



March 1, 2023

QSAM BIOSCIENCES, INC. (OTCQB – QSAM)

Industry: Biotechnology

Price Target: \$11.00



QSAM BIOSCIENCES, INC.

Positioned to Transform Treatment of Bone Cancer and Related Diseases

Rob Goldman March 1, 2023

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QSAM BIOSCIENCES INC. (OTCQB – QSAM - \$4.31)		
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COMPANY SNAPSHOT

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.

KEY STATISTICS

Price as of 2/28/23	\$4.31
52 Week High – Low	\$14.00 - \$3.50
Est. Shares Outstanding	3.2M
Market Capitalization	\$13.8M
Average Volume	1,836
Exchange	OTCQB

COMPANY INFORMATION

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INVESTMENT HIGHLIGHTS

QSAM is poised to emerge as a key player in bone cancer treatment via its focus on the novel use of radiopharmaceutical therapy (RPT). RPT has significant advantages over existing therapies, such as chemotherapy.

The RPT market is huge and a migration toward its use, along with high value M&A, are on the rise. The market is expected to reach \$9.6 billion in 2026, up from about \$4.8 billion in 2018.

QSAM's lead product is a clinical-stage bone seeking cancer-killing therapy. This product features a specialized binding molecule designed to safely and specifically deliver targeted radiation therapy to sites of high mineral turnover in the skeletal system found around bone tumors and kill cancer cells via a radioisotope.

The Company is on track to meet a series of key developmental milestones and has dosed 3 patients in its Phase 1 clinical trial. These events should lead to the next clinical phase and a potentially major increase in QSAM's market value.

Our \$11.00 twelve-month price target reflects a NPV for QSAM, based on industry transactions and its publicly traded peer group. Further, we believe QSAM could be sold in 24-36 months, when key milestones are achieved. Investors should be confident in such an exit as QSAM's leadership has shepherded numerous drugs and devices through the FDA and sold companies in the space.

COMPANY OVERVIEW

The View from 30,000 Feet

An emerging firm in radiopharmaceuticals therapy, **QSAM Biosciences**, **Inc.** (**OTCQB: QSAM**) is poised to emerge as a key player in bone cancer treatment via its focus on the novel use of radiopharmaceutical therapy (RPT). QSAM is developing next-generation, targeted therapeutic radiopharmaceuticals, including lead therapeutic candidate Samarium-153-DOTMP (*CycloSam®*), for which the Company has made significant progress since our initial report in January 2021. There has been a huge surge in the use of radiopharmaceuticals for the diagnosis and treatment of chronic diseases, with the market expected to reach \$13.8 billion in 2028, up from about \$7.6 billion in 2021.

CycloSam® is being developed to treat cancer that has either originated in the bone or has metastasized to the bone from the breast, lung, prostate, and other organs. These are areas of high unmet medical need that affect over 400,000 new patients a year in the US, and unfortunately can often result in death. Although the development and use of therapeutic radiopharmaceuticals are a relatively new approach in the fight against cancer, it is experiencing meaningful growth in application among medical professionals and interest from global pharmaceutical companies.

CycloSam®, is a clinical-stage bone seeking therapy along with a specialized binding molecule designed to safely and specifically deliver targeted radiation therapy to sites of high mineral turnover in the skeletal system found around bone tumors and kill cancer cells via a radioisotope. In animal studies and a recent small human trial, this approach appears to show early signs of efficacy and safety.

Initial research has identified four initial potential indications for *CycloSam®*, which represent a large, multi-billion-dollar market. This includes osteosarcoma, Ewing's sarcoma, metastatic bone cancers, and bone marrow ablation. Following the completion of its Phase I study focused on metastatic bone cancer, QSAM plans to commence a new, multi-site Phase 2A clinical trial in the US to further the development of the therapy, which has 8 patents issued and 6 pending.

Competitive Positioning

Management believes that *CycloSam®* offers hidden value to the Company as compared with other approaches seeking to treat bone cancer and other related diseases. Interestingly, this asset may offer meaningful opportunity from a clinical perspective and perhaps less risk from a manufacturing, regulatory, and clinical standpoint than many other new drug development efforts.

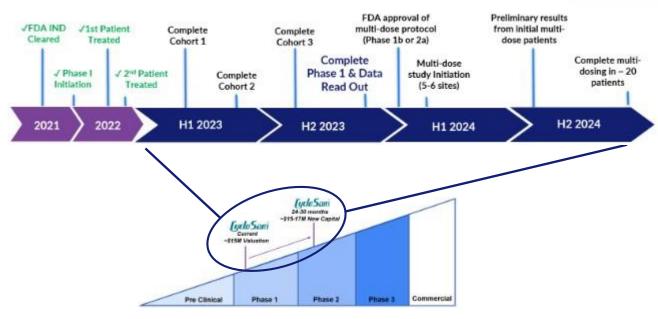
CycloSam® recorded strong small and large animal data and provided QSAM compelling data indicating safety in a single patient study performed at the Cleveland Clinic in 2020. This event served as the catalyst for the Company electing to initiate the clinical development for CycloSam® with the benefit of human data showing efficacy in the treatment of bone tumors using a prior version of the radioisotope, Samarium-153.

Leveraging these favorable events along the R&D path, QSAM has been awarded a series of designations for *CycloSam®*. These include Orphan Drug Designation and Rare Pediatric Disease Designation for *CycloSam®* for the treatment osteosarcoma, a devastating form of bone cancer that afflicts mostly children and young adults. The Orphan Drug Designation can lead to a Priority Review, expediting the FDA approval process. Moreover, Rare Pediatric Disease Designation makes QSAM eligible to receive a Priority Review Voucher that is transferable upon drug approval by the FDA and could lead to financial incentives for a prospective buyer of QSAM. In August 2019, AstraZeneca purchased a Priority Review for \$95 million and in February 2022, BioMarin sold a PRV for \$110 million. Surely, a PRV for Pediatric Cancers (such as Osteosarcoma) would offer upside to an acquirer.

Looking Ahead

Near-Term Milestones & Value Inflection Points





Forward looking statements – actual results may differ materially.

Image 1: QSAM Development Timeline

Source: QSAM Biosciences, Inc.

QSAM has completed the completion of enrollment in the first participant grouping of its Phase 1 study evaluating *CycloSam*® in the treatment of bone cancer. The Company has now dosed three patients in its Phase 1 clinical study. The preliminary data collected demonstrate early signs of safety and efficacy, although the Company states that such early results may not be indicative of future trial results. *CycloSam*® performed in these three patients in the same manner observed in animal studies in that the drug and its highly targeted radiation was delivered to the bone at and around the site of tumors. Plus, the remainder of the drug product was then rapidly eliminated from the body. Further, patients reported a significant reduction in pain, even months after the dosing.

Against this favorable backdrop, QSAM is enrolling patients in multiple sites, including the Rutgers Cancer Institute of New Jersey and the Ellis Fischel Cancer Center at the University of Missouri, with more sites slated to come online in the coming months. Management seeks to enroll and treat as many as 17 patients in the Phase 1 trial. During this time, we expect QSAM could raise \$15-\$17M to launch its Phase 2A study, leveraging its strong assets and very positive development path. Management planned to conclude such a raise in conjunction with an up-listing to NASDAQ last year but elected to defer the funding until market conditions improved.

Once the Phase I study is complete, QSAM plans to commence a Phase 2 study in 1H24 which will include providing patients with multiple doses of *CycloSam®* over a four-to-six-month regimen. Preliminary data from prior investigators demonstrate efficacy in treating bone cancer when Samarium-153 is used on a repeated basis to bombard tumors. As a result, management seeks to replicate relevant portions of that study starting in 2024 with the Company's newer version of this targeted cancer-therapy radioisotope. At this juncture, we believe that QSAM may seek to enroll up to 30 patients for this Phase 2A study with the potential for top-line data release in 24+ months.

Valuation

If multi-dose data and efficacy matches QSAM's primary and secondary objectives, we believe that this data could serve as a catalyst for a mid-tier – to top tier pharmaceutical firm to either acquire QSAM or seek to enter into an investment and related licensing or partnership arrangement in exchange for future R&D. Similar transactions have valued underlying companies in the billions of dollars. If endpoints and objectives are met, it is possible that an acquisition or other deal could be in the cards in 24-36 months, though perhaps not in the billions as some of the QSAM peer transactions have recorded. But a future deal in the hundreds of millions is not out of the question, in our view. Peer transactions include:

- Bayer acquired Xofigo® for \$800M, Algeta for \$2.9B
- Novartis (NYSE: NVS) acquired Endocyte w/2 Phase 2 drugs (Pluvicto) for \$2.1B
- Novartis acquired AAA 2 NDAs in process (Lutathera) for \$3.9B

In 2022:

- Lantheus (NASDAQ: LNTH) licensed 2 Phase 3 drugs from Point BioPharma for \$2B
- Full Life Therapeutics acquires Focus-X (2 preclinical assets) for \$245M

It should be noted that to date, the acquired assets have proven valuable to the buyers. Bayer's Xofigo® achieved peak annual sales of \$464M while Novartis' Lutathera generated \$445M in sales in 2020. The recently approved Pluvicto recorded 3Q22 sales of \$80M for Novartis and offers a reportedly estimated \$2B in annual sales in the next two years.

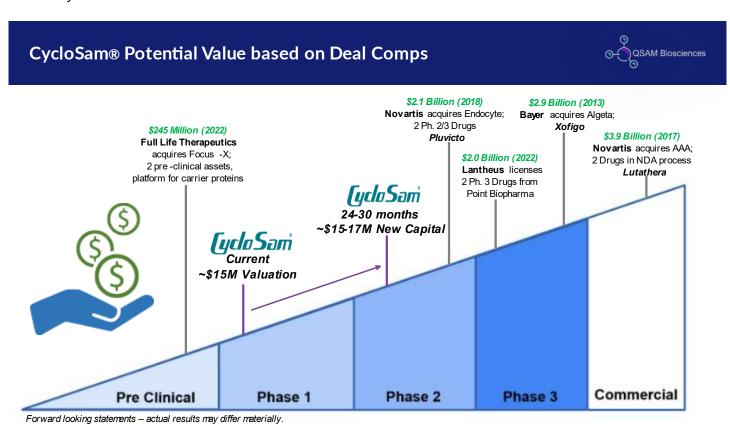


Image 2: QSAM Peer Transactions Source: QSAM Biosciences, Inc.

In addition to the peer transactions, a handful of publicly traded peers at a similar development phase, trade at outsized valuations. Notably, **Fusion Pharmaceuticals Inc. (NASDAQ: FUSN)** has products in Phase I and just recently made an acquisition of another asset in conjunction with a \$60M public offering. Since the deal closed, Fusion's market cap has risen by 36% to the \$210M level. In addition to its assets, Fusion has a development collaboration with **Astra Zeneca (NASDAQ: AZN)** that includes milestone and other payments. As illustrated in the image below, three of the four firms are at the Phase 1/2 level and have executed partnerships with major pharmaceutical firms. Thus, our thesis remains that QSAM remains on a similar track.

Public Market Comps Support Opportunity for Significant Valuation Appreciation



Company	Transactions	Clinical Asset(s)	Stage	Market Cap*
Fusion	R&D Partnership AstraZeneca	Three/Alpha Prostate, Solid Tumors "Fast -Clear" Linker	Phase I	Nasdaq: FUSN \$210M
AlpheTAU	2021 SPAC Transaction Israeli Corp.	Four/Alpha Skin, Oral, Prostate, Pancreas "Alpha DaRT" Brachytherapy	Phase I/II	Nasdaq: DRTS \$216M
Actinium Pharmaceuticals, Inc.	Partnerships: astellas ONCOLOGY	One/Beta Leukemia/Stem Cell Transplant Three in Phase 1 - Alpha/Beta	Phase I/III	NYSE: ATNM \$252M
BIOPHARMA	Partnerships and Investors: Common Gommon INNOVATION Common	Two/Beta Prostate and Gastro "Can -SEEK" Activation	Phase III	Nasdaq: PNT \$795M

^{*} Public information as oFebruary 272023

Image 3: QSAM Public Comps Source: QSAM Biosciences, Inc.

Our \$11.00 twelve-month price target is directly based upon a discount to the valuations which were afforded QSAM peers upon reaching similar, key development milestones and engaging in investment or acquisition transactions with Big Pharma players. As a corollary, we have provided the current valuation for QSAM's publicly traded peers. These smaller firms are currently in a similar development phase as QSAM but trade at greater valuations reflecting Big Pharma partnerships and multiple assets presently in R&D.

In our view, these series of M&A and pubco valuations represent the potential value for QSAM in the next 24-36 months. Our current target valuation could be considered conservative as the Company's lead candidate could treat multiple, large markets, offers inherent competitive advantages, deep IP, and positioning for potential expedited approval. Still, we elected to use a \$150M valuation in the next 30+ months, discounted back 24 months to reflect our year-end target timing. We note that this 30+month timeframe matches the projected Phase 2 milestone of dosage completion and the release of top-line data. This NPV calculation included a 40% discount rate thus arriving at a roughly \$75M Net Present Value. The \$11.00 figure is arrived by dividing \$75M by an estimated future shares outstanding of 7.2M, reflecting an expected \$15-17M in equity funding.

We should note that QSAM's leadership has shepherded numerous drugs and devices through the FDA and sold companies in the space while serving in C-level status and have a combined 100+ years of successful healthcare experience. In fact, senior advisors to the Company could be considered the de facto experts in the field of radiopharmaceuticals as they spent more than 30 years each at Dow Chemical helping build that Company's radiopharmaceutical division. Moreover, they led development of *Quadramet*, an injectable radiopharmaceutical used for pain relief in cancer patients suffering from osteoblastic metastatic bone lesions.

Against this backdrop, we believe that once top-line data is released and dosing is completed, the value of QSAM could be well beyond our current \$11.00 price target. An opportunistic, larger firm could strike a deal to continue development for current and new huge market indications making the product's total addressable market (TAM) even larger and more valuable to a firm with its own salesforce.

RADIOPHARMACEUTICALS: A PRIMER

There has been a surge in the use of radiopharmaceuticals for the diagnosis and treatment of chronic diseases in recent years, with the market expected to reach \$9.6 billion in 2026, up from about \$4.8 billion in 2018. According to an article published in a July 2020 edition of Nature.com:

"Radiopharmaceutical therapy (RPT) is defined by the delivery of radioactive atoms to tumor-associated targets. RPT is a novel therapeutic modality for the treatment of cancer, providing several advantages over existing therapeutic approaches. Unlike radiotherapy, the radiation is not administered from outside the body, but instead is delivered systemically or locoregionally, akin to chemotherapy or biologically targeted therapy. The cytotoxic radiation is delivered to cancer cells or to their microenvironment either directly or, more typically, using delivery vehicles that either bind specifically to endogenous targets or accumulate by a wide variety of physiological mechanisms characteristic of neoplasia, enabling a targeted therapeutic approach. Unlike biologic therapy, it is far less dependent on an understanding of signaling pathways and on identifying agents that interrupt the putative cancer phenotype-driving pathway. Notably, the clinical trial failure rate of 'targeted' (that is, biologic) cancer therapies is 97%, which is in part due to the drugs selected for clinical trial investigation targeting the wrong pathway."

Nuclear medicine imaging techniques and other advanced diagnostics to assess targeting of the agent offer a defined advantage over existing therapeutic approaches and enables a precision medicine approach to RPT delivery. Moreover, as compared with most cancer treatment options, RPT has shown efficacy with limited toxicity. In addition, unlike chemotherapy, responses with RPT agents typically do not require multiple cycles of therapy and are often observed after 1-3 injections.

Another advantage RPT has is pre-use observation. Having imaging and treatment molecules that use the same target is that imaging can then give doctors a preview of whether the treatment is likely to work. If an imaging compound administered beforehand in a PET scan finds its way to the cancer cells and is detected on the scan, then observers can assume that the corresponding radiopharmaceutical treatment will hit its target.

Product Snapshots

Bayer-acquired Xofigo® (radium Ra 223 dichloride) is used to treat prostate cancer that no longer responds to hormonal or surgical treatment that lowers testosterone. It is for men whose prostate cancer has spread to the bone with symptoms but not to other parts of the body. Radium-223 traces its roots to 1905 and has been used for skeletal metastases. Unfortunately, since its decay is 95% alpha radiation, radium-223 is estimated to give targeted osteogenic cells a radiation dose several times higher than other non-targeted tissues.

Novartis' Lutathera[®], was awarded FDA approval for treatment of neuroendocrine tumors of the pancreas and small intestine and reportedly generated \$445M in 2022 sales. Recently approved Pluvicto, is a radiopharmaceutical medication used for the treatment of prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer. Lutetium vipivotide tetraxetan is a targeted radioligand therapy. Clearly, we are in the early stages of a migration toward the broader use of RPT to treat a variety of cancers.

QSAM: A WINNING APPROACH

CycloSam® is a bone seeking therapy designed to safely and specifically deliver targeted radiation therapy in the form of the radioisotope Samarium-153 (Sm-153) to areas of bone formation by employing the proposed superior chelant (a molecule that binds to positively charged metal ions) — DOTMP. Sm-153 emits beta and gamma radiation and kills nearby cancer cells.

QSAM holds the worldwide exclusive license this clinical stage novel radiopharmaceutical meant to treat different types of bone cancer and related diseases. This technology was developed by IsoTherapeutics Group LLC, leaders in the nuclear medicine space. It should be noted that IsoTherapeutics also developed FDA-approved and commercially available *Quadramet*® (Samarium-153 EDTMP), indicated for pain palliation.

CycloSam® uses the same Sm-153 radioisotope as Quadramet®, an FDA-approved and commercially released drug, but due to the proposed new manufacturing process and improved chelant, which management believes materially reduces impurities in the formulation, efficacy and safety are expected to be significantly improved. CycloSam® was assigned to IsoTherapeutics Group's affiliated company, IGL Pharma, Inc., presently QSAM's licensor.

Bone Cancer is High Unmet Need with Significant Market Potential

Bone Metastasis
Breast, Lung, Prostate (others)

4.00K New Cases US¹ >50% of cancer results in bone metastasis ²

350K Deaths US¹ Standard of Care<u>Not</u> Effective

\$20B TAM
Using competitive pricing

Osteosarcoma & Ewings Sarcoma

~1,200 New Cases³ MOSTLY PEDIATRIC

Umb Amputation Frequent
No material treatment
advances in
40 yrs

\$125M TAM US \$100M value of Rare Pediatric Voucher

1. <u>Huane, J., et al.</u> 2020. <u>Incidence Of Patients With Bone Met astates At Diaenosis Of Solid Tumors In Adults: A Laree Population-Based Study.</u>
2. Cleveland Clinic Journal of Medicinel uly 2022,89 (7) 393-399; DOI: https://doi.org/10.3949/ccjm.89a21062

Key Statistics for Osteosarcoma (cancer.org)

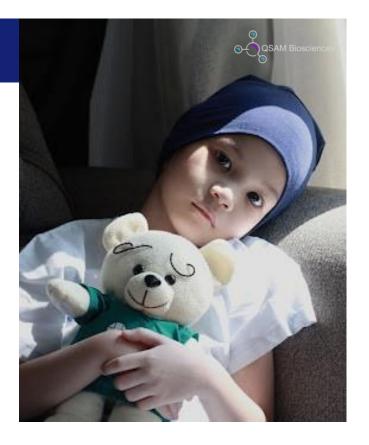


Image 4: QSAM Addressable Markets Source: QSAM Biosciences, Inc.

CycloSam® has already demonstrated preliminary safety and efficacy in animal studies and a single patient FDA-cleared successful human trial performed earlier in 2020. This nuclear technology uses low specific activity Samarium-153 (resulting in far less europium) and DOTMP, a chelator which is believed to eliminate off-target migration and targets sites of high bone turn over making it, in management's belief, an ideal agent to treat osteosarcoma or bone metastases. Osteosarcoma is the most common malignant bone tumor among children and adolescents. Due to its innate ability to deliver radiation to the skeletal system, it is also believed to be an effective agent to perform bone marrow ablation as pre-conditioning for bone marrow transplantation.

This drug candidate utilizes an FDA approved radioisotope combined with a novel chelant that has demonstrated increased efficacy and decreased side effects in animal models. Further, *CycloSam*® utilizes a streamlined, just-in-time manufacturing process. Given these factors, management believes there is a strong pathway to commercialization.

Osteosarcoma is the most common primary bone cancer with 800-900 cases per year affecting adolescents and adults (typically people aged 10-30 years). Current treatments include surgery, amputation, radiation therapy, and chemotherapy. While the cure rate with chemotherapy on a localized basis is 70%, the metastatic disease has no cure with short life expectancies (long-term survival rates of <25%).

Metastatic bone cancers originate from other parts of the body but have metastasized to the bone. They are difficult and often times impossible to treat. The most common metastatic bone cancers originate from cancers of the prostate, breast, and lung. Seven out of every 10 breast and prostate cancer patients will have bone metastases. *CycloSam®* may or is proposed to be an effective tool for the treatment of metastatic bone cancers and as a single agent for pain palliation (similar to Xofigo® population). In combination with immunotherapy for potential systemic effect as Sm-153 increases tumor antigenicity in animal models, suggesting potential synergy with immunotherapy.

Potential to Lower High Dose Radiation

CycloSam® offers the potential to lower recommended high dose radiation to levels that reduce undesirable tissue and organ damage. Today, high dose radiation is a threat to bones in the thoracic cavity, near joints, near organs, or other sensitive tissue causes scarring of those tissues. This potential indication could be separate from any indication for primary treatment of a cancer and is often to assist with a goal of reduction in radiation that is part of an overall treatment program for bone cancer.

QSAM LEADERSHIP TEAM

Executive Team

C. Richard Piazza, Ph.D., Executive Chairman

Mr. Piazza was appointed as a member and the Executive Chairman of the board of the Company in November 2020. Mr. Piazza has also served since 2017 as President and CEO of IGL Pharma Inc., the licensor of CycloSam®, and a consultant to IsoTherapeutics Group, LLC, the inventors of the technology. Mr. Piazza also currently serves on the board of directors of NovaScan LLC, a privately held cancer detection and diagnostics company. Prior to his work with IGL Pharma, from 2014 to 2016, he was CEO of SynVivo, Inc., a cancer diagnostics company. Mr. Piazza has more than 48 years of healthcare experience in both medical devices and pharmaceutical/biotech and has led several technology companies to market success including numerous FDA approvals in both sectors. Previously, he served in general management positions in both public and private international companies including Ohmeda, Smith & Nephew Pharmaceuticals, Marquest and VitaGen (world's first bioartifical liver). Over his career, he has provided advisory services to some of world's leading institutions including MD Anderson Cancer Center, Baylor College of Medicine, University of California San Diego, University of Chicago and Kings College Hospital (London). In 2019, he co-founded QSAM Therapeutics, Inc. with Douglas Baum, CEO. Mr. Piazza obtained a BS in Economics and a BS in Speech Pathology from the State University of New York and MA & PhD in Economics from the University of Buffalo and Leeds University.

Douglas R. Baum, Chief Executive Officer & Director

Mr. Baum was appointed to the board of the Company in January 2020 and to the position of CEO in November 2020. He brings to the Company over 30 years of experience in the bioscience and biotech industries, including development, FDA/EMA approval and commercialization of multiple drugs and medical devices. Over his long senior executive tenure, he has overseen 15 product approvals through the FDA and EMA and raised over \$85 million in capital to fund breakthrough technologies. Between 2017 and 2020, Mr. Baum consulted with multiple medical schools, biotech and pharmaceutical companies; and between 2012 and 2017, he served as President, Chief Executive Officer and Director of Xeris Pharmaceuticals Inc. (currently, NASDAQ: XERS). Previously, he served as Executive Vice President and Chief Operating Officer of Macuclear Inc., and other executive level positions with clinical trial research firms including SCIREX and Premier Research Group, Inc. He holds a Master of Science in Technology Commercialization and BBA in International Business and Marketing from the University of Texas.

Christopher Nelson, General Counsel

Mr. Nelson has been General Counsel of the Company since 2015 and was appointed as Secretary by the board of directors on March 23, 2022. He was our President from 2016 to November 2020 and director from 2015 to March 2022. In these roles, he has overseen corporate and governance legal matters, finance and business development for the Company. He has also served since 2016 as Managing Director of GreenBlock Capital LLC in Palm Beach, Florida, a boutique mergers and acquisitions advisory firm specializing in biotechnology, agtechnology and similar sector business combination transactions; and since 2019 as General Counsel for Earth Property Holdings, LLC, a private equity-backed company engaged in soil health and compost manufacturing in Texas and Florida. Mr. Nelson has practiced law in Florida for over 26 years, and during that time has represented many start-up, early stage and established businesses seeking financing, acquisitions and general growth management counseling. Earlier in his career, Mr. Nelson was an associate with Greenberg Traurig PA, and an associate with Akerman Senterfitt PA, both in Miami, Florida. At both firms he served in their corporate and securities practice, representing NYSE and NASDAQ companies. Mr. Nelson received a BA from Princeton University, and JD from University of Miami School of Law, and is a member of the Florida Bar.

Adam King, CPA, Chief Financial Officer

Mr. King was appointed as CFO of the Company on March 3, 2022, a position he has held in interim role since December 6, 2021. Mr. King is the founder and CEO of King Consulting Group, where he provides a range of financial and reporting services for clients that include large private equity-backed international companies to small start-ups. Before founding King Consulting Group in January 2021, Mr. King was the CFO for Netsertive, a venture-backed digital marketing company in Research Triangle Park, North Carolina. From 2016 to 2018, he was Office Managing Audit Director for BDO's Greenville, SC office, in addition to Audit Director in Raleigh, NC, and Boston. While at BDO, Mr. King worked with various clients, from Tech and Life Science start-ups to large billion-dollar publicly traded companies. Before his time at BDO, he served as the Director of Revenue Assurance

and Internal Controls at Bandwidth.com and as Audit Manager at Ernst & Young. Mr. King holds a Bachelor of Science in Accounting from Elon University and is a CPA in Raleigh, NC.

Directors and Advisors

Charles J. Link, Jr., Director

Dr. Link was appointed to the Board in February 2021 and brings decades of biotech and drug development experience to the Company. He currently serves on the executive committee of the Board of Directors at NovaScan Inc., a clinical-stage company focused on cancer detection. Dr. Link also serves on the Board of Directors for Viewpoint Molecular Targeting, a clinical stage company developing alpha-particle radiopharmaceuticals; and is the founder and Executive Director of biotech start-up Syncromune. He is also a founder of biotech start-up ChainLink Pharma. Previously, Dr. Link was the CEO, CSO, Chairman, and founder of NewLink Genetics, a NASDAQ-listed immunotherapy company focused on developing novel immuno-oncology product candidates, from 1999 until his retirement in 2019. During his tenure at NewLink, Dr. Link led a series of collaborative transactions totaling hundreds of millions of dollars with Merck, Roche and the United States government. He also oversaw the collaboration with Merck to develop EVERBO, the first Ebola vaccine to receive FDA approval. Prior to founding NewLink Genetics, Dr. Link was an attending physician at the National Cancer Institute. He has authored more than 100 peer-reviewed papers. Dr. Link received an M.D. from Stanford University, and he attended the U.S. Air Force Academy.

Adriann Sax, Director

Ms. Sax was appointed Director in January 2022. She has a distinguished 30+ year career in biotech and life sciences, serving in leadership, operational and business development roles with a focus on oncology for both Fortune 100 and start-up companies. Since May 2020, she has served as CEO and co-founder of Vetigenics LLC, an animal health biotech company, where she has secured partnerships with Merck, obtained federal grants, and was named 2021 Start-up of the Year by the Penn Center for Innovation at the University of Pennsylvania. From 2019 to 2020, she served as CEO and Director of Orsenix LLC, a clinical staged oncology biotech, and from 2014 through 2019, as Entrepreneur in Residence at Fortress Biotech. Previously she was EVP and Chief Commercial Officer at Kadmon Corp., a division of Sanofi Company, and before that served in various leadership capacities at large pharmaceutical companies, notably Vice President at Bristol Myers Squibb, Executive Director at Merck & Co., and Executive Vice President in charge of Business Development and Strategic Planning at King Pharmaceuticals, leading to its \$6.5 Billion acquisition by Pfizer. Ms. Sax holds an MBA from the Keller Graduate School and a BS in Animal Science from the University of Delaware. She is an active advisor and board member for many industry associations, academic institutions, and non-public company boards.

Barry Sugarman, Scientific Advisor

Mr. Sugarman has held the position of senior regulatory and scientific advisor with the Company since November 2020. Mr. Sugarman has over 30 years of experience spanning public and private companies in the pharmaceutical, medical device, dietary supplement and cosmetic industries. Mr. Sugarman has considerable direct experience in pharmaceutical product development, manufacturing, clinical trials, regulatory affairs, FDA and government relations, marketing, and distribution; as well as Good Manufacturing Practices (GMP's), Good Clinical Practices (GCP's), Good Laboratory Practices (GLP's), and International Conference for Harmonization (ICH) requirements. He is an author and co-author of numerous FDA filings and approvals including Investigational New Drug Applications, New Drug Applications, Abbreviated New Drug Applications, and Medical Device Applications 510(k)'s. Mr. Sugarman is a member of the Regulatory Affairs Professional Society, American Association of Pharmaceutical Scientists, Association of Clinical Research Professionals, and the National Association of Corporate Directors. He is a co-author of "Prompt, Accurate Diagnosis of Pediatric Cancer and Leukemia for Pediatricians, Orthopedists, and Family Practitioners" (2007).

Richard "Keith" Frank, Scientific Advisor

Dr. Frank has served as scientific advisor to the Company since April 2020. Since 2006, he has served as CEO, President and co-founder of IsoTherapeutics Group, LLC, a radiopharmaceutical R&D and contract manufacturing company that invented CycloSam® and provides services for both large and small biotechnology companies. He also serves as Chairman of IGL Pharma, Inc., the Company's licensor of CycloSam®. Prior to these positions, Dr. Frank spent over 20 years in numerous senior scientific positions at Dow Chemical Company. At Dow, he was a collaborator in the development of bone-seeking radiopharmaceuticals Quadramet (Sm-153-EDTMP) and STR (Ho-166-DOTMP). Additionally, Dr. Frank was the lead inventor of lotrex™ for use in the GliaSite® Radiation Therapy System. He also initiated and was the technical leader of Dow's ChelaMedSM Radiopharmaceutical Services offering.

Jaime "Jim" Simon, Scientific Advisor

Dr. Simon has served as scientific advisor to the Company since April 2020. Since 2006, he has served as Vice President and Chief Science Officer, and co-founder of IsoTherapeutics Group, LLC, a radiopharmaceutical R&D and contract manufacturing company that invented CycloSam® and provides services for both large and small biotechnology companies. Prior to co-founding IsoTherapeutics, Dr. Simon spent over 25 years as a senior scientist at Dow Chemical Company where his initial proposals led to the creation of Dow's radiopharmaceutical group. At Dow, Dr. Simon was the lead inventor for all bone agent patents including Sm-153-EDTMP and Ho-166-DOTMP. Dr. Simon has been involved in numerous FDA submissions for clinical trials and has coordinated the radioisotope activities at the University of Missouri Research Reactor (isotope production), the University of Missouri Veterinary School (dog studies), and The Harry S. Truman Veterans Administration Hospital (human clinical studies).

FINANCIALS AND VALUATION SNAPSHOT

Management runs a tight ship at QSAM. It is expected that QSAM will reach a series of milestones in 2023 and 2024 which should serve as catalysts for the Company's stock, including Phase I study progress such as enrollment, and the addition of new sites, leading to commencement of the Phase 2 study in early 2024. Management believes that future development efforts will require a \$15-\$17 funding which would cover the studies, additional IP filings, and limited G&A expenses for the next 18-24 months.

As is the case with most R&D stage companies, we believe that a series of valuation "steps" could occur, prior to a potential exit in 24+ months time. Based on addressable market sizes, underlying diseases and the number of indications, the current R&D phase(s), studies data, IP, and other factors, biotech companies are afforded market values based upon where they stand upon the development path. Top-line data of a Phase I and the transition to a Phase 2 study is a related "step" along the valuation path.

Given the underlying disease category, multiple indications, method of action, safety, and efficacy we believe that QSAM shares could be afforded a \$75M market value, or \$11.00 in the next 12 months, on a NPV basis. This NPV calculation included a 40% discount rate thus arriving at a \$75M Net Present Value. The \$11.00 figure is arrived by dividing \$75M by an estimated future shares outstanding of 7.2M, reflecting an expected \$15-17M in equity funding.

Our price target is directly based upon a discount to the valuations which were afforded QSAM peers upon reaching similar, key development milestones and engaging in investment or acquisition transactions with Big Pharma players. As a corollary, we have provided the current valuation for QSAM's publicly traded peers. These smaller firms are currently in a similar development phase as QSAM but trade at greater valuations reflecting Big Pharma partnerships and multiple assets presently in R&D.

In our view, these series of M&A and pubco valuations represent the potential value for QSAM in the next 24-36 months. Our current target valuation could be considered conservative as the Company's lead candidate could treat multiple, large markets, offers inherent competitive advantages, deep IP, and positioning for potential expedited approval. Still, we elected to use a \$150M valuation in the next 30+ months, discounted back 24 months to reflect our year-end target timing. We note that this 30+month timeframe matches the projected Phase 2 milestone of dosage completion and the release of top-line data.

We should note that QSAM's leadership has shepherded numerous drugs and devices through the FDA and sold companies in the space while serving in C-level status and have a combined 100+ years of successful healthcare experience. In fact, senior advisors to the Company could be considered the de facto experts in the field of radiopharmaceuticals as they spent more than 30 years each at Dow Chemical helping build that Company's radiopharmaceutical division. Moreover, they led development of *Quadramet*, an injectable radiopharmaceutical used for pain relief in cancer patients suffering from osteoblastic metastatic bone lesions.

Against this backdrop, we believe that once top-line data is released and dosing is completed, the value of QSAM could be well beyond our current \$11.00 price target. An opportunistic, larger firm could strike a deal to continue development for current and new huge market indications making the product's total addressable market (TAM) even larger and more valuable to a firm with its own salesforce.

RISK FACTORS

In our view, the Company's biggest risk to QSAM is related to the results of the current Phase I study and the launch of the Phase 2A, multi-dosing study. Specifically, risks include reaching the enrollment targets in a timely fashion along with achieving the primary and secondary safety and efficacy objectives of the studies. It is possible that results are favorable but not statistically significant related to efficacy or QoL. These risks are consistent with those facing firms of similar size and status to QSAM. Moreover, we believe that prior study and trial results, along with the history of the use of the QSAM approach, reduce the risks outlined above. Separately, we believe that the current and prospective patent portfolio underscores the strength of the Company's platform.

Volatility and liquidity are typical concerns for microcap stocks that trade on the over the counter (OTC) stock market and can impair or delay prospective funding plans. However, given the favorable positioning and data to date, we do not believe that such a risk is material. Moreover, we believe that such a transaction could be timed in a fashion to limit potential dilution to investors. Further, since the proceeds of any future funding would be used in large part to advance major clinical development, we believe that any dilutive effect from such a funding could be offset by related increases in market value.

CONCLUSION

QSAM is poised to emerge as a key player in bone cancer treatment via its focus on the novel use of radiopharmaceutical therapy (RPT). RPT has significant advantages over existing therapies, such as chemotherapy. The RPT market is huge and a migration toward its use, along with high value M&A, are on the rise. The market is expected to reach \$9.6 billion in 2026, up from about \$4.8 billion in 2018.

QSAM's lead product is a clinical-stage bone seeking cancer-killing therapy. This product features a specialized binding molecule designed to safely and specifically deliver targeted radiation therapy to sites of high mineral turnover in the skeletal system found around bone tumors, and kill cancer cells via a radioisotope. The Company is on track to meet a series of key developmental milestones. These events should lead to the next clinical phase and a potentially major increase in QSAM's market value.

Our \$11.00 twelve-month price target reflects a NPV for QSAM, based on similar industry transactions and its publicly traded peer group. <u>Further, we believe QSAM could be sold in 24-36 months, when key milestones are achieved and initial top-line data released.</u> Investors should be confident in such an exit as QSAM's leadership has shepherded numerous drugs and devices through the FDA and sold companies in the space.



RECENT TRADING HISTORY FOR QSAM

(Source: www.StockTA.com)



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