QSAM Biosciences

January 13, 2021

QSAM BIOSCIENCES, INC.

(OTCQB – QSAM)

Industry: Biotechnology

Price Target: $3.00

QSAM BIOSCIENCES, INC.

Built for Multiple Cancer Therapy Clinical Trial Success and a Company Sale

Rob Goldman
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January 13, 2021

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Industry: Biotechnology	Price Target: $3.00

COMPANY SNAPSHOT

QSAM is developing next generation nuclear medicines for the treatment of cancer and related diseases and conditions with high unmet need. The Company's flagship product, *Cyclosam*®, is a clinical-stage bone seeking therapeutic radiopharmaceutical designed to safely and specifically deliver targeted radiation therapy to kill cancer cells in and near the bone. In animal studies and a recent single patient human trial, this approach appears to improve efficacy and safety. QSAM plans to commence additional trials during 2021.

KEY STATISTICS

Price as of 1/12/21	$0.63
52 Week High – Low	$2.10- $0.20
Est. Shares Outstanding	18.1M
Market Capitalization	$11.6M
Average Volume	39,914
Exchange	OTCQB

COMPANY INFORMATION

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INVESTMENT HIGHLIGHTS

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

The RPT market is huge, and its adoption along with 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 kill cancer cells in and near the bone via a radioisotope.

QSAM's flagship represents multiple indications with a potential addressable market in the billions. Separately, QSAM is primed to be awarded Orphan Drug Status for its lead indication and possibly an expedited program status following strong studies and a single patient human trial.

With multiple milestones ahead, our six-month target is $3.00, with $5.00 in the cards later in 2021. Management's collective experience rivals midcap biotechs, with experience getting products through FDA and negotiating successful exits. QSAM is next on the list.

COMPANY OVERVIEW

The View from 30,000 Feet

QSAM Biosciences, Inc. (OTCQB – QSAM) is poised to emerge as a key player in bone cancer treatment and other related diseases and indications via its focus on the novel use of radiopharmaceutical therapy (RPT). There has been a significant surge in the use of radiopharmaceuticals for the diagnosis and treatment of chronic diseases, with the market expected to reach $9.6 billion in 2026, up from about $4.8 billion in 2018.

The Company's flagship product, *CycloSam*®, is a clinical stage bone-seeking radiopharmaceutical therapy designed to specifically and safely deliver targeted radiation therapy to kill cancer cells in and near the bone. In animal studies and a recent single patient human trial, this approach appears to improve efficacy and safety.

Initial research has identified four potential indications for *CycloSam*® that represent a large, multi-billion-dollar market. This includes osteosarcoma, metastatic bone cancers from the breast, prostate and lungs, bone marrow ablation, and the reduction in external radiation. Later this year, QSAM plans to commence a new, multi-site clinical trial in the US to further the development of the therapy. QSAM has two issued patents in the US, one allowed patent in Europe and fourteen pending patents that protect the use of CycloSam® as a radiopharmaceutical in the U.S. and internationally.

Enviable Positioning

The Company's initial indication for *CycloSam*® is for osteosarcoma, a bone cancer afflicting 800-900 adolescents in the US each year. Current therapies are sub-optimal in terms of efficacy and quality of life (QoL). As evidenced by results from animal studies and an FDA-cleared Single Patient IND in 2020, , management believes it is in a good position to be awarded Orphan Drug Designation and qualify for an FDA Expedited Program for *CycloSam*® to be potentially used as a front-line therapy for pain palliation, tumor resolution and QoL.

Key results of the trial include:

- *CycloSam*® trafficked exactly as seen in multi-species animal models
- *CycloSam*® targeted bone - primary tumor and metastasis visible
- 50% of *CycloSam*® delivered to bone
- No unexpected adverse effects. Cleared major organs within hours.
- *CycloSam*® delivered an ablative radiation dose to marrow as well as primary tumor and metastases

This nuclear technology uses low specific activity Samarium-153 (resulting in far less undesirable) and DOTMP, a novel chelant which is believed to eliminate off-target migration and targets sites of high bone turnover making it an ideal agent to treat osteosarcoma or other bone metastases. Due to its ability to deliver radiation directly to the skeletal system, it is also believed to be an effective agent to use in bone marrow ablation as pre-conditioning for bone marrow transplantation. Based on these factors and other advantages outlined later in this report, *CycloSam*® could emerge as the standard of care versus current therapies, representing an estimated $105M market for osteosarcoma and $1 billion for bone marrow ablation.

Additionally, management intends to further the clinical development of CycloSam® as a treatment for metastatic bone cancer, representing a $20 billion market.

Looking Ahead

It is expected that QSAM will reach a number of milestones in 2021 which should serve as catalysts for the Company's stock. These include IND filings, trial enrollments, and new center additions leading to commencement. This will require an initial, nominal fundraise of an estimated $2-3 million.

On the heels of the concluded FDA-cleared Single Patient trial, an investigator-led IND has been cleared by FDA and a Phase I clinical study has been approved to commence enrolling and dosing at Albert Einstein College of Medicine in patients with osteosarcoma and bone metastases. The study protocol, principal investigator, and manufacturing plan are all finalized; clinical trial is ready to commence. An additional 5-7 sites (with an estimated 20 patients) are coming online in 2Q-3Q 2021. Given this approval, we believe that it is possible QSAM is awarded Orphan Drug and expedited program status this year.

Separately, *CycloSam*® was cleared by the FDA under a second single-patient IND to be used in bone marrow ablation prior to allogenic marrow transplantation (BMA/T) with encouraging results. This trial will be followed by QSAM filing for an open-label Phase I/II trial under corporate IND for bone metastasis and could begin enrollment in multiple centers in 4Q 2021.

Valuation

Our $3.00 six-month price target is based upon the milestones outlined above, the size of the markets, inherent competitive advantages, IP, and positioning for expedited (Fast Track or Breakthrough Therapy) approval. Most companies that achieve this development status are afforded a valuation of around $50 million, which dovetails with our price target.

We should note that QSAM's leadership has guided numerous drugs through the FDA and sold companies in the space while serving in C-level status, and each have 30+ years of successful healthcare experience. Plus, senior advisors to the Company could be considered the de facto experts in the field of radiopharmaceuticals given their development of *Quadramet*®, an injectable radiopharmaceutical used for pain relief in cancer patients suffering from osteoblastic metastatic bone lesions. In our view, if the flagship product generates its expected dosing, safety, and efficacy results in upcoming trials, we believe that QSAM is built for potential sale to a larger pharma company within two years. This event could occur following the release of results for the bone metastases trial. Against this backdrop, we believe that once enrollment in the second trial commences, the value of QSAM could reach the $5.00 mark and be worth much more in a sale within 24+ months. A larger firm could continue development for current and additional 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 huge surge in the use of radiophamaceuticals for the diagnosis and treatment of chronic diseases, 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 injections.

Another advantage RPT has is pre-use observation. Having imaging and treatment molecules that use the same target as that imaging can 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.

There is a history of successful M&A in the RPT arena. Bayer acquired Xofigo in 2009 for $800 million followed by Algeta for $2.9B billion n 2014. Xofigo is estimated to have enjoyed peak sales of $1.5 billion, a historically significant deal in the industry.

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 and exhibit 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.

Separately, Novartis acquired Endocyte and AAA in 2018 for $3.9 billion. Interestingly, the lead drug, Lutathera®, was awarded FDA approval in 2018 for treatment of neuroendocrine tumors of the pancreas and small intestine. According to an NCI article:

"The game-changer for the field came in 2018, said Jacek Capala, Ph.D., of NCI's Radiation Research Program, when FDA approved lutetium Lu 177-dotatate (Lutathera) for the treatment of certain cancerous neuroendocrine tumors (NETs) affecting the digestive tract.

"This showed that solid tumors can also be targeted this way," with a radiopharmaceutical built from scratch, he said. In this case, the targets are certain hormone receptors found in abundance on the surface of NET cells.

Lutetium Lu 177-dotatate was better at slowing NET growth than any previous drug tested, explained Aman Chauhan, M.D., of the University of Kentucky, who is leading several new clinical trials of the drug. "This was a huge step forward for our field," he said."

Clearly, we are in the early stages of a migration toward the broader use of RPT to treat a variety of cancers.

THE QSAM DIFFERENCE

QSAM is developing next generation nuclear medicines for the treatment of cancer and related diseases and conditions with high unmet need. The Company's flagship product, *Cyclosam*®, is a clinical stage bone-seeking radiopharmaceutical therapy designed to specifically and safely deliver targeted radiation to kill cancer cells in and near the bone via a radioisotope. In animal studies and a recent single-patient human trial, this approach appears to improve efficacy and safety. QSAM plans to commence additional trials during 2021.With two issued patents in the US, one allowed patent in Europe and fourteen pending patents that protect the use of CycloSam®, QSAM is set to protect its most valuable resource and enable management to leverage its IP going forward.

CycloSam®

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

QSAM Therapeutics Inc, a wholly owned subsidiary of QSAM, holds the worldwide license to this clinical stage, novel radiopharmaceutical meant to treat different types of bone cancer and related diseases. This therapeutic was developed by IsoTherapeutics Group LLC, leaders in the nuclear medicine space. It should be noted that while working at The Dow Chemical Company the founders of IsoTherapeutics Group also developed FDA-approved and commercially available *Quadramet*® (Samarium-153 EDTMP), indicated for pain palliation. *CycloSam*® uses Sm-153 radioisotope like *Quadramet*®, an FDA-approved and commercially released drug, but due to the proposed improved chelant, efficacy and safety are expected to be significantly improved. Long-lived radionuclidic impurities found in Quadramet are significantly reduced. *CycloSam*® was assigned to IsoTherapeutics Group's subsidiary, IGL Pharma, Inc., presently a partner to QSAM.

CycloSam® has already demonstrated preliminary safety and efficacy in animal studies and a successful FDA-cleared single patient human trial performed earlier in 2020. This nuclear therapeutic 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 an ideal agent to treat osteosarcoma or other 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 be used in 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.

CycloSam® is cleared by the FDA under an investigator-initiated IND to commence human dosing immediately in patients with osteosarcoma and bone metastasis. *CycloSam*® was also cleared by FDA and successfully used under a single-patient IND to be used in bone marrow ablation prior to allogenic marrow transplantation (BMA/T) in 2020.

Competitive Advantages

Samarium-153 boasts a short, 46-hour half-life and is a beta-emitter with verifiable 3mm bone cancer penetration, plus the DOTMP offers lower toxicity due to firm binding of Sm-153. Plus, its dosage is administered via IV and is cleared in a matter of hours. Manufacturing costs are lower due to a scalable cold kit production and inventory which has excellent stability and a two-year shelf life. The product has undergone extensive controlled animal studies and “real world” veterinary clinical settings at University of Missouri School of Veterinary Medicine.

Finally, one key commercially compelling advantage is the uninterrupted supply of the isotope. *CycloSam*® is made in the reflector of the reactor allowing daily access (and fewer long-lived impurities), providing significant supply chain advantages. Conversely, former standard-bearer *Quadramet*® is made in the flux trap of the reactor and can only be accessed 1 day a week.

Initial Indication: Osteosarcoma

QSAM believes *CycloSam®,* in this population, will potentially qualify for:

One or more Expedited Programs (Breakthrough Therapy, Fast Track, Accelerated Approval, or Priority Review) because from 2012-2017, the FDA approved 58 new cancer drugs, of which 55, or 95%,were expedited under at least one program. These programs offer inherent value to companies and their investors.

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%). It should be noted that *Quadramet*® is currently in the guidelines for second-line relapsed/refractory disease.

Clinical Trials

As evidenced by results from an FDA-Cleared Single Patient IND in 2020, along with other studies, management believes it is in a good position to qualify for an FDA Expedited Program for *CycloSam*® to be potentially used as a front-line therapy for pain palliation, tumor resolution and QoL. Trial objectives including dosage calculation, tolerance and tumor response were met.

Key results of the trial include:

- *CycloSam*® trafficked exactly as seen in multi-species animal models
- *CycloSam*® targeted bone - primary tumor and metastasis visible
- 50% of *CycloSam*® delivered to bone
- No adverse effects. Cleared major organs within hours.
- *CycloSam*® delivered an ablative radiation dose to marrow as well as to primary tumor and metastases

A US IND has been cleared by FDA and a clinical study approved to start enrolling patients at Albert Einstein College of Medicine with up to 7 additional top-line centers targeted to be recruited, (e.g., John Hopkins, Cleveland Clinic, MD Anderson Cancer Center). It is anticipated that most centers will be approved to enroll patients in early 2021, and the study calls for 5 cohorts of 3 patients with increasing dose levels. The study is "open label" allowing for early efficacy and safety information, and the potential exists to allow for current study to rollover into pivotal study once an optimal dose is determined.

Blockbuster Indications

Market	Patients	TAM
Primary bone cancers – Osteosarcoma	850	$105 M
Other Primary bone cancers	2,400	$168 M
Bone Metastases (Breast, Prostate, Lung)	280,000	$20 B
Bone Marrow Ablation	15,000	$1 B

Estimates based on Xofigo's pricing model.

Bone Marrow Ablation

Certain cancers, immune system diseases, blood diseases including sickle cell disease require bone marrow ablation/transplantation (BMA/T). The standard protocol for BMA/T consists of high dose chemotherapy and/or Total Body Irradiation (TBI). This standard treatment is physically devastating to patients, especially younger and older patients.

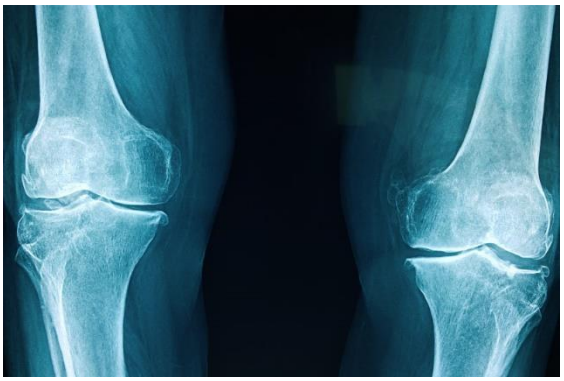
RPT is potentially the best option because there may be fewer patient side effects. Many radiopharmaceuticals have excellent safety records. However, current products have long half-lives and high levels of impurities, meaning patients could be immunocompromised for unacceptably long periods of time.

CycloSam® may be able to become the new standard of care. The short half-life (46 hours) and low impurity profile means a patient may be able to be treated and transplanted a few days later. As noted in the primer, existing therapies are sub-optimal solutions. This is especially the case with high dose chemotherapy agents which require multiple doses over multiple days and disrupt the short-term cell production cycle resulting in mucositis, along with potential damage to soft tissue. We all know that side effects can last days to months, among other negatives.

Conversely, *CycloSam*® Sm-153 DOTMP is a one-day dose that is not shown to disrupt short-term cell production or damage soft tissue. *CycloSam*® radiation is directed to the bone and away from soft tissue while most of the non-bone-bound dose is eliminated from the body within hours.

Advanced attributes of *CycloSam*® indicate a strong potential to successfully treat bone metastases based on published work on *Sm-153-EDTMP* by H.Sinzinger *et. al.* which reported positive results in therapy for bone metastases from both prostate and breast cancers.

Metastatic Bone Cancers



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

Use of CycloSam® in treatment regimens 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

Douglas R. Baum, President, Chief Executive Officer

Douglas R. Baum has 28+ years of experience serving in a number of executive management and business development positions within the drug development and life sciences industries. Currently, he serves as the CEO, President and Director of QSAM and its subsidiary, QSAM Therapeutics, Inc., a company he co-founded

in 2019. QSAM is an Austin, Texas based clinical stage specialty pharmaceutical company developing a pipeline of radiopharmaceuticals focused on various bone and solid tumor cancers.

Previously, Doug was the President and CEO of Xeris Pharmaceuticals Inc. (NASDAQ: XERS) a specialty pharmaceutical company focused on developing drugs for diabetes and related metabolic diseases. Prior to Xeris he served as the COO of MacuCLEAR, a specialty pharmaceutical company developing novel treatments for retinal diseases of the eye. Prior to MacuCLEAR, Doug served as the Vice President, Global Corporate Development at Premier Research Group (PRG), Inc. a global contract research organization serving the pharmaceutical, biotechnology and medical device industries. In 2007 PRG acquired SCIREX Corporation where Doug served as Executive Vice President & General Manager, Early Drug Development. He also serves on the Board of Directors of Regent Technologies, Inc. and previously served on the boards of Xeris, MacuCLEAR, Halsa Pharmaceuticals, Inc., and the Texas Medical Device Alliance.

Doug obtained his Bachelor of Business Administration degree and his Master of Science degree in Technology Commercialization degree from the University of Texas at Austin.

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

C. Richard Piazza, Ph.D. is a career healthcare executive with 48 years of experience in medical devices as well as the pharmaceutical/biotechnology sectors. Included in this is 44 years in general management positions in both public and private international companies including Ohmeda, Smith & Nephew Pharmaceuticals, Marquest & VitaGen (world's first bioartifical liver). In 2019 he co-founded QSAM Therapeutics, Inc. with Doug Baum and currently serves as its Executive Chairman.

Richard has gained a reputation of not only introducing new technologies and driving them to success but recruiting and motivating "world class," highly focused management teams. In addition to a highly successful business career, Richard has served on industry association boards & committees (Advamed, Biocomm, BioHouston etc.) and was an industry representative working with the FDA and the Congress to craft the FDA Modernization Act for Medical Devices.

His Board experience also includes numerous directorships and Chairman roles in both public and private healthcare companies. In addition to industry affiliations, Richard remains committed to working with well-known medical pioneers to identify and advance new technologies. He acts as an advisor to some of world's leading institutions. These include MD Anderson Cancer Center, Baylor College of Medicine, University of California San Diego, University of Chicago & Kings College Hospital (London.) Richard has been a guest Lecturer in Sales & Marketing strategy at numerous Universities including Rice University School of Management, UCLA, University of Wisconsin, CAL Tech-MIT forum, University of British Columbia & University of California San Diego.

Richard 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.

Barry Sugarman, Senior Advisor

Barry Sugarman is a Senior Executive Generalist with over 30 years of experience spanning public and private companies in the pharmaceutical, medical device, dietary supplement, and cosmetic industries. Barry has

considerable direct experience in pharmaceutical product development, manufacturing, clinical trials, regulatory affairs, FDA and government relations, marketing, and distribution.

Barry possesses broad experience in clinical trial operations and management, mergers, acquisitions, turnarounds, start-ups, reorganization, process improvements, and sales management and a very strong knowledge of 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 (IND's), New Drug Applications (NDA's), Abbreviated New Drug Applications (ANDA's), and Medical Device Applications 510(k)'s.

Barry is a member of the Regulatory Affairs Professional Society (www.raps.org), American Association of Pharmaceutical Scientists (www.aaps.org), Association of Clinical Research Professionals (www.acrpnet.org), and the National Association of Corporate Directors (www.nacdonline.org). He is a co-author of "Prompt, Accurate Diagnosis of Pediatric Cancer and Leukemia for Pediatricians, Orthopedists, and Family Practitioners" – Paperback (Aug. 28, 2007) by Andrew Pendleton, Jennifer Minigh, Lainie Shapiro, and Barry Sugarman.

Drs. R. Keith Frank, and Jim Simón, Advisory Board

- Each member has over 30 years of experience with Dow Chemical leading R&D efforts in Radiopharmaceuticals and Chelators
- Developed Quadramet®
- Founded IsoTherapeutics in 2005 performing contract R&D for Big Pharma with emphasis on radio-labeling
- Authored/co-authored more than 100 scientific papers and publications
- Recognized as leading authorities in radiopharmaceuticals
- 60+ Patents
- Internationally recognized experts in radiopharmaceuticals
- Extensive interaction with research institutions, investigators, and hospitals

FINANCIALS SNAPSHOT

Management runs a tight ship at QSAM. It is expected that QSAM will reach a number of milestones in 2021, including IND filings, clinical trial enrollments, and new center additions leading to commencement, which should serve as catalysts for increased Company stock value. This will require an initial, nominal fund-raise of an estimated $2-3 million, which would fund the clinical trials, IP, and limited G&A expenses for the next 12 months. An additional round is likely needed in the near future for additional studies/trials, albeit likely at substantially higher valuation.

On the heels of the concluded FDA-Cleared Single Patient human trial, an investigator -led IND has been cleared by FDA and a Phase I clinical study has been approved to commence enrolling and dosing patients with osteosarcoma and bone metastasis at Albert Einstein College of Medicine. The study protocol, principal investigator, and manufacturing plan are all finalized; clinical trial is ready to commence. An additional 5-7 sites

(with an estimated 20 patients) are coming online in 2Q-3Q 2021. Given this approval, we believe that it is possible QSAM is awarded Orphan Drug and expedited program status this year.

Separately, *CycloSam*® is cleared by the FDA under a second single-patient IND to be used in bone marrow ablation prior to allogenic marrow transplantation (BMA/T). This trial will be followed by QSAM filing for an open-label Phase I/II trial under corporate IND for bone metastasis and could begin enrollment in multiple centers in 4Q21.

RISK FACTORS

In our view, the Company's biggest risk is related to the results of future clinical trials and studies, particularly for osteosarcoma and other proposed indications that represent multi-billion dollar markets. It is possible that results are favorable, but not statistically significant related to efficacy or QoL. A secondary risk is related to timing of the launch of the upcoming trials under corporate IND as there may be delays with the FDA or enrollment, given the circumstances regarding the current COVID-19 pandemic. 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 QSAM's strategic approach reduces the risk 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. It is also possible that the share count could increase to fund future clinical trials. However, an overriding financial benefit as a public company is the favorable access to and the availability of capital to fund research and development, product studies and launches, and other initiatives. Since the proceeds of any future funding would be used, in large part, to advance major business 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 and other related diseases and indications via its focus on the novel use of radiopharmaceutical therapy (RPT). RPT has significant advantages over existing therapies, such as chemotherapy and radiation. The RPT market is huge, and its adoption along with 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 kill cancer cells in and near the bone via a radioisotope. QSAM's flagship represents multiple indications with a potential addressable market in the billions. Separately, QSAM is primed to be awarded Orphan Drug Status for its lead indication and possibly an expedited program status following strong studies and a single patient human trial.

With multiple milestones ahead, our six-month target is $3.00, with $5.00 in the cards later in 2021. Management's collective experience rivals midcap biotechs, with experience getting products through FDA and negotiating successful exits. QSAM is next on the list.

RECENT TRADING HISTORY FOR QSAM

(Source: www.BigCharts.com)

SENIOR ANALYST: ROBERT GOLDMAN

Rob Goldman founded Goldman Small Cap Research in 2009 and has over 25 years of investment and company research experience as a senior research analyst and as a portfolio and mutual fund manager. During his tenure as a sell side analyst, Rob was a senior member of Piper Jaffray's Technology and Communications teams. Prior to joining Piper, Rob led Josephthal & Co.'s Washington-based Emerging Growth Research Group. In addition to his sell-side experience Rob served as Chief Investment Officer of a boutique investment management firm and Blue and White Investment Management, where he managed Small Cap Growth portfolios and *The Blue and White Fund*.

ANALYST CERTIFICATION

I, Robert Goldman, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report.

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