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): August 16, 2023

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

Delaware	**000-41337**	**20-1602779**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 8.01 Other Events

On August 16, 2023, QSAM Biosciences, Inc. (the "Company") issued a letter to shareholders, which was distributed as a press release on the same day. The Company may use this letter and information contained in it, possibly with modifications, in future presentations to current and potential investors, analysts, lenders, business partners, acquisition candidates, customers, employees and others with an interest in the Company and its business.

A copy of the letter to shareholders is also made available on the Company's website at https://ir.qsambio.com/. Materials on the Company's website are not part of or incorporated by reference into this report.

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	QSAM Biosciences, Inc. Press Release providing Letter to Shareholders, dated August 16, 2023.
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: August 16, 2023

QSAM Biosciences, Inc.

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

Exhibit 99.1

QSAM Biosciences Provides Update to Shareholders on Phase 1 Progress and Preliminary Clinical Data

AUSTIN, Texas, August 16, 2023 – 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 issued the following letter to its shareholders.

Dear Shareholders:

We are pleased to provide you with an update on the progress and preliminary data from our Phase 1 trial studying the safety and early signs of efficacy of CycloSam® in patients with cancer that has metastasized to the bone from the breast, lung, prostate and other organs; as well as important goals we will be looking to accomplish through the end of the year.

Initial Analysis of Trial Data - First Cohort

In the first three patients dosed with the lowest radiation levels in our study (0.5 mCi/kg), representing the first cohort (group) of trial participants, the preliminary findings are as follows:

- Safety: No serious adverse events and all three patients maintained normal red and white blood cell and platelet counts within normal ranges throughout the treatment period with slight dips that quickly recovered.

- SUV Scores: This is a biomarker that measures metabolic rates in tumor cells. Published papers correlate this biomarker with efficacy[1]. In our first patient, we measured four bone tumors and noted a 56% - 64% decrease in SUV (meaning the metabolic activity of the cancer cells was reduced by approximately half). In patients two and three, SUV scores are variable (meaning there was a mixed response with some lesions showing a decrease, some an increase, and most remaining stable, all of which was not unexpected in this first single, low-dose stage of the trial).

- RECIST Scores: This is a measurement of the size of tumors before and after CycloSam® administrations and accompanying CT scans; and is used in later stage trials to determine efficacy. In patients one and three, we saw no progression of tumor size at the four month follow-up. In patient two, we saw a 53% reduction in tumor size in one lesion and the second lesion completely resolved, measuring 0 mm.

- Pain Scores: The first two patients experienced significant pain relief and improved mobility within a week after treatment, which lasted for approximately six months. The third patient, whose cancer had metastasized to the spine from the breast, experienced moderate pain relief. This limited pain relief in patient three may be attributable to the size and particular location of the tumor in the spine.

[1] Marin, et al., (2021), Whole Skeletal Mean SUV Measured on 18F-NaF PET/CT Studies as a Prognostic Indicator in Patients with Bone Metastatic Breast Cancer doi:10.2967/jnmt.121.262907. Baucknehtt, et al., (2021), The Prognostic Power of 18F-FDG PET/CT Extends to Estimating Systemic Treatment Response Duration in Metastatic Castration-Resistant Prostate Cancer (mCRPC) Patients, Doi:10.1038/s41391-021-00391-8.

We are highly encouraged by these results. We must remind our shareholders, however, that these results are very early and are not necessarily indicative of future results in our trials. Further, this summary is not a formal read-out of data, but rather, a preliminary analysis of our Cohort 1 findings.

Last month we dosed patient number four in our trial with the next higher level of radiation (1 mCi/kg), and we are currently screening for patient number five. Provided our safety targets are hit, as we saw in the initial patients, the fifth patient would complete our second of four cohorts and allow us to progress to the next higher-dose cohort.

It is our goal to complete Cohort 3 by the end of the year, which will set us up to complete Phase 1 in Q1 2024. This is a few months behind our original timetable; but we believe the groundwork we have achieved over the last six months — including initiating new trial sites, qualifying a second nuclear reactor, completing several important manufacturing studies and tasks, and implementing and launching a fully-integrated digital and social media patient recruitment strategy — will help us advance more quickly into and through the critical Phase 2 efficacy trials next year.

Market Opportunity and Growth of the Broader Radiopharmaceutical Sector

With respect to the market for a bone directed radiotherapeutic agent, we continue to refine and define the potential patient population and future market opportunities. In the United States, there are over 400,000 new patients diagnosed each year with metastatic bone cancer and 350,000 patient deaths.[2] The incidence of advanced malignant tumors with bone metastasis can be up to 70%, especially common in patients with advanced prostate and breast cancer.[3] More specifically, we believe there is a great need for a bone directed radiopharmaceutical to fill significant gaps in treatment plans arising in instances that may include the following:

1) Female breast cancer represents the largest percentage of cancer diagnoses (31%) with 65%-75% of patients having relative cancer incidence in the bone and a median survival from diagnosis of 19-25 months. [2,4]

2) Prostate cancer represents the second largest percentage of cancer diagnoses (29%) with 65%-75% of patients having relative cancer incidence in the bone and a median survival from diagnosis of 12-53 months. [2,4] Up to 20% of these patients' prostate cancer does not express PSMA[5] and, therefore, are not ideal candidates for currently approved PSMA targeted treatment options.

3) Lung cancer is the third largest cancer diagnosis (13%) with 30%-40% having relative incidence in the bone and only a median survival of 6 months from diagnosis.[2,4]

Concentrating on these specific areas of high unmet need is not only important for the well being and survival of cancer patients, but also for the pharmaceutical companies that are commercializing radiopharmaceutical drugs to treat the types of cancer that often metastasize to the bone. This oncology sector has seen significant commercial growth in just the last year, driven in large part by new PSMA directed multi-dose radiotherapies which are showing promise in the fight against prostate cancer. This success has created an environment whereby frontline physicians treating these diseases may be more likely now to look to radiopharmaceuticals as a first or second line of therapy for their patients.

[2] Huang, J., et al., (2020). Incidence Of Patients with Bone Metastases At Diagnosis Of Solid Tumors In Adults: A Large Population-Based Study. Doi: 10.21037/atm.2020.03.55.

[3] Colsia, et al., (2022). The Burden of Metastatic Cancer-Induced Bone Pain: A Narrative Review. Doi:10.2147/JPR.S371337.

[4] Cancer Facts & Figures 2023, American Cancer Society (cancer.org), Atlanta, Georgia, 2023; Wang, et al., (2019). Bone Tropism in Cancer Metastases , Doi:10.1101/cshperspect.a036848.
[5] Shore, et al, (2022). How Can PSMA Provide a Tailored Approach in Advanced Prostate Cancer.

Furthermore, the supply chains and infrastructure supporting the use of radiopharmaceuticals – drugs that require certain specialized manufacturing processes and just-in-time delivery to the point-of-care – are rapidly expanding to meet this new demand. We believe this emerging ecosystem surrounding the use and supply of radiopharmaceuticals is extremely positive for the future of CycloSam®.

Capital Requirements and Plans

The plans we have outlined will require capital. We reiterate our previously discussed strategy to seek this capital most likely through an underwritten offering and concurrent NASDAQ listing to fund our clinical trials through Phase 2 and possibly initiate additional trials. We estimate that this equity raise will be possible in Q4 this year, but of course, we cannot guarantee timing or success given market conditions and other external factors that may be beyond our control. Management is currently working towards this corporate objective, but there is always the possibility that other opportunities may arise that could provide greater value to our shareholders.

We look forward to more progress in the second half of 2023, which we expect will continue to de-risk our technology and create value for our shareholders. We are confident in our team, our technology, and our ability to advance CycloSam® through the FDA process. Ultimately, however, our primary mission is to help the hundreds of thousands of adults and children each year suffering from bone cancer.

Thank you again for your support.

Sincerely,
C. Richard Piazza, Executive Chairman and Co-Founder
Douglas Baum, CEO and Co-Founder

About QSAM Biosciences

QSAM Biosciences, Inc. is developing next-generation nuclear medicines for the treatment of cancer and other 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 developed the FDA-approved Quadramet® (Samarium-153 EDTMP), which is indicated for bone cancer pain palliation. QSAM is led by an experienced executive team and board of directors that have completed numerous FDA approvals and multiple successful biotech exits.

CycloSam® is currently being studied in an open-label, dose escalating Phase 1 safety study at four clinical trial sites in the United States, with a focus on bone cancer that has metastasized from the breast, lung, prostate or other organs. The drug candidate has demonstrated preliminary safety and efficacy in animal studies and a single patient FDA-cleared human trial performed in 2020 at the Cleveland Clinic. QSAM has also received Orphan Drug and Rare Pediatric Disease Designations from the FDA for the indication of osteosarcoma, a disease that mostly affects children and young adults.

CycloSam® uses a patented formulation of low specific activity Samarium-153 (resulting in far less long-lived europium impurities) and DOTMP, a chelator that targets sites of high bone turnover and is believed to reduce or eliminate off-target migration, making it, in management's opinion based on scientific data, an ideal agent to treat primary and secondary bone cancers. Through the carrier vehicle DOTMP, CycloSam® delivers targeted radiation selectively to the skeletal system with high uptake adjacent to areas of bone tumors where the beta-emitting Samarium-153 can irradiate and potentially destroy cancer cells. Because of CycloSam's mechanism of action and demonstrated safety profile to date, it is also believed to be a candidate for effectiveness trials in bone marrow ablation as preconditioning for stem cell transplantation, as well as in procedures to reduce external beam radiation to bone tumors. Further, CycloSam® utilizes a streamlined, just-in-time manufacturing process that is already significantly in place. Given these factors, management believes there is a strong pathway to commercialization for CycloSam®.

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, pandemic or endemic related issues or delays, 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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