January 10, 2023

QSAM Biosciences Provides 2022 Update and 2023 Milestones to Shareholders

AUSTIN, Texas, Jan. 10, 2023 (GLOBE NEWSWIRE) -- 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 provides the following update to shareholders regarding progress made in 2022 and milestone goals for 2023.

Dear Shareholders:

We are pleased to provide you with an update on QSAM Biosciences' progress over the last year and what you can expect from us in 2023.

As many of you are aware, we are developing our lead therapeutic radiopharmaceutical drug candidate, CycloSam®, to treat cancer that has either originated in the bone or has metastasized to the bone from the breast, prostate, lung, or other organs. These are areas of high unmet medical need that affect over 400,000 new patients a year in the US, and all too often results in death. Therapeutic radiopharmaceuticals are a relatively new sector in the fight against cancer that is experiencing significant growth in application among medical professionals and interest from global pharmaceutical companies.

CycloSam® is an asset that, in our opinion, is less risky from a clinical, manufacturing and regulatory standpoint than many other new drug development efforts. In addition to strong small and large animal data, we have initiated the clinical development for CycloSam® with the benefit of human data showing efficacy in the treatment of bone tumors using a prior version of our radioisotope, Samarium-153[1]. We also have compelling data indicating safety in a single patient study we performed at the Cleveland Clinic in 2021.

We believe that what we have accomplished to date demonstrates the experience of our management team in successfully and efficiently navigating drug candidates through the FDA process. Our 2022 milestones include:

Received Rare Pediatric Disease Designation for CycloSam® for the treatment osteosarcoma, a devastating form of bone cancer that afflicts mostly children and young adults. This designation is in addition to the **Orphan Drug Designation** received in 2021 and may provide substantial financial incentives by making QSAM eligible for a transferrable and saleable Priority Review Voucher (PRV) upon drug approval by the FDA.

Dosed initial two patients in our Phase 1 clinical trial The preliminary data we have collected demonstrate early signs of safety and efficacy. CycloSam performed in these two patients in the same manner observed in animal patients in that the drug and its highly

targeted radiation was delivered to the bone at and around the site of tumors and the remainder of the drug product was then rapidly eliminated from the body. Further, both patients reported a significant reduction of pain, even months after the dosing. This is early data that may not be indicative of future results, but it is quite encouraging.

Established two clinical trial sites, including Rutgers Cancer Institute of New Jersey (RCINJ), part of Rutgers Health and New Jersey's only National Cancer Institute (NCI) – designated Comprehensive Cancer Center, an elite recognition that is granted competitively to institutions based on their scientific leadership, resources, and outstanding track record of research discoveries and ability to translate these discoveries to benefit cancer patients.

Completed approximately $1.5 million in common stock and warrant funding to continue to advance our trials; and reduced our balance sheet liabilities by approximately $800,000 in the fourth quarter and ongoing overhead expenses by approximately $600,000 per year so that we can dedicate more resources to the clinical trials.

Building upon these accomplishments, our goals for 2023 are clear and focused, primarily:

Complete our Phase 1 study, consisting of up to 17 patients, and commence our Phase 2 study which will include providing patients with multiple doses of CycloSam® over a four to six month regimen. We have preliminary data from prior investigators that demonstrates the efficacy in treating bone cancer when Samarium-153 is used on a repeated basis to bombard tumors (see the "Vienna Protocol" per FN1), and we seek to replicate relevant portions of that study starting in late 2023 with our newer version of this targeted cancer-therapy radioisotope.

Secure capital through an underwritten offering and concurrent NASDAQ uplisting to fund our clinical trials through Phase 2a, which we estimate to be approximately $12 - $15 million. Such a transaction, which we attempted but suspended in early 2022 due to market conditions, could provide our QSAM shareholders with added liquidity, and with what we believe to be a more appropriate valuation given the strength of our asset and progress achieved in our clinical studies.

In reaching these goals, shareholders should expect to see progress through several nearer-term milestones, such as: securing additional trial sites and starting enrollment of patients at those sites; completing patient cohorts (groupings) in our Phase 1 trial which will lead to escalating doses in subsequent cohorts; establishing a more robust supply chain through the qualification of additional nuclear reactors and other key vendors; and other important achievements.

QSAM will also be presenting at the Emerging Growth Conference on Wednesday, January 25, 2023. More information, including links to the presentation, will be provided in a subsequent press release closer to that date.

We are looking forward to progress in 2023 which we expect will create fundamental value for our shareholders. While we cannot predict the tide of external market forces, 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, and from all of us at QSAM, we wish you a happy, healthy and prosperous 2023.

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 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, 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.

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[1] 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.

Source: QSAM Biosciences Inc.