	(142,492)	(57,084)	(930,609)
Loss from operations before income taxes	(1,233,741)	(1,054,192)	(4,305,432)	(8,364,455)
INCOME TAXES	-	-	-	-
NET LOSS	(1,233,741)	(1,054,192)	(4,305,432)	(8,364,455)
Series A preferred contractual dividends	(7,200)	(7,259)	(20,420)	(22,338)
Series B preferred contractual dividends	(38,034)	(168,370)	(113,276)	(168,370)
Deemed dividend on conversion of Series A preferred stock to common stock	-	-	-	(542,500)
Deemed dividend on warrant modification	-	(694,575)	(41,225)	(850,213)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (1,278,975)	\$ (1,924,396)	\$ (4,480,353)	\$ (9,947,876)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS: BASIC AND DILUTED:	\$ (0.75)	\$ (2.45)	\$ (2.66)	\$ (14.57)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: BASIC AND DILUTED	1,699,444	786,321	1,685,074	682,960

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

	For the nine months ended September 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (4,305,432)	\$ (8,364,455)
Adjustments to reconcile net loss to net cash used in operations:		
Common stock issued for services	325,719	1,039,932
Stock-based compensation to employees and directors	1,156,674	5,252,599
Loss on conversion of bridge notes and accrued interest	-	744,505
Loss on conversion of debentures and accrued expense to common stock	-	390,068
Paid-in-kind interest - convertible bridge notes	-	35,983
Amortization of debt discount	27,225	-
Gain on forgiveness of debt	-	(142,942)
Changes in operating assets and liabilities		
Decrease (increase) in prepaid expenses and other current assets	68,855	(6,301)
(Decrease) increase in accounts payable and accrued expenses	451,329	(44,392)
Increase in accrued payroll and related expenses	715,054	-
Increase in accrued interest – related parties	-	1,478
Net cash used in operating activities	<u>(1,560,576)</u>	<u>(1,093,525)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayments on promissory notes – related parties	-	(33,492)
Deferred offering costs	35,000	(35,000)
Proceeds for the issuance of preferred stock – Series B	-	2,221,000
Sale of common stock and warrants	925,000	-
Net cash provided by financing activities	<u>960,000</u>	<u>2,152,508</u>
NET INCREASE (DECREASE) IN CASH	(600,576)	1,058,982
CASH - Beginning of period	1,499,866	8,304
CASH - End of period	<u>\$ 899,290</u>	<u>\$ 1,067,287</u>
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Payment of interest in cash	\$ -	\$ -
Payment of income taxes	\$ -	\$ -
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Accrual of contractual Series A convertible preferred stock	\$ 20,420	\$ 22,238
Accrual of contractual dividends on Series B convertible preferred stock	\$ 113,276	\$ 168,370
Deemed dividend on conversion of Series A preferred stock to common stock	\$ 542,500	\$ 542,500
Deemed dividend on warrant modifications	\$ 41,225	\$ 850,213
Conversion of convertible bridge notes and accrued interest to 165,692 shares of common stock	\$ -	\$ 3,633,983
Conversion of debentures and accrued expenses to common stock	\$ -	\$ 125,000
Conversion of Series A preferred stock to common stock	\$ -	\$ 120,000
Conversion of notes payable with related parties to Series B preferred stock and warrants	\$ -	\$ 23,000

About QSAM Biosciences

QSAM Biosciences, Inc. is developing next-generation nuclear medicines for the treatment of cancer and related diseases. QSAM's initial technology, CycloSam[®] (Samarium-153 DOTMP), is a clinical-stage bone targeting radiopharmaceutical developed by IsoTherapeutics Group LLC, pioneers in the nuclear medicine space who also have developed other FDA-approved radiopharmaceutical products. QSAM is led by an experienced executive team and Board of Directors that have completed numerous FDA approvals and multiple successful biotech exits.

CycloSam[®] has demonstrated preliminary safety and efficacy in animal studies and a single patient FDA-cleared human trial performed in 2020 at the Cleveland Clinic. This nuclear technology uses low specific activity Samarium-153 (resulting in far less undesirable europium impurity) and DOTMP, a chelator which targets sites of high mineral turnover (bone) and is believed to reduce or eliminate off-target migration making it, in management's opinion, an ideal agent to treat primary and secondary bone cancers. Since CycloSam[®] delivers targeted radiation selectively to the skeletal system, it is also believed to be an important candidate for use in bone marrow ablation as pre-conditioning for bone marrow transplantation, and in procedures to reduce external beam radiation to bone tumors. This multi-patented drug candidate utilizes a radioisotope previously approved by the FDA, combined with a novel targeting chelant that has demonstrated preliminary increased efficacy and decreased side effects in animal models and veterinary treatment of bone cancer in dogs. Further, CycloSam[®] utilizes a streamlined, just-in-time manufacturing process that is well established.

Legal Notice Regarding Forward-Looking Statements This news release contains "Forward-looking Statements." These statements relate to future events or our future financial performance. These statements are only predictions and may differ materially from actual future results or events. We disclaim any intention or obligation to revise any forward-looking statements whether as a result of new information, future developments or otherwise. There are important risk factors that could cause actual results to differ from those contained in forward-looking statements, including, but not limited to our ability to fully commercialize our technology, risks associated with changes in general economic and business conditions, regulatory risks, clinical trial risks, early stage versus late stage product safety and efficacy, actions of our competitors, the extent to which we are able to develop new products and markets, supply chain risks, the time and expense involved in such development activities, the ability to secure additional financing, the ability to consummate acquisitions and ultimately integrate them, the level of demand and market acceptance of our products, and changes in our business strategies. This is not an offering of securities and securities may not be offered or sold absent registration or an applicable exemption from the registration requirements.

Corporate Communications

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